



Manual 38
Blood Pressure Monitoring Procedures
(Ambulatory and Home BPM)
ARIC Visit 10

Version 0.1 – 11/01/2021

DRAFT



Ambulatory and Home Blood Pressure Monitoring
Manual of Procedures
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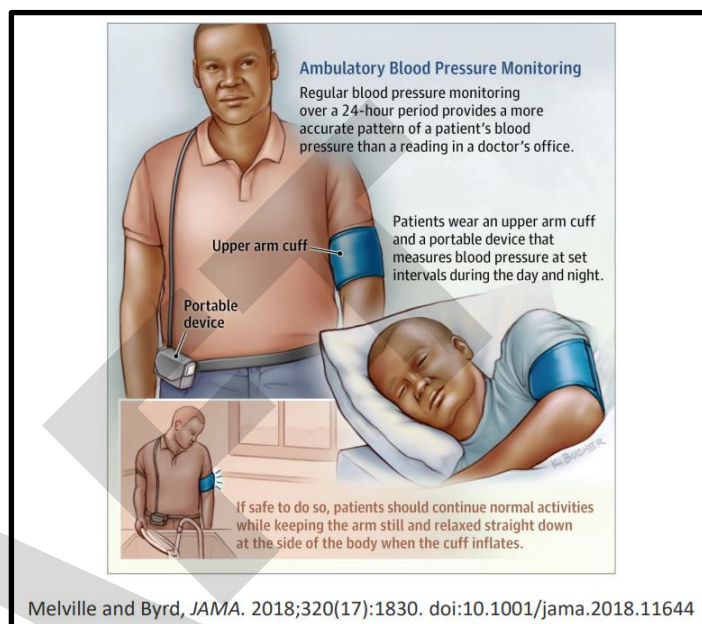
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1 AMBULATORY BLOOD PRESSURE MONITORING

1.1 OVERVIEW

1.1.1 Purpose

Ambulatory blood pressure monitoring (ABPM) is considered the gold standard way to measure blood pressure by taking multiple blood pressure measurement through one's day. Notably, ABPM is useful for identifying important types of blood pressure like "Masked Hypertension" (i.e., a normal blood pressure in clinic, but an elevated blood pressure at home) or "White Coat Hypertension" (i.e., a high blood pressure in clinic, but a normal blood pressure at home). These types of blood pressure patterns are associated with a number of long-term, adverse clinical events. However, there are virtually no cohorts with ABPM in older adults in the United States.



1.1.2 When

- Consent
 - Beginning of visit 10. Participants will be asked to participate in the ABPM protocol later in the day.
- Visit 10 protocol
 - Near the end of visit 10.

1.1.3 Who

- 1 physical examiner for ABPM placement, instructions, device tracking, and data download

1.1.4 Equipment, Materials, and Supplies

- 1 Spacelabs OnTrak ABPM device monitor with velcro holster
- 1 computer or laptop with Spacelabs Sentinel software
- 1 appropriately sized blood pressure cuff
- 1 USB cable (comes with ABPM device)
- 2 AA batteries
- Waist carrier bag
- Yarn for helping with battery removal



1.1.5 Forms, Logs, and Scripts

- Printed Participant Checklists, Forms, and Logs
 - ABPM Participant Cuff Placement Instructions
 - ABPM Participant Checklist
 - ABPM Participant Activity Log (ABPM_PL)
 - ABPM Participant Experience Form
- CDART Data Collection Forms
 - ABPM Initialization Form (ABP)
 - ABPM Return Form (ABPR)
 - Blood Pressure Monitoring Check-in Call Form (BPMC)
- Scripts and Instructions
 - ARIC OH-ABPM-HBPM Introduction Handout
 - ARIC ABPM Protocol Instruction Script
 - ABPM_HBPM_Check-in call script_ARIC

1.1.6 Consent Process

ABPM is incorporated into the standard consent form. However, as ABPM involves some activities outside the clinic (blood pressure measurements, mailing back the device), it is anticipated that some participants will decline ABPM. Participants are free to decline ABPM at any point in the visit (e.g., they may sign the consent that includes ABPM but later decide not to take part in this assessment).

1.1.7 Timeline Schematic



1.2 STUDY PROCEDURES

1.2.1 Prior to Visit (during visit reminder call)

- Ask participants to wear a short or loose sleeve shirt to facilitate blood pressure cuff placement over bare skin. Participants can wear a long-sleeve shirt over the cuff.

1.2.2 Set-up of Monitor (see Appendix A)

- Start desktop or laptop computer and click on the icon for the Sentinel 11 or Sentinel 11.5 software (version depends on when the software was purchased)
- Verify participant ID and consent
- Affix participant-specific label onto the ABP and ABPR forms
- Place new batteries in the monitor
- Plug the monitor into the computer using the monitor cable. A small box will appear, cancel it.
- Turn on the monitor, which should say “Connected to PC”.
- Follow Sentinel 11/OnTrak ABP instructions.
- Verify that the correct settings are selected (note this should reflect the pre-programmed “ARIC ABPM” protocol with Day starting at 5:00 and Night starting at 00:00. Day intervals will be 20 minutes and Night intervals will be 30 minutes. Blood pressure will be measured every 20 minutes until the end of the measurement period. TIME IS MILITARY TIME. Note: do not need to specify the start time in Sentinel.

