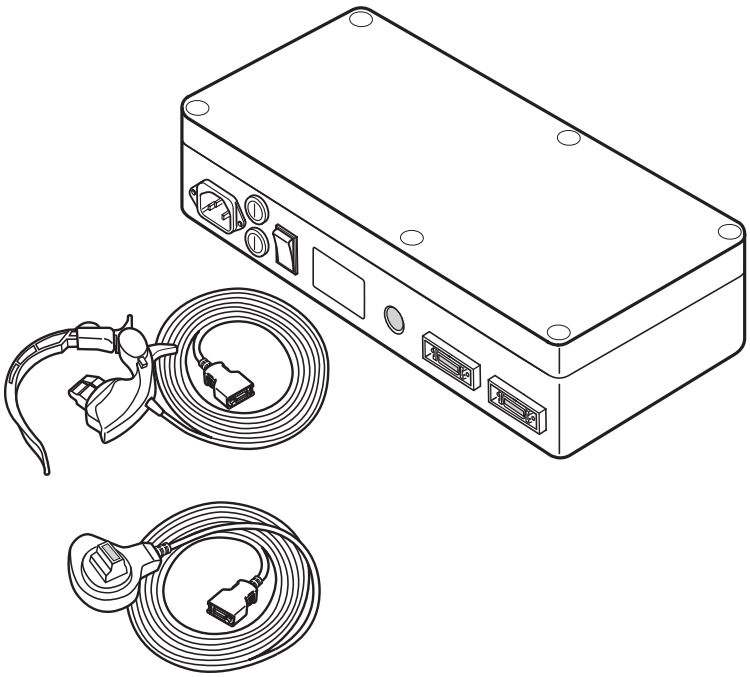
OMRON

TU-100 CAP Sensor / FAP Sensor

Pulse Wave Unit BP-203RPE Series

Instruction Manual



Thank you for purchasing the OMRON Pulse Wave Unit TU-100.

Read all of the instructions in the manual before you operate the unit and keep the manual near the unit at all times for future reference.

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Disclaimer

Our company assumes no responsibility for the following:

1. Failures, damage, or injuries due to maintenance or repair work performed by other than our company or a company that we specify.
2. Failures or damage to one of our products caused by a product of another manufacturer not delivered by us.
3. Failures, damage, or injuries due to maintenance or repair work using a repair part other than a part that we specify.
4. Failures, damage, or injuries caused by failure to observe the safety instructions and operational procedures given in this manual.
5. Use of the product in conditions that do not conform to the product usage conditions indicated in this manual, including power, installation, and storage conditions.
6. Failures, damage, or injuries due to modification or inappropriate repair of the product.
7. Failures, damage, or injuries due to natural calamities such as fire, earthquake, flooding, or lightning.

Principles

1. The contents of this manual are subject to change without notice.
2. Considerable care has been taken in the preparation of this manual. In the unlikely event that an error or other problem is discovered in the manual, please contact us.
3. Unauthorized reproduction of all or part of this manual is prohibited. Use other than individual (corporate) use without the permission of our company is prohibited by copyright.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

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Before Use

Omron Healthcare Co., Ltd. would like to thank you for purchasing this unit.

Intended Use

The TU-100 can be connected to the BP-203RPE Series of Non-invasive Vascular Screening Devices to support evaluation of hardness of the artery and early detection and diagnosis of Peripheral Arterial Disease (PAD) by means of PWV, AI, and electrocardiogram indications.

Please be sure to familiarize yourself with usage, warnings, capacity, and limitations in order to apply this device safely. After reading, please locate this manual in a convenient place for everyone who uses this device.

Note:
This manual gives an explanation only regarding examination when using the TU-100. Therefore, refer to the operation manual for BP-203RPE series together when conducting the examination.

Safety Information

The warning signs and symbol examples indicated below are intended to ensure safe use of the product and prevent damage and injury to you and others. The signs and symbols are explained below.

Explanation of Symbols

⚠ **Warning**	Indicates a situation where incorrect handling may cause human death or serious injury.
⚠ **Caution**	Indicates a situation where incorrect handling may cause human injury or physical damage.*

* Physical damage means serious damage to your house and household goods, and serious injury to pets or other domestic animals.

● indicates "mandatory" (an action that must be observed).
The actual action that is mandatory is indicated inside or next to ● .
The icon at left indicates "disconnect the power plug".

⃠ indicates "forbidden" (an action that must not be taken).
The actual action that is forbidden is indicated inside or next to ⃠ .
The icon at left indicates that "disassembly is forbidden".

Note:
This indicates information that should be known when operating the device.

⚠ Warning:

Safety rules when using the product

Do not use a frayed or damaged power cord or plug. Otherwise electric shock, short circuiting, or fire may result.

Do not touch the power plug with wet hands. Otherwise electric shock or injury may result.

Do not connect the power plug to the outlet if the electrical ratings or wiring is outside the range of 100 - 240 VAC. The voltage range must be checked on the rating label before use. This may cause fire.

Safety rules when performing measurement

This device is only to be used by qualified medical personnel, or under the guidance of such personnel. Otherwise incorrect diagnosis and treatment or device failure may result.

The results of measurement should only be interpreted by a doctor. If you are concerned about a measurement result, consult your doctor. Otherwise incorrect diagnosis and treatment may result.

The CAP sensor (carotid arterial pulse sensor) detects pulse waves when pressed against the neck. Use it in a short period of time for measurement. Otherwise an accident may result.

Pay constant attention to patient's condition during measurement. Otherwise an accident may result.

If the patient has any of conditions below, do not perform measurement. Otherwise incorrect diagnosis and treatment may result.

- The patient has an aneurysm.
- The patient has insufficient peripheral circulation, noticeably low blood pressure, or low body temperature.
- The patient frequently has an irregular pulse.

Follow the physician's advice before performing measurement on the following patients. Otherwise an accident may result.

- Patients who have not fully recovered from wounds in neck.
- Patients who frequently cough due to asthma or bronchial inflammation.
- Patients who may have a history of stroke.

Use caution when performing measurement on the following patient. Otherwise an accident may result.

- Patients with a history of carotid-cavernous syndrome (hypersensitivity, fainting and Adam's stokes syndrome).
- Patients who may have serious arterial sclerotic lesions.
- Patients who may have inflamed lesions.

Do not apply strong force to the neck with improper application of the CAP sensor or carotid massage. Otherwise the following may result.

- Carotid plaque breaking off
- Arrhythmia, low blood pressure, cold sweats, fainting

Pay constant attention to patient's condition and level of consciousness. Stop measurement if an irregularity occurs. Otherwise an accident may result.

- After application of the CAP sensor (carotid arterial pulse sensor), it is possible that the patient may feel uncomfortable or pain, or that the patient may experience decreased pulse rate or reduced consciousness. Constantly monitor the condition and level of consciousness of the patient and perform measurement following the instructions of the physician. (Be cautious of carotid-cavernous fainting and carotid-cavernous reflex syndrome.)

If the heartbeat beep becomes irregular while the CAP sensor is attached, immediately remove the CAP sensor, stop measurement, and consult the patient's physician. Otherwise an accident may result.

Use only specified accessories and options. Otherwise an accident may result.

External vibration or patient movement during measurement may cause an incorrect indication.

Installation

Do not use this device in the presence of a flammable gas such as a highly inflammable anesthetic, or in a high-pressure oxygen chamber or tent. Fire and explosion may result.

Do not install or store the device in a location where water or chemicals may splash on the device. Electric shock may result.

Maintenance

Do not disassemble, repair or modify the device. Electric shock may result.

After cleaning the device, dry it completely before turning on the power again. Otherwise electric shock or current leakage may result.

⚠Caution:

Safety rules when using the product

Observe the below rules when handling the power cord. Failure to observe these rules may result in electric shock or device failure.

- Do not damage the cord.
- Do not break the cord.
- Do not modify the cord.
- Do not bend or pull on the cord with undue force.
- Do not twist the cord.
- Do not tightly coil the cord when in use.
- Do not place heavy objects on the cord.
- Do not let the cord become pinched.

Insert the power plug all the way into the outlet. Otherwise electric shock, short circuiting, or fire may result.

Wipe dust off the power plug. Otherwise electric shock, short circuiting, or fire may result.

After using the device, turn the power switch to the "off" position and disconnect the power plug. When the device is installed to the stand, turn off the main power switch on the stand and disconnect the power plug of the stand. Failure to do so may cause deterioration of the insulation and result in electric shock, current leakage, or fire.

When removing the power plug from the outlet, grasp and pull on the plug, not the cord. Pulling on the cord may break wires and cause a short circuit, resulting in fire or electric shock.

If a power failure occurs while using the device, turn the power switch to the "off" position and disconnect the power plug. Failure to do so may result in a product failure or other problem.

Please be sure to turn off the main power switch before removing or connecting each unit or sensors. Otherwise electric shock or device failure may result.

Safety rules when performing measurement

For safe and proper use, the device has to be checked before use. Otherwise an accident may result.

Do not use in an MRI, CT, X-ray room, room with microwaves, an operating room, or other rooms where radio noise is generated. Otherwise incorrect diagnosis and treatment, or an accident may result.

Do not use the device near a cellular phone. Incorrect diagnosis and treatment may result.

For patients with the following disease or symptoms, accurate measurement may not be possible due to motion artifacts or disordered waveforms. Bear this condition in mind when performing measurement. Incorrect diagnosis and treatment may result.

Classification		Symptoms or Disease
Circulatory system	Carotid artery	Carotid artery thrombendarterectomy was done in the past. Stenosis is suspected on the carotid artery.
	Heart	Severe cardiac failure Unstable angina Excessive bradycardia Sinus function failure syndrome Intraventricular conduction block
Respiratory system		Severe respiratory insufficiency Severe chronic obstructive lung disease Severe bronchial asthma
Central nerve system		Acute stroke (4 months) Inadequately controlled convulsive disorders Involuntary movement
Others		Excessive kyphoscoliosis

When using the device in combination with another medical device, read the manual of the other device well and understand all warnings and cautions. Otherwise incorrect diagnosis and treatment may result.

Do not reposition the patient who has physical pain. This may cause bone breakage or nerve paralysis.

Do not use the device in a location with loud noise. Incorrect diagnosis and treatment may result.

Attach the PCG sensor correctly. Incorrect diagnosis and treatment may result.

Take care that the PCG sensor does not fall on the patient. This may cause injury.

If you need to measure the circumference of the patient's neck, do so while the patient is lying down face up. Otherwise incorrect diagnosis and treatment may result.

Make sure that the sensor arm does not catch the patient's neck. This may cause injury.

The more pressure is applied on the neck with the CAP sensor, the more strain is placed on the patient. Find a suitable position where measurement is performed with less pressure. Otherwise an accident or injury may result.

Confirm regularly that the device is functioning properly during measurement. Otherwise an accident may result.

Installation

Do not perform measurement when the ambient temperature is 15 °C or less. Otherwise a device failure may result, or incorrect diagnosis and treatment may result due to inaccurate measurement results in the following conditions.

•Blood pressure measures higher due to vessel constriction in patient's hands and feet.

•Accuracy of the sensor is reduced.

The room temperature for measurement should be maintained approximately at 25 °C and the device should be placed in the room at least 30 minutes prior to measurement. Otherwise incorrect diagnosis and treatment may result.

If the device is brought in from a vehicle or a hot location, the device should sit for at least one hour in a room at a constant temperature of about 25 °C prior to measurement.

Otherwise incorrect diagnosis and treatment, or device failure may result.

If the device is brought in from a cold location, water condensation may form inside the device. Wipe it completely dry with a soft cloth before use. Otherwise electric shock, short circuiting, or fire may result.

Do not place objects on the device. Liquid may spill or a foreign object may get into the device. This may result fire or electric shock.

Do not use in a moving vehicle such as an ambulance. Incorrect diagnosis and treatment, or an accident may result due to inaccurate measurement.

If you are not using the device stand, exercise sufficient caution when moving the device. The device is heavy and may slip out of your hands, causing injury.

Maintenance

Before cleaning or maintaining the device, disconnect the power plug. Otherwise electric shock or injury may result.

Before cleaning or maintaining the device, disconnect the plug of the power strip. Otherwise electric shock or injury may result.

Notes

During defibrillation, remove the sensors from the patient and do not touch the device.

The device and the accessories are precision instruments. Applying excessive force on the device or treating it roughly may cause damage. If excessive force is applied on the device, confirm that the device is functioning without any problem before use.

When cleaning the device, avoid using any solvents like thinner, benzene or concentrated alcohol. Refer to page 45 for more detail on maintenance.

Do not turn off the power during printing, data transmission, or writing.

The device should be installed in the following locations:

- The power supply conditions must be 230 VAC ±10 %.
- A level and stable surface for the device to sit on.
- A location with the appropriate space with sufficient airflow.
- Ambient temperature between 15 - 40 °C and humidity between 30 - 85 %.

Do not install the device in the following locations:

- A location with prolonged exposure to direct sunlight.
- A location with no dusty or salt air.
- On an inclined surface or a location subject to vibration, shock, or noise.
- A location where chemicals are stored or gas is emitted.

The following locations are not suitable for storing the device:

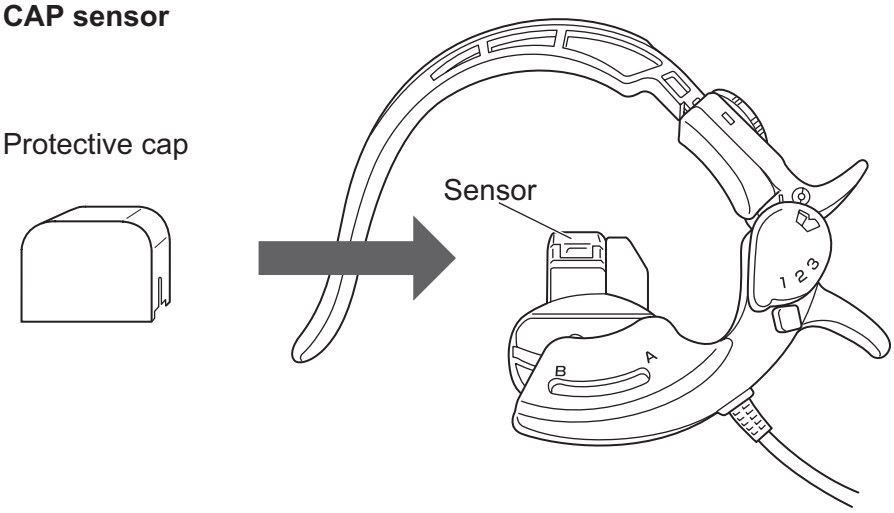
- Ambient temperatures decrease below -5 °C or higher than 50 °C or the humidity decreases below 10 % or higher than 95 %.
- Extremely hot locations.
  If the device is left out in direct sunlight, in a car with the windows closed in summer, or in any other extremely hot location, the device may not be possible to use due to deformation of the parts.

Caution for Handling Sensors

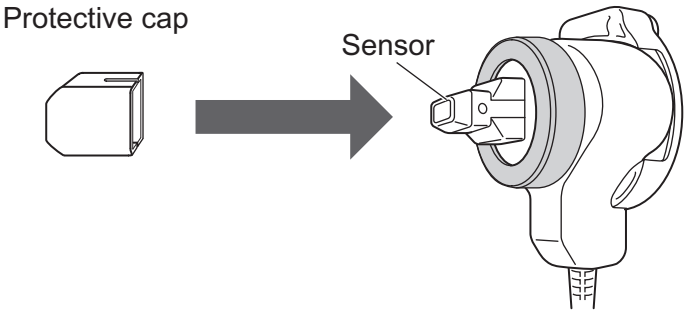
The sensor is a high-precision device that detects faint pulse waves in arteries.
Exercise caution when handling the sensor, as dropping the sensor or subjecting it to shock may damage the internal structure of the sensor.

Make sure to reattach the PROTECTIVE CAP immediately after measurement.

CAP sensor



FAP sensor



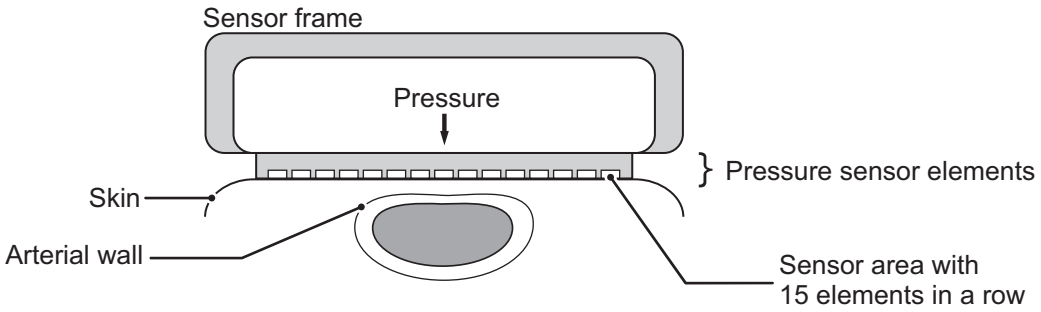
Outline of Tonometry

About the Product

The TU-100 is a device that uses the tonometry method to measure pulse waveforms. Connect it to the BP-203RPE series for operation.

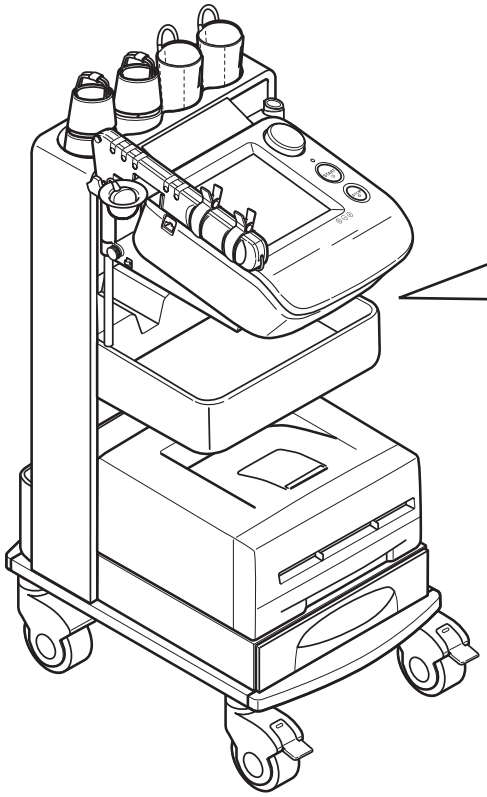
Pulse Wave Detection

In tonometry, the pressure pulse wave sensor presses on the skin to flatten the arterial wall, and consequently the pressure inside the artery is directly detected by the pressure sensor. The pressure sensor is a multi-element sensor that contains a row of 15 sensor elements. The device analyzes the signal from the pressure sensor and selects the sensor elements that are in the optimum position. The pulse wave measured with the signals from the elements are used in analysis.

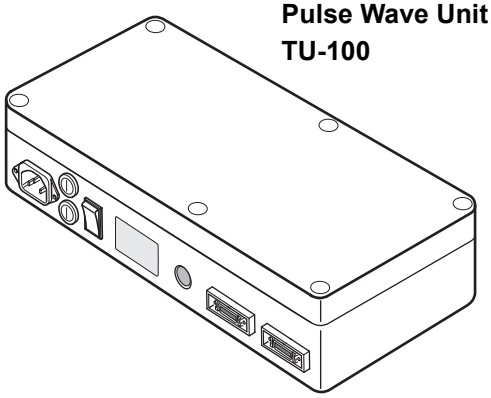


Configuration

BP-203RPEⅢ



Pulse Wave Unit
TU-100

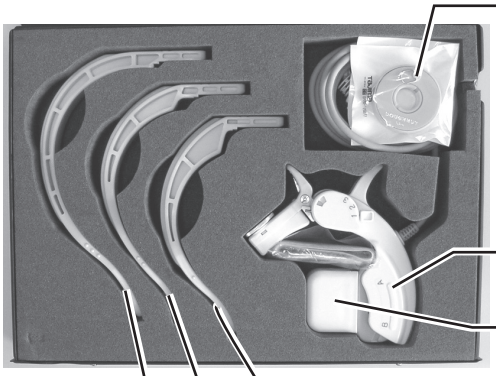


The TU-100 Pulse Wave Unit is an expansion unit for the BP-203RPE Series. It is installed on the stand for the BP-203RPE Series.

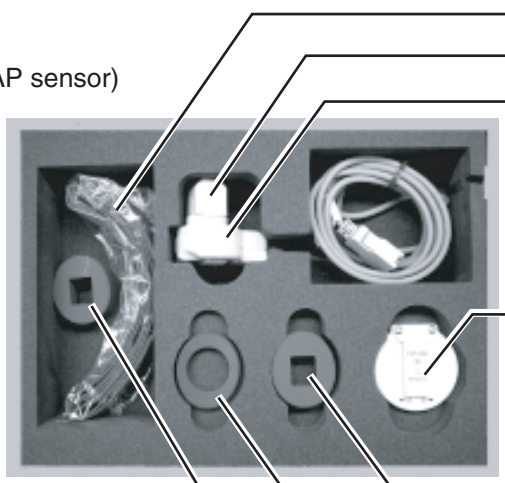
The appearance is subject to change without notice.

Tonometry Sensors

The CAP-350AZ
Carotid arterial pulse sensor (CAP sensor)



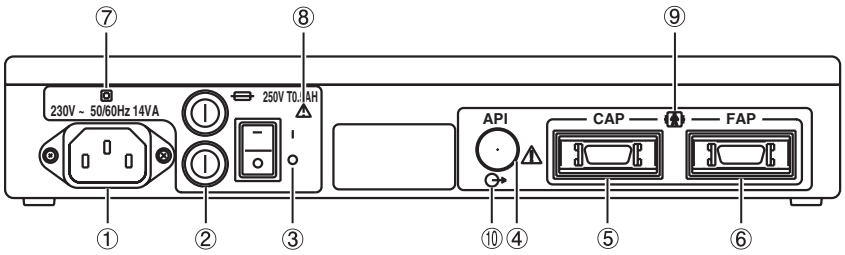
The FAP-350AZ
Femoral arterial pulse sensor (FAP sensor)



⚠ **Warning**	Use only specified accessories and options. Otherwise an accident may result.

Name of Each Part

Back of TU-100



① **AC connector:** connector for the power cord.

② **Fuse holder / fuse:**
Please contact a dealer or an Omron Healthcare technical support representative to replace the fuses.

③ **Power switch:** Keep it ON.
To turn on/off the power of this unit, use the main power switch on the stand.

④ **API (BP-203RPEⅡ):**
Connector for the API unit.

Main unit connector (BP-203RPEⅢ):
Connector for the main unit.

⑤ **CAP:** Connector for the CAP sensor.

⑥ **FAP:** Connector for the FAP sensor.

⑦ Class Ⅱ

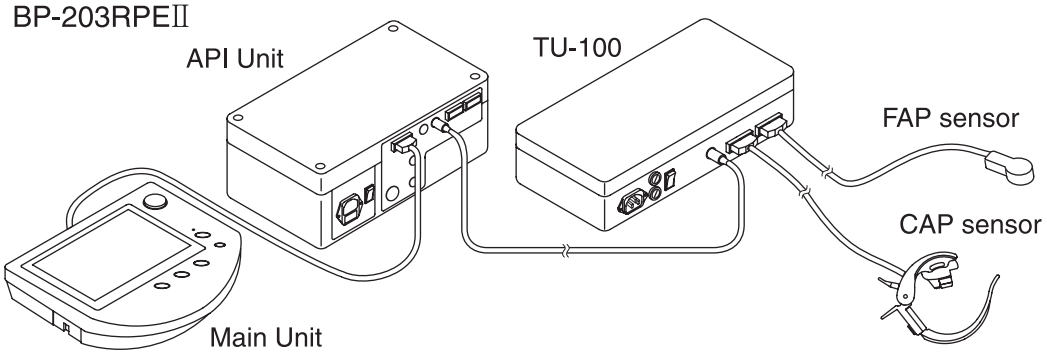
⑧ Refer to the instruction manual

⑨ Type BF
Classification by leakage current levels with defibrillation protection.

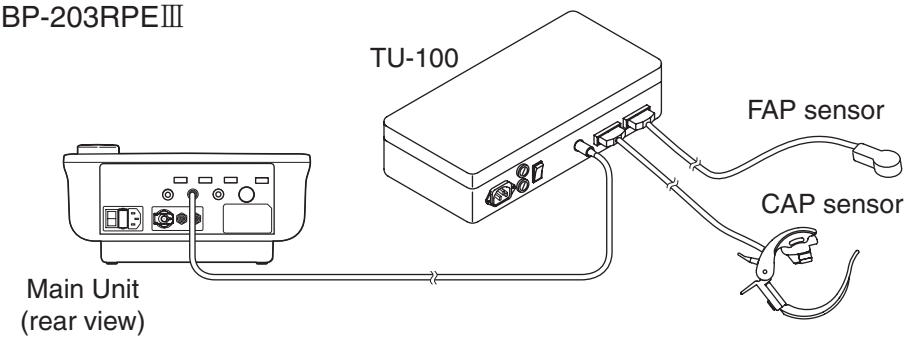
⑩ Output

TU-100 connected to the main unit

BP-203RPEⅡ

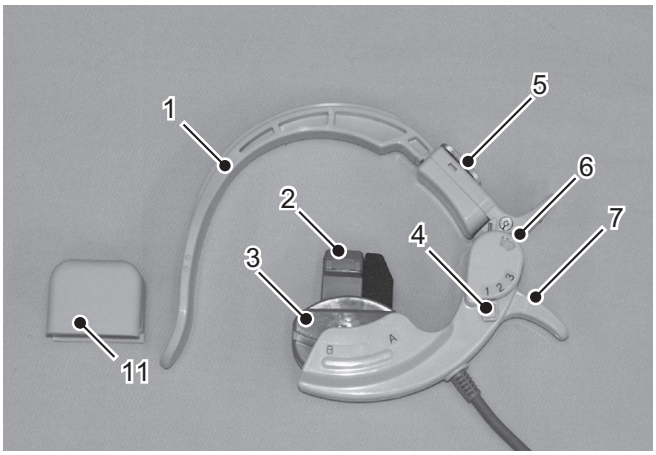


BP-203RPEⅢ



⚠ Caution	Please be sure to turn off the main unit power before removing or connecting each unit and sensors. Otherwise electric shock or device failure may result.

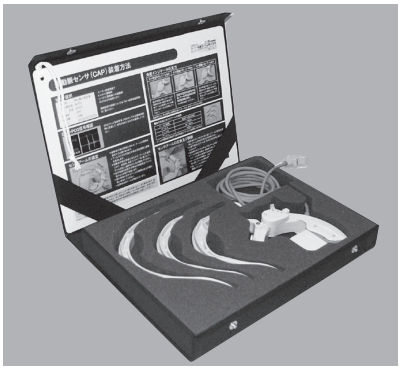
Names of Carotid Arterial Pulse (CAP) Sensor Parts



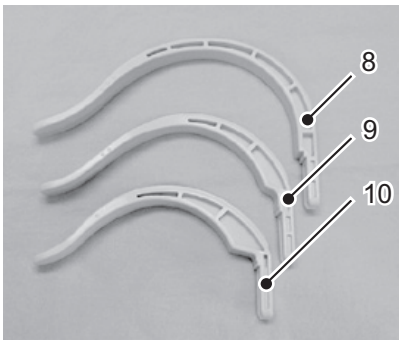
1 Arm
2 Sensor
3 Sliding sensor head
4 Pressure adjustment lever
5 Arm adjustment screw
6 Angle indicator
7 Opening lever
8 Arm L
9 Arm M
10 Arm S
11 Protective cap

* Keep the protective cap on when the unit is not in use.

Items stored in storage case



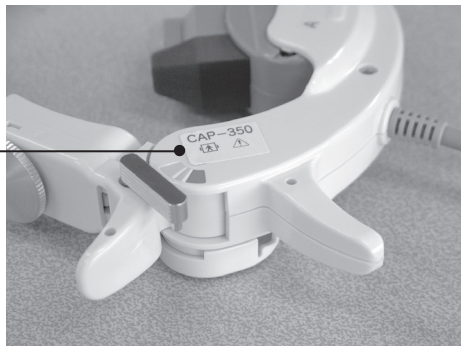
Three arm sizes



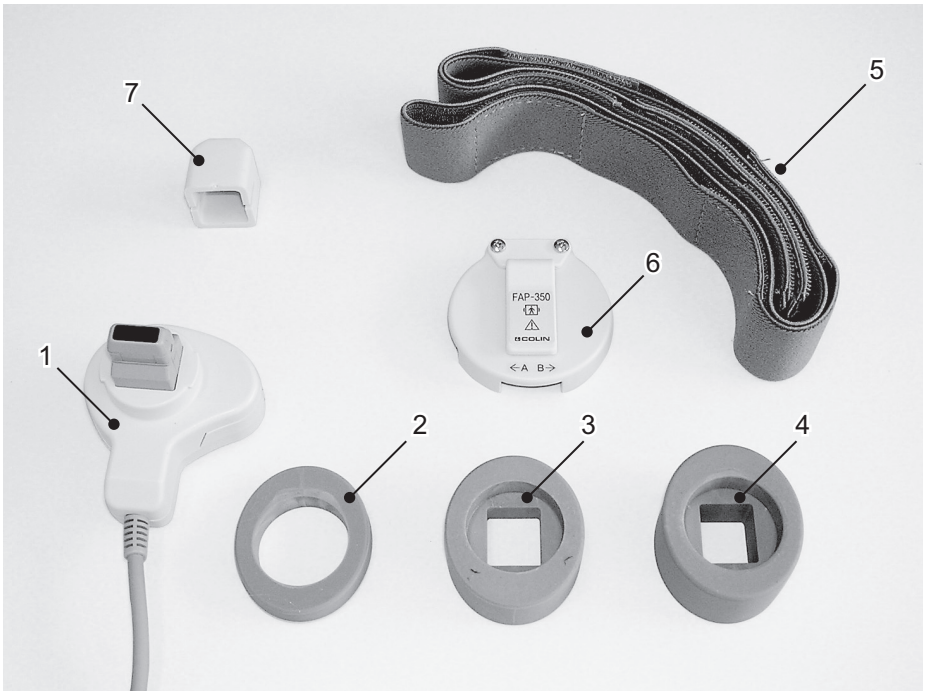
Explanation of Symbols

Type BF
Classification by leakage current levels with defibrillation protection.

Refer to the instruction manual.

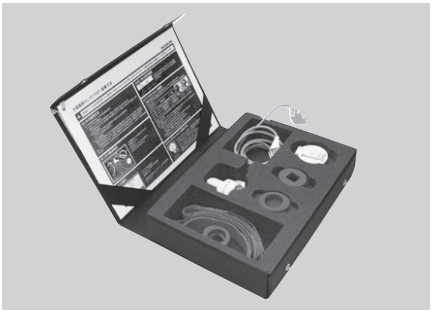


Names of Femoral Arterial Pulse (FAP) Sensor Parts



1 Sensor
2 Spacer cushion (small)
3 Spacer cushion (medium)
4 Spacer cushion (large)
5 Strap
6 Strap holder
7 Protective cap
* Keep the protective cap on when the unit is not in use.

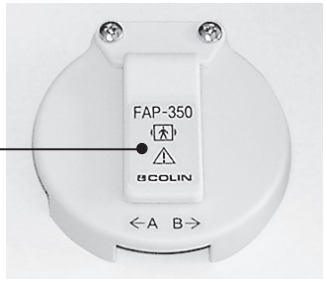
Items stored in the storage case



Explanation of Symbols

Type BF
Classification by leakage current levels with defibrillation protection.

Refer to the instruction manual.



Check Before Use

⚠ **Caution**	For safe and proper use, the device has to be checked before use. Otherwise an accident may result.

Prior to daily use, the following should be ensured:

Before Turning the Power ON

Appearance

- There is no damage on the unit.
- The unit is clean.
- It is not wet.
- The sensors are securely connected.
- The power cords are arranged properly.
- The parts of the sensor that contact the patient are clean.

Power Cord

- The power cord is securely connected to the main unit.
- The cord is placed where it cannot be stepped on and that nothing rests on it.
- It is not frayed; no wires are exposed or broken.

Note:
If the device is turned on while the sensors are cold after sitting in a cold location for a long period of time, it may cause a temperature error. Please wait until the sensors are allowed to warm to room temperature.

After Turning the Power ON

- There is no smoke or abnormal smell.
- There is no abnormal noise.

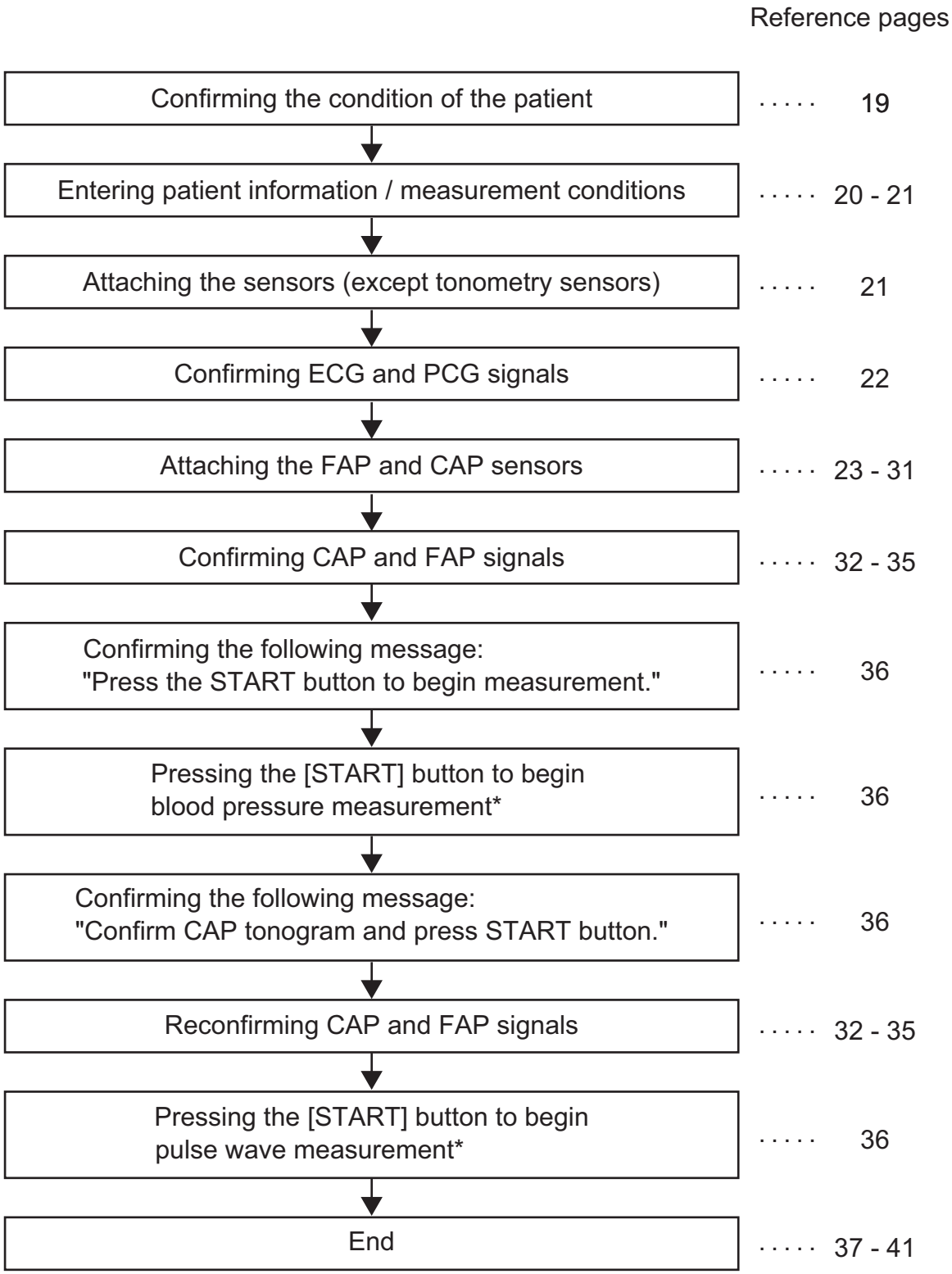
Measurement Environment

Maintain a constant temperature of about 25 °C in the room where measurement is performed and create an environment where the patient can feel relaxed.

⚠ **Caution**	Do not perform measurement when the ambient temperature is 15 °C or less. Incorrect diagnosis and treatment may result. • The blood vessels in the patient's hands and feet will constrict, the blood pressure will rise, and accurate measurement will not be possible. • The sensor will be affected, and it will result in inaccurate measurement result.

Measurement Procedure

Measurement Flow



* If the [START] button for pulse wave measurement is not pressed within 160 seconds after blood pressure measurement starts, pulse wave measurement automatically begins.

Confirming the Condition of the Patient

To allow the blood pressure to stabilize, have the patient lie down face up for 5 to 10 minutes prior to measurement.

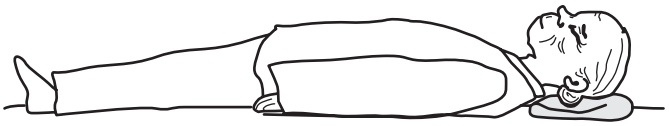
- **The patient should urinate before measurement.**
- **The patient must not smoke before measurement.**
- **The patient does not need to remove wristwatches, necklaces, or other accessories.**

Position of the Patient

Appropriate position

Have the patient lie down face up on the bed.

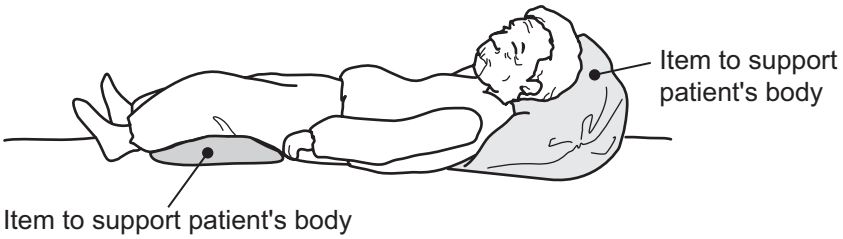
Do not use a pillow; however, for elderly patients with neck stiffness, use an item to support the neck such as a folded towel.



If the patient has kyphosis (round back)

It is best to have the patient lie in a supine position; however, some elderly people have deformation of cervical vertebrae or spine due to osteoporosis. In such a case, support the patient's body with pillows and folded towels so that the patient comfortably lies down face up.

It is recommended that the patient stays in the same position when multiple measurements are performed.



⚠ **Caution**	Do not force the patient to move or stay in a position when any part of the body is in pain. This may cause bone fracture or nerve paralysis.

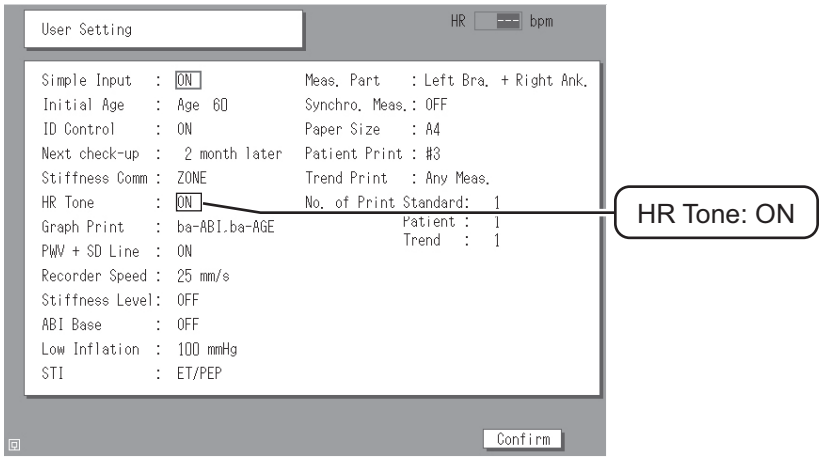
Entering Patient Information / Measurement Conditions

This manual only explains the settings and entry procedures for the TU-100 Pulse Wave Unit. For settings and entry procedures other than those described above, see the manual for the BP-203RPE Series.

BP-203RPEⅡ

Setting in the user setting screen

Set "HR Tone" as shown below.

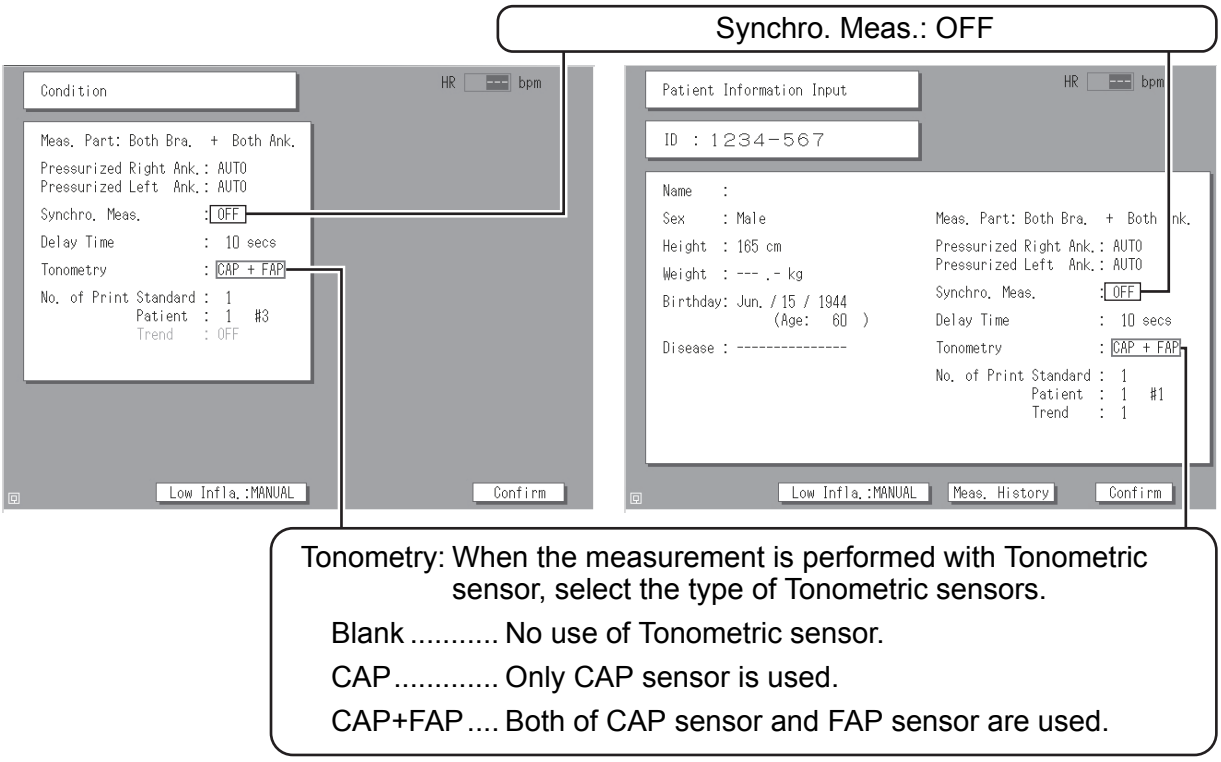


Entry of patient information and measurement conditions

Set "Synchro Measurement" and "Tonometry" as shown below.

"Condition" screen for "Simple Input:"

"Patient Information Input" screen for "Ordinary Input:"



Note:
Be sure to set "Synchro measurement" to "OFF" in order not to perform the second measurement. Otherwise it may cause pain to the patient.

BP-203RPEⅢ

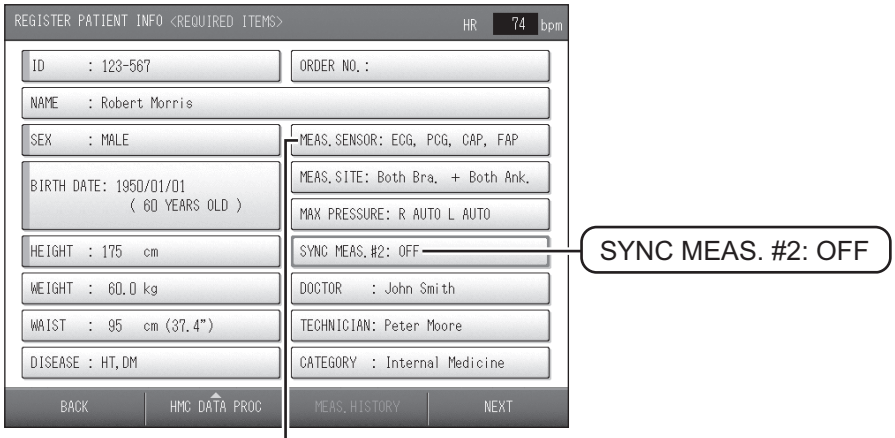
Setting in the user setting screen

Set "HR Synchronized tone" as shown below.

Entry of patient information and measurement conditions

Set "Synchro Measurement" and "Measurement Sensor" as shown below.

"Register patient information" screen or "Confirm patient information" screen



MEAS. SENSOR: When the measurement is performed with Tonometric sensor, select the type of Tonometric sensors.

- ECG, PCG ..... No use of Tonometric sensor.
- ECG, PCG, CAP ..... Only CAP sensor is used.
- ECG, PCG, CAP, FAP ... Both of CAP sensor and FAP sensor are used.

Attaching the sensors (except tonometry sensors)

Attach the ECG clips, PCG sensor and the cuff to the patient.

For the procedures on attaching the sensors, see the manual for the BP-203RPE Series.

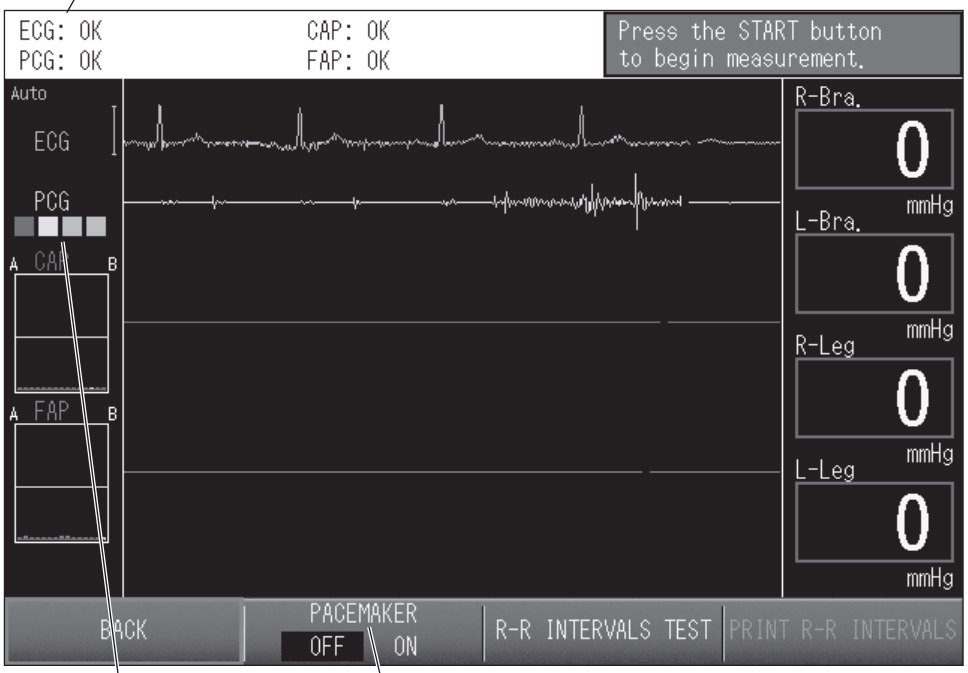
Confirming ECG and PCG Signals

Enter the necessary information for the patient and make sure that the ECG and PCG are stable on the waveform screen.

For details on messages, see the manual for the BP-203RPE Series. The example below shows the screen of the BP-203RPEⅢ.

ECG and PCG messages:

Make sure that the ECG and PCG messages show "OK".



Pacemaker:

"Pacemaker" is on when the patient uses the pacemaker.

PCG Level meter:

Make sure that three or more blocks of light are on.

Notes:

- Measurement can be started even if "PCG: OK" does not appear; however, it may result in inaccurate measurement or analysis.
- Attach the ECG sensor and PCG sensor before attaching the CAP sensor. Otherwise the warning will appear.
- On the BP-203RPEⅢ, measurement can be started by pressing the [START] button three times even when "ECG:OK" is not indicated; however, it may result in inaccurate measurement or analysis. On the BP-203RPEⅡ, measurement cannot be started if the ECG signal cannot be correctly detected.

Attaching the FAP Sensor

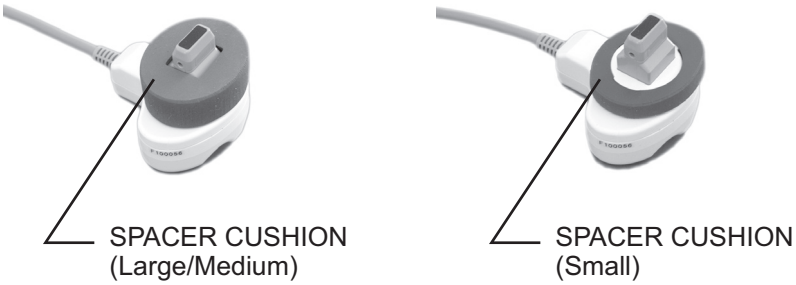
Attaching the Spacer Cushion

The FAP sensor can be used with a spacer cushion for applying an appropriate amount of pressure.

Use the table below as a guideline to select a suitable spacer cushion for the patient.

Spacer cushion	Suitable body types	Pulse detection
Large	Slender to normal	Good
Medium	Slightly overweight	Weak
Small	Overweight	Faint

Fit the spacer cushion on to the protruding part of the sensor with your fingers.



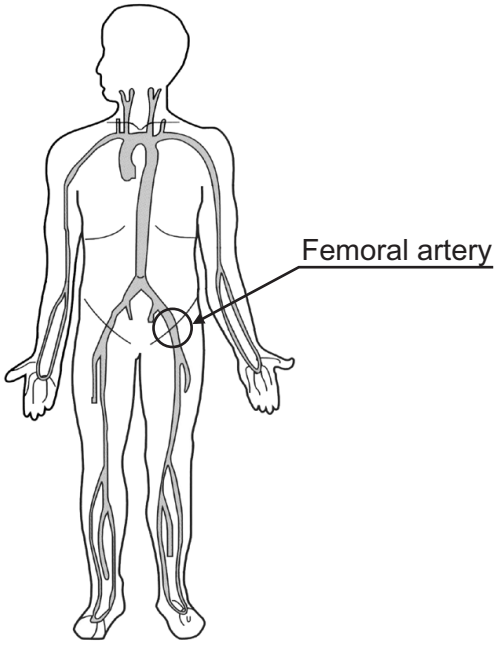
In the following cases, the spacer cushion may not be suitable for the patient's body type. Select a suitable spacer cushion.

A The selected spacer cushion is too small
- The FAP sensor tilts or does not remain stable even when held firmly with the strap or hand.
- Lightly pressing on the sensor causes the wave to widely fluctuate.

B The selected spacer cushion is too large
- The wave remains weak even when the sensor is pressed firmly with the strap or hand.

Position to Attach the FAP Sensor

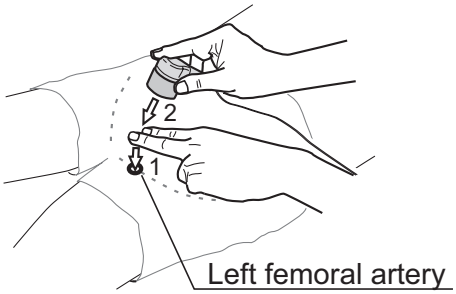
The FAP sensor is attached on the femoral artery. Feel for the left femoral artery with your finger and attach the sensor where the pulse is pronounced.



Feel for the left femoral artery with your finger and locate the part where the pulse is most pronounced. Place the sensor head of the FAP sensor on the part where the pulse is most pronounced.

Measurement is possible with the sensor attached on the femoral artery over thin underwear.

There are three ways for attaching the sensor. These are described in the next section.



1. Feel for the left femoral artery and locate the part where the pulse is most pronounced.
2. Place the sensor head of the FAP sensor.

Note:
The FAP sensor is primarily for measurement of the femoral artery pulse wave; however, it can also be used on other parts. If used for measurement on other parts, the PWV value will differ from the actual value.

How to Attach the FAP Sensor

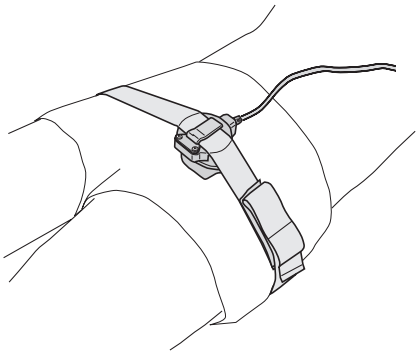
There are three ways to attach the FAP sensor.

■ Using the Strap

Wrap around the strap and secure it with the strap holder to attach the sensor at a good position.

- The strap should be perpendicular to the vertical line of the patient's body.
- If the strap is twisted or not wrapped horizontally, the sensor will be inclined or will not be horizontally to the artery, and will be unstable.
- It is recommended that you lay out the strap before the patient lies on the bed.

The pressure can be adjusted properly for stable measurement.



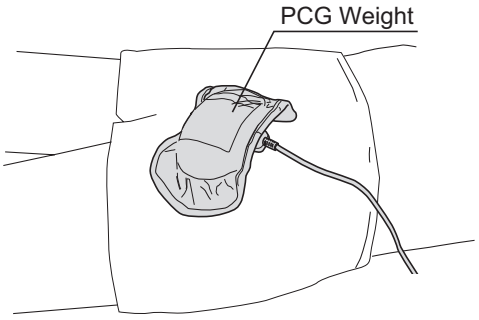
*How to attach the strap holder to the strap
see “Attaching the Strap Holder” (page 26).

■ Using the PCG Weight

Place the PCG weight gently on the FAP sensor.

- Place the weight gently on the sensor in such a way that it will not slide off during measurement.
- The weight may slide off depending on the patient's body shape. In this case, use the strap together with the weight.

Multiple measurements can be performed when sensor pressure is stable by using the PCG weight.



■ Holding with the Hand

Measurement is possible by holding the FAP sensor with your hand.

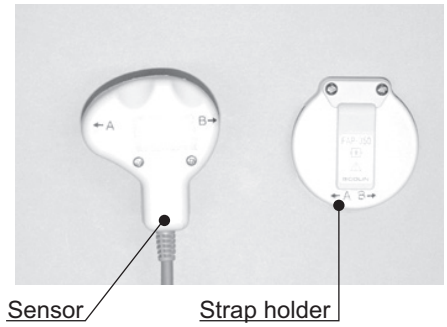
- With a muscle or tendon, it may be difficult to place the sensor on the artery, the sensor can be held with your hand. However, experience is required for stable measurement by holding the FAP sensor with the hand. It is recommended to use the strap and/or the weight.
- When holding the FAP sensor with your hand, the CAP sensor should be first attached followed by the FAP sensor.

Note that measurement accuracy may be decreased if stable pressure is not detected by holding the FAP sensor with the hand.

Attaching the Strap Holder

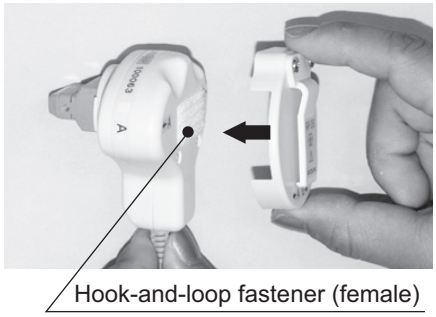
The strap holder can be easily attached to or detached from the strap.

Attach the strap holder on the back of the FAP sensor to secure the strap to the sensor.



Attach the strap holder with the hook-and-loop fastener (male) to the FAP sensor with the hook-and-loop fastener (female).

With the hook-and-loop fastener, the strap holder can be attached and detached with ease.



Lay the strap out on the bed before attaching it to the patient. Have the patient lie down in a supine position on the strap, wrap the strap around the patient and secure with the buckle, and then insert the strap into the strap holder.

Notes:

- If a patient is having convulsions or with a venous pulse, it may not be able to record accurate carotid pulse waveform.
- If a patient has an arrhythmia, the PWV may not be able to be accurately measured due to insufficient number of detected pulses.
- The sensor head is very sensitive. Applying excessive pressure on the sensor head or treating the sensor roughly may cause damage. Keep the protective cap on the sensor when the unit is not in use, and store it in a safe place.

Attaching the CAP Sensor

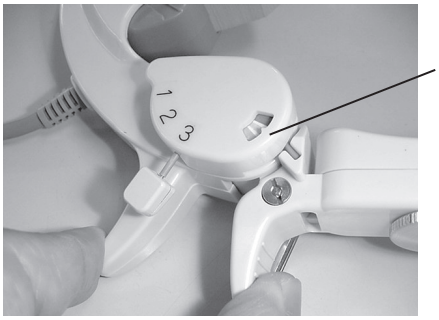
Applying pressure on the carotid artery for a prolonged time will impose a strain on the patient. Attach the CAP sensor after all other sensors have been attached.

Selection of Arm

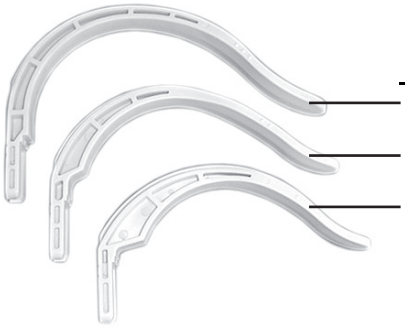
An appropriate arm size must be selected to properly attach the arm on the neck of the patient, or pulses will not be accurately detected.

Check the angle indicator

Check the angle indicator when the sensor is attached.
Make sure that the needle points to the "**green**" range.



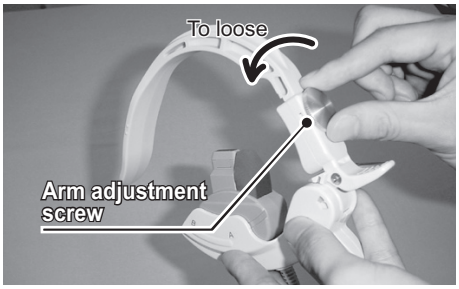
If the needle points to the "**red**" range, the arm is too large.
If the needle points to the "**blue**" range, the arm is too small.

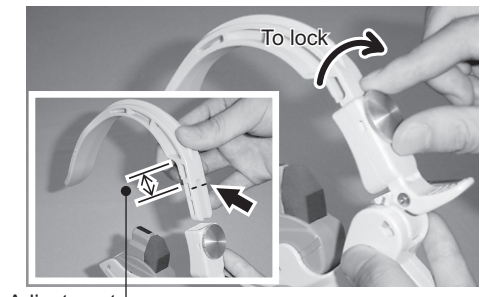


	Circumference of the patient's neck
ARM L	> 42 cm
ARM M	36 ~ 42 cm
ARM S	< 36 cm

Adjustment of arm

Turn the screw counter-clockwise to detach the arm or adjust it to fit the neck of the patient. Turn the screw clockwise to lock the arm.





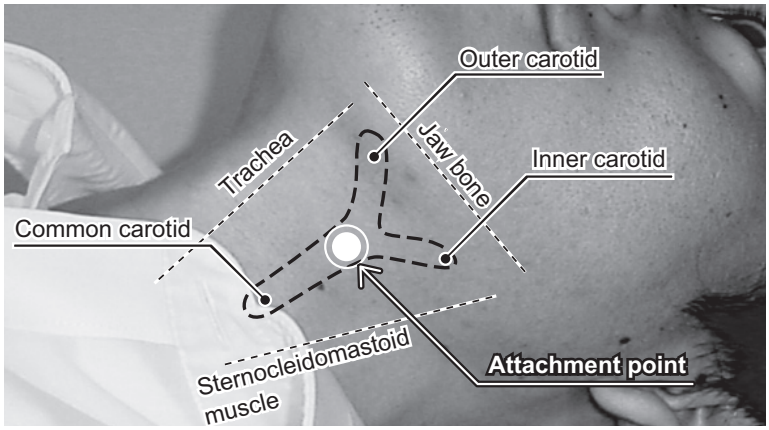
*The red line indicates the maximum point to which the arm can be pulled out. Do not pull the arm out beyond this line.

⚠ **Caution**	•Select a suitable arm size. Otherwise incorrect diagnosis and treatment may result. •If you need to measure the circumference of the patient's neck, do so with the patient lying on the bed. Otherwise incorrect diagnosis and treatment may result.

Position to Place the CAP Sensor Head

It is recommended to place the CAP sensor head on the left common carotid artery to perform measurement.

If it is difficult to detect the pulse on the left common carotid artery, place the sensor head on the right one.



In the triangle formed by the trachea, jaw bone, and sternocleidomastoid muscle, place the sensor head slightly below (about 5 mm) the branch between the outer carotid and the inner carotid at the ampulla of the common carotid. The branch of the common carotid is the part where you can feel the pulse with your finger.

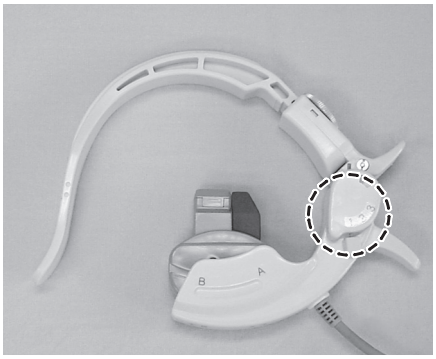
Attaching the CAP Sensor

When attaching the CAP sensor to the patient, pay attention to the following.

- Do not use a pillow. The pulse will not be properly detected.
- Feel the neck to find the pulse, then place the sensor so that it is on the area where the pulse can be felt.
- Attach the sensor so that the sensor arm supports the back of the neck.
- Make sure that the sensor arm does not catch the patient's neck.
- Attach the CAP sensor promptly to minimize strain on the patient.

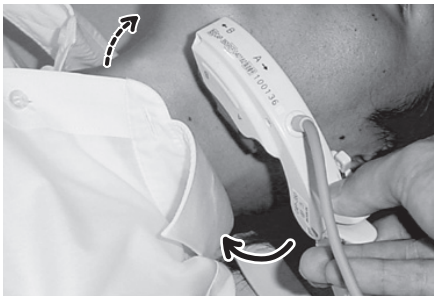
Attach the sensor according to the following instructions.

1. Make sure the pressure adjustment lever is at "1".

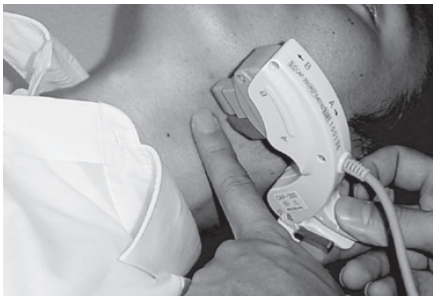


2. Insert the sensor arm behind the neck so that the sensor will be securely attached with the arch of the arm supporting the back of the neck.

Hold the arm with your right hand to open the arm.

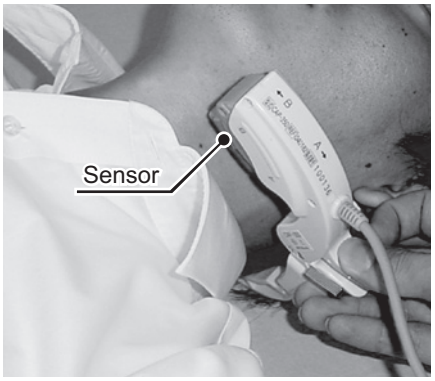


3. Keeping the arm open with your right hand, feel the patient's neck with your left index finger and locate the part where the artery pulse is most pronounced.



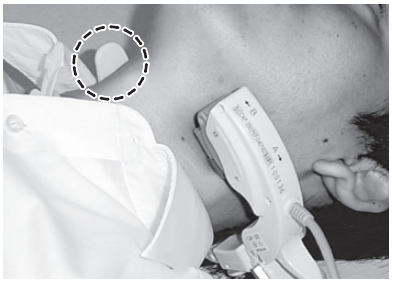
4. Place the sensor head on the part where the pulse can be detected.

Do not place the sensor head on a tendon or on the Adam's apple.



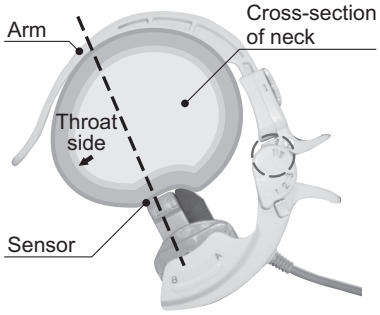
Is the CAP Sensor Properly Attached?

Make sure that the tip of the arm appears the opposite side of the neck.



Make sure that the sensor and the arm are positioned diagonally and the neck is securely supported.

Make sure that the angle indicator is "green".



Notes:

- If a patient is having convulsions or with a venous pulse, it may not be able to record accurate carotid pulse waveform.
- If a patient has an arrhythmia, the PWV and STI may not be able to be accurately measured due to insufficient number of detected pulses.

⚠ **Caution**	Make sure that the sensor arm does not catch the patient's neck. This may cause injury.

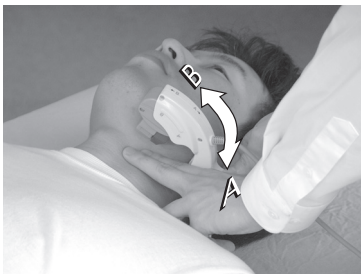
Checking the Attachment

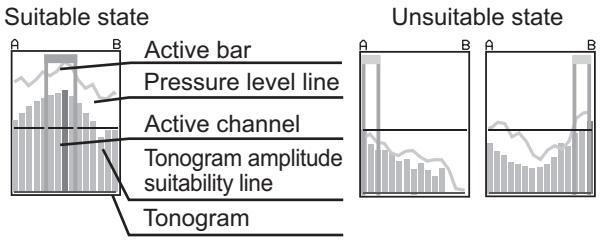
Fix the position of sensor by checking the tonogram on the screen. Adjust the position of the sensor so that the tonogram will be a mountain shape.

Make sure that the arm is securely supporting the back of the neck.

Adjustment of the position

When the message "Move sensor toward A-side" or "Move sensor toward B-side" is displayed, move the sensor in the indicated direction to adjust the position.





⚠ Caution	Do not slide the sensor on the skin when it is repositioned for measurement. It may cause damage to the sensor.

Adjusting hold-down pressure

If the "Weak Signal" message appears, leave the sensor in place and adjust the pressure by changing levels from level 1 to level 2, and then to level 3 if needed.

1

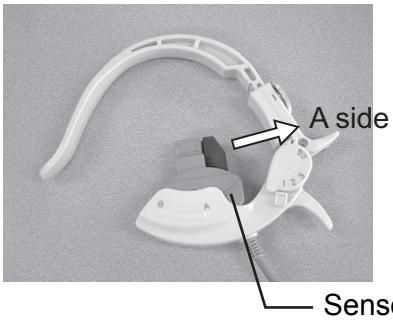
2

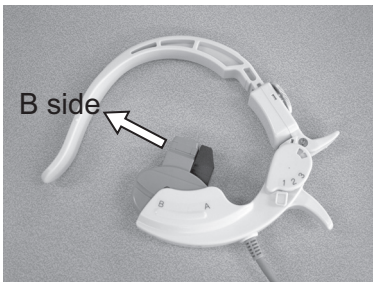
3

Angle adjustment

Angle of CAP sensor can be adjusted by sliding sensor head to either A side or B side.

Check Tonogram indicator on the display and adjust sensor angle to hold-down carotid artery vertically with the sensor head.





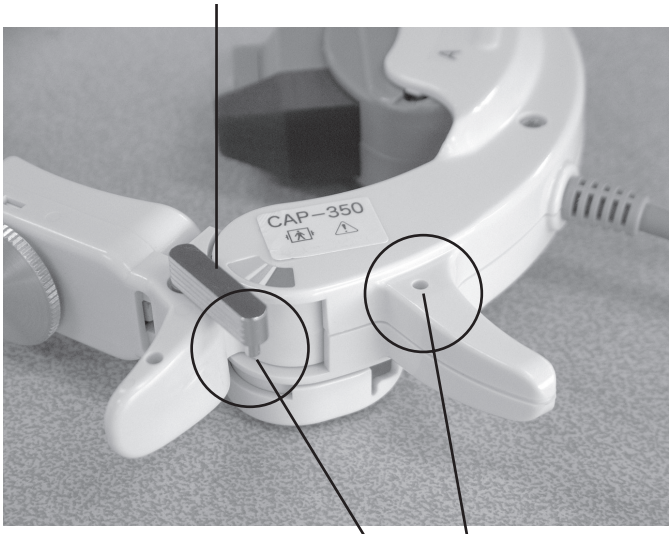
Note:
The sensor head is very sensitive.
Applying excessive pressure on the sensor head or treating the sensor roughly may cause damage.

Usage of the CAP sensor lock lever

Arm of sensor can be held open with the lock lever.

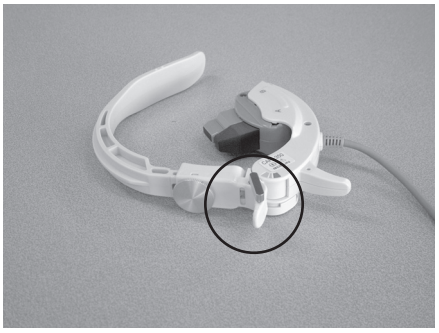
Use the lock lever when searching an appropriate position for the sensor head to be placed or when temporarily detaching the sensor from the neck between continuous measurements in order to reduce strain on the patient.

Lock lever

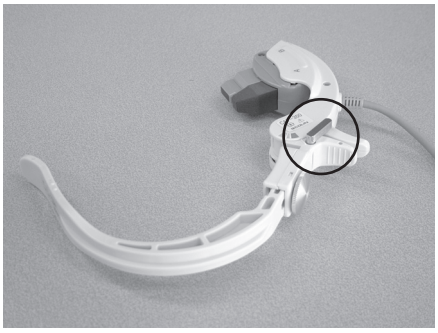


The projecting part of this lever is inserted into this hole.

Normal position



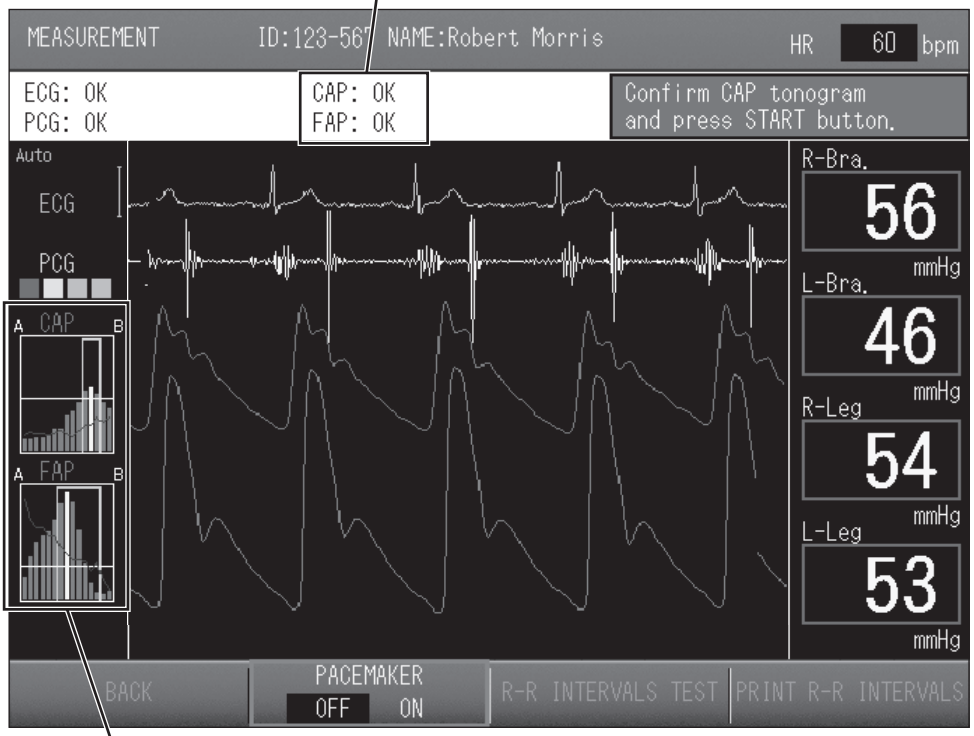
Lock position

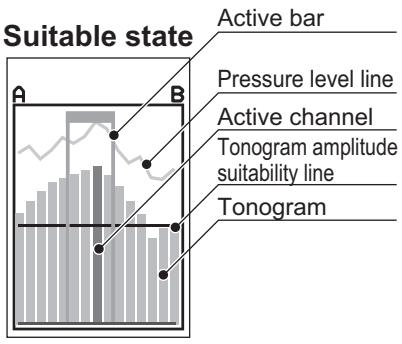


Confirming CAP and FAP Signals

Check the stability of CAP and FAP signals.
The example below shows the screen of the BP-203RPEⅢ.

CAP and FAP message
Make sure that the CAP and FAP messages are both "OK". If not, see the next page for the list of messages.





Confirm the active bar, tonogram, active channel and pressure level in order to ensure that the CAP sensor head and the FAP sensor head are positioned in the center of blood vessel.

First, make sure that the tonogram is a mountain shape. Next, confirm that the active channel points to the peak of the mountain and the top of the active bar is green. Finally, check if the pressure level is appropriate.

* See pages 34 - 35 for each of the adjustment procedures.

Note:
The tonogram cannot be displayed when ECG electrodes are not attached to the patient.

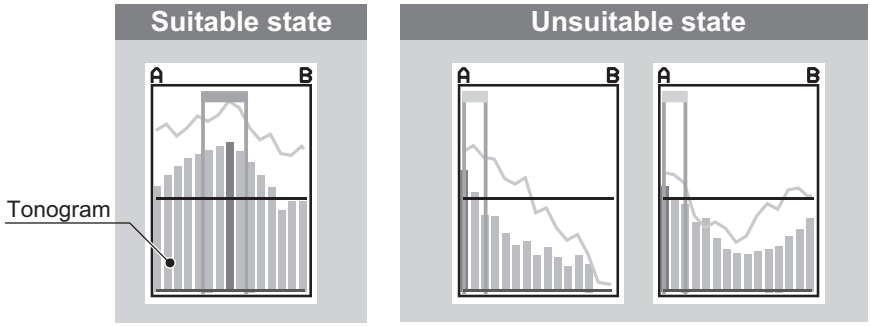
If one of the messages below appears, follow the instructions corresponding to message.

Screen message	Countermeasure
Initializing Stabilizing	Please wait for a while.
Ungetable Signal	Adjust the position of the sensor.
Time out	Check ECG.
Adjust Sliding Sensor Head	Move the sliding sensor head and adjust the sensor. *See page 34 for the adjustment procedure.
Weak Signal	■ CAP sensor Keep the sensor attached and change the pressure adjustment lever from 1 to 2 or 3. *See page 35 for the adjustment procedure. ■ FAP sensor Tighten the strap with the sensor attached, or add another PCG weight. (A light object such as a towel can be used in place of the weight.)
Move sensor toward A-side Move sensor toward B-side	■ CAP sensor Move the sensor in the indicated direction. *See page 34 for the adjustment procedure. ■ FAP sensor Move the sensor head in the direction indicated on the back of the FAP sensor. As a guideline, the width of the sensor head is about 10 mm, and thus the sensor head should be moved about 5 mm. 

Checking the Positioning on the Display

Checking the tonogram

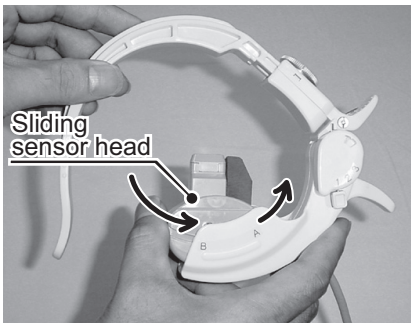
Adjust the position of the sensor so that the tonogram is in the shape of a mountain.



Adjust the inclination of the tonogram with the sliding sensor head.

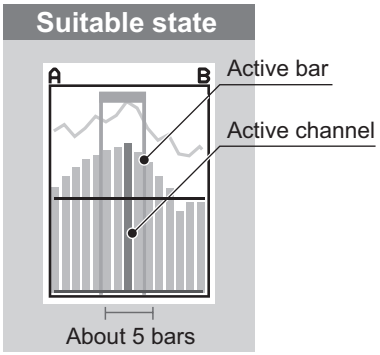
If the tonogram shows a steep incline as shown above, adjust the position and inclination by sliding the sliding sensor head.

To slide the sliding sensor head, press the side with your finger.



Checking the active channel and active bar

Adjust so that the active channel (yellow bar) points to the peak of the tonogram mountain and the top of the active bar is green. If the active channel is out of the suitable range, the top of the active bar will appear orange. Confirm that the active channel is one of the five active bars in the center of those 15 bars.



Reposition the sensor head.

If the active channel is away from the center in the "A" or "B" direction, pull the opening lever and reposition the sensor head.

As a guideline for moving the sensor head in the "A" or "B" direction, the width of the sensor head is about 10 mm, and thus the sensor head should be moved about 5 mm.

Note:

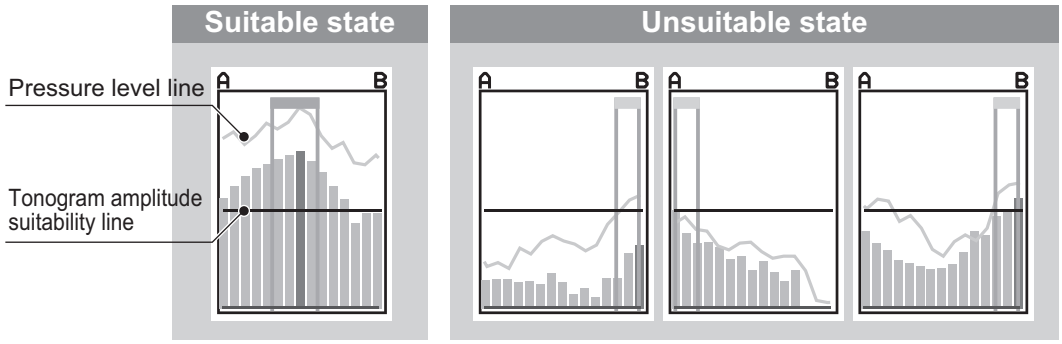
If the active channel does not point to the peak of the mountain during measurement, accurate measurement will not be possible.

Checking the Pressure Level Line

The pressure level line indicates the degree of contact between the sensor and the skin. Adjust so that the pressure level line appears as a relatively smooth line.

Excessive pressure alarm sound

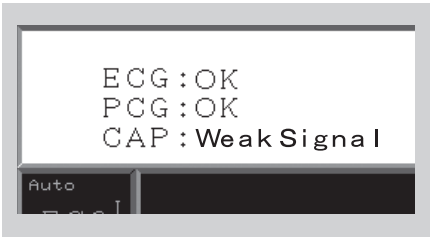
If the CAP sensor is pressed unnecessarily strongly against the neck, the error message "Excessive CAP pressure" will appear and an alarm will sound. If the alarm continues to sound, reduce the pressure.
(The alarm may sound temporarily when the patient swallows or in other conditions.)



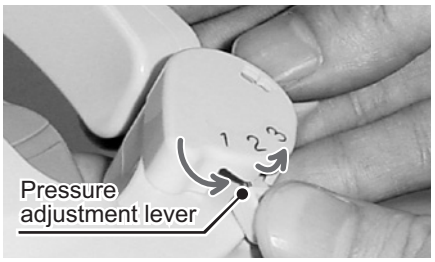
If a suitable waveform is not displayed, adjust the position or reattach the sensor.

Adjust the pressure with the pressure adjustment lever.

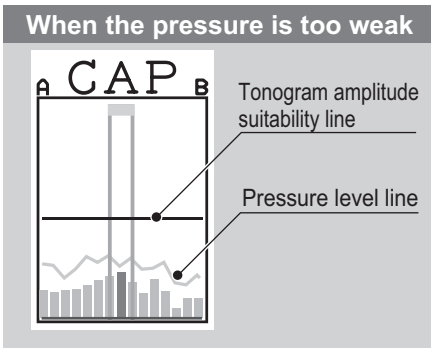
When the pressure is weak, an error message such as "Weak Signal" or "Amplitude width is small" will appear on the screen of the main unit.



Press the pressure adjustment lever and slide to adjust the pressure in steps. Pressure levels are 1, 2, and 3, with 3 the highest level.



Increase the pressure with the pressure adjustment lever one level at a time, checking the tonogram at each level.



⚠ **Caution**	The higher the pressure level, the more strain on the patient. Find a suitable position and perform measurement with as low a pressure as possible. This may cause an accident or injury.

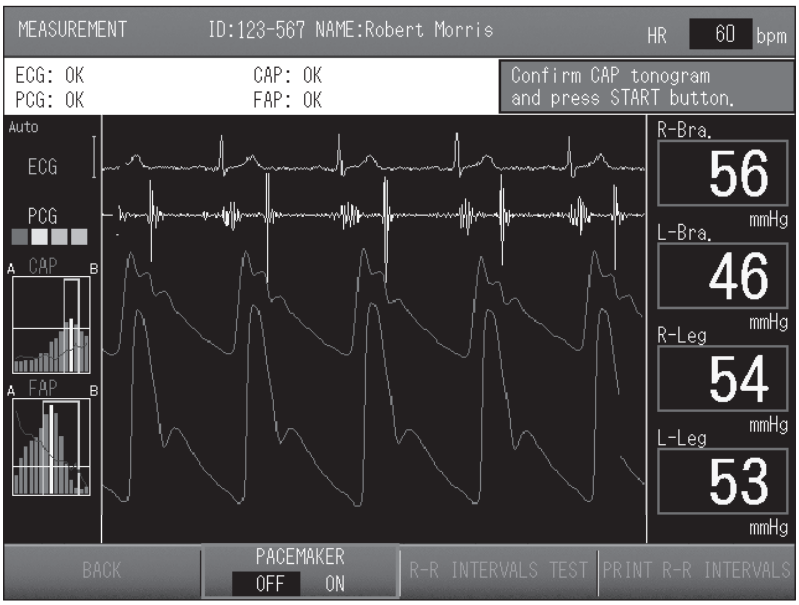
Start Measurement

After attaching the sensor, press the [START] button to start measuring blood pressure. After the blood pressures of the limbs are measured and the cuff is maintained at a fixed pressure, the message "Confirm CAP tonogram and press START button" is displayed and measurement pauses. The sensor sometimes moves during blood pressure measurement. Confirm the shape of tonogram again, and readjust the sensor if necessary.

After you have verified the shape of tonogram and confirm that the CAP signal is stable, press the [START] button to begin pulse wave measurement.

Make sure that "OK" appears for all items on the screen. If the [START] button is pressed when the signals are unstable, accurate measurement will not be possible.

The example below is the screen of the BP-203RPEⅢ.



If the [START] button for the pulse wave measurement is not pressed within 160 seconds after the blood pressure measurement started, the system will start measuring the pulse wave automatically.

⚠ **Warning**	• The CAP sensor detects pulse waves by being pressed against the neck of the patient. Do not use except for testing within a short period of time. This may cause an accident. • Pay constant attention to patient's condition and level of consciousness. Stop measurement if an irregularity occurs. This may cause an accident. After application of the CAP sensor, it is possible that the patient may feel uncomfortable or sense some pain, or that the patient may experience a drop in pulse or lapse in consciousness. Constantly monitor the condition and level of consciousness of the patient and perform tests according to instructions from the physician. (Be cautious of carotid-cavernous fainting and carotid-cavernous reflex syndrome.) • If the HR synchronized tone becomes irregular while the CAP sensor is attached, immediately remove the CAP sensor, stop measurement, and consult the patient's physician. This may cause an accident.

Notes:

- Measurement can be started even when "OK" is not indicated; however, in that case, the measurement analysis result may not be accurate.
- If the CAP sensor creates too much of a load on the patient, there is no need to keep it attached during blood pressure measurement. The CAP sensor can be attached for pulse wave measurement while the measurement is paused following blood pressure measurement. However, skill and practice are required in order to properly attach the CAP sensor on the patient in a short period of time.

Completion of Measurement

1. Confirm that measurement has ended.

- After measurement ends, re-measurement may take place in some cases. Wait until the examination results appear on the screen.
- The examination results will appear on the screen, and if the number of printed pages is set, report printing will start.
- If re-measurement is necessary, press the [REMEASUREMENT] button ([Remeas.] button on the BP-203RPEⅡ), set the re-measurement conditions, and prepare for measurement.
- If post stress measurement will be performed, press the [STRESS MODE] button ([Post Exer.Mode] button on the BP-203RPEⅡ) and prepare for measurement.

For details on re-measurement and post stress measurement, see the manual for the BP-203RPE Series.

2. Promptly remove the CAP sensor as it may impose a strain on the patient, and then remove the cuff and other sensors.

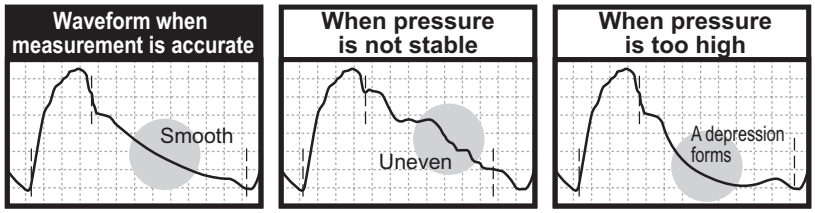
3. Press the [END] button (the Stop button on the BP-203RPEⅡ) to end the examination.

Check the pulse wave at the same time.

Is the shape of pulse wave good?

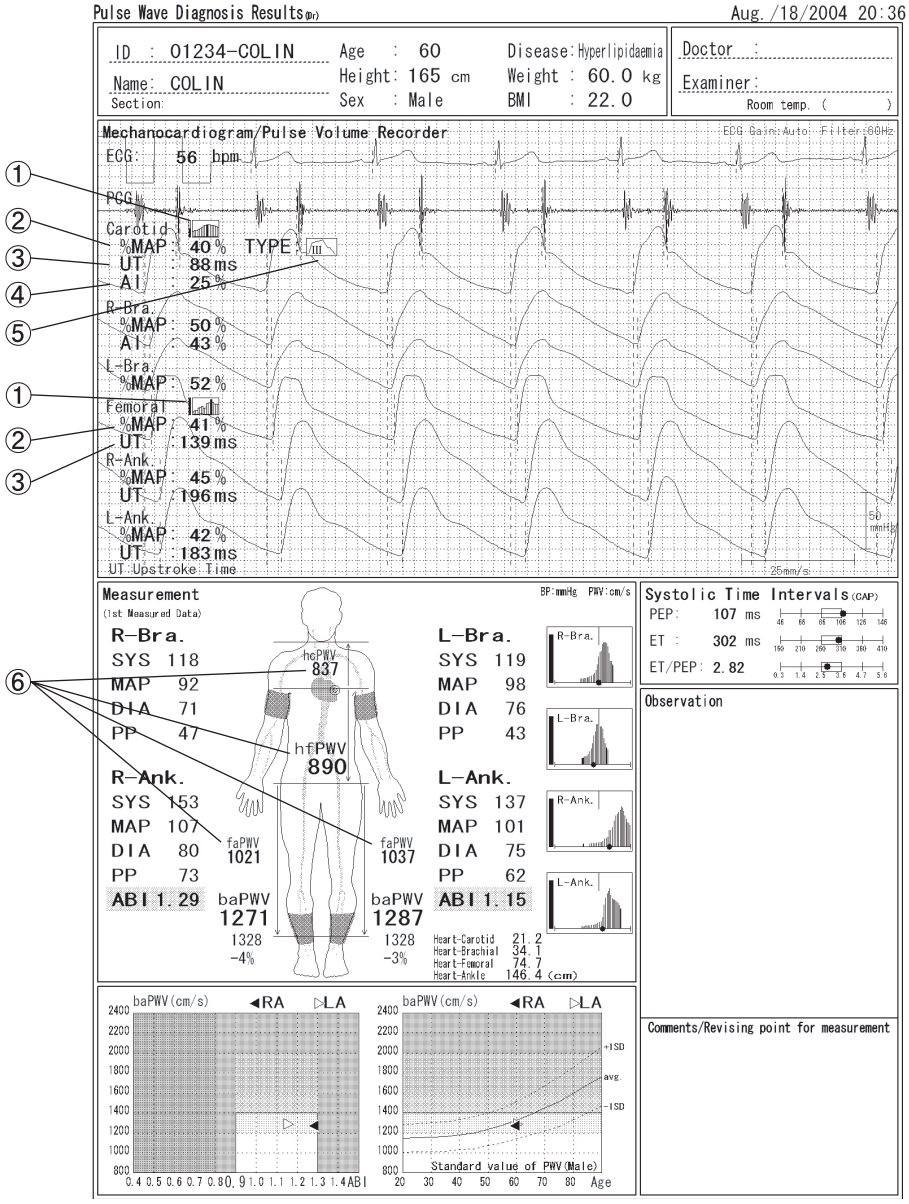
If the pressure to the sensor is too weak or the sensor is loosely attached, accurate measurement is not possible.

Confirm the shape of the pulse wave in the measuring screen and in the examination results.



Print Results

Analysis results can be printed after completion of measurements.
This section describes only the printed results obtained using Pulse Wave Unit TU-100.
Refer to the operation manual for BP-203RPE series for other information.



Note:
Do not turn off the power during printing.
Otherwise the CF memory may be corrupted.

① **Tonogram**

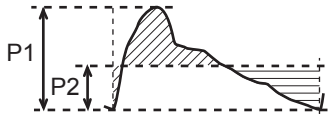
This graph shows the pressure level and amplitude level acquired using the multi-tonometry sensor.

In the case of carotid artery data, the tonogram per beat is shown.

② **%MAP (%Mean Arterial Pressure)**

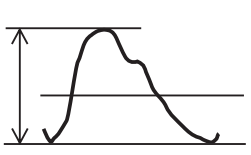
This value is one of the pulse waveform indexes that is calculated from the blood pressure values. It indicates, as a percentage, a value from the area of the wave form (P2) divided by the amplitude of the pulse (P1). This value is calculated with the following formula:

$$\%MAP = \frac{P1}{P2} \times 100\ (\%)$$

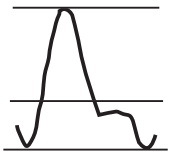


P1: Pulse wave amplitude

P2: Mean value of the area
(the level at which ▨ and ▭ are equal.)



Soft (i.e. 45 %)

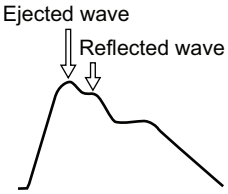


Hard (i.e. 38 %)

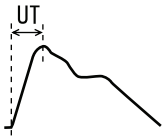
Constricted (i.e. 50 %)

③ **UT (Upstroke Time)**

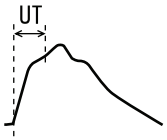
This is the time from the start of the pulse wave to its peak. However, when the reflected wave is higher than the ejected wave, the time until the start of the reflected wave will be considered as the UT.



In a pulse wave in a carotid artery, two peaks will be observed, which are the ejected wave and the reflected wave respectively.



When the ejected wave is higher than the reflected wave, the time until the peak of the ejected wave is the UT.

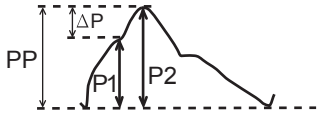


When the reflected wave is higher than the ejected wave, the time until the start of the reflected wave is the UT.

④ **Argumentation Index (AI)**

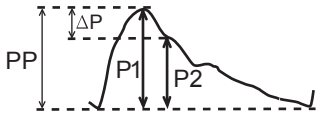
The argumentation index is a numerical value that indicates the percentage of the reflected pressure wave with respect to the driven pressure wave in the brachial pressure pulse wave. △P expresses the post-systolic component after subtraction of the maximum wave height of the pre-systolic component.

$$AI = \frac{\triangle P}{PP} \times 100\ (\%)$$



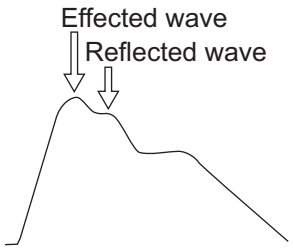
Example of the increase in the AI value as the wave height of the post-systolic component rises

$$AI = \frac{\triangle P}{PP} \times 100\ (\%)$$



Example of the decrease in the AI value as the wave height of the pre-systolic component rises

⑤ **Waveform Shape**



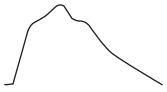
Two peaks are observed in the waveform, which are the effected wave and the reflected wave respectively. The shape of waveform with these peaks is classified into the following types.

type Ⅰ 

The effected wave is higher than the reflected wave.

type Ⅱ 

The reflected wave is higher than the effected wave and there is a small valley between the two.

type Ⅲ 

The reflected wave is higher than the effected wave and there is an inflection point between the two.

type Ⅳ 

The effected wave cannot be distinguished from the reflected wave.

For most of healthy subjects at a young age, the waveform is type Ⅰ. As artery walls harden with age, the wave form will be type Ⅱ or higher.

⑥ **PWV (Pulse Wave Velocity)**

Pulse wave velocity is the speed in which the pulse is transmitted from the heart to the end artery when blood is ejected during contraction. It is mainly used to evaluate arterial wall stiffness.

$$PWV = \frac{L\ (distance)}{PTT\ (Pulse\ Transit\ Time)}$$

With this device, the PTT of each segment is calculated from the waveform taken from each sensor as shown in the illustration below.

hcPWV data: Ascending Aorta - Carotid Artery PWV

hfPWV data: Ascending Aorta - Femoral Artery PWV

faPWV data: Femoral Artery - Ankle PWV

haPWV data: Ascending Aorta - Ankle PWV
(This is an option)

Ascending Aorta - Carotid Artery PWV

$$hcPWV = \frac{Lhc}{Tc}$$

Ascending Aorta - Femoral Artery PWV

$$hfPWV = \frac{Lhf}{Tc + Tcf}$$

Femoral Artery - Ankle PWV

$$faPWV = \frac{Lfa}{Tfa}$$

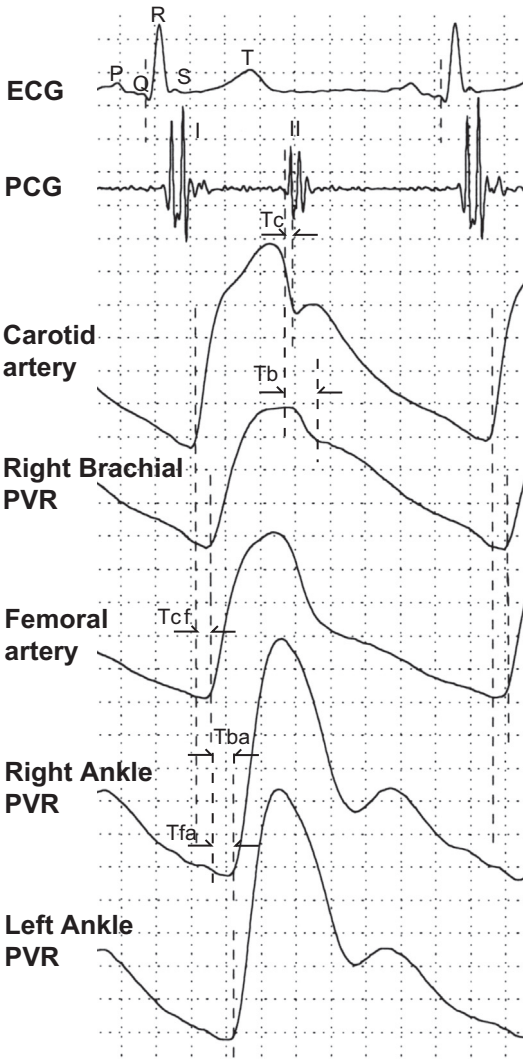
Right Brachial - Ankle PWV

$$baPWV = \frac{Lba}{Tba}$$

Ascending Aorta -Ankle PWV

$$haPWV = \frac{Lha}{Tb + Tba}$$

Distance (L) is automatically calculated by patient's height based on statistical studies.



Error Messages and Troubleshooting

Error Messages and Corrective Measures Related to the CAP and FAP Units

MESSAGES	CAUSE / COUNTER-MEASURE
CAP sensor Failure*1 FAP sensor Failure*2	A sensor cannot be initialized. The sensor may not be functioning. Turn off the power and replace the sensor with another one. If it is difficult to replace the sensor, contact a dealer or an Omron Healthcare technical support representative. If measurement is being performed in a mode that does not use a sensor, press the Stop button to stop the alarm sound. To resume measurement, press the Stop button again.
CAP sensor Temperature Error FAP sensor Temperature Error	Proper measurement cannot be taken due to low room temperature. Power on again after keeping the room temperature at 15 °C.
Check Cable Connection	An incorrect sensor is connected. Turn off the power, and connect the correct sensor. If a sensor is not necessary for measurement, press Alarm Mute so that measurement can be continued.
CAP Sensor Communication Error FAP Sensor Communication Error	Communication with the sensor is detached from the TU-100 connector, or the sensor may not be functioning. Confirm that the sensor is properly connected, and then turn on the power again. Check whether a sensor is properly connected, then turn on Power again. If the appropriate sensor cannot be selected by "Menu" > "User settings screen" > "Measurement part", a sensor failure may have occurred. Turn off Power, and then replace the sensor with another one. Measurement can be continued if a sensor is not required for the measurement.

*1 CAP sensor : Carotid arterial pulse sensor
*2 FAP sensor : Femoral arterial pulse sensor

Error Messages and Corrective Measures Related to the CAP and FAP Units (continued)

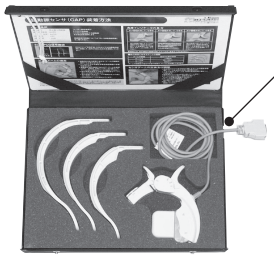
MESSAGES	CAUSE / COUNTER-MEASURE
Weak Signal	Detected signal is not strong enough for accurate analysis. Adjust the position of the sensor. For the CAP sensor, use a different-sized arm, or adjust the angle of the sensor head or the hold-down pressure.
Unstable ECG Signal	Waiting for stabilization and acquisition of the R wave of the ECG signal. Refer to the ECG status display to check this.
Unstable Signal	Pulse waveform is fluctuating. Tell a patient to stay still. If the waveform still fluctuates, adjust the position of the sensor. For the CAP sensor, use a different-sized arm, or adjust the angle of the sensor head or the hold-down pressure.
ECG R-wave Not Detected	R-wave of ECG, essential for pulse waveform analysis, cannot be detected. Confirm that ECG signal is stable.
Adjust Sliding Sensor Head	Pressure to the sensor head is not sufficient. Change the angle of the head or adjust the position of the sensor.
Move Sensor toward A (B) -side	The sensor head is not well-positioned in the center of artery. Move the entire sensor to "A" ("B").
Excessive CAP pressure	The CAP sensor is pressed against the neck too strong. Reduce the pressure. (Note that this may be caused when the patient swallows.)
Excessive FAP pressure	The FAP sensor is pressed against the measurement site too strong. Reduce the pressure.

Note:
Increased pressure on the measurement site will impose a strain on the patient. Ensure that the sensor head is properly placed and that unnecessary pressure is not applied.

Storing the Sensors

CAP Sensor

1. Attach the protective cap on the sensor head.
2. Return the spring strength to "1" with the spring adjustment lever.
3. Detach the arm.
4. Store the items in the sensor case.

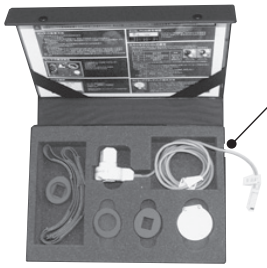


Notch

The sensor case has a notch to allow the cable to be brought outside the sensor case.

FAP Sensor

1. Attach the protective cap on the sensor head.
2. Store the items in the sensor case.



Notch

The sensor case has a notch to allow the cable to be brought outside the sensor case.

Note:
The following locations are not suitable for storing the device:

- Ambient temperatures is below -5 °C or higher than 50 °C or the humidity is below 10 % or higher than 95 %.
- Extremely hot locations.
  If the device is left out in direct sunlight, in a car with the windows closed in summer, or in any other extremely hot location, the device may not be possible to use due to deformation of the parts.

Maintenance

Based on the rules set by medical institutions, maintenance should be conducted as follows.

Unit

Clean the unit by wiping them with a well-wrung out cloth moistened with a diluted neutral detergent or a diluted alcohol for disinfection. However, do not wipe the area around the electrical connectors.

Tonometry sensor

Wipe with 30 - 50 % isopropyl alcohol or 70 % ethyl alcohol.

Apply pressure to the sensor as little as possible. Never press strongly on the sensors. Otherwise the sensor may be damaged.

Before measurement is performed, it is recommended to clean the skin where the sensor directly contacts. It will facilitate the maintenance of the sensor.

Notes:

- Do not soak the accessories in solutions. Avoid the connectors being wet.
- When using sterilizing solution, follow the manufacturer's instructions.
- Do not use solvents such as thinner and benzene for cleaning. Also avoid using cleaners with abrasives. This could damage the unit surface.
- Accessories should not be sterilized with autoclave or gases (EOG, formaldehyde gas, high-density ozone, and the like).
- When the patient has an infectious disease. To prevent infection from spreading in the hospital, disinfect the neck of the patient before performing measurement, and disinfect the sensor after measurement.

Technical Specifications

PRODUCT NAME: Pulse Wave Unit
MODEL: TU-100

General

Dimension	294 (W) × 145 (D) × 55 (H) mm
Weight	approx. 1.4 kg
Protection class	Class II
Degree of protection	Type BF with defibrillator protection

Environmental conditions

Power supply		
	Type 120	Type 230
Rating	AC 120 V	AC 230 V
Frequency	50/60 Hz	50/60 Hz
Power consumption	14 VA	14 VA
Fuse	250 V, T1AH (time-lag, HBC) Cat.No.215001 (Little fuse,Inc.)	250 V, T0.5AH (time-lag, HBC) Cat.No.215.500 (Little fuse,Inc.)
Operational temperature and humidity		
Temperature range	+10 - +40 °C	
Humidity range	30 - 85 % (not condensed)	
Atmospheric pressure	700 - 1060 hPa	
Storage and transportation		
Temperature range	-10 - +60 °C	
Humidity range	30 - 95 % (including condensed)	
Atmospheric pressure	500 - 1060 hPa	

Tonometry

Measurement method	Multi semiconductor strain gauge (2ch)
Frequency characteristic	DC - 300 Hz
Signal output range	0 - 5.0 V
Sensitivity	Variable (Automatic Gain Control)

Accessories

Standard accessories:
Instruction Manual

Accessories sold separately:
TU box for attachment (including screws)
TU Data Cable
AC Power Cord
CAP Sensor CAP SA-350AZ
FAP Sensor FAP SA-350AZ

Manufacturer 	**OMRON HEALTHCARE Co., Ltd.** 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto, 615-0084, JAPAN
Production Facility	**OMRON MATSUSAKA Co., Ltd.** 1855-370, Kubo-cho, Matsusaka-city, Mie-prefecture 515-8503, Japan

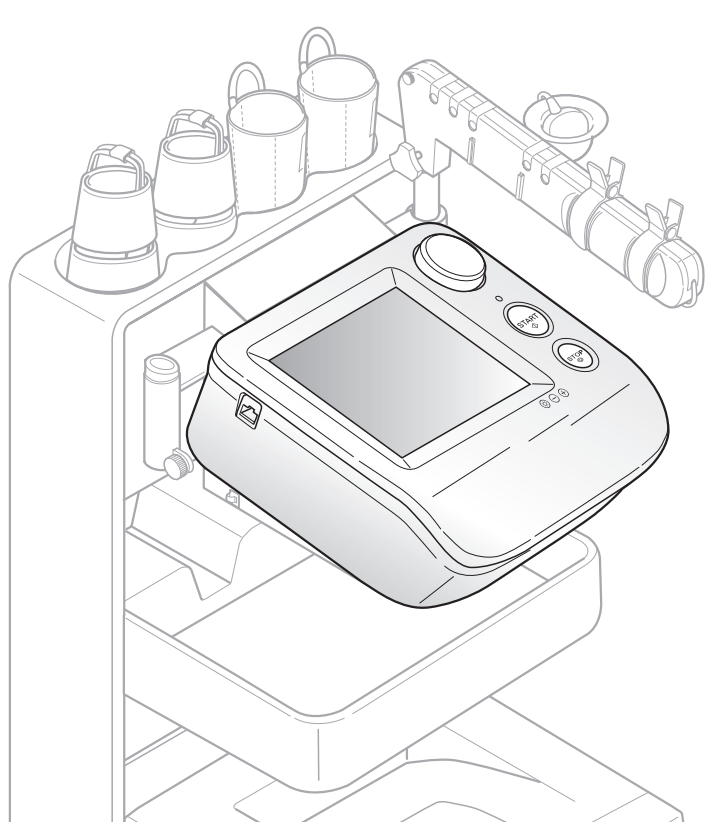
OMRON

Non-invasive Vascular Screening Device

BP-203RPEⅢ

VP-1000 plus

Instruction Manual



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Thank you for purchasing the OMRON BP-203RPEⅢ unit.

Read all of the instructions in the manual before you operate the unit and keep the manual near the unit at all times for future reference.

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1. Before Use

1-1. Exemptions

Disclaimer

Our company assumes no responsibility for the following:

1. Failures, damage, or injuries due to maintenance or repair work performed by other than our company or a company that we specify.
2. Failures or damage to one of our products caused by a product of another manufacturer not delivered by us.
3. Failures, damage, or injuries due to maintenance or repair work using a repair part other than a part that we specify.
4. Failures, damage, or injuries caused by failure to observe the safety instructions and operational procedures given in this manual.
5. Use of the product in conditions that do not conform to the product usage conditions indicated in this manual, including power, installation, and storage conditions.
6. Failures, damage, or injuries due to modification or inappropriate repair of the product.
7. Failures, damage, or injuries due to natural calamities such as fire, earthquake, flooding, or lightning.

Principles

1. The contents of this manual are subject to change without notice.
2. Considerable care has been taken in the preparation of this manual. In the unlikely event that an error or other problem is discovered in the manual, please contact us.
3. Unauthorized reproduction of all or part of this manual is prohibited. Use other than individual (corporate) use without the permission of our company is prohibited by copyright.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

1-2. Intended Use

Medical Purpose	This is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases.
Using Population	Legally certified medical experts, such as doctor, nurse and ME.
Patient Population	It is used on adult patients only.
Environment	The instrument is used in a vascular laboratory, clinic, hospital, doctor's office, and other medical facilities where the non-invasive peripheral vascular test is conducted.
Durable Period	5 years, provided that the appropriate maintenance has been done from production date. (Self-certification through OMRON HEALTHCARE's own data)
Measurement Parameter	■ Non-invasive Blood Pressure ■ Heart Rate ■ Pulse Wave ■ Heart Sound
Calculating Parameter	■ ABI (Ankle Brachial Index) ■ Pulse Wave Velocity ■ Augmentation Index ■ Systolic Time Interval ■ Upstroke Time
Precautions for use	Warnings and cautions described in the instruction manual should be observed.

1-3. Meaning of Symbols

	Start (of action)		Class Ⅱ equipment
	Stop (of action)		Stacking limit by number
	"ON" (Power)		Temperature limitation
	"OFF" (Power)	REF	Catalogue number
	Caution (Refer to safety information)		Use by
	Do not reuse	LOT	Batch code
	Defibrillation-proof type BF applied part		Fragile; Handle with care
	Defibrillation-proof type CF applied part	SN	Serial number
CE	CE mark		This way up
	Humidity limitation		Keep away from rain
	Atmospheric pressure limitation		

1-4. Safety Information

The warning signs and symbol examples indicated below are intended to ensure safe use of the product and prevent damage and injury to you and others. The signs and symbols are explained below.

Explanation of Symbols

⚠ **Warning**	Indicates a situation where incorrect handling may cause human death or serious injury.
⚠ **Caution**	Indicates a situation where incorrect handling may cause human injury or physical damage.*

* Physical damage means serious damage to your house and household goods, and serious injury to pets or other domestic animals.

● indicates "mandatory" (an action that must be observed).
The actual action that is mandatory is indicated inside or next to ● .
The icon at left indicates "disconnect the power plug".

⃠ indicates "forbidden" (an action that must not be taken).
The actual action that is forbidden is indicated inside or next to ⃠ .
The icon at left indicates that "disassembly is forbidden".

Note:
This indicates information that should be known when operating the device.

⚠Warning:

Safety rules when using the product

	Do not use a frayed or damaged power cord or plug. Otherwise electric shock, short circuiting, or fire may result.
	Do not touch the power plug with wet hands. Otherwise electric shock or injury may result.
	Be sure to plug the three-prong power plug into a grounded (three-prong) outlet for medical use (when a printer is included). Otherwise electric shock or current leakage may result.
	Use a dedicated outlet. Otherwise electric shock or current leakage may result.
	Do not poke or scratch the buttons or display with a sharp or pointed object. Incorrect diagnosis and treatment or an accident may result.
	Do not connect the power plug to the outlet if the electrical ratings are outside the specified range below: 220 - 240 VAC. This may cause fire.
	Do not touch the unit when discharging a defibrillator.

Safety rules when performing measurement

	This device is only to be used by qualified medical personnel, or under the guidance of such personnel. Otherwise incorrect diagnosis and treatment or device failure may result.
	The results of measurement should only be interpreted by a doctor. If you are concerned about a measurement result, consult your doctor. Otherwise incorrect diagnosis and treatment may result.
	This device is intended to perform measurement for examination. Do not use the device for patient monitoring. Otherwise an accident may result.
	If pressurization does not stop during measurement or another abnormal condition occurs, remove the cuff or air tube and disconnect the power. Otherwise peripheral nerve may be damaged.
	Use only the specified supplies for the cord, cuff, USB devices, and other parts. Do not install other than specified options. Otherwise an accident may result.
	Do not connect the air tube or cuff to any other device tubes attached to the body. Otherwise air may enter the blood vessels and an accident may result.

Do not attach the arm cuff for patient during medical treatment with intravenous drip or blood transfusion. This may result incorrect diagnosis and treatment.

Do not use this device on a patient that cannot express pain. If cuff pressurization does not stop in a specified time, internal hemorrhaging may occur in the upper arm or ankle.

This device cannot be used during MRI imaging. This may cause an accident.

Pay constant attention to patient's condition during measurement. Otherwise an accident may result.

Do not perform measurement without cleaning and sterilizing the device, cuffs and sensors after measuring for patient with infection.

Pay extra attention to a patient with pacemaker during measurement. Rate meters may continue to count the pacemaker rate during occurrence of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarm. Refer to the pacemaker pulse rejection capability in this manual.

Installation

As this device conforms to the IEC60601-1-2 standard, it can be used in combination with another medical device. While or after an electrosurgical knife or a device which generates noise being used near this device however, make sure that it is properly functioning. Otherwise incorrect diagnosis and treatment or device failure may result.

Do not use this device in the presence of a flammable gas such as a highly inflammable anesthetic, or in a high-pressure oxygen chamber or tent. Fire and explosion may result.

Do not install or store the device in a location where water or chemicals may splash on the device. Electric shock may result.

Do not connect any electric device, without the approval of IEC60601-1, or not fulfilling IEC60601-1-1. For the use of a PC or a printer with this device, the connecting device should be approved according to standards mentioned above. (This unit meets the restricted level of leakage current required for medical devices and it does not include all the connected devices. Connecting to other device is not allowed unless the total leakage current of such a combination is within the restricted level.) Neglecting this caution, it could cause electric shock to the device.

Maintenance

After cleaning the device, dry it completely before turning on the power again.
Otherwise electric shock or current leakage may result.

⚠Caution:

Safety rules when using the product

Observe the rules below when handling the power cord. Failure to observe these rules may result in electric shock or device failure.

- •Do not damage the cord
- •Do not break the cord
- •Do not modify the cord
- •Do not bend or pull on the cord with undue force
- •Do not twist the cord
- •Do not tightly coil the cord when in use
- •Do not place heavy objects on the cord
- •Do not let the cord become pinched

Insert the power plug all the way into the outlet. Otherwise electric shock, short circuiting, or fire may result.

Wipe dust off the power plug. Otherwise electric shock, short circuiting, or fire may result.

After using the device, turn the power switch to the "off" position and disconnect the power plug. Failure to do so may cause deterioration of the insulation and result in electric shock, current leakage, or fire.

When removing the power plug from the outlet, grasp and pull on the plug, not the cord. Pulling on the cord may break wires and cause a short circuit, resulting in electric shock or fire.

If a power failure occurs while using the device, turn the power switch to the "off" position and disconnect the power plug. Failure to do so may result in a product failure or other problem.

If the device becomes wet, wipe it completely dry with a soft cloth before use. Otherwise electric shock, short circuiting, or fire may result.

Do not pull the power cord when moving the stand. Electric shock, short circuiting or fire may result.

Do not replace the fuses on your own. Electric shock or fire might result.

- •The fuses are specifically designed for this device.
  Contact a dealer or an Omron Healthcare technical support representative for replacement of the fuses.
  - Fuse model: 5HT-R 2A (BEL FUSE LTD.)

Safety rules when performing measurement

If the patient has any of conditions below, do not perform measurement. Otherwise incorrect diagnosis and treatment may result.

- •The patient has an aneurysm
- •The patient has insufficient peripheral circulation, noticeably low blood pressure, or low body temperature.
- •The patient frequently has an irregular pulse.

	In the following situations, check by auscultation or palpation. Otherwise incorrect diagnosis and treatment may result. •When irregular pulse waves are indicated. External vibration or patient movement during measurement may cause an incorrect indication. •When an error occurs or when a measured value is questionable.
	If a power failure occurs during measurement, immediately remove the cuff. If the patient's ankle or upper arm is pressurized for a long time, internal hemorrhaging may result.
	Do not attach the cuff on the measurement site below: •Arm with intravenous drip •Upper limb in which a shunt is placed in for hemodialysis Incorrect diagnosis and treatment or an accident may result.
	If there is acute inflammation, a pyogenic ailment, or an external wound where the cuff is to be attached, follow the instructions of a doctor. Symptoms may become worse.
	When there is impossibility of test or doubts about the measurement values, please confirm the patient's condition first. The patient's condition may have deteriorated to the point where measurement limits are exceeded. Always verify that the cuff and cuff hose are appropriately used and are not bent or blocked. If the display continues to show 0, the monitor's pressure may be 0. But if the cuff hose is blocked or bent there may be air remaining in the cuff. At this time disconnect the hose from the cuff to ensure that blood flow is not restricted and no disorders occur to the peripheral nerves.
	When using the device in combination with another medical device, read the manual of the other device well and understand all warnings and cautions. Incorrect diagnosis and treatment may result.
	Do not use the device in a location with loud noise. Incorrect diagnosis and treatment may result.
	Attach the PCG sensor correctly. Incorrect diagnosis and treatment may result.
	Take care that the PCG sensor does not fall on the patient. This may cause injury.
	Wrap the cuff on bare skin or on a thin layer of clothing. Otherwise internal hemorrhaging may result.
	Make sure that the ECG clips are attached in the correct positions. Otherwise incorrect diagnosis and treatment may result.
	Do not use the device near a cellular phone. Incorrect diagnosis and treatment may result.
	Do not use in an MRI, CT, X-ray room, an operating room, or other rooms where radio noise is generated. Incorrect diagnosis and treatment or an accident may result.

Do not use a worn or expired ECG clip electrode or PCG sensor pad. Otherwise incorrect diagnosis and treatment may result.
(ECG clip electrode and PCG sensor pad have an expiry date. After the expiry date, the pad becomes dry and incapable of accurate measurement. Use only a pad or electrode whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

On a bedridden patient, check for lower-limb deep venous thrombus before taking a measurement. Otherwise an accident may result.

The ECG clip electrode and PCG sensor pad are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result.

The sensor box removal lever uses a strong spring mechanism. Take care not to injure yourself on the metal edges. Hold the sensor box firmly and press down hard on the lever from the exterior to remove the connector. This may cause injury with the metal edges.

Do not use an air hose of an arm cuff or an ankle cuff that is bent or collapsed. Incorrect diagnosis and treatment may result.

Connect the USB cable for the printer to the USB port marked with ⚠. Otherwise electric shock or current leakage may result.

Installation

Do not install in a location where the temperature or humidity is outside the allowed range. This may cause malfunctioning or device failure.

Do not use in a moving vehicle such as an ambulance. Incorrect measurement may result. Incorrect diagnosis and treatment or an accident may result.

If you are not using the device stand, exercise sufficient caution when moving the device. The device is heavy and may slip out of your hands, causing injury.

Do not place objects on the device. This may cause injury.

Maintenance

Do not disassemble, repair or modify the device. This may cause electric shock.

Before cleaning or maintaining the device, disconnect the power plug. Otherwise electric shock or injury may result.

Do not touch the patient when changing the toner or feeding paper. Otherwise electric shock or current leakage may result.

Important:

Before use

- Make sure that all cords and tubes are firmly connected.
- Inspect dials and buttons and verify that the device operates correctly.
- Check printer toner, paper, and other supplies.
- Confirm the expiry date of the ECG clip electrodes and the PCG sensor pad. The expiry date can be calculated from the lot number as follows:

(Example)

Lot Number: 6 0 7 1 0 1 1

Production Date: 2006 July 10th

Expiry Date: 2008 July (2 years after the production date)

During use

- Do not pressurize when the cuff is not wrapped.
- Do not use a torn cuff.
- The device may be used on the patients below. If used on patients other than those described below, incorrect measurement may result or measurement may not be possible.
  - Height: 120 to 210 cm
  - Circumference of arm: 20 to 32 cm (using the standard cuff) / 16 to 38 cm (using the optional cuff)
  - Circumference of ankle: 16 to 33 cm
- Do not disconnect the USB or LAN cable while data is being transmitted. This may corrupt the data.
- Do not turn off the power during printing, data transmission, or writing.
- Do not pull out the paper before printing is finished.
- Make sure the date and time setting is correct. If the date and time setting is not correct, the date and time of measurement will not be recorded correctly.
- Do not connect an ECG clip to another conductive part including the ground.
- The electrical energy from a defibrillator may damage the device. During defibrillation, remove the sensors from the patient and do not touch the device.
- When moving or using the device, do not drop or subject the device to shock. This may cause the electric components and precision mechanisms to fail.

After use

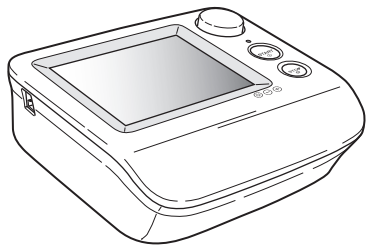
- Clean the device and accessories and arrange properly for storage.
- Do not wash or moisten the cuff.
- Do not use solvents such as thinner, benzene, or concentrated alcohol to clean the device.
- Do not use an autoclave, ultraviolet radiation, or gas disinfection (EOG, formaldehyde gas, concentrated ozone, etc.) to disinfect the device.
- If the power cord is damaged, it must not be replaced by user. Contact a dealer or an Omron Healthcare technical support representative.
- Do not install the unit in the following locations.
  - A location with prolonged exposure to direct sunlight
  - A location with dusty or salt air
  - On an inclined surface or a location subject to vibration, shock, or noise
  - A location where chemicals are stored or gas is emitted
- If the patient has one of the following conditions, a correct measurement may not be obtained.
  - The patient has body movements due to convulsions caused by rheumatism or otherwise
  - The patient has diabetic arteriosclerosis (blood pressure at leg joints tends to be high)
  - The patient has false high blood pressure
  - The patient has convulsions or tremors
- When the unit is incapable of ECG measurement, the message "Electrode removed" is displayed.

1-5. Product and Accessories

Before using this product, make sure that no accessories are missing and that neither the unit nor the accessories are damaged. Contact a dealer or an Omron Healthcare technical support representative if any accessory is missing or damaged.

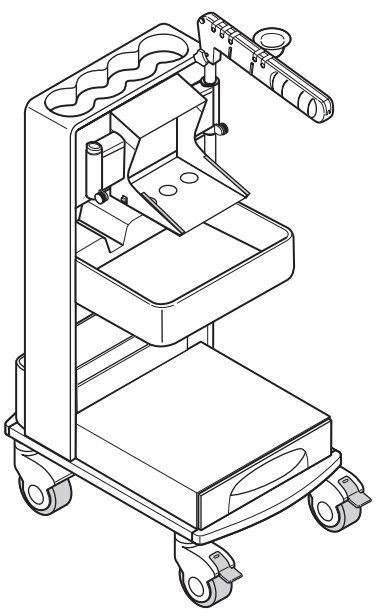
Main Unit

Non-invasive Vascular Screening Device
BP-203RPEⅢ



Standard Accessories

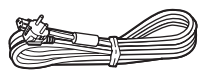
BP-203RPEⅢ stand



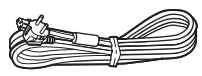
BP-203RPEⅢ stand cover

BP-203RPEⅢ hook-and-loop fastener for the sensor box

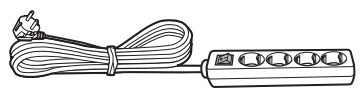
Power cord for main unit (0.8 m)



Power cord for printer (1.1 m)

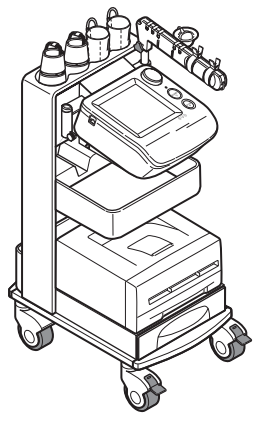


BP-203RPEⅢ power tap

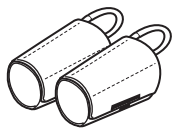


USB cable (for printer)

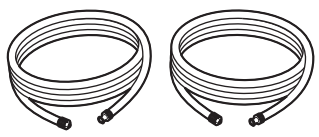
Items on this page will be assembled on delivery as follows:



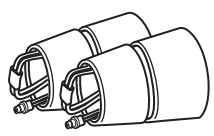
BP-203RPEⅢ arm cuffs, left and right pair
(M size: For arm circumferences of 20 to 32 cm)



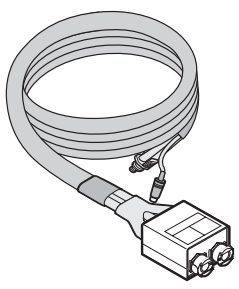
BP-203RPEⅢ arm cuff hoses, left and right pair



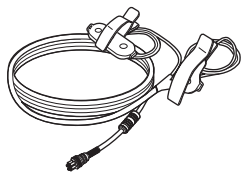
BP-203RPEⅢ ankle cuffs, left and right pair



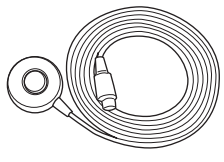
Sensor box



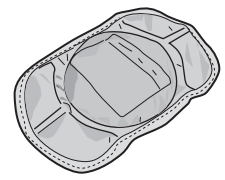
ECG clips



Phonocardiogram sensor (PCG sensor)



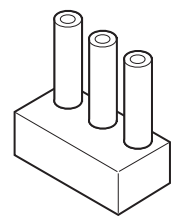
PCG weight



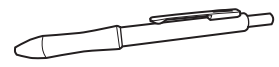
Sensor gel packet (consumable packet) 5 sets

- PCG sensor pad, 1 piece x 5
- ECG clip electrodes, 3 pieces x 5

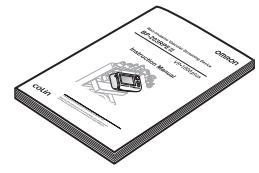
Blood vessel model



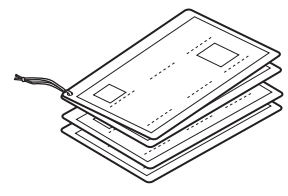
BP-203RPEⅢ touch pen



BP-203RPEⅢ instruction manual



Quick manuals



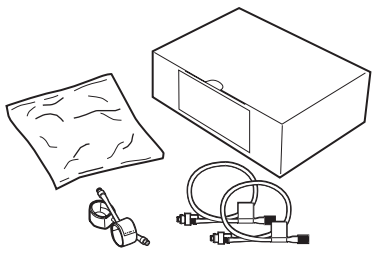
Accessories (Sold Separately)

Product description	REF	Model
Right arm cuff, S size	9999492-9	HEM-CS30-RIGHT
Right arm cuff, M size	9999490-2	HEM-CR30-RIGHT
Right arm cuff, L size	9999496-1	HEM-CL30-RIGHT
Left arm cuff, S size	9999494-5	HEM-CS30-LEFT
Left arm cuff, M size	9999491-0	HEM-CR30-LEFT
Left arm cuff, L size	9999498-8	HEM-CL30-LEFT
Arm cuff air tube (right)	9999505-4	HEM-CR30R-TUBE
Arm cuff air tube (left)	9999504-6	HEM-CR30L-TUBE
Ankle cuff (right)	9999500-3	HEM-CR31-RIGHT
Ankle cuff (left)	9999501-1	HEM-CR31-LEFT
ECG clips	9999503-8	HFA-RPE3-ECG
PCG sensor	9999507-0	HFA-RPE3-PCG
PCG weight	9999506-2	HFA-RPE3-W700
Sensor gel packet (20 sets)	9967933-0	HBP-FORM-101S
Blood vessel model	9999510-0	HFA-FORM-ARTVS
Touch pen	9996749-2	HBP-PEN
LAN cable (straight)	9997621-1	HFA-RPE3-LANS
LAN cable (cross)	9997622-0	HFA-RPE3-LANX
Toe standard disposable cuff	9957110-6	HBP-DCUFF-TBI31
Toe small disposable cuff	9957111-4	HBP-DCUFF-TBI32
Toe cuff tube (right)	9957112-2	HBP-FORM-TBICR
Toe cuff tube (left)	9957113-0	HBP-FORM-TBICL
Stand cover	9511950-0	HFA-RPE3-CVR
Hook-and-loop fastener for the sensor box	9511951-9	HFA-RPE3-SBF

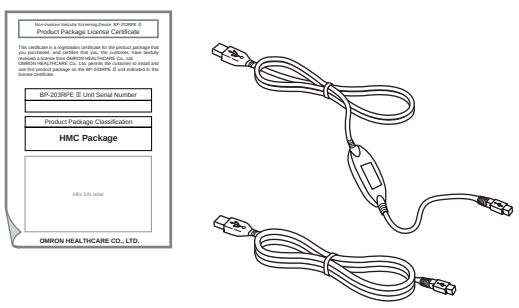
Options

Software and unit options can be purchased to expand the functionality of the product. For details on the uses and functions of the options, see Chapter 4.Refer to "4-1. Options" (page 121)

TBI package

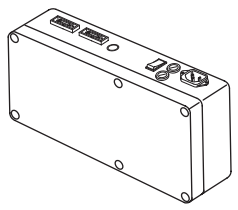


HMC package

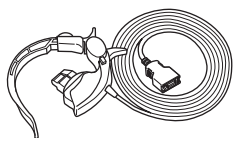


Pulse wave unit

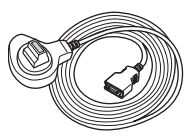
• Pulse wave unit TU-100



• CAP sensor unit

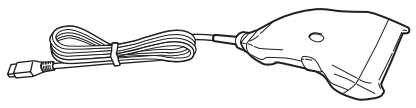


• FAP sensor unit



BP-203RPEⅢ bar code reader set

• Bar code reader
• Bar code reader holder



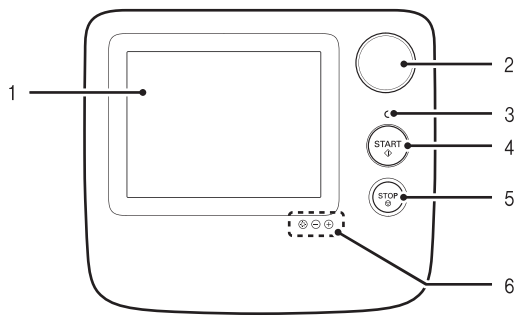
Product description	REF	Model
TBI package	9512233-1	HFA-TBI-ENG
HMC package	9512232-3	HFA-RPE3-HMCPE
Pulse wave unit TU-100 (230V)	9968295-1	HBP-FORM-TU230V
Attachment package for TU-100	9515540-0	HFA-TUATT-230V
CAP sensor unit	9512240-4	HFA-FORM-CAPE
FAP sensor unit	9512241-2	HFA-FORM-FAPE
Bar Code Reader Set	9996743-3	HBP-RPE3-BAR

1-6. Name and Function of Each Part

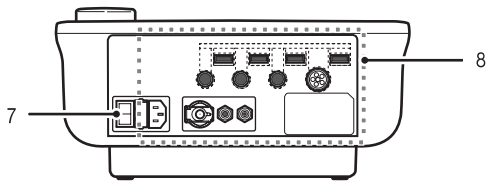
Main Unit

Enter patient information, configure settings, and perform measurement.

Front of unit



Back of unit



1. **LCD display (touch screen)**
   When configuring settings: Setting buttons appear. Touch the setting buttons with the touch pen to enter settings.
   During measurement: Measured values, measured waveforms, and operation buttons appear.

2. **Jog dial**
   Settings can be entered using the jog dial.
   Turn the jog dial right or left to select an item and press to enter.

3. **Display lamps**
   Off: Power is off
   Green (on): Power is on (normal mode)
   Orange (on): Power is on (sleep mode)

4. **[START] button**
   Press to begin measurement.

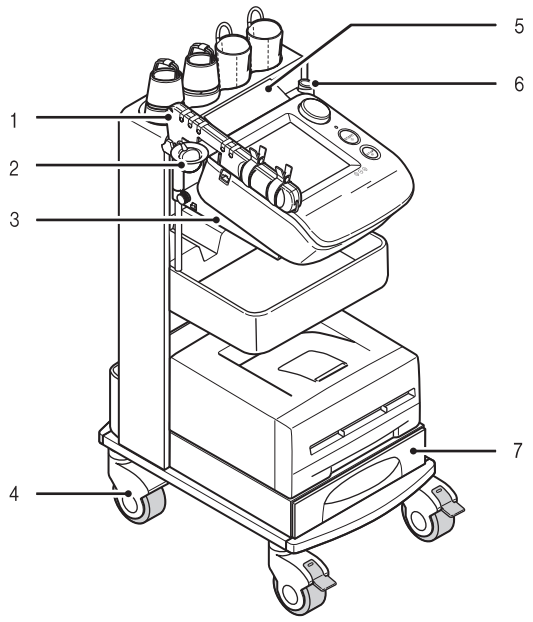
5. **[STOP] button**
   Press to interrupt and stop measurement.
   On the screen with [BACK], the [STOP] button can be also used to return to the previous screen.

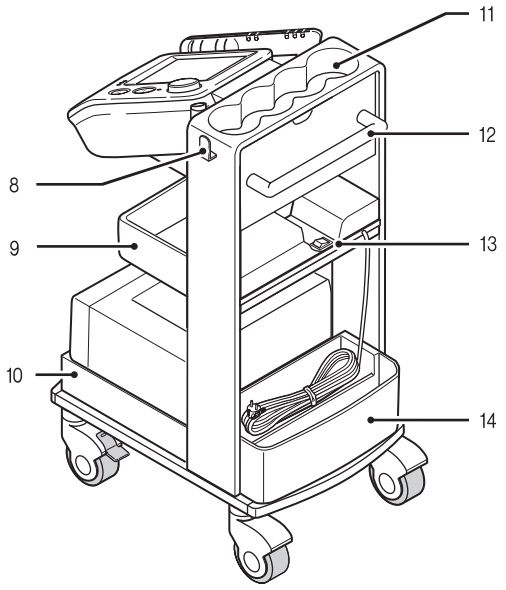
6. **Brightness button**
   ☼ : This enables the "-" and "+" brightness buttons.
   ⊖ : Dims the screen.
   ⊕ : Brightens the screen.

7. **Power on/off switch**
   Turns the power on and off. The power is normally turned on and off with the power switch on the stand, so keep the main unit power switched on.

8. **Connectors**
   For details on the connectors, see Chapter 5.
   Refer to "5-3. Connections" (page 127)

Stand





1. Arm
Place the sensors.

2. PCG sensor pocket
Store the PCG sensor.

3. Main unit holder
The main unit is placed on this holder.

4. Casters
During examination, lock the casters to keep the stand from moving. Unlock before moving the stand.

5. Cable cover
This prevents dust from collecting on the connectors on the back of the main unit.

6. Arm stand / touch pen stand
Attach the arm either on the left or the right. Then attach the touch pen holder on the other side. Refer to "5-4. Changing the Arm Position" (page 129).

7. Drawer
Store printing paper and other supplies in the drawer.

8. Cable hook
Hang the sensor box cable on this hook.

9. Tray
Store supplies on the tray.

10. Laser printer holder

11. Cuff storage pocket
Store arm and ankle cuffs in this pocket.

12. Handle
Hold this when moving the main unit.

13. Power on/off switch
This turns the power of the main unit, printer, and options on/off together.

(I) Power is on.
(O) Power is off.

14. Back pocket
Store manuals and the power cord (when moving the stand in this pocket.).

1-7. Installation/Moving

⚠ **Warning**	Do not install or store the device in a location where water or chemicals may splash on the device. Electric shock may result.
⚠ **Caution**	Do not install in a location where the temperature or humidity is outside the allowed range. This may cause malfunctioning or device failure.

Inspecting the Unit Before Use

For safe and proper use, inspect the device at the start of each day. When installing the device, be sure to follow the instructions on pages 7 to 12.

Before turning the power on

Main Unit

- Are the sensors that contact the patient clean?
- Are the cords arranged properly?
- Is the device kept dry?
- Is the device undamaged?
- Do the casters operate properly and are they free from debris?

Power Cord

- Is the cord placed where it cannot be stepped on and that nothing rests on it?
- Is it not frayed; no wires are exposed or broken?

Supplies

- Are ECG clip electrodes and PCG sensor pads ready?
- Is toner level adequate?
- Is enough paper loaded for daily use?

After turning the power on

Main Unit

- Is there no smoke or abnormal smell?
- Is there no abnormal noise?

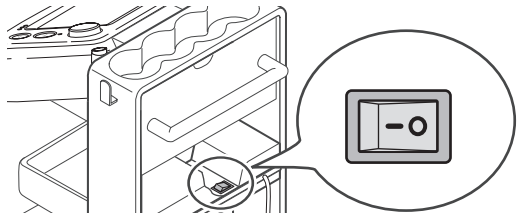
Check the date and time setting

- Are the date and time correct?
  If not, see page 93 to set the correct date and time.

Moving the Unit

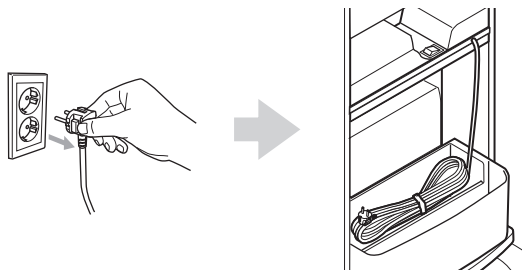
When you need to move the device, follow the procedure below.

1. Switch the power to off (O).

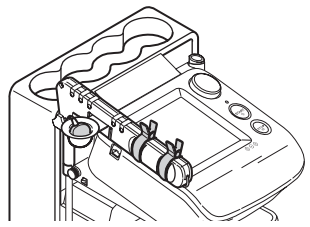


2. Remove the power plug from the outlet and coil the cord.

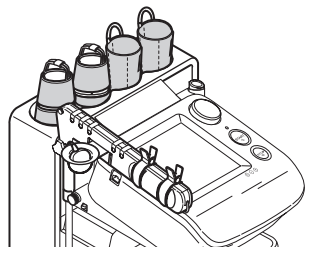
Do not pull on the cord.



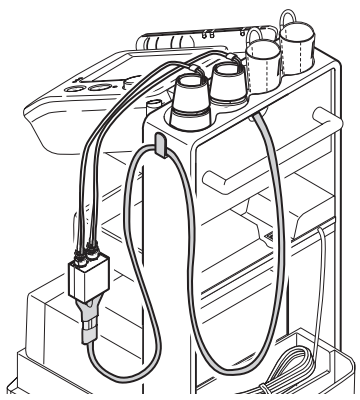
3. Place the sensors on the arm.



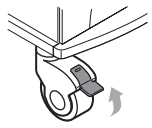
4. Store the cuffs in the cuff storage pocket.



5. Hang the sensor box cable on the cable hook.

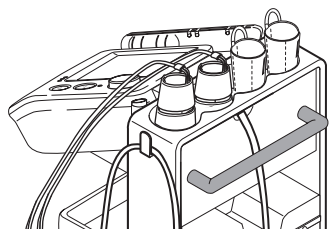


6. Unlock the casters.

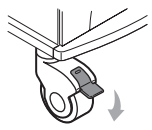


7. Grasp the handle and move the device.

Do not press on parts other than the handle.



8. After moving the device, lock the casters to secure the stand.



2. Measurement Procedure

2-1. Preparing for Measurement

Measurement Procedure

Turn the power on

↓

Position patient so that they are supine on the bed
and instruct the patient to remain quiet and still

↓

Input new patient information or confirm
existing patient information

↓

Attach the cuffs and sensors to the patient

↓

Make sure that "ECG: OK" and
"PCG: OK" appear on the display

↓

Press the [START] button
to begin measurement

↓

To stop measurement,
press the [STOP] button

Measurement ends.
Measurement results will be displayed and/or
measurement report will be printed.

Patient Information

Store patient information properly to maintain a measurement history. Input items marked "Required" must be entered.

Item name	Input	Page
ID	Required	**26**
Sex		**29**
Birth Date		**30**
Height		**31**
Name	Optional or Default setting	**28**
Weight		**31**
Waist		**32**
Disease		**32**
Order Number*		**33**
Measurement Sensors		**34**
Measurement Sites		**35**
Upper limit of inflation		**36**
Synchro measurement		**38**
Doctor		**38**
Technician		**39**
Category		**39**

*Order Number is required if SEARCH KEY is set to "EXAM ORDER NUMBER" in USER DEFAULT SETTINGS.
In this case, patient information must be stored in advance.

There are two methods for entering patient information.

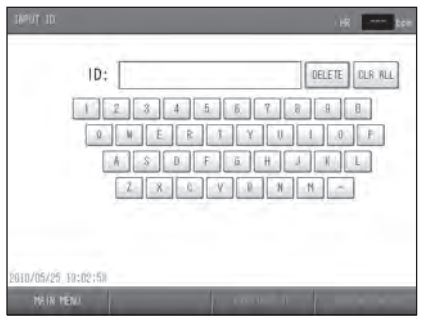
A Enter the patient's information on the touch screen at the time of measurement.

B Enter the patient's information in advance from "Advanced Registration of Patient Information". This is convenient for group examinations.
Refer to "3-8. Advanced Registration of Patient Information" (page 105).

Initial Screen (ID Entry Screen)

Following a brief interval after the power is turned on, the ID entry screen appears. This screen is called the "initial screen" in this manual. Enter the patient ID on this screen.
You can select whether the ID input type is all numbers, or both numbers and letters. It is recommended that you decide which type of ID will be used in advance.
Choose which type of ID to use by selecting "ID Input type" in advance.
Refer to "3-2. User Default Settings" "ID Input Type" (page 76).

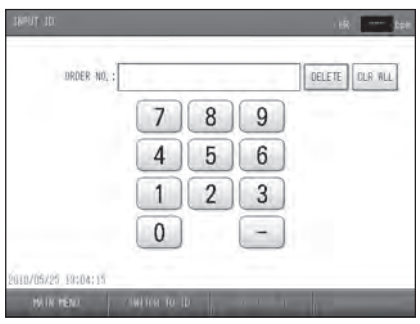
Initial screen (ID input type: numbers)



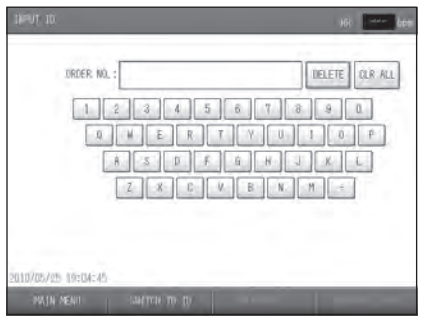
Initial screen (ID input type: numbers and characters)

If you manage patient information data with "Order Number" associated with order entry system, SEARCH KEY can be set to "EXAM ORDER NUMBER" in USER DEFAULT SETTINGS. In this case, patient information must be stored in advance.

Refer to "3-2. User Default Settings" "Search Key" (page 76).



Initial screen: order number entry screen
(Input type: numbers)



Initial screen: order number entry screen
(Input type: numbers and characters)

[MAIN MENU]: Select this to go to the main menu screen to configure basic settings (refer to page 74).

[SWITCH TO ID]: If you are measuring a patient that does not have an order number, you can change back to ID number entry.

Entering and Editing Patient Information

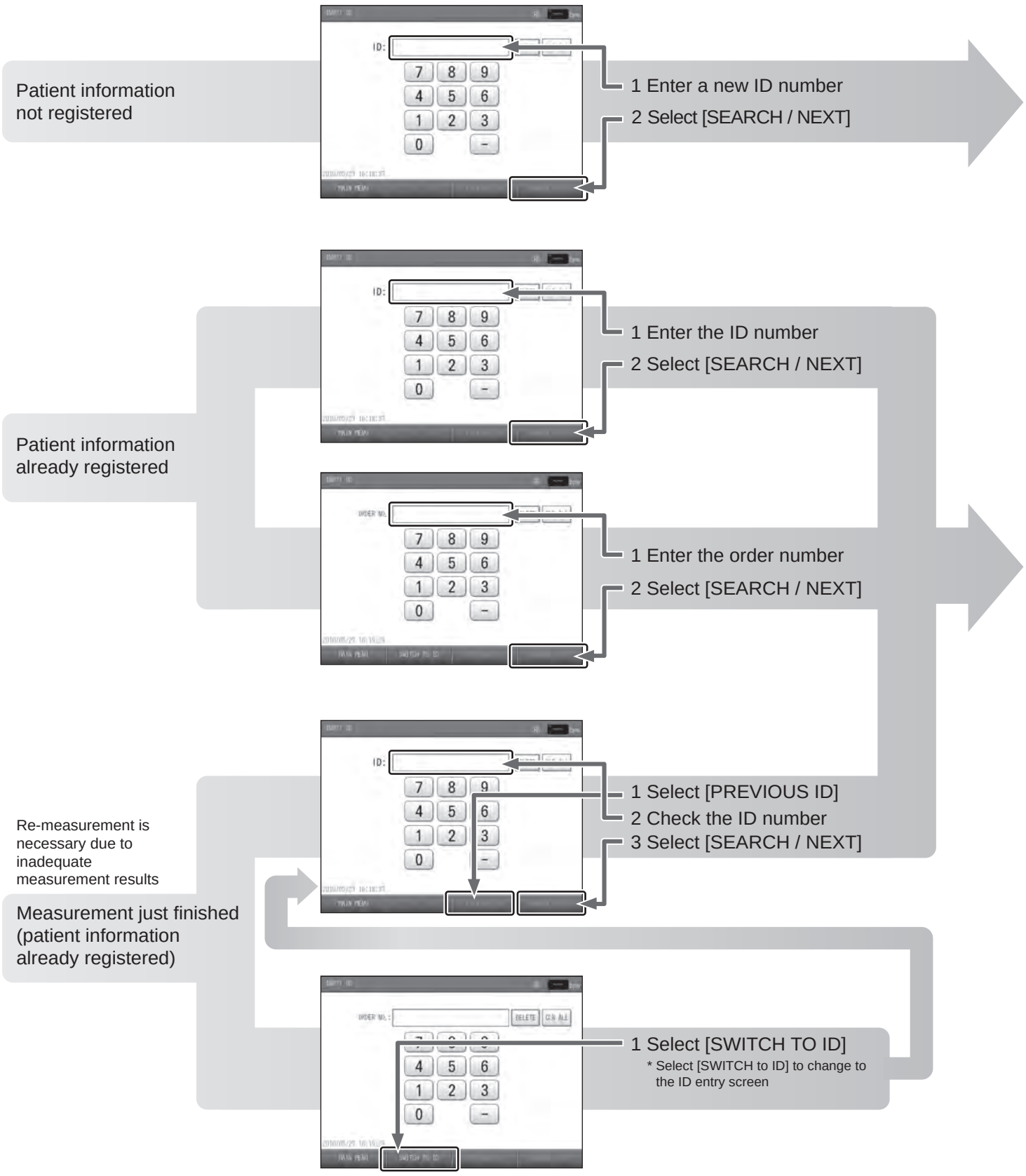
You can enter patient information and edit previously stored patient information.

Notes:

- Do not assign multiple IDs to a single patient. Even if all other information such as the name is the same, the system treats the IDs as belonging to separate patients. In this case, measurements can be performed with the separate IDs as "separate patients"; however, you will not be able to make full use of the device functions for long-term storage of patient measurement histories and diagnosis support.
- The number of digits must be the same or the ID will be treated as two separate IDs. For example, "300" and "0300" are different IDs.
- You must enter the ID, SEX, BIRTH DATE, and HEIGHT to perform a measurement.
- When patient information is extracted with an ID or order number in the initial screen, the ID or order number cannot be modified.
- Take care to avoid mistakes when entering information and numerical values, as the examination results will be printed based on this information.
- If you return to the initial screen while entering patient information, the information is deleted. Select SAVE or SEARCH NEXT to save the information.

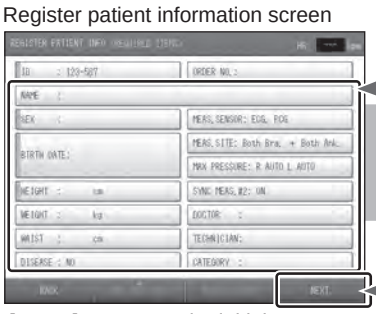
Entering the ID Number

Follow these steps to enter patient information with a new ID number or confirm patient information with an existing ID number.
You can enter up to 13 characters including hyphens.
To confirm patient information with an order number, you can enter up to 20 numeric characters including hyphens.



*The initial screen for "ID input type: numbers" is shown as an example. The key arrangement is different for "ID input type: numbers and characters".

Register patient information screen



To enter each item of patient information, see pages 28 to 39.

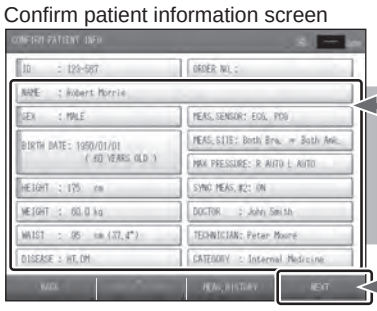
1 Enter patient information

2 Select [NEXT]

[BACK]: Return to the initial screen.
[HMC DATA PROC]:
Can be used when the optional HMC Package is connected.
[NEXT]: Proceed to the measurement screen.

Proceed to the measurement screen. Attach the cuffs and sensors to the patient and start measuring. Refer to page 41.

Confirm patient information screen



To enter each item of patient information, see pages 28 to 39.

1 Check the patient information. Fill in empty items as needed.

2 Select [NEXT]

[BACK]: Return to the initial screen.
[HMC DATA PROC]:
Can be used when the optional HMC Package is connected.
[MEAS. HISTORY]: Show the patient's measurement history.
[NEXT]: Proceed to the measurement screen.

Entering the Name

1. Select [NAME].

2. Enter the name.

- Enter up to 40 characters.
- A space counts as one character.
- To enter a space, Select [SPACE].
- To switch between upper case and lower case, toggle between the [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters that have been entered, select [CLR ALL].

3. Select [OK].

To cancel your entry, select [CANCEL].

Entering the Sex

This item is required to perform measurement.

1. Select [SEX].

2. Select the sex.

As you select the item, the value switches between MALE and FEMALE.

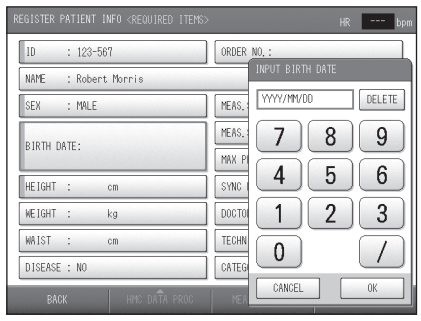
Entering the Date of Birth

This item is required to perform measurement.
A date of birth must be one year of age or older when patient information is entered.
Measurement cannot be performed for infants less than one year of age.

1. Select [BIRTH DATE].

2. Enter the day, month, and year of birth.

Enter the date in the format "YYYY/MM/DD".



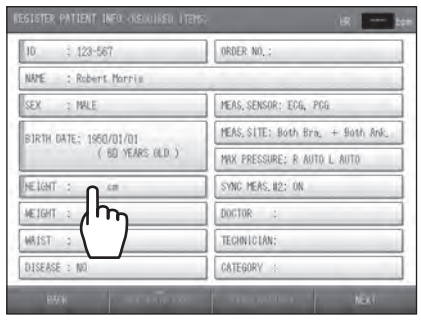
3. Select [OK].

To cancel your entry, select [CANCEL].

Entering the Height

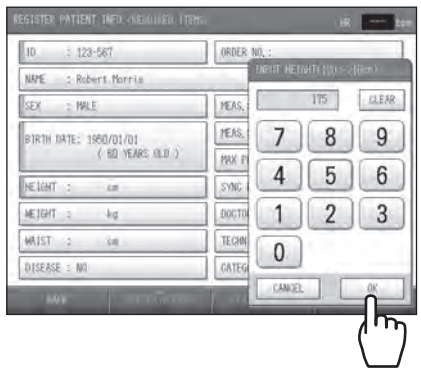
This item is required to perform measurement and to calculate PWV (Pulse Wave Velocity).

1. Select [HEIGHT].



2. Enter the height and Select [OK].

- The input range is 120 cm to 210 cm.
- To cancel your entry, select [CANCEL].



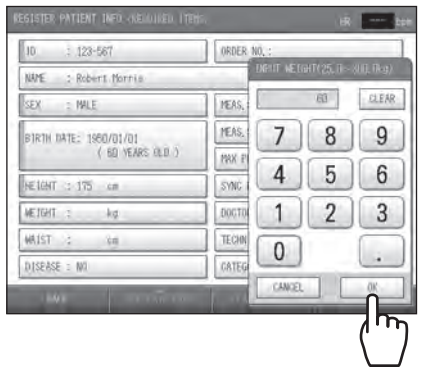
Entering the Weight

The weight is used in calculating the body mass index (BMI).

1. Select [WEIGHT].

2. Enter the weight and select [OK].

- The input range is 25.0 kg to 300.0 kg.
- To cancel your entry, select [CANCEL].

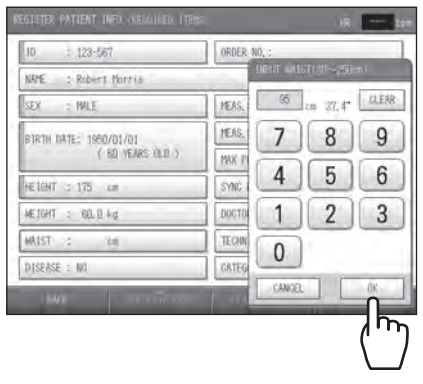


Entering the Waist

1. Select [WAIST].

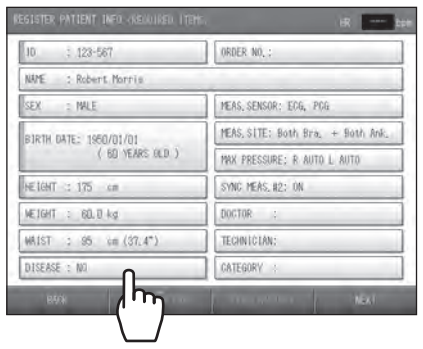
2. Enter the waist and select [OK].

- The input range is 30 cm to 250 cm.
- To cancel your entry, select [CANCEL].



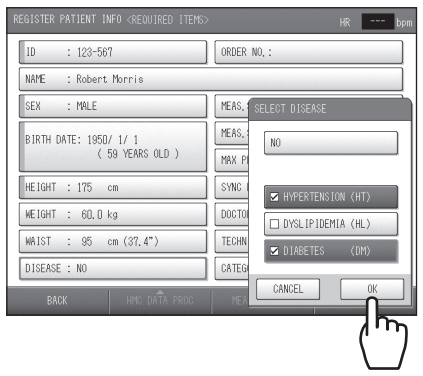
Selecting the Disease

1. Select [DISEASE].



2. Check the disease(s) and select [OK].

- Multiple items can be selected.
- If none is applicable, select [NO].
- To cancel your entry, select [CANCEL].



Entering the Order Number

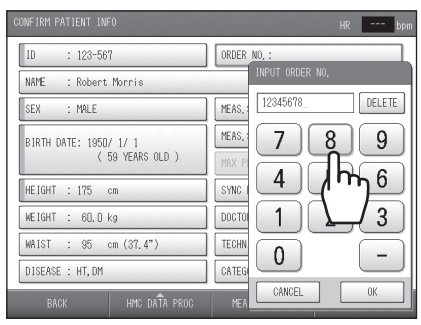
You can enter the order number used in the order entry system associated with the medical records of the patient.

Note:
When patient information is extracted with an order number on the initial screen, the order number cannot be modified.

1. Select [ORDER NO.].

2. Enter the order number.

Enter up to 20 numeric characters including hyphens.



3. Select [OK].

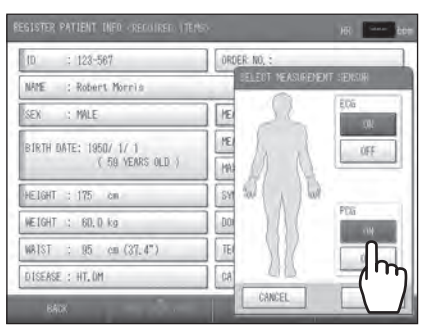
To cancel your entry, select [CANCEL].

Setting the Measurement Sensors

1. Select [MEAS. SENSOR].

2. Specify settings for the ECG, PCG, CAP and FAP sensor.

- Sensor attached: [ON]
  Sensor not attached: [OFF]
- CAP and FAP only appear when the optional TU-100 pulse wave unit is connected.



3. Select [OK].

To cancel your entry, select [CANCEL].

Notes:

- If the ECG clip is attached and the HR Synchronized tone is set to "ON", beep will sound even though ECG is set to "OFF".
- When the TU-100 pulse wave unit is connected, read the manual for the unit.

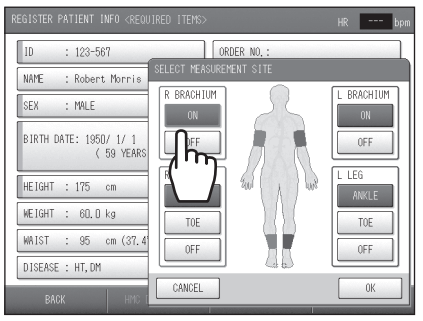
Setting the Measurement Sites

The cuffs are normally attached to both arms and both ankles.
If a shunt is placed on an upper arm for hemodialysis, do not attach a cuff to or perform measurement on that arm.