1.2.3 In-Clinic Procedures

- Set-up monitor as described in section 1.2.2.
- There is a serial number on every ABPM device which will be used for tracking. A barcode can be found on the box the ABPM device comes as well as on the individual ABPM device (on the back of the device). See Appendix H.
 - Be sure to scan the barcode and record this on the ABPM initialization form and the ABPM return form to appropriately track the devices.
- Place ABPM on participant.
 - Cuff placement should be performed following similar practices as performed for seated BP. Can use prior arm measurements to select appropriate cuff size. Ideally use the same arm as used for seated blood pressure (note that the non-dominant arm may be preferred for convenience due to the frequency of measurements, but for blood pressure comparison the same arm used for seated would be ideal). Cuff should be positioned over bare skin.
 - The tube should run up the arm and around the back of the participant
 - NOTE: tubing can sometimes be cumbersome and catch on door knobs. Consider clipping to clothing to avoid fall risk.

- Explain that the blood pressure readings are visible at first but hidden after the initial readings.
- Ask participant about anticipated **sleep and wake times and record** (this is critical for data interpretation).
- Complete the ABP form in CDART
- Provide participant an activity log and participant experience form to take home. The log should include sleep time, wake time, and end of study time. Participant should return the log and experience form in the mail with the device.
 - The participant may remove the monitor to shower/bathe, for heavy exercise, or while driving. Do not turn off the monitor. Show the participant how to properly replace the cuff if they remove it. *(See participant instruction sheet for ABPM cuff. Should the participant need to take their cuff off at any time, or should the cuff become loose, this sheet can be used to show them how to correctly position the cuff back on their arm. This sheet can be printed out and given to participant along with the ABPM_PL to take home.)*
 - After the participant has completed 26 hours of blood pressure monitoring, they should do one manual measurement (by pushing the action button) and then remove the monitor. Instruct the participant to remove the batteries and **record the time** on their activity log. To facilitate, the research technician should **record the anticipated end time for participants on their activity log**. Tying some yarn around one of the batteries during the preparation stage is recommended to help participants with battery removal. If this approach is used, it is recommended that you call attention to the yard when explaining battery removal to the participant. (See figure in Appendix A).
- Unplug the monitor from the USB port and press action button to begin first measurement. **Document time, SBP, DBP, and HR from the first measurement on the data collection form (ABP) and the time on the participant's ABPR as well as their anticipated end time.**
- Remind participant to place monitor and BP cuff into the pre-paid FedEx, overnight envelope with their activity log and participant experience form.
- Participant may proceed with ARIC visit, but they should be observed undergoing at least 1 successful, spontaneous second BP measurement before going home (this is to ensure appropriate firing frequency after 20 minutes).
- Remind participant you will call them on Day 2 of their ABPM to ensure they have completed the assessment and have returned the device or are in the process of returning it with their log and participant experience form.

1.2.4 First Check-in Call (See Appendix F for Check-in Call Schedule)

Please refer to the Check-in Call script.

- Call participant the day after the in-person visit within 2 hours of the ABPM measurement.

- Ask if they encountered any difficulty wearing the device or with device measurement and document response.
- Review plans for mailing device and encourage mailing that day.
- Use this visit to remind the participant about HBPM starting the following morning and to review procedures.
- Enter this information on the Blood Pressure Monitoring Check-in Call Form (BPMC).

1.2.5 Device Tracking

There is a serial number on every ABPM device which will be used for tracking. A barcode can be found on the box the ABPM device comes as well as on the individual ABPM device (on the back of the device). See Appendix H.

Be sure to scan the barcode and record this on the ABPM initialization form. When the device is returned to the clinic, the ABPM serial number should be verified against the serial number that is automatically applied in the ABPR form (prefilled from ABP form). In the case of a mismatch, the serial number should be reconciled with the serial number recorded in the ABP form and the Coordinating Center should be notified with any discrepancies.

1.2.6 Device Return

Please adapt the following instructions below according to what method of returning works best for your field center or based on participant's preference:

Drop the package off at your nearest FedEx location, see <https://www.fedex.com/en-us/home.html>

OR

Return in person to the ARIC Field Center at Piedmont Plaza or the front reception desk on the ground floor of the Sticht Center at Wake Forest Medical Center at Medical Center Boulevard. Winston Salem, NC 27157. The Sticht Center is located next to the main hospital.

OR

Schedule local pick-up and drop-off with courier service. Be sure to record date of scheduled return on the ABP form.

1.3 DATA AND RESULTS REPORTING

1.3.1 Data Download Instructions (see Appendix B with screen shots)

- Log into Sentinel 11.
- Connect the monitor to the computer using the USB cable.

- Turn the monitor, “On” (recommended fresh batteries).
- Click, “ABP”.
- Confirm participant ID.
- Select “Download recording” then manually identify the participant.
- Select “Review Test” enter settings then under statistics and select preprogrammed “ARIC Report” statistics.
- Select “Save”.
- Select “Review Test” and “Print”.
- Select Report Format (top right drop down menu), “Full Report”, print 1 copy of the graph.
- A small window will appear, save file at “[subjectID]”.
- Record day-time average from report and refer to safety algorithm below.
- In Sentinel, click on admin, and then “Export to ART”. Please refer to the “Appendix D. ABP Export from Sentinel 11” instructions in the Appendix with screenshots for details.
- Save .art file as “[SubjectID].art” onto the desktop or laptop computer (e.g., W123456.art).
- Wipe down cuff and ABPM monitor for the next participant’s use using antiviral disinfectant wipes. Wipes should be used over the cuff, the cuff tubing, the ABPM device, and the Velcro sleeve.