1. Select [MEAS. SITE].

2. Specify settings for the right arm and left arm.

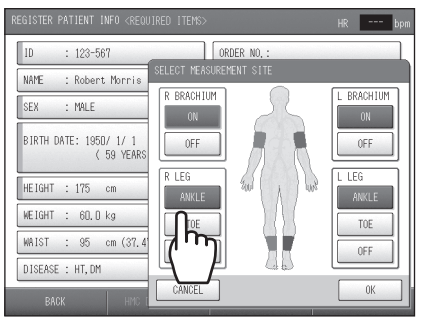
Cuff attached: [ON]
Cuff not attached: [OFF]



3. Specify settings for the right ankle/toe and left ankle/toe.

Ankle cuff attached: [ANKLE]
Toe cuff attached: [TOE]
Cuff not attached: [OFF]

- [TOE] can be selected only when the TBI package is installed.



4. Select [OK].

To cancel your entry, select [CANCEL].

Notes:

- When the TBI package is installed, read the manual for the package.
- Either right arm or left arm needs to be "ON".
- Measurement cannot be performed with both ankle cuff and toe cuff attached.

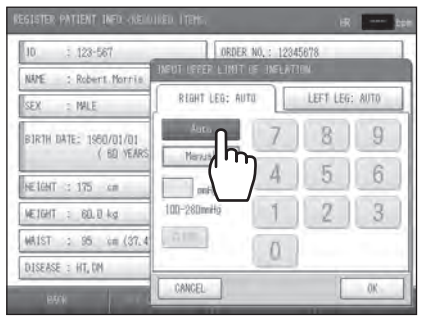
Setting the Upper Limit of Inflation

Specify the upper limit of inflation settings for the right ankle and left ankle.
Normally "Auto" is selected. When "Auto" is set, the system inflates the cuff and measures the patient's blood pressure automatically. If the patient complains of discomfort due to cuff inflation, change the setting to "Manual" and set an upper limit of inflation.

1. Select [MAX PRESSURE].

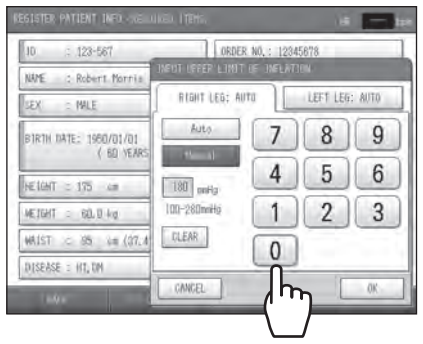
2. Select [Auto] or [Manual] for the right leg.

If you selected [Auto], skip step 3.

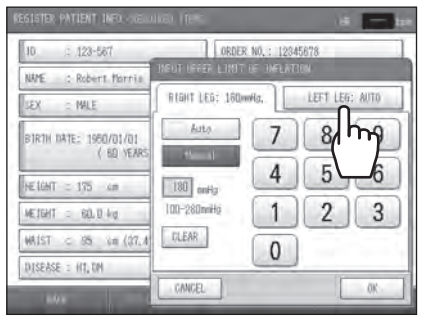


3. Set the upper limit of inflation.

The input range is 100 mmHg to 280 mmHg.



4. Repeat steps 2 and 3 for the left leg.

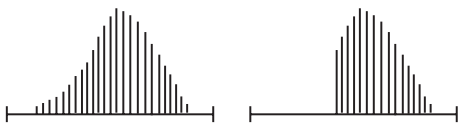


5. Select [OK].

To cancel your entry, select [CANCEL].

Notes:

- The optimum value for the inflation limit is generally "maximum blood pressure + 60 mmHg".
- If the inflation upper limit setting is not suitable, the measured values of the blood pressure may be low as shown below.
  Set the inflation upper limit while checking measurement accuracy on a pulsation variation graph.



Good accuracy

Poor accuracy when pressurizing is not sufficient

Synchro Measurement Setting

In synchro measurement, blood pressure is measured twice. In the second measurement, the measurement timing is automatically adjusted based on the blood pressure value of the first measurement and all four limbs are measured simultaneously.

1. Select [SYNC MEAS. #2].

"ON" or "OFF" is already selected. If the setting does not need to be changed, go to the next item.
As you select the item, the value switches between "ON" and "OFF".

Selecting the Doctor

Select the doctor from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more information.

1. Select [DOCTOR].

2. Select the doctor and select [OK].

- If a doctor name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].

Selecting the Technician

Select the technician from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more information.

1. Select [TECHNICIAN].

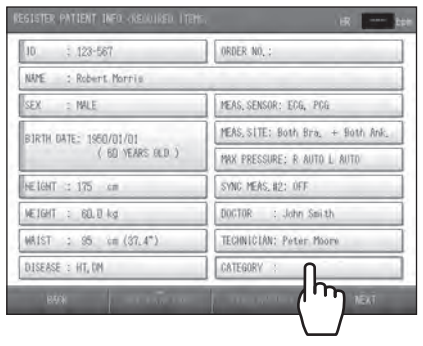
2. Select the technician and select [OK].

- If an technician name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].

Selecting the Category

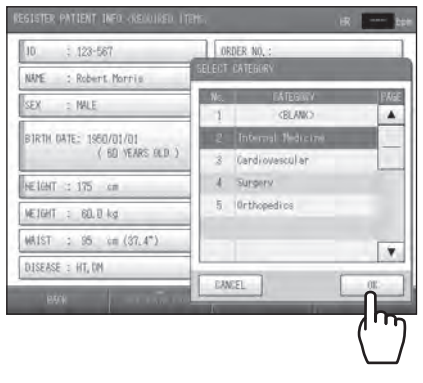
Select the medical department for the patient from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more detail.

1. Select [CATEGORY].



2. Select the category and select [OK].

- If a category name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].

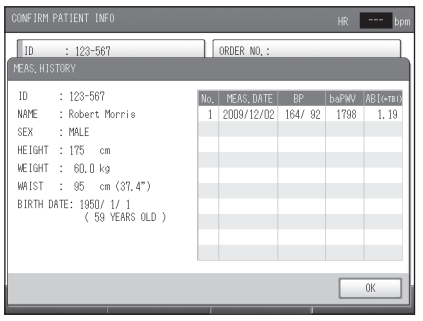


Displaying the Measurement History

A history of the patient's past measurement data can be displayed from the CONFIRM PATIENT INFO screen.

1. Select [MEAS. HISTORY].

2. View the measurement history in the measurement history screen.



The value shown in baPWV is the higher of the left and right values, and the value shown in ABI is the lower of the left and right values.

3. Select [OK].

You return to the patient information screen.

Notes:

- TBI values are marked with * .
- The TBI package is required for TBI measurement. When the TBI package is installed, read the manual for the package.

Attaching the Cuffs and Sensors

⚠ **Caution**	•Make sure that a cuff or an air hose is not bent or collapsed. If the cuff does not deflate, it may damage peripheral nerves caused by blood circulation disorder. •Use a suitable cuff size to avoid inaccurate measurement results. If the cuff is too large or too small, blood pressure measures lower or higher than the actual value. Make sure that the cuff is not too loose or too tight before measurement. •Make sure that air does not leak from the cuff. Otherwise, it may cause inaccurate measurement results.

For the conditions required for measurement, precautions during measurement, and conditions where examination is not possible, see "Safety rules when performing measurement" (pages 7, 9, and 12).

Attaching an Arm Cuff

Notes:
- If you will be measuring using a single arm only, set the arm that is not used to "OFF" in SELECT MEASUREMENT SITE when you enter the patient information. (Refer to page 35)
- Keep the arm with the cuff attached at the level of the heart.
- The cuffs for the right and left arms are different. Do not attach the wrong cuff.
- Use a cuff size that is appropriate for the patient.

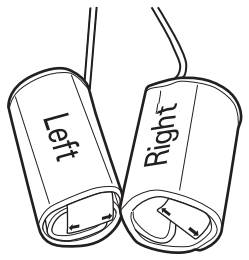
If necessary, wipe the patient's arm with diluted antiseptic alcohol or a similar product.

1. Select a cuff appropriate for the patient

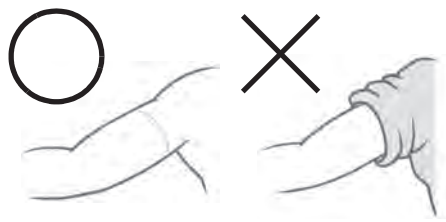
- Size M: Standard Accessory
  Circumference of upper arm: 20 to 32 cm
- Size L: Option
  Circumference of upper arm: 30 to 38 cm
- Size S: Option
  Circumference of upper arm: 16 to 25 cm

2. Make sure that the right cuff and the left one are attached on the correct arms.

- Right arm: orange
- Left arm: dark blue

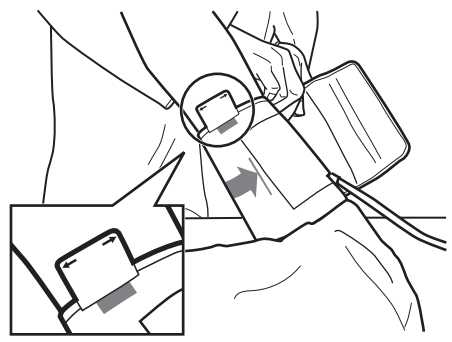


3. Have the patient lie down face up. Expose the patient's upper arm so that it is bare or over a thin sleeve.



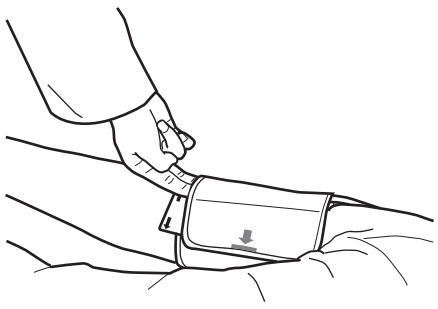
If the cuff is wrapped over a sleeve, straighten it as shown in the image. Otherwise, blood pressure may measure higher than the actual value.

4. Position the arrows on the creases.



5. Wrap the cuff.

Make sure that it is wrapped loosely enough so that two fingers can be inserted between the cuff and the arm.



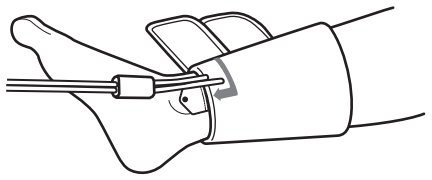
Attaching an Ankle Cuff

Notes:

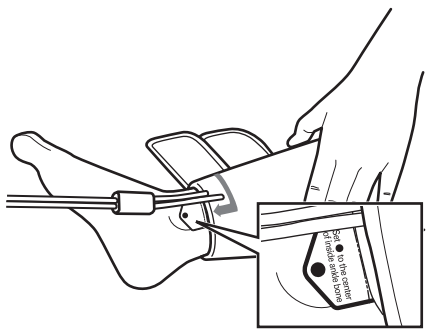
- If you will be measuring using a single ankle only, set the ankle that is not used to "OFF" in SELECT MEASUREMENT SITE when you enter patient information. (Refer to page 35)
- Keep the foot with the cuff attached at the level of the heart.
- The cuffs for the right and left ankles are different. Do not attach the wrong cuff.

When necessary, wipe the patient's ankle with diluted antiseptic alcohol or a similar product.

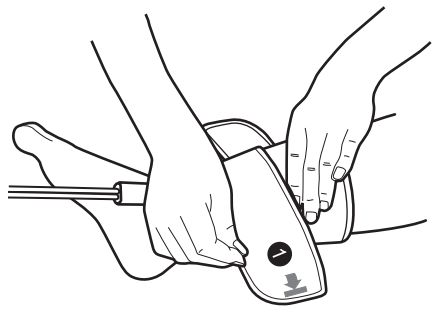
1. Align the tag on the ankle cuff with the top edge of the inside ankle bone.



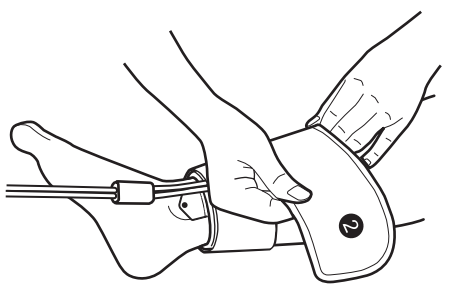
2. Position the ● mark on the tag at the center of the inside ankle bone.



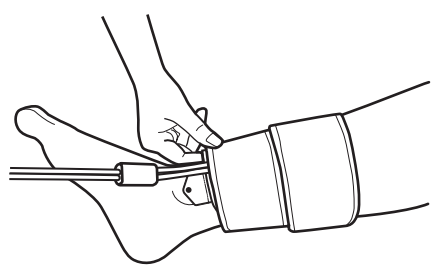
3. Wrap the ankle side ❶ of the cuff first.



4. Then, wrap the calf side ❷.



5. Tighten the cuff so that one finger can be just barely inserted under the cuff.



Attaching the ECG clips

⚠ **Caution**	•ECG clip electrodes are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result. •Do not use a worn or expired ECG clip electrode. Otherwise incorrect diagnosis and treatment may result. (ECG clip electrode have an expiry date. After the expiry date, the electrode becomes dry and incapable of accurate measurement. Use only an electrode whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

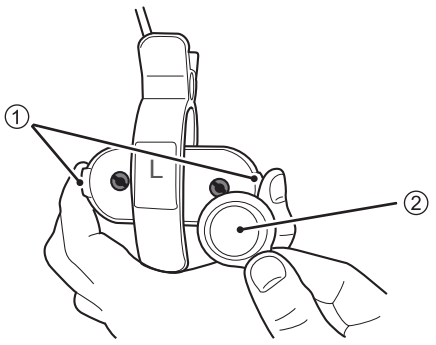
Notes:

- The ECG clip for the right arm and the one for the left arm are different. Do not use the wrong clip.
- As a basic rule, the ECG clips are to be attached to both wrists of the patient. If the ECG signal is weak and measurement is difficult on the patient's wrists, attach the clip for the left wrist to the instep of the left foot (secondary induction).
- If the patient uses a pacemaker, the R wave may not be correctly detected and measurement will not be possible.
- If regular pulse waves cannot be detected due to arrhythmia, accurate measurement will not be possible.

When necessary, wipe the application site with diluted antiseptic alcohol or a similar product.

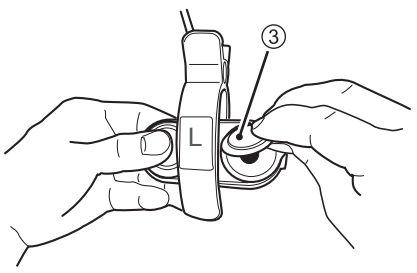
1. Prepare three ECG clip electrodes (disposable).

2. While squeezing the side buttons ① of the ECG clip for the left wrist, attach two ECG clip electrodes ② in the holes.



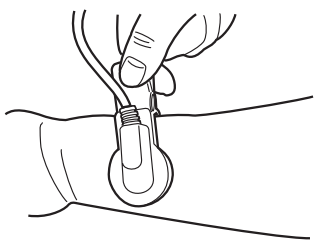
3. Attach one ECG clip electrode on the ECG clip for the right wrist in the same way.

4. Remove all protective sheets ③ from the ECG clip electrodes.



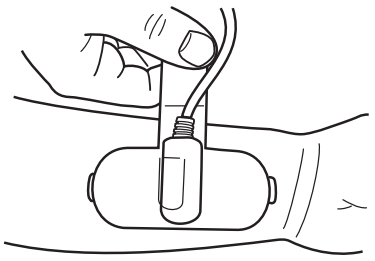
5. Attach the ECG clip on the right wrist.

Make sure that the electrode is on the inner side of the wrist.



6. Attach the other ECG clip for the left wrist.

- Make sure that the electrode is on the inner side of the wrist.
- Confirm that both electrodes are in full contact with the wrist.



Attaching the PCG sensor

⚠ **Caution**	•PCG sensor pads are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result. •Take care that the PCG sensor does not fall on the patient. This may cause injury. •Do not use a worn or expired PCG sensor pad. Otherwise incorrect diagnosis and treatment may result. (PCG sensor pad have an expiry date. After the expiry date, the pad becomes dry and incapable of accurate measurement. Use only a pad whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

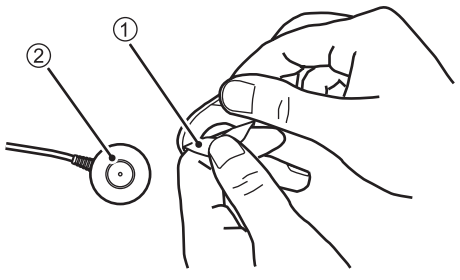
Notes:

- If a patient has heart murmur or abnormal sounds, the second heart sound cannot be properly detected and measurement is not possible.
- If a patient generates noise while breathing, the second heart sound cannot be properly detected and measurement is not possible.

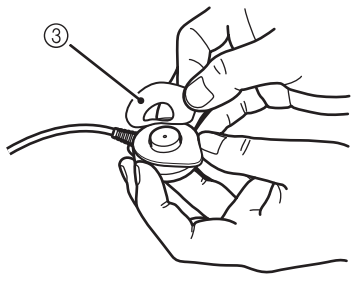
When necessary, wipe the application site with diluted antiseptic alcohol or a similar product.

1. Prepare one PCG sensor pad (disposable).

2. Remove the light blue sheet ① from the PCG sensor pad, and attach the pad on the PCG sensor ②.

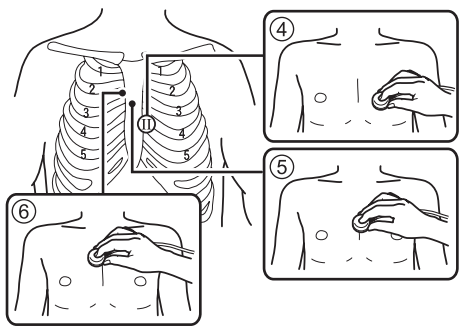


3. Remove the clear protective sheet from the PCG sensor pad ③.



4. Attach the PCG sensor.

- Normally the PCG sensor is placed at the left edge of the sternum in the fourth intercostal space ④. If the second heart sound is not clear, place the sensor in the middle of the third intercostal space ⑤, or near the right edge of the sternum in the second intercostal space ⑥.
- Adjust the position where the 2nd sound is clearly detected while confirming that "PCG: OK" is displayed.



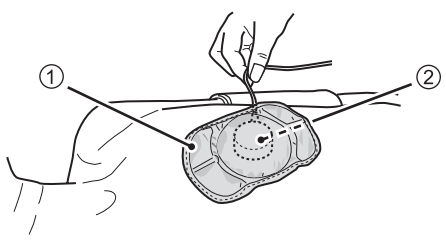
■ Using the PCG Sensor Weight

Use the PCG sensor weight if "PCG:OK" does not show on the display, due to the following:

- Thick fat or muscle that attenuates the heart sound.
- Body hair prevents the PCG sensor from full contact to the skin.
- The contour of the body surface does not allow the PCG sensor to fully contact to the skin.
- The PCG sensor is tilted on the body and it is not firmly attached to the skin.

1. Place the PCG sensor weight ① on top of the PCG sensor ②.

The PCG sensor weight can be placed over the clothes.



2. Make sure that "PCG: OK" is displayed.

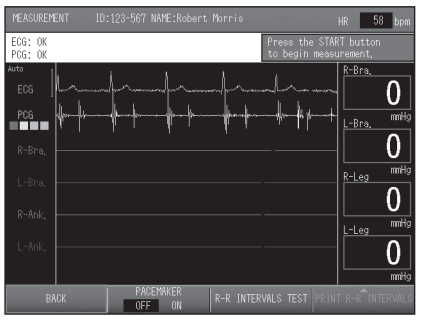
Notes:

- Do not use the weight if it has a hole or tear on it.
- If the filling leaks out of the weight, immediately dispose it.
- Be careful not to damage the surface of the weight with a ballpoint pen or other pointed object.
- If sweat or water gets on the weight, wipe it off immediately.
- Do not wash it.

2-2. Basic Measurement

Viewing the Measurement Screen

You can begin a measurement after entering patient information and attaching the cuffs and sensors to the patient.
Select [NEXT] on the new patient information registration screen or the patient information review screen to change to the measurement screen.



Note:
If ECG or PCG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered (refer to page 34), ECG/PCG messages, ECG waveform, PCG level or PCG waveform will not be displayed.

Contents of the Measurement Screen

1	ECG Message	Displays the ECG status (refer to page 49).
2	PCG Message	Displays the PCG status (refer to page 50).
3	PCG level	Shows the detected PCG level using a four-level meter. Level 3 or 4 is recommended to obtain accurate measurement results. With level 1 or 2, accurate results may not be achieved. Adjust the position of the PCG sensor or use the PCG sensor weight (refer to page 46).
4	[PACEMAKER] option	If the patient has a pacemaker implanted, select "ON". The pacemaker setting reverts to "OFF" at the end of measurement. Select "ON" each time you perform a measurement.
5	Heart Rate	Displays the patient's heart rate.
6	ECG wave	Displays ECG waveform. The ECG display gain is normally set by auto-gain. However, when the pacemaker setting is "ON", the gain is fixed at 10 mm/mV.
7	PCG wave	Displays the PCG waveform.
8	[PRINT R-R INTERVALS] option	This prints the R-R interval exam report.
9	[R-R INTERVALS TEST] option	Use this to measure fluctuations in the interval between heartbeats in order to check the autonomic function of the cardiovascular system (refer to page 65).

ECG Messages

Note:
If ECG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered (refer to page 34), ECG messages and the ECG waveform will not be displayed.

The ECG messages are explained below. When "OK" is not displayed, accurate measurement results may not be obtained. Follow the correspondent solutions to the messages in the chart below.

Messages	Status	Notes / Solutions
OK	ECG is stable.	It is ready to begin measurement.
Initializing	Initializing ECG.	Have the patient remain quiet and wait briefly.
Unstable R-R	The electrodes are dry or dirty.	Replace with new electrodes (refer to page 44).
	Myoelectrical signal is detected as patient arm is tensed.	Have the patient relax the arm and rest quietly.
	Noise from radio interference is affecting the ECG waveform.	If a cell phone or other device is in use nearby, move it away.
	The signal is too weak.	Try moving the ECG clip on the left wrist to the instep of the left foot (secondary induction).
Check Electrodes	An ECG electrode is not attached to the ECG clip.	Confirm that all of the three electrodes are properly attached. (refer to page 44).
	The protective sheet is on the ECG electrode.	Remove the protective sheet from the ECG electrode (refer to page 44).
	An ECG cable is not connected.	Confirm that all ECG cables are securely connected (refer to page 128).

PCG Messages

Note:
If PCG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered (refer to page 34), PCG messages and the PCG level indicator will not be displayed.

The PCG messages are explained below. When "OK" is not displayed, accurate measurement results may not be obtained. Follow the correspondent solutions to the messages in the chart below.

Messages	Status	Notes / Solutions
OK	PCG is stable.	It is ready to begin measurement.
Initializing	PCG initializing.	Have the patient remain quiet and wait briefly.
Out of Range	Noise is detected as the sensor has been touched or other reason.	Have the patient rest quietly and wait briefly.
Weak Signal	The PCG sensor has come off or the patient's shirt or other clothing has come under it.	Make sure the PCG sensor is in full contact with the skin. If it is difficult to keep the sensor in full contact, use the PCG sensor weight (refer to page 46).
	The PCG sensor pad is dry or dirty.	Replace with a new PCG sensor pad (refer to page 45).
	The wrong side of the PCG sensor is attached.	Attach the PCG sensor correctly (refer to page 45).
	Level 3 or 4 is recommended to obtain accurate measurement results. With level 1 or 2, accurate results may not be achieved.	
Re-Position	The sensor is not attached on an appropriate position.	Re-attach the PCG sensor on an appropriate position (refer to page 45).
	For patients with cardiac murmur or respiratory noise, it may be difficult to clearly distinguish the first and second heart sound. This may cause an inaccuracy measurement.	

Starting and Ending Measurement

Note:
In some cases one measurement is required, but in other cases two measurements are required to complete measurement. The following cases require two measurements:
- "Synchro measurement" is set to "ON" (refer to page 38).
- "Synchro measurement" is set to "OFF"; however, blood pressure was not correctly measured.
- "ABI Remeasurement" is set to "ON" and the measured ABI is lower than the set value (refer to page 78).

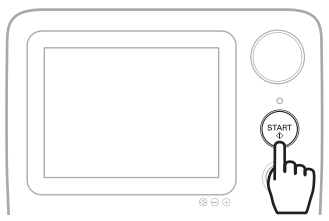
The ECG signal and the PCG signal must be stable before measurement begins.

1. Make sure that "ECG: OK" and "PCG: OK" are displayed.

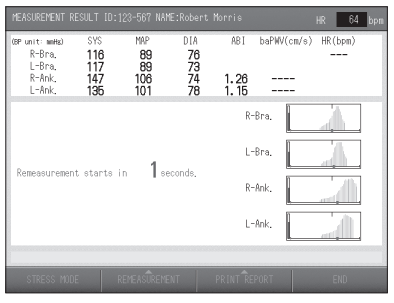
- R-R interval examination can be performed before measurement is started.
  Refer to "2-4. R-R Interval Examination" (page 65).
- If the optional CAP sensor unit or FAP sensor unit is attached, check the CAP message or the FAP message.

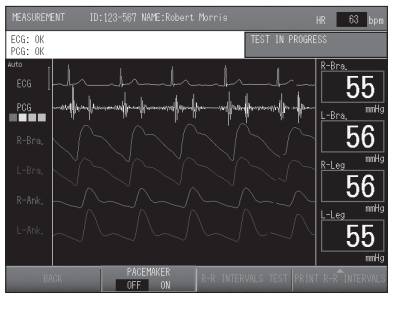
2. Press the [START] button.

Measurement begins.



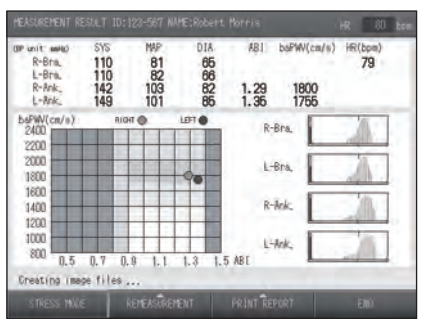
If a second measurement is required, the standby time is displayed. Measurement begins when the count ends.





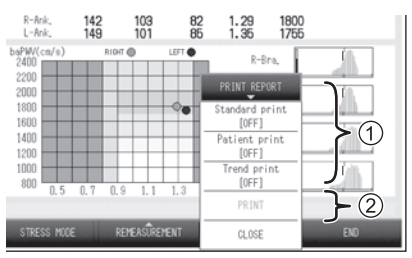
3. Confirm that measurement has successfully ended.

- When measurement ends, the measurement results screen appears.
  Refer to "Contents of the Measurement Screen" (page 48).
- If the number of printed pages is set in "Print Default Settings" (page 80), a measurement results report is printed.
  Refer to "Measurement Results Reports" (page 54)

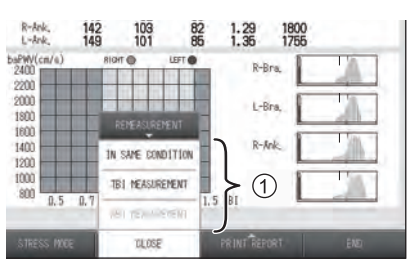


Measurement results screen

- To reprint a measurement results report, select [PRINT REPORT], select the number of pages to be printed ① and then press [PRINT] ②.

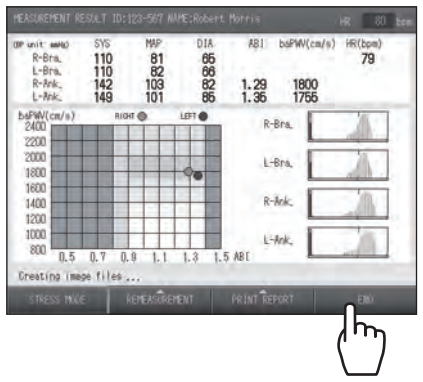


- To repeat a measurement, select [REMEASUREMENT], and then select the repeat measurement condition ① and prepare for measurement.



4. To perform post stress measurement, skip the remaining steps and follow the steps for post stress measurement (refer to page 67).

5. Select [END].

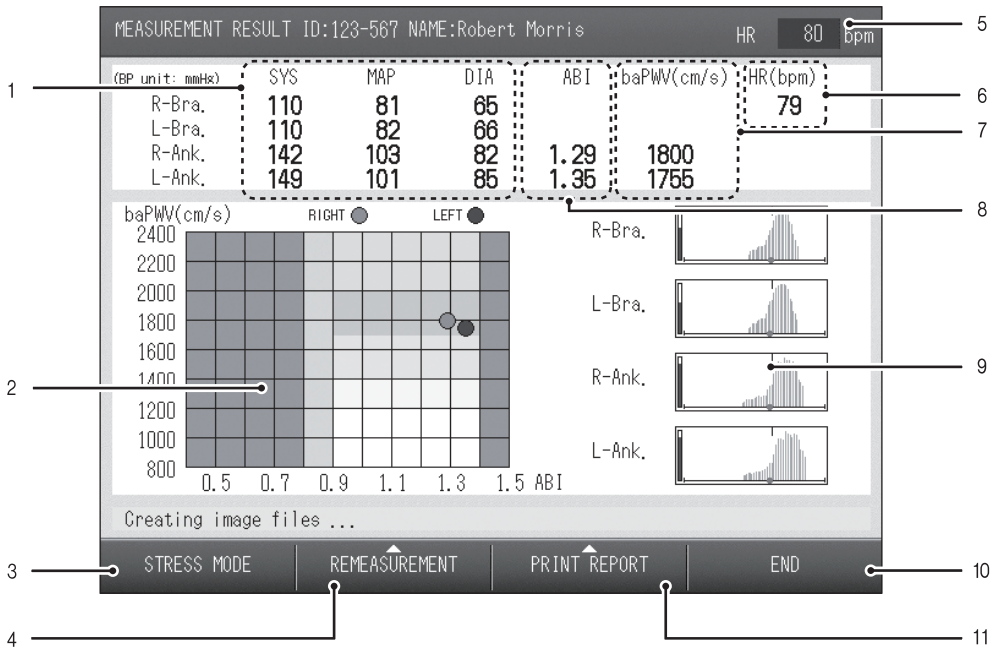


6. Remove the cuffs and sensors from the patient.

2-3. Measurement Results

Contents of the Measurement Results Screen

The measurement results screen that appears when measurement ends is explained below.



1	Blood pressure value	Displays the blood pressure values at each site where measurement was performed. Sites where measurement was not performed are not displayed.
2	Graph	This graph shows the relationship between baPWV and ABI.
3	[STRESS MODE] option	Select to perform post stress measurement.
4	[REMEASUREMENT] option	Select to repeat measurement. Select "IN SAME CONDITION", "TBI measurement"*, or "ABI measurement".
5	Heart Rate	Displays the real-time heart rate from the R-R interval obtained from ECG.
6	Heart Rate/ Pulse Rate	Displays the heart rate as the test result from the R-R interval obtained from ECG. If "ECG" was set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered, displays the pulse rate. (refer to page 34)
7	baPWV	This displays the PWV value calculated from the interval from the start of the brachial pulse wave to the start of the ankle pulse wave.
8	ABI	Displays the right and left ABI. When blood pressure is measured at both arms, the ABI is calculated from the higher brachial pressure value.
9	Pulsatile variation graph	This graph shows the pulsatile variation obtained from each cuff. Synchronization line is not displayed if the time phases do not match due to re-measurement or other reasons.
10	[END]	Select to end measurement and return to the initial screen.
11	[PRINT REPORT] option	Select to print a measurement results report.

*Select this to perform TBI measurement. The TBI package is required for TBI measurement.
If the TBI package is installed, read the manual for the package.

Measurement Results Reports

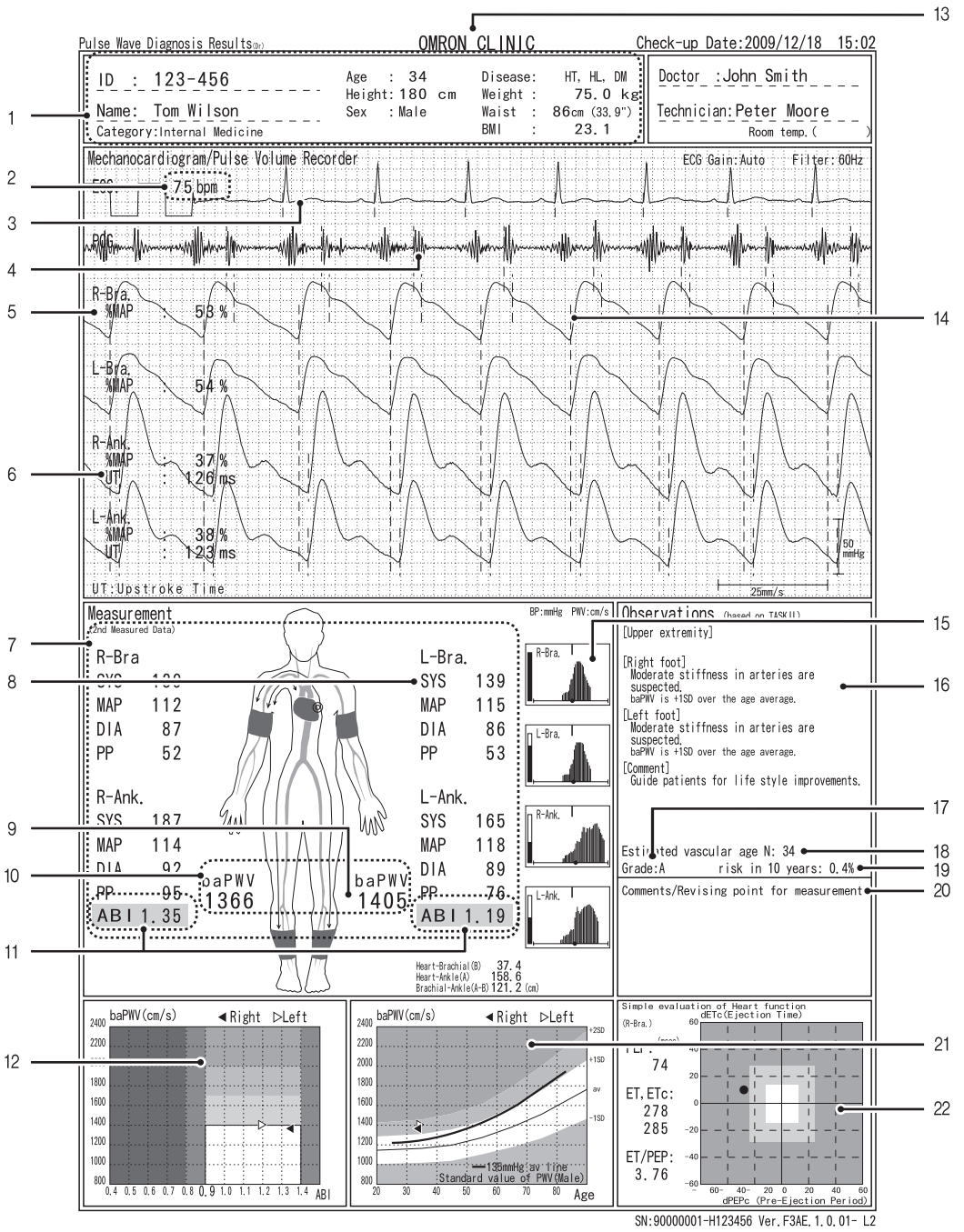
The measurement results reports that are printed when measurement ends are explained below. The types of reports are as follows.

Type	Description	Page
Standard	Measurement results report that is retained by the medical organization that conducted the examination.	**55**
Patient	Measurement results report to be given to the patient.	**60**
Trend	This indicates measurement data trends based on comparison with past data.	**64**

Notes:

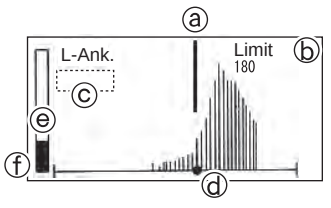
- Do not turn off the power while printing is in progress. This may damage the internal memory.
- You can also set reports to not print after measurement. The initial setting is "1 sheet". Refer to "3-3. Print Default Settings" (page 80).
- To print additional reports after measurement, select "PRINT REPORT" on the measurement results screen. You can also print a report without performing measurement. Refer to "Reprinting Measurement Data" (page 95).
- The special LAN cable that is sold separately can be used to connect the device to a computer to send a report to it. Refer to "3-11. Transferring Report Data to a Computer" (page 120).
- When using the optional TU-100 pulse wave unit or TBI package, read the manual for the package.

Standard Report



1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

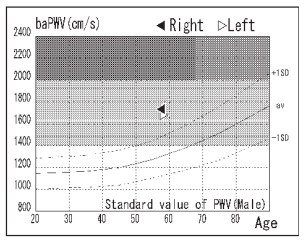
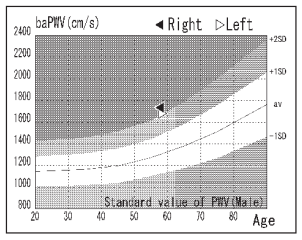
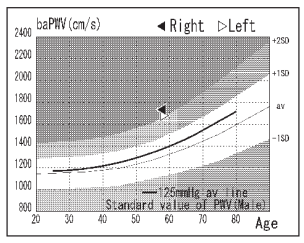
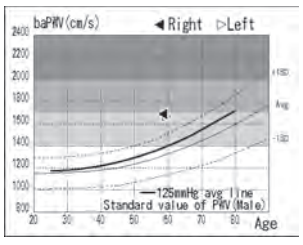
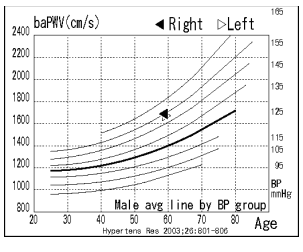
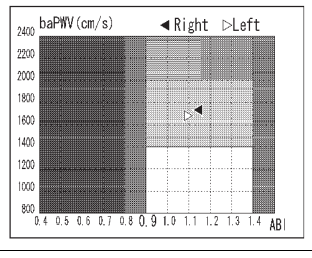
go to next page

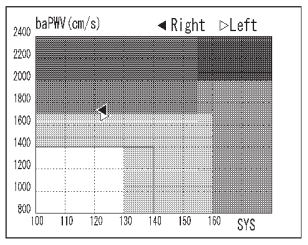
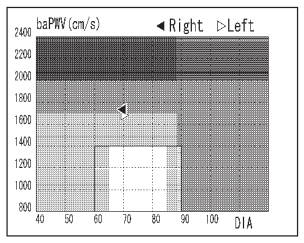
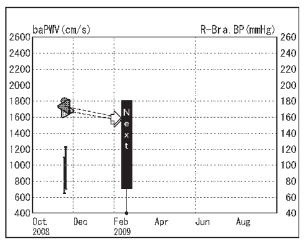
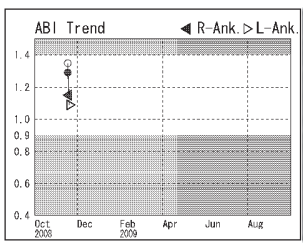
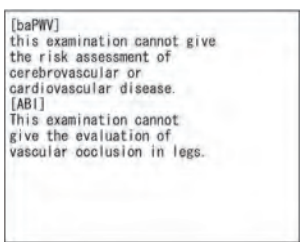
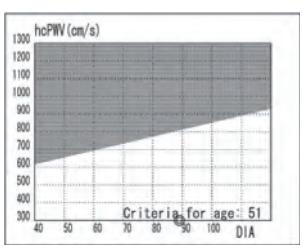
1	Patient information	The patient information that was entered before measurement.
2	Heart Rate/ Pulse Rate	Shows the heart rate. If "ECG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, the pulse rate will be displayed instead. (refer to page 34)
3	Electrocardiogram	The ECG waveform. If "ECG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, this will not appear (refer to page 34).
4	Phonocardiogram	The PCG waveform. If "PCG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, this will not appear (refer to page 34).
5	%MAP	This value is one of the pulse waveform indices that are calculated from the blood pressure values. Refer to "5-10. Explanation of Technical Terms" (page 144)
6	UT	Time from the start of the pulse wave to its peak. However, for measurement in the carotid artery, the time from the start of the pulse wave to the peak of the effected wave or the start point of the reflected wave. Refer to "5-10. Explanation of Technical Terms" (page 144)
7	Blood pressure value	The blood pressure values for the left and right arm and left and right ankle. "- - -" is printed if measurement was not possible.
8	Blood pressure left-right difference	When the difference in the blood pressure values for the right and left upper arms is greater than 16 mmHg, the maximum blood pressure of the arm with the lower blood pressure is shaded.
9	Measured value reliability	If a measured value appears in parentheses, the accuracy of that value was low for some reason and it is indicated only for reference.
10	PWV	baPWV: The PWV value calculated from the interval from the start of the brachial pulse wave to the start of the ankle pulse wave. Refer to "5-10. Explanation of Technical Terms" (page 144)
11	ABI	Shows the right and left ABI values. Refer to "5-10. Explanation of Technical Terms" (page 144)
12	Graph 1	The indices are shown on a graph. Details are explained from page 58.
13	Facility name	This is shown if a facility name is entered (refer to page 86).
14	PVR waveform	The obtained pulse wave. Because the printed amplitude is calibrated from the measured blood pressure values, the printed amplitude may be different than the amplitude shown on the screen.
15	Pulsatile variation graph	This graph shows the pulsatile variation obtained from each cuff. a) Synchronization line: Not printed if synchro measurement was not possible. b) Inflation upper limit: When the inflation upper limit is set to other than "AUTO," the setting is printed. c) Measurement accuracy: When "Estimate" or "First Measurement" is displayed, accuracy may be poor. d) ●: Shows the maximum blood pressure value. Not printed if measurement was not possible. e) Level meter: Shows the size of the pulse wave. f) Frame: When constriction of the upper arm or ankle is suspected, the frame is printed in bold. 
16	Dr. Support	A Dr. Support is displayed based on the examination results. The content varies depending on the level setting of "Dr. Support" in the "Print Default Settings" (page 83).
17	Over all grade	When "Show result" is selected under "Over all grade" in "Print Default Settings", an over all grade of the examination results is shown using three levels (A, B, C) (refer to page 84).

18	Vascular age	When "Vascular age" or "Vascular age (N)" is selected in "Stiffness" in the "Print Default Settings", this shows arterial stiffness as a vascular age (refer to page 84).
19	Risk of Pathogenesis	When "Risk of Pathogenesis" is set to "ON" in the "Print Default Settings", the risk of cardiovascular disease within the next 10 years is calculated and displayed, based on age, sex and baPWV. (refer to page 84).
20	Comments / Revising point for measurement	This shows errors detected during measurement and points to be checked to prevent errors.
21	Graph 2	The indices are shown on a graph. Details are explained from page 58.
22	Simple Evaluation of Heart Function	STI (Systolic Time Intervals) is printed. If PCG is set to "OFF" for MEAS. SENSOR when entering patient information, this area will be blank. Refer to page 34 for more detail on PCG, and the detail on STI is in Quick Manual.

■ Graph 1 (Graph 2)

The graphs that appear in Graph 1 and Graph 2 are set in advance with the "Standard report layout" setting in "Print Default Settings". (page 83).

Type	Description	Displayed graph
1. Age-baPWV	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV.	
2. Age-baPWV/SD	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line.	
3. Age-baPWV/SD+Nomo	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line. (Shows mean age ± SD line and mean line of applicable blood pressure group.)	
4. Age-baPWV/Nomo1	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV. (Shows mean age ± SD line and mean line of applicable blood pressure group.)	
5. Age-baPWV/Nomo	This shows baPWV vs. age on the horizontal axis. (Shows mean line of each blood pressure group.)	
6. ABI-baPWV	This shows baPWV vs. ABI on the horizontal axis.	

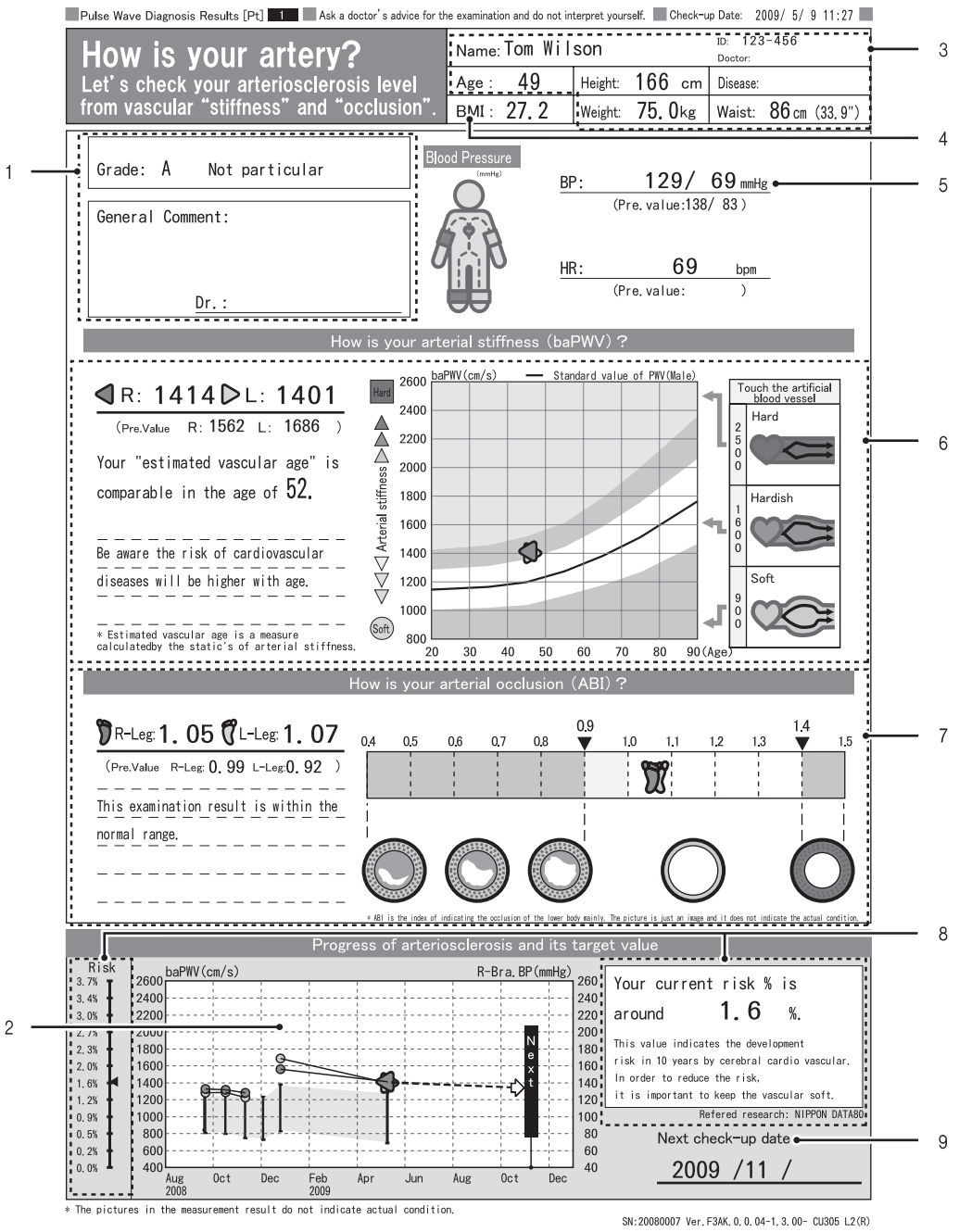
Type	Description	Displayed graph
7. SYS-baPWV	This shows baPWV vs. maximum blood pressure value on the horizontal axis.	
8. DIA-baPWV	This shows baPWV vs. minimum blood pressure value on the horizontal axis.	
9. baPWV Trend	This shows baPWV vs. date on the horizontal axis.	
10. ABI Trend	This shows ABI vs. date on the horizontal axis.	
11. Vascular Comment	This shows comments on vascular sclerosis. This is the same content as in the patient report (refer to page 60).	
12. DIA-hcPWV	This shows hcPWV vs. minimum blood pressure value on the horizontal axis. (Only when the optional TU-100 pulse wave unit is connected.)	

Patient Report

This is the measurement results report that is given to the patient. Select from three types depending on the patient and the diagnosis policy. For the type of No. 1 and No. 2, the report layout can be selected. The report type is set in advance in "Report type" in "Print Default Settings" (page 81) and the layout is set in "Patient Report Layout" (page 84).

■ Patient Report No. 1

The measured values, graphs, and images are arranged uniformly. Select from two types of layouts based on the "Risk of Pathogenesis" selection (page 84).



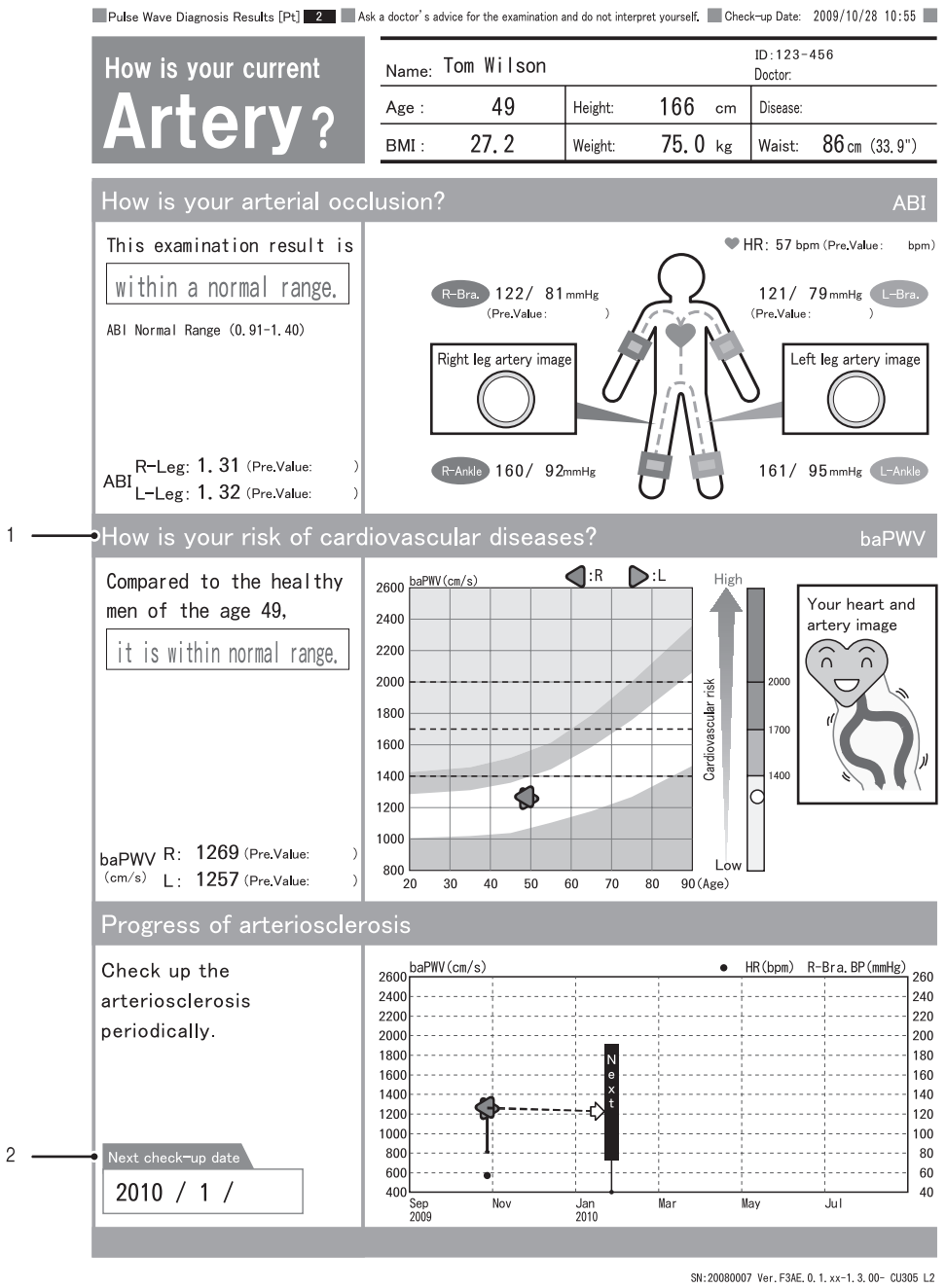
1	Over all grade	This is printed when "Show frame" or "Show result" is selected in the "Over all grade" setting in "Patient report layout". An over all grade of the test results is given in "Show result" (refer to page 84). A: Not particular B: Follow-up is required C: Re-examination is required
2	Trend graph	This shows a graph of trends over the treatment period.
3	Patient information	The patient information that is entered before measurement. The standard weight is shown if the patient's weight is entered.
4	Body Mass Index (BMI)	This is shown if the patient's weight is entered.
5	Blood pressure value	Displays the blood pressure value of the right upper arm. If it is not measured due to constriction, the blood pressure value of the left arm is shown.
6	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout or "Vascular age" layout can be selected in the "Stiffness" setting of "Patient report layout". "Vascular age (N)" is not supported (refer to page 84).
7	Arterial stenosis (ABI)	The degree of stenosis in lower-extremity arteries is shown in a graph with images of artery.
8	Risk of pathogenesis	When "Risk of pathogenesis" is set to "ON" in "Patient Report Layout", the risk of cardiovascular disease is shown in a graph along with a numerical value (refer to page 84).
9	Next check-up	This is printed when "Next check-up" is set in "Patient report layout" (refer to page 84).

■ Patient Report No. 2

This mainly consists of graphs for clogging and flexibility of arteries. Select from three types of layouts based on the "Stiffness (Vascular sclerosis indication)" selection (page 84).

Notes:

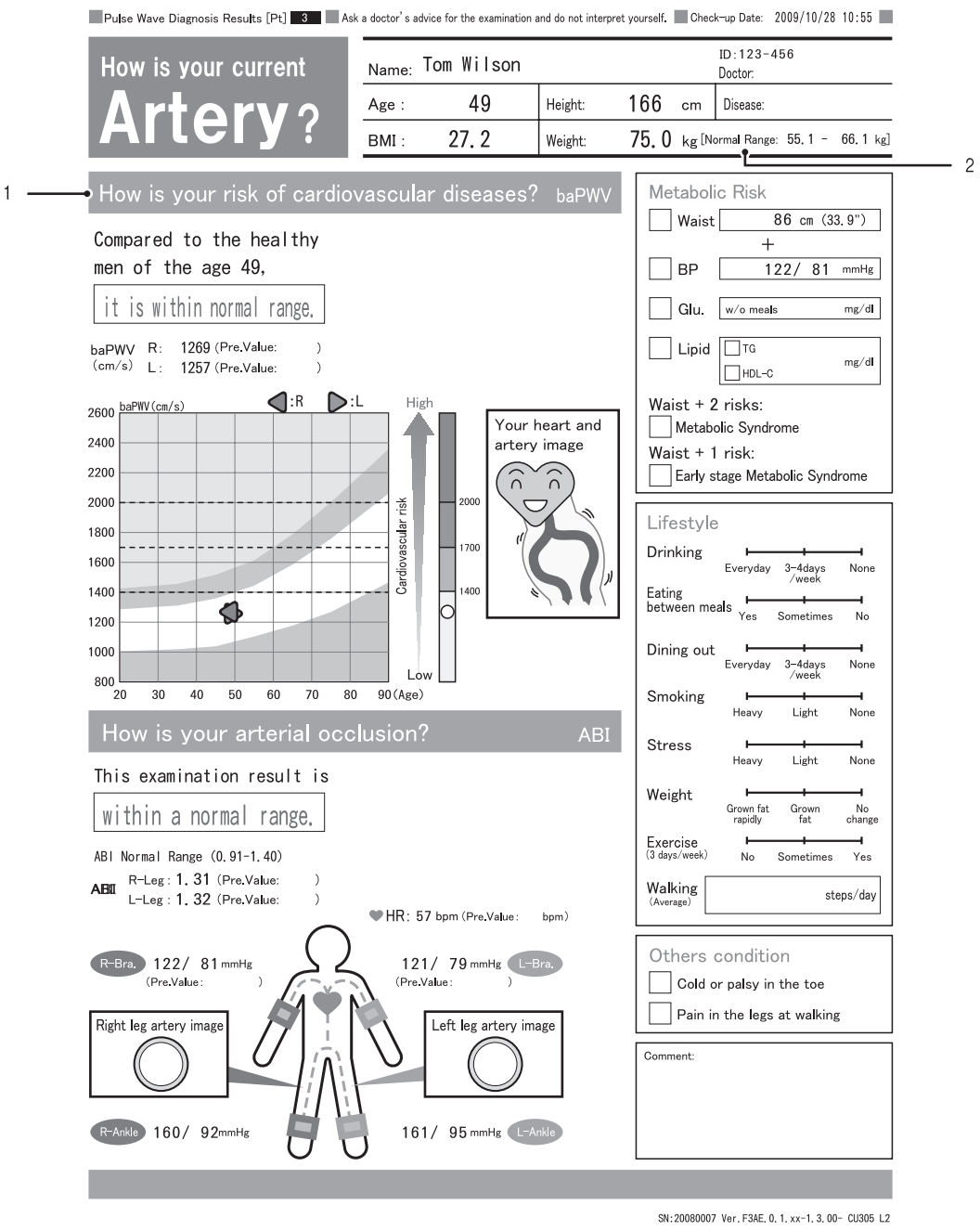
- The horizontal axis representing time on the artery flexibility trend graph is automatically set within a range of 1 to 5 years depending on the patient's past data.
- The next scheduled examination can be set in increments of one month from the day of the most recent examination.



1	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout, "Vascular age" layout, or "Vascular age (N)" layout can be selected in the "Stiffness" setting of "Patient report layout" (refer to page 84).
2	Next check-up	This is printed when "Next check-up" is set in "Patient report layout" (refer to page 84).

■ Patient Report No. 3

This indicates the risk of cardiovascular disease using illustrations that are easy for the patient to understand.



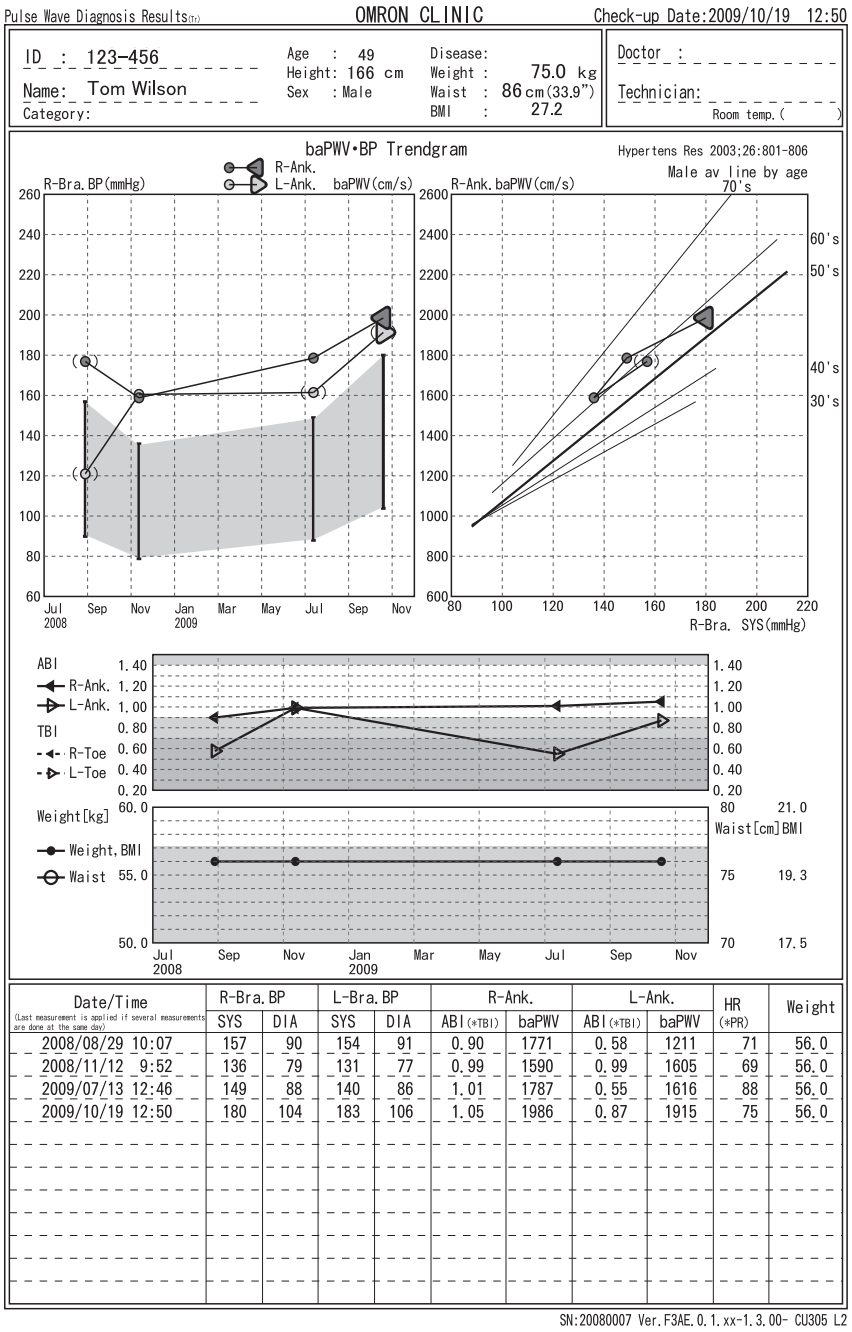
1	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout or "Vascular age" layout can be selected in the "Stiffness" setting of "Patient report layout". "Vascular age (N)" is not supported. (Refer to page 84)
2	Standard weight	This is shown if the patient's weight is entered.

Trend Report

This chart indicates measurement data trends based on comparison with past data. This is normally only printed if there is a patient history; however, it can be set to print regardless of whether or not there is a patient history.
Refer to "Print Default Settings" "Trend Print" (page 82).

Note:

The horizontal axis representing time on the trend graph is automatically set within a range of one to five years based on the patient's past data.



Date/Time (Last measurement is applied if several measurements are done at the same day)	R-Bra. BP		L-Bra. BP		R-Ank.		L-Ank.		HR	Weight
	SYS	DIA	SYS	DIA	ABI (*TBI)	baPWV	ABI (*TBI)	baPWV	(*PR)	
2008/08/29 10:07	157	90	154	91	0.90	1771	0.58	1211	71	56.0
2008/11/12 9:52	136	79	131	77	0.99	1590	0.99	1605	69	56.0
2009/07/13 12:46	149	88	140	86	1.01	1787	0.55	1616	88	56.0
2009/10/19 12:50	180	104	183	106	1.05	1986	0.87	1915	75	56.0

SN:20080007 Ver.F3AE.0.1.xx-1.3.00- CU305 L2

Standard measurement

*This is a sample report when measurement is performed with the TBI package installed.

2-4. R-R Interval Examination

Use this to measure fluctuations in the interval between heartbeats in order to check the autonomic function of the cardiovascular system. The one hundred heartbeats that are required for analysis are acquired, and the resulting histogram and trend are printed.

Starting and Ending R-R Interval Examination

Notes:
- R-R interval examination is only possible when ECG clips are attached.
- An R-R interval examination and basic measurement cannot be performed simultaneously.

1. Prepare for measurement.

If you are performing an R-R interval examination before basic measurement, go to step 2.

1. Turn the power on.
2. Enter the patient information.
   Refer to "Entering and Editing Patient Information" (page 25).
3. Attach the ECG clips to the patient.
   Refer to "Attaching the ECG clips" (page 44).

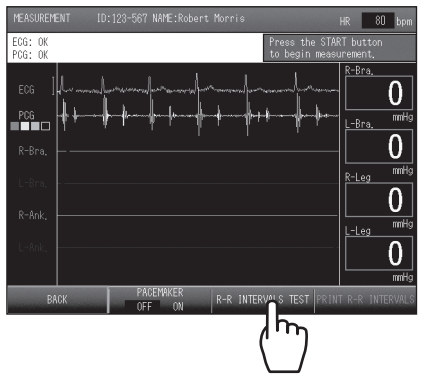
2. Confirm that "ECG: OK" is displayed on the measurement screen.

It is not necessary to attach the PCG sensor.

3. Select [R-R INTERVALS TEST].

Heartbeat counting begins. When the effective heartbeats count reaches 100, measurement ends and an R-R interval exam report is printed.
Refer to "R-R Interval Examination Results" (page 66).

If you performed an R-R interval examination before basic measurement, return to page 51 step 1.

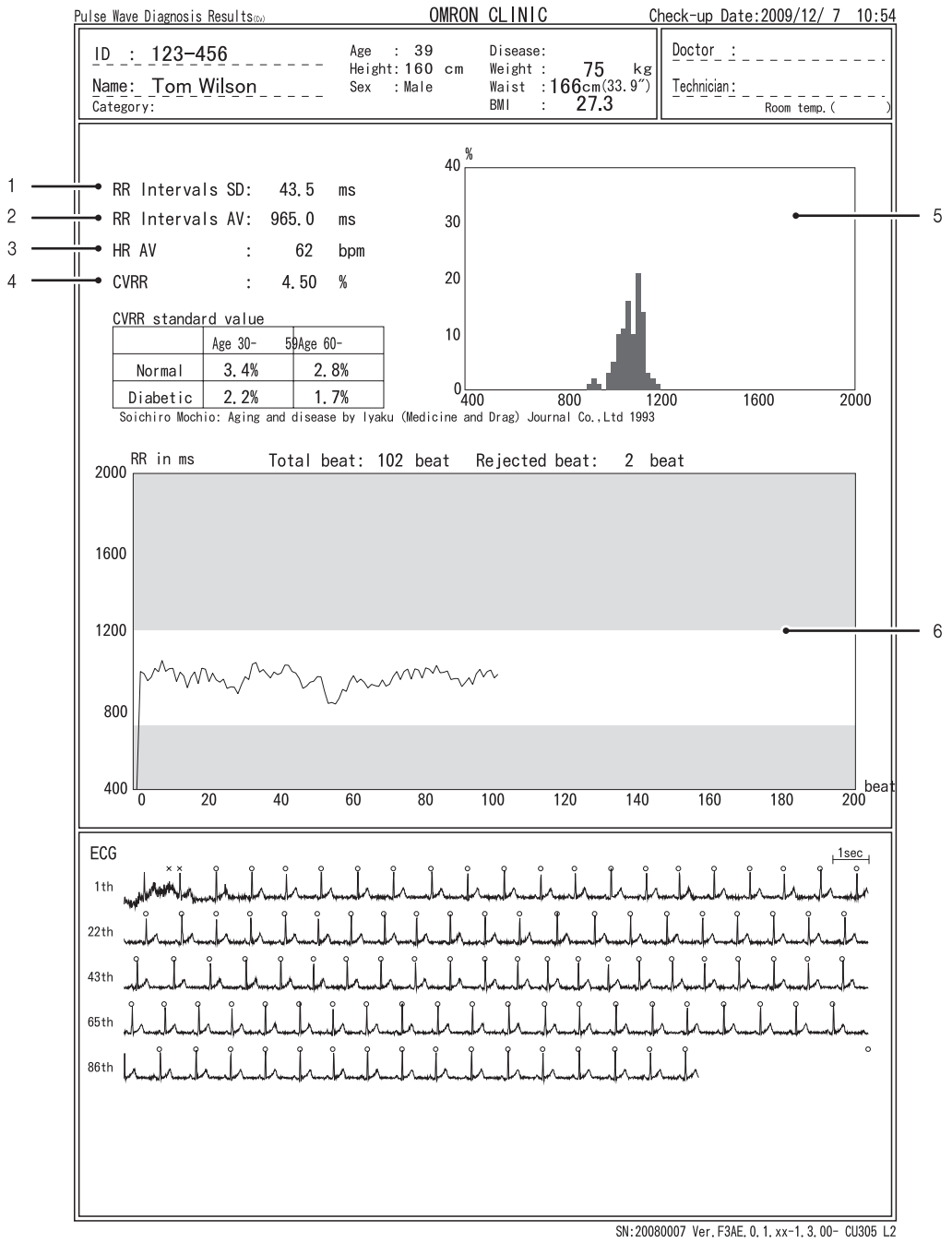


4. Remove ECG sensors from the patient.

R-R Interval Examination Results

The results of R-R interval examination are described below.

R-R Interval Examination Report



1	R-R interval standard deviation	This shows the standard deviation of the R-R interval.
2	R-R interval mean value	This shows the mean value of the R-R interval.
3	HR mean value	This shows the mean value of the heart rate.
4	CVRR	This shows the coefficient of variance of the R-R interval.
5	Histogram	This shows the histogram of the R-R interval.
6	Trend chart	This shows the trend graph of the R-R interval.

2-5. Stress Mode

This mode is used to measure blood pressure immediately after the heart is subjected to a set exercise load on a treadmill or similar device. After exercise is finished, the ECG and blood pressure gradually return to the rest state. By measuring this process (Post Stress), abnormalities can be discovered that would not be apparent when the patient is at rest.

Notes:

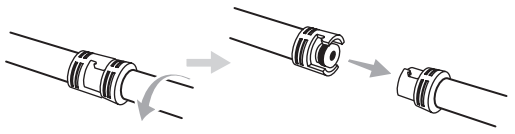
- The amount of exercise that the patient performs must be determined in consultation with a doctor. While the patient exercises, always pay close attention to the patient's condition.
- When applying an exercise load to a patient with heart disease, a doctor must be present and sufficient emergency measures must be prepared.
- Perform recovery measurement immediately after application of the exercise load. Measurement is not possible after 60 minutes have elapsed.
- Measurement is normally performed at the same parts as basic measurement.

Starting and Ending Post Stress Measurement

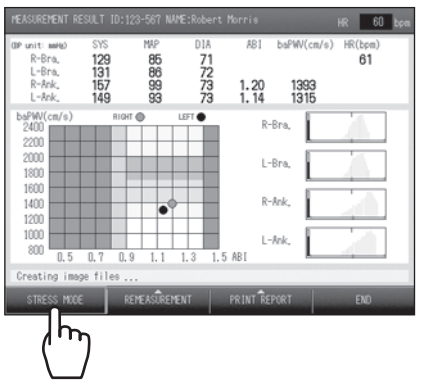
1. Perform basic measurement with the patient in the rest state.
Refer to "Starting and Ending Measurement" (page 51) steps 1 to 3.

2. Remove the ankle cuffs, ECG clips, and PCG sensor from the patient.

Disconnect the arm cuff from the cuff hose and leave the cuff on the patient.

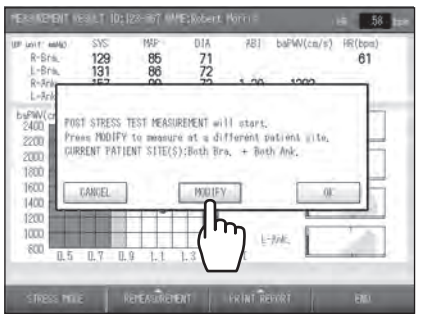


3. Select [STRESS MODE].

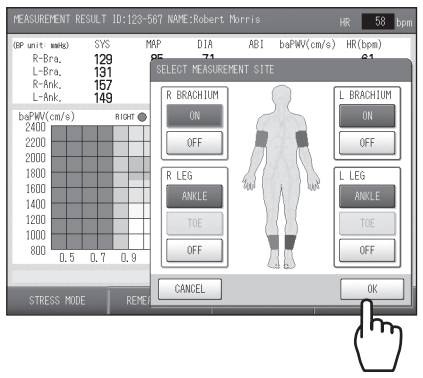


4. To change the measurement sites, select [MODIFY].

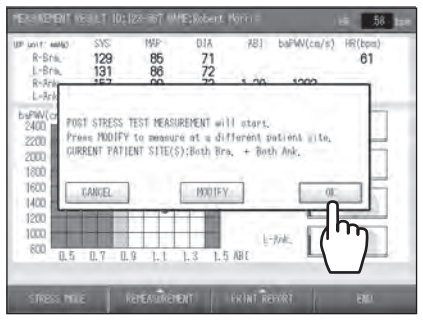
If you do not need to change the measurement sites, go to step 6.



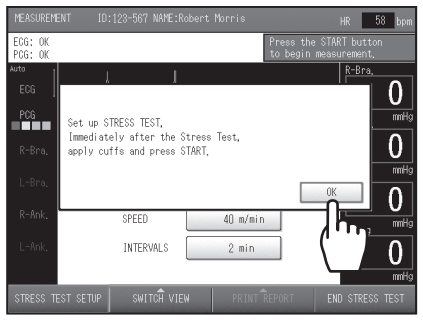
5. Select the measurement sites and select [OK].



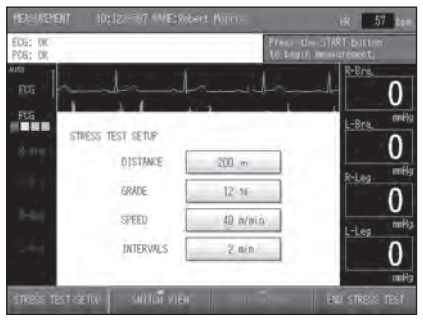
6. Select [OK].



7. Select [OK].



8. Set the exercise stress conditions.



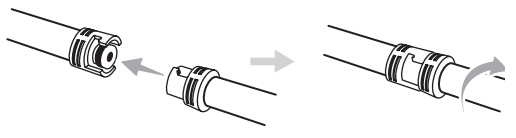
- DISTANCE: 0 to 1000 m
  (Walking distance)
- GRADE: 0 to 30%
  (Angle of treadmill)
- SPEED: 0 to 100 m/min
  (Treadmill speed)
- INTERVALS: 2, 3, 4, 5 minutes
  (Time from the start of one measurement until the start of the next measurement:
  for example, a 2 minute interval includes some number of seconds for the measurement, then a pause for the remainder of the 2 minutes, after which another measurement is taken, and so on.)

9. Start applying the exercise stress to the patient.

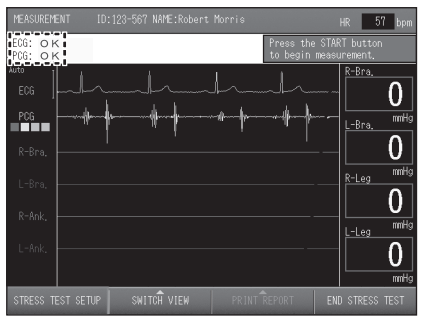
Apply the exercise stress to the patient based on the exercise stress conditions set in step 8.

10. Re-attach cuffs and sensors to the patient.

After applying the exercise stress, immediately attach the ankle cuff, ECG clips, and PCG sensor. Connect the arm cuff to the cuff hose.

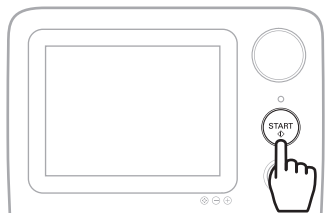


11. Confirm that "ECG: OK" and "PCG: OK" are displayed.

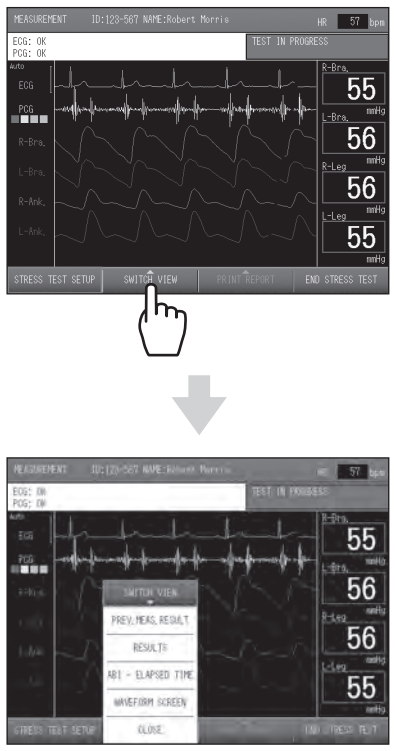


12. Press the [START] button.

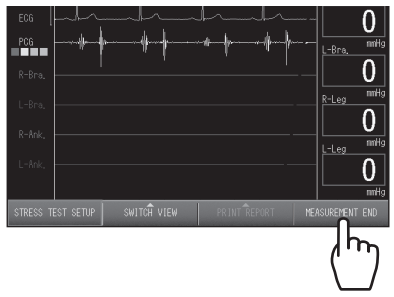
Measurement begins.



- During measurement the waveform appears. To view numerical values during measurement, select [SWITCH VIEW], and select the desired screen from the three screen types.
  Refer to "Checking Numerical Values During Post Stress Measurement" (page 71).



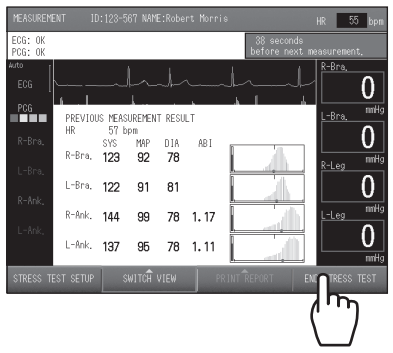
• To cancel measurement, select [MEASUREMENT END].



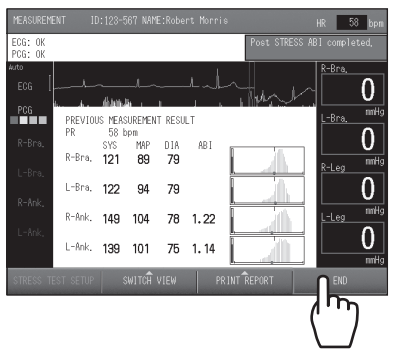
13. When the ABI returns to the state before exercise stress, select [END STRESS TEST] and then [OK] to end.

To cancel, select [CANCEL].

Measurement ends, the post stress measurement report will be printed.



14. Select [END].



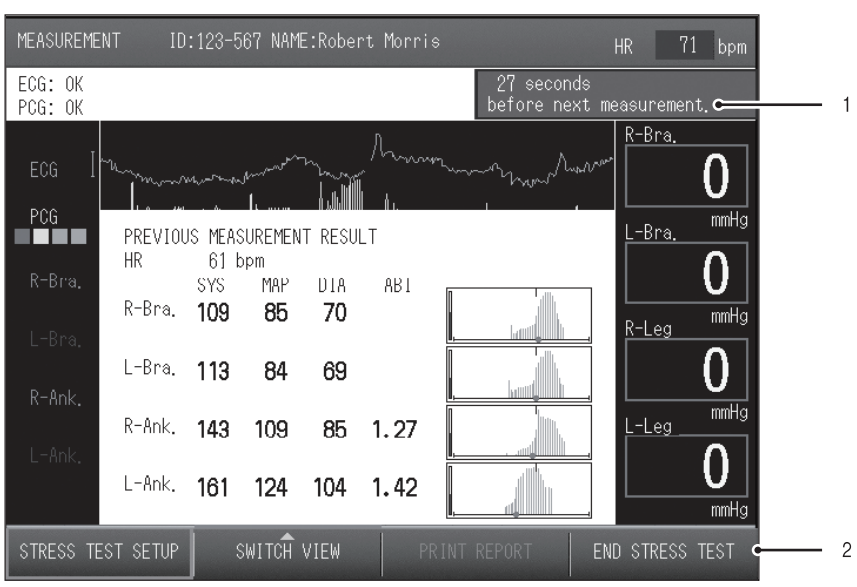
15. Remove the cuffs and sensors from the patient.

Checking Numerical Values During Post Stress Measurement

Selecting [SWITCH VIEW] on the waveform screen during or after post stress measurement switches among "Previous measurement result", "List of results", "ABI - Elapsed time", and "Waveform screen". View changes to the values being measured on any of these screens. Select an appropriate screen for the patient and the circumstances.

Previous measurement result screen

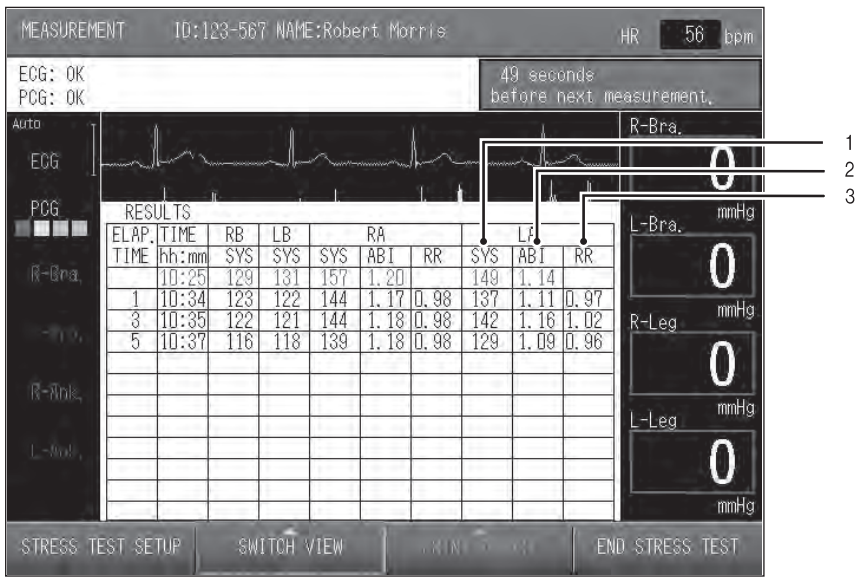
This screen graphs of the most recently measured values and pulsatile variation.



1	Interval	Counts the standby time until the next measurement.
2	[END STRESS TEST]	Press to stop Post Stress measurement.

List of results screen

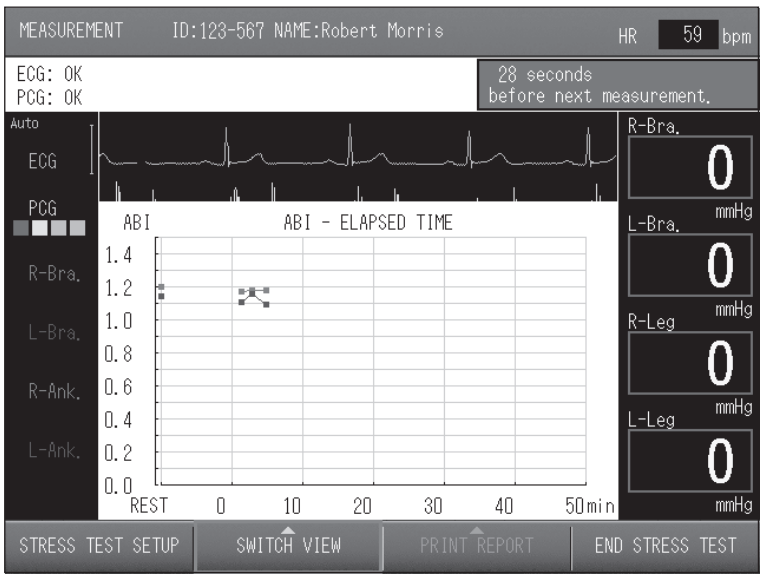
This screen shows measured values over time.



1	SYS	Shows the maximum blood pressure value.
2	ABI	Shows the ABI value.
3	RR	This shows the recovery ratio, which is the ratio of measured ABI to ABI at rest. This approaches 1 as time elapses.

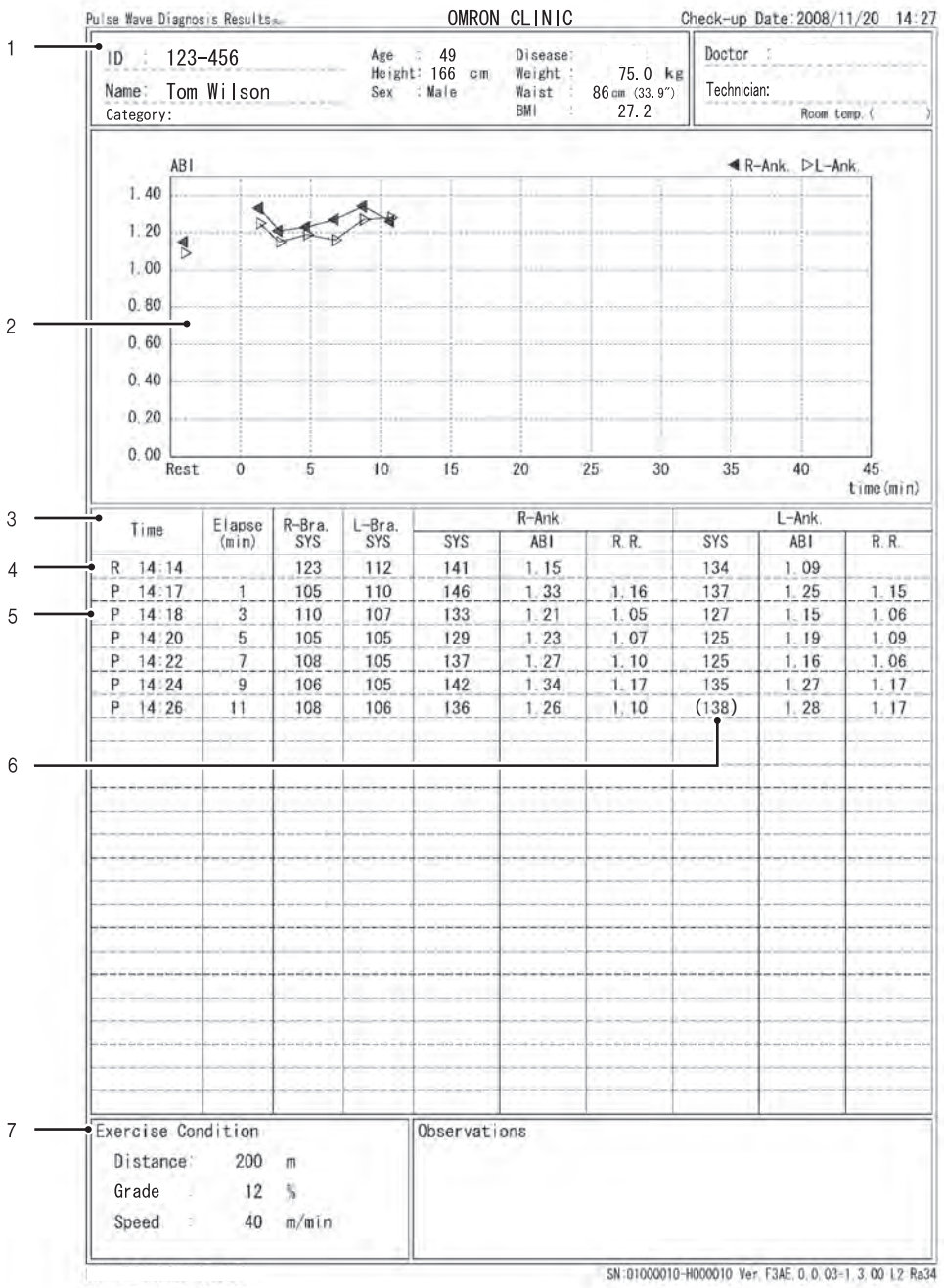
ABI - Elapsed time

This screen shows the trend of the ABI value over time.



Post Stress Measurement Results

When post stress measurement ends, the post stress measurement report is printed.



1	Patient information	The patient information that was entered before measurement.
2	Trend chart	This shows the trend of the ABI value over time.
3	List data	Shows a list of the measurement results together with the elapsed time. 4 : "R" indicates a measurement taken in the rest state. 5 : "P" indicates a post stress measurement. 6 : Parentheses indicate that the accuracy of the value was low for some reason and the value is indicated only for reference.
7	Exercise Conditions	Shows the set exercise stress conditions.

3. Settings and Data Processing

3-1. Main Menu Screen

To display the main menu screen, select [MAIN MENU] on the initial screen that appears after the power is turned ON. The main menu screen is used to configure basic settings related to the device and settings for printing measurement results, and to process past measurement data.

The items in the menu are described below.

Type	Name	Description	Page
DEVICE SETTINGS	USER DEFAULT SETTINGS	Conditions related to patient information such as search keys and ID input type, and settings related to measurement such as measurement sensors and measurement sites.	**76**
	PRINT DEFAULT SETTINGS	You can configure print settings such as paper size, number of printed pages, and print layout.	**80**
	FACIL / DR. / TECHNICIAN / CATEGORY	Facility name, doctor, technician, and category settings can be stored, edited, and deleted.	**86**
	DATE & TIME SETTINGS	Use this to set the date and time in the device.	**93**
SYSTEM INFORMATION		The device serial number, program version, system configuration, and other information can be displayed.	**133**
MAINTENANCE MENU		This is used to test for air leakage and other inflation/deflation speed and pressure accuracy problems in the measurement functions (inspection and maintenance).	**134**

Type	Name	Description	Page
DATA PROCESSING	PRINT REPORT / EDIT PATIENT INFO	The information of previously examined patients can be edited, deleted, and reprinted.	**94**
	TREND REPORT PRINTING	You can search for the information of a previously examined patient using the patient ID or date of examination, and reprint the trend report.	**101**
	REGISTER / MANAGE PATIENT INFO	Patient information can be registered in advance, edited, and deleted.	**105**
	USAGE FREQ. RPT: FACIL / PATIENT	A frequency of use report and a facility patient report can be printed.	**113**
	DATA EXPORT / IMPORT	Measurement data can be exported to USB flash drive and imported from USB flash drive for registration.	**116**
	HMC DATA IMPORT / REPORT PRINT	The optional HMC package can be used to import data from a household measuring device and print a report. For details, see the manual that accompanies the HMC package.	

3-2. User Default Settings

The user default settings are used to configure conditions related to patient information such as search keys and ID character type, and default settings related to measurement such as heartbeat beep, measurement sensors, and measurement sites.

Items That Can Be Set

For the procedure to change these settings, see page 79. The gray selection in the table indicates the factory setting.

Search Key

Enter patient information and select a search key.

Selections	Description
PATIENT ID	Select this to enter and search for patient information by patient ID.
EXAM ORDER NUMBER	Select this to enter and search for patient information by exam order number.

ID Input Type

Select the type of characters that can be entered for the ID number and order number in the new patient information registration screen.

Selections	Description
NUMBERS	Numeric characters and hyphens (-) can be entered.
NUMBERS AND CHR	Alphanumeric characters and hyphens (-) can be entered.

Default Age

Set the default age that appears in the new patient information registration screen when the patient's age is entered.

- Setting the average patient age as the default age makes it easier to enter a patient's age by jog dial.
- This can be adjusted within the range of 0 to 100. The default setting is "60".

HR Synchronized Tone

A beep sounds at each R wave of ECG during measurement.

Selections	Description
ON	A beep sounds.
OFF	No sound is made.

Measurement Sensors

Set default settings for attachment of sensors on the patient. Specify settings for ECG, PCG, CAP* and FAP*.

Selections	Description
ON	Attached.
OFF	Not attached.

* CAP and FAP only appear when the optional TU-100 pulse wave unit is connected.
When it is connected, read the manual for the unit.

Measurement Sites

Set default settings for attachment of cuffs on the patient.

- Cuffs are normally attached on both arms and both ankles.
- If a shunt is placed in an upper arm for hemodialysis, do not attach an arm cuff to or perform measurement on that arm.
- Measurement cannot be performed when both ankle cuffs and toe cuffs are attached.

Selections		Description
RIGHT BRACHIUM / LEFT BRACHIUM	ON	Arm cuff attached.
	OFF	Arm cuff not attached.
RIGHT LEG / LEFT LEG	ANKLE	Ankle cuff attached.
	OFF	Ankle cuff not attached.

Synchro Measurement

Set the default setting for "synchro measurement".

Selections	Description
ON	Perform synchro measurement.
OFF	Do not perform synchro measurement.

ABI Remeasurement

This sets the base ABI value that determines whether or not a second measurement will be performed.

Selections	Description
OFF	Do not judge whether or not to perform a second measurement using the base ABI value.
ON	When the measured ABI is lower than the set value, automatically perform a second measurement. Set the base ABI value within the range of 0.30 to 1.40.

Measurement Delay

Set the delay time from the end of the first measurement to the start of the second measurement for "synchro measurement" and "ABI remeasurement".
Select from [10 sec] to [120 sec]. The default setting is [10 sec].

User Default Settings

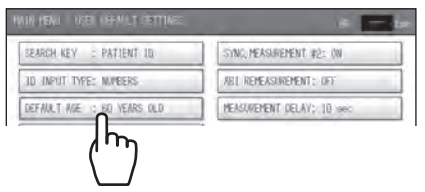
Select [MAIN MENU] on the initial screen. Configure "User Default Settings" from the main menu screen.

1. Select [USER DEFAULT SETTINGS].

2. Select the button of the item you wish to configure.

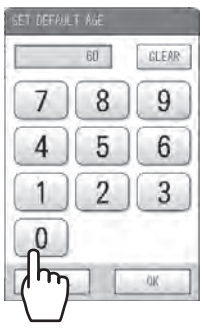
3. Select or enter a setting.

A. To select a setting from multiple selections, repeatedly select the item button until the desired setting appears.



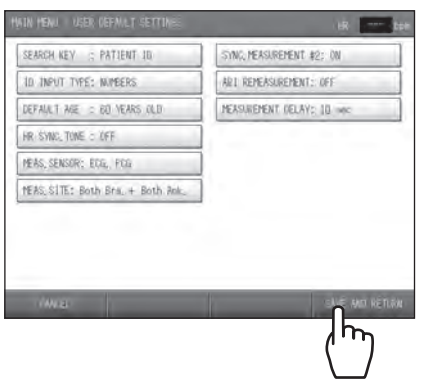
B. If a value must be entered, use the keyboard that appears.

- To clear a mistake, select [CLEAR].
- When the setting is completed, select [OK].
- To cancel, select [CANCEL].



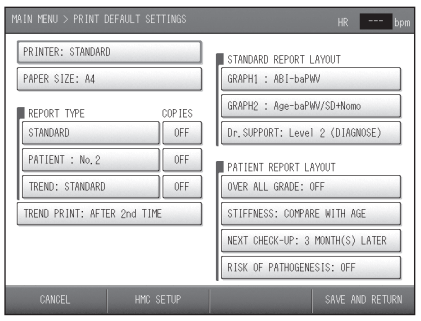
4. Repeat steps 2 and 3 to configure other items.

5. Select [SAVE AND RETURN].



3-3. Print Default Settings

You can configure print default settings such as paper size, copies, and print layout.



Items That Can Be Set

For the procedure to change these settings, see page 85. The gray selection in the table indicates the factory default setting.

Printer

Set the connected printer.

Selections	Description
STANDARD	Select this to use the printer that accompanies the device.
SERVER (COLOR) *	Select this to use a color printer other than the printer that accompanies the device.
SERVER (BLACK & WHITE) *	Select this to use a black & white printer other than the printer that accompanies the device.
OFF	Select this when a printer will not be used.

* To use a printer other than the printer that accompanies the device, contact a dealer or an Omron Healthcare technical support representative.

Paper size

Set the size of paper that is loaded in the printer.

Selections	Description
A4	Select this when A4 size paper is loaded.
B5	Select this when B5 size paper is loaded.

Note:
Do not use the size of paper other than the one specified in the paper size setting.

Report Type

The report type can be set for the patient report and trend report. Refer to the examples starting on page 54. Configure the settings in accordance with your examination policies, including the print conditions and report layout.

■ Standard Report

This report is for the doctor. There is one type.

■ Patient Report

There are four types. There are 2 different layouts for No.1, No.2, and No.4 (No.4 is for the optional HMC package).

Refer to "Patient Report" (page 60).

Selections	Description
NO.1	This type shows measured values, graphs, and images in a uniform arrangement.
NO.2	This type focuses on arterial stiffness and arterial stenosis in graph format.
NO.3	This type shows the risk of cardiovascular disease using easy-to-understand illustrations.
NO.4*	This type is for the optional HMC package.

* No. 4 is only enabled when the optional HMC package is used. For details, see the manual for the HMC package.

■ Trend Reports

Refer to "Trend Report" (page 64).

Selections	Description
STANDARD	This type shows measurement data trends based on comparison with past data.
HMC*	This type is for the optional HMC package.

* This is only enabled when the optional HMC package is used. For details, see the manual for the HMC package.

Number of Printed Pages

Set the number of copies printed for the standard report, patient report, and trend chart.

Selections	Description
OFF	Do not print.
1 PAGE - 10 PAGES	The set number of copies is printed. The default setting is [1 page].

Note:
If you will not be using a printer, set all settings for the standard report, patient report, and trend chart to "OFF".

Trend Print

Set the condition for printing a trend report.

Selections	Description
AFTER 2nd TIME	Only print when there is a patient history.
ALWAYS	Print regardless of whether or not there is a patient history.

Standard Report Layout

■ Graph 1

Select the type of graph to be printed on the lower left of the standard report.
(Example: page 55)

Selections	Description
1. Age-baPWV	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV.
2. Age-baPWV/SD	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line.
3. Age-baPWV/SD+Nomo	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line. (Shows mean age ± SD line and mean line of applicable blood pressure group.)
4. Age-baPWV/Nomo (1)	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV. (Shows mean age ± SD line and mean line of applicable blood pressure group.)
5. Age-baPWV/Nomo	This shows baPWV vs. age on the horizontal axis. (Shows mean line of each blood pressure group.)
6. ABI-baPWV	This shows baPWV vs. ABI on the horizontal axis.
7. SYS-baPWV	This shows baPWV vs. maximum blood pressure value on the horizontal axis.
8. DIA-baPWV	This shows baPWV vs. minimum blood pressure value on the horizontal axis.
9. baPWV Trend	This shows baPWV vs. date on the horizontal axis.
10. ABI Trend	This shows ABI vs. date on the horizontal axis.
11. Vascular Comment	This shows comments on vascular sclerosis and foot vascular clogging. This is the same content as in the patient report.
12. DIA-hcPWV*	This shows hcPWV vs. minimum blood pressure value on the horizontal axis.

* Can only be selected when an optional TU-100 pulse wave unit is connected. When a TU-100 pulse wave unit is connected, read the manual for the unit.

■ Graph 2

Select the type of graph to be printed on the lower center of the standard report. Selectable graph types are the same as for graph 1 above. The initial setting is [3. Age-baPWV/SD+Nomo].

■ Dr. support

Set the Dr. support level to be printed on the standard report.

Selections	Description
LEVEL 2 (DIAGNOSE)	This prints a suspected disease from measurement results such as "Possibility of constriction".
LEVEL 1 (NOTICE)	This prints facts such as "Measured baPWV is higher than mean value".
LEVEL 0 (NO COMMENT)	This prints information on reliability such as "Reliability of measurement results low due to noise".

Patient Report Layout

■ Over All Grade

An over all grade of measurement results is given using three levels: A, B, and C. The print settings for the over all grade field are explained below.

Selections	Description
OFF	Do not print.
SHOW FRAME	In the blood pressure value field of patient report No. 1, print the "Evaluation:" "Overall diagnosis:", and "Doctor:" fields.
SHOW RESULT	In the blood pressure value field of patient report No. 1, print the "Evaluation:" "Overall diagnosis:" "Doctor:" field, and the evaluation result. The evaluation result is also printed in the opinion field of the standard print.

■ Stiffness (Arterial stiffness indication)

Select the vascular sclerosis indication printed in patient report No.1 and No. 2.

Selections	Description
COMPARE WITH AGE	The result of baPWV measurement is compared with the mean value in a group of healthy people of the same age.
VASCULAR AGE	The result of baPWV measurement is calculated/estimated and displayed as a vascular age.
VASCULAR AGE (N)	Vascular age calculated/estimated from a blood pressure nomogram. (Patient Report No. 2 only.)

■ Next check-up

Specify whether or not "Date of next check-up" and "Target value of next check-up" are printed in patient report No. 1 and 2.

Selections	Description
OFF	Do not print.
1 MONTH - 12 MONTHS	Set in increments of one month from the measurement date. The initial setting is "3 months".

■ Risk of Pathogenesis

This indicates the risk of cardiovascular disease within the next 10 years.

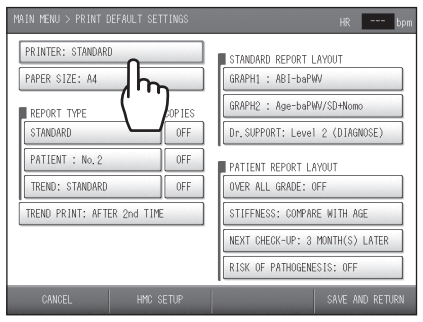
Selections	Description
ON	Print the risk of pathogenesis on Patient Report No. 1.
OFF	Do not print.

Print Default Settings

Select [MAIN MENU] on the initial screen. Configure "Print Default Settings" from the main menu screen.

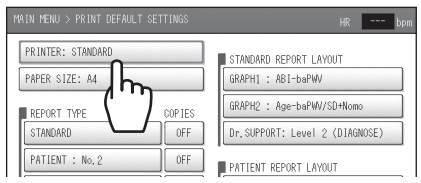
1. Select [PRINT DEFAULT SETTINGS].

2. Select the button of the item you wish to configure.



3. Select or enter a setting.

A. To select a setting from multiple selections, repeatedly select the item button until the desired setting appears.

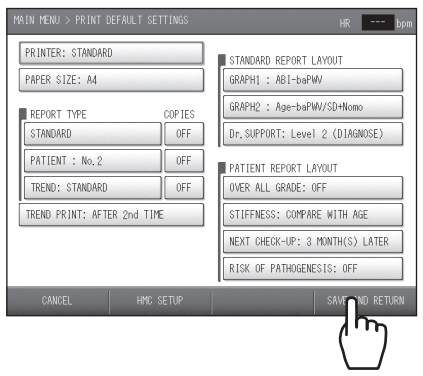


B. If a value must be entered, use the keyboard that appears.

- When the setting is completed, select [OK].
- To cancel, select [CANCEL].

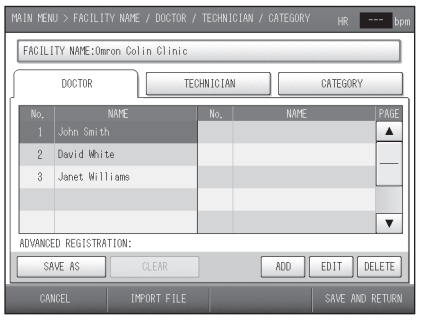
4. Repeat steps 2 and 3 to configure other items.

5. Select [SAVE AND RETURN].

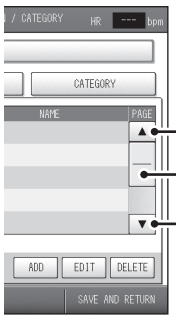


3-4. Facility name / Doctor / Technician / Category Settings

Facility names, doctors, technicians, and categories can be entered as lists, edited, deleted, and selected before performing measurements.



Note:
Use the scroll bar that appears on the right side of the screen when a doctor, technician or other list appears as explained below.



Return to the previous page.
Approximate position within the list.
Move to the next page.

Selecting the Method for Entering Lists

There are two methods for entering facility name, doctor, technician, and category lists.

A Import a text file

B Input from the touch screen

In method A, facility name, doctor, technician, or category data is prepared in advance and imported into the device. Data that has been imported into and stored in the device can be individually edited or deleted at the touch screen. Method B allows easy and immediate entry, editing, and deletion of data.

Entering Lists

Select [MAIN MENU] on the initial screen. "Facility name / doctor / technician / category" are configured from the main menu screen.

A. Importing a text file

1. You will need a USB flash drive to transfer files.

2. Create the data on a computer.

The format and number of characters are as follows:

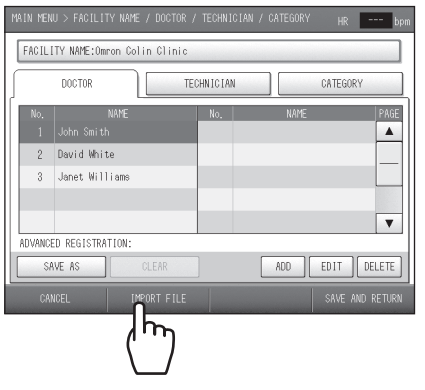
- Data format: text file
- File name: CLINIC.TXT
- Alphanumeric characters, hyphen, space, period, and apostrophe are allowed.
- Section name:
  Enter the content of each list under the following section names.
  [FACILITY], [DOCTOR], [TECHNICIAN], [CATEGORY]
- Facility name: 40 characters maximum
- Doctor / technician / category: 40 characters maximum
- Comment lines begin with a semicolon (;)

```
[FACILITY]
Omron Colin Clinic

[DOCTOR]
John Smith
David White
Janet Williams

[TECHNICIAN]
Peter Moore
Tom Brown
Jane Wilson

[CATEGORY]
Internal Medicine
Cardiovascular
Surgery
Orthopedics
```

3. Save the created data to USB flash drive and insert the memory stick to the USB port on the device.

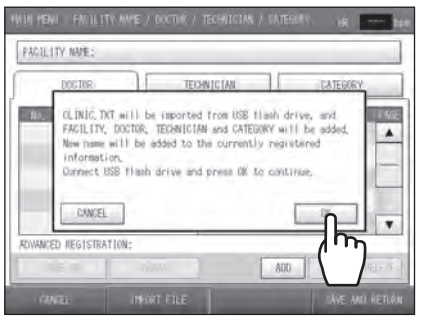
4. Select [FACIL / DR. / TECHNICIAN / CATEGORY].

5. Select [IMPORT FILE].



6. Select [OK].

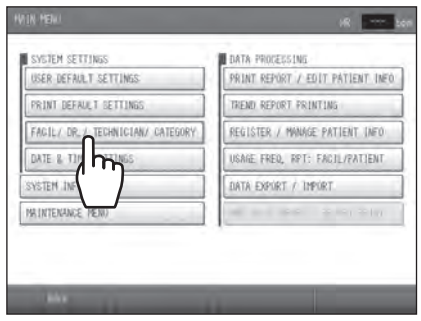
To cancel the import, select [CANCEL].



B. Input from the touch screen

■ To enter or edit the facility name:

1. Select [FACIL / DR. / TECHNICIAN / CATEGORY].



2. Select [FACILITY NAME].

3. Enter or edit the facility name.

- You can enter up to 40 characters.
- A space counts as one character.
- To enter a space, select [SPACE].
- To switch between upper case and lower case, use [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters you entered, select [CLR ALL].

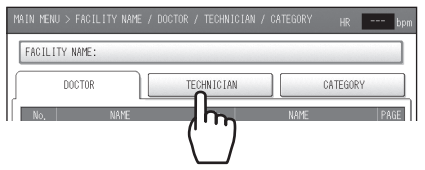
4. Select [OK].

To cancel, select [CANCEL].

> **Note:**
> The facility name entered above will appear at the top of various reports.
> Refer to page 55.

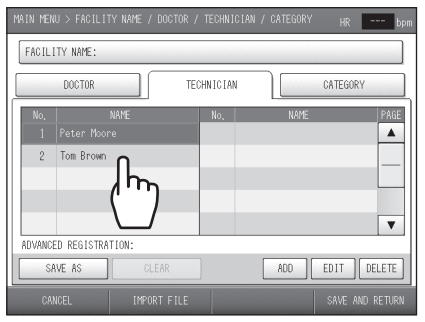
■ To enter, edit or delete a doctor, technician, or category entry:

1. Select [DOCTOR], [TECHNICIAN], or [CATEGORY] as appropriate for the item that you wish to add, edit, or delete.



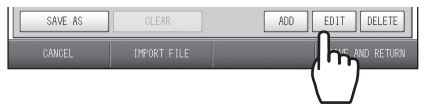
2. To add a new item, select [ADD]. To edit or delete an item, select the name.

If you selected [ADD], go to step 4.



3. Select [EDIT] or [DELETE].

If you selected [DELETE], go to step 5.



4. Enter or edit the item.

- You can enter up to 40 characters.
- A space counts as one character.
- To enter a space, select [SPACE].
- To switch between upper case and lower case, use [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters you entered, select [CLR ALL].

5. Select [OK].

To cancel, select [CANCEL].

6. Repeat steps 1 and 5 to configure other items.

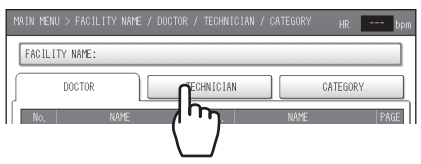
7. Select [SAVE AND RETURN].

Configuring Pre-selection Settings

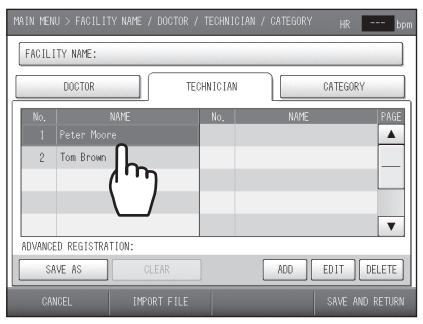
Configure pre-selection settings for the "Doctor", "Technician", and "Category". When patient information is entered, the names set in the pre-selection settings will initially appear in "Doctor", "Technician", and "Category" on the screen.

1. Select [FACIL / DR. / TECHNICIAN / CATEGORY].

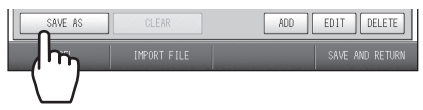
2. Select the button of the item you wish to pre-select.



3. Select the name that will be pre-selected.

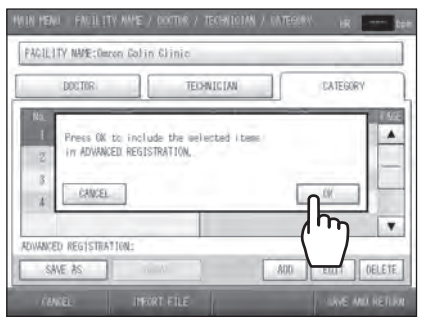


4. Select [SAVE AS].



5. Select [OK].

To cancel, select [CANCEL].



6. Repeat steps 2 through 5 to configure other items.

7. Select [SAVE AND RETURN].

Note:
If there is no need to print the "Doctor", "Technician", and "Category" on measurement result reports, select [CLEAR].

3-5. Date & Time Settings

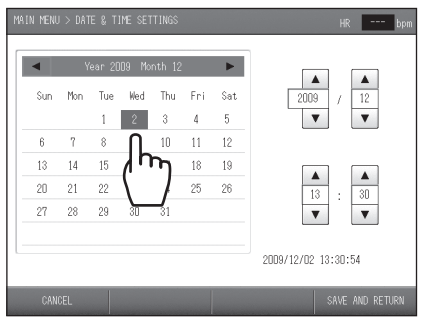
The date and time were set at the factory. If you need to adjust the date and time, follow the steps below.

Select [MAIN MENU] on the initial screen. Configure "Date & Time Settings" from the main menu screen.

1. Select [DATE & TIME SETTINGS].

2. Set the date and time.

- Change the year, month, and time with the [▲] [▼] arrows.
  - [▲] arrow: Change to the next higher value.
  - [▼] arrow: Change to the next lower value.
- Directly select the day on the calendar.

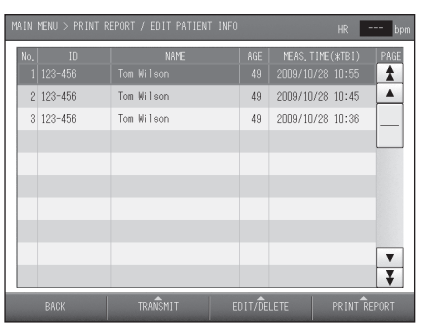


3. Select [SAVE AND RETURN].

To cancel, select [CANCEL].

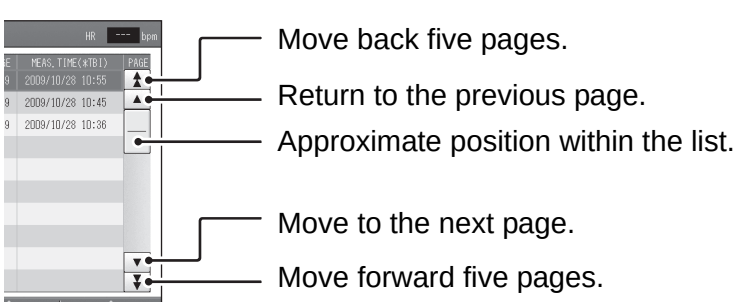
3-6. Printing Reports and Editing Patient Information

200 most recent examination reports can be reprinted, patient information can be edited, and measurement data can be deleted.



Notes:

- Data marked with "*" at the right of the date and time of measurement is TBI (Toe Brachial Index) data. TBI can be measured when the TBI package is installed. If the TBI package is installed, read the manual for the package.
- The scroll bar that appears on the right side of the screen when the patient list appears is used as explained below.

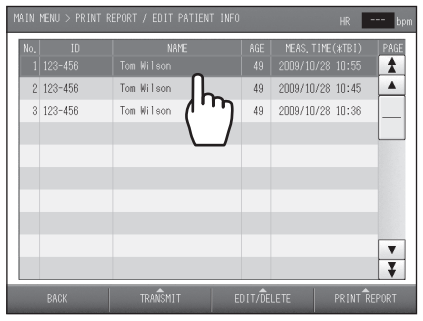


Reprinting Measurement Data

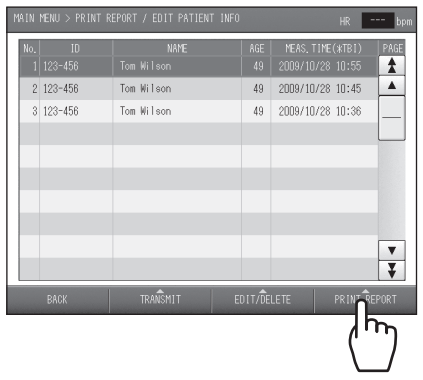
Follow the steps below to only reprint measurement data. A specified range of measurement data of multiple patients can be printed in one operation.
Select [MAIN MENU] on the initial screen. Reprint from "Print report / Edit Patient Info".

1. Select [PRINT REPORT / EDIT PATIENT INFO].

2. Select the first measurement data that you wish to reprint.

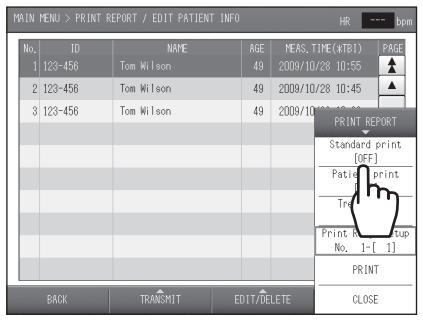


3. Select [PRINT REPORT].

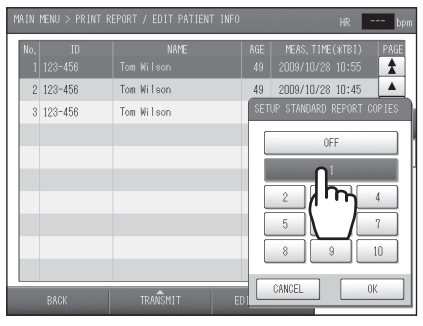


4. Check / change the number of copies to be printed.

1) Select the report for which you wish to change the number of copies printed. If no change is needed, go to step 5.



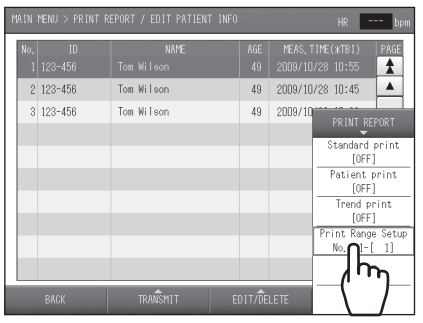
2) Select the number of copies to be printed.



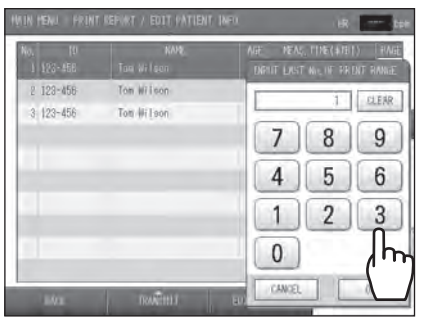
3) Select [OK].
To cancel, select [CANCEL].

4) Repeat steps 1) to 3) as needed to change the number of copies of other reports.

5. Select [Print Range Setup].



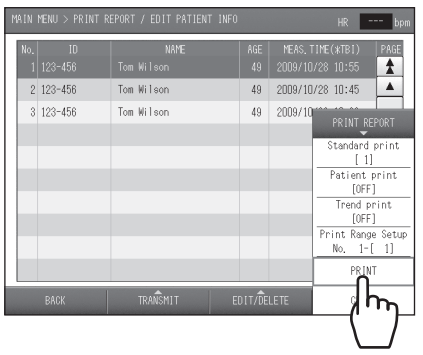
6. Enter the number of pages for the last measurement data that you wish to reprint.



7. Select [OK].

To cancel, select [CANCEL].

8. Select [PRINT].



9. Select [OK].

To cancel printing, select [CANCEL].

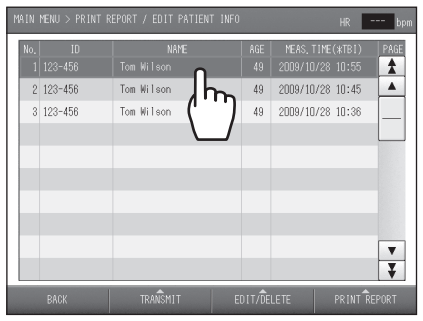
Note:
To cancel printing after it has begun, select [CANCEL] or press the [STOP] button on the device.

Editing Patient Information

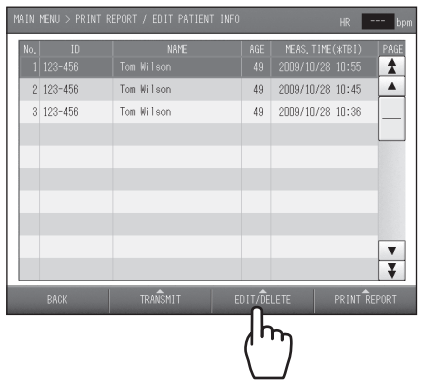
Select [MAIN MENU] on the initial screen. Edit patient information from "Print report / Edit Patient Info".

1. Select [PRINT REPORT / EDIT PATIENT INFO].

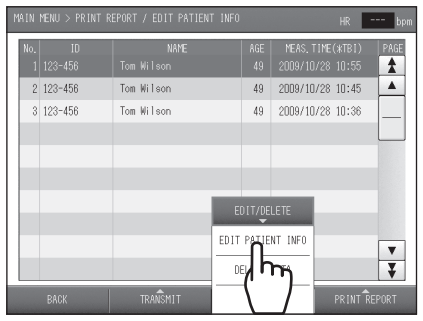
2. Select the patient information that you wish to edit.



3. Select [EDIT/DELETE].

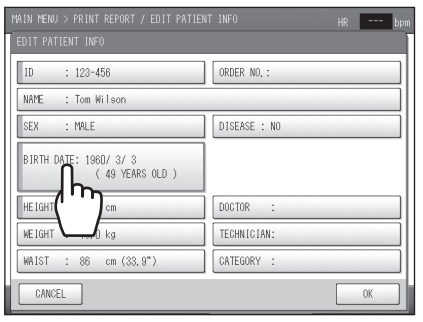


4. Press [EDIT PATIENT INFO].



5. Select the item and edit it.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (refer to page 25).



6. Select [OK].

To cancel editing, select [CANCEL].

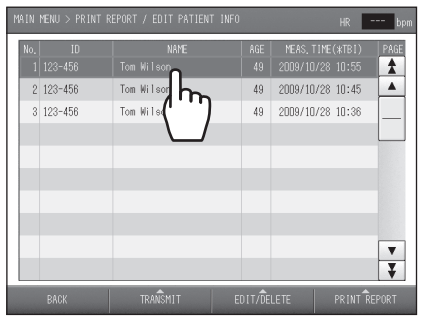
7. Select [BACK].

Deleting Measurement Data

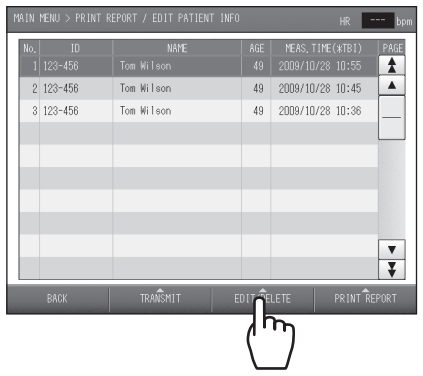
Select [MAIN MENU] on the initial screen. Delete measurement data from "Print report / Edit Patient Info".

1. Select [PRINT REPORT / EDIT PATIENT INFO].

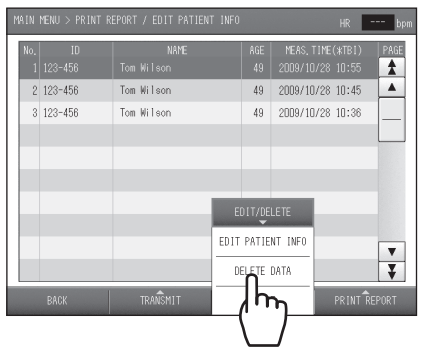
2. Select the measurement data that you wish to delete.



3. Select [EDIT/DELETE].

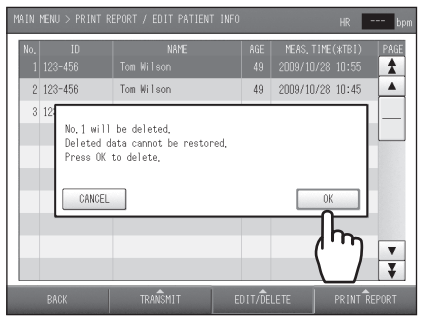


4. Press [DELETE DATA].



5. Select [OK].

To cancel the deletion, select [CANCEL].



6. Select [BACK].

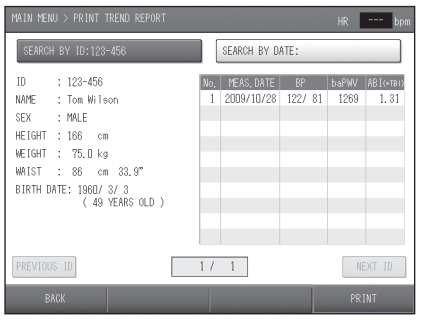
Note:
Deleted data cannot be restored.

3-7. Printing a Trend Report

A trend report showing trends in patient's measurement data can be printed. The patient data to be printed can be searched for by ID number or by date of measurement.

Select [MAIN MENU] on the initial screen. Perform "Trend Report Printing" from the main menu screen.

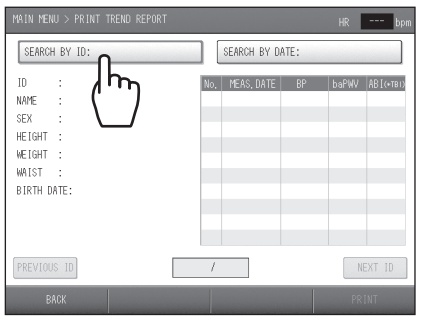
Note:
Data marked with "＊" at the right of the date and time of measurement is TBI (Toe Brachial Index) data. TBI can be measured when the TBI package is installed. If the TBI package is installed, read the manual for the package.



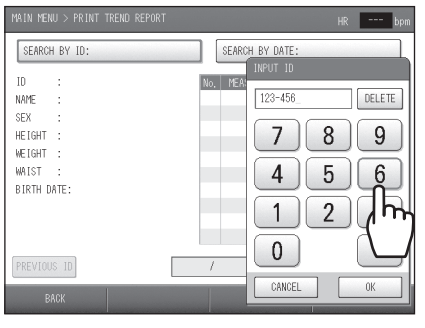
Searching by ID number

1. Select [TREND REPORT PRINTING].

2. Select [SEARCH BY ID].



3. Enter the ID number.



4. Select [OK].

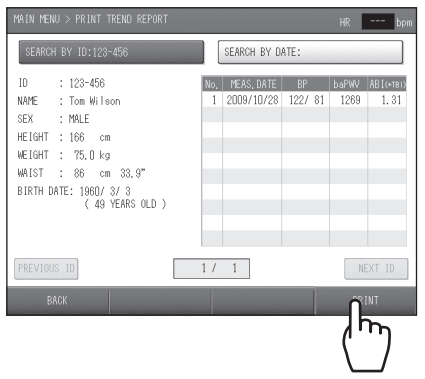
To cancel, select [CANCEL].

Note:
You can search for an ID number by entering just the initial digits of the number; it is not necessary to enter all digits. If there are multiple matches for the entered number, scroll through the IDs as follows:

- Select [PREVIOUS ID] to show the previous ID.

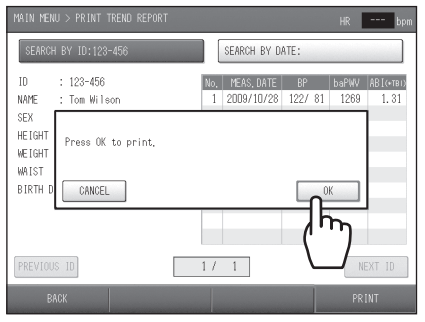
- Select [NEXT ID] to show the next ID.

5. Select [PRINT].



6. Select [OK].

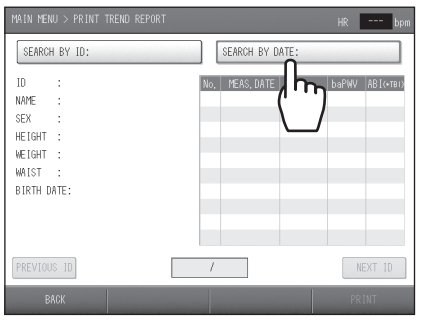
To cancel printing, select [CANCEL].



Searching by date of measurement

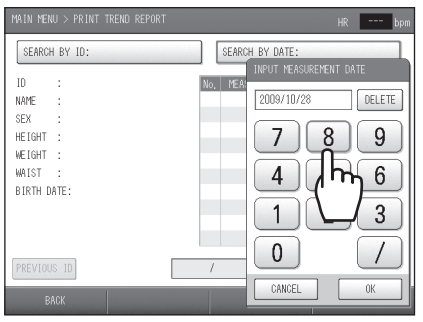
1. Select [TREND REPORT PRINTING].

2. Select [SEARCH BY DATE].



3. Enter the date of measurement.

Enter the date in the date format of "YYYY/MM/DD".



4. Select [OK].

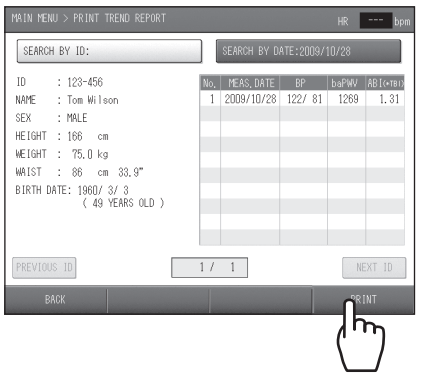
To cancel, select [CANCEL].

Note:
When there are multiple sets of data with the same date, scroll through the data as follows.

- Select [PREVIOUS ID] to show the previous ID.

- Select [NEXT ID] to show the next ID.

5. Select [PRINT]

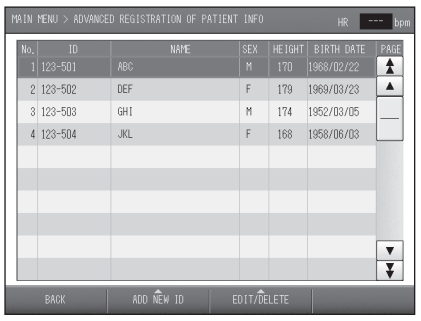


6. Select [OK].

To cancel printing, select [CANCEL].

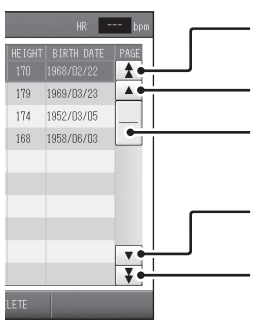
3-8. Advanced Registration of Patient Information

When there are many patients, patient information can be stored in advance. Information can also be edited and deleted.



Notes:

- When measurement is finished, the pre-registered patient information is removed from the pre-registered patient list.
- The scroll bar that appears on the right side of the screen when the pre-registered patient list appears is used as explained below.



Selecting the Method for Registration

There are two methods for registering patient information in advance.

A Import a text file

B Input with the touch screen

In method A, the patient information is prepared in advance on a computer and the information is imported into the device. Data that has been imported into and stored in the device can be individually edited or deleted at the touch screen. Method B allows easy and immediate registration, editing, and deletion of data.

Registration Procedure

Select [MAIN MENU] on the initial screen. Register patient information from the main menu screen.

A. Importing a text file

1. You will need a USB flash drive to transfer files.

2. Create the data on a computer.

The import file is as follows:

- Data format: comma-delimited text file*1
- File name: PATIENT.CSV

Each patient record includes the following data:

1. ID: Letters (upper case) and numbers, hyphens (-); 13 character maximum
2. Name: letters and spaces only, 40 character maximum
3. Sex: Code input; female = 0, male = 1
4. Birth date: YYYY/MM/DD (leading zeros, eg., 1/1 instead of 01/01, can be omitted)
5. Height: 120 to 210, units = cm
6. Weight: 25.0 to 300.0, units = kg
7. Waist: 30 to 250, units = cm
8. Disease: Code input*2, in one-byte character
9. Measurement site: Code input*2, 1 one-byte character
10. Doctor: Character type same as for Name
11. Technician: Character type same as for Name
12. Category: Character type same as for Name
13. Order number: Letters and numbers, 20 character maximum; optional, but even if unused, the comma after the Category must remain

*1 To use an XML file, consult a dealer or an Omron Healthcare technical support.

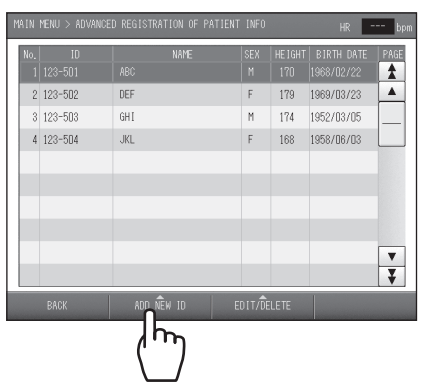
*2 Code Table (refer to page 107)

```
A-123, ABC,1, 1955/6/7, 168, 61.2, 85, 3, 4, GHI, , Internal, 1234-5
A-124, DEF, 0, 1947/11/02, 158, 52, 68, 0, A, JKL, , Internal, 1234-6
```

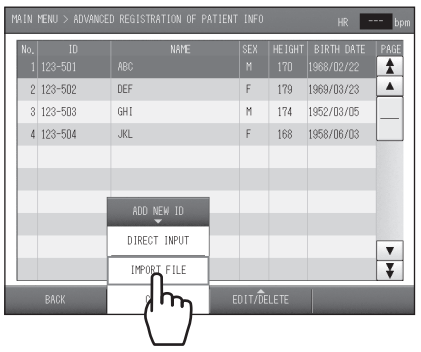
3. Save the created data to a USB flash drive and insert the flash drive in the USB port on the device.

4. Select [REGISTER / MANAGE PATIENT INFO].

5. Select [ADD NEW ID].

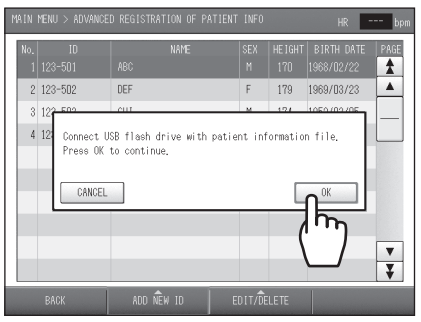


6. Press [IMPORT FILE].



7 Select [OK].

- If previously registered data exists, the new data is added to that data.
- To cancel the import, select [CANCEL].



8. Select [BACK].

Table of Codes for Disease

Code	Description
0	None
1	Hypertension
2	Hyperlipidemia
3	Diabetes
4	Hypertension + diabetes
5	Hyperlipidemia + diabetes
6	Hypertension + Hyperlipidemia
7	Hypertension + Hyperlipidemia + diabetes

Table of Codes for Measurement Sites

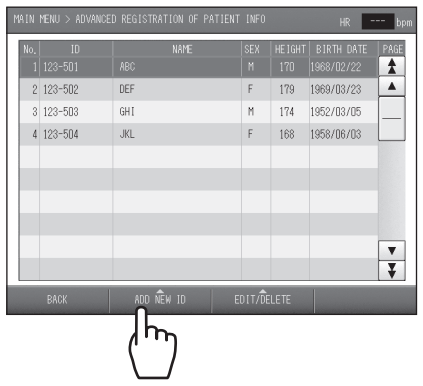
Code	Measurement sites*3
0	Right brachium + both ankles
1	Right brachium + right ankle
2	Right brachium + left ankle
3	Right brachium
4	Both brachia + both ankles
5	Both brachia + right ankle
6	Both brachia + left ankle
7	Both brachia (cannot be specified)
8	Left brachium + both ankles
9	Left brachium + right ankle
A	Left brachium + left ankle
B	Left brachium

*3 "Toe" cannot be specified as a measurement site.

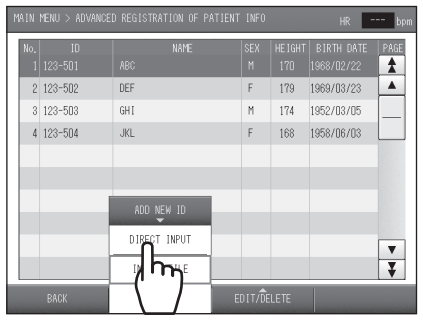
B. Input with the touch screen

1. Select [REGISTER / MANAGE PATIENT INFO].

2. Select [ADD NEW ID].



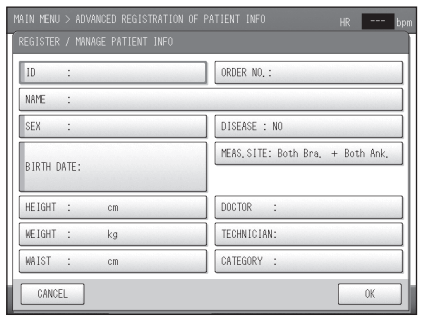
3. Press [DIRECT INPUT].



4. Select each item and enter the information.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (page 25).

It is not necessary to enter [HEIGHT] for Advanced Registration of Patient Information.



5. Select [OK].

To cancel the information entered, select [CANCEL].

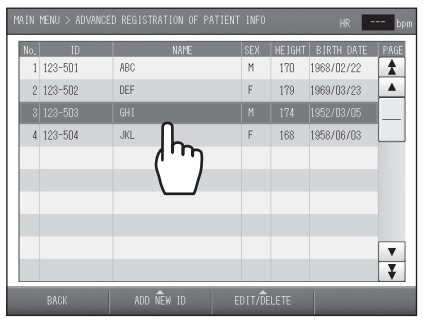
6. Select [BACK].

Editing Patient Information

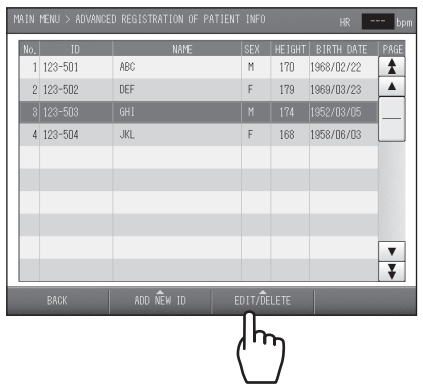
Select [MAIN MENU] on the initial screen. Patient information can be edited from "Register / Manage patient info".

1. Select [REGISTER / MANAGE PATIENT INFO].

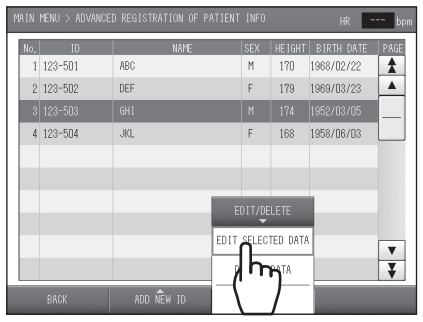
2. Select the patient information that you wish to edit.



3. Select [EDIT/DELETE].

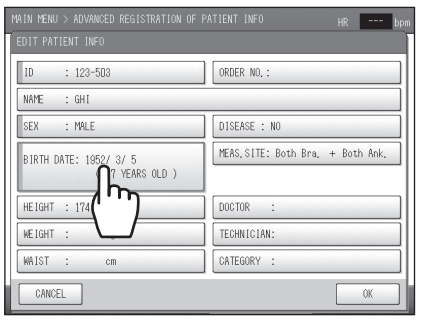


4. Press [EDIT SELECTED DATA].



5. Select the item that you wish to edit, and edit it.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (page 25).



6. Select [OK].

To cancel editing, select [CANCEL].

7. Select [BACK].

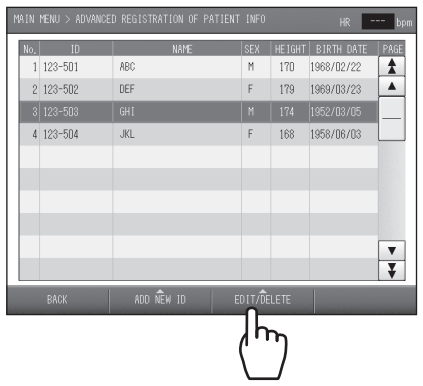
Deleting Patient Information

Select [MAIN MENU] on the initial screen. Patient information can be deleted from "Register / Manage patient info".

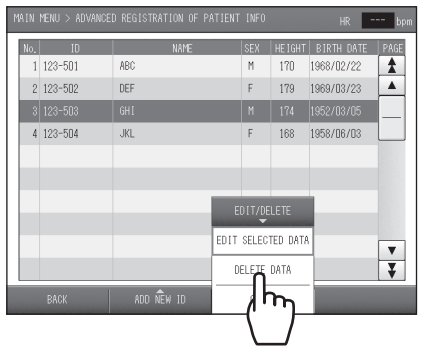
1. Select [REGISTER / MANAGE PATIENT INFO].

2. Select the patient information that you wish to delete.

3. Select [EDIT/DELETE].

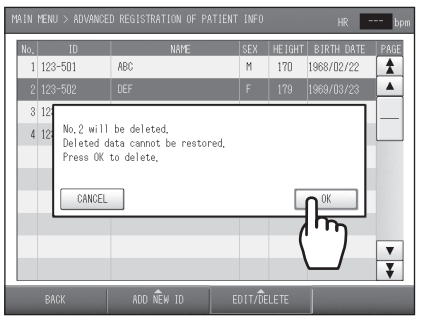


4. Press [DELETE DATA].



5. Select [OK].

To cancel the deletion, select [CANCEL].



6. Select [BACK].

Note:
Deleted information cannot be restored.

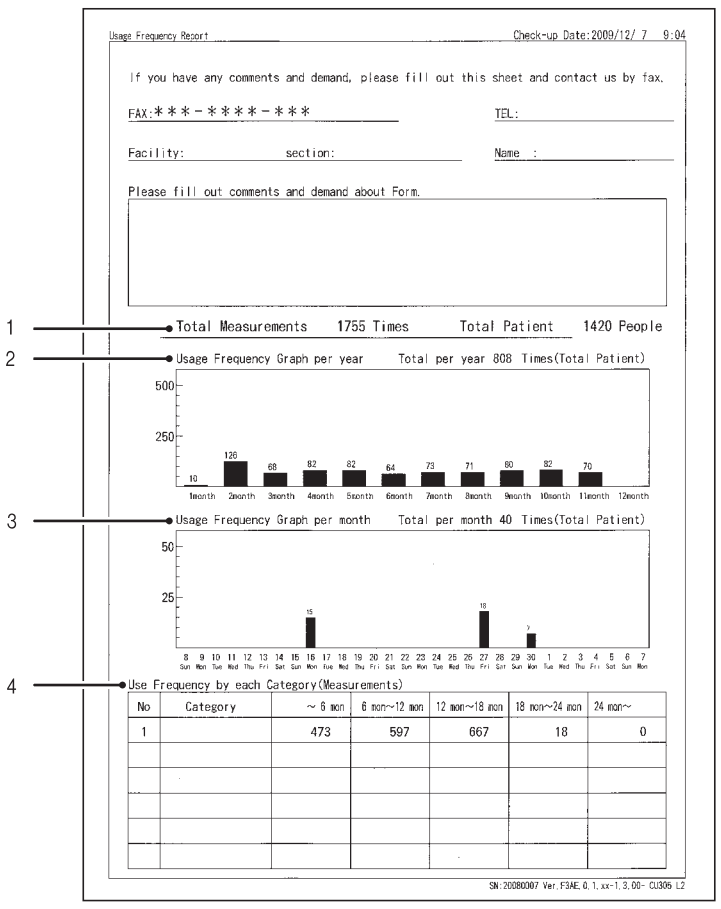
3-9. Printing Usage Frequency / Facility Patient Reports

Usage frequency and facility patient reports can be printed.

Types of Reports

Usage Frequency Report

This function lets you to check past usage frequency.

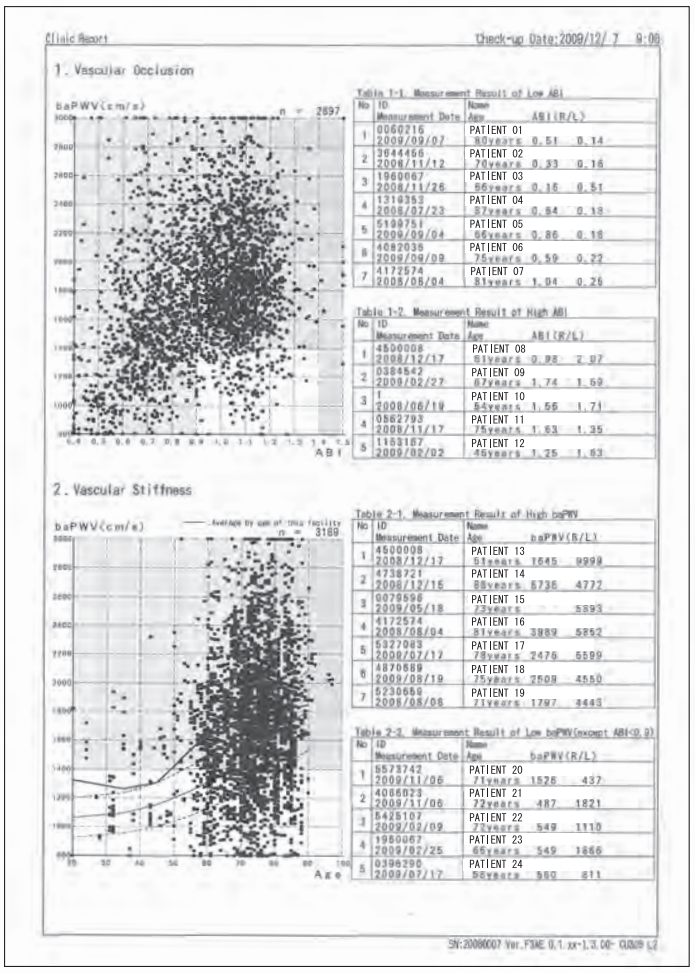


1	Total times / Total patients	Prints the total number of measurements performed and the total number of patients.
2	One-year usage frequency graph	This graphs the frequency of use by month over the past 12 months.
3	One-month usage frequency graph	This graphs the frequency of use by day over the last month.
4	Category usage frequency	This shows usage by category (refer to page 39).

Facility Patient Report

ABI and baPWV can be extracted from the recorded measurement data and shown as a graph.

- High measured value data are printed followed by low measured value data.
- Mean values of baPWV are calculated over 10-year intervals and shown as a mean-value line.



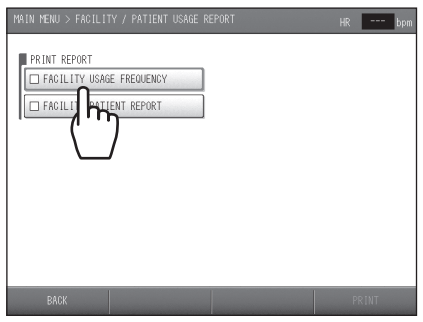
Printing Usage Frequency / Facility Patient Reports

Select [MAIN MENU] on the initial screen.

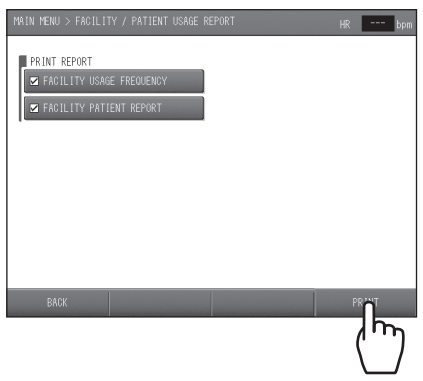
1. Select [USAGE FREQ. RPT: FACIL / PATIENT].

2. Select the report that you wish to print.

You can select multiple reports.



3. Select [PRINT].



4. Select [OK].

To cancel printing, select [CANCEL].

3-10. Data Export / Import (USB Flash Drive)

Measurement data can be exported to USB flash drive and imported from USB flash drive. Select [MAIN MENU] on the initial screen. Select [DATA EXPORT/IMPORT] from the main menu screen.

Data Processing Items

Processing category	Description
DATA EXPORT	Export measurement data to a USB flash drive.
DATA IMPORT	Import measurement data from a USB flash drive
DATA EXPORT (FORMER UNIT)	Export measurement data in the BP-203RPE or BP-203RPEⅡ data format to a USB flash drive.
DATA IMPORT (FORMER UNIT)	Import BP-203RPE and BP-203RPEⅡ data. This is only possible for Ver. CX002 or later.

Data Processing Procedure

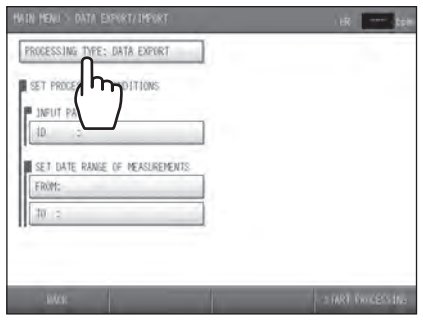
Three items are set in order to perform data export and import processing, however, processing is possible without setting these items. Processing is as follows depending on whether or not the items are specified:

Items	Specified yes/no	
	Yes	No
ID	Only data of specified IDs are processed	All data are processed
FROM:	Data from the specified date and later are processed	All data are processed
TO:	Data prior to the specified date are processed	All data are processed

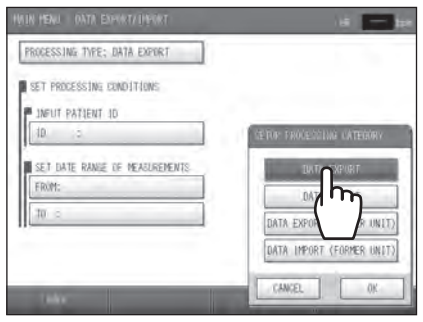
1. Select [DATA EXPORT / IMPORT].

2. Set the processing type.

1. Select [PROCESSING TYPE].



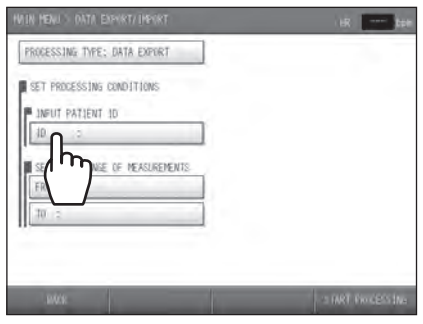
2. Select the desired "processing type".



3. Select [OK].
   To cancel, select [CANCEL].

3. Specify the conditions for the data to be processed.

1. Select [ID].

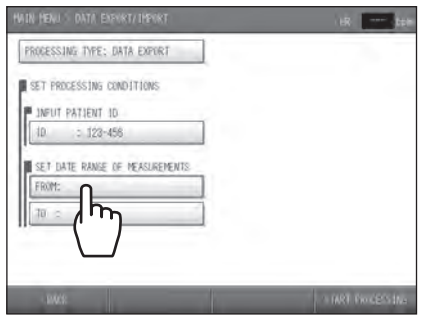


2. Enter the ID number.

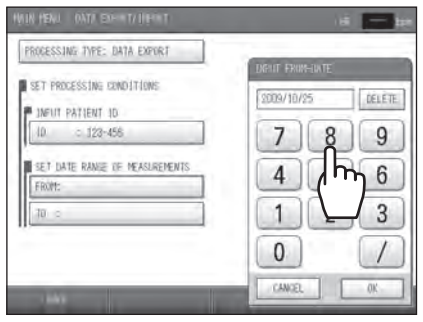
3. Select [OK].
   To cancel, select [CANCEL].

4 Specify the data range of measurements.

1. Select [FROM].



2. Enter the starting date in the format "YYYY/MM/DD".



3. Select [OK].
   To cancel, select [CANCEL].

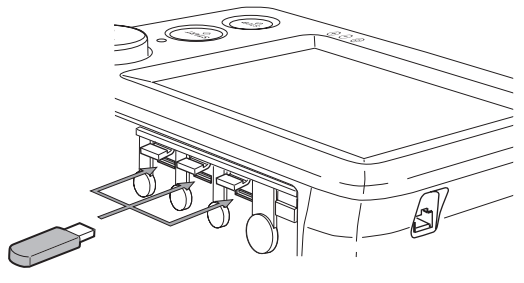
4. Select [TO].

5. Enter the ending date in the format "YYYY/MM/DD".

6. Select [OK].
   To cancel, select [CANCEL].

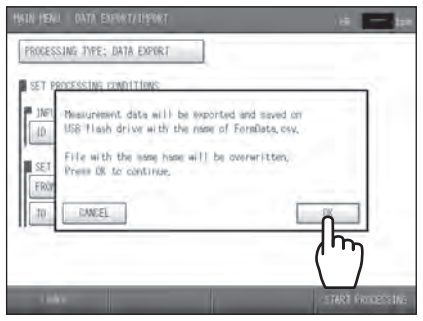
5. Select [START PROCESSING].

6. Insert the USB memory stick into the USB port on the device.



7. Select [OK].

To cancel processing, select [CANCEL].



The displayed message varies depending on the processing.

3-11. Transferring Report Data to a Computer

The separately sold special LAN cable can be connected to the device to send measurement report data to a computer. Please consult a dealer or an Omron Healthcare technical support representative to configure network settings to enable use of this function.

Types of reports that can be exported to a computer:

- Standard Reports
- Patient Reports
- Trend Reports

4. Options

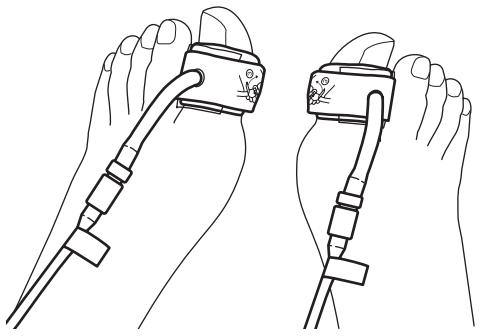
4-1. Options

Read the manual that accompanies each optional package or unit to ensure correct use of the option.

TBI Package

TBI (Toe Brachial Index) can be calculated by installing the TBI package. It also measures toe systolic blood pressure, TBI (Toe Brachial Index) and toe pulse waveform. The results are useful for the following:

- When disease is suspected in the foot below the ankle (heel, top of foot, bottom of foot).
- When ankle blood pressure is high due to diabetic arteriosclerosis (calcification) or other reason (calcification tends not to extend to peripheral areas).



Measurable items

Toe systolic blood pressure (maximum blood pressure)

Measurement range: 40 mmHg - 260 mmHg (However, in the vicinity of 40 mmHg, fluctuations of about ±10 mmHg may occur due to pulse amplitude.)

TBI (Toe Brachial Index)

TBI = Toe systolic pressure / brachial systolic pressure (higher of left and right pressures)

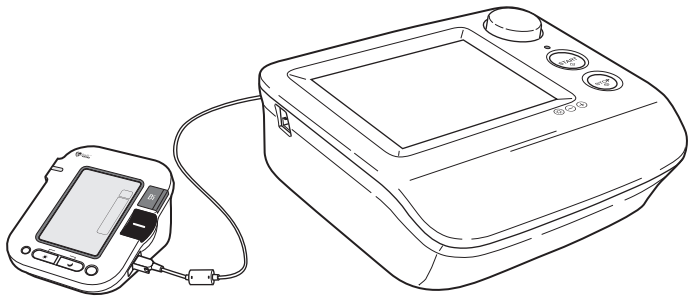
(The TBI of a healthy person is generally 0.7 or higher; a TBI of less than 0.7 may indicate a pathological change.)

Toe pulse waveform (PVR)

Pulse waveform is displayed when a constant pressure is applied to the toe cuff.

HMC package

The HMC Package is a system that enables measurement data to be imported from a home digital blood pressure monitor, pedometer, or body composition monitor. Imported data can be printed on the trend chart together with measurement results from the main unit.



Data to be imported

Measurement device	Data item
Blood pressure monitor	Systolic blood pressure value, diastolic blood pressure value, pulse rate, date and time of measurement
Pedometer	Total steps in one day, date of measurement
Body composition monitor	Weight, date of measurement

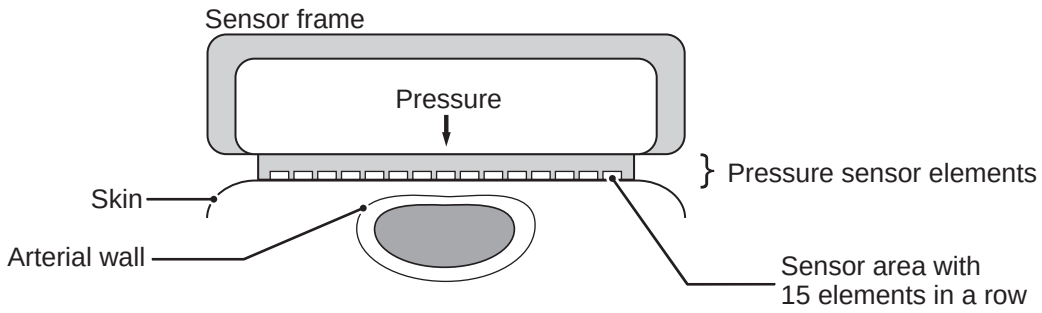
* Contact a dealer or an Omron Healthcare technical support representative for more information.

Pulse Wave Unit TU-100 and CAP/FAP Sensor Unit

The TU-100 and CAP/FAP Sensor Unit use tonometry to measure pulse waveforms. This device supports the diagnosis of artery flexibility and level of arterial stiffness with measurement results of PWV on the carotid artery and aorta, neck region AI, and pulse wave recording.

Pulse wave detection

In tonometry, the pressure pulse wave sensor presses on the skin to flatten the arterial wall, and consequently the pressure inside the artery is directly detected by the pressure sensor. The pressure sensor is a multi-element sensor that contains a row of 15 sensor elements. The device analyzes the signal from the pressure sensor and selects the sensor elements that are in the optimum position. The pulse wave measured with the signals from the elements are used in analysis.



Bar Code Reader Set

When clinical charts or registration tickets have a bar code, it can be used to obtain patient information. Consult a dealer or an Omron Healthcare technical support representative beforehand to confirm that the bar code reader can be used.

initial screen :
ID number entry

5. Maintenance

5-1. Routine Maintenance

⚠ **Warning**	• After cleaning the device, dry it completely before turning on the power again. Otherwise electric shock or current leakage may result. • Use only the specified supplies for the cord, cuff, and other parts. Do not install other than specified options. An accident may result.
⚠ **Caution**	• Before cleaning or maintaining the device, disconnect the power plug. Otherwise electric shock or injury may result. • The ECG clip electrode and PCG sensor pad are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result.