1.3.2 Data Transmission

- Mail one copy of the report to the participant (graph) with the participant summary of results.
- Attach “.art” file with raw data to ABPR form in CDART. Please refer to the "Appendix E. Attaching Data to a CDART Form" instructions for details.
- Complete the ABPR form in CDART.
 - Data from the ABPM Participant Log and ABPM Participant Experience form will be entered into the ABPR form.
- Data download and transmission should occur within 1 week of the device being returned. Preferably sooner to avoid accidental data deletion with next use.

1.3.3 Safety

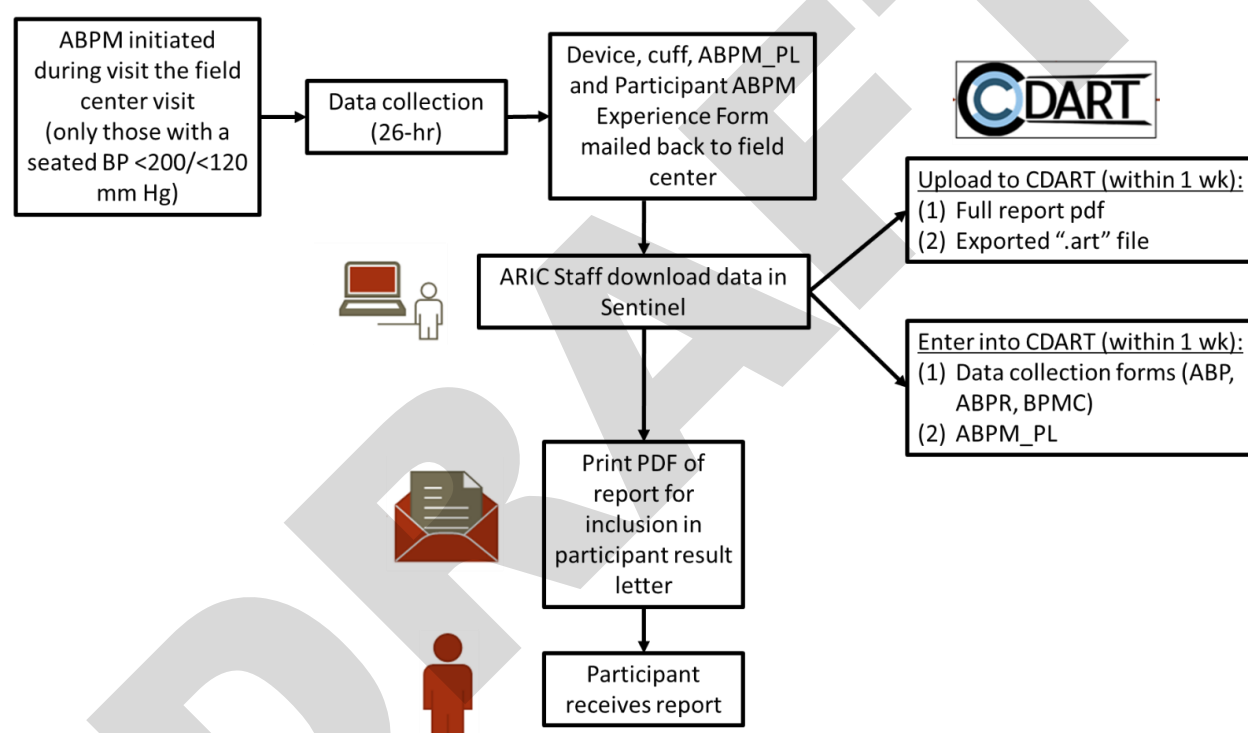
There are no alerts as the data are not available in real-time and the data collected are not clinically actionable at the time of the data download. Seated blood pressure is already reported to participants as part of the parent ARIC NCS protocol. Staff will generate a 3-page (.pdf) report based on blood pressure readings downloaded from the monitor. This report will be stored locally on secure server. It is also recommended that Field Centers keep a paper copy, stored in a secure fashion.

1.3.4 Results Reporting

Results will be provided to participants using a CDART reported based on the ABPM results report template.

The Coordinating Center will calculate the percentage of successful daytime attempts, the mean daytime SBP, and the mean DBP. During the course of the ABPM protocol, it is possible to encounter clinically concerning blood pressure measurements. Response to blood pressure measurements should be based on average readings at the end of the 26-hr period (not based on individual readings) and need to be confirmed in a clinic setting by the participant's healthcare provider. See Table 1 for details related to results reporting.

Figure 1. Summary of data collection and results reporting process for ABPM.



1.4 TRAINING AND CERTIFICATION

Training webinars will be held prior to the ancillary study start date. After the initial training webinars, study coordinators are responsible for training new staff using certified examiners based on standardized MOP and QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual.
- Attend ARIC training session on administration techniques (or observe administration by experienced examiner).