Regular maintenance will maximize the service life of the device. Routine maintenance procedures and supplies are explained below.

Maintenance Procedures

Main Unit

Note:
Do not wipe the ports on the back of the unit.

To clean the surface of the main unit, use a damp cloth moistened with a neutral detergent or disinfectant alcohol.

Cuffs

Note:
Dispose of dirty or old cuffs as medical waste. Do not recycle.

To clean parts that come in direct contact with the skin, use a damp cloth moistened with a diluted disinfectant alcohol. For other parts, simply remove foreign objects and dust; do not wipe with alcohol or water.

ECG clips / PCG sensor / air hoses

Note:
Keep ECG clip electrodes and PCG sensor pads out of direct sunlight and away from high temperatures and high humidity. Store them at room temperature (10 to 35°C).
If the electrodes are dry, accurate measurement may not be possible.

Wipe with a damp cloth moistened with 30 - 50% isopropyl alcohol, 70% ethyl alcohol, or a neutral detergent.

Supplies

Note:
Dispose of ECG clip electrodes and PCG sensor pads as medical waste after use.

Keep an adequate amount of supplies. Use the model number when ordering supplies.
Refer to "Accessories (Sold Separately)" (page 15).

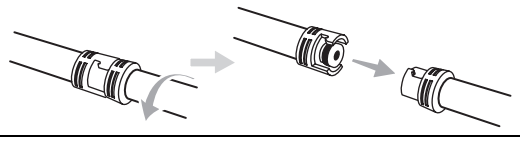
5-2. Replacing Cuffs

⚠ **Caution**	The sensor box removal lever uses a strong spring mechanism. Hold the sensor box firmly and press down hard on the lever from the exterior to remove the connector. This may cause injury with the metal edges.

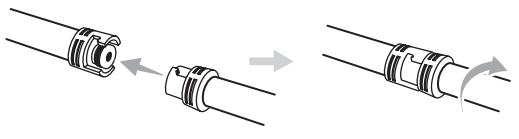
The procedures for disconnecting and connecting the air hose when replacing a soiled, old, or unusable cuff with a new cuff or changing the cuff to a different size cuff is explained below.

Replacing an Arm Cuff

1. Rotate the air hose connector counterclockwise to disconnect the hose from the cuff.



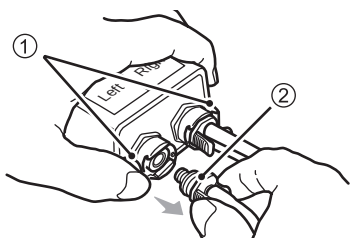
2. Insert the connector on the new cuff into the air hose. Rotate the connector clockwise until it clicks into place.



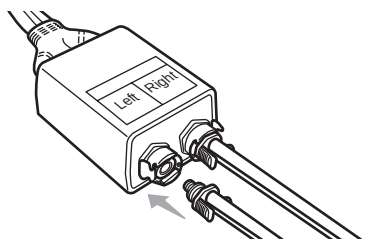
Replacing an Ankle Cuff

1. Squeeze the removal levers ① on the sensor box and remove each cuff connector ②.

The levers are small and slippery.
Squeeze the levers firmly.



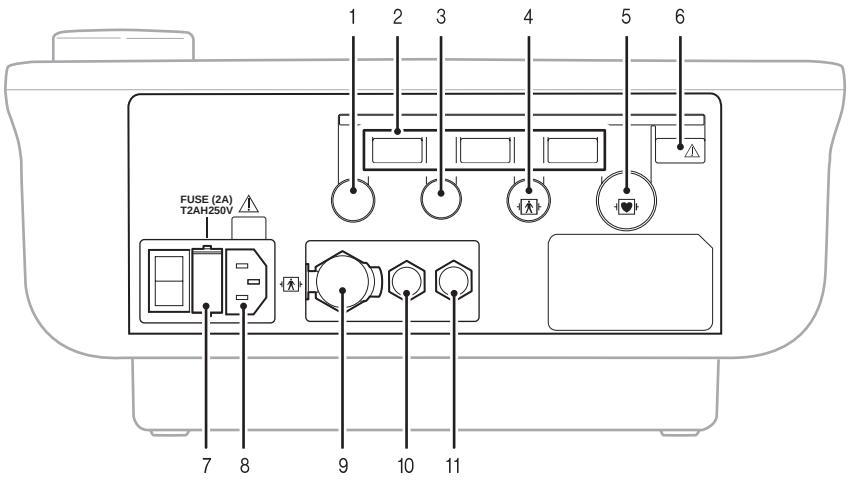
2. Insert each connector on the new cuff into the sensor box until it clicks into place.



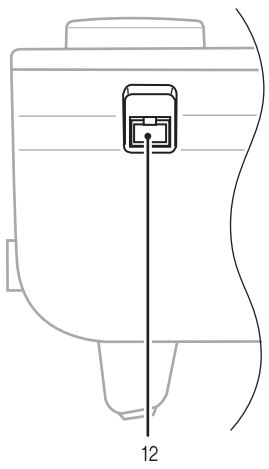
5-3. Connections

Connectors on the Device

Back



Left side



1. **Sensor box connector**

2. **USB ports**
   HMC Package communication, bar code reader, and USB flash drive can be connected to these ports.

3. **Pulse wave unit TU-100 (option) connector**

4. **PCG sensor connector**

5. **ECG clip connector**

6. **USB printer port**
   Attach the printer to this port marked with ⚠.

7. **Fuse holder / fuse**
   Do not replace the fuses on your own. Electric shock or fire might result.
   - The fuses are specifically designed for this device. Contact a dealer or an Omron Healthcare technical support representative for replacement of the fuses.
     - Fuse model: 5HT-R 2A (BEL FUSE LTD.)

8. **AC connector**
   Connector for the power cord.

9. **Sensor box hose joint**
   Connector for the sensor box air hose.

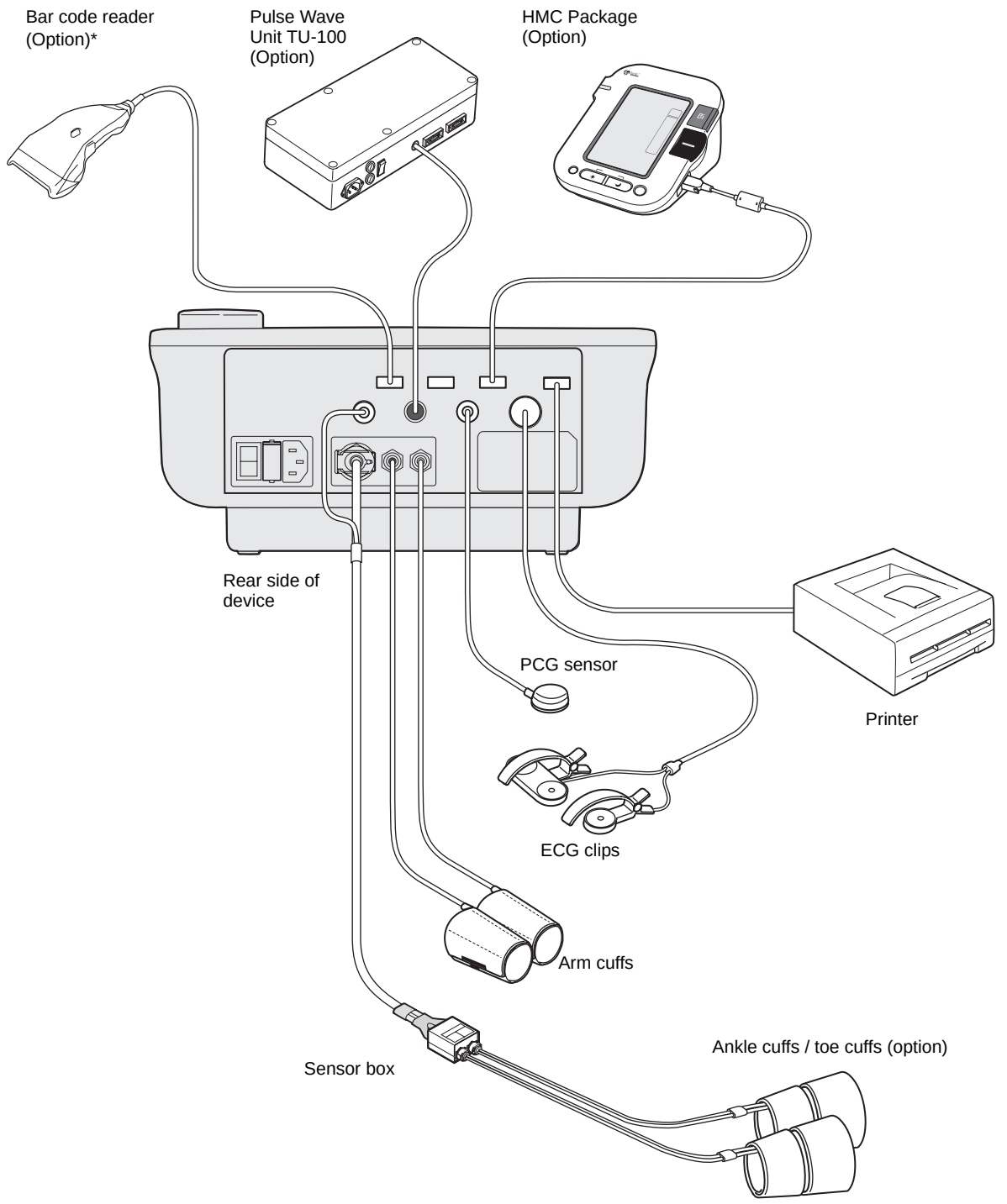
10. **Left arm cuff hose joint**
    Connector for the left arm cuff hose.

11. **Right arm cuff hose joint**
    Connector for the right arm cuff hose.

12. **LAN cable connector**
    A computer can be connected to the device using the approved LAN cable.

Basic Connections

Connect the sensors, options, and printer to the device as shown below.



The appearance of the device is subject to change without notice.

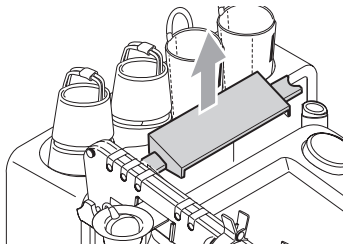
* Verification of bar code content and changing of device settings are required in advance. For more information, consult a dealer or an Omron Healthcare technical support representative.

5-4. Changing the Arm Position

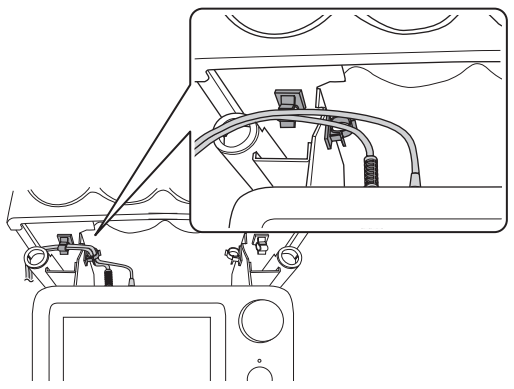
The arm can be attached on either side of the stand, which is more convenient for measurement in the examination environment.

1. Turn off the system power.

2. Remove the cable cover.

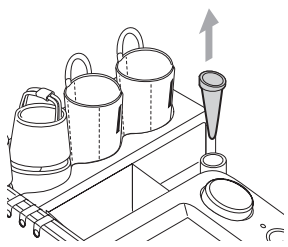


3. Detach the cables (one for the ECG clips and the other for the PCG sensor) from the fasteners behind the main unit.

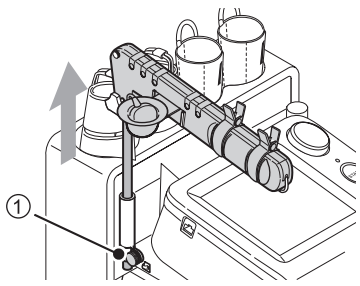


4. Disconnect the ECG clip and the PCG sensor from the connectors on the back of the main unit.

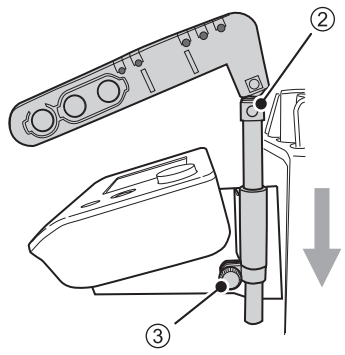
5. Remove the touch pen stand.



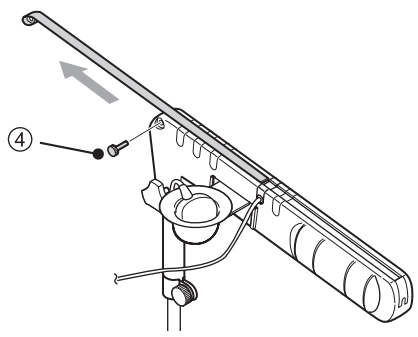
6. Loosen the screw ① and pull out the arm.



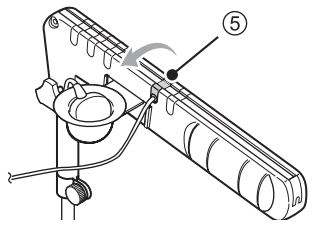
7. Push the arm in so that metal screw ② on the arm will face out, and tighten screw ③.



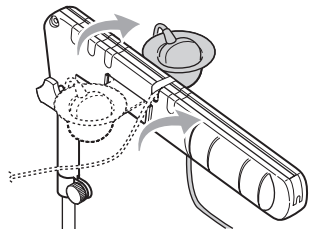
8. Loosen the screw ④ and slide the arm rail off.



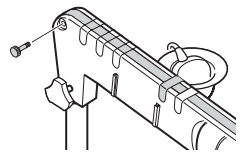
9. Remove the fastener ⑤ for the PCG sensor cable.



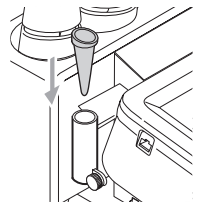
10. Move the PCG sensor cable and the PCG sensor pocket to the outer side.



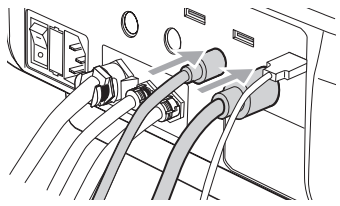
11. Attach the arm rail and PCG sensor cable fastener ⑤, and tighten screw ④.



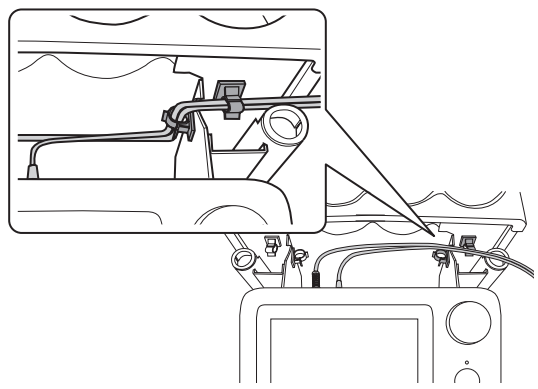
12. Insert the touch pen stand.



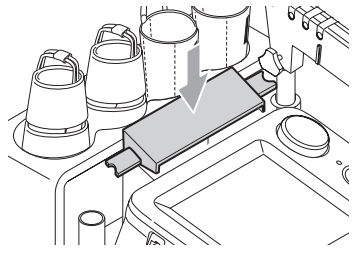
13. Reconnect the ECG clip and the PCG sensor connectors on the back of the main unit.



14. Secure the ECG clip and the PCG sensor cables in the cable notch and fasten the two cable fasteners.



15. Attach the cable cover.



5-5. Handling Errors

If an error occurs while the unit is on, an alarm sounds and an error message appears. If the error still occurs after you follow the instructions in the message, turn off the power and contact a dealer or an Omron Healthcare technical support representative.

Types of Audible Alarms

Audible alarm	Error level	Description
"Beep beep beep (pause) beep beep"	High	The alarm sounds repeatedly. A serious problem has occurred in the device, or an abnormality has occurred in the patient. Measurement cannot be performed in this state. You must check the error.
"Beep beep beep"	Medium	The alarm sounds repeatedly. A problem has occurred that makes measurement difficult. You must check the error.

5-6. Displaying System Information

You can view the device serial number, program version, system configuration, and other information.

Select [MAIN MENU] on the initial screen (ID entry screen) and select "System Information" from the main menu screen.

When you call a dealer or an Omron Healthcare technical support representative, you may be asked to provide this information.

1. Select [SYSTEM INFORMATION].

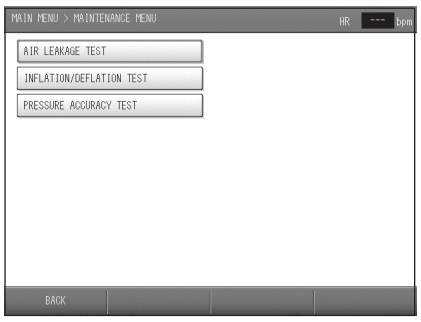
2. Select the item that you wish to view.

To print the system information, select [PRINT] at the bottom right of the screen.

The content that appears varies depending on the program version and the options that are installed.

5-7. Maintenance Menu

Use the maintenance menu when you perform maintenance and testing. When you contact customer service, you may be asked to perform one of the procedures below.
Select [MAIN MENU] on the initial screen (ID entry screen) and select "Maintenance menu" from the main menu screen to perform testing.



Item	Description
AIR LEAKAGE TEST	Perform this test to check for air leaks in the air system, including the cuffs.
INFLATION / DEFLATION TEST	Use this to check the speed of inflation and deflation of the air system.
PRESSURE ACCURACY TEST	Use this to test the accuracy of pressure detection.

5-8. Specifications

Specifications of BP-203RPEⅢ System (Main unit, TU-100 and Stand)

General:

Name:	Non-invasive Vascular Screening Device System
Model:	BP-203RPEⅢ System
Dimension (W x H x D):	400 x 1060 x 600 mm
Weight:	Approx. 35 kg (excluding printer)
Standards:	IEC60601-1-1 Medical electrical equipment-Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

Power supply:

Rating:	AC 220 - 240 V
Frequency:	50/60 Hz
Power consumption:	1200 VA max (including printer)

Multiple Portable Socket-outlets:

Type:	TDZ-4
Rated current and Voltage:	AC 250 V 16 A
Power outlet number:	4
Power switch type:	Illuminated rocker switch Green clear

Specifications of BP-203RPEⅢ (Main unit)

General:

Name:	Non-invasive Vascular Screening Device
Model:	BP-203RPEⅢ (HFA-RPE3-KOR)
Dimension (W x H x D):	310 x 110 x 270 mm (excluding protrusions)
Weight:	Approx. 4.1 kg
Display part:	
Method	8.4" TFT color LCD
Resolution	640 x 480 pixel
Safety standards:	IEC60601-1 Medical electrical equipment-Part 1: General requirements for safety
Protection class:	Class Ⅱ
Degree of protection:	
NIBP	Type BF with defibrillator protection
ECG	Type CF with defibrillator protection
PCG	Type BF with defibrillator protection
Mode of operation:	Continuous
Other standards:	IEC62304 Medical device software-software life cycle processes ISO14971 Medical devices-Application of risk management to medical devices

Environmental Conditions:

Power supply:	
Rating	AC 100 - 240 V
Frequency	50/60 Hz
Power consumption	150 VA
Fuses	Quantity 2, 250 V, T2AH (Time-lag, High Breaking Capacity (HBC))
Operational temperature/humidity/atmospheric pressure:	
Temperature range	+10 - +40°C
Humidity range	15 - 85% (no condensation)
Atmospheric pressure	700 - 1060 hPa
Storage and transportation temperature/humidity/atmospheric pressure:	
Temperature range	-20 - +60°C
Humidity range	10 - 95% (no condensation)
Atmospheric pressure	500 - 1060 hPa
Dust and water resistance:	Class IPX0 Reference: IEC60529: Degrees of protection provided by enclosures (IP Code)
EMC:	
Reference standard	IEC60601-1-2 Medical electrical equipment-Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Non-invasive Blood Pressure (NIBP):

Measurement method:	Oscillometric method
Measurement technology:	Linear deflation
Pressure display range:	0, 10 - 300 mmHg
Pressure display accuracy:	Less than ±3 mmHg
NIBP Measurement range:	
[Arm]	
SYS	60 - 250 mmHg
MAP	40 - 235 mmHg
DIA	40 - 220 mmHg
Pulse rate	40 - 180 bpm
[Ankle]	
SYS	40 - 250 mmHg
MAP	30 - 235 mmHg
DIA	25 - 220 mmHg
NIBP accuracy:	Mean error and standard deviation per ANSI/AAMI SP-10: Manual, electronic, or automated sphygmomanometers
Usable cuff size:	10 - 15 cm (width of bladder)
Numbers of cuff:	4 Right and Left Brachia, Right and Left Ankles
Reference standards:	IEC60601-2-30 Medical electrical equipment Part 2-30: Particular requirements for safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment

Pulse Wave Velocity (baPWV):

Brachial Ankle Pulse Wave Velocity (baPWV) is measured by the pulse transit time between the brachial pulse wave and the ankle pulse wave.
The distance between those points is calculated from the height of the patient.

ECG:

Lead selection:	I
Display sensitivity:	Variable (Automatic Gain Control 2 - 30 mm/mV) 10 mm/mV at Pacemaker: ON
Display sweep speed:	25 mm/s
Input impedance:	5 M ohm or more
Frequency characteristics:	
HPF	0.1 Hz
LPF	100 Hz
Ham filter	50 or 60 Hz (Automatic selecting filter)
Wave size selection	Automatic selectivity control
R wave detection sensitivity	200 µV or less
Tall T wave rejection	1.0 mV
HR display range	0, 30 - 240 bpm
HR measurements accuracy	±1% or ±1 beat
HR response time:	9 sec or less
HR averaging:	4 beats moving average at HR<120 8 beats moving average at 120 =<HR
HR updating rate:	Every beats
Pacemaker pulse rejection:	Amplitude ±2 - ±700 mV Pulse width 0.1 - 0.7 ms
Reference standards:	IEC60601-2-27 Medical electrical equipment-Part 2: Particular requirements for the safety of Electrocardiographic monitoring equipment

PCG:

Measurement method:	Electret Capacitance Microphone
Display sensitivity:	Variable (Automatic Gain Control)
Display sweep speed:	25 mm/s
Frequency characteristics:	
LPF	300 Hz
Wave size selection	Variable Automatic selectivity control

Specifications of TU-100

General:

Name:	Pulse Wave Unit
Model:	TU-100
Dimension (W x H x D):	294 x 145 x 55 mm
Weight:	Approx. 1.4 kg
Safety standards:	IEC60601-1 Medical electrical equipment-Part 1: General requirements for safety
Protection class:	Class Ⅱ
Degree of protection:	Type BF with defibrillator protection
Mode of operation:	Continuous

Environmental Conditions:

Power supply:	
Rating	AC 230 V
Frequency	50/60 Hz
Power consumption	14 VA
Fuses	250 V, T1AH (Time-lag, High Breaking Capacity (HBC))
Operational temperature/humidity/atmospheric pressure:	
Temperature range	+10 - +40°C
Humidity range	30 - 85% (no condensation)
Atmospheric pressure	700 - 1060 hPa
Storage and transportation temperature/humidity/atmospheric pressure:	
Temperature range	-5 - +50°C
Humidity range	10 - 95% (including condensation)
Atmospheric pressure	500 - 1060 hPa
Dust and water resistance:	Class IPX0 Reference: IEC529 (1989): Degrees of protection provided by enclosures (IP Code)
EMC:	
Reference standard	IEC60601-1-2 Medical electrical equipment Part1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Tonometry:

Measurement method:	Multi semiconductor strain gauge (2ch)
Frequency characteristic:	DC - 300 Hz
Signal output range:	0 - 5.0 V
Sensitivity:	Variable (Automatic Gain Control)

5-9. Guidance and Manufacturer's Declaration

⚠ Warning	Use only the specified supplies for the cord, cuff, and other parts. Do not install other than specified options. Otherwise and accident may result.

The BP-203RPEⅢ is intended for use in the electromagnetic environment specified below. The customer or the user of the BP-203RPEⅢ should assure that it is used in such an environment.

Electromagnetic emissions IEC60601-1-2		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The BP-203RPEⅢ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BP-203RPEⅢ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity IEC60601-1-2			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BP-203RPEⅢ requires continued operation during power mains interruptions, it is recommended that the BP-203RPEⅢ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150 kHz to 80 MHz 80%AM (2Hz) 3 V/m 80 MHz to 2.5 GHz 80%AM (2Hz)	3Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BP-203RPEⅢ, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BP-203RPEⅢ is used exceeds the applicable RF compliance level above, the BP-203RPEⅢ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BP-203RPEⅢ. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the BP-203RPEⅢ

The BP-203RPEⅢ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP-203RPEⅢ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP-203RPEⅢ as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.5GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Cables IEC 60601-1-2		
Cables and Sensors	**Maximum Length**	**Complies with**
AC power cord for Main Unit	0.8 m	- RF emissions, CISPR 11, ClassA / Group 1
AC power cord for Printer	1.1 m	- Harmonic emissions, IEC61000-3-2
LAN cable	10.0 m	- Voltage fluctuations/flicker emission, IEC61000-3-3
USB cable	1.2 m	- Electrostatic discharge (ESD), IEC61000-4-2
Arm Cuff Hose	2.4 m	- Electric fast transient/burst, IEC61000-4-4
Ankle Cuff Hose	0.5 m	- Surge, IEC61000-4-5
ECG lead cable	2.3 m	- Conducted RF, IEC61000-4-6
PCG cable	2.0 m	- Radiated RF, IEC61000-4-3
Sensor cable	3.0 m	
Table-tap	3.5 m	

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potential unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical device.

This medical device manufactured by OMRON Healthcare conforms to this IEC60601-1-2 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- Do not use mobile (cellular) telephones and other devices which generate strong electrical or electromagnetic fields, near the medical device.

This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Further documentation in accordance with IEC60601-1-2 is available at OMRON Healthcare at the address mentioned in this instruction manual.

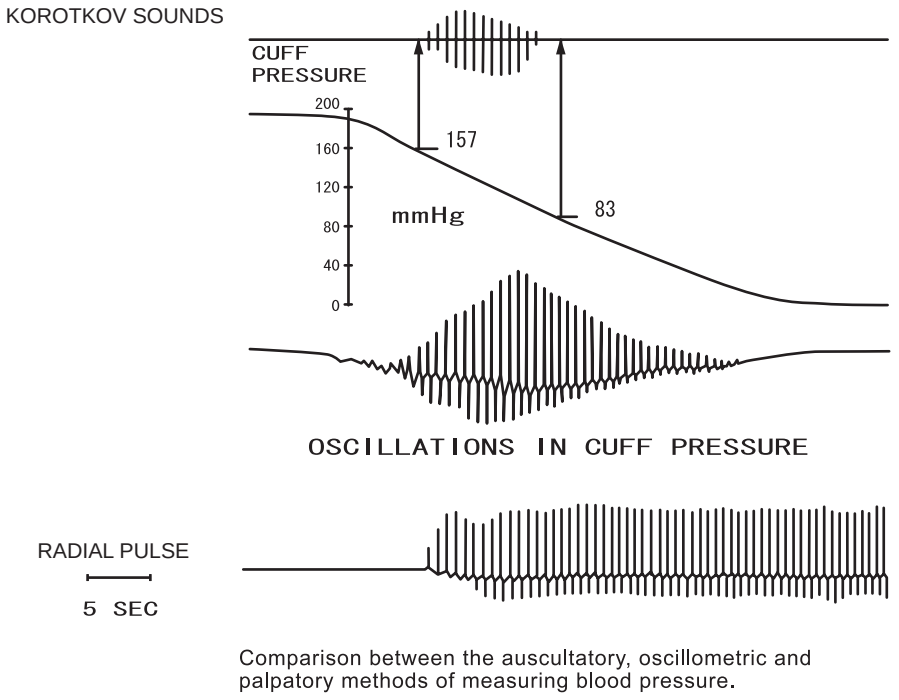
5-10. Explanation of Technical Terms

Oscillometric Measurement

The device uses the oscillometric method to measure blood pressure.

A cuff is wrapped onto the upper arm and inflated to constrict the blood vessels and temporarily stop the flow of blood. As the constriction is then gradually eased, the pressure of the blood becomes greater than the pressure of the cuff. At this point, the blood starts to flow intermittently due to the heartbeat.

At the stage of depressurization following pressurization of the cuff, the oscillometric method determines the blood pressure value by checking the variation in cuff pressure (pressure pulse wave) due to vibration of the blood vessel wall synchronized with the heartbeat. In general, the cuff pressure when the pressure pulse wave suddenly grows large is the "maximum blood pressure" and the cuff pressure when the pressure pulse wave suddenly becomes small is the "minimum blood pressure".



Comparison between the auscultatory, oscillometric and palpatory methods of measuring blood pressure.

L.A. Geddes,
" The Direct and Indirect Measurement of Blood Pressure ", Year Book Medical Publishers, Inc. 1970

In the above example, the maximum blood pressure is 157 mmHg and the minimum blood pressure is 83 mmHg.

ABI (Ankle / Brachial Pressure Index)

ABI is calculated by the equation below.

$$\text{ABI} = \frac{\text{Ankle systolic blood pressure}}{\text{Brachial systolic blood pressure (higher of left and right brachia)}}$$

The ABI can be used to diagnose arteriosclerosis obliterans and evaluate the health of the cardiovascular system in the entire body. ABI is mainly used to evaluate atherosclerosis (hardening of arteries due to an atheromatous plaque).

TBI (Toe Brachial Index)

The TBI is calculated as follows:

$$\text{TBI} = \frac{\text{Toe systolic pressure}}{\text{Brachial systolic pressure (higher of left and right brachia)}}$$

This index is an evaluation of the severity of constriction and blockage of lower limb peripheral arteries. It is mainly used to evaluate blockage of blood flow in peripheral arteries of patients with the following diseases or conditions.

- Diabetes
- Dialysis patients
- Burger's disease (TAO)
- Collagen disease

PWV (Pulse Wave Velocity)

Pulse wave velocity is the speed at which the pulse is transmitted from the heart to the end artery when blood is expelled during contraction. The harder the arteries, the faster the pulse travels. This is mainly used to evaluate hardness of the artery wall.

The PWV is calculated as follows:

$$\text{PWV} = \frac{\text{L (distance)}}{\text{PTT (Pulse Transit Time)}}$$

The wave velocity in the arteries can be measured at the following sites, allowing PWV values to be calculated for each. In general the device uses the "right brachial - ankle PWV (baPWV)" as the PWV.

- Ascending aorta - carotid artery hcPWV
- Ascending aorta - right brachial hbPWV
- Ascending aorta - femoral artery hfPWV
- Femoral artery - ankle PWV faPWV
- Right brachial - ankle baPWV
- Ascending aorta -ankle PWV haPWV

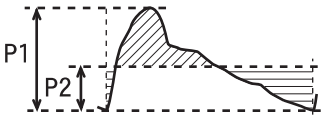
PVR (Pulse Volume Recording)

This is a record of the size of the pulse wave. The device measures this from the arm cuffs and ankle cuffs.

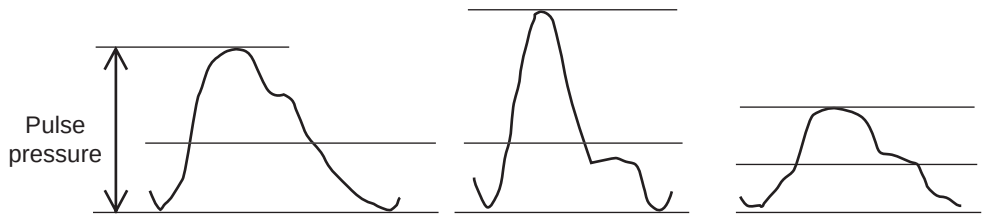
%MAP (%Mean Arterial Pressure)

This value is one of the pulse waveform indices that are calculated from the blood pressure values. It expresses as a percentage the mean value (P2) of the area of the PVR waveform divided by the amplitude of the pulse (P1). This value is calculated as follows:

$$\%MAP = \frac{P2}{P1} \times 100\ (\%)$$



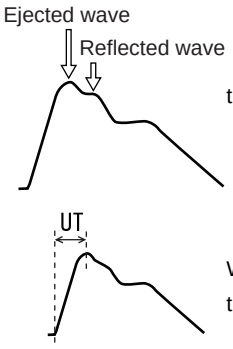
P1: Pulse wave amplitude
P2: Mean value of the area (the level at which ▨ and ▤ are equal)



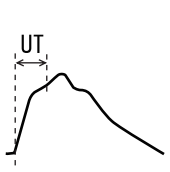
Soft (i.e. 45%) Hard (i.e. 38%) Constricted (i.e. 50%)

UT (Upstroke Time)

This is the time from the start of the pulse wave to its peak. However, for measurement in the carotid artery, this is the time from the start of the pulse wave to the peak of the ejected wave or the start point of the reflected wave.



In a pulse wave in a carotid artery,
the ejected wave and the reflected wave each form humps near the peak of the wave.



When the ejected wave is higher than the reflected wave,
the time until the peak of the ejected wave is the UT.

When the reflected wave is higher than the ejected wave,
the time until the start of the reflected wave is the UT.

ET (Ejection Time)

This index evaluates cardiac function based on the time from the opening to the closing of the aortic valve. The normal range is 285 ±25 msec, however, this is affected by the heart rate.

PEP (Pre-Ejection Period)

The time between electrical agitation in the heart chamber and the opening of the aortic valve. The normal range is 96 ±10 msec. The value becomes greater as cardiac function deteriorates.

ET/PEP (Ejection Index)

This index is calculated from the ET (Ejection Time) and PEP (Pre-Ejection Period). Correlations with left ventricular end-diastolic volume and pressure (LVEDV, LVEDP), ejection efficiency (EF), stroke volume (SV), and cardiac muscle contraction speed (VCF) can also be indicated.

This index can be expressed in the form ET/PEP or in the form PEP/ET.

Q-II (Overall control period)

The time from the start of the Q wave to the closing of the aortic valve (II sound) in an electrocardiogram.

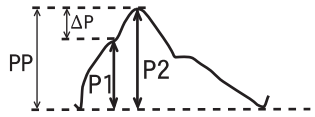
STI (Systolic Time Intervals)

ET and PEP are generally called STI and are used for quantitative evaluation of cardiac functions.

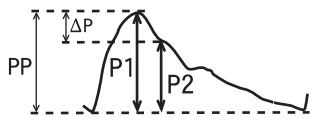
AI (Augmentation Index)

This indicates the percentage of the pressure wave effected in the carotid artery wave that is reflected to form the reflected wave. ΔP expresses the post-systolic component (P2) after subtraction of the maximum wave height (P1) of the presystolic component.

$$AI = \frac{\Delta P}{PP} \times 100\ (\%)$$



Example of increasing AI value as the wave height of the post-systolic component rises



Example of decreasing AI value as the wave height of the pre-systolic component rises

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5-11. Disposal

When disposing or recycling the device or its internal batteries, do so in accordance with local rules and regulations as there is a risk of environmental pollution.

Main materials

Component	Part	Material
Package	Box	Cardboard
	Packing material	Cardboard
	Bag	Polyethylene
Main Unit	Main unit	ABS resin, rubber
	Internal parts	Common electronic components*1, rubber
	Chassis	Iron, aluminum
	Cuffs	Cloth, vinyl chloride, PP resin
	Batteries on board	Lithium manganese dioxide battery*2
Stand	Chassis	Iron, aluminum, PP resin

*1 This device includes a fluorescent light that contains mercury. Dispose in accordance with local rules and regulations.
*2 This device includes a lithium battery. Dispose in accordance with local rules and regulations.

Manufacturer	**OMRON HEALTHCARE Co., Ltd.** 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto 615-0084 JAPAN
Production facility	**OMRON MATSUSAKA Co., Ltd.** 1855-370, Kubo-cho, Matsusaka-city, Mie-prefecture, 515-8503, Japan

5329329-2A

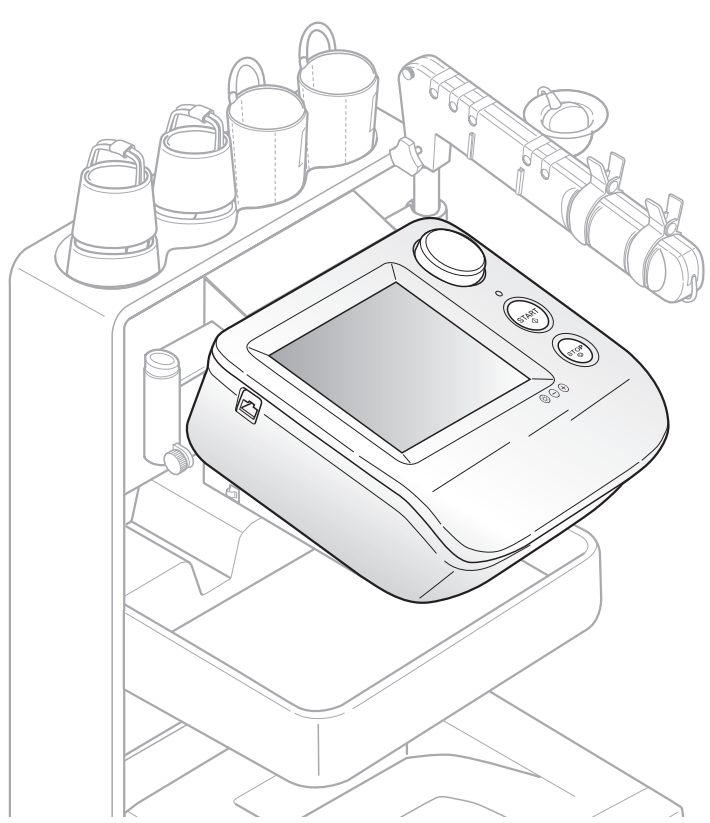
OMRON

Non-invasive Vascular Screening Device

BP-203RPEⅢ

VP-1000 plus

Instruction Manual



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Thank you for purchasing the OMRON BP-203RPEⅢ unit.

Read all of the instructions in the manual before you operate the unit and keep the manual near the unit at all times for future reference.

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1. Before Use

1-1. Exemptions

Disclaimer

Our company assumes no responsibility for the following:

1. Failures, damage, or injuries due to maintenance or repair work performed by other than our company or a company that we specify.
2. Failures or damage to one of our products caused by a product of another manufacturer not delivered by us.
3. Failures, damage, or injuries due to maintenance or repair work using a repair part other than a part that we specify.
4. Failures, damage, or injuries caused by failure to observe the safety instructions and operational procedures given in this manual.
5. Use of the product in conditions that do not conform to the product usage conditions indicated in this manual, including power, installation, and storage conditions.
6. Failures, damage, or injuries due to modification or inappropriate repair of the product.
7. Failures, damage, or injuries due to natural calamities such as fire, earthquake, flooding, or lightning.

Principles

1. The contents of this manual are subject to change without notice.
2. Considerable care has been taken in the preparation of this manual. In the unlikely event that an error or other problem is discovered in the manual, please contact us.
3. Unauthorized reproduction of all or part of this manual is prohibited. Use other than individual (corporate) use without the permission of our company is prohibited by copyright.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

1-2. Intended Use

Medical Purpose	This is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases.
Using Population	Legally certified medical experts, such as doctor, nurse and ME.
Patient Population	It is used on adult patients only.
Environment	The instrument is used in a vascular laboratory, clinic, hospital, doctor's office, and other medical facilities where the non-invasive peripheral vascular test is conducted.
Durable Period	5 years, provided that the appropriate maintenance has been done from production date. (Self-certification through OMRON HEALTHCARE's own data)
Measurement Parameter	■ Non-invasive Blood Pressure ■ Heart Rate ■ Pulse Wave ■ Heart Sound
Calculating Parameter	■ ABI (Ankle Brachial Index) ■ Pulse Wave Velocity ■ Augmentation Index ■ Systolic Time Interval ■ Upstroke Time
Precautions for use	Warnings and cautions described in the instruction manual should be observed.

1-3. Meaning of Symbols

	Start (of action)		Class Ⅱ equipment
	Stop (of action)		Stacking limit by number
	"ON" (Power)		Temperature limitation
	"OFF" (Power)		Catalogue number
	Caution (Refer to safety information)		Use by
	Do not reuse		Batch code
	Defibrillation-proof type BF applied part		Fragile; Handle with care
	Defibrillation-proof type CF applied part		Serial number
	CE mark		This way up
	Humidity limitation		Keep away from rain
	Atmospheric pressure limitation		

1-4. Safety Information

The warning signs and symbol examples indicated below are intended to ensure safe use of the product and prevent damage and injury to you and others. The signs and symbols are explained below.

Explanation of Symbols

⚠ **Warning**	Indicates a situation where incorrect handling may cause human death or serious injury.
⚠ **Caution**	Indicates a situation where incorrect handling may cause human injury or physical damage.*

* Physical damage means serious damage to your house and household goods, and serious injury to pets or other domestic animals.

● indicates "mandatory" (an action that must be observed).
The actual action that is mandatory is indicated inside or next to ● .
The icon at left indicates "disconnect the power plug".

⃠ indicates "forbidden" (an action that must not be taken).
The actual action that is forbidden is indicated inside or next to ⃠ .
The icon at left indicates that "disassembly is forbidden".

Note:
This indicates information that should be known when operating the device.

⚠Warning:

Safety rules when using the product

	Do not use a frayed or damaged power cord or plug. Otherwise electric shock, short circuiting, or fire may result.
	Do not touch the power plug with wet hands. Otherwise electric shock or injury may result.
	Be sure to plug the three-prong power plug into a grounded (three-prong) outlet for medical use (when a printer is included). Otherwise electric shock or current leakage may result.
	Use a dedicated outlet. Otherwise electric shock or current leakage may result.
	Do not poke or scratch the buttons or display with a sharp or pointed object. Incorrect diagnosis and treatment or an accident may result.
	Do not connect the power plug to the outlet if the electrical ratings are outside the specified range below: 220 - 240 VAC. This may cause fire.
	Do not touch the unit when discharging a defibrillator.

Safety rules when performing measurement

	This device is only to be used by qualified medical personnel, or under the guidance of such personnel. Otherwise incorrect diagnosis and treatment or device failure may result.
	The results of measurement should only be interpreted by a doctor. If you are concerned about a measurement result, consult your doctor. Otherwise incorrect diagnosis and treatment may result.
	This device is intended to perform measurement for examination. Do not use the device for patient monitoring. Otherwise an accident may result.
	If pressurization does not stop during measurement or another abnormal condition occurs, remove the cuff or air tube and disconnect the power. Otherwise peripheral nerve may be damaged.
	Use only the specified supplies for the cord, cuff, USB devices, and other parts. Do not install other than specified options. Otherwise an accident may result.
	Do not connect the air tube or cuff to any other device tubes attached to the body. Otherwise air may enter the blood vessels and an accident may result.

	Do not attach the arm cuff for patient during medical treatment with intravenous drip or blood transfusion. This may result incorrect diagnosis and treatment.
	Do not use this device on a patient that cannot express pain. If cuff pressurization does not stop in a specified time, internal hemorrhaging may occur in the upper arm or ankle.
	This device cannot be used during MRI imaging. This may cause an accident.
	Pay constant attention to patient's condition during measurement. Otherwise an accident may result.
	Do not perform measurement without cleaning and sterilizing the device, cuffs and sensors after measuring for patient with infection.
	Pay extra attention to a patient with pacemaker during measurement. Rate meters may continue to count the pacemaker rate during occurrence of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarm. Refer to the pacemaker pulse rejection capability in this manual.

Installation

	As this device conforms to the IEC60601-1-2 standard, it can be used in combination with another medical device. While or after an electrosurgical knife or a device which generates noise being used near this device however, make sure that it is properly functioning. Otherwise incorrect diagnosis and treatment or device failure may result.
	Do not use this device in the presence of a flammable gas such as a highly inflammable anesthetic, or in a high-pressure oxygen chamber or tent. Fire and explosion may result.
	Do not install or store the device in a location where water or chemicals may splash on the device. Electric shock may result.
	Do not connect any electric device, without the approval of IEC60601-1, or not fulfilling IEC60601-1-1. For the use of a PC or a printer with this device, the connecting device should be approved according to standards mentioned above. (This unit meets the restricted level of leakage current required for medical devices and it does not include all the connected devices. Connecting to other device is not allowed unless the total leakage current of such a combination is within the restricted level.) Neglecting this caution, it could cause electric shock to the device.

Maintenance

	After cleaning the device, dry it completely before turning on the power again. Otherwise electric shock or current leakage may result.

⚠Caution:

Safety rules when using the product

Observe the rules below when handling the power cord. Failure to observe these rules may result in electric shock or device failure.

- •Do not damage the cord
- •Do not break the cord
- •Do not modify the cord
- •Do not bend or pull on the cord with undue force
- •Do not twist the cord
- •Do not tightly coil the cord when in use
- •Do not place heavy objects on the cord
- •Do not let the cord become pinched

Insert the power plug all the way into the outlet. Otherwise electric shock, short circuiting, or fire may result.

Wipe dust off the power plug. Otherwise electric shock, short circuiting, or fire may result.

After using the device, turn the power switch to the "off" position and disconnect the power plug. Failure to do so may cause deterioration of the insulation and result in electric shock, current leakage, or fire.

When removing the power plug from the outlet, grasp and pull on the plug, not the cord. Pulling on the cord may break wires and cause a short circuit, resulting in electric shock or fire.

If a power failure occurs while using the device, turn the power switch to the "off" position and disconnect the power plug. Failure to do so may result in a product failure or other problem.

If the device becomes wet, wipe it completely dry with a soft cloth before use. Otherwise electric shock, short circuiting, or fire may result.

Do not pull the power cord when moving the stand. Electric shock, short circuiting or fire may result.

Do not replace the fuses on your own. Electric shock or fire might result.

- •The fuses are specifically designed for this device.
  Contact a dealer or an Omron Healthcare technical support representative for replacement of the fuses.
  - Fuse model: 5HT-R 2A (BEL FUSE LTD.)

Safety rules when performing measurement

If the patient has any of conditions below, do not perform measurement. Otherwise incorrect diagnosis and treatment may result.

- •The patient has an aneurysm
- •The patient has insufficient peripheral circulation, noticeably low blood pressure, or low body temperature.
- •The patient frequently has an irregular pulse.

	In the following situations, check by auscultation or palpation. Otherwise incorrect diagnosis and treatment may result. •When irregular pulse waves are indicated. External vibration or patient movement during measurement may cause an incorrect indication. •When an error occurs or when a measured value is questionable.
	If a power failure occurs during measurement, immediately remove the cuff. If the patient's ankle or upper arm is pressurized for a long time, internal hemorrhaging may result.
	Do not attach the cuff on the measurement site below: •Arm with intravenous drip •Upper limb in which a shunt is placed in for hemodialysis Incorrect diagnosis and treatment or an accident may result.
	If there is acute inflammation, a pyogenic ailment, or an external wound where the cuff is to be attached, follow the instructions of a doctor. Symptoms may become worse.
	When there is impossibility of test or doubts about the measurement values, please confirm the patient's condition first. The patient's condition may have deteriorated to the point where measurement limits are exceeded. Always verify that the cuff and cuff hose are appropriately used and are not bent or blocked. If the display continues to show 0, the monitor's pressure may be 0. But if the cuff hose is blocked or bent there may be air remaining in the cuff. At this time disconnect the hose from the cuff to ensure that blood flow is not restricted and no disorders occur to the peripheral nerves.
	When using the device in combination with another medical device, read the manual of the other device well and understand all warnings and cautions. Incorrect diagnosis and treatment may result.
	Do not use the device in a location with loud noise. Incorrect diagnosis and treatment may result.
	Attach the PCG sensor correctly. Incorrect diagnosis and treatment may result.
	Take care that the PCG sensor does not fall on the patient. This may cause injury.
	Wrap the cuff on bare skin or on a thin layer of clothing. Otherwise internal hemorrhaging may result.
	Make sure that the ECG clips are attached in the correct positions. Otherwise incorrect diagnosis and treatment may result.
	Do not use the device near a cellular phone. Incorrect diagnosis and treatment may result.
	Do not use in an MRI, CT, X-ray room, an operating room, or other rooms where radio noise is generated. Incorrect diagnosis and treatment or an accident may result.

Do not use a worn or expired ECG clip electrode or PCG sensor pad. Otherwise incorrect diagnosis and treatment may result.
(ECG clip electrode and PCG sensor pad have an expiry date. After the expiry date, the pad becomes dry and incapable of accurate measurement. Use only a pad or electrode whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

On a bedridden patient, check for lower-limb deep venous thrombus before taking a measurement. Otherwise an accident may result.

The ECG clip electrode and PCG sensor pad are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result.

The sensor box removal lever uses a strong spring mechanism. Take care not to injure yourself on the metal edges. Hold the sensor box firmly and press down hard on the lever from the exterior to remove the connector. This may cause injury with the metal edges.

Do not use an air hose of an arm cuff or an ankle cuff that is bent or collapsed. Incorrect diagnosis and treatment may result.

Connect the USB cable for the printer to the USB port marked with ⚠. Otherwise electric shock or current leakage may result.

Installation

Do not install in a location where the temperature or humidity is outside the allowed range. This may cause malfunctioning or device failure.

Do not use in a moving vehicle such as an ambulance. Incorrect measurement may result.
Incorrect diagnosis and treatment or an accident may result.

If you are not using the device stand, exercise sufficient caution when moving the device. The device is heavy and may slip out of your hands, causing injury.

Do not place objects on the device. This may cause injury.

Maintenance

Do not disassemble, repair or modify the device. This may cause electric shock.

Before cleaning or maintaining the device, disconnect the power plug. Otherwise electric shock or injury may result.

Do not touch the patient when changing the toner or feeding paper. Otherwise electric shock or current leakage may result.

Important:

Before use

- Make sure that all cords and tubes are firmly connected.
- Inspect dials and buttons and verify that the device operates correctly.
- Check printer toner, paper, and other supplies.
- Confirm the expiry date of the ECG clip electrodes and the PCG sensor pad. The expiry date can be calculated from the lot number as follows:

(Example)

Lot Number: 6 0 7 1 0 1 1

Production Date: 2006 July 10th

Expiry Date: 2008 July (2 years after the production date)

During use

- Do not pressurize when the cuff is not wrapped.
- Do not use a torn cuff.
- The device may be used on the patients below. If used on patients other than those described below, incorrect measurement may result or measurement may not be possible.
  - Height: 120 to 210 cm
  - Circumference of arm: 20 to 32 cm (using the standard cuff) / 16 to 38 cm (using the optional cuff)
  - Circumference of ankle: 16 to 33 cm
- Do not disconnect the USB or LAN cable while data is being transmitted. This may corrupt the data.
- Do not turn off the power during printing, data transmission, or writing.
- Do not pull out the paper before printing is finished.
- Make sure the date and time setting is correct. If the date and time setting is not correct, the date and time of measurement will not be recorded correctly.
- Do not connect an ECG clip to another conductive part including the ground.
- The electrical energy from a defibrillator may damage the device. During defibrillation, remove the sensors from the patient and do not touch the device.
- When moving or using the device, do not drop or subject the device to shock. This may cause the electric components and precision mechanisms to fail.

After use

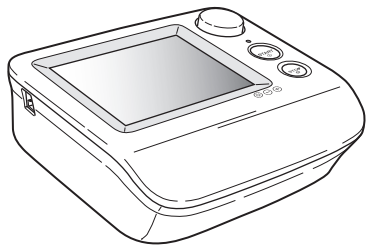
- Clean the device and accessories and arrange properly for storage.
- Do not wash or moisten the cuff.
- Do not use solvents such as thinner, benzene, or concentrated alcohol to clean the device.
- Do not use an autoclave, ultraviolet radiation, or gas disinfection (EOG, formaldehyde gas, concentrated ozone, etc.) to disinfect the device.
- If the power cord is damaged, it must not be replaced by user. Contact a dealer or an Omron Healthcare technical support representative.
- Do not install the unit in the following locations.
  - A location with prolonged exposure to direct sunlight
  - A location with dusty or salt air
  - On an inclined surface or a location subject to vibration, shock, or noise
  - A location where chemicals are stored or gas is emitted
- If the patient has one of the following conditions, a correct measurement may not be obtained.
  - The patient has body movements due to convulsions caused by rheumatism or otherwise
  - The patient has diabetic arteriosclerosis (blood pressure at leg joints tends to be high)
  - The patient has false high blood pressure
  - The patient has convulsions or tremors
- When the unit is incapable of ECG measurement, the message "Electrode removed" is displayed.

1-5. Product and Accessories

Before using this product, make sure that no accessories are missing and that neither the unit nor the accessories are damaged. Contact a dealer or an Omron Healthcare technical support representative if any accessory is missing or damaged.

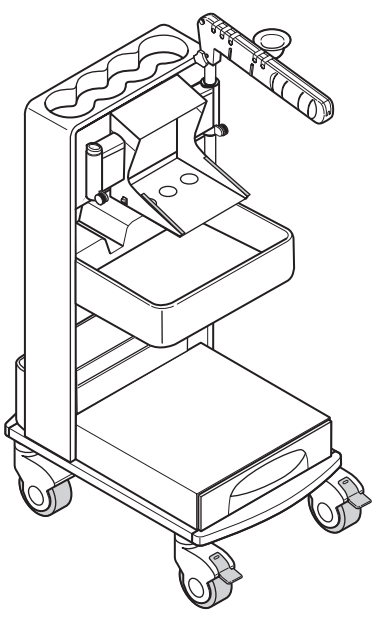
Main Unit

Non-invasive Vascular Screening Device
BP-203RPEⅢ



Standard Accessories

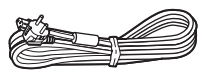
BP-203RPEⅢ stand



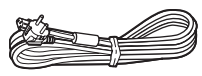
BP-203RPEⅢ stand cover

BP-203RPEⅢ hook-and-loop fastener for the sensor box

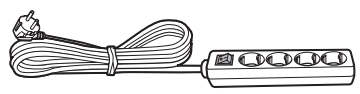
Power cord for main unit (0.8 m)



Power cord for printer (1.1 m)

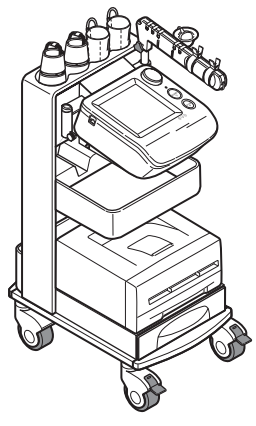


BP-203RPEⅢ power tap

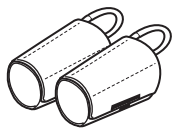


USB cable (for printer)

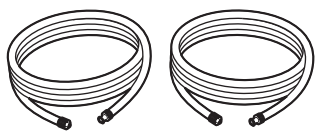
Items on this page will be assembled on delivery as follows:



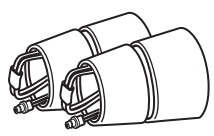
BP-203RPEⅢ arm cuffs, left and right pair (M size: For arm circumferences of 20 to 32 cm)



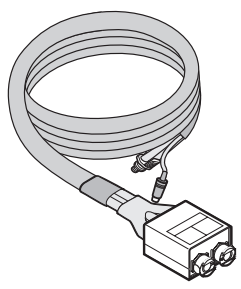
BP-203RPEⅢ arm cuff hoses, left and right pair



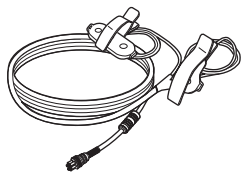
BP-203RPEⅢ ankle cuffs, left and right pair



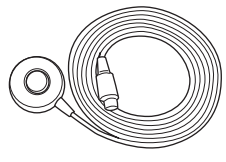
Sensor box



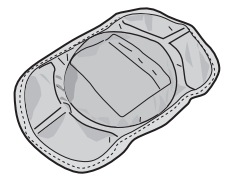
ECG clips



Phonocardiogram sensor (PCG sensor)



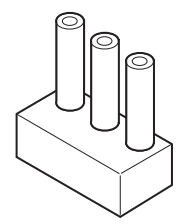
PCG weight



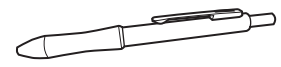
Sensor gel packet (consumable packet) 5 sets

- PCG sensor pad, 1 piece x 5
- ECG clip electrodes, 3 pieces x 5

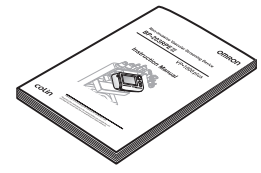
Blood vessel model



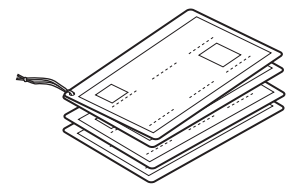
BP-203RPEⅢ touch pen



BP-203RPEⅢ instruction manual



Quick manuals



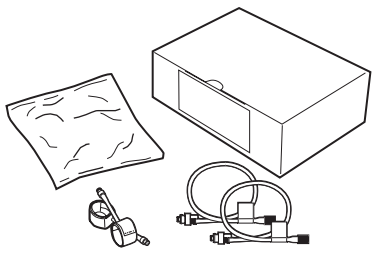
Accessories (Sold Separately)

Product description	REF	Model
Right arm cuff, S size	9999492-9	HEM-CS30-RIGHT
Right arm cuff, M size	9999490-2	HEM-CR30-RIGHT
Right arm cuff, L size	9999496-1	HEM-CL30-RIGHT
Left arm cuff, S size	9999494-5	HEM-CS30-LEFT
Left arm cuff, M size	9999491-0	HEM-CR30-LEFT
Left arm cuff, L size	9999498-8	HEM-CL30-LEFT
Arm cuff air tube (right)	9999505-4	HEM-CR30R-TUBE
Arm cuff air tube (left)	9999504-6	HEM-CR30L-TUBE
Ankle cuff (right)	9999500-3	HEM-CR31-RIGHT
Ankle cuff (left)	9999501-1	HEM-CR31-LEFT
ECG clips	9999503-8	HFA-RPE3-ECG
PCG sensor	9999507-0	HFA-RPE3-PCG
PCG weight	9999506-2	HFA-RPE3-W700
Sensor gel packet (20 sets)	9967933-0	HBP-FORM-101S
Blood vessel model	9999510-0	HFA-FORM-ARTVS
Touch pen	9996749-2	HBP-PEN
LAN cable (straight)	9997621-1	HFA-RPE3-LANS
LAN cable (cross)	9997622-0	HFA-RPE3-LANX
Toe standard disposable cuff	9957110-6	HBP-DCUFF-TBI31
Toe small disposable cuff	9957111-4	HBP-DCUFF-TBI32
Toe cuff tube (right)	9957112-2	HBP-FORM-TBICR
Toe cuff tube (left)	9957113-0	HBP-FORM-TBICL
Stand cover	9511950-0	HFA-RPE3-CVR
Hook-and-loop fastener for the sensor box	9511951-9	HFA-RPE3-SBF

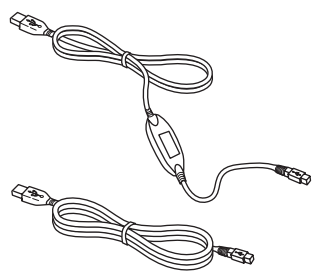
Options

Software and unit options can be purchased to expand the functionality of the product. For details on the uses and functions of the options, see Chapter 4.Refer to "4-1. Options" (page 121)

TBI package

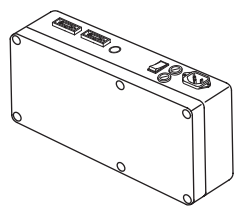


HMC package

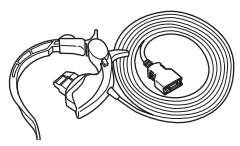


Pulse wave unit

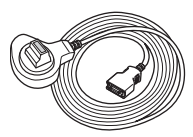
- Pulse wave unit TU-100



- CAP sensor unit

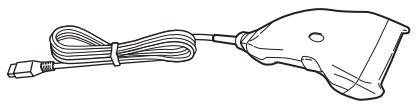


- FAP sensor unit



BP-203RPEⅢ bar code reader set

- Bar code reader
- Bar code reader holder



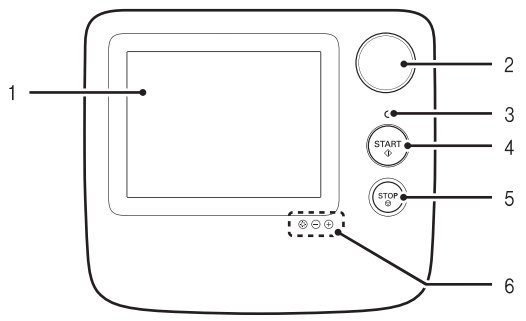
Product description	REF	Model
TBI package	9512233-1	HFA-TBI-ENG
HMC package	9512232-3	HFA-RPE3-HMCPE
Pulse wave unit TU-100 (230V)	9968295-1	HBP-FORM-TU230V
Attachment package for TU-100	9515540-0	HFA-TUATT-230V
CAP sensor unit	9512240-4	HFA-FORM-CAPE
FAP sensor unit	9512241-2	HFA-FORM-FAPE
Bar Code Reader Set	9996743-3	HBP-RPE3-BAR

1-6. Name and Function of Each Part

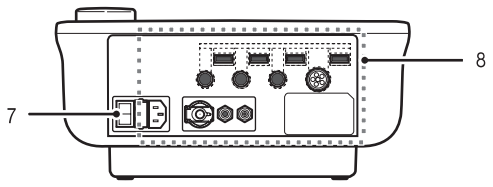
Main Unit

Enter patient information, configure settings, and perform measurement.

Front of unit



Back of unit



1. **LCD display (touch screen)**
   When configuring settings: Setting buttons appear. Touch the setting buttons with the touch pen to enter settings.
   During measurement: Measured values, measured waveforms, and operation buttons appear.

2. **Jog dial**
   Settings can be entered using the jog dial.
   Turn the jog dial right or left to select an item and press to enter.

3. **Display lamps**
   Off: Power is off
   Green (on): Power is on (normal mode)
   Orange (on): Power is on (sleep mode)

4. **[START] button**
   Press to begin measurement.

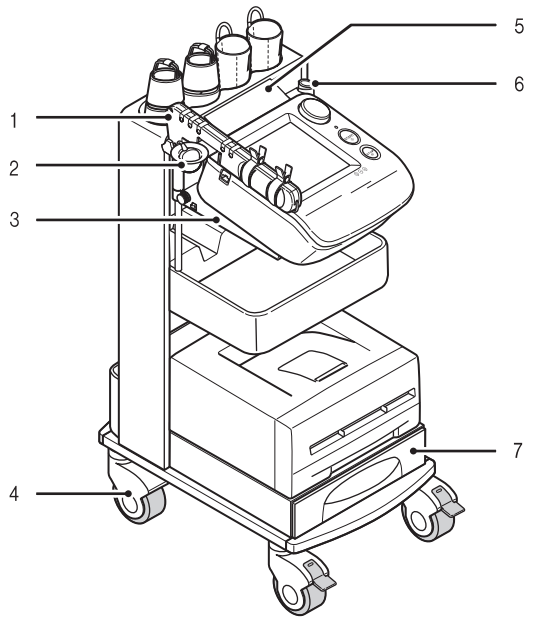
5. **[STOP] button**
   Press to interrupt and stop measurement.
   On the screen with [BACK], the [STOP] button can be also used to return to the previous screen.

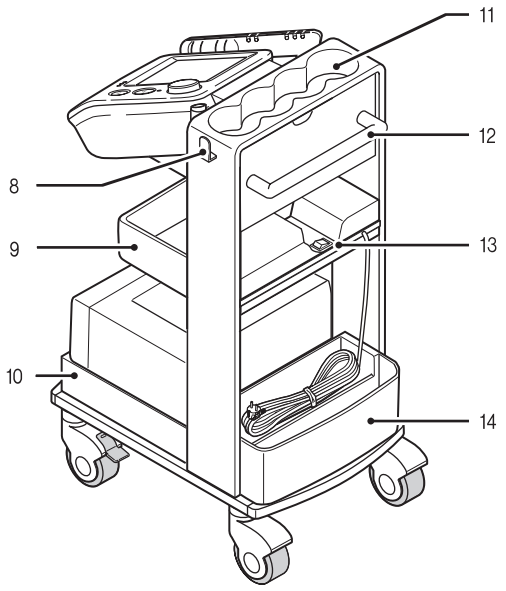
6. **Brightness button**
   ☼ : This enables the "-" and "+" brightness buttons.
   ⊖ : Dims the screen.
   ⊕ : Brightens the screen.

7. **Power on/off switch**
   Turns the power on and off. The power is normally turned on and off with the power switch on the stand, so keep the main unit power switched on.

8. **Connectors**
   For details on the connectors, see Chapter 5.
   Refer to "5-3. Connections" (page 127)

Stand





1. Arm
Place the sensors.

2. PCG sensor pocket
Store the PCG sensor.

3. Main unit holder
The main unit is placed on this holder.

4. Casters
During examination, lock the casters to keep the stand from moving. Unlock before moving the stand.

5. Cable cover
This prevents dust from collecting on the connectors on the back of the main unit.

6. Arm stand / touch pen stand
Attach the arm either on the left or the right. Then attach the touch pen holder on the other side. Refer to "5-4. Changing the Arm Position" (page 129).

7. Drawer
Store printing paper and other supplies in the drawer.

8. Cable hook
Hang the sensor box cable on this hook.

9. Tray
Store supplies on the tray.

10. Laser printer holder

11. Cuff storage pocket
Store arm and ankle cuffs in this pocket.

12. Handle
Hold this when moving the main unit.

13. Power on/off switch
This turns the power of the main unit, printer, and options on/off together.

(I) Power is on.
(O) Power is off.

14. Back pocket
Store manuals and the power cord (when moving the stand in this pocket.).

1-7. Installation/Moving

⚠ **Warning**	Do not install or store the device in a location where water or chemicals may splash on the device. Electric shock may result.
⚠ **Caution**	Do not install in a location where the temperature or humidity is outside the allowed range. This may cause malfunctioning or device failure.

Inspecting the Unit Before Use

For safe and proper use, inspect the device at the start of each day. When installing the device, be sure to follow the instructions on pages 7 to 12.

Before turning the power on

Main Unit

- Are the sensors that contact the patient clean?
- Are the cords arranged properly?
- Is the device kept dry?
- Is the device undamaged?
- Do the casters operate properly and are they free from debris?

Power Cord

- Is the cord placed where it cannot be stepped on and that nothing rests on it?
- Is it not frayed; no wires are exposed or broken?

Supplies

- Are ECG clip electrodes and PCG sensor pads ready?
- Is toner level adequate?
- Is enough paper loaded for daily use?

After turning the power on

Main Unit

- Is there no smoke or abnormal smell?
- Is there no abnormal noise?

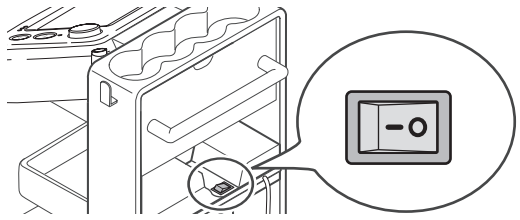
Check the date and time setting

- Are the date and time correct?
  If not, see page 93 to set the correct date and time.

Moving the Unit

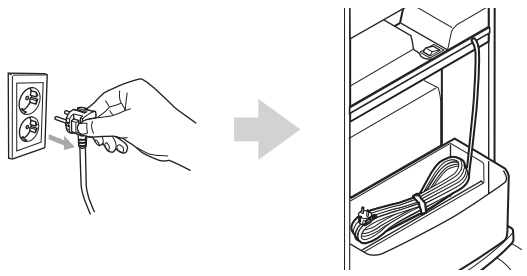
When you need to move the device, follow the procedure below.

1. Switch the power to off (O).

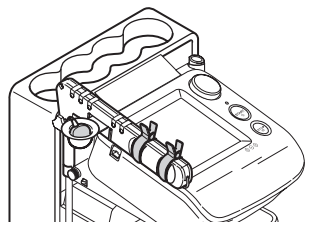


2. Remove the power plug from the outlet and coil the cord.

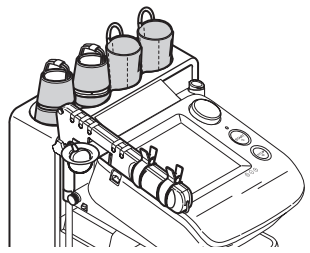
Do not pull on the cord.



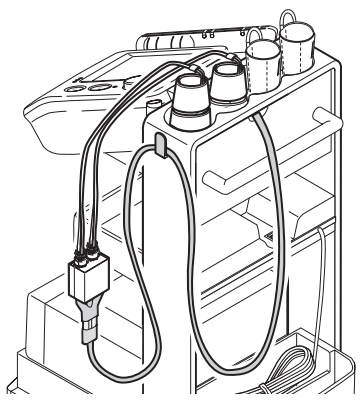
3. Place the sensors on the arm.



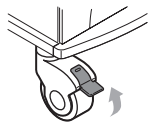
4. Store the cuffs in the cuff storage pocket.



5. Hang the sensor box cable on the cable hook.

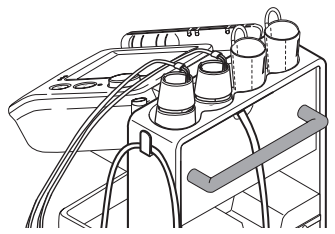


6. Unlock the casters.

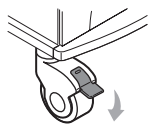


7. Grasp the handle and move the device.

Do not press on parts other than the handle.



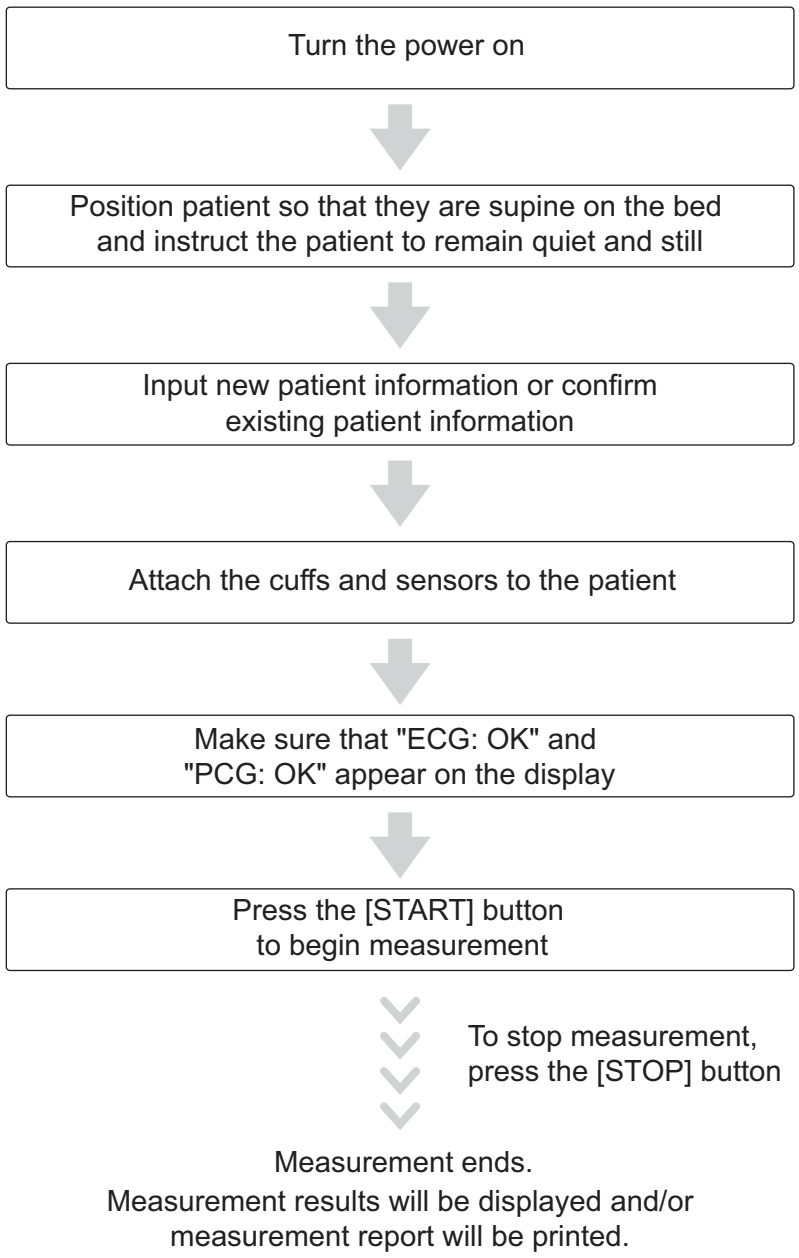
8. After moving the device, lock the casters to secure the stand.



2. Measurement Procedure

2-1. Preparing for Measurement

Measurement Procedure



Patient Information

Store patient information properly to maintain a measurement history. Input items marked "Required" must be entered.

Item name	Input	Page
ID	Required	**26**
Sex		**29**
Birth Date		**30**
Height		**31**
Name	Optional or Default setting	**28**
Weight		**31**
Waist		**32**
Disease		**32**
Order Number*		**33**
Measurement Sensors		**34**
Measurement Sites		**35**
Upper limit of inflation		**36**
Synchro measurement		**38**
Doctor		**38**
Technician		**39**
Category		**39**

*Order Number is required if SEARCH KEY is set to "EXAM ORDER NUMBER" in USER DEFAULT SETTINGS.
In this case, patient information must be stored in advance.

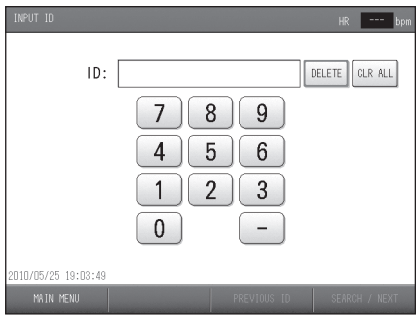
There are two methods for entering patient information.

A Enter the patient's information on the touch screen at the time of measurement.

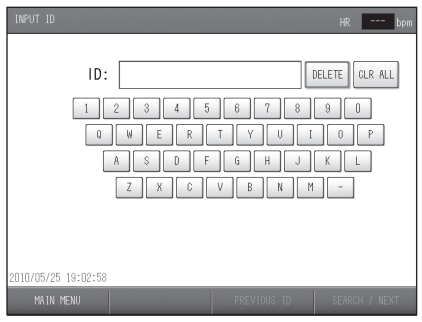
B Enter the patient's information in advance from "Advanced Registration of Patient Information". This is convenient for group examinations.
Refer to "3-8. Advanced Registration of Patient Information" (page 105).

Initial Screen (ID Entry Screen)

Following a brief interval after the power is turned on, the ID entry screen appears. This screen is called the "initial screen" in this manual. Enter the patient ID on this screen.
You can select whether the ID input type is all numbers, or both numbers and letters. It is recommended that you decide which type of ID will be used in advance.
Choose which type of ID to use by selecting "ID Input type" in advance.
Refer to "3-2. User Default Settings" "ID Input Type" (page 76).



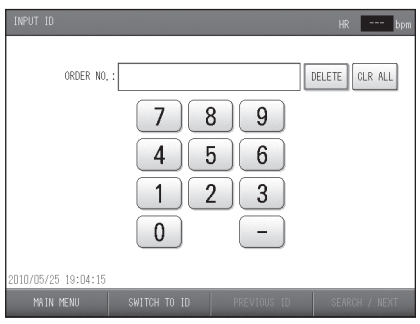
Initial screen (ID input type: numbers)



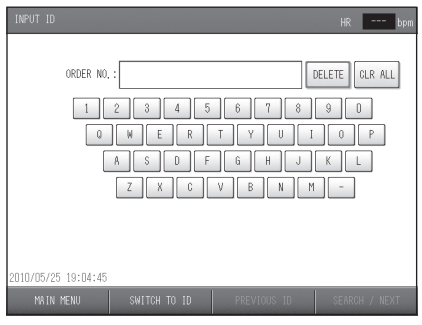
Initial screen (ID input type: numbers and characters)

If you manage patient information data with "Order Number" associated with order entry system, SEARCH KEY can be set to "EXAM ORDER NUMBER" in USER DEFAULT SETTINGS. In this case, patient information must be stored in advance.

Refer to "3-2. User Default Settings" "Search Key" (page 76).



Initial screen: order number entry screen
(Input type: numbers)



Initial screen: order number entry screen
(Input type: numbers and characters)

[MAIN MENU]: Select this to go to the main menu screen to configure basic settings (refer to page 74).

[SWITCH TO ID]: If you are measuring a patient that does not have an order number, you can change back to ID number entry.

Entering and Editing Patient Information

You can enter patient information and edit previously stored patient information.

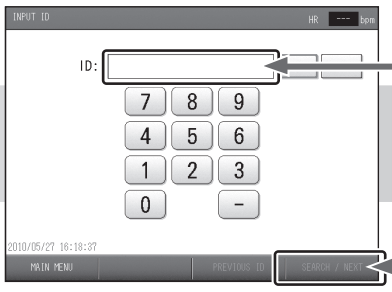
Notes:

- Do not assign multiple IDs to a single patient. Even if all other information such as the name is the same, the system treats the IDs as belonging to separate patients. In this case, measurements can be performed with the separate IDs as "separate patients"; however, you will not be able to make full use of the device functions for long-term storage of patient measurement histories and diagnosis support.
- The number of digits must be the same or the ID will be treated as two separate IDs. For example, "300" and "0300" are different IDs.
- You must enter the ID, SEX, BIRTH DATE, and HEIGHT to perform a measurement.
- When patient information is extracted with an ID or order number in the initial screen, the ID or order number cannot be modified.
- Take care to avoid mistakes when entering information and numerical values, as the examination results will be printed based on this information.
- If you return to the initial screen while entering patient information, the information is deleted. Select SAVE or SEARCH NEXT to save the information.

Entering the ID Number

Follow these steps to enter patient information with a new ID number or confirm patient information with an existing ID number.
You can enter up to 13 characters including hyphens.
To confirm patient information with an order number, you can enter up to 20 numeric characters including hyphens.

Patient information not registered

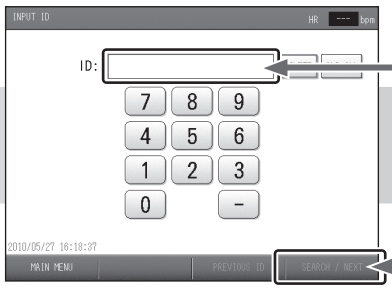


1 Enter a new ID number
2 Select [SEARCH / NEXT]

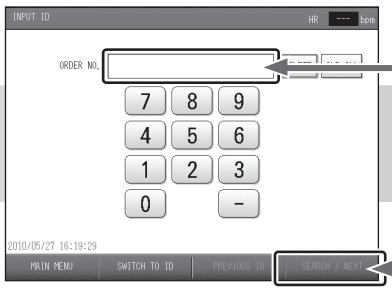
Register patie

[BACK] butto
[HMC DATA
Can be used
[NEXT] butto

Patient information already registered



1 Enter the ID number
2 Select [SEARCH / NEXT]



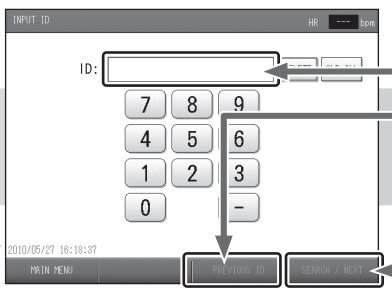
1 Enter the order number
2 Select [SEARCH / NEXT]

Confirm patie

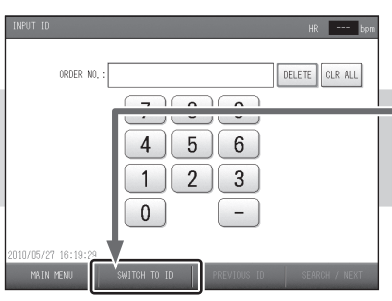
[BACK] butto
[HMC DATA
Can be used
[MEAS. HIST
[NEXT] butto

Re-measurement is necessary due to inadequate measurement results

Measurement just finished (patient information already registered)



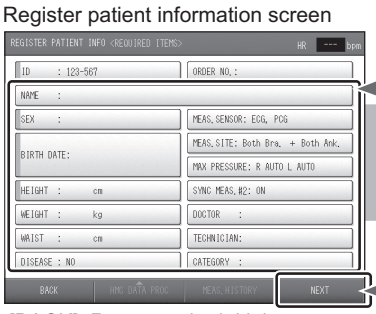
1 Select [PREVIOUS ID]
2 Check the ID number
3 Select [SEARCH / NEXT]



1 Select [SWITCH TO ID]
* Select [SWITCH to ID] to change to the ID entry screen

*The initial screen for "ID input type: numbers" is shown as an example. The key arrangement is different for "ID input type: numbers and characters".

Register patient information screen



To enter each item of patient information, see pages 28 to 39.

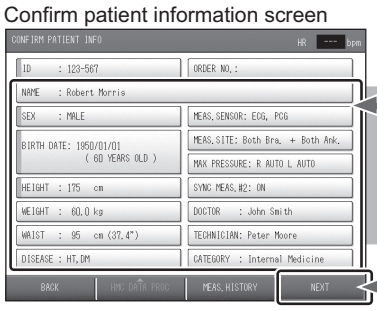
1 Enter patient information

2 Select [NEXT]

[BACK]: Return to the initial screen.
[HMC DATA PROC]:
Can be used when the optional HMC Package is connected.
[NEXT]: Proceed to the measurement screen.

Proceed to the measurement screen. Attach the cuffs and sensors to the patient and start measuring. Refer to page 41.

Confirm patient information screen



To enter each item of patient information, see pages 28 to 39.

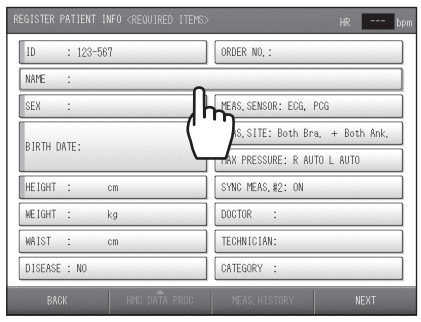
1 Check the patient information. Fill in empty items as needed.

2 Select [NEXT]

[BACK]: Return to the initial screen.
[HMC DATA PROC]:
Can be used when the optional HMC Package is connected.
[MEAS. HISTORY]: Show the patient's measurement history.
[NEXT]: Proceed to the measurement screen.

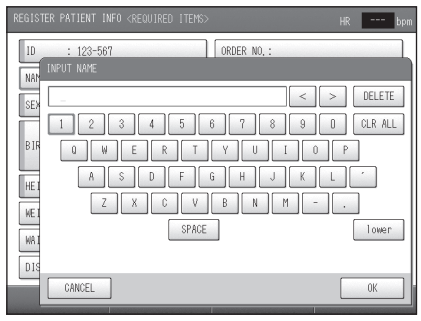
Entering the Name

1. Select [NAME].



2. Enter the name.

- Enter up to 40 characters.
- A space counts as one character.
- To enter a space, Select [SPACE].
- To switch between upper case and lower case, toggle between the [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters that have been entered, select [CLR ALL].



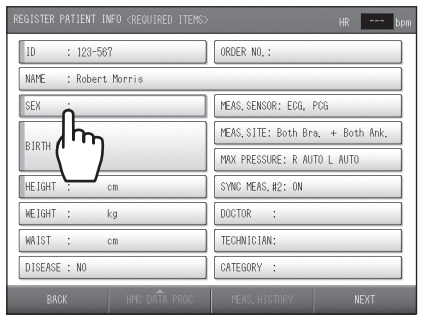
3. Select [OK].

To cancel your entry, select [CANCEL].

Entering the Sex

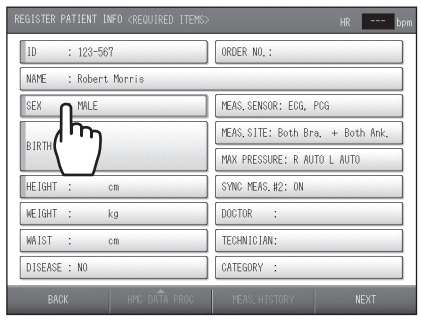
This item is required to perform measurement.

1. Select [SEX].



2. Select the sex.

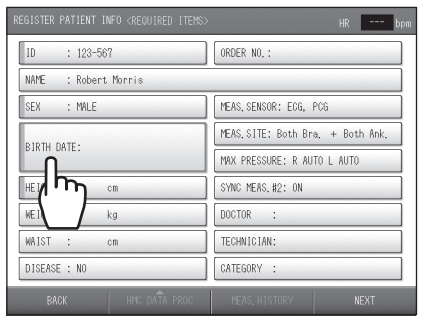
As you select the item, the value switches between MALE and FEMALE.



Entering the Date of Birth

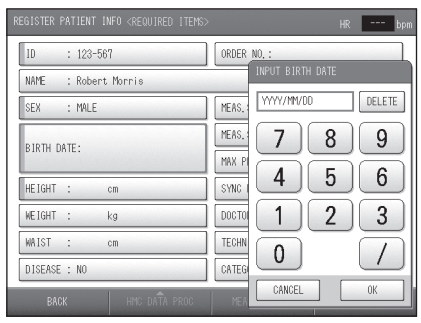
This item is required to perform measurement.
A date of birth must be one year of age or older when patient information is entered.
Measurement cannot be performed for infants less than one year of age.

1. Select [BIRTH DATE].



2. Enter the day, month, and year of birth.

Enter the date in the format "YYYY/MM/DD".



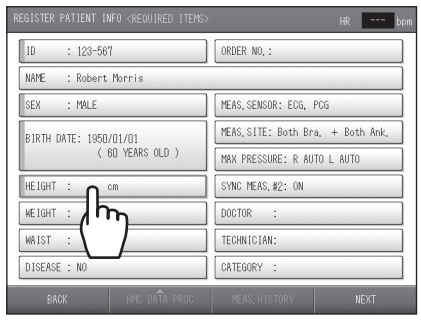
3. Select [OK].

To cancel your entry, select [CANCEL].

Entering the Height

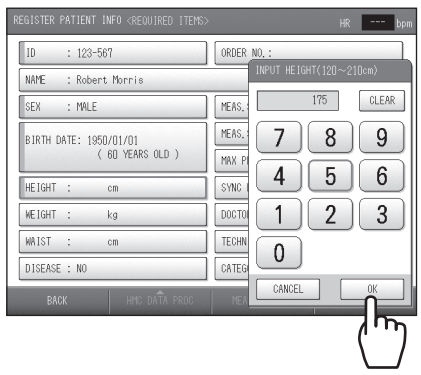
This item is required to perform measurement and to calculate PWV (Pulse Wave Velocity).

1. Select [HEIGHT].



2. Enter the height and Select [OK].

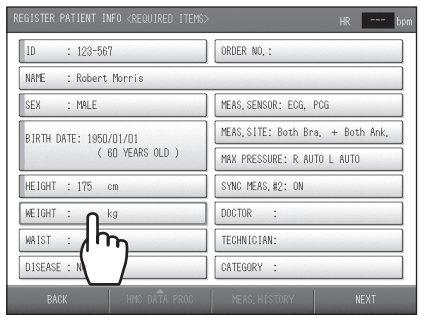
- The input range is 120 cm to 210 cm.
- To cancel your entry, select [CANCEL].



Entering the Weight

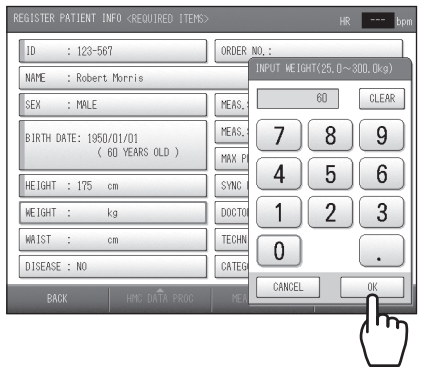
The weight is used in calculating the body mass index (BMI).

1. Select [WEIGHT].



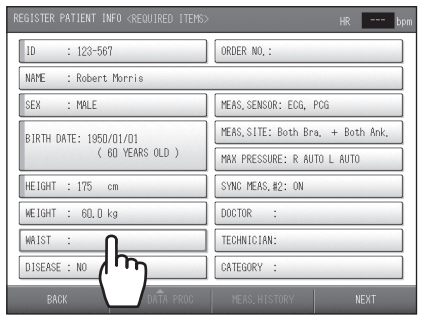
2. Enter the weight and select [OK].

- The input range is 25.0 kg to 300.0 kg.
- To cancel your entry, select [CANCEL].



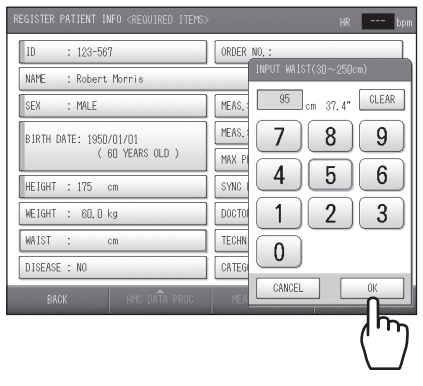
Entering the Waist

1. Select [WAIST].



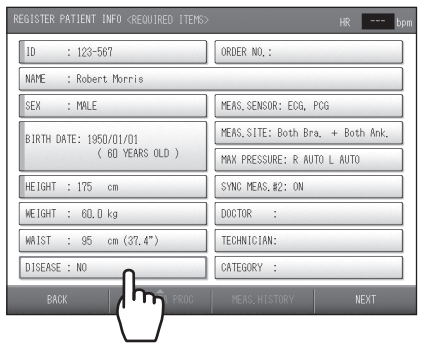
2. Enter the waist and select [OK].

- The input range is 30 cm to 250 cm.
- To cancel your entry, select [CANCEL].



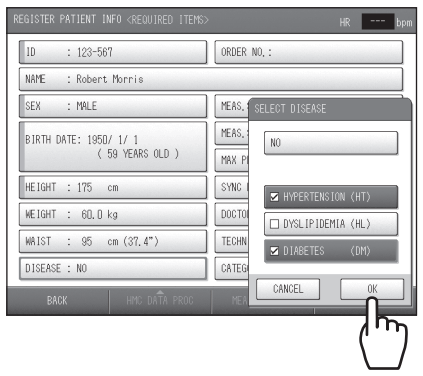
Selecting the Disease

1. Select [DISEASE].



2. Check the disease(s) and select [OK].

- Multiple items can be selected.
- If none is applicable, select [NO].
- To cancel your entry, select [CANCEL].

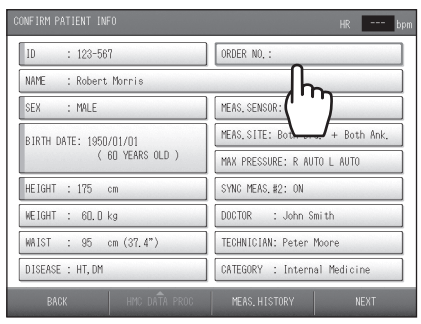


Entering the Order Number

You can enter the order number used in the order entry system associated with the medical records of the patient.

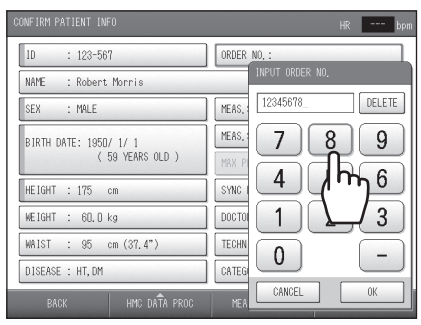
Note:
When patient information is extracted with an order number on the initial screen, the order number cannot be modified.

1. Select [ORDER NO.].



2. Enter the order number.

Enter up to 20 numeric characters including hyphens.

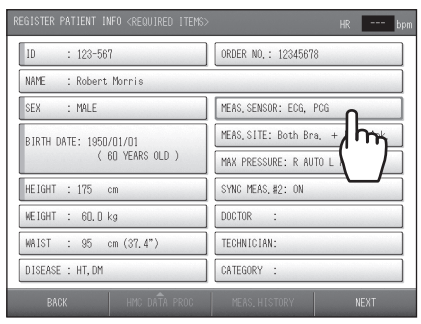


3. Select [OK].

To cancel your entry, select [CANCEL].

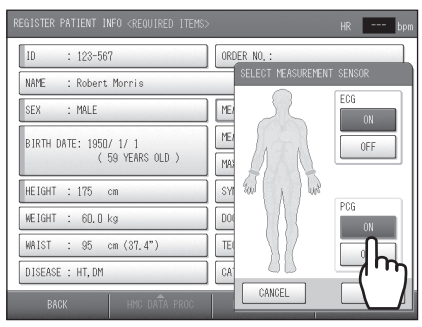
Setting the Measurement Sensors

1. Select [MEAS. SENSOR].



2. Specify settings for the ECG, PCG, CAP and FAP sensor.

- Sensor attached: [ON]
  Sensor not attached: [OFF]
- CAP and FAP only appear when the optional TU-100 pulse wave unit is connected.



3. Select [OK].

To cancel your entry, select [CANCEL].

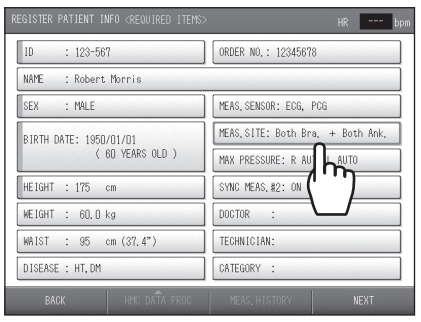
Notes:

- If the ECG clip is attached and the HR Synchronized tone is set to "ON", beep will sound even though ECG is set to "OFF".
- When the TU-100 pulse wave unit is connected, read the manual for the unit.

Setting the Measurement Sites

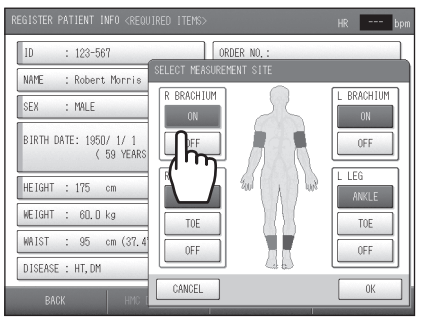
The cuffs are normally attached to both arms and both ankles.
If a shunt is placed on an upper arm for hemodialysis, do not attach a cuff to or perform measurement on that arm.

1. Select [MEAS. SITE].



2. Specify settings for the right arm and left arm.

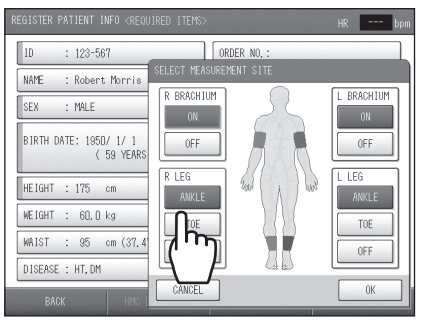
Cuff attached: [ON]
Cuff not attached: [OFF]



3. Specify settings for the right ankle/toe and left ankle/toe.

Ankle cuff attached: [ANKLE]
Toe cuff attached: [TOE]
Cuff not attached: [OFF]

- [TOE] can be selected only when the TBI package is installed.



4. Select [OK].

To cancel your entry, select [CANCEL].

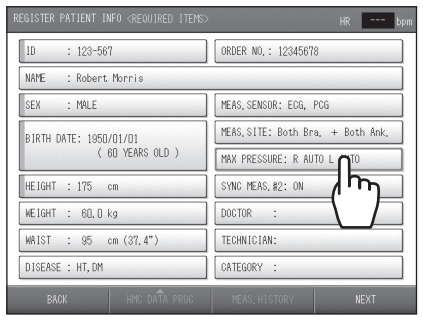
Notes:

- When the TBI package is installed, read the manual for the package.
- Either right arm or left arm needs to be "ON".
- Measurement cannot be performed with both ankle cuff and toe cuff attached.

Setting the Upper Limit of Inflation

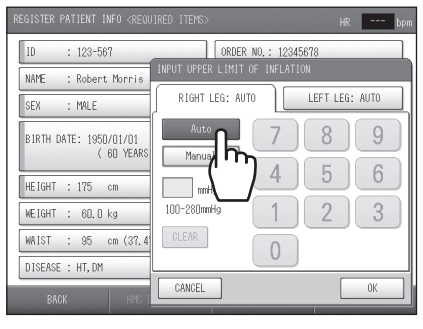
Specify the upper limit of inflation settings for the right ankle and left ankle.
Normally "Auto" is selected. When "Auto" is set, the system inflates the cuff and measures the patient's blood pressure automatically. If the patient complains of discomfort due to cuff inflation, change the setting to "Manual" and set an upper limit of inflation.

1. Select [MAX PRESSURE].



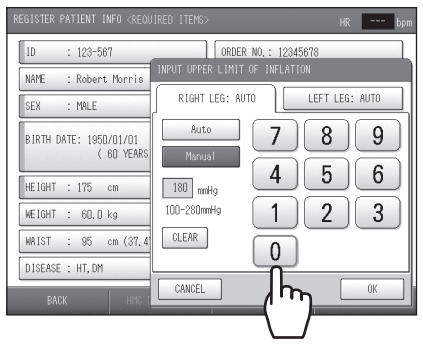
2. Select [Auto] or [Manual] for the right leg.

If you selected [Auto], skip step 3.

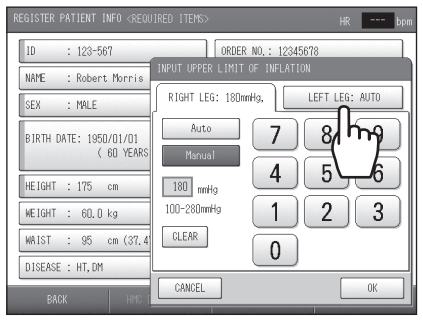


3. Set the upper limit of inflation.

The input range is 100 mmHg to 280 mmHg.



4. Repeat steps 2 and 3 for the left leg.

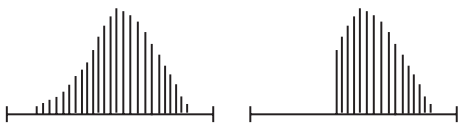


5. Select [OK].

To cancel your entry, select [CANCEL].

Notes:

- The optimum value for the inflation limit is generally "maximum blood pressure + 60 mmHg".
- If the inflation upper limit setting is not suitable, the measured values of the blood pressure may be low as shown below.
  Set the inflation upper limit while checking measurement accuracy on a pulsation variation graph.



Good accuracy

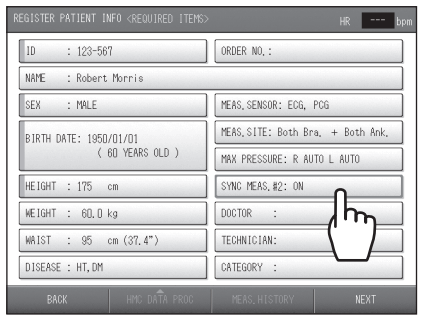
Poor accuracy when pressurizing is not sufficient

Synchro Measurement Setting

In synchro measurement, blood pressure is measured twice. In the second measurement, the measurement timing is automatically adjusted based on the blood pressure value of the first measurement and all four limbs are measured simultaneously.

1. Select [SYNC MEAS. #2].

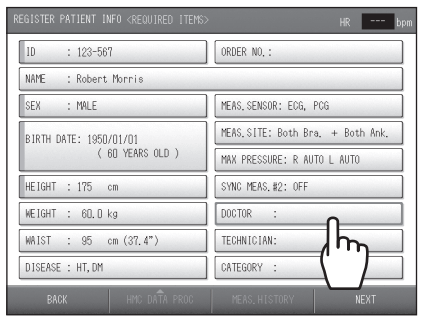
"ON" or "OFF" is already selected. If the setting does not need to be changed, go to the next item.
As you select the item, the value switches between "ON" and "OFF".



Selecting the Doctor

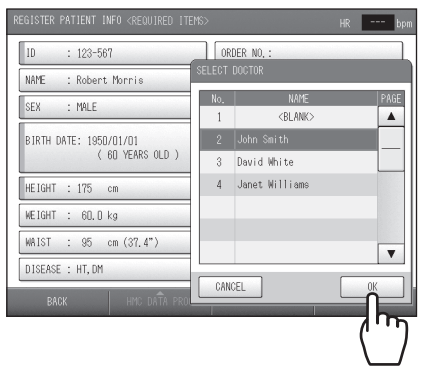
Select the doctor from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more information.

1. Select [DOCTOR].



2. Select the doctor and select [OK].

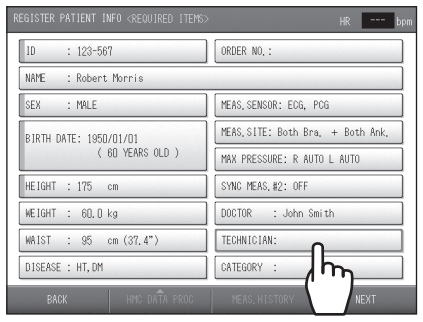
- If a doctor name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].



Selecting the Technician

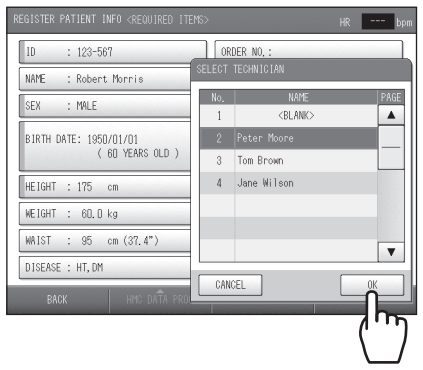
Select the technician from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more information.

1. Select [TECHNICIAN].



2. Select the technician and select [OK].

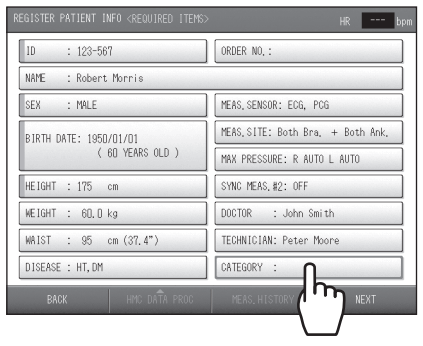
- If an technician name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].



Selecting the Category

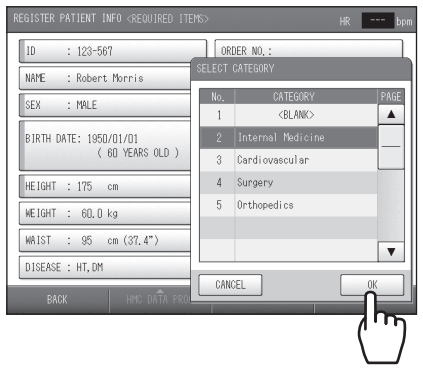
Select the medical department for the patient from the list. The list must be stored in advance.
Refer to "3-4. Facility name / Doctor / Technician / Category Settings" (page 86) for more detail.

1. Select [CATEGORY].



2. Select the category and select [OK].

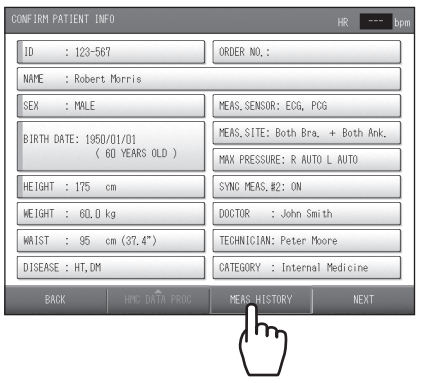
- If a category name is not necessary, select <BLANK>.
- To cancel your entry, select [CANCEL].



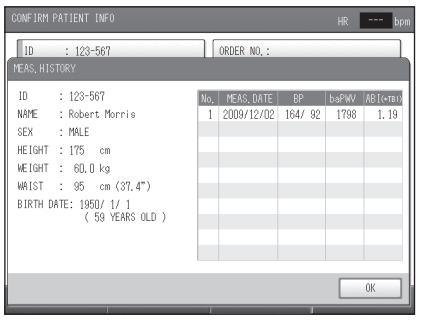
Displaying the Measurement History

A history of the patient's past measurement data can be displayed from the CONFIRM PATIENT INFO screen.

1. Select [MEAS. HISTORY].



2. View the measurement history in the measurement history screen.



The value shown in baPWV is the higher of the left and right values, and the value shown in ABI is the lower of the left and right values.

3. Select [OK].

You return to the patient information screen.

Notes:

- TBI values are marked with * .
- The TBI package is required for TBI measurement. When the TBI package is installed, read the manual for the package.

Attaching the Cuffs and Sensors

⚠ **Caution**	•Make sure that a cuff or an air hose is not bent or collapsed. If the cuff does not deflate, it may damage peripheral nerves caused by blood circulation disorder. •Use a suitable cuff size to avoid inaccurate measurement results. If the cuff is too large or too small, blood pressure measures lower or higher than the actual value. Make sure that the cuff is not too loose or too tight before measurement. •Make sure that air does not leak from the cuff. Otherwise, it may cause inaccurate measurement results.

For the conditions required for measurement, precautions during measurement, and conditions where examination is not possible, see "Safety rules when performing measurement" (pages 7, 9, and 12).

Attaching an Arm Cuff

Notes:
- If you will be measuring using a single arm only, set the arm that is not used to "OFF" in SELECT MEASUREMENT SITE when you enter the patient information. (Refer to page 35)
- Keep the arm with the cuff attached at the level of the heart.
- The cuffs for the right and left arms are different. Do not attach the wrong cuff.
- Use a cuff size that is appropriate for the patient.

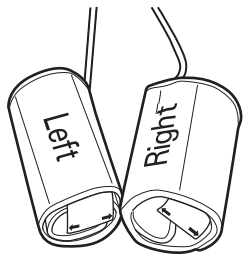
If necessary, wipe the patient's arm with diluted antiseptic alcohol or a similar product.

1. Select a cuff appropriate for the patient

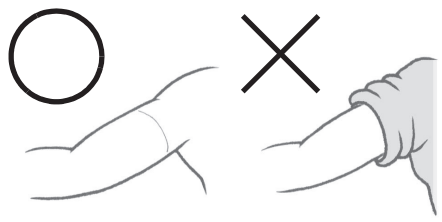
- Size M: Standard Accessory
  Circumference of upper arm: 20 to 32 cm
- Size L: Option
  Circumference of upper arm: 30 to 38 cm
- Size S: Option
  Circumference of upper arm: 16 to 25 cm

2. Make sure that the right cuff and the left one are attached on the correct arms.

- Right arm: orange
- Left arm: dark blue

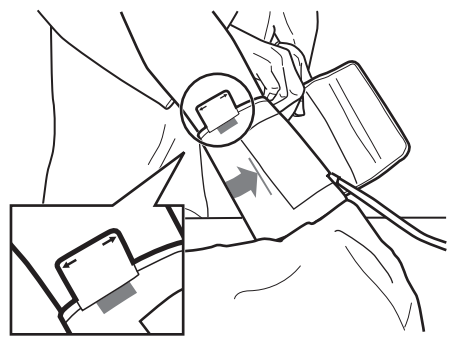


3. Have the patient lie down face up. Expose the patient's upper arm so that it is bare or over a thin sleeve.



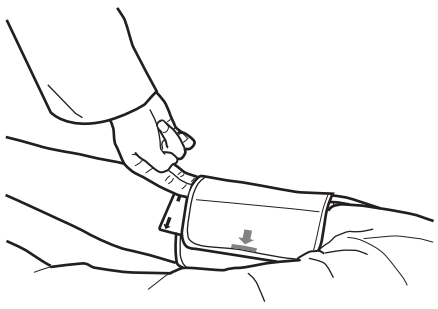
If the cuff is wrapped over a sleeve, straighten it as shown in the image. Otherwise, blood pressure may measure higher than the actual value.

4. Position the arrows on the creases.



5. Wrap the cuff.

Make sure that it is wrapped loosely enough so that two fingers can be inserted between the cuff and the arm.

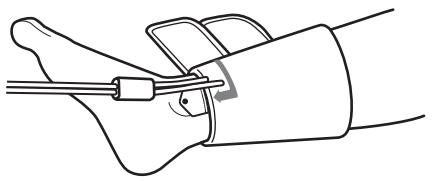


Attaching an Ankle Cuff

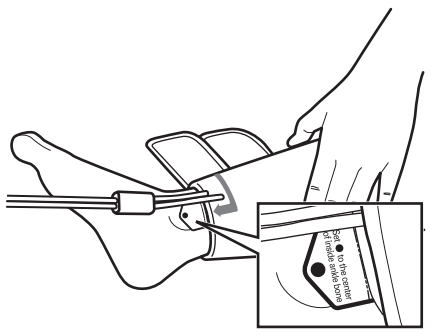
Notes:
- If you will be measuring using a single ankle only, set the ankle that is not used to "OFF" in SELECT MEASUREMENT SITE when you enter patient information. (Refer to page 35)
- Keep the foot with the cuff attached at the level of the heart.
- The cuffs for the right and left ankles are different. Do not attach the wrong cuff.

When necessary, wipe the patient's ankle with diluted antiseptic alcohol or a similar product.

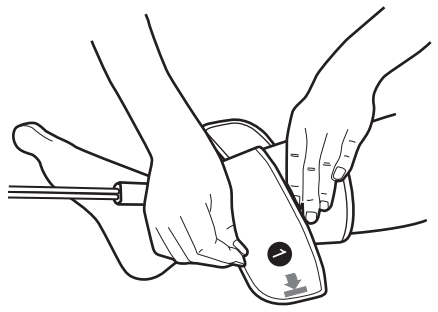
1. Align the tag on the ankle cuff with the top edge of the inside ankle bone.



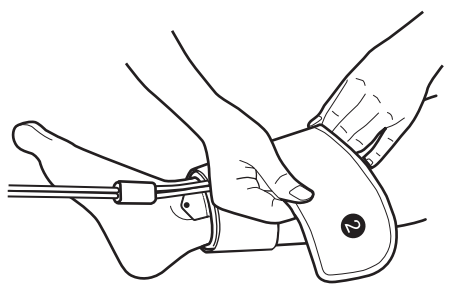
2. Position the ● mark on the tag at the center of the inside ankle bone.



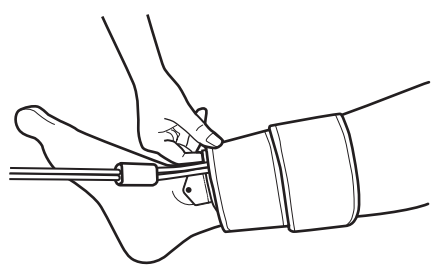
3. Wrap the ankle side ❶ of the cuff first.



4. Then, wrap the calf side ❷.



5. Tighten the cuff so that one finger can be just barely inserted under the cuff.



Attaching the ECG clips

⚠ **Caution**	•ECG clip electrodes are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result. •Do not use a worn or expired ECG clip electrode. Otherwise incorrect diagnosis and treatment may result. (ECG clip electrode have an expiry date. After the expiry date, the electrode becomes dry and incapable of accurate measurement. Use only an electrode whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

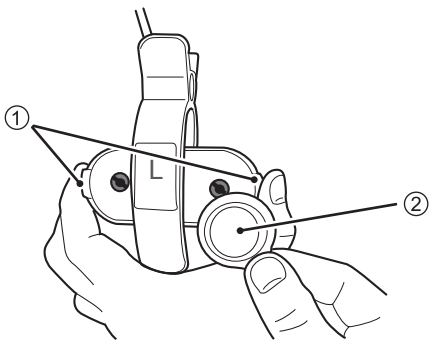
Notes:

- The ECG clip for the right arm and the one for the left arm are different. Do not use the wrong clip.
- As a basic rule, the ECG clips are to be attached to both wrists of the patient. If the ECG signal is weak and measurement is difficult on the patient's wrists, attach the clip for the left wrist to the instep of the left foot (secondary induction).
- If the patient uses a pacemaker, the R wave may not be correctly detected and measurement will not be possible.
- If regular pulse waves cannot be detected due to arrhythmia, accurate measurement will not be possible.

When necessary, wipe the application site with diluted antiseptic alcohol or a similar product.

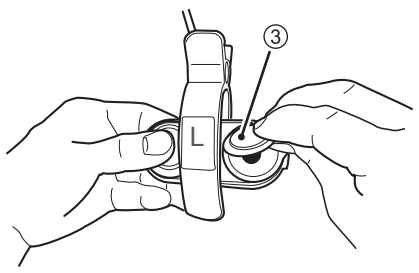
1. Prepare three ECG clip electrodes (disposable).

2. While squeezing the side buttons ① of the ECG clip for the left wrist, attach two ECG clip electrodes ② in the holes.



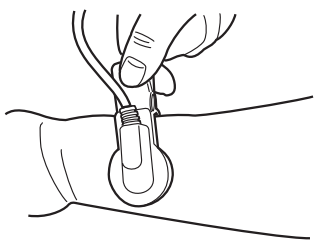
3. Attach one ECG clip electrode on the ECG clip for the right wrist in the same way.

4. Remove all protective sheets ③ from the ECG clip electrodes.



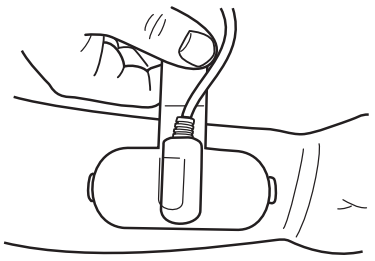
5. Attach the ECG clip on the right wrist.

Make sure that the electrode is on the inner side of the wrist.



6. Attach the other ECG clip for the left wrist.

- Make sure that the electrode is on the inner side of the wrist.
- Confirm that both electrodes are in full contact with the wrist.



Attaching the PCG sensor

⚠ **Caution**	•PCG sensor pads are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result. •Take care that the PCG sensor does not fall on the patient. This may cause injury. •Do not use a worn or expired PCG sensor pad. Otherwise incorrect diagnosis and treatment may result. (PCG sensor pad have an expiry date. After the expiry date, the pad becomes dry and incapable of accurate measurement. Use only a pad whose indicated expiry date has not passed. Refer to page 12 for how to confirm the expiry date.)

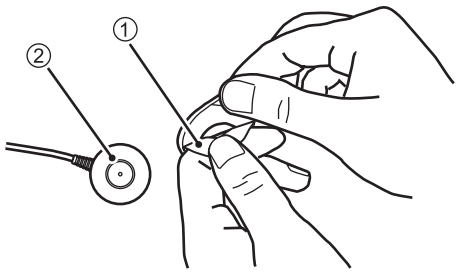
Notes:

- If a patient has heart murmur or abnormal sounds, the second heart sound cannot be properly detected and measurement is not possible.
- If a patient generates noise while breathing, the second heart sound cannot be properly detected and measurement is not possible.

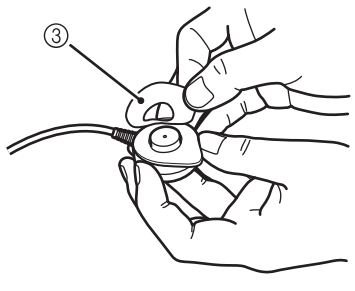
When necessary, wipe the application site with diluted antiseptic alcohol or a similar product.

1. Prepare one PCG sensor pad (disposable).

2. Remove the light blue sheet ① from the PCG sensor pad, and attach the pad on the PCG sensor ②.

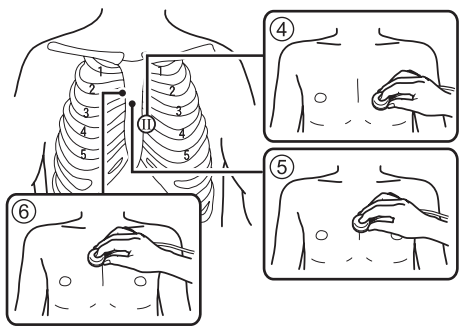


3. Remove the clear protective sheet from the PCG sensor pad ③.



4. Attach the PCG sensor.

- Normally the PCG sensor is placed at the left edge of the sternum in the fourth intercostal space ④. If the second heart sound is not clear, place the sensor in the middle of the third intercostal space ⑤, or near the right edge of the sternum in the second intercostal space ⑥.
- Adjust the position where the 2nd sound is clearly detected while confirming that "PCG: OK" is displayed.



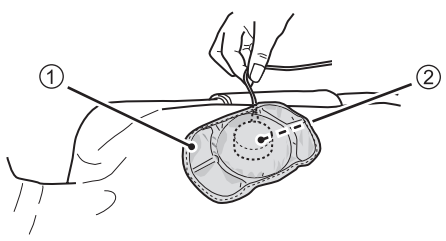
■ Using the PCG Sensor Weight

Use the PCG sensor weight if "PCG:OK" does not show on the display, due to the following:

- Thick fat or muscle that attenuates the heart sound.
- Body hair prevents the PCG sensor from full contact to the skin.
- The contour of the body surface does not allow the PCG sensor to fully contact to the skin.
- The PCG sensor is tilted on the body and it is not firmly attached to the skin.

1. Place the PCG sensor weight ① on top of the PCG sensor ②.

The PCG sensor weight can be placed over the clothes.



2. Make sure that "PCG: OK" is displayed.

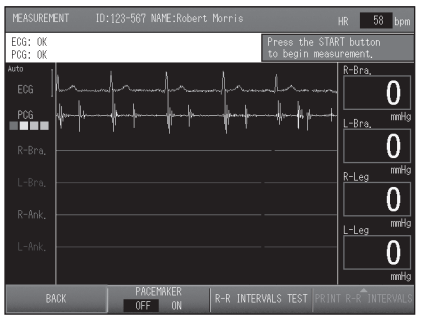
Notes:

- Do not use the weight if it has a hole or tear on it.
- If the filling leaks out of the weight, immediately dispose it.
- Be careful not to damage the surface of the weight with a ballpoint pen or other pointed object.
- If sweat or water gets on the weight, wipe it off immediately.
- Do not wash it.

2-2. Basic Measurement

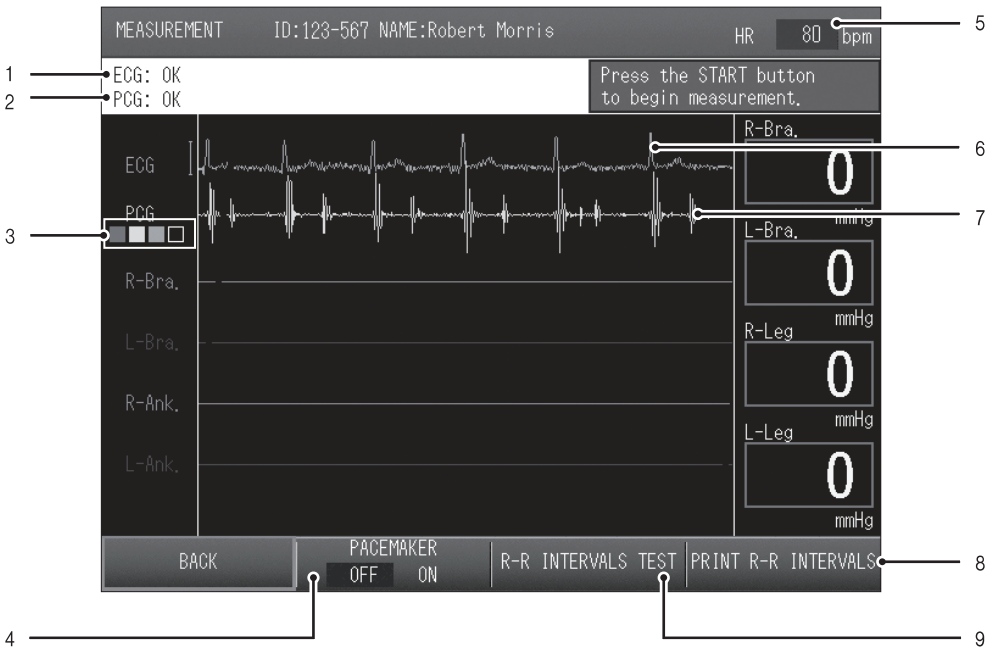
Viewing the Measurement Screen

You can begin a measurement after entering patient information and attaching the cuffs and sensors to the patient.
Select [NEXT] on the new patient information registration screen or the patient information review screen to change to the measurement screen.



Note:
If ECG or PCG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered (refer to page 34), ECG/PCG messages, ECG waveform, PCG level or PCG waveform will not be displayed.

Contents of the Measurement Screen



1	ECG Message	Displays the ECG status (refer to page 49).
2	PCG Message	Displays the PCG status (refer to page 50).
3	PCG level	Shows the detected PCG level using a four-level meter. Level 3 or 4 is recommended to obtain accurate measurement results. With level 1 or 2, accurate results may not be achieved. Adjust the position of the PCG sensor or use the PCG sensor weight (refer to page 46).
4	[PACEMAKER] option	If the patient has a pacemaker implanted, select "ON". The pacemaker setting reverts to "OFF" at the end of measurement. Select "ON" each time you perform a measurement.
5	Heart Rate	Displays the patient's heart rate.
6	ECG wave	Displays ECG waveform. The ECG display gain is normally set by auto-gain. However, when the pacemaker setting is "ON", the gain is fixed at 10 mm/mV.
7	PCG wave	Displays the PCG waveform.
8	[PRINT R-R INTERVALS] option	This prints the R-R interval exam report.
9	[R-R INTERVALS TEST] option	Use this to measure fluctuations in the interval between heartbeats in order to check the autonomic function of the cardiovascular system (refer to page 65).

ECG Messages

Note:
If ECG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered (refer to page 34), ECG messages and the ECG waveform will not be displayed.

The ECG messages are explained below. When "OK" is not displayed, accurate measurement results may not be obtained. Follow the correspondent solutions to the messages in the chart below.

Messages	Status	Notes / Solutions
OK	ECG is stable.	It is ready to begin measurement.
Initializing	Initializing ECG.	Have the patient remain quiet and wait briefly.
Unstable R-R	The electrodes are dry or dirty.	Replace with new electrodes (refer to page 44).
	Myoelectrical signal is detected as patient arm is tensed.	Have the patient relax the arm and rest quietly.
	Noise from radio interference is affecting the ECG waveform.	If a cell phone or other device is in use nearby, move it away.
	The signal is too weak.	Try moving the ECG clip on the left wrist to the instep of the left foot (secondary induction).
Check Electrodes	An ECG electrode is not attached to the ECG clip.	Confirm that all of the three electrodes are properly attached. (refer to page 44).
	The protective sheet is on the ECG electrode.	Remove the protective sheet from the ECG electrode (refer to page 44).
	An ECG cable is not connected.	Confirm that all ECG cables are securely connected (refer to page 128).

PCG Messages

Note:
If PCG is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered (refer to page 34), PCG messages and the PCG level indicator will not be displayed.

The PCG messages are explained below. When "OK" is not displayed, accurate measurement results may not be obtained. Follow the correspondent solutions to the messages in the chart below.

Messages	Status	Notes / Solutions
OK	PCG is stable.	It is ready to begin measurement.
Initializing	PCG initializing.	Have the patient remain quiet and wait briefly.
Out of Range	Noise is detected as the sensor has been touched or other reason.	Have the patient rest quietly and wait briefly.
Weak Signal	The PCG sensor has come off or the patient's shirt or other clothing has come under it.	Make sure the PCG sensor is in full contact with the skin. If it is difficult to keep the sensor in full contact, use the PCG sensor weight (refer to page 46).
	The PCG sensor pad is dry or dirty.	Replace with a new PCG sensor pad (refer to page 45).
	The wrong side of the PCG sensor is attached.	Attach the PCG sensor correctly (refer to page 45).
	Level 3 or 4 is recommended to obtain accurate measurement results. With level 1 or 2, accurate results may not be achieved.	
Re-Position	The sensor is not attached on an appropriate position.	Re-attach the PCG sensor on an appropriate position (refer to page 45).
	For patients with cardiac murmur or respiratory noise, it may be difficult to clearly distinguish the first and second heart sound. This may cause an inaccuracy measurement.	

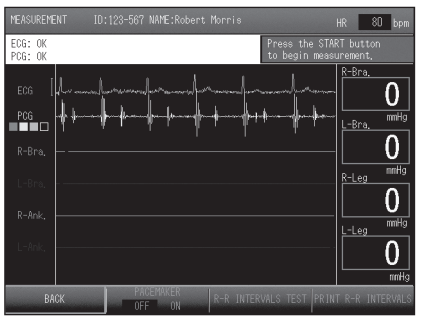
Starting and Ending Measurement

Note:
In some cases one measurement is required, but in other cases two measurements are required to complete measurement. The following cases require two measurements:
- "Synchro measurement" is set to "ON" (refer to page 38).
- "Synchro measurement" is set to "OFF"; however, blood pressure was not correctly measured.
- "ABI Remeasurement" is set to "ON" and the measured ABI is lower than the set value (refer to page 78).

The ECG signal and the PCG signal must be stable before measurement begins.

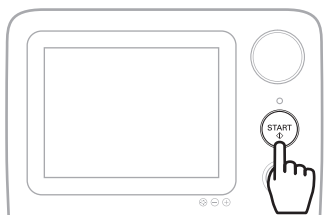
1. Make sure that "ECG: OK" and "PCG: OK" are displayed.

- R-R interval examination can be performed before measurement is started.
  Refer to "2-4. R-R Interval Examination" (page 65).
- If the optional CAP sensor unit or FAP sensor unit is attached, check the CAP message or the FAP message.

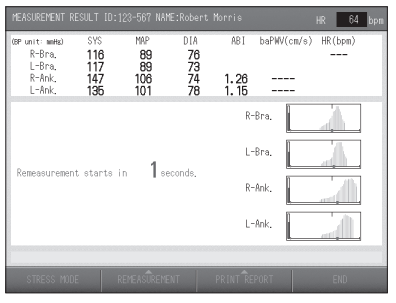


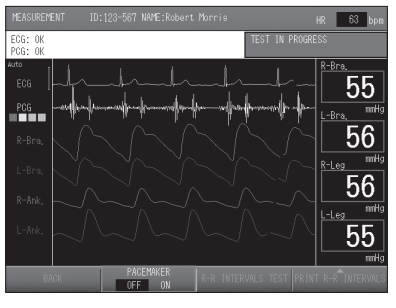
2. Press the [START] button.

Measurement begins.



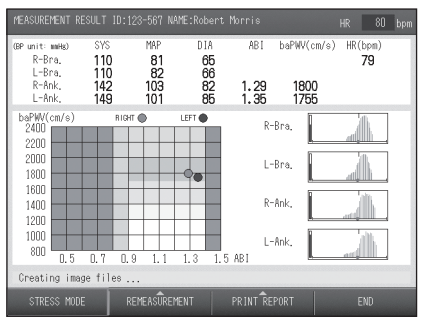
If a second measurement is required, the standby time is displayed. Measurement begins when the count ends.



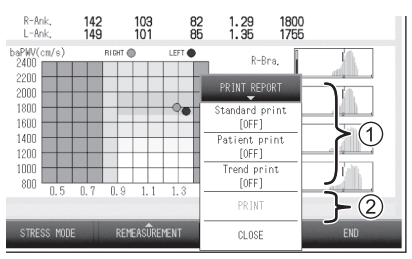


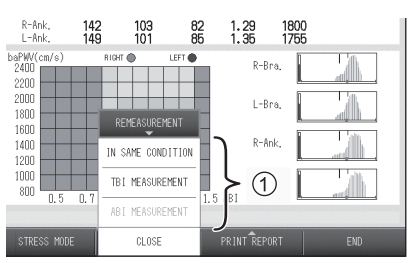
3. Confirm that measurement has successfully ended.

- When measurement ends, the measurement results screen appears.
  Refer to "Contents of the Measurement Screen" (page 48).
- If the number of printed pages is set in "Print Default Settings" (page 80), a measurement results report is printed.
  Refer to "Measurement Results Reports" (page 54)
- To reprint a measurement results report, select [PRINT REPORT], select the number of pages to be printed ① and then press [PRINT] ②.
- To repeat a measurement, select [REMEASUREMENT], and then select the repeat measurement condition ① and prepare for measurement.



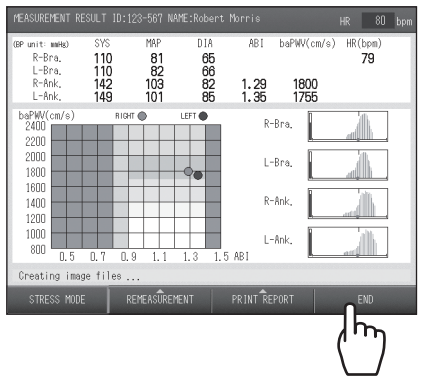
Measurement results screen





4. To perform post stress measurement, skip the remaining steps and follow the steps for post stress measurement (refer to page 67).

5. Select [END].

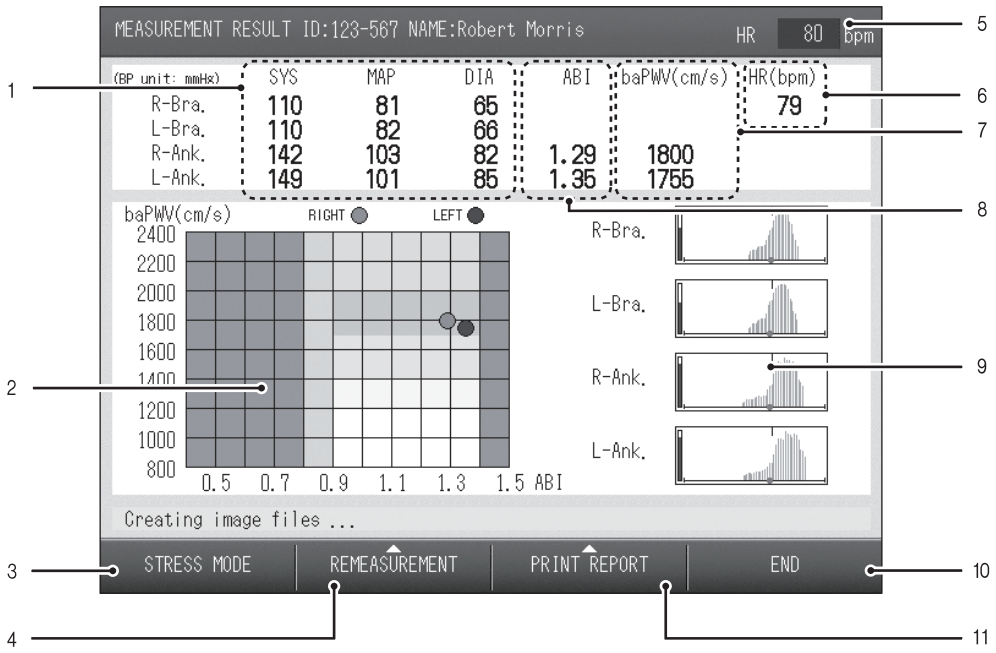


6. Remove the cuffs and sensors from the patient.

2-3. Measurement Results

Contents of the Measurement Results Screen

The measurement results screen that appears when measurement ends is explained below.



1	Blood pressure value	Displays the blood pressure values at each site where measurement was performed. Sites where measurement was not performed are not displayed.
2	Graph	This graph shows the relationship between baPWV and ABI.
3	[STRESS MODE] option	Select to perform post stress measurement.
4	[REMEASUREMENT] option	Select to repeat measurement. Select "IN SAME CONDITION", "TBI measurement"*, or "ABI measurement".
5	Heart Rate	Displays the real-time heart rate from the R-R interval obtained from ECG.
6	Heart Rate/ Pulse Rate	Displays the heart rate as the test result from the R-R interval obtained from ECG. If "ECG" was set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient's information was entered, displays the pulse rate. (refer to page 34)
7	baPWV	This displays the PWV value calculated from the interval from the start of the brachial pulse wave to the start of the ankle pulse wave.
8	ABI	Displays the right and left ABI. When blood pressure is measured at both arms, the ABI is calculated from the higher brachial pressure value.
9	Pulsatile variation graph	This graph shows the pulsatile variation obtained from each cuff. Synchronization line is not displayed if the time phases do not match due to re-measurement or other reasons.
10	[END]	Select to end measurement and return to the initial screen.
11	[PRINT REPORT] option	Select to print a measurement results report.

*Select this to perform TBI measurement. The TBI package is required for TBI measurement.
If the TBI package is installed, read the manual for the package.

Measurement Results Reports

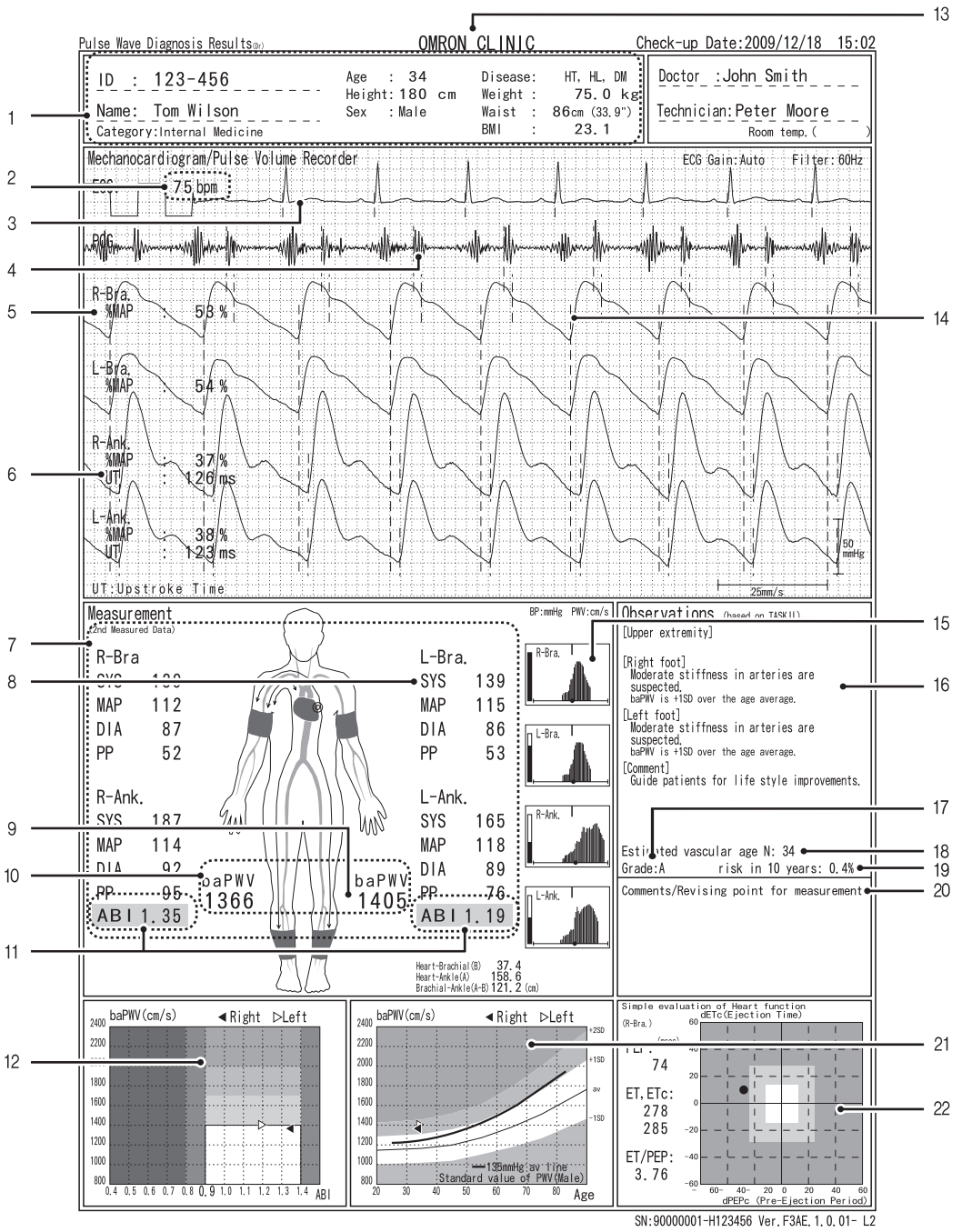
The measurement results reports that are printed when measurement ends are explained below. The types of reports are as follows.

Type	Description	Page
Standard	Measurement results report that is retained by the medical organization that conducted the examination.	**55**
Patient	Measurement results report to be given to the patient.	**60**
Trend	This indicates measurement data trends based on comparison with past data.	**64**

Notes:

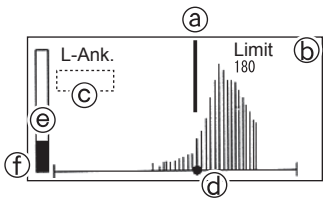
- Do not turn off the power while printing is in progress. This may damage the internal memory.
- You can also set reports to not print after measurement. The initial setting is "1 sheet". Refer to "3-3. Print Default Settings" (page 80).
- To print additional reports after measurement, select "PRINT REPORT" on the measurement results screen. You can also print a report without performing measurement. Refer to "Reprinting Measurement Data" (page 95).
- The special LAN cable that is sold separately can be used to connect the device to a computer to send a report to it. Refer to "3-11. Transferring Report Data to a Computer" (page 120).
- When using the optional TU-100 pulse wave unit or TBI package, read the manual for the package.

Standard Report



1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

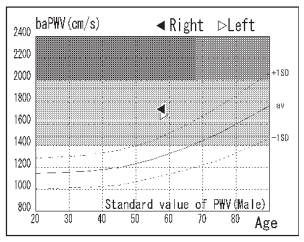
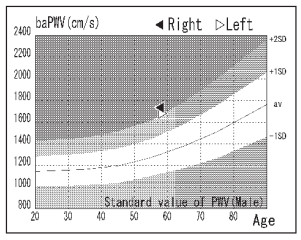
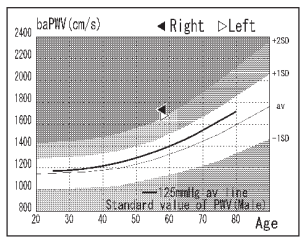
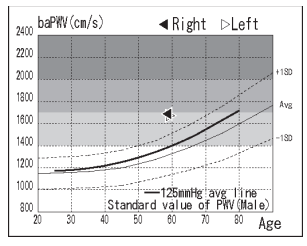
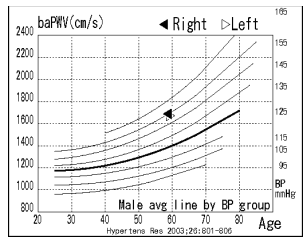
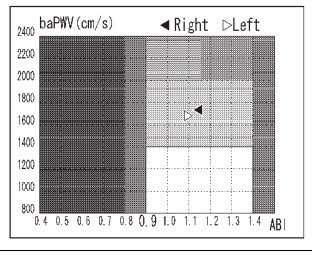
go to next page

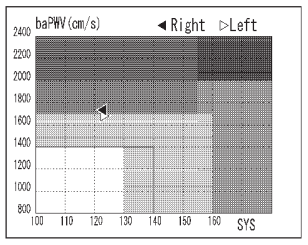
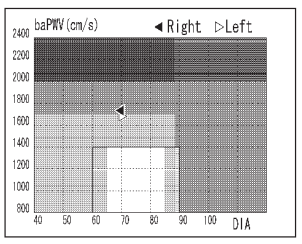
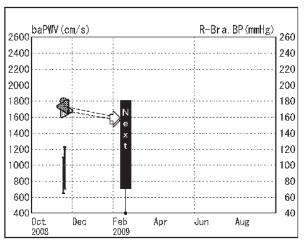
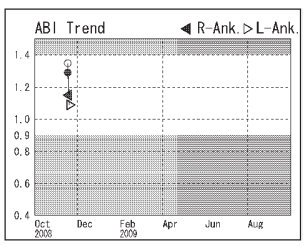
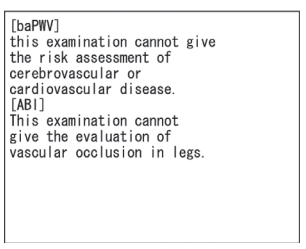
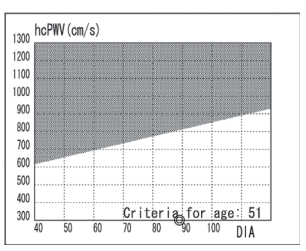
1	Patient information	The patient information that was entered before measurement.
2	Heart Rate/ Pulse Rate	Shows the heart rate. If "ECG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, the pulse rate will be displayed instead. (refer to page 34)
3	Electrocardiogram	The ECG waveform. If "ECG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, this will not appear (refer to page 34).
4	Phonocardiogram	The PCG waveform. If "PCG" is set to "OFF" in the SELECT MEASUREMENT SENSOR when the patient information is entered, this will not appear (refer to page 34).
5	%MAP	This value is one of the pulse waveform indices that are calculated from the blood pressure values. Refer to "5-10. Explanation of Technical Terms" (page 144)
6	UT	Time from the start of the pulse wave to its peak. However, for measurement in the carotid artery, the time from the start of the pulse wave to the peak of the effected wave or the start point of the reflected wave. Refer to "5-10. Explanation of Technical Terms" (page 144)
7	Blood pressure value	The blood pressure values for the left and right arm and left and right ankle. "- - -" is printed if measurement was not possible.
8	Blood pressure left-right difference	When the difference in the blood pressure values for the right and left upper arms is greater than 16 mmHg, the maximum blood pressure of the arm with the lower blood pressure is shaded.
9	Measured value reliability	If a measured value appears in parentheses, the accuracy of that value was low for some reason and it is indicated only for reference.
10	PWV	baPWV: The PWV value calculated from the interval from the start of the brachial pulse wave to the start of the ankle pulse wave. Refer to "5-10. Explanation of Technical Terms" (page 144)
11	ABI	Shows the right and left ABI values. Refer to "5-10. Explanation of Technical Terms" (page 144)
12	Graph 1	The indices are shown on a graph. Details are explained from page 58.
13	Facility name	This is shown if a facility name is entered (refer to page 86).
14	PVR waveform	The obtained pulse wave. Because the printed amplitude is calibrated from the measured blood pressure values, the printed amplitude may be different than the amplitude shown on the screen.
15	Pulsatile variation graph	This graph shows the pulsatile variation obtained from each cuff. a) Synchronization line: Not printed if synchro measurement was not possible. b) Inflation upper limit: When the inflation upper limit is set to other than "AUTO," the setting is printed. c) Measurement accuracy: When "Estimate" or "First Measurement" is displayed, accuracy may be poor. d) ●: Shows the maximum blood pressure value. Not printed if measurement was not possible. e) Level meter: Shows the size of the pulse wave. f) Frame: When constriction of the upper arm or ankle is suspected, the frame is printed in bold. 
16	Dr. Support	A Dr. Support is displayed based on the examination results. The content varies depending on the level setting of "Dr. Support" in the "Print Default Settings" (page 83).
17	Over all grade	When "Show result" is selected under "Over all grade" in "Print Default Settings", an over all grade of the examination results is shown using three levels (A, B, C) (refer to page 84).

18	Vascular age	When "Vascular age" or "Vascular age (N)" is selected in "Stiffness" in the "Print Default Settings", this shows arterial stiffness as a vascular age (refer to page 84).
19	Risk of Pathogenesis	When "Risk of Pathogenesis" is set to "ON" in the "Print Default Settings", the risk of cardiovascular disease within the next 10 years is calculated and displayed, based on age, sex and baPWV. (refer to page 84).
20	Comments / Revising point for measurement	This shows errors detected during measurement and points to be checked to prevent errors.
21	Graph 2	The indices are shown on a graph. Details are explained from page 58.
22	Simple Evaluation of Heart Function	STI (Systolic Time Intervals) is printed. If PCG is set to "OFF" for MEAS. SENSOR when entering patient information, this area will be blank. Refer to page 34 for more detail on PCG, and the detail on STI is in Quick Manual.

■ Graph 1 (Graph 2)

The graphs that appear in Graph 1 and Graph 2 are set in advance with the "Standard report layout" setting in "Print Default Settings". (page 83).

Type	Description	Displayed graph
1. Age-baPWV	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV.	
2. Age-baPWV/SD	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line.	
3. Age-baPWV/SD+Nomo	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line. (Shows mean age ± SD line and mean line of applicable blood pressure group.)	
4. Age-baPWV/Nomo1	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV. (Shows mean age ± SD line and mean line of applicable blood pressure group.)	
5. Age-baPWV/Nomo	This shows baPWV vs. age on the horizontal axis. (Shows mean line of each blood pressure group.)	
6. ABI-baPWV	This shows baPWV vs. ABI on the horizontal axis.	

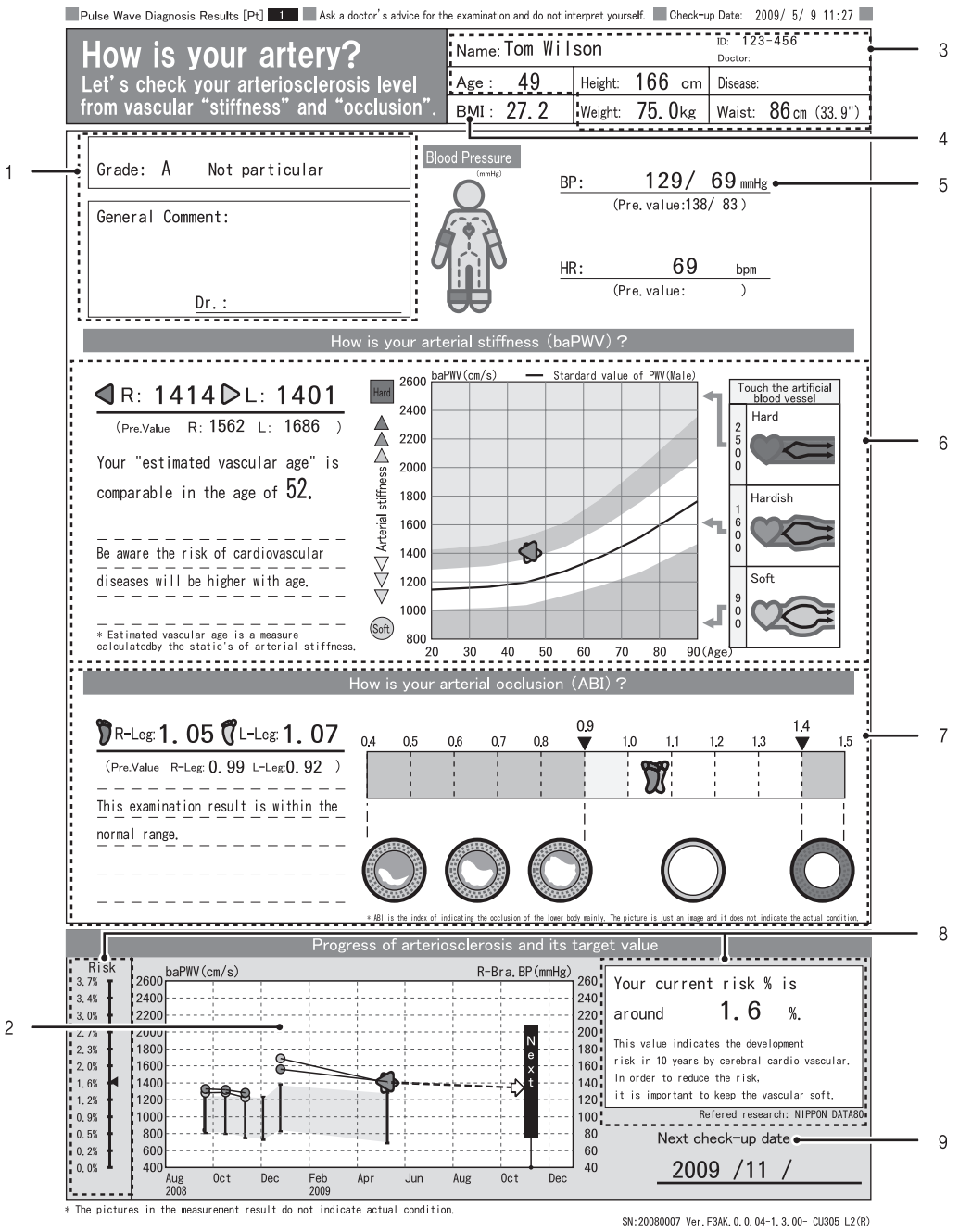
Type	Description	Displayed graph
7. SYS-baPWV	This shows baPWV vs. maximum blood pressure value on the horizontal axis.	
8. DIA-baPWV	This shows baPWV vs. minimum blood pressure value on the horizontal axis.	
9. baPWV Trend	This shows baPWV vs. date on the horizontal axis.	
10. ABI Trend	This shows ABI vs. date on the horizontal axis.	
11. Vascular Comment	This shows comments on vascular sclerosis. This is the same content as in the patient report (refer to page 60).	
12. DIA-hcPWV	This shows hcPWV vs. minimum blood pressure value on the horizontal axis. (Only when the optional TU-100 pulse wave unit is connected.)	

Patient Report

This is the measurement results report that is given to the patient. Select from three types depending on the patient and the diagnosis policy. For the type of No. 1 and No. 2, the report layout can be selected. The report type is set in advance in "Report type" in "Print Default Settings" (page 81) and the layout is set in "Patient Report Layout" (page 84).

■ Patient Report No. 1

The measured values, graphs, and images are arranged uniformly. Select from two types of layouts based on the "Risk of Pathogenesis" selection (page 84).



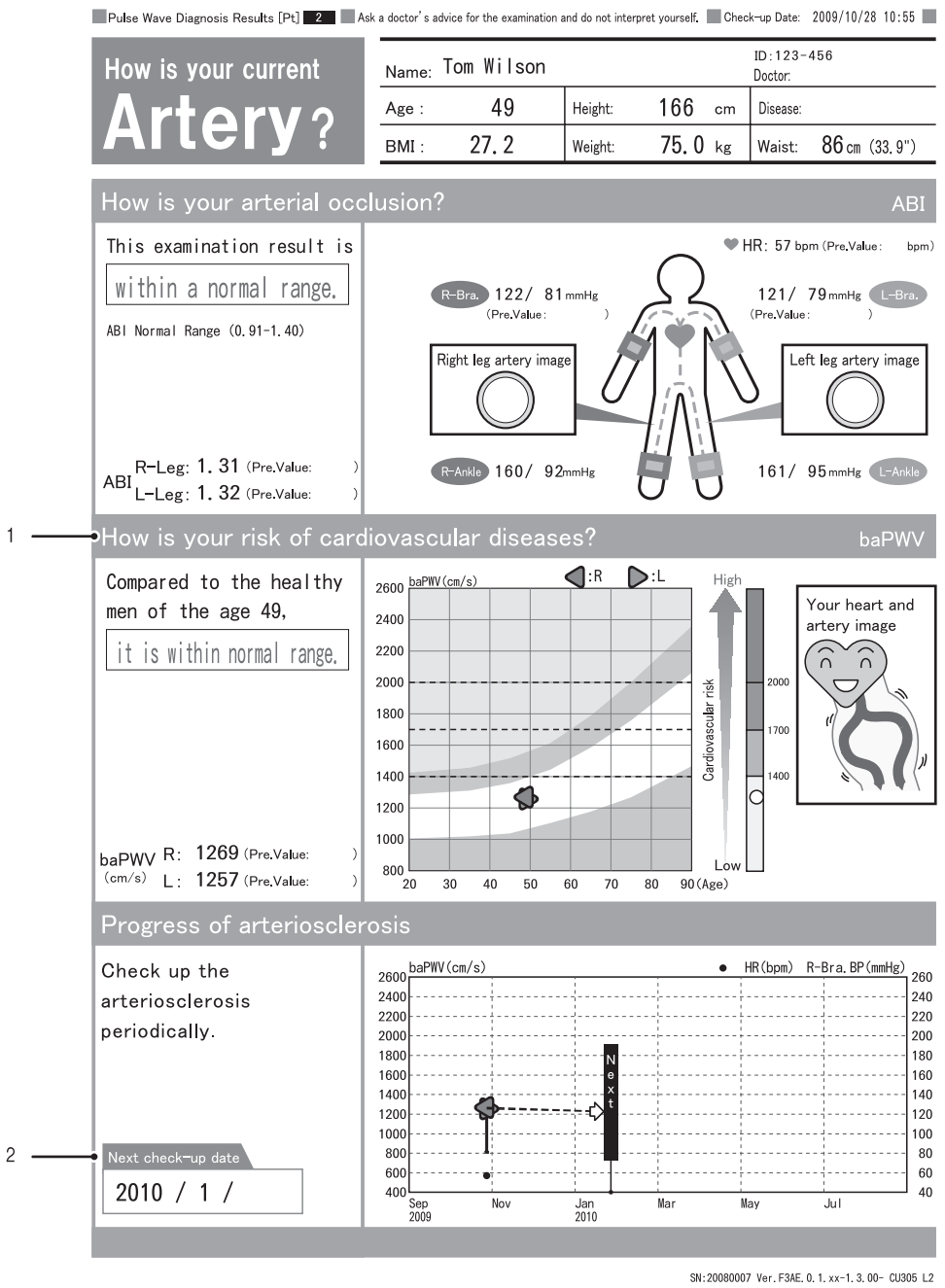
1	Over all grade	This is printed when "Show frame" or "Show result" is selected in the "Over all grade" setting in "Patient report layout". An over all grade of the test results is given in "Show result" (refer to page 84). A: Not particular B: Follow-up is required C: Re-examination is required
2	Trend graph	This shows a graph of trends over the treatment period.
3	Patient information	The patient information that is entered before measurement. The standard weight is shown if the patient's weight is entered.
4	Body Mass Index (BMI)	This is shown if the patient's weight is entered.
5	Blood pressure value	Displays the blood pressure value of the right upper arm. If it is not measured due to constriction, the blood pressure value of the left arm is shown.
6	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout or "Vascular age" layout can be selected in the "Stiffness" setting of "Patient report layout". "Vascular age (N)" is not supported (refer to page 84).
7	Arterial stenosis (ABI)	The degree of stenosis in lower-extremity arteries is shown in a graph with images of artery.
8	Risk of pathogenesis	When "Risk of pathogenesis" is set to "ON" in "Patient Report Layout", the risk of cardiovascular disease is shown in a graph along with a numerical value (refer to page 84).
9	Next check-up	This is printed when "Next check-up" is set in "Patient report layout" (refer to page 84).

■ Patient Report No. 2

This mainly consists of graphs for clogging and flexibility of arteries. Select from three types of layouts based on the "Stiffness (Vascular sclerosis indication)" selection (page 84).