- Practice on other staff or volunteers.
- Discuss problems and questions with local expert or QC officer.

Certification will include:

- Complete training requirements.
- Recite exclusions.
- Conduct exam on two volunteers according to protocol, as demonstrated by a completed ABPM Certification Checklists.

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Table. ABPM threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care				
Threshold values/ Trigger conditions	Reported to participant as:			Script for report
SBP < 90 or DBP < 50		Abnormal*		* <u>Conditional abnormal</u> only if being treated for hypertension. Your reading was abnormally low. You should see your healthcare practitioner within two weeks, to determine whether treatment should be held or changed. If you have not done so already, please see your healthcare practitioner soon.
SBP 90-129 and DBP 50-79	Normal			Your blood pressure was normal. Please recheck it in one year. If you are being treated for high blood pressure, your healthcare practitioner may have given you a schedule for your next check-up. Please follow that schedule.
SBP 130-149 or DBP 80-89		Abnormal		Your reading was elevated. At the time of your visit, we indicated that you should have your blood pressure checked within two months by a healthcare practitioner. If you are being treated for high blood pressure, your healthcare practitioner may have given you a schedule for your next check-up. Please follow that schedule.
SBP 150-174 or DBP 90-104			Alert	Your reading was elevated. You should have your blood pressure checked within a month by a healthcare practitioner.
SBP 175-194 or DBP 105-114			Alert	Your reading was significantly elevated. You should see your healthcare practitioner within one week, to determine whether treatment should be started or changed. If you have not done so already, please see your healthcare practitioner soon.
SBP ≥195 or DBP ≥115			Alert	Your blood pressure reading was very high. You must see your healthcare practitioner at the earliest opportunity to confirm this finding. If you have not done so already, please see your healthcare practitioner soon.

Note: For a valid estimate, the average should have at least a 70% success rate. These thresholds differ from the seated table based on ACC/AHA recommended conversion values for out of office BP measurements.

2 HOME BLOOD PRESSURE MONITORING

2.1 OVERVIEW

2.1.1 Purpose

Home blood pressure monitoring (HBPM) has the potential to improve blood pressure measurement and inform more timely blood pressure treatment. However, the optimal protocol to measure blood pressure at home as well as the interpretation of home blood pressure measurements, remains uncertain. In this study, we will perform home blood pressure monitoring in consenting ARIC participants. This protocol is an optional ancillary study. Select images and text are adapted from the Omron Series 10 Instruction Manual.



2.1.2 When

- Consent
 - Visit 10
 - During this process, participants will be asked if they are able to dedicate 10-days to perform additional blood pressure measurements at home.
- Visit 10 protocol
 - End of visit after the other ARIC ancillaries are complete.

2.1.3 Who

- 1 research technician to perform consent and explain study protocols during the visit.
- 1 research technician for data transmission and acquisition (either at the field center once the monitor is returned, or at the participant's home).

2.1.4 Equipment, Materials, and Supplies

- Omron series 10 (BP7450 or BP7450CAN), Bluetooth enabled, upper arm blood pressure monitor.

- Large Omron semi-rigid cuff (22-42 cm or 9-17 cm) (included in monitor box)
- 4 AA batteries (for Omron) and AC power adapter (included in box)
- Return mail envelope (for ABPM and possible HBPM)



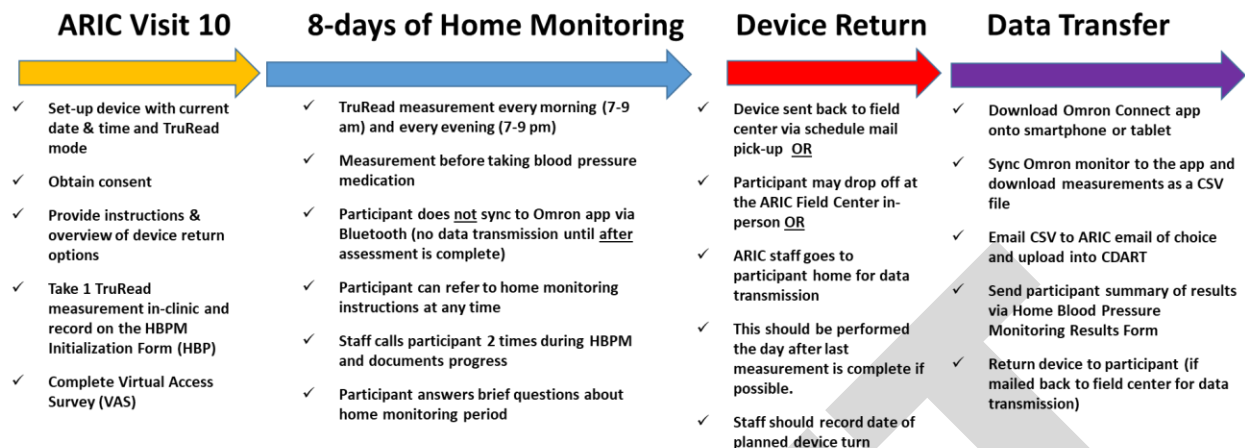
2.1.5 Forms, Logs, and Scripts

- Printed Participant Checklists, Forms, and Logs
 - HBPM Participant Experience Form
 - HBPM Participant Checklist for In-Home Blood Pressure Monitoring
- CDART Data Collection Forms
 - Home Blood Pressure Monitor Initialization Data Collection Form (HBP)
 - Home Blood Pressure Monitor Return Form (HBPR)
 - Blood Pressure Monitoring Check-in Call Form (BPMC)
 - Virtual Access Survey (VAS)
- Scripts and Instructions
 - ARIC OH-ABPM-HBPM Introduction Handout
 - ARIC HBPM Protocol Instruction Script
 - ABPM_HBPM_Check-in call script_ARIC

2.1.6 Consent Process

HBPM is incorporated into the standard consent form; however, as HBPM involves activities outside of the clinic, it is anticipated that some participants will decline HBPM. The HBPM consent form will be reviewed after other ancillary consent documents at the beginning of visit 10. Signed consent documentation will be placed in participants' record.

2.1.7 Timeline Schematic

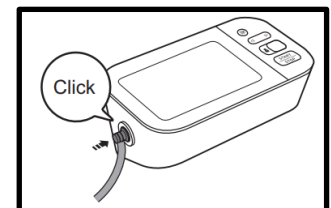


2.2 STUDY PROCEDURES

2.2.1 Set-up of Omron Series 10 (For ARIC staff to complete prior to visit)

Monitor should be set up morning of participant visit (if possible). No more than 1 week prior to visit (to save battery life).

- Open Omron box and insert batteries. Affix arm cuff into monitor using the air ply to ensure a secure connection. Listen for a “click”.
- Press START/STOP to turn on device. Set **current** Date and Time. Use the arrows to move between numbers, and the Bluetooth button on rear surface as an “enter or OK” button once you’ve selected the correct number. (See pages 17 & 18 in Manual for more instructions).
- Check that Omron is programmed to obtain 3 blood pressure measurements separated by 60 seconds each (see page 18, 26 in Manual); this is referred to a “TruRead” mode. (See **Omron series 10 configuration** below).
- Select user ID 1 (explain to participant that this should not be changed during the study protocol). Consider using scotch tape to prevent user changes during the protocol.
- Do not turn on Bluetooth or sync monitor to any device. Re-emphasize to participant that they should not pair any personal device with the monitor via Bluetooth.
 - All BP measurements will be downloaded after the 8 days of monitoring. Research technician or ARIC staff will pair smartphone or tablet with the BP monitor once all BP readings are completed.
- Affix participant-specific label onto the HBP form if collecting on paper.



Omron Series 10 configuration

- Turn on the TruRead mode to capture 3 blood pressure measurements with a 1-minute interval:


2.4 Setting the TruRead Mode

The TruRead mode takes 3 consecutive measurements. The monitor will inflate, take a measurement, and deflate - 3 times, separated by a short interval between each measurement. The TruRead mode is set to "oFF" by default.

- 1. Set or bypass the date and time settings.**

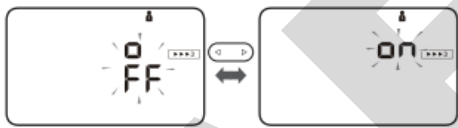
Follow the steps in sub-section 2.3 and set or bypass the date and time settings.

After it is completed, the "▶▶▶3" symbol appears on the display.

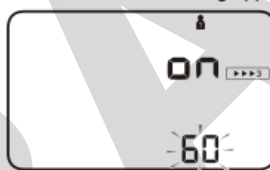

- 2. To enable TruRead mode, press the ◀ or ▶ button.**

"oN" will appear in the display.


To keep TruRead mode disabled, press the Ⓢ button (rear surface of the monitor).


- 3. Press the Ⓢ button to confirm.**

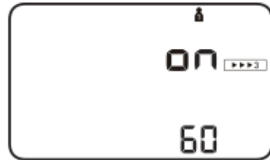
If "on" is selected, the interval setting appears.


- 4. Press the ◀ or ▶ button to change the interval.**

It can be set 15, 30, 60, or 120 seconds.


- 5. Press the Ⓢ button to confirm.**

Your monitor will automatically turn off in 3 seconds.



To take a measurement in TruRead mode, refer to "Using the TruRead Mode" in sub-section 3.1.

2.2.2 In-Clinic Procedures

- Set-up monitor as described in section 2.2.1.

- Make sure date and time are set correctly and the monitor is configured to “TruRead” mode.
- Confirm the participant's arm circumference is within the range of the Omron cuff. If outside of the cuff range, then the participant is not eligible to participate in the study.
- There is a serial number on every Omron monitor that can be used for tracking. A QR code for scanning can be found on the box and on the bottom of the Omron monitor. See Appendix H.
 - This 11-digit serial number will be recorded on both the HBPM initialization (HBP) form and HBPM return form (HBPR) for tracking purposes.
- Place the cuff on the same arm the participant used for the in-clinic, seated blood pressure. Perform a single triplicate measurement for comparison with the in-clinic measurement. Use this validation set to demonstrate the measurement process. We will use these data later for a study on in-clinic device validation.
- Educate participants on appropriate technique and instructions for 8-day monitoring in the morning (7-9a) and evening (7-9p) before antihypertensive medications, using the HBPM protocol instructions script).
- Advise participant it is okay to lightly read (or any activity that can quickly be put aside) during the wait time prior to blood pressure measurement.
- Complete the Virtual Access Survey (VAS) using instructions script.
- Provide participant with the ARIC HBPM Participant Checklist and HBPM Participant Experience Form.
- Call participants on days 2, 4, and 8 of the protocol (1, 3, and 7 days after the completed clinic visit) to address any concerns and ensure compliance. Refer to the delayed start plan if needed.
- Note that the participant has to have 2 full days of monitoring or a minimum of 12 measurements completed to be included in the study.