Notes:

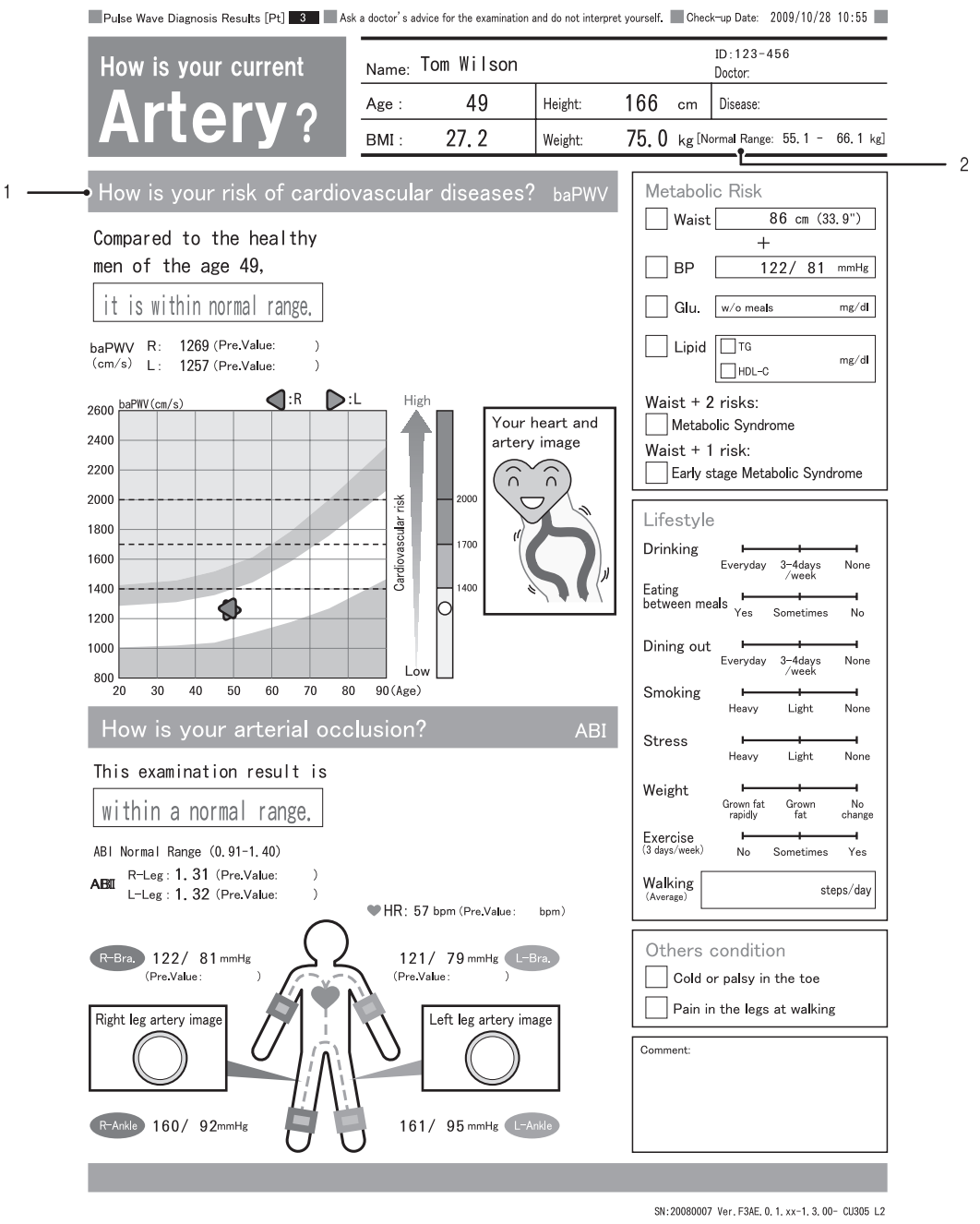
- The horizontal axis representing time on the artery flexibility trend graph is automatically set within a range of 1 to 5 years depending on the patient's past data.
- The next scheduled examination can be set in increments of one month from the day of the most recent examination.



1	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout, "Vascular age" layout, or "Vascular age (N)" layout can be selected in the "Stiffness" setting of "Patient report layout" (refer to page 84).
2	Next check-up	This is printed when "Next check-up" is set in "Patient report layout" (refer to page 84).

■ Patient Report No. 3

This indicates the risk of cardiovascular disease using illustrations that are easy for the patient to understand.



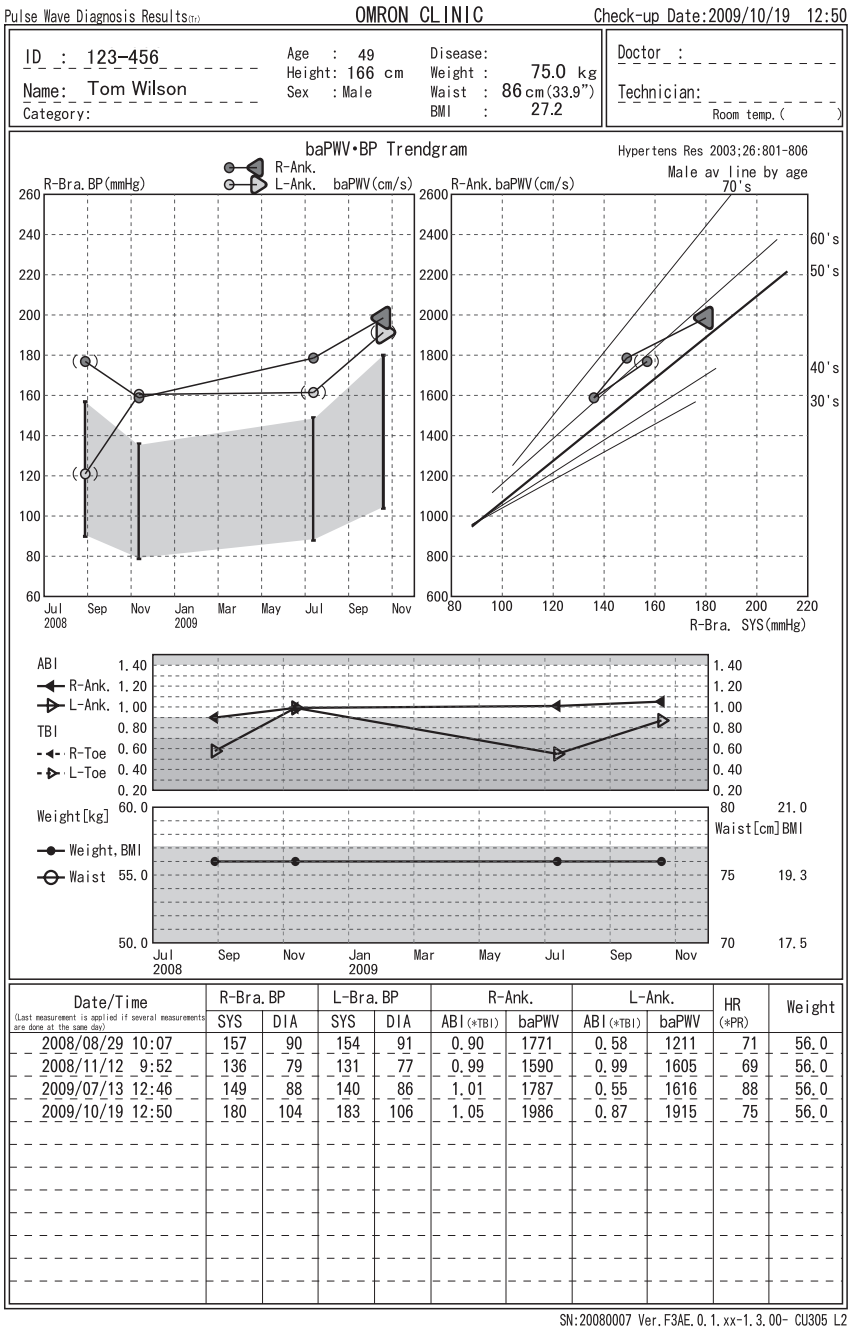
1	Arterial stiffness (baPWV)	This is evaluated based on an age standard. The "Compare with age" layout or "Vascular age" layout can be selected in the "Stiffness" setting of "Patient report layout". "Vascular age (N)" is not supported. (Refer to page 84)
2	Standard weight	This is shown if the patient's weight is entered.

Trend Report

This chart indicates measurement data trends based on comparison with past data. This is normally only printed if there is a patient history; however, it can be set to print regardless of whether or not there is a patient history.
Refer to "Print Default Settings" "Trend Print" (page 82).

Note:

The horizontal axis representing time on the trend graph is automatically set within a range of one to five years based on the patient's past data.



Date/Time (Last measurement is applied if several measurements are done at the same day)	R-Bra. BP		L-Bra. BP		R-Ank.		L-Ank.		HR	Weight
	SYS	DIA	SYS	DIA	ABI (*TBI)	baPWV	ABI (*TBI)	baPWV	(*PR)	
2008/08/29 10:07	157	90	154	91	0.90	1771	0.58	1211	71	56.0
2008/11/12 9:52	136	79	131	77	0.99	1590	0.99	1605	69	56.0
2009/07/13 12:46	149	88	140	86	1.01	1787	0.55	1616	88	56.0
2009/10/19 12:50	180	104	183	106	1.05	1986	0.87	1915	75	56.0

SN:20080007 Ver.F3AE.0.1.xx-1.3.00- CU305 L2

Standard measurement

*This is a sample report when measurement is performed with the TBI package installed.

2-4. R-R Interval Examination

Use this to measure fluctuations in the interval between heartbeats in order to check the autonomic function of the cardiovascular system. The one hundred heartbeats that are required for analysis are acquired, and the resulting histogram and trend are printed.

Starting and Ending R-R Interval Examination

Notes:
- R-R interval examination is only possible when ECG clips are attached.
- An R-R interval examination and basic measurement cannot be performed simultaneously.

1. Prepare for measurement.

If you are performing an R-R interval examination before basic measurement, go to step 2.

1. Turn the power on.
2. Enter the patient information.
   Refer to "Entering and Editing Patient Information" (page 25).
3. Attach the ECG clips to the patient.
   Refer to "Attaching the ECG clips" (page 44).

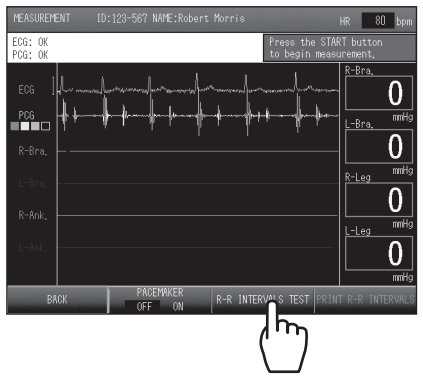
2. Confirm that "ECG: OK" is displayed on the measurement screen.

It is not necessary to attach the PCG sensor.

3. Select [R-R INTERVALS TEST].

Heartbeat counting begins. When the effective heartbeats count reaches 100, measurement ends and an R-R interval exam report is printed.
Refer to "R-R Interval Examination Results" (page 66).

If you performed an R-R interval examination before basic measurement, return to page 51 step 1.

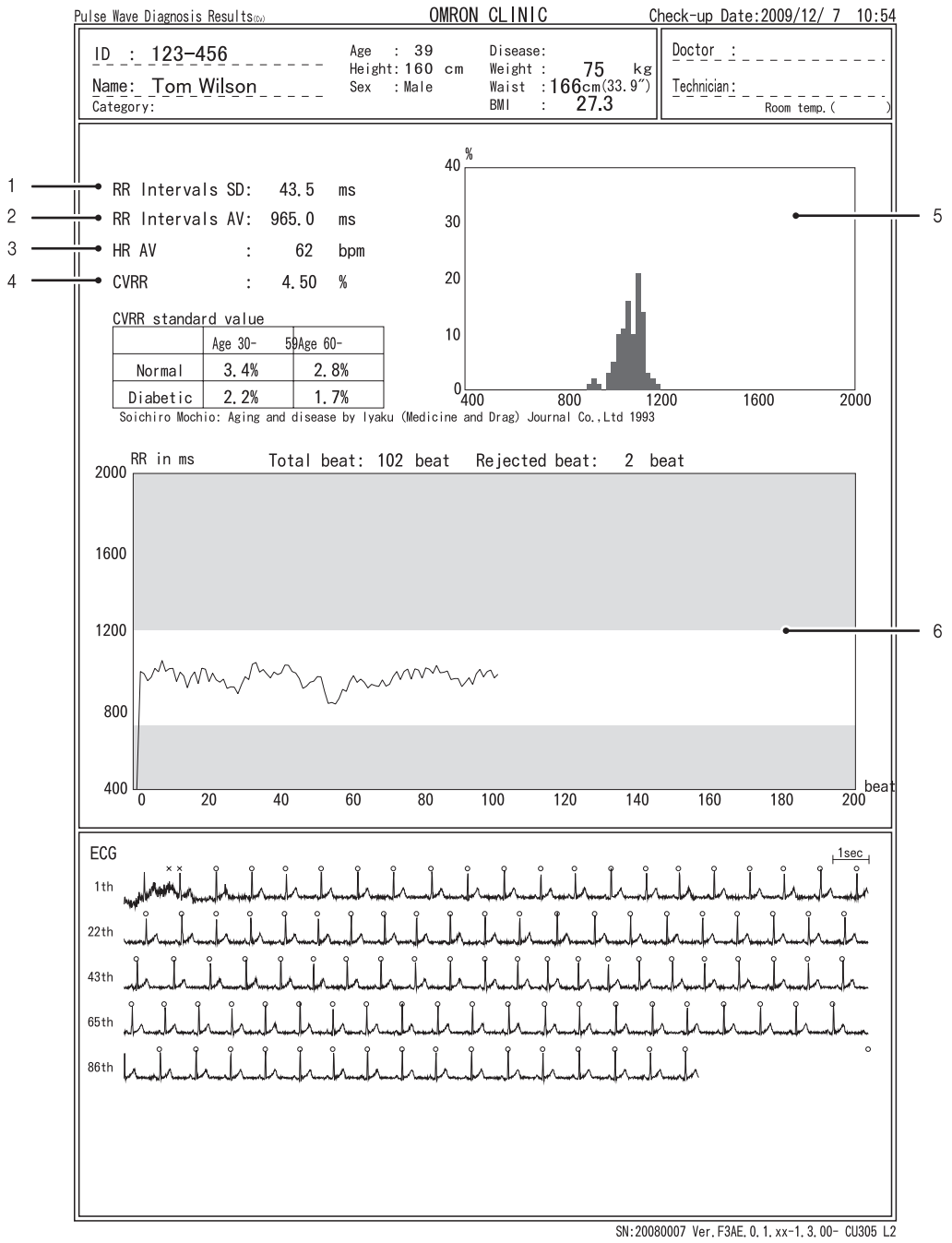


4. Remove ECG sensors from the patient.

R-R Interval Examination Results

The results of R-R interval examination are described below.

R-R Interval Examination Report



1	R-R interval standard deviation	This shows the standard deviation of the R-R interval.
2	R-R interval mean value	This shows the mean value of the R-R interval.
3	HR mean value	This shows the mean value of the heart rate.
4	CVRR	This shows the coefficient of variance of the R-R interval.
5	Histogram	This shows the histogram of the R-R interval.
6	Trend chart	This shows the trend graph of the R-R interval.

2-5. Stress Mode

This mode is used to measure blood pressure immediately after the heart is subjected to a set exercise load on a treadmill or similar device. After exercise is finished, the ECG and blood pressure gradually return to the rest state. By measuring this process (Post Stress), abnormalities can be discovered that would not be apparent when the patient is at rest.

Notes:

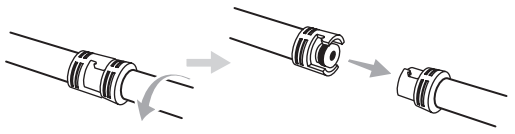
- The amount of exercise that the patient performs must be determined in consultation with a doctor. While the patient exercises, always pay close attention to the patient's condition.
- When applying an exercise load to a patient with heart disease, a doctor must be present and sufficient emergency measures must be prepared.
- Perform recovery measurement immediately after application of the exercise load. Measurement is not possible after 60 minutes have elapsed.
- Measurement is normally performed at the same parts as basic measurement.

Starting and Ending Post Stress Measurement

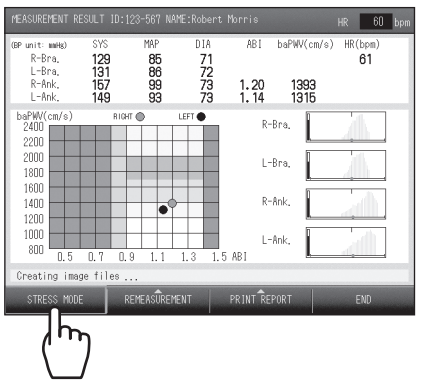
1. Perform basic measurement with the patient in the rest state.
Refer to "Starting and Ending Measurement" (page 51) steps 1 to 3.

2. Remove the ankle cuffs, ECG clips, and PCG sensor from the patient.

Disconnect the arm cuff from the cuff hose and leave the cuff on the patient.

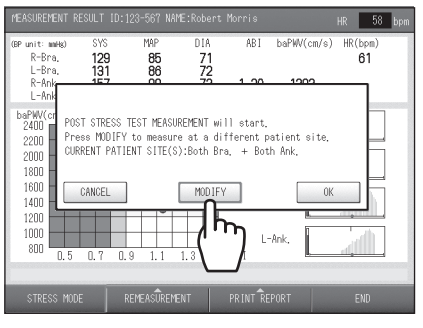


3. Select [STRESS MODE].

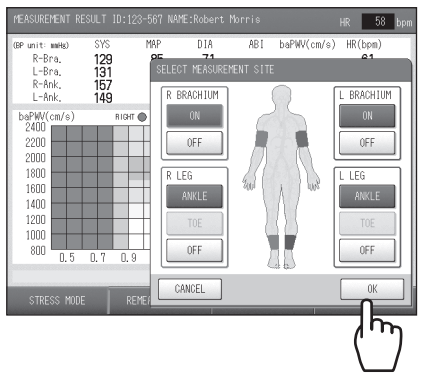


4. To change the measurement sites, select [MODIFY].

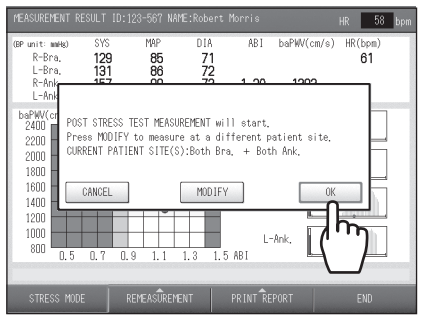
If you do not need to change the measurement sites, go to step 6.



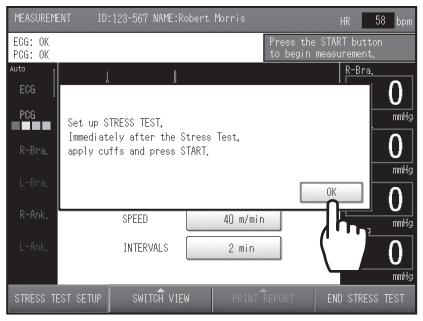
5. Select the measurement sites and select [OK].



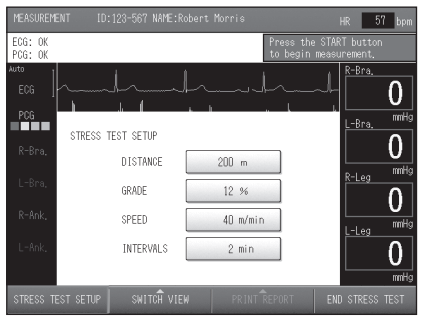
6. Select [OK].



7. Select [OK].



8. Set the exercise stress conditions.



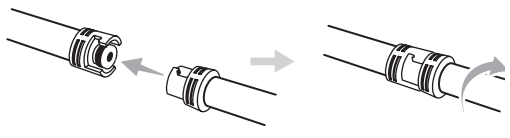
- DISTANCE: 0 to 1000 m
  (Walking distance)
- GRADE: 0 to 30%
  (Angle of treadmill)
- SPEED: 0 to 100 m/min
  (Treadmill speed)
- INTERVALS: 2, 3, 4, 5 minutes
  (Time from the start of one measurement until the start of the next measurement:
  for example, a 2 minute interval includes some number of seconds for the measurement, then a pause for the remainder of the 2 minutes, after which another measurement is taken, and so on.)

9. Start applying the exercise stress to the patient.

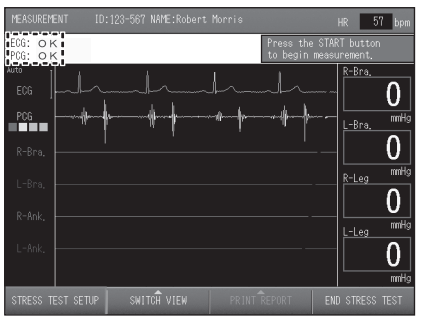
Apply the exercise stress to the patient based on the exercise stress conditions set in step 8.

10. Re-attach cuffs and sensors to the patient.

After applying the exercise stress, immediately attach the ankle cuff, ECG clips, and PCG sensor. Connect the arm cuff to the cuff hose.

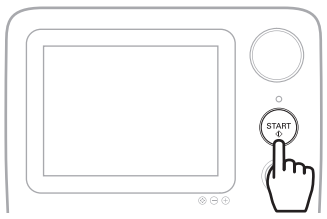


11. Confirm that "ECG: OK" and "PCG: OK" are displayed.

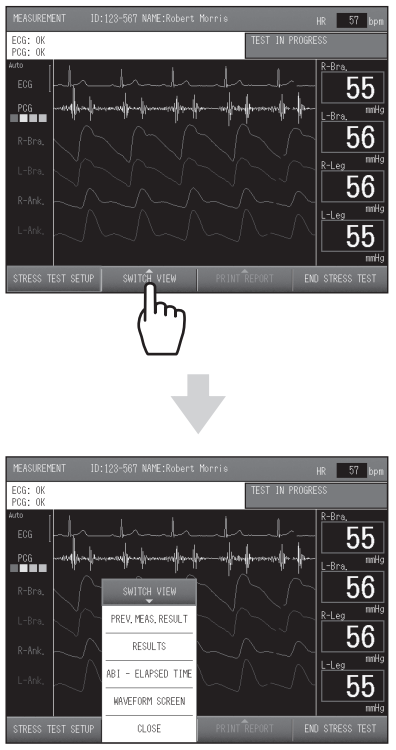


12. Press the [START] button.

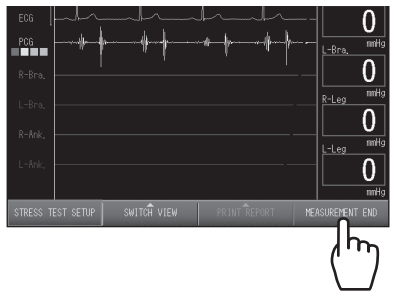
Measurement begins.



- During measurement the waveform appears. To view numerical values during measurement, select [SWITCH VIEW], and select the desired screen from the three screen types.
  Refer to "Checking Numerical Values During Post Stress Measurement" (page 71).



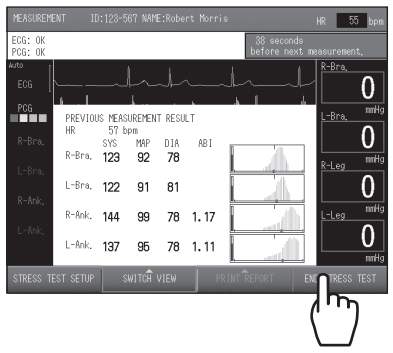
• To cancel measurement, select [MEASUREMENT END].



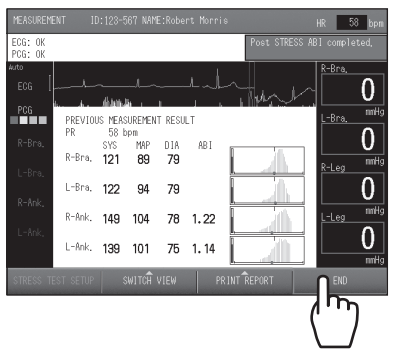
13. When the ABI returns to the state before exercise stress, select [END STRESS TEST] and then [OK] to end.

To cancel, select [CANCEL].

Measurement ends, the post stress measurement report will be printed.



14. Select [END].



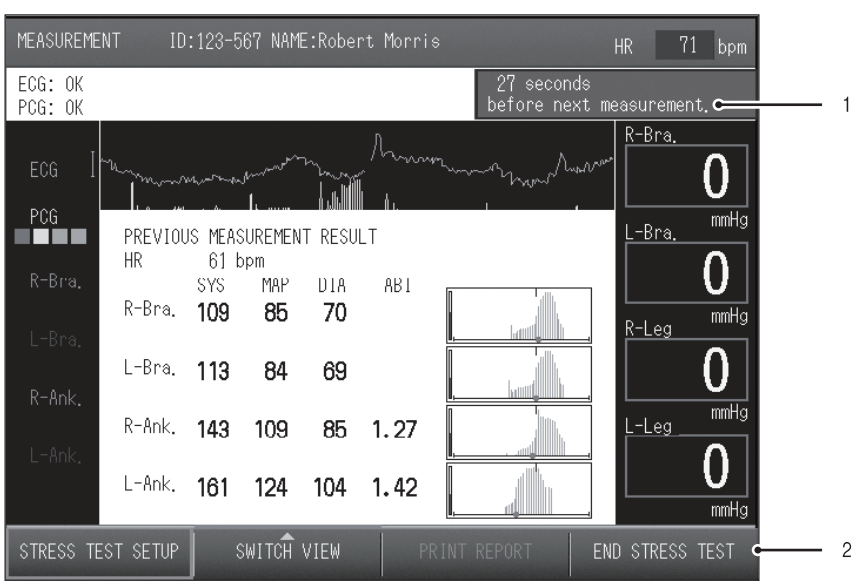
15. Remove the cuffs and sensors from the patient.

Checking Numerical Values During Post Stress Measurement

Selecting [SWITCH VIEW] on the waveform screen during or after post stress measurement switches among "Previous measurement result", "List of results", "ABI - Elapsed time", and "Waveform screen". View changes to the values being measured on any of these screens. Select an appropriate screen for the patient and the circumstances.

Previous measurement result screen

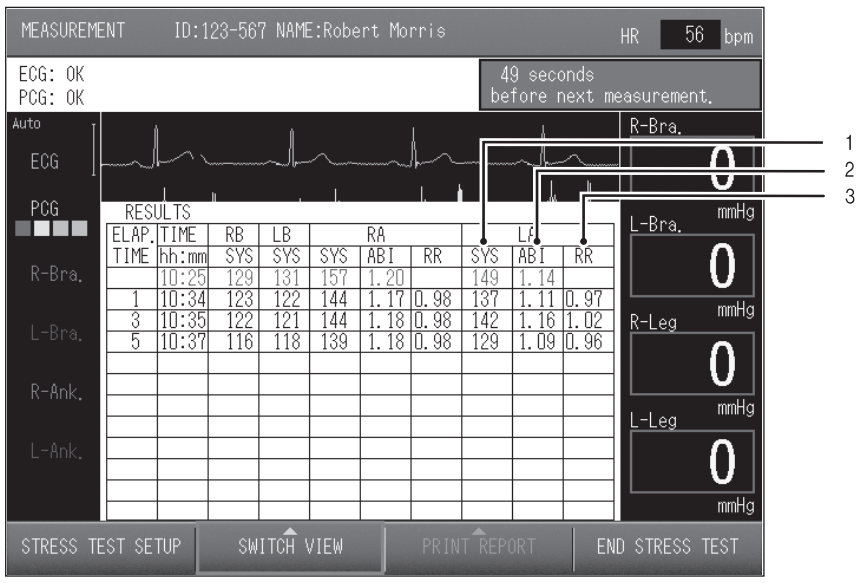
This screen graphs of the most recently measured values and pulsatile variation.



1	Interval	Counts the standby time until the next measurement.
2	[END STRESS TEST]	Press to stop Post Stress measurement.

List of results screen

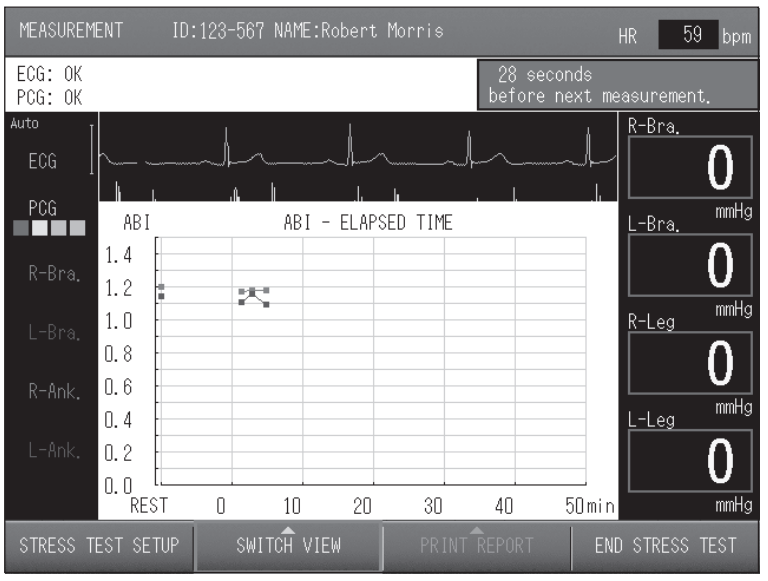
This screen shows measured values over time.



1	SYS	Shows the maximum blood pressure value.
2	ABI	Shows the ABI value.
3	RR	This shows the recovery ratio, which is the ratio of measured ABI to ABI at rest. This approaches 1 as time elapses.

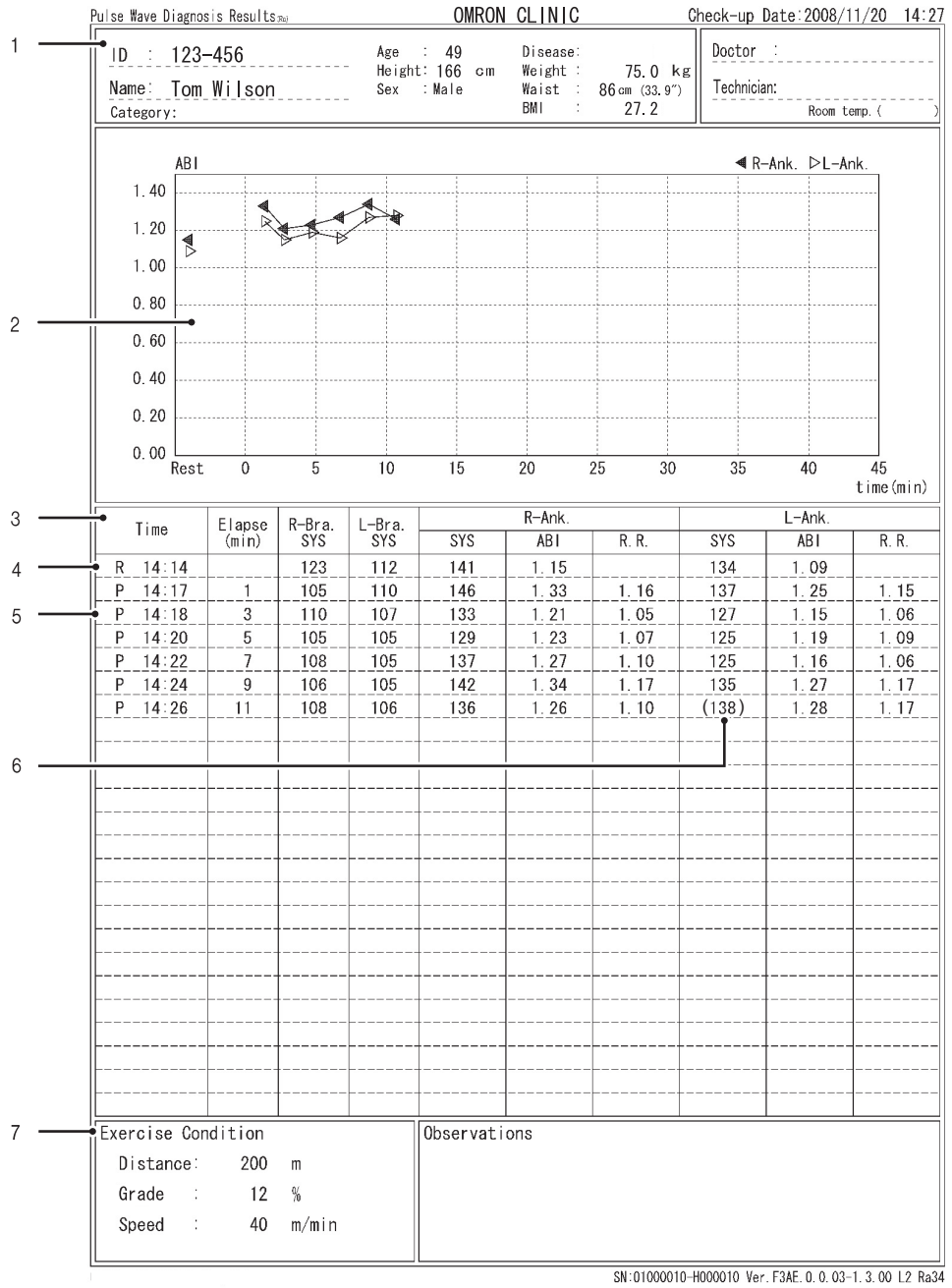
ABI - Elapsed time

This screen shows the trend of the ABI value over time.



Post Stress Measurement Results

When post stress measurement ends, the post stress measurement report is printed.

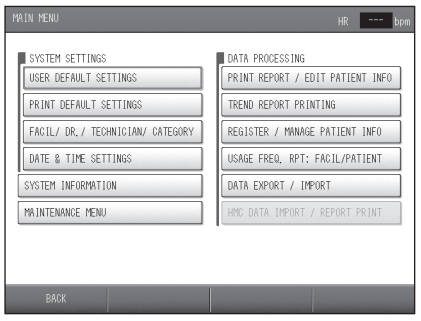


1	Patient information	The patient information that was entered before measurement.
2	Trend chart	This shows the trend of the ABI value over time.
3	List data	Shows a list of the measurement results together with the elapsed time. 4 : "R" indicates a measurement taken in the rest state. 5 : "P" indicates a post stress measurement. 6 : Parentheses indicate that the accuracy of the value was low for some reason and the value is indicated only for reference.
7	Exercise Conditions	Shows the set exercise stress conditions.

3. Settings and Data Processing

3-1. Main Menu Screen

To display the main menu screen, select [MAIN MENU] on the initial screen that appears after the power is turned ON. The main menu screen is used to configure basic settings related to the device and settings for printing measurement results, and to process past measurement data.



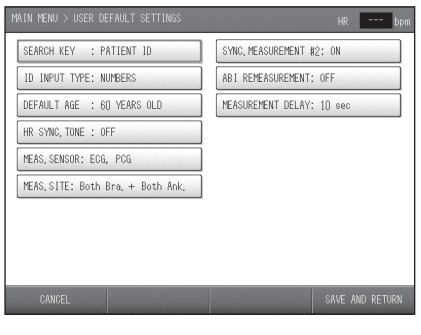
The items in the menu are described below.

Type	Name	Description	Page
DEVICE SETTINGS	USER DEFAULT SETTINGS	Conditions related to patient information such as search keys and ID input type, and settings related to measurement such as measurement sensors and measurement sites.	**76**
	PRINT DEFAULT SETTINGS	You can configure print settings such as paper size, number of printed pages, and print layout.	**80**
	FACIL / DR. / TECHNICIAN / CATEGORY	Facility name, doctor, technician, and category settings can be stored, edited, and deleted.	**86**
	DATE & TIME SETTINGS	Use this to set the date and time in the device.	**93**
SYSTEM INFORMATION		The device serial number, program version, system configuration, and other information can be displayed.	**133**
MAINTENANCE MENU		This is used to test for air leakage and other inflation/deflation speed and pressure accuracy problems in the measurement functions (inspection and maintenance).	**134**

Type	Name	Description	Page
DATA PROCESSING	PRINT REPORT / EDIT PATIENT INFO	The information of previously examined patients can be edited, deleted, and reprinted.	**94**
	TREND REPORT PRINTING	You can search for the information of a previously examined patient using the patient ID or date of examination, and reprint the trend report.	**101**
	REGISTER / MANAGE PATIENT INFO	Patient information can be registered in advance, edited, and deleted.	**105**
	USAGE FREQ. RPT: FACIL / PATIENT	A frequency of use report and a facility patient report can be printed.	**113**
	DATA EXPORT / IMPORT	Measurement data can be exported to USB flash drive and imported from USB flash drive for registration.	**116**
	HMC DATA IMPORT / REPORT PRINT	The optional HMC package can be used to import data from a household measuring device and print a report. For details, see the manual that accompanies the HMC package.	

3-2. User Default Settings

The user default settings are used to configure conditions related to patient information such as search keys and ID character type, and default settings related to measurement such as heartbeat beep, measurement sensors, and measurement sites.



Items That Can Be Set

For the procedure to change these settings, see page 79. The gray selection in the table indicates the factory setting.

Search Key

Enter patient information and select a search key.

Selections	Description
PATIENT ID	Select this to enter and search for patient information by patient ID.
EXAM ORDER NUMBER	Select this to enter and search for patient information by exam order number.

ID Input Type

Select the type of characters that can be entered for the ID number and order number in the new patient information registration screen.

Selections	Description
NUMBERS	Numeric characters and hyphens (-) can be entered.
NUMBERS AND CHR	Alphanumeric characters and hyphens (-) can be entered.

Default Age

Set the default age that appears in the new patient information registration screen when the patient's age is entered.

- Setting the average patient age as the default age makes it easier to enter a patient's age by jog dial.
- This can be adjusted within the range of 0 to 100. The default setting is "60".

HR Synchronized Tone

A beep sounds at each R wave of ECG during measurement.

Selections	Description
ON	A beep sounds.
OFF	No sound is made.

Measurement Sensors

Set default settings for attachment of sensors on the patient. Specify settings for ECG, PCG, CAP* and FAP*.

Selections	Description
ON	Attached.
OFF	Not attached.

* CAP and FAP only appear when the optional TU-100 pulse wave unit is connected.
When it is connected, read the manual for the unit.

Measurement Sites

Set default settings for attachment of cuffs on the patient.

- Cuffs are normally attached on both arms and both ankles.
- If a shunt is placed in an upper arm for hemodialysis, do not attach an arm cuff to or perform measurement on that arm.
- Measurement cannot be performed when both ankle cuffs and toe cuffs are attached.

Selections		Description
RIGHT BRACHIUM / LEFT BRACHIUM	ON	Arm cuff attached.
	OFF	Arm cuff not attached.
RIGHT LEG / LEFT LEG	ANKLE	Ankle cuff attached.
	OFF	Ankle cuff not attached.

Synchro Measurement

Set the default setting for "synchro measurement".

Selections	Description
ON	Perform synchro measurement.
OFF	Do not perform synchro measurement.

ABI Remeasurement

This sets the base ABI value that determines whether or not a second measurement will be performed.

Selections	Description
OFF	Do not judge whether or not to perform a second measurement using the base ABI value.
ON	When the measured ABI is lower than the set value, automatically perform a second measurement. Set the base ABI value within the range of 0.30 to 1.40.

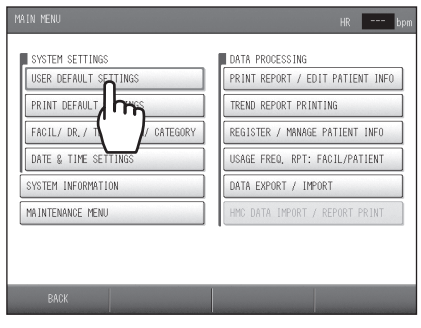
Measurement Delay

Set the delay time from the end of the first measurement to the start of the second measurement for "synchro measurement" and "ABI remeasurement".
Select from [10 sec] to [120 sec]. The default setting is [10 sec].

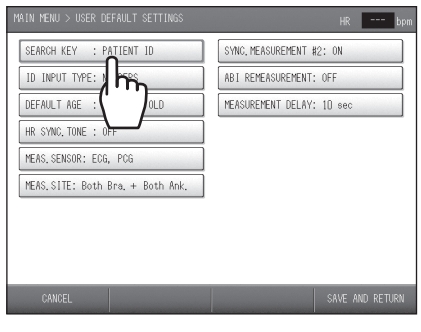
User Default Settings

Select [MAIN MENU] on the initial screen. Configure "User Default Settings" from the main menu screen.

1. Select [USER DEFAULT SETTINGS].

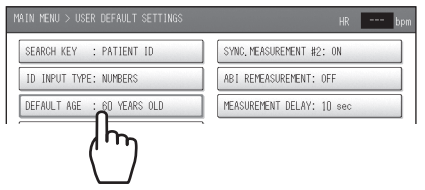


2. Select the button of the item you wish to configure.

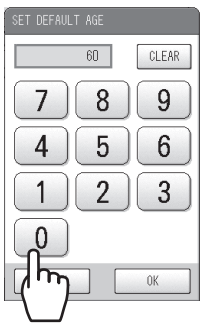


3. Select or enter a setting.

A. To select a setting from multiple selections, repeatedly select the item button until the desired setting appears.

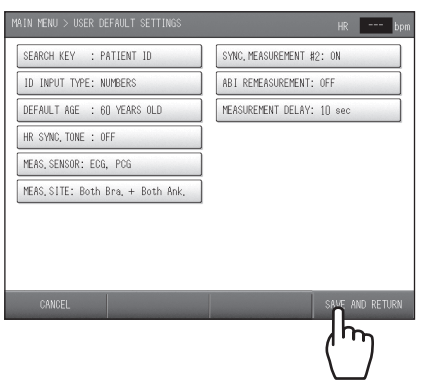


B. If a value must be entered, use the keyboard that appears.
- To clear a mistake, select [CLEAR].
- When the setting is completed, select [OK].
- To cancel, select [CANCEL].



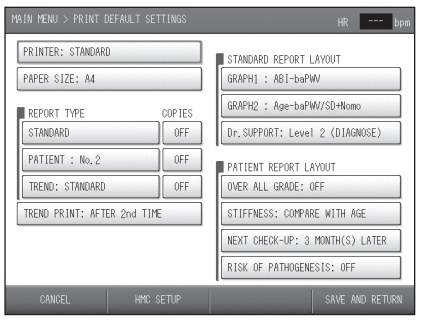
4. Repeat steps 2 and 3 to configure other items.

5. Select [SAVE AND RETURN].



3-3. Print Default Settings

You can configure print default settings such as paper size, copies, and print layout.



Items That Can Be Set

For the procedure to change these settings, see page 85. The gray selection in the table indicates the factory default setting.

Printer

Set the connected printer.

Selections	Description
STANDARD	Select this to use the printer that accompanies the device.
SERVER (COLOR) *	Select this to use a color printer other than the printer that accompanies the device.
SERVER (BLACK & WHITE) *	Select this to use a black & white printer other than the printer that accompanies the device.
OFF	Select this when a printer will not be used.

* To use a printer other than the printer that accompanies the device, contact a dealer or an Omron Healthcare technical support representative.

Paper size

Set the size of paper that is loaded in the printer.

Selections	Description
A4	Select this when A4 size paper is loaded.
B5	Select this when B5 size paper is loaded.

Note:
Do not use the size of paper other than the one specified in the paper size setting.

Report Type

The report type can be set for the patient report and trend report. Refer to the examples starting on page 54. Configure the settings in accordance with your examination policies, including the print conditions and report layout.

■ Standard Report

This report is for the doctor. There is one type.

■ Patient Report

There are four types. There are 2 different layouts for No.1, No.2, and No.4 (No.4 is for the optional HMC package).

Refer to "Patient Report" (page 60).

Selections	Description
NO.1	This type shows measured values, graphs, and images in a uniform arrangement.
NO.2	This type focuses on arterial stiffness and arterial stenosis in graph format.
NO.3	This type shows the risk of cardiovascular disease using easy-to-understand illustrations.
NO.4*	This type is for the optional HMC package.

* No. 4 is only enabled when the optional HMC package is used. For details, see the manual for the HMC package.

■ Trend Reports

Refer to "Trend Report" (page 64).

Selections	Description
STANDARD	This type shows measurement data trends based on comparison with past data.
HMC*	This type is for the optional HMC package.

* This is only enabled when the optional HMC package is used. For details, see the manual for the HMC package.

Number of Printed Pages

Set the number of copies printed for the standard report, patient report, and trend chart.

Selections	Description
OFF	Do not print.
1 PAGE - 10 PAGES	The set number of copies is printed. The default setting is [1 page].

Note:
If you will not be using a printer, set all settings for the standard report, patient report, and trend chart to "OFF".

Trend Print

Set the condition for printing a trend report.

Selections	Description
AFTER 2nd TIME	Only print when there is a patient history.
ALWAYS	Print regardless of whether or not there is a patient history.

Standard Report Layout

■ Graph 1

Select the type of graph to be printed on the lower left of the standard report.
(Example: page 55)

Selections	Description
1. Age-baPWV	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV.
2. Age-baPWV/SD	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line.
3. Age-baPWV/SD+Nomo	This shows baPWV vs. age on the horizontal axis. Graph shading is based on the SD line. (Shows mean age ± SD line and mean line of applicable blood pressure group.)
4. Age-baPWV/Nomo (1)	This shows baPWV vs. age on the horizontal axis. Graph shading is based on baPWV. (Shows mean age ± SD line and mean line of applicable blood pressure group.)
5. Age-baPWV/Nomo	This shows baPWV vs. age on the horizontal axis. (Shows mean line of each blood pressure group.)
6. ABI-baPWV	This shows baPWV vs. ABI on the horizontal axis.
7. SYS-baPWV	This shows baPWV vs. maximum blood pressure value on the horizontal axis.
8. DIA-baPWV	This shows baPWV vs. minimum blood pressure value on the horizontal axis.
9. baPWV Trend	This shows baPWV vs. date on the horizontal axis.
10. ABI Trend	This shows ABI vs. date on the horizontal axis.
11. Vascular Comment	This shows comments on vascular sclerosis and foot vascular clogging. This is the same content as in the patient report.
12. DIA-hcPWV*	This shows hcPWV vs. minimum blood pressure value on the horizontal axis.

* Can only be selected when an optional TU-100 pulse wave unit is connected. When a TU-100 pulse wave unit is connected, read the manual for the unit.

■ Graph 2

Select the type of graph to be printed on the lower center of the standard report. Selectable graph types are the same as for graph 1 above. The initial setting is [3. Age-baPWV/SD+Nomo].

■ Dr. support

Set the Dr. support level to be printed on the standard report.

Selections	Description
LEVEL 2 (DIAGNOSE)	This prints a suspected disease from measurement results such as "Possibility of constriction".
LEVEL 1 (NOTICE)	This prints facts such as "Measured baPWV is higher than mean value".
LEVEL 0 (NO COMMENT)	This prints information on reliability such as "Reliability of measurement results low due to noise".

Patient Report Layout

■ Over All Grade

An over all grade of measurement results is given using three levels: A, B, and C. The print settings for the over all grade field are explained below.

Selections	Description
OFF	Do not print.
SHOW FRAME	In the blood pressure value field of patient report No. 1, print the "Evaluation:" "Overall diagnosis:", and "Doctor:" fields.
SHOW RESULT	In the blood pressure value field of patient report No. 1, print the "Evaluation:" "Overall diagnosis:" "Doctor:" field, and the evaluation result. The evaluation result is also printed in the opinion field of the standard print.

■ Stiffness (Arterial stiffness indication)

Select the vascular sclerosis indication printed in patient report No.1 and No. 2.

Selections	Description
COMPARE WITH AGE	The result of baPWV measurement is compared with the mean value in a group of healthy people of the same age.
VASCULAR AGE	The result of baPWV measurement is calculated/estimated and displayed as a vascular age.
VASCULAR AGE (N)	Vascular age calculated/estimated from a blood pressure nomogram. (Patient Report No. 2 only.)

■ Next check-up

Specify whether or not "Date of next check-up" and "Target value of next check-up" are printed in patient report No. 1 and 2.

Selections	Description
OFF	Do not print.
1 MONTH - 12 MONTHS	Set in increments of one month from the measurement date. The initial setting is "3 months".

■ Risk of Pathogenesis

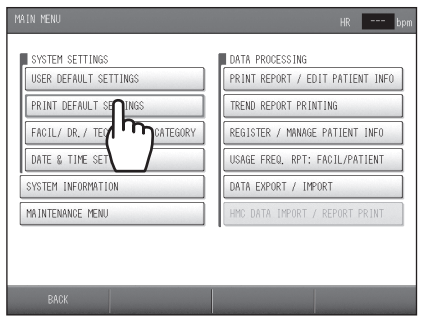
This indicates the risk of cardiovascular disease within the next 10 years.

Selections	Description
ON	Print the risk of pathogenesis on Patient Report No. 1.
OFF	Do not print.

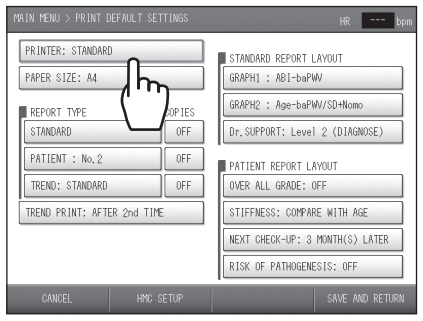
Print Default Settings

Select [MAIN MENU] on the initial screen. Configure "Print Default Settings" from the main menu screen.

1. Select [PRINT DEFAULT SETTINGS].

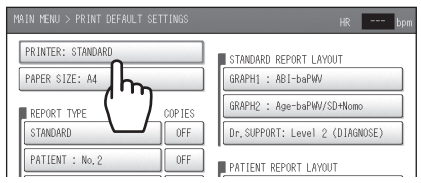


2. Select the button of the item you wish to configure.



3. Select or enter a setting.

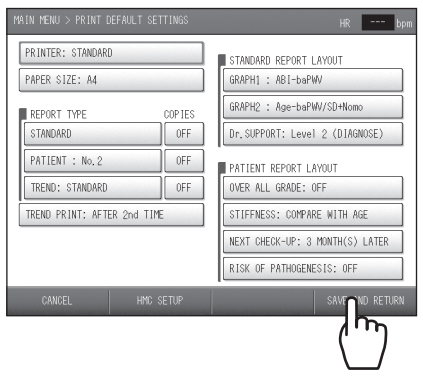
A. To select a setting from multiple selections, repeatedly select the item button until the desired setting appears.



B. If a value must be entered, use the keyboard that appears.
- When the setting is completed, select [OK].
- To cancel, select [CANCEL].

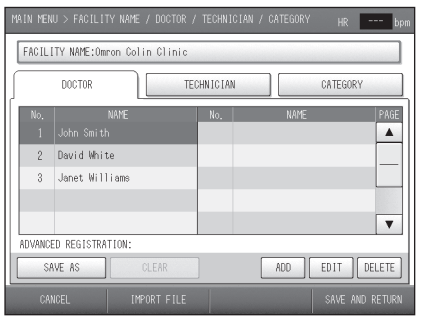
4. Repeat steps 2 and 3 to configure other items.

5. Select [SAVE AND RETURN].

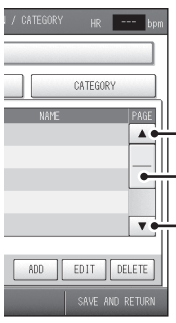


3-4. Facility name / Doctor / Technician / Category Settings

Facility names, doctors, technicians, and categories can be entered as lists, edited, deleted, and selected before performing measurements.



Note:
Use the scroll bar that appears on the right side of the screen when a doctor, technician or other list appears as explained below.



Return to the previous page.
Approximate position within the list.
Move to the next page.

Selecting the Method for Entering Lists

There are two methods for entering facility name, doctor, technician, and category lists.

A Import a text file

B Input from the touch screen

In method A, facility name, doctor, technician, or category data is prepared in advance and imported into the device. Data that has been imported into and stored in the device can be individually edited or deleted at the touch screen. Method B allows easy and immediate entry, editing, and deletion of data.

Entering Lists

Select [MAIN MENU] on the initial screen. "Facility name / doctor / technician / category" are configured from the main menu screen.

A. Importing a text file

1. You will need a USB flash drive to transfer files.

2. Create the data on a computer.

The format and number of characters are as follows:

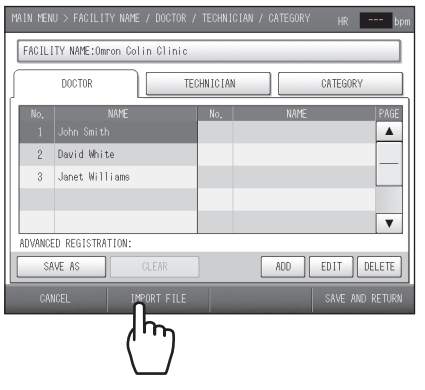
- Data format: text file
- File name: CLINIC.TXT
- Alphanumeric characters, hyphen, space, period, and apostrophe are allowed.
- Section name:
  Enter the content of each list under the following section names.
  [FACILITY], [DOCTOR], [TECHNICIAN], [CATEGORY]
- Facility name: 40 characters maximum
- Doctor / technician / category: 40 characters maximum
- Comment lines begin with a semicolon (;)

```
[FACILITY]
Omron Colin Clinic

[DOCTOR]
John Smith
David White
Janet Williams

[TECHNICIAN]
Peter Moore
Tom Brown
Jane Wilson

[CATEGORY]
Internal Medicine
Cardiovascular
Surgery
Orthopedics
```

3. Save the created data to USB flash drive and insert the memory stick to the USB port on the device.

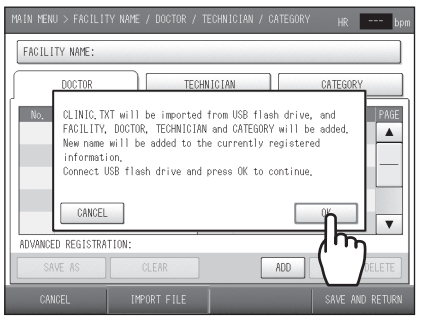
4. Select [FACIL / DR. / TECHNICIAN / CATEGORY].

5. Select [IMPORT FILE].



6. Select [OK].

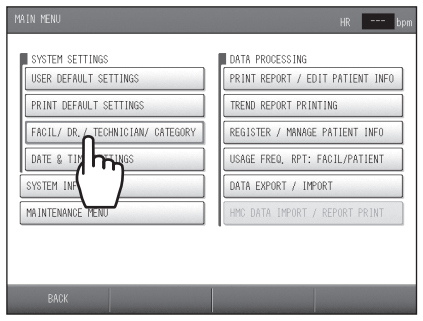
To cancel the import, select [CANCEL].



B. Input from the touch screen

■ To enter or edit the facility name:

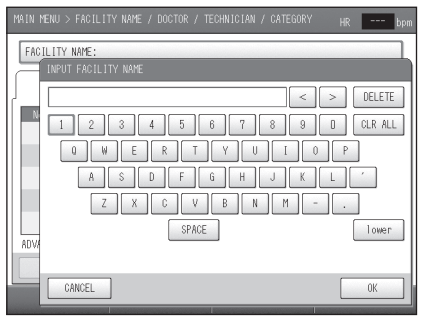
1. Select [FACIL / DR. / TECHNICIAN / CATEGORY].



2. Select [FACILITY NAME].

3. Enter or edit the facility name.

- You can enter up to 40 characters.
- A space counts as one character.
- To enter a space, select [SPACE].
- To switch between upper case and lower case, use [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters you entered, select [CLR ALL].



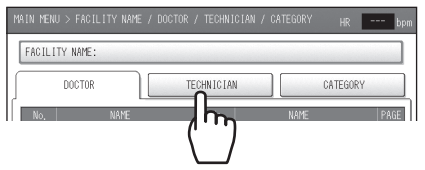
4. Select [OK].

To cancel, select [CANCEL].

Note:
The facility name entered above will appear at the top of various reports.
Refer to page 55.

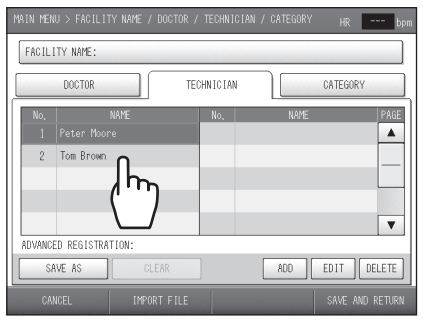
■ To enter, edit or delete a doctor, technician, or category entry:

1. Select [DOCTOR], [TECHNICIAN], or [CATEGORY] as appropriate for the item that you wish to add, edit, or delete.



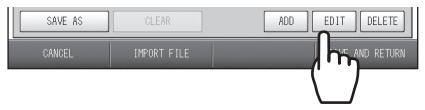
2. To add a new item, select [ADD]. To edit or delete an item, select the name.

If you selected [ADD], go to step 4.



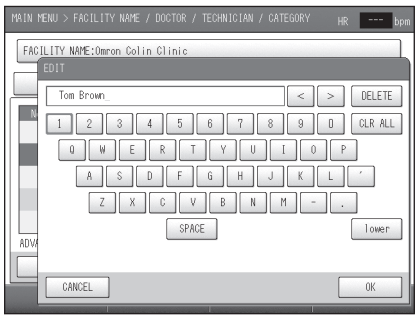
3. Select [EDIT] or [DELETE].

If you selected [DELETE], go to step 5.



4. Enter or edit the item.

- You can enter up to 40 characters.
- A space counts as one character.
- To enter a space, select [SPACE].
- To switch between upper case and lower case, use [UPPER] and [lower].
- To change a character, select [<] or [>] to move the cursor to that character, select [DELETE], and enter the new character.
- To delete all characters you entered, select [CLR ALL].



5. Select [OK].

To cancel, select [CANCEL].

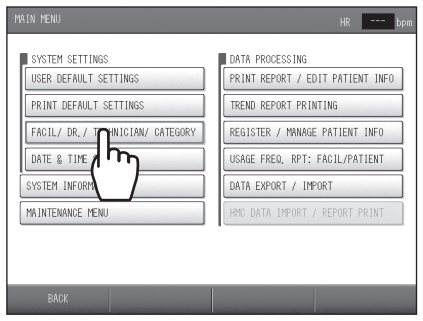
6. Repeat steps 1 and 5 to configure other items.

7. Select [SAVE AND RETURN].

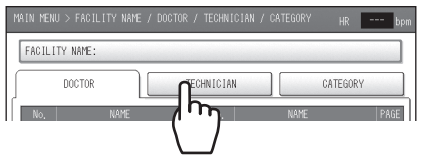
Configuring Pre-selection Settings

Configure pre-selection settings for the "Doctor", "Technician", and "Category". When patient information is entered, the names set in the pre-selection settings will initially appear in "Doctor", "Technician", and "Category" on the screen.

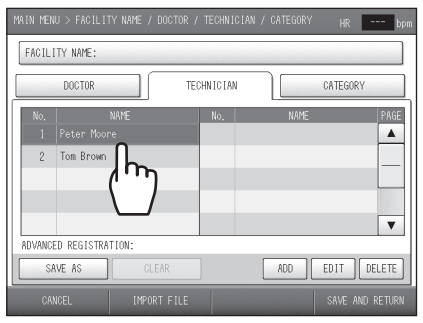
1. Select [FACIL / DR. / TECHNICIAN / CATEGORY].



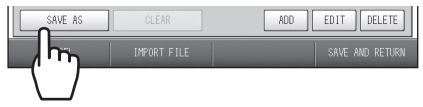
2. Select the button of the item you wish to pre-select.



3. Select the name that will be pre-selected.

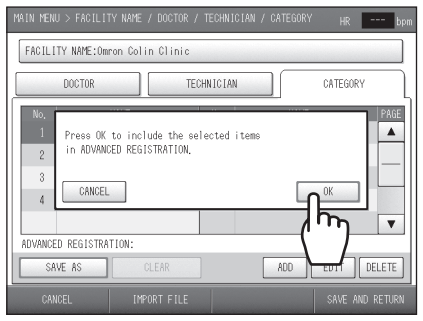


4. Select [SAVE AS].



5. Select [OK].

To cancel, select [CANCEL].



6. Repeat steps 2 through 5 to configure other items.

7. Select [SAVE AND RETURN].

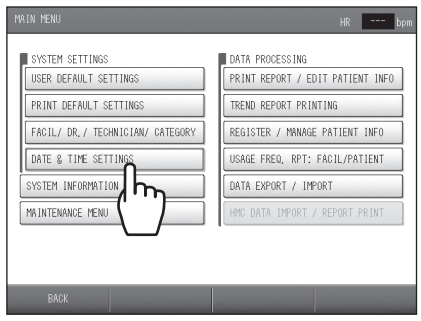
Note:
If there is no need to print the "Doctor", "Technician", and "Category" on measurement result reports, select [CLEAR].

3-5. Date & Time Settings

The date and time were set at the factory. If you need to adjust the date and time, follow the steps below.

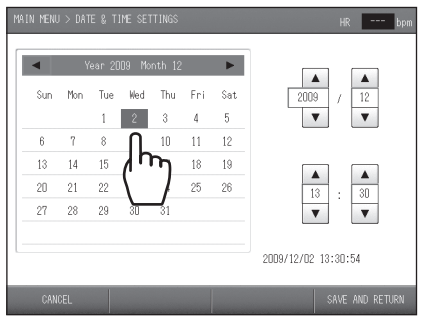
Select [MAIN MENU] on the initial screen. Configure "Date & Time Settings" from the main menu screen.

1. Select [DATE & TIME SETTINGS].



2. Set the date and time.

- Change the year, month, and time with the [▲] [▼] arrows.
  - [▲] arrow: Change to the next higher value.
  - [▼] arrow: Change to the next lower value.
- Directly select the day on the calendar.

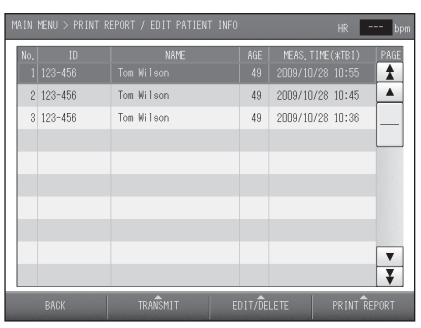


3. Select [SAVE AND RETURN].

To cancel, select [CANCEL].

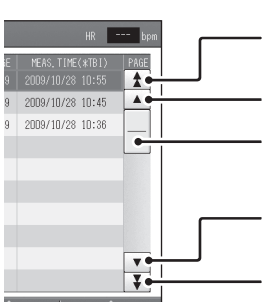
3-6. Printing Reports and Editing Patient Information

200 most recent examination reports can be reprinted, patient information can be edited, and measurement data can be deleted.



Notes:

- Data marked with "＊" at the right of the date and time of measurement is TBI (Toe Brachial Index) data. TBI can be measured when the TBI package is installed. If the TBI package is installed, read the manual for the package.
- The scroll bar that appears on the right side of the screen when the patient list appears is used as explained below.



Move back five pages.

Return to the previous page.

Approximate position within the list.

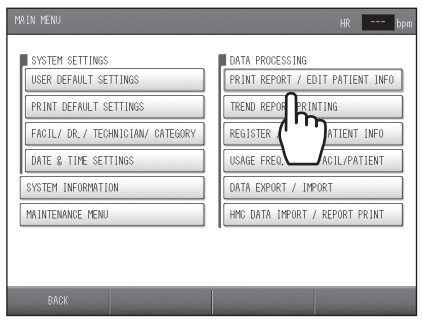
Move to the next page.

Move forward five pages.

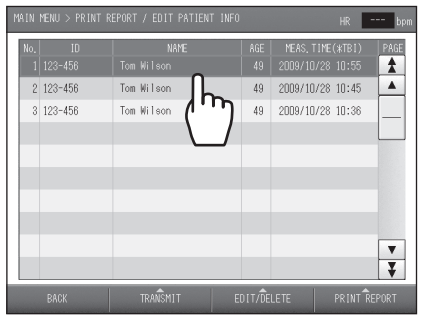
Reprinting Measurement Data

Follow the steps below to only reprint measurement data. A specified range of measurement data of multiple patients can be printed in one operation.
Select [MAIN MENU] on the initial screen. Reprint from "Print report / Edit Patient Info".

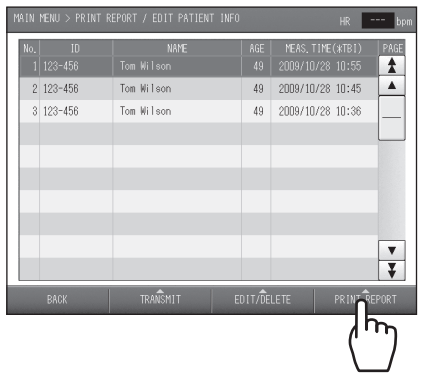
1. Select [PRINT REPORT / EDIT PATIENT INFO].



2. Select the first measurement data that you wish to reprint.

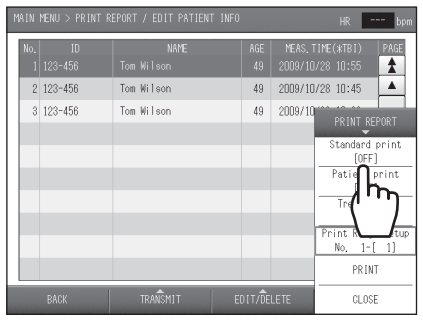


3. Select [PRINT REPORT].

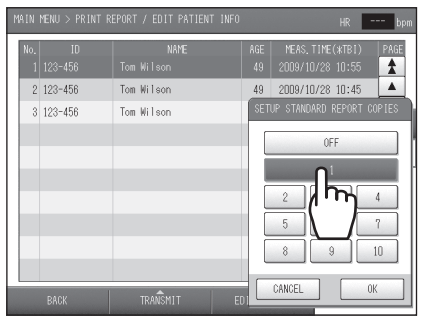


4. Check / change the number of copies to be printed.

1) Select the report for which you wish to change the number of copies printed. If no change is needed, go to step 5.



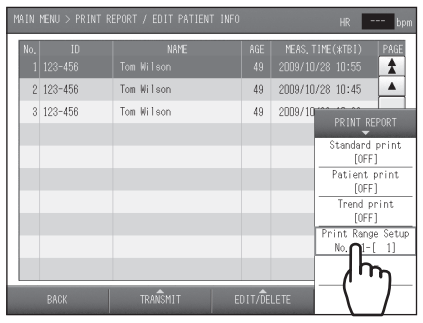
2) Select the number of copies to be printed.



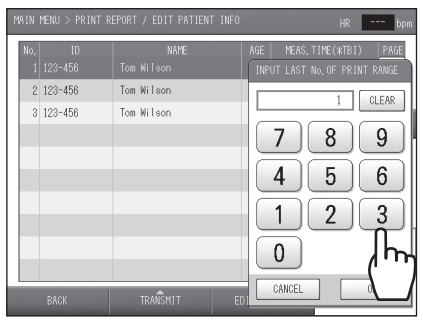
3) Select [OK].
To cancel, select [CANCEL].

4) Repeat steps 1) to 3) as needed to change the number of copies of other reports.

5. Select [Print Range Setup].



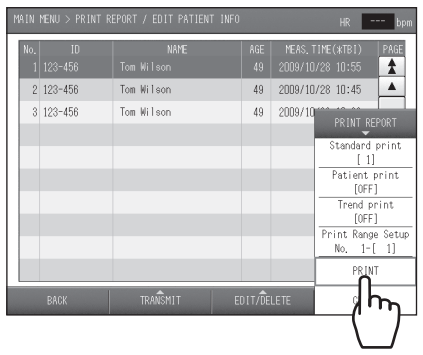
6. Enter the number of pages for the last measurement data that you wish to reprint.



7. Select [OK].

To cancel, select [CANCEL].

8. Select [PRINT].



9. Select [OK].

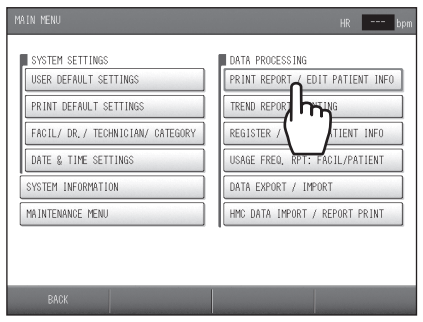
To cancel printing, select [CANCEL].

> **Note:**
> To cancel printing after it has begun, select [CANCEL] or press the [STOP] button on the device.

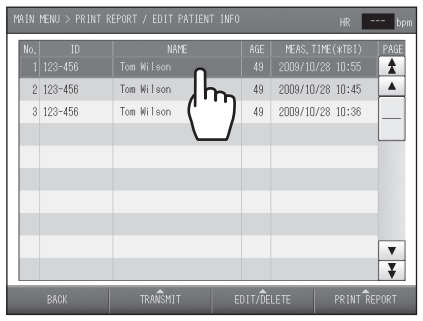
Editing Patient Information

Select [MAIN MENU] on the initial screen. Edit patient information from "Print report / Edit Patient Info".

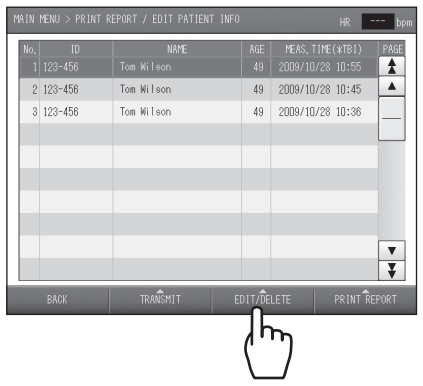
1. Select [PRINT REPORT / EDIT PATIENT INFO].



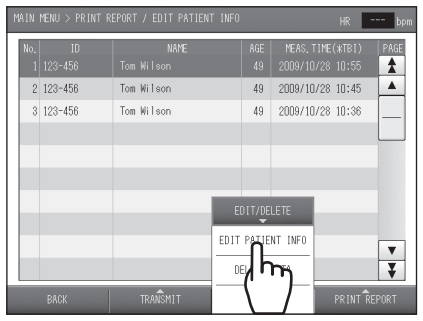
2. Select the patient information that you wish to edit.



3. Select [EDIT/DELETE].

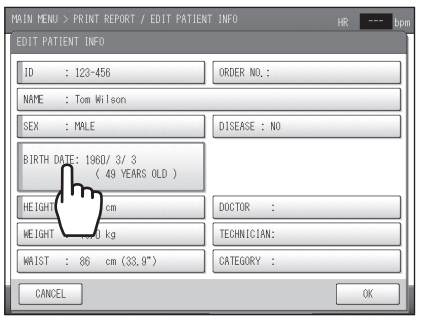


4. Press [EDIT PATIENT INFO].



5. Select the item and edit it.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (refer to page 25).



6. Select [OK].

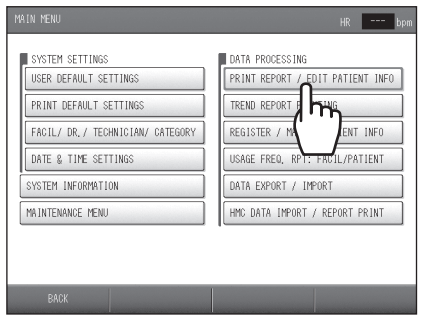
To cancel editing, select [CANCEL].

7. Select [BACK].

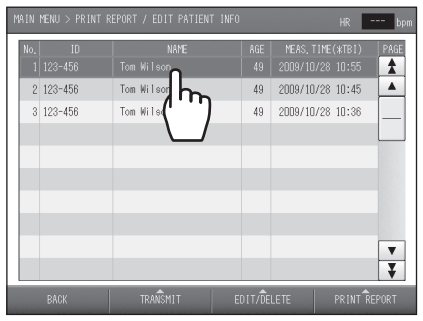
Deleting Measurement Data

Select [MAIN MENU] on the initial screen. Delete measurement data from "Print report / Edit Patient Info".

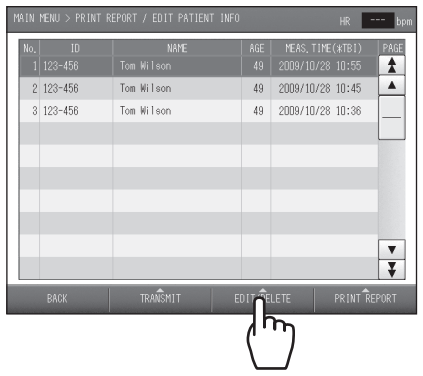
1. Select [PRINT REPORT / EDIT PATIENT INFO].



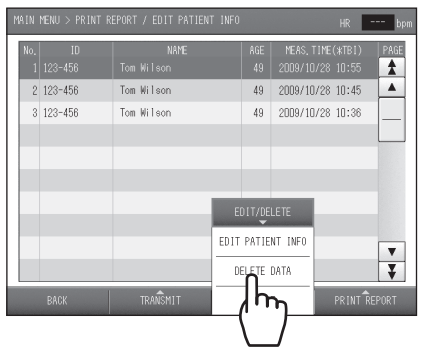
2. Select the measurement data that you wish to delete.



3. Select [EDIT/DELETE].

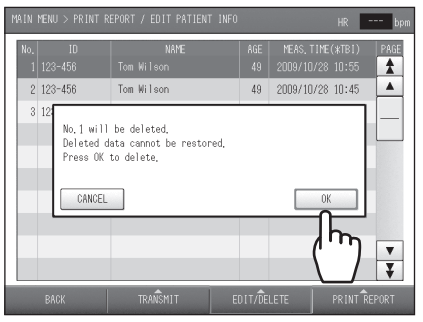


4. Press [DELETE DATA].



5. Select [OK].

To cancel the deletion, select [CANCEL].



6. Select [BACK].

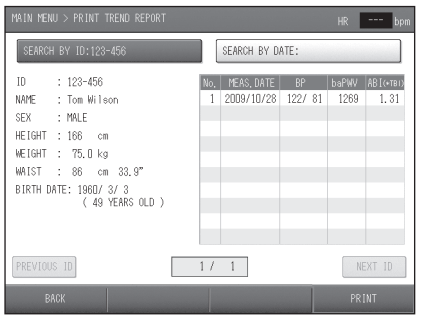
Note:
Deleted data cannot be restored.

3-7. Printing a Trend Report

A trend report showing trends in patient's measurement data can be printed. The patient data to be printed can be searched for by ID number or by date of measurement.

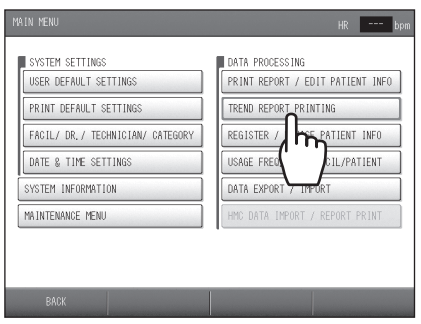
Select [MAIN MENU] on the initial screen. Perform "Trend Report Printing" from the main menu screen.

> **Note:**
> Data marked with "＊" at the right of the date and time of measurement is TBI (Toe Brachial Index) data. TBI can be measured when the TBI package is installed. If the TBI package is installed, read the manual for the package.

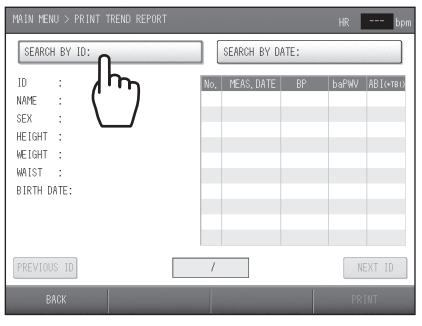


Searching by ID number

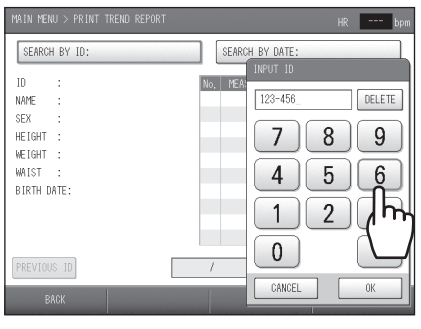
1. Select [TREND REPORT PRINTING].



2. Select [SEARCH BY ID].



3. Enter the ID number.



4. Select [OK].

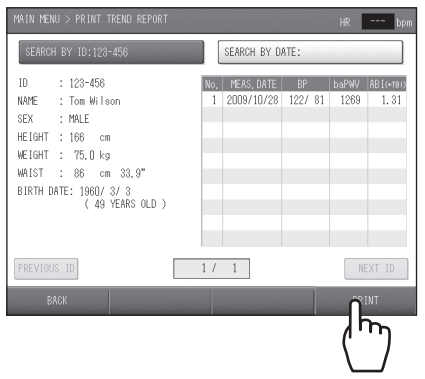
To cancel, select [CANCEL].

Note:
You can search for an ID number by entering just the initial digits of the number; it is not necessary to enter all digits. If there are multiple matches for the entered number, scroll through the IDs as follows:

- Select [PREVIOUS ID] to show the previous ID.

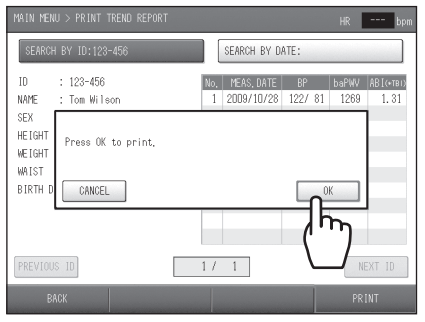
- Select [NEXT ID] to show the next ID.

5. Select [PRINT].



6. Select [OK].

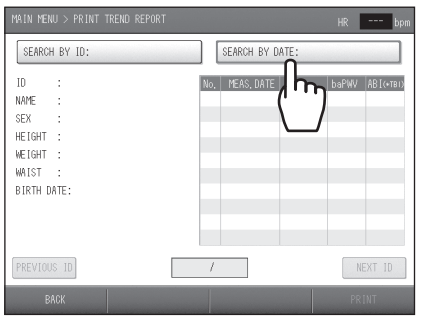
To cancel printing, select [CANCEL].