Some helpful videos:

- Participant-oriented video on how to take blood pressure at home (9:44)
<https://vimeo.com/486860545/c41bcd5009>
- Measurement and data transfer to app using the Omron Series 10:
https://www.youtube.com/watch?v=1xn_3eB6P7Q (see 6-9 minutes)
- How to take blood pressure correctly – Omron tutorial
<https://www.youtube.com/watch?v=iEwqy3lzK0c> (1 minute)
- How to use Omron series 10 and set up Bluetooth data transfer
<https://www.youtube.com/watch?v=c4-R-OeFew4> (8 minutes)

2.2.3 Second and Third Check-in Call (see Appendix F for Check-in Call schedule)

Please refer to the Check-in Call script

Check-in Call 2 (~4 days after ABPM start date):

- Call participant 1 day after they are supposed to begin HBPM.
- Ask the participant if they were able to begin home blood pressure monitoring the day prior to this call.
 - If they have not started, ask them why and record on the BPMC form.
 - Tell the participant to begin monitoring tomorrow and that you will call back in 2 days to ensure they started.
 - If they did start, confirm the date they started and record on the BPMC form.

Check-in Call 3 (~8 days after ABPM start date):

- Call the participant 2 days before they are scheduled to end their home monitoring with the Omron device. (This should be the 6th day of home monitoring if there were no delays).
- Confirm with the participant what their data transmission plan is (scheduled FedEx pickup, ARIC staff home download, participant drops-off monitor in person at field center).
- Record this response on the BPMC form.

2.2.4 Device Tracking

There is a serial number on every Omron monitor which will be used for tracking. A QR code for scanning can be found on the box and on the bottom of the Omron monitor. See Appendix H.

Be sure to scan the QR code and record this 11-digit serial number on the HBPM initialization form. When the device is returned to the clinic, the HBPM serial number should be verified against the serial number that is automatically applied in the HBPR form (prefilled from HBP form). In the case of a mismatch, the serial number should be reconciled with the serial number recorded in the HBP form and the Coordinating Center should be notified with any discrepancies.

2.2.5 Device Return

Please adapt the following instructions below according to what method of returning works best for your field center or based on participant's preference:

Drop the package off at your nearest FedEx location, see <https://www.fedex.com/en-us/home.html>

OR

Return in person to the ARIC Field Center at Piedmont Plaza or the front reception desk on the ground floor of the Sticht Center at Wake Forest Medical

Center at Medical Center Boulevard. Winston Salem, NC 27157. The Sticht Center is located next to the main hospital.

OR

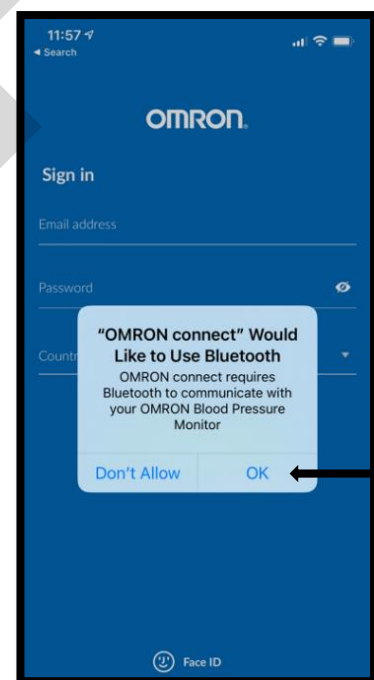
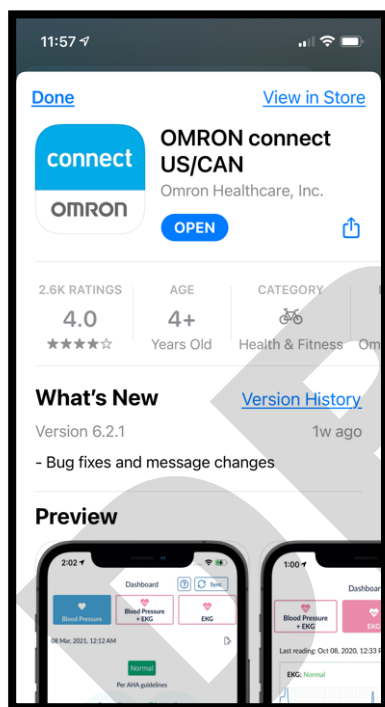
Schedule local pick-up and drop-off with courier service. Be sure to record date of scheduled return on the BMPC form.

The device return will be recorded on the BMPC form after staff speaks with the participant during check-in call #3.

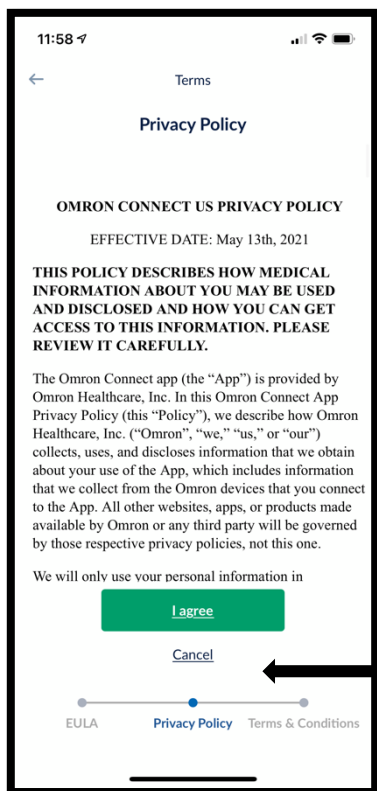
2.3 DATA AND RESULTS REPORTING

2.3.1 Data Download Instructions

1. Download app
2. Allow Bluetooth and sync with device



3. Agree to Privacy Policy / Terms & Conditions

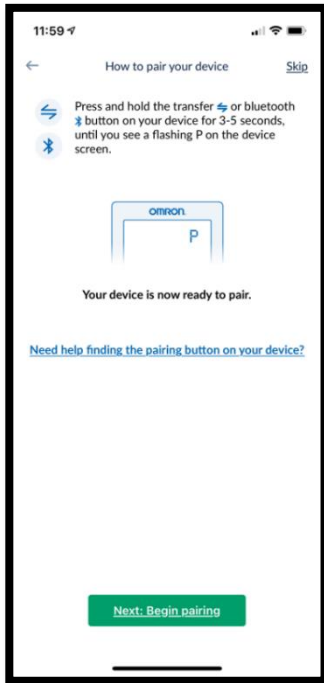


4. Choose the correct device



BP7450
OR
BP7540
CAN

5. Connect via Bluetooth



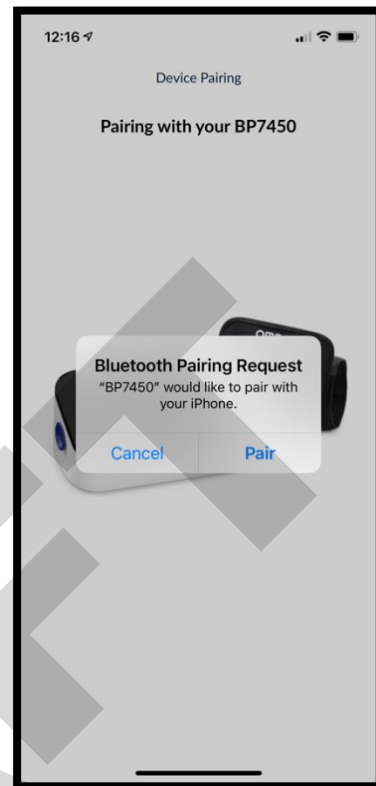
Make sure Bluetooth is turned on (device and monitor)