Searching by date of measurement

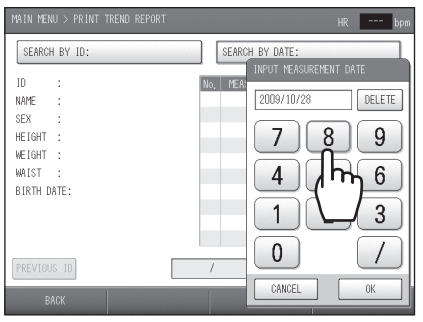
1. Select [TREND REPORT PRINTING].

2. Select [SEARCH BY DATE].



3. Enter the date of measurement.

Enter the date in the date format of "YYYY/MM/DD".



4. Select [OK].

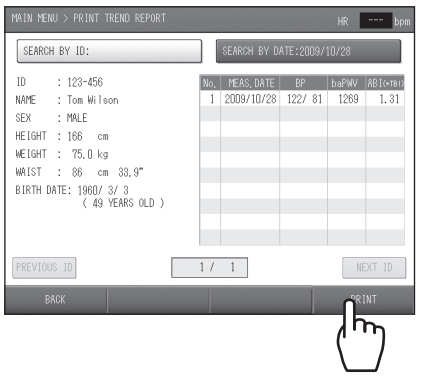
To cancel, select [CANCEL].

Note:
When there are multiple sets of data with the same date, scroll through the data as follows.

- Select [PREVIOUS ID] to show the previous ID.

- Select [NEXT ID] to show the next ID.

5. Select [PRINT]

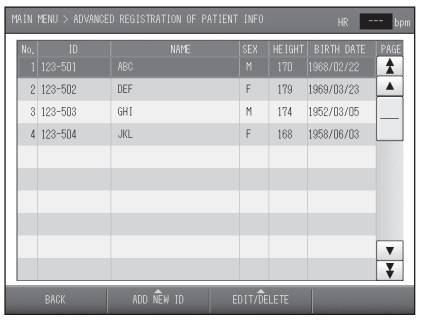


6. Select [OK].

To cancel printing, select [CANCEL].

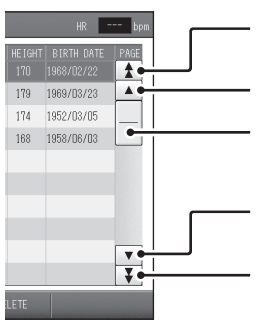
3-8. Advanced Registration of Patient Information

When there are many patients, patient information can be stored in advance. Information can also be edited and deleted.



Notes:

- When measurement is finished, the pre-registered patient information is removed from the pre-registered patient list.
- The scroll bar that appears on the right side of the screen when the pre-registered patient list appears is used as explained below.



Selecting the Method for Registration

There are two methods for registering patient information in advance.

A Import a text file

B Input with the touch screen

In method A, the patient information is prepared in advance on a computer and the information is imported into the device. Data that has been imported into and stored in the device can be individually edited or deleted at the touch screen. Method B allows easy and immediate registration, editing, and deletion of data.

Registration Procedure

Select [MAIN MENU] on the initial screen. Register patient information from the main menu screen.

A. Importing a text file

1. You will need a USB flash drive to transfer files.

2. Create the data on a computer.

The import file is as follows:

- Data format: comma-delimited text file*1
- File name: PATIENT.CSV

Each patient record includes the following data:

1. ID: Letters (upper case) and numbers, hyphens (-); 13 character maximum
2. Name: letters and spaces only, 40 character maximum
3. Sex: Code input; female = 0, male = 1
4. Birth date: YYYY/MM/DD (leading zeros, eg., 1/1 instead of 01/01, can be omitted)
5. Height: 120 to 210, units = cm
6. Weight: 25.0 to 300.0, units = kg
7. Waist: 30 to 250, units = cm
8. Disease: Code input*2, in one-byte character
9. Measurement site: Code input*2, 1 one-byte character
10. Doctor: Character type same as for Name
11. Technician: Character type same as for Name
12. Category: Character type same as for Name
13. Order number: Letters and numbers, 20 character maximum; optional, but even if unused, the comma after the Category must remain

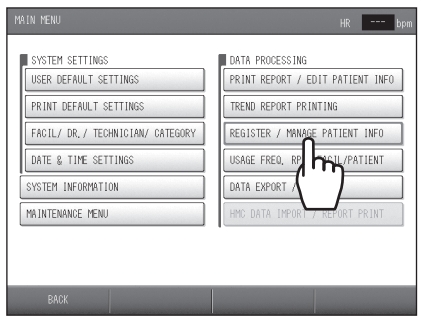
*1 To use an XML file, consult a dealer or an Omron Healthcare technical support.

*2 Code Table (refer to page 107)

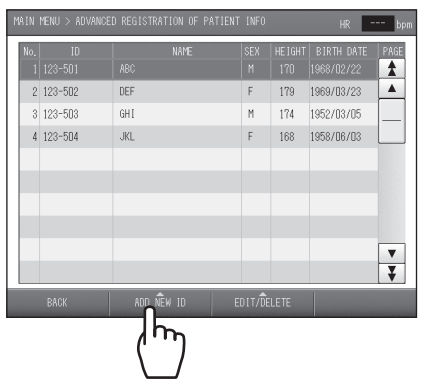
```
A-123, ABC,1, 1955/6/7, 168, 61.2, 85, 3, 4, GHI, , Internal, 1234-5
A-124, DEF, 0, 1947/11/02, 158, 52, 68, 0, A, JKL, , Internal, 1234-6
```

3. Save the created data to a USB flash drive and insert the flash drive in the USB port on the device.

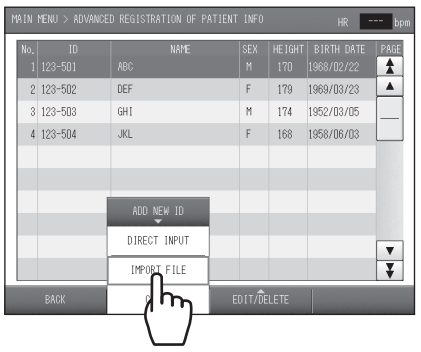
4. Select [REGISTER / MANAGE PATIENT INFO].



5. Select [ADD NEW ID].

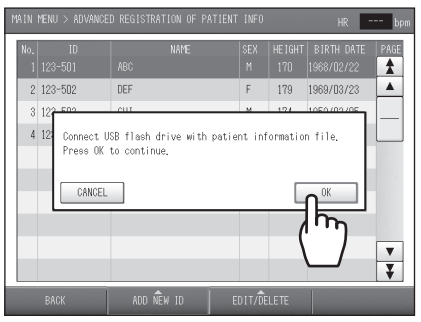


6. Press [IMPORT FILE].



7 Select [OK].

- If previously registered data exists, the new data is added to that data.
- To cancel the import, select [CANCEL].



8. Select [BACK].

Table of Codes for Disease

Code	Description
0	None
1	Hypertension
2	Hyperlipidemia
3	Diabetes
4	Hypertension + diabetes
5	Hyperlipidemia + diabetes
6	Hypertension + Hyperlipidemia
7	Hypertension + Hyperlipidemia + diabetes

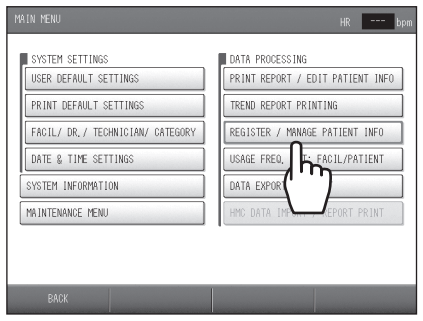
Table of Codes for Measurement Sites

Code	Measurement sites*3
0	Right brachium + both ankles
1	Right brachium + right ankle
2	Right brachium + left ankle
3	Right brachium
4	Both brachia + both ankles
5	Both brachia + right ankle
6	Both brachia + left ankle
7	Both brachia (cannot be specified)
8	Left brachium + both ankles
9	Left brachium + right ankle
A	Left brachium + left ankle
B	Left brachium

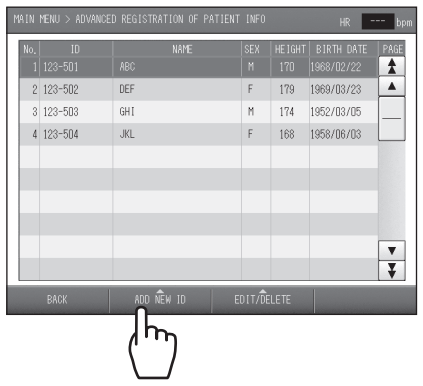
*3 "Toe" cannot be specified as a measurement site.

B. Input with the touch screen

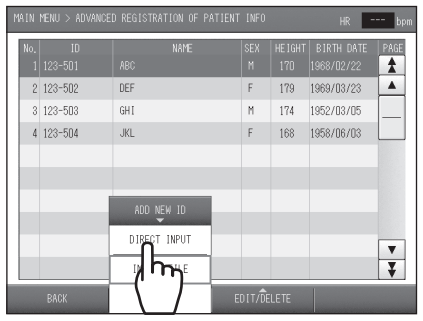
1. Select [REGISTER / MANAGE PATIENT INFO].



2. Select [ADD NEW ID].



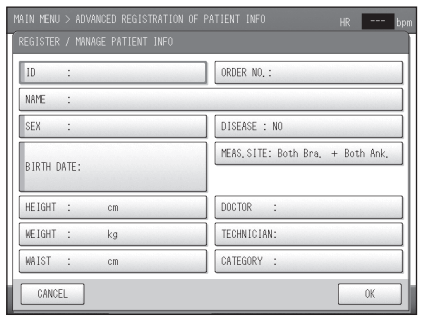
3. Press [DIRECT INPUT].



4. Select each item and enter the information.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (page 25).

It is not necessary to enter [HEIGHT] for Advanced Registration of Patient Information.



5. Select [OK].

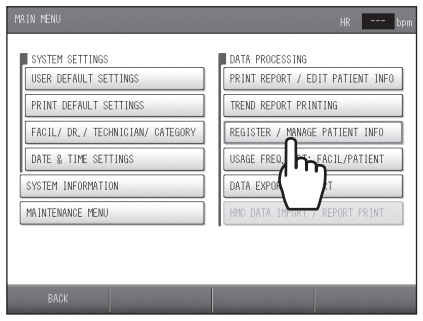
To cancel the information entered, select [CANCEL].

6. Select [BACK].

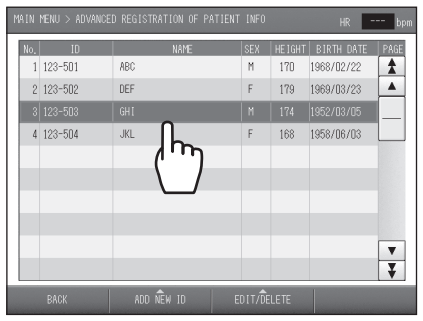
Editing Patient Information

Select [MAIN MENU] on the initial screen. Patient information can be edited from "Register / Manage patient info".

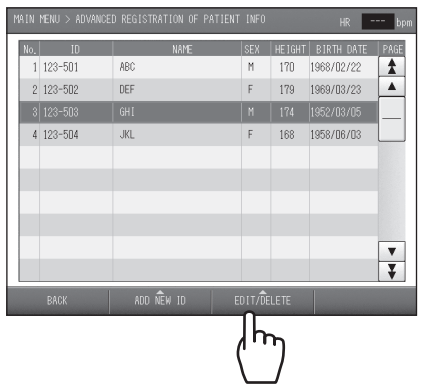
1. Select [REGISTER / MANAGE PATIENT INFO].



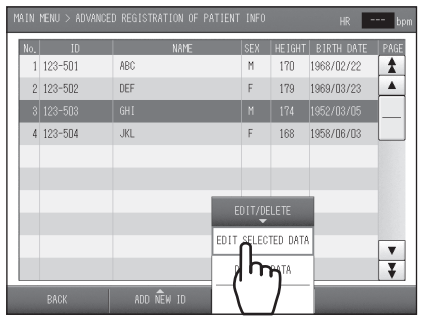
2. Select the patient information that you wish to edit.



3. Select [EDIT/DELETE].

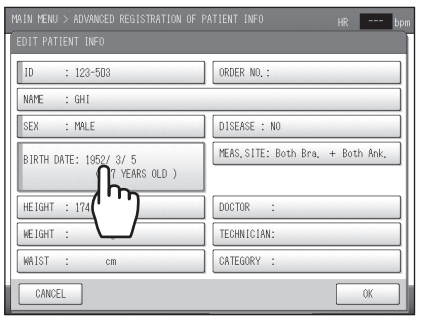


4. Press [EDIT SELECTED DATA].



5. Select the item that you wish to edit, and edit it.

For details on each item and editing procedures, see "Entering and Editing Patient Information" (page 25).



6. Select [OK].

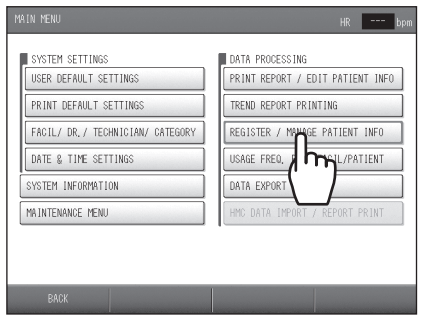
To cancel editing, select [CANCEL].

7. Select [BACK].

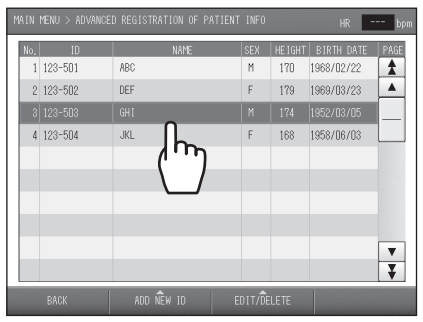
Deleting Patient Information

Select [MAIN MENU] on the initial screen. Patient information can be deleted from "Register / Manage patient info".

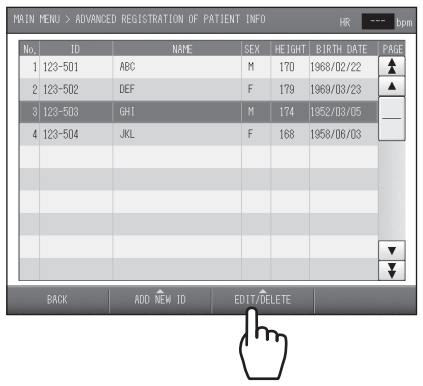
1. Select [REGISTER / MANAGE PATIENT INFO].



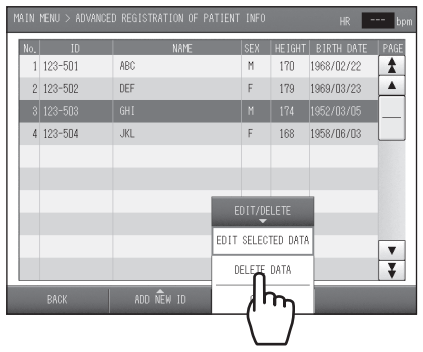
2. Select the patient information that you wish to delete.



3. Select [EDIT/DELETE].

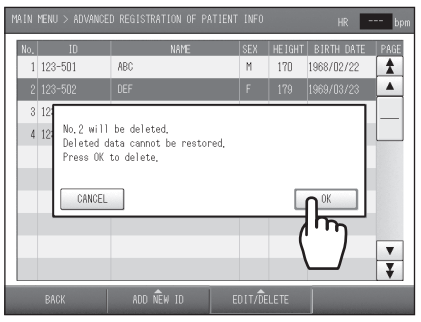


4. Press [DELETE DATA].



5. Select [OK].

To cancel the deletion, select [CANCEL].



6. Select [BACK].

Note:
Deleted information cannot be restored.

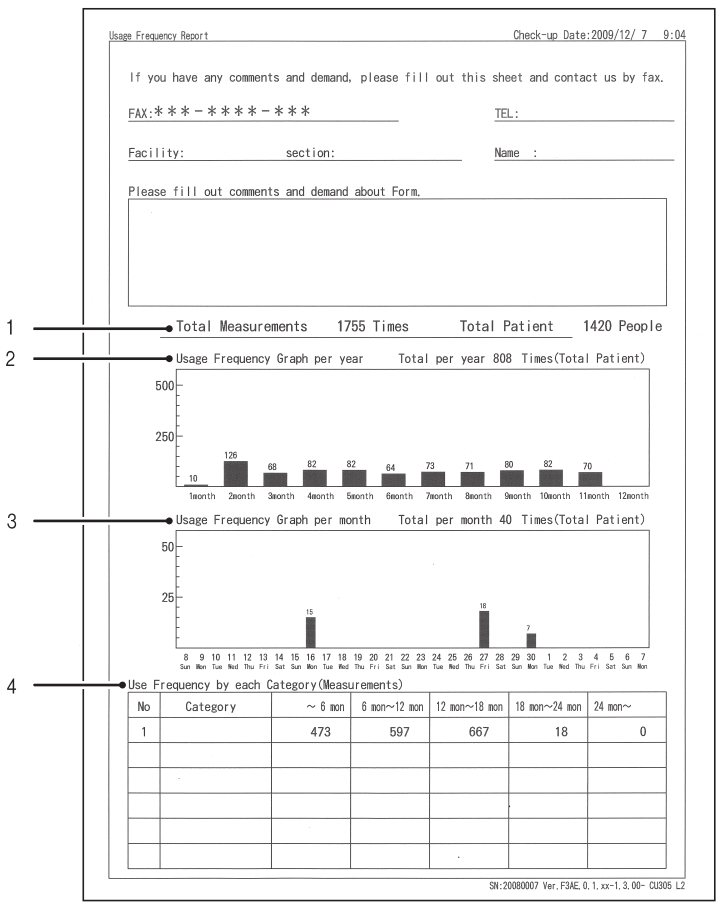
3-9. Printing Usage Frequency / Facility Patient Reports

Usage frequency and facility patient reports can be printed.

Types of Reports

Usage Frequency Report

This function lets you to check past usage frequency.

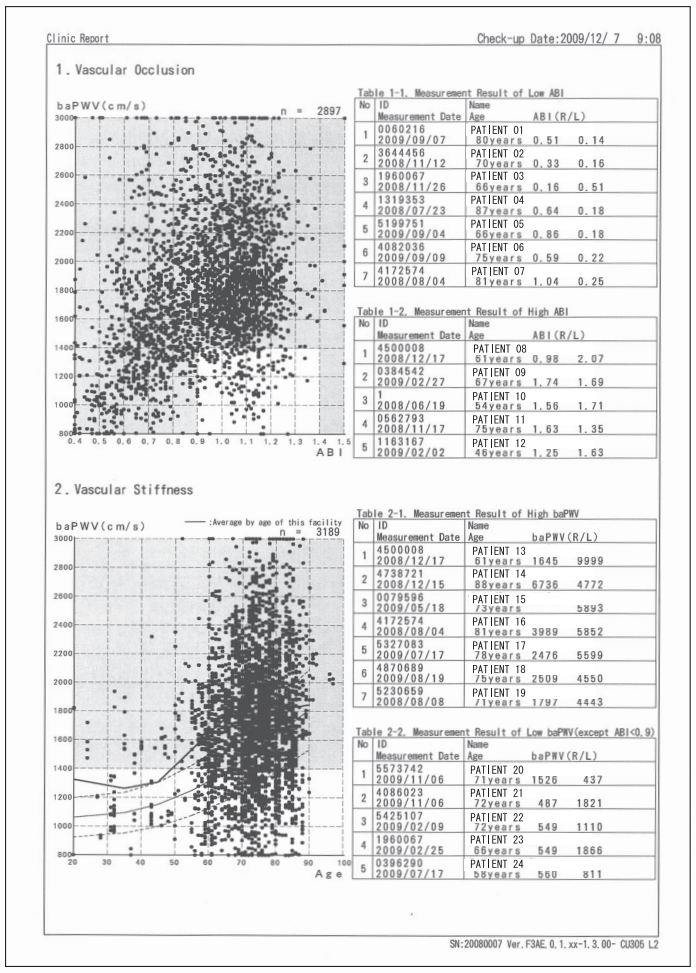


1	Total times / Total patients	Prints the total number of measurements performed and the total number of patients.
2	One-year usage frequency graph	This graphs the frequency of use by month over the past 12 months.
3	One-month usage frequency graph	This graphs the frequency of use by day over the last month.
4	Category usage frequency	This shows usage by category (refer to page 39).

Facility Patient Report

ABI and baPWV can be extracted from the recorded measurement data and shown as a graph.

- High measured value data are printed followed by low measured value data.
- Mean values of baPWV are calculated over 10-year intervals and shown as a mean-value line.



Clinic Report Check-up Date:2009/12/ 7 9:08

1. Vascular Occlusion

baPWV(cm/s) n = 2897

ABI

Table 1-1. Measurement Result of Low ABI

No	ID / Measurement Date	Name / Age	ABI(R/L)	
1	0060216 2009/09/07	PATIENT 01 80years	0.51	0.14
2	3644456 2008/11/12	PATIENT 02 70years	0.33	0.16
3	1960067 2008/11/26	PATIENT 03 66years	0.16	0.51
4	1319353 2008/07/23	PATIENT 04 87years	0.64	0.18
5	5199751 2009/09/04	PATIENT 05 66years	0.86	0.18
6	4082036 2009/09/09	PATIENT 06 75years	0.59	0.22
7	4172574 2008/08/04	PATIENT 07 81years	1.04	0.25

Table 1-2. Measurement Result of High ABI

No	ID / Measurement Date	Name / Age	ABI(R/L)	
1	4500008 2008/12/17	PATIENT 08 61years	0.98	2.07
2	0384542 2009/02/27	PATIENT 09 67years	1.74	1.69
3	1 2008/06/19	PATIENT 10 54years	1.56	1.71
4	0562793 2008/11/17	PATIENT 11 75years	1.63	1.35
5	1163167 2009/02/02	PATIENT 12 46years	1.25	1.63

2. Vascular Stiffness

baPWV(cm/s) —— :Average by age of this facility n = 3189

Age

Table 2-1. Measurement Result of High baPWV

No	ID / Measurement Date	Name / Age	baPWV(R/L)	
1	4500008 2008/12/17	PATIENT 13 61years	1645	9999
2	4738721 2008/12/15	PATIENT 14 88years	6736	4772
3	0079596 2009/05/18	PATIENT 15 73years		5893
4	4172574 2008/08/04	PATIENT 16 81years	3989	5852
5	5327083 2009/07/17	PATIENT 17 78years	2476	5599
6	4870689 2009/08/19	PATIENT 18 75years	2509	4550
7	5230659 2008/08/08	PATIENT 19 71years	1797	4443

Table 2-2. Measurement Result of Low baPWV(except ABI<0.9)

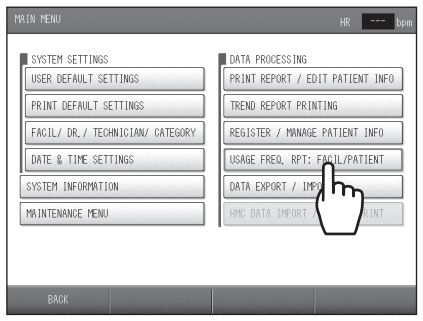
No	ID / Measurement Date	Name / Age	baPWV(R/L)	
1	5573742 2009/11/06	PATIENT 20 71years	1526	437
2	4086023 2009/11/06	PATIENT 21 72years	487	1821
3	5425107 2009/02/09	PATIENT 22 72years	549	1110
4	1960067 2009/02/25	PATIENT 23 66years	549	1866
5	0396290 2009/07/17	PATIENT 24 59years	550	811

SN:20080007 Ver.F3AE.0.1.xx-1.3.00- CU305 L2

Printing Usage Frequency / Facility Patient Reports

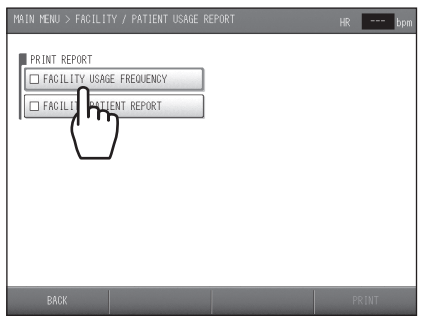
Select [MAIN MENU] on the initial screen.

1. Select [USAGE FREQ. RPT: FACIL / PATIENT].

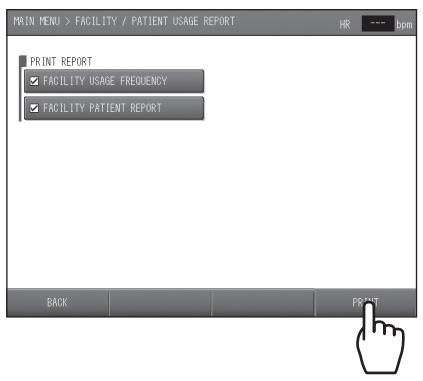


2. Select the report that you wish to print.

You can select multiple reports.

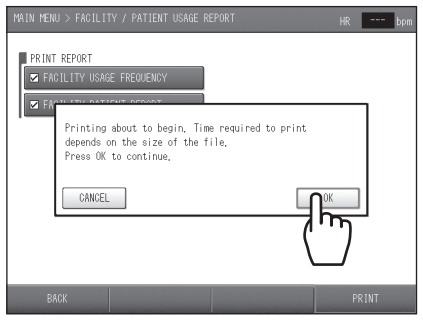


3. Select [PRINT].



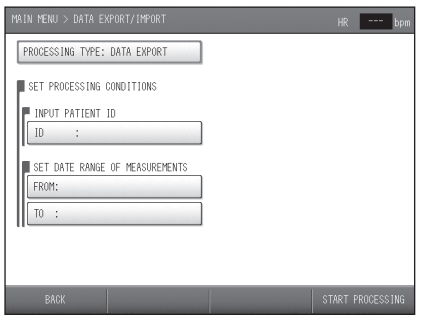
4. Select [OK].

To cancel printing, select [CANCEL].



3-10. Data Export / Import (USB Flash Drive)

Measurement data can be exported to USB flash drive and imported from USB flash drive. Select [MAIN MENU] on the initial screen. Select [DATA EXPORT/IMPORT] from the main menu screen.



Data Processing Items

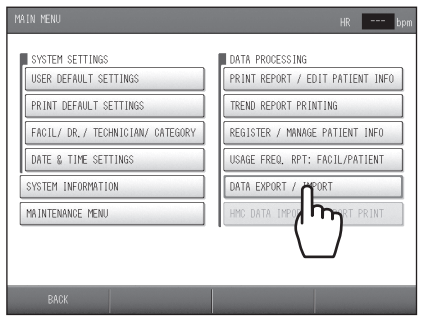
Processing category	Description
DATA EXPORT	Export measurement data to a USB flash drive.
DATA IMPORT	Import measurement data from a USB flash drive
DATA EXPORT (FORMER UNIT)	Export measurement data in the BP-203RPE or BP-203RPEⅡ data format to a USB flash drive.
DATA IMPORT (FORMER UNIT)	Import BP-203RPE and BP-203RPEⅡ data. This is only possible for Ver. CX002 or later.

Data Processing Procedure

Three items are set in order to perform data export and import processing, however, processing is possible without setting these items. Processing is as follows depending on whether or not the items are specified:

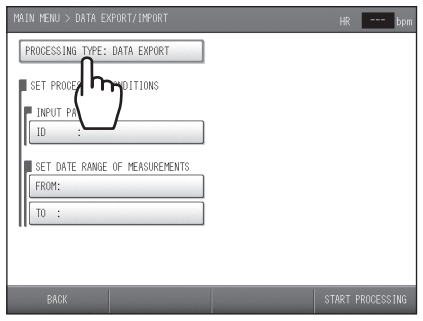
Items	Specified yes/no	
	Yes	No
ID	Only data of specified IDs are processed	All data are processed
FROM:	Data from the specified date and later are processed	All data are processed
TO:	Data prior to the specified date are processed	All data are processed

1. Select [DATA EXPORT / IMPORT].

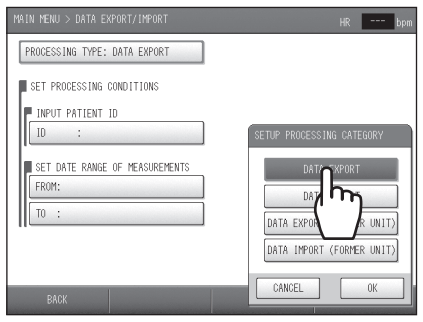


2. Set the processing type.

1. Select [PROCESSING TYPE].



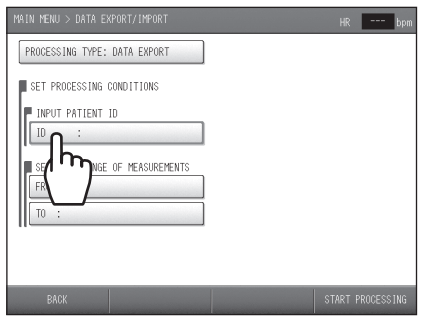
2. Select the desired "processing type".



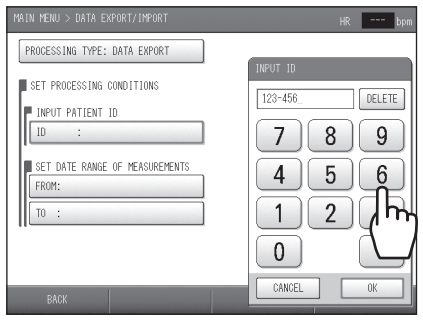
3. Select [OK].
   To cancel, select [CANCEL].

3. Specify the conditions for the data to be processed.

1. Select [ID].



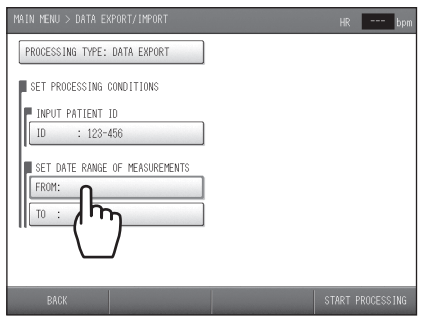
2. Enter the ID number.



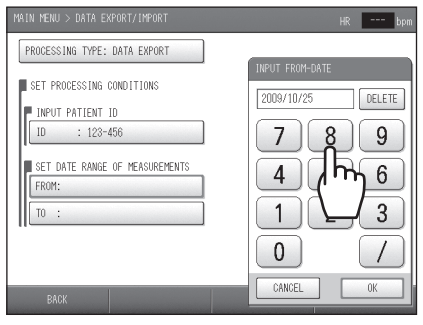
3. Select [OK].
   To cancel, select [CANCEL].

4 Specify the data range of measurements.

1. Select [FROM].



2. Enter the starting date in the format "YYYY/MM/DD".



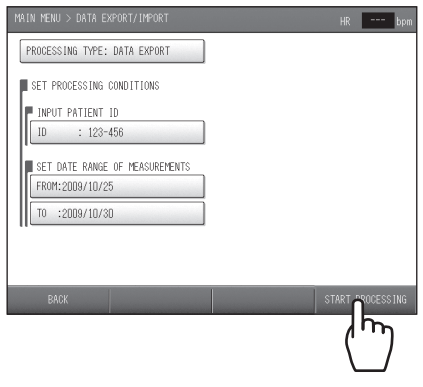
3. Select [OK].
   To cancel, select [CANCEL].

4. Select [TO].

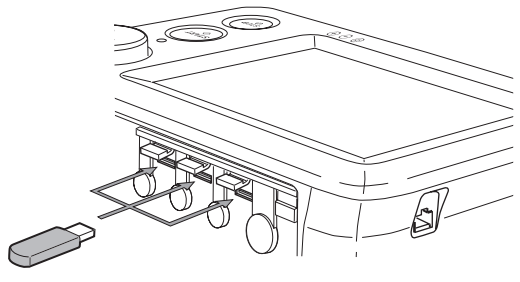
5. Enter the ending date in the format "YYYY/MM/DD".

6. Select [OK].
   To cancel, select [CANCEL].

5. Select [START PROCESSING].

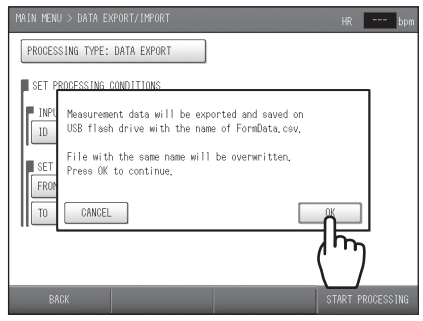


6. Insert the USB memory stick into the USB port on the device.



7. Select [OK].

To cancel processing, select [CANCEL].



The displayed message varies depending on the processing.

3-11. Transferring Report Data to a Computer

The separately sold special LAN cable can be connected to the device to send measurement report data to a computer. Please consult a dealer or an Omron Healthcare technical support representative to configure network settings to enable use of this function.

Types of reports that can be exported to a computer:

- Standard Reports
- Patient Reports
- Trend Reports

4. Options

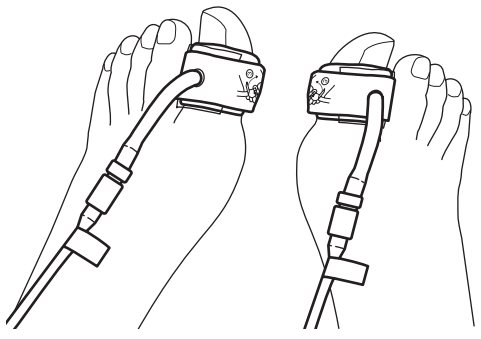
4-1. Options

Read the manual that accompanies each optional package or unit to ensure correct use of the option.

TBI Package

TBI (Toe Brachial Index) can be calculated by installing the TBI package. It also measures toe systolic blood pressure, TBI (Toe Brachial Index) and toe pulse waveform. The results are useful for the following:

- When disease is suspected in the foot below the ankle (heel, top of foot, bottom of foot).
- When ankle blood pressure is high due to diabetic arteriosclerosis (calcification) or other reason (calcification tends not to extend to peripheral areas).



Measurable items

Toe systolic blood pressure (maximum blood pressure)

Measurement range: 40 mmHg - 260 mmHg (However, in the vicinity of 40 mmHg, fluctuations of about ±10 mmHg may occur due to pulse amplitude.)

TBI (Toe Brachial Index)

TBI = Toe systolic pressure / brachial systolic pressure (higher of left and right pressures)

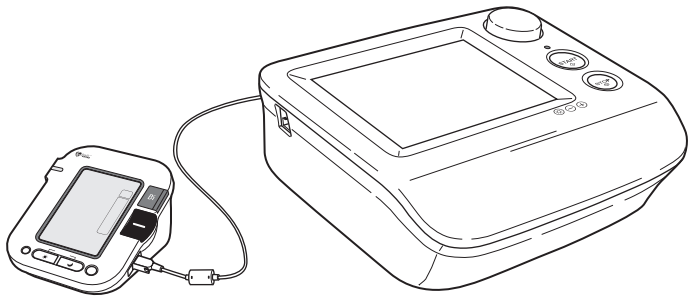
(The TBI of a healthy person is generally 0.7 or higher; a TBI of less than 0.7 may indicate a pathological change.)

Toe pulse waveform (PVR)

Pulse waveform is displayed when a constant pressure is applied to the toe cuff.

HMC package

The HMC Package is a system that enables measurement data to be imported from a home digital blood pressure monitor, pedometer, or body composition monitor. Imported data can be printed on the trend chart together with measurement results from the main unit.



Data to be imported

Measurement device	Data item
Blood pressure monitor	Systolic blood pressure value, diastolic blood pressure value, pulse rate, date and time of measurement
Pedometer	Total steps in one day, date of measurement
Body composition monitor	Weight, date of measurement

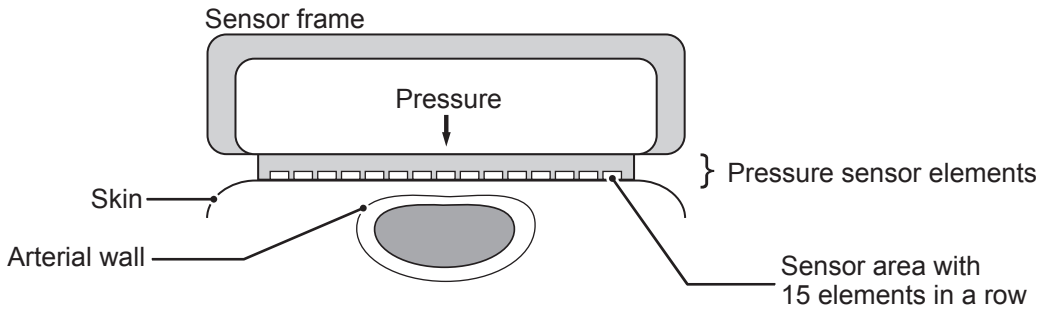
* Contact a dealer or an Omron Healthcare technical support representative for more information.

Pulse Wave Unit TU-100 and CAP/FAP Sensor Unit

The TU-100 and CAP/FAP Sensor Unit use tonometry to measure pulse waveforms. This device supports the diagnosis of artery flexibility and level of arterial stiffness with measurement results of PWV on the carotid artery and aorta, neck region AI, and pulse wave recording.

Pulse wave detection

In tonometry, the pressure pulse wave sensor presses on the skin to flatten the arterial wall, and consequently the pressure inside the artery is directly detected by the pressure sensor. The pressure sensor is a multi-element sensor that contains a row of 15 sensor elements. The device analyzes the signal from the pressure sensor and selects the sensor elements that are in the optimum position. The pulse wave measured with the signals from the elements are used in analysis.



Bar Code Reader Set

When clinical charts or registration tickets have a bar code, it can be used to obtain patient information. Consult a dealer or an Omron Healthcare technical support representative beforehand to confirm that the bar code reader can be used.

initial screen :
ID number entry

5. Maintenance

5-1. Routine Maintenance

⚠ **Warning**	• After cleaning the device, dry it completely before turning on the power again. Otherwise electric shock or current leakage may result. • Use only the specified supplies for the cord, cuff, and other parts. Do not install other than specified options. An accident may result.
⚠ **Caution**	• Before cleaning or maintaining the device, disconnect the power plug. Otherwise electric shock or injury may result. • The ECG clip electrode and PCG sensor pad are disposable supplies. Do not reuse them once they are removed. If they have been applied on moist, injured or infected skin, dispose them right after use. Otherwise an infection may result.

Regular maintenance will maximize the service life of the device. Routine maintenance procedures and supplies are explained below.

Maintenance Procedures

Main Unit

Note:
Do not wipe the ports on the back of the unit.

To clean the surface of the main unit, use a damp cloth moistened with a neutral detergent or disinfectant alcohol.

Cuffs

Note:
Dispose of dirty or old cuffs as medical waste. Do not recycle.

To clean parts that come in direct contact with the skin, use a damp cloth moistened with a diluted disinfectant alcohol. For other parts, simply remove foreign objects and dust; do not wipe with alcohol or water.

ECG clips / PCG sensor / air hoses

Note:
Keep ECG clip electrodes and PCG sensor pads out of direct sunlight and away from high temperatures and high humidity. Store them at room temperature (10 to 35˚C).
If the electrodes are dry, accurate measurement may not be possible.

Wipe with a damp cloth moistened with 30 - 50% isopropyl alcohol, 70% ethyl alcohol, or a neutral detergent.

Supplies

Note:
Dispose of ECG clip electrodes and PCG sensor pads as medical waste after use.

Keep an adequate amount of supplies. Use the model number when ordering supplies.
Refer to "Accessories (Sold Separately)" (page 15).

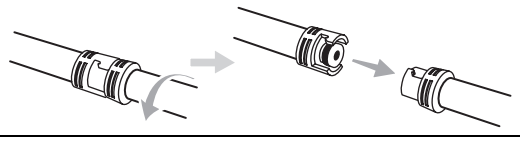
5-2. Replacing Cuffs

⚠ **Caution**	The sensor box removal lever uses a strong spring mechanism. Hold the sensor box firmly and press down hard on the lever from the exterior to remove the connector. This may cause injury with the metal edges.

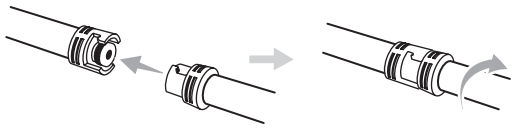
The procedures for disconnecting and connecting the air hose when replacing a soiled, old, or unusable cuff with a new cuff or changing the cuff to a different size cuff is explained below.

Replacing an Arm Cuff

1. Rotate the air hose connector counterclockwise to disconnect the hose from the cuff.



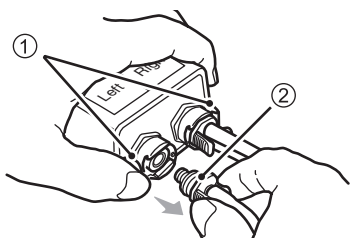
2. Insert the connector on the new cuff into the air hose. Rotate the connector clockwise until it clicks into place.



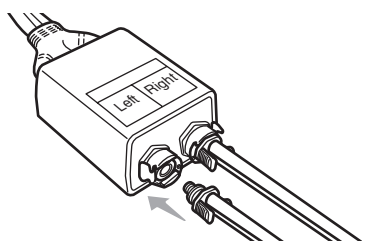
Replacing an Ankle Cuff

1. Squeeze the removal levers ① on the sensor box and remove each cuff connector ②.

The levers are small and slippery.
Squeeze the levers firmly.



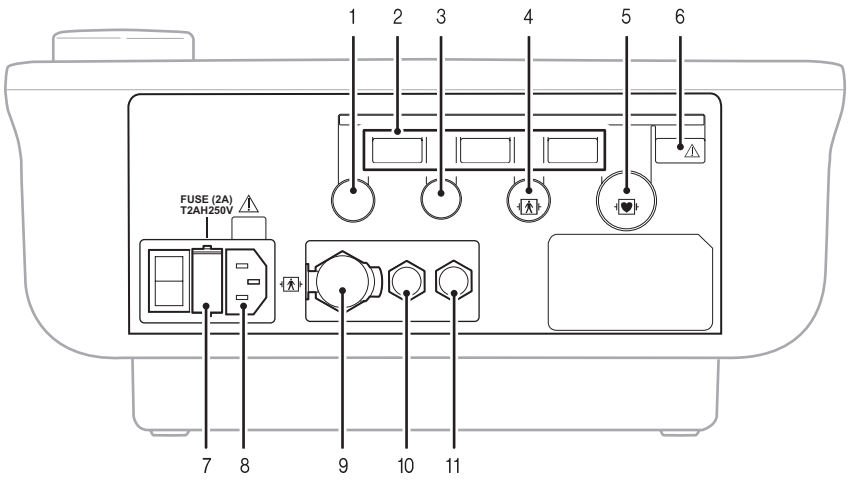
2. Insert each connector on the new cuff into the sensor box until it clicks into place.



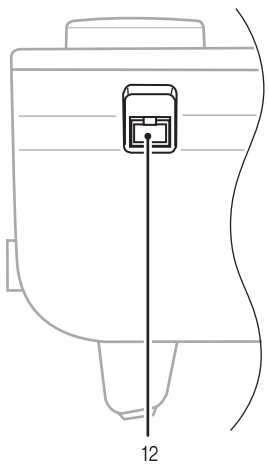
5-3. Connections

Connectors on the Device

Back



Left side



1. **Sensor box connector**

2. **USB ports**
   HMC Package communication, bar code reader, and USB flash drive can be connected to these ports.

3. **Pulse wave unit TU-100 (option) connector**

4. **PCG sensor connector**

5. **ECG clip connector**

6. **USB printer port**
   Attach the printer to this port marked with ⚠.

7. **Fuse holder / fuse**
   Do not replace the fuses on your own. Electric shock or fire might result.
   - The fuses are specifically designed for this device. Contact a dealer or an Omron Healthcare technical support representative for replacement of the fuses.
     - Fuse model: 5HT-R 2A (BEL FUSE LTD.)

8. **AC connector**
   Connector for the power cord.

9. **Sensor box hose joint**
   Connector for the sensor box air hose.

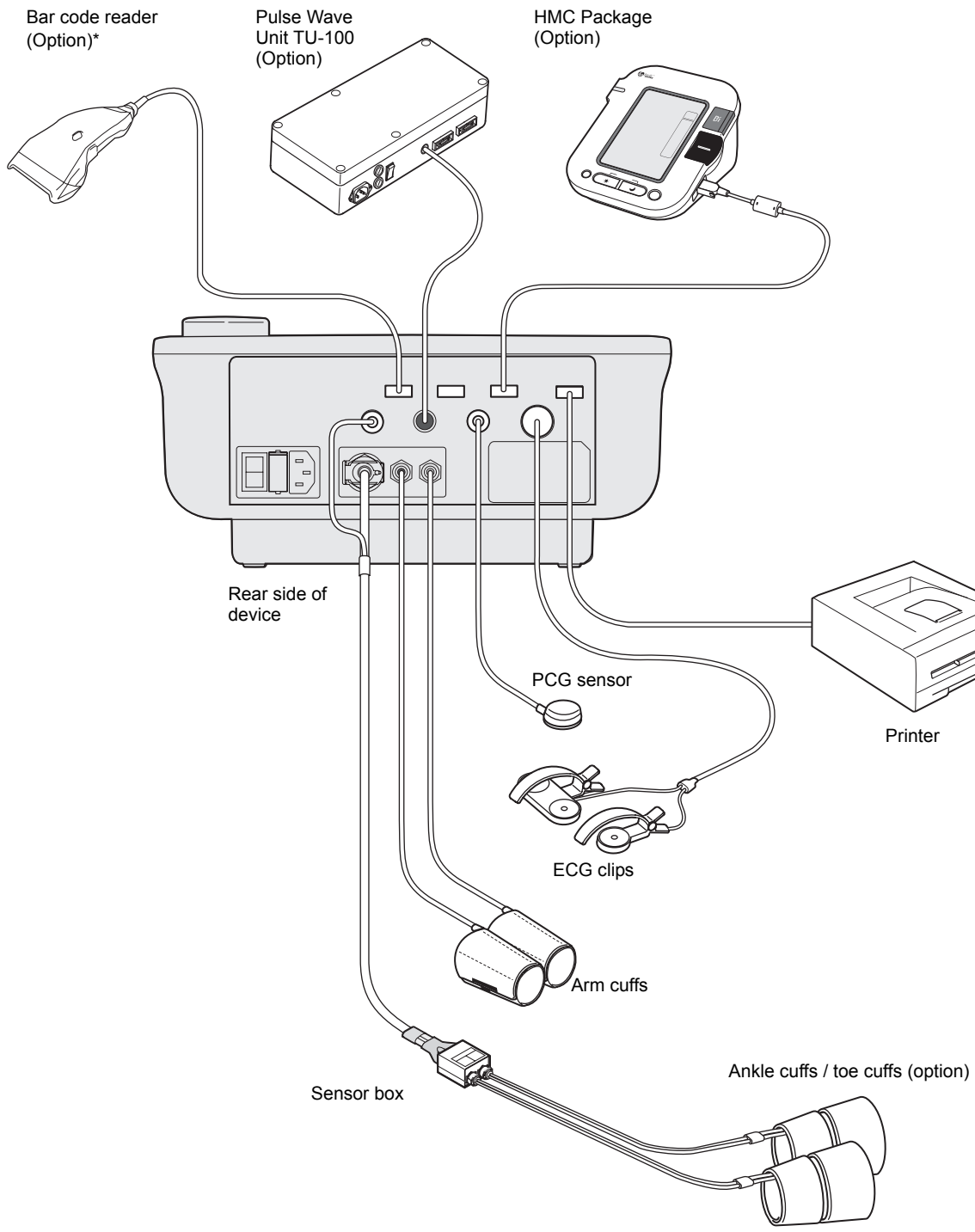
10. **Left arm cuff hose joint**
    Connector for the left arm cuff hose.

11. **Right arm cuff hose joint**
    Connector for the right arm cuff hose.

12. **LAN cable connector**
    A computer can be connected to the device using the approved LAN cable.

Basic Connections

Connect the sensors, options, and printer to the device as shown below.



The appearance of the device is subject to change without notice.

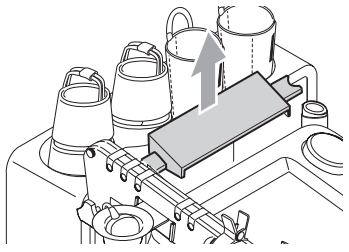
* Verification of bar code content and changing of device settings are required in advance. For more information, consult a dealer or an Omron Healthcare technical support representative.

5-4. Changing the Arm Position

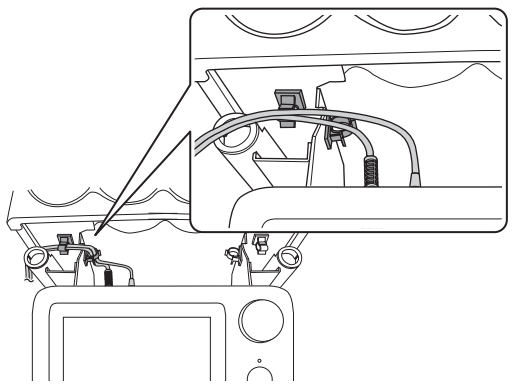
The arm can be attached on either side of the stand, which is more convenient for measurement in the examination environment.

1. Turn off the system power.

2. Remove the cable cover.

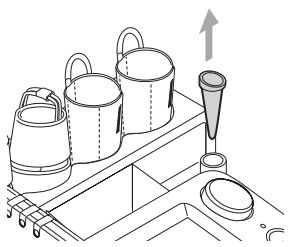


3. Detach the cables (one for the ECG clips and the other for the PCG sensor) from the fasteners behind the main unit.

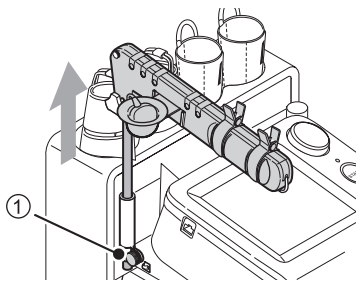


4. Disconnect the ECG clip and the PCG sensor from the connectors on the back of the main unit.

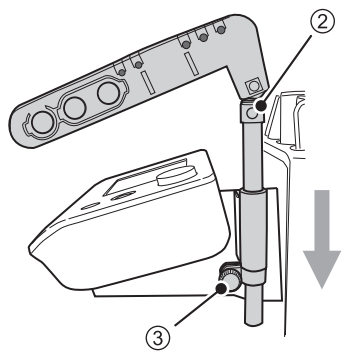
5. Remove the touch pen stand.



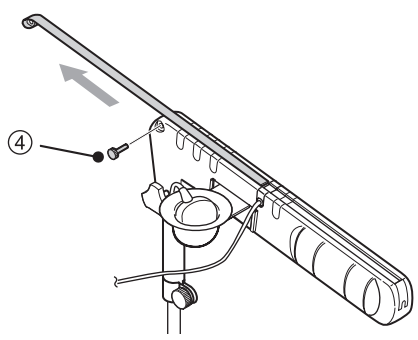
6. Loosen the screw ① and pull out the arm.



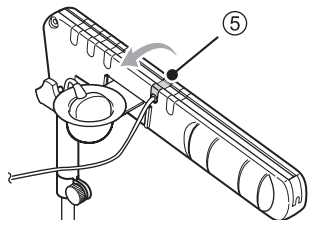
7. Push the arm in so that metal screw ② on the arm will face out, and tighten screw ③.



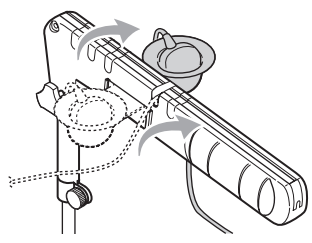
8. Loosen the screw ④ and slide the arm rail off.



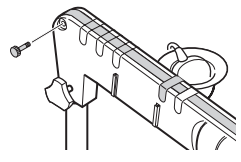
9. Remove the fastener ⑤ for the PCG sensor cable.



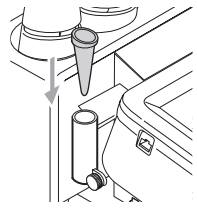
10. Move the PCG sensor cable and the PCG sensor pocket to the outer side.



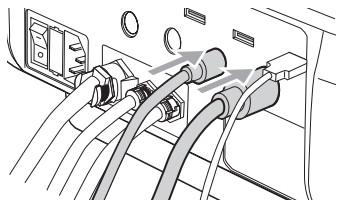
11. Attach the arm rail and PCG sensor cable fastener ⑤, and tighten screw ④.



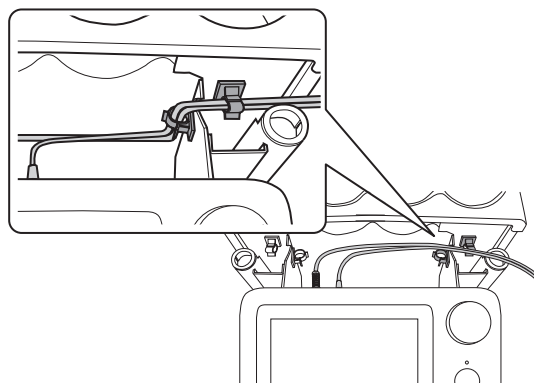
12. Insert the touch pen stand.



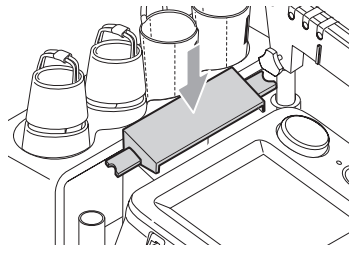
13. Reconnect the ECG clip and the PCG sensor connectors on the back of the main unit.



14. Secure the ECG clip and the PCG sensor cables in the cable notch and fasten the two cable fasteners.



15. Attach the cable cover.



5-5. Handling Errors

If an error occurs while the unit is on, an alarm sounds and an error message appears. If the error still occurs after you follow the instructions in the message, turn off the power and contact a dealer or an Omron Healthcare technical support representative.

Types of Audible Alarms

Audible alarm	Error level	Description
"Beep beep beep (pause) beep beep"	High	The alarm sounds repeatedly. A serious problem has occurred in the device, or an abnormality has occurred in the patient. Measurement cannot be performed in this state. You must check the error.
"Beep beep beep"	Medium	The alarm sounds repeatedly. A problem has occurred that makes measurement difficult. You must check the error.

5-6. Displaying System Information

You can view the device serial number, program version, system configuration, and other information.

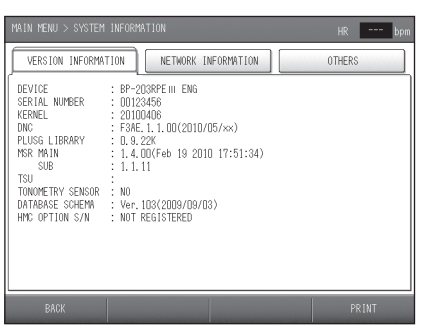
Select [MAIN MENU] on the initial screen (ID entry screen) and select "System Information" from the main menu screen.

When you call a dealer or an Omron Healthcare technical support representative, you may be asked to provide this information.

1. Select [SYSTEM INFORMATION].

2. Select the item that you wish to view.

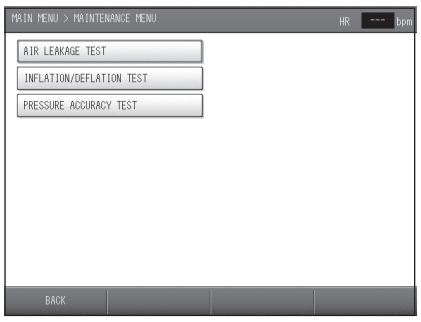
To print the system information, select [PRINT] at the bottom right of the screen.



The content that appears varies depending on the program version and the options that are installed.

5-7. Maintenance Menu

Use the maintenance menu when you perform maintenance and testing. When you contact customer service, you may be asked to perform one of the procedures below.
Select [MAIN MENU] on the initial screen (ID entry screen) and select "Maintenance menu" from the main menu screen to perform testing.



Item	Description
AIR LEAKAGE TEST	Perform this test to check for air leaks in the air system, including the cuffs.
INFLATION / DEFLATION TEST	Use this to check the speed of inflation and deflation of the air system.
PRESSURE ACCURACY TEST	Use this to test the accuracy of pressure detection.

5-8. Specifications

Specifications of BP-203RPEⅢ System (Main unit, TU-100 and Stand)

General:

Name:	Non-invasive Vascular Screening Device System
Model:	BP-203RPEⅢ System
Dimension (W x H x D):	400 x 1060 x 600 mm
Weight:	Approx. 35 kg (excluding printer)
Standards:	IEC60601-1-1 Medical electrical equipment-Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

Power supply:

Rating:	AC 220 - 240 V
Frequency:	50/60 Hz
Power consumption:	1200 VA max (including printer)

Multiple Portable Socket-outlets:

Type:	TDZ-4
Rated current and Voltage:	AC 250 V 16 A
Power outlet number:	4
Power switch type:	Illuminated rocker switch Green clear

Specifications of BP-203RPEⅢ (Main unit)

General:

Name:	Non-invasive Vascular Screening Device
Model:	BP-203RPEⅢ (HFA-RPE3-KOR)
Dimension (W x H x D):	310 x 110 x 270 mm (excluding protrusions)
Weight:	Approx. 4.1 kg
Display part:	
Method	8.4" TFT color LCD
Resolution	640 x 480 pixel
Safety standards:	IEC60601-1 Medical electrical equipment-Part 1: General requirements for safety
Protection class:	Class Ⅱ
Degree of protection:	
NIBP	Type BF with defibrillator protection
ECG	Type CF with defibrillator protection
PCG	Type BF with defibrillator protection
Mode of operation:	Continuous
Other standards:	IEC62304 Medical device software-software life cycle processes ISO14971 Medical devices-Application of risk management to medical devices

Environmental Conditions:

Power supply:	
Rating	AC 100 - 240 V
Frequency	50/60 Hz
Power consumption	150 VA
Fuses	Quantity 2, 250 V, T2AH (Time-lag, High Breaking Capacity (HBC))
Operational temperature/humidity/atmospheric pressure:	
Temperature range	+10 - +40°C
Humidity range	15 - 85% (no condensation)
Atmospheric pressure	700 - 1060 hPa
Storage and transportation temperature/humidity/atmospheric pressure:	
Temperature range	-20 - +60°C
Humidity range	10 - 95% (no condensation)
Atmospheric pressure	500 - 1060 hPa
Dust and water resistance:	Class IPX0 Reference: IEC60529: Degrees of protection provided by enclosures (IP Code)
EMC:	
Reference standard	IEC60601-1-2 Medical electrical equipment-Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Non-invasive Blood Pressure (NIBP):

Measurement method:	Oscillometric method
Measurement technology:	Linear deflation
Pressure display range:	0, 10 - 300 mmHg
Pressure display accuracy:	Less than ±3 mmHg
NIBP Measurement range:	
[Arm]	
SYS	60 - 250 mmHg
MAP	40 - 235 mmHg
DIA	40 - 220 mmHg
Pulse rate	40 - 180 bpm
[Ankle]	
SYS	40 - 250 mmHg
MAP	30 - 235 mmHg
DIA	25 - 220 mmHg
NIBP accuracy:	Mean error and standard deviation per ANSI/AAMI SP-10: Manual, electronic, or automated sphygmomanometers
Usable cuff size:	10 - 15 cm (width of bladder)
Numbers of cuff:	4 Right and Left Brachia, Right and Left Ankles
Reference standards:	IEC60601-2-30 Medical electrical equipment Part 2-30: Particular requirements for safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment

Pulse Wave Velocity (baPWV):

Brachial Ankle Pulse Wave Velocity (baPWV) is measured by the pulse transit time between the brachial pulse wave and the ankle pulse wave.
The distance between those points is calculated from the height of the patient.

ECG:

Lead selection:	I
Display sensitivity:	Variable (Automatic Gain Control 2 - 30 mm/mV) 10 mm/mV at Pacemaker: ON
Display sweep speed:	25 mm/s
Input impedance:	5 M ohm or more
Frequency characteristics:	
HPF	0.1 Hz
LPF	100 Hz
Ham filter	50 or 60 Hz (Automatic selecting filter)
Wave size selection	Automatic selectivity control
R wave detection sensitivity	200 µV or less
Tall T wave rejection	1.0 mV
HR display range	0, 30 - 240 bpm
HR measurements accuracy	±1% or ±1 beat
HR response time:	9 sec or less
HR averaging:	4 beats moving average at HR<120 8 beats moving average at 120 =<HR
HR updating rate:	Every beats
Pacemaker pulse rejection:	Amplitude ±2 - ±700 mV Pulse width 0.1 - 0.7 ms
Reference standards:	IEC60601-2-27 Medical electrical equipment-Part 2: Particular requirements for the safety of Electrocardiographic monitoring equipment

PCG:

Measurement method:	Electret Capacitance Microphone
Display sensitivity:	Variable (Automatic Gain Control)
Display sweep speed:	25 mm/s
Frequency characteristics:	
LPF	300 Hz
Wave size selection	Variable Automatic selectivity control

Specifications of TU-100

General:

Name:	Pulse Wave Unit
Model:	TU-100
Dimension (W x H x D):	294 x 145 x 55 mm
Weight:	Approx. 1.4 kg
Safety standards:	IEC60601-1 Medical electrical equipment-Part 1: General requirements for safety
Protection class:	Class Ⅱ
Degree of protection:	Type BF with defibrillator protection
Mode of operation:	Continuous

Environmental Conditions:

Power supply:	
Rating	AC 230 V
Frequency	50/60 Hz
Power consumption	14 VA
Fuses	250 V, T1AH (Time-lag, High Breaking Capacity (HBC))
Operational temperature/humidity/atmospheric pressure:	
Temperature range	+10 - +40°C
Humidity range	30 - 85% (no condensation)
Atmospheric pressure	700 - 1060 hPa
Storage and transportation temperature/humidity/atmospheric pressure:	
Temperature range	-5 - +50°C
Humidity range	10 - 95% (including condensation)
Atmospheric pressure	500 - 1060 hPa
Dust and water resistance:	Class IPX0 Reference: IEC529 (1989): Degrees of protection provided by enclosures (IP Code)
EMC:	
Reference standard	IEC60601-1-2 Medical electrical equipment Part1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Tonometry:

Measurement method:	Multi semiconductor strain gauge (2ch)
Frequency characteristic:	DC - 300 Hz
Signal output range:	0 - 5.0 V
Sensitivity:	Variable (Automatic Gain Control)

5-9. Guidance and Manufacturer's Declaration

⚠ Warning	Use only the specified supplies for the cord, cuff, and other parts. Do not install other than specified options. Otherwise and accident may result.

The BP-203RPEⅢ is intended for use in the electromagnetic environment specified below. The customer or the user of the BP-203RPEⅢ should assure that it is used in such an environment.

Electromagnetic emissions IEC60601-1-2		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The BP-203RPEⅢ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BP-203RPEⅢ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity IEC60601-1-2			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BP-203RPEⅢ requires continued operation during power mains interruptions, it is recommended that the BP-203RPEⅢ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150 kHz to 80 MHz 80%AM (2Hz) 3 V/m 80 MHz to 2.5 GHz 80%AM (2Hz)	3Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BP-203RPEⅢ, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BP-203RPEⅢ is used exceeds the applicable RF compliance level above, the BP-203RPEⅢ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BP-203RPEⅢ. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the BP-203RPEⅢ

The BP-203RPEⅢ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP-203RPEⅢ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP-203RPEⅢ as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.5GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Cables IEC 60601-1-2		
Cables and Sensors	**Maximum Length**	**Complies with**
AC power cord for Main Unit	0.8 m	- RF emissions, CISPR 11, ClassA / Group 1
AC power cord for Printer	1.1 m	- Harmonic emissions, IEC61000-3-2
LAN cable	10.0 m	- Voltage fluctuations/flicker emission, IEC61000-3-3
USB cable	1.2 m	- Electrostatic discharge (ESD), IEC61000-4-2
Arm Cuff Hose	2.4 m	- Electric fast transient/burst, IEC61000-4-4
Ankle Cuff Hose	0.5 m	- Surge, IEC61000-4-5
ECG lead cable	2.3 m	- Conducted RF, IEC61000-4-6
PCG cable	2.0 m	- Radiated RF, IEC61000-4-3
Sensor cable	3.0 m	
Table-tap	3.5 m	

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potential unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical device.

This medical device manufactured by OMRON Healthcare conforms to this IEC60601-1-2 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- Do not use mobile (cellular) telephones and other devices which generate strong electrical or electromagnetic fields, near the medical device.

This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Further documentation in accordance with IEC60601-1-2 is available at OMRON Healthcare at the address mentioned in this instruction manual.

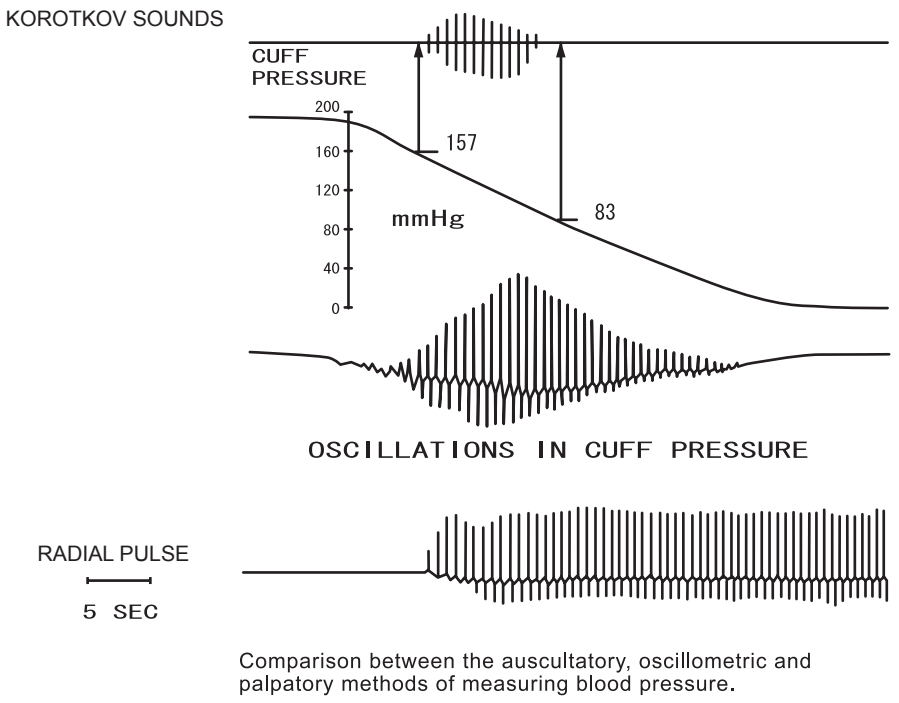
5-10. Explanation of Technical Terms

Oscillometric Measurement

The device uses the oscillometric method to measure blood pressure.

A cuff is wrapped onto the upper arm and inflated to constrict the blood vessels and temporarily stop the flow of blood. As the constriction is then gradually eased, the pressure of the blood becomes greater than the pressure of the cuff. At this point, the blood starts to flow intermittently due to the heartbeat.

At the stage of depressurization following pressurization of the cuff, the oscillometric method determines the blood pressure value by checking the variation in cuff pressure (pressure pulse wave) due to vibration of the blood vessel wall synchronized with the heartbeat. In general, the cuff pressure when the pressure pulse wave suddenly grows large is the "maximum blood pressure" and the cuff pressure when the pressure pulse wave suddenly becomes small is the "minimum blood pressure".



Comparison between the auscultatory, oscillometric and palpatory methods of measuring blood pressure.

L.A. Geddes,
" The Direct and Indirect Measurement of Blood Pressure ", Year Book Medical Publishers, Inc. 1970

In the above example, the maximum blood pressure is 157 mmHg and the minimum blood pressure is 83 mmHg.

ABI (Ankle / Brachial Pressure Index)

ABI is calculated by the equation below.

$$\text{ABI} = \frac{\text{Ankle systolic blood pressure}}{\text{Brachial systolic blood pressure (higher of left and right brachia)}}$$

The ABI can be used to diagnose arteriosclerosis obliterans and evaluate the health of the cardiovascular system in the entire body. ABI is mainly used to evaluate atherosclerosis (hardening of arteries due to an atheromatous plaque).

TBI (Toe Brachial Index)

The TBI is calculated as follows:

$$\text{TBI} = \frac{\text{Toe systolic pressure}}{\text{Brachial systolic pressure (higher of left and right brachia)}}$$

This index is an evaluation of the severity of constriction and blockage of lower limb peripheral arteries. It is mainly used to evaluate blockage of blood flow in peripheral arteries of patients with the following diseases or conditions.

- Diabetes
- Dialysis patients
- Burger's disease (TAO)
- Collagen disease

PWV (Pulse Wave Velocity)

Pulse wave velocity is the speed at which the pulse is transmitted from the heart to the end artery when blood is expelled during contraction. The harder the arteries, the faster the pulse travels. This is mainly used to evaluate hardness of the artery wall.

The PWV is calculated as follows:

$$\text{PWV} = \frac{\text{L (distance)}}{\text{PTT (Pulse Transit Time)}}$$

The wave velocity in the arteries can be measured at the following sites, allowing PWV values to be calculated for each. In general the device uses the "right brachial - ankle PWV (baPWV)" as the PWV.

- Ascending aorta - carotid artery hcPWV
- Ascending aorta - right brachial hbPWV
- Ascending aorta - femoral artery hfPWV
- Femoral artery - ankle PWV faPWV
- Right brachial - ankle baPWV
- Ascending aorta -ankle PWV haPWV

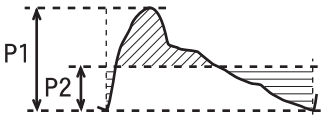
PVR (Pulse Volume Recording)

This is a record of the size of the pulse wave. The device measures this from the arm cuffs and ankle cuffs.

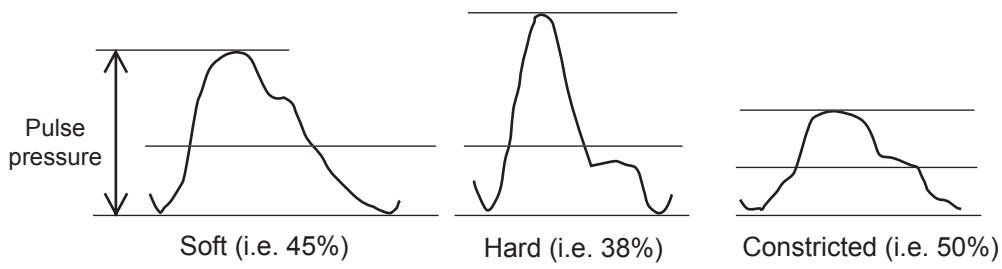
%MAP (%Mean Arterial Pressure)

This value is one of the pulse waveform indices that are calculated from the blood pressure values. It expresses as a percentage the mean value (P2) of the area of the PVR waveform divided by the amplitude of the pulse (P1). This value is calculated as follows:

$$\%MAP = \frac{P2}{P1} \times 100\ (\%)$$

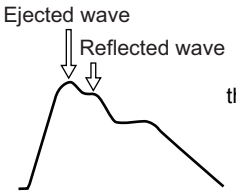


P1: Pulse wave amplitude
P2: Mean value of the area (the level at which ▨ and ▤ are equal)

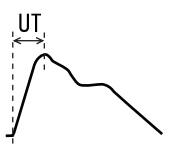


UT (Upstroke Time)

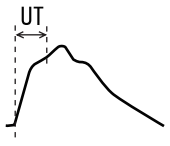
This is the time from the start of the pulse wave to its peak. However, for measurement in the carotid artery, this is the time from the start of the pulse wave to the peak of the ejected wave or the start point of the reflected wave.



In a pulse wave in a carotid artery,
the ejected wave and the reflected wave each form humps near the peak of the wave.



When the ejected wave is higher than the reflected wave,
the time until the peak of the ejected wave is the UT.



When the reflected wave is higher than the ejected wave,
the time until the start of the reflected wave is the UT.

ET (Ejection Time)

This index evaluates cardiac function based on the time from the opening to the closing of the aortic valve. The normal range is 285 ±25 msec, however, this is affected by the heart rate.

PEP (Pre-Ejection Period)

The time between electrical agitation in the heart chamber and the opening of the aortic valve. The normal range is 96 ±10 msec. The value becomes greater as cardiac function deteriorates.

ET/PEP (Ejection Index)

This index is calculated from the ET (Ejection Time) and PEP (Pre-Ejection Period). Correlations with left ventricular end-diastolic volume and pressure (LVEDV, LVEDP), ejection efficiency (EF), stroke volume (SV), and cardiac muscle contraction speed (VCF) can also be indicated.

This index can be expressed in the form ET/PEP or in the form PEP/ET.

Q-II (Overall control period)

The time from the start of the Q wave to the closing of the aortic valve (II sound) in an electrocardiogram.

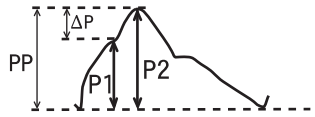
STI (Systolic Time Intervals)

ET and PEP are generally called STI and are used for quantitative evaluation of cardiac functions.

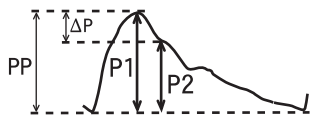
AI (Augmentation Index)

This indicates the percentage of the pressure wave effected in the carotid artery wave that is reflected to form the reflected wave. ΔP expresses the post-systolic component (P2) after subtraction of the maximum wave height (P1) of the presystolic component.

$$AI = \frac{\Delta P}{PP} \times 100\ (\%)$$



Example of increasing AI value as the wave height of the post-systolic component rises



Example of decreasing AI value as the wave height of the pre-systolic component rises

5-11. Disposal

When disposing or recycling the device or its internal batteries, do so in accordance with local rules and regulations as there is a risk of environmental pollution.

Main materials

Component	Part	Material
Package	Box	Cardboard
	Packing material	Cardboard
	Bag	Polyethylene
Main Unit	Main unit	ABS resin, rubber
	Internal parts	Common electronic components*1, rubber
	Chassis	Iron, aluminum
	Cuffs	Cloth, vinyl chloride, PP resin
	Batteries on board	Lithium manganese dioxide battery*2
Stand	Chassis	Iron, aluminum, PP resin

*1 This device includes a fluorescent light that contains mercury. Dispose in accordance with local rules and regulations.
*2 This device includes a lithium battery. Dispose in accordance with local rules and regulations.

Manufacturer	**OMRON HEALTHCARE Co., Ltd.** 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto 615-0084 JAPAN
Production facility	**OMRON MATSUSAKA Co., Ltd.** 1855-370, Kubo-cho, Matsusaka-city, Mie-prefecture, 515-8503, Japan

5329329-2A

Pulse Wave Velocity/Ankle-Brachial Index Data Sheet

ID NUMBER: ☐☐☐☐☐☐☐

Instructions:. *This **paper** form is completed by the PWV/ABI technician prior to entering the information recorded in the PWV/ABI system.*

SECTION A – ADMINISTRATIVE

1. Date PWV/ABI performed ..... ☐☐/☐☐/☐☐☐☐
   M M D D Y Y Y Y

2. Technician ID ..... ☐☐☐

SECTION B – DATA FOR PWV/ABI DMS

3. Arm circumference (cm) ..... ☐☐

4. Arm cuff chosen ..... ☐
   - Small (16-25 cm) ..... S
   - Medium (20-32 cm) ..... M
   - Large (30-38 cm) L

5. Ankle circumference (cm) ..... ☐☐

6. Ankle cuff chosen ..... ☐
   - Medium (16-33 cm) ..... M
   - Large (30-38 cm) L

7. Neck circumference (cm) ..... ☐☐

8. Neck arm chosen ..... ☐
   - Small (<36 cm) ..... S
   - Medium (36-42 cm) ..... M
   - Large (>42 cm) L

9. Carotid-femoral distance (cm) ..... ☐☐.☐
   Suprasternal notch – carotid distance (cm) ..... ☐☐.☐
   Difference in distance (cm) ..... ☐☐.☐

Note: _____

Pulse Wave Velocity/Ankle-Brachial Index Maintenance Sheet

Instructions:. *This **paper** form is completed by the PWV/ABI technician during the maintenance procedure on the PWV/ABI system.*

SECTION A – ADMINISTRATIVE

1. Date the maintenance is performed..... ☐☐/☐☐/☐☐☐☐
   M M D D Y Y Y Y

2. Technician ID..... ☐☐☐

SECTION B – AIR LEAKAGE TEST

3. Enter the values on the last column ("Diff") values

- Small right arm cuff..... ☐☐
- Small left arm cuff..... ☐☐
- Medium right arm cuff..... ☐☐
- Medium left arm cuff..... ☐☐
- Large right arm cuff..... ☐☐
- Large left arm cuff..... ☐☐
- Medium right ankle cuff..... ☐☐
- Medium left ankle cuff..... ☐☐
- Large right ankle cuff..... ☐☐
- Large left ankle cuff..... ☐☐

SECTION C - PRESSURE ACCURACY TEST

4. At 250 mmHg

- Netech DigiMano reading (mmHg)..... ☐☐☐
- Right arm (mmHg)..... ☐☐☐
- Left arm (mmHg)..... ☐☐☐
- Right ankle (mmHg)..... ☐☐☐
- Left ankle (mmHg)..... ☐☐☐

5. At 150 mmHg

- Netech DigiMano reading (mmHg)..... ☐☐☐
- Right arm (mmHg)..... ☐☐☐
- Left arm (mmHg)..... ☐☐☐
- Right ankle (mmHg)..... ☐☐☐
- Left ankle (mmHg)..... ☐☐☐

6. At 50 mmHg

Netech DigiMano reading (mmHg) ..... | | | |

Right arm (mmHg) ..... | | | |

Left arm (mmHg)..... | | | |

Right ankle (mmHg)..... | | | |

Left ankle (mmHg) ..... | | | |