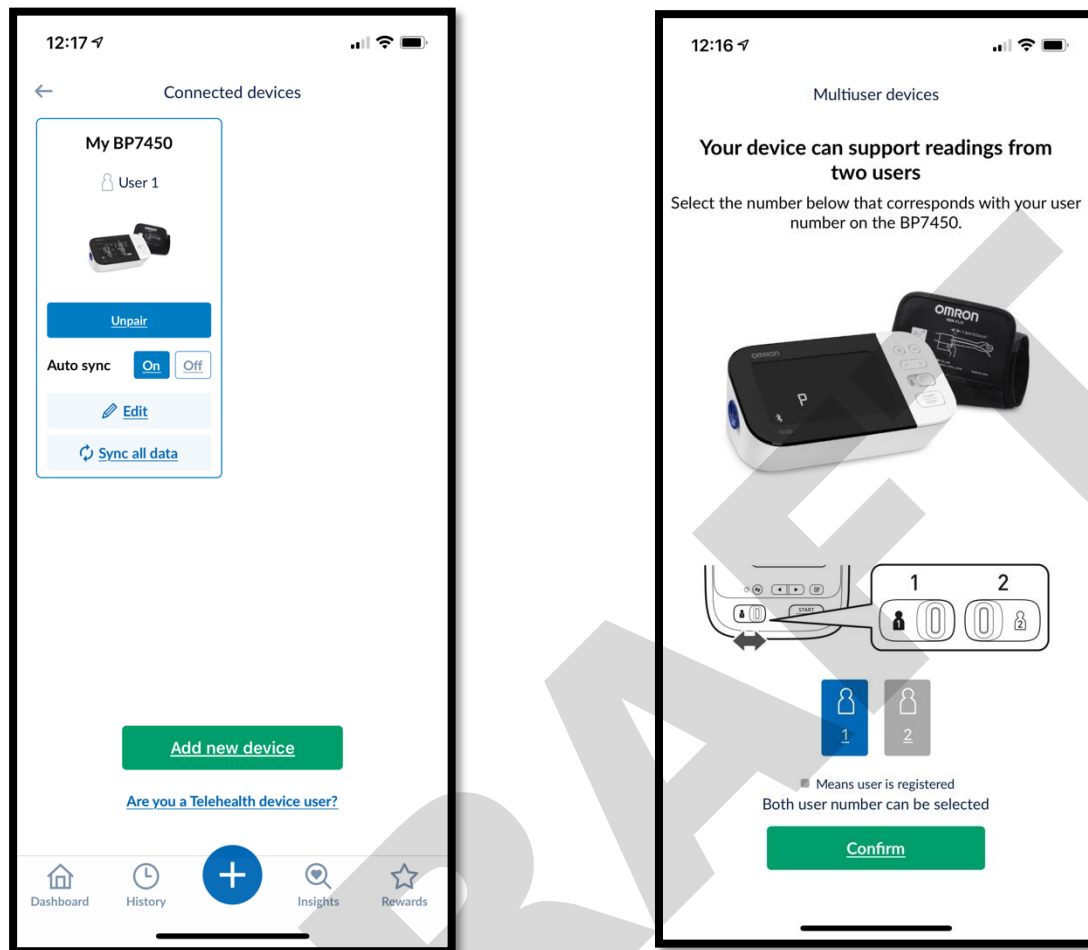
6. Select the device when it appears



7. Pair device w/ monitor

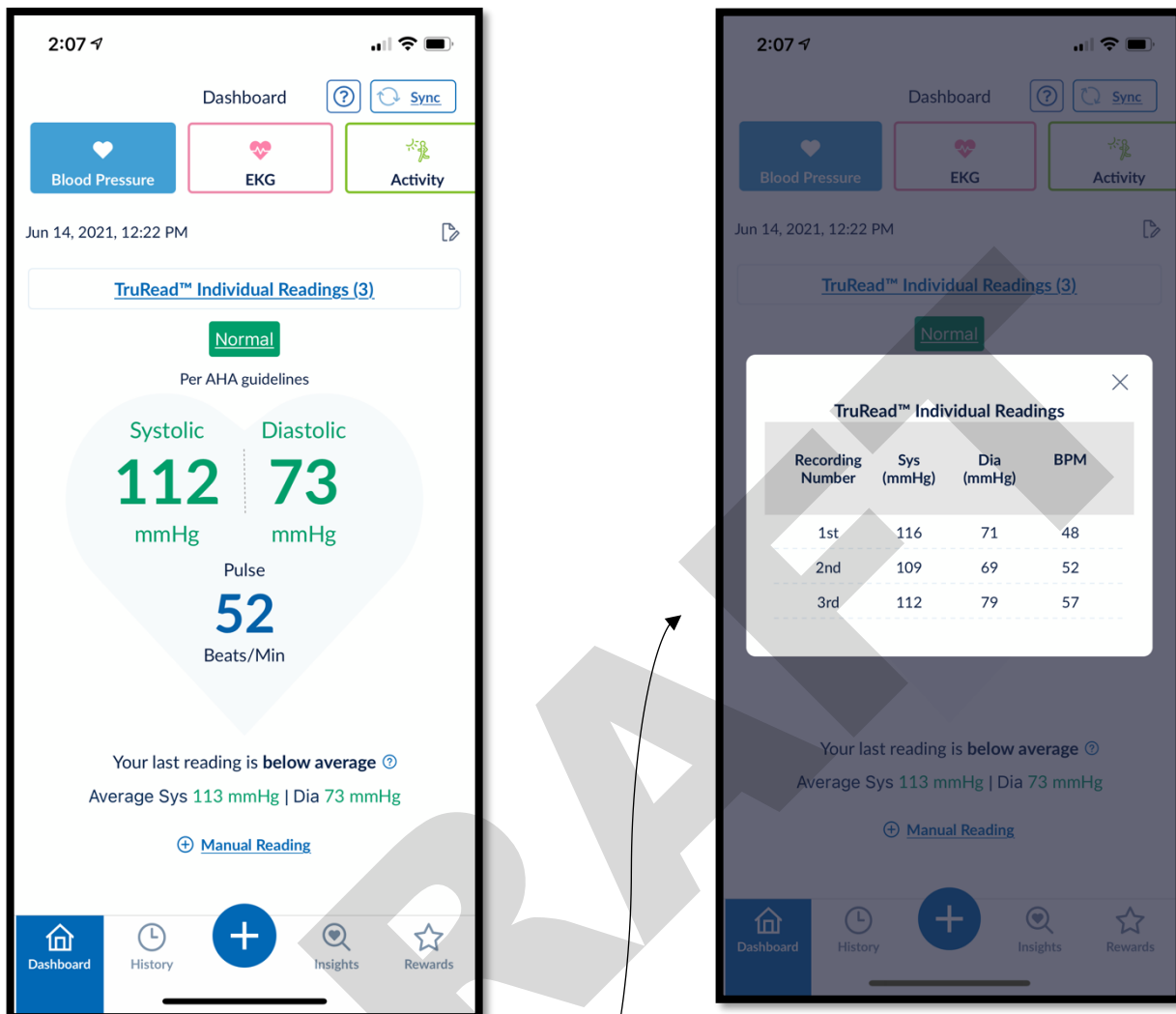


8. Select **User 1** (or whichever User the respective ARIC participant used for the 8-day HBPM)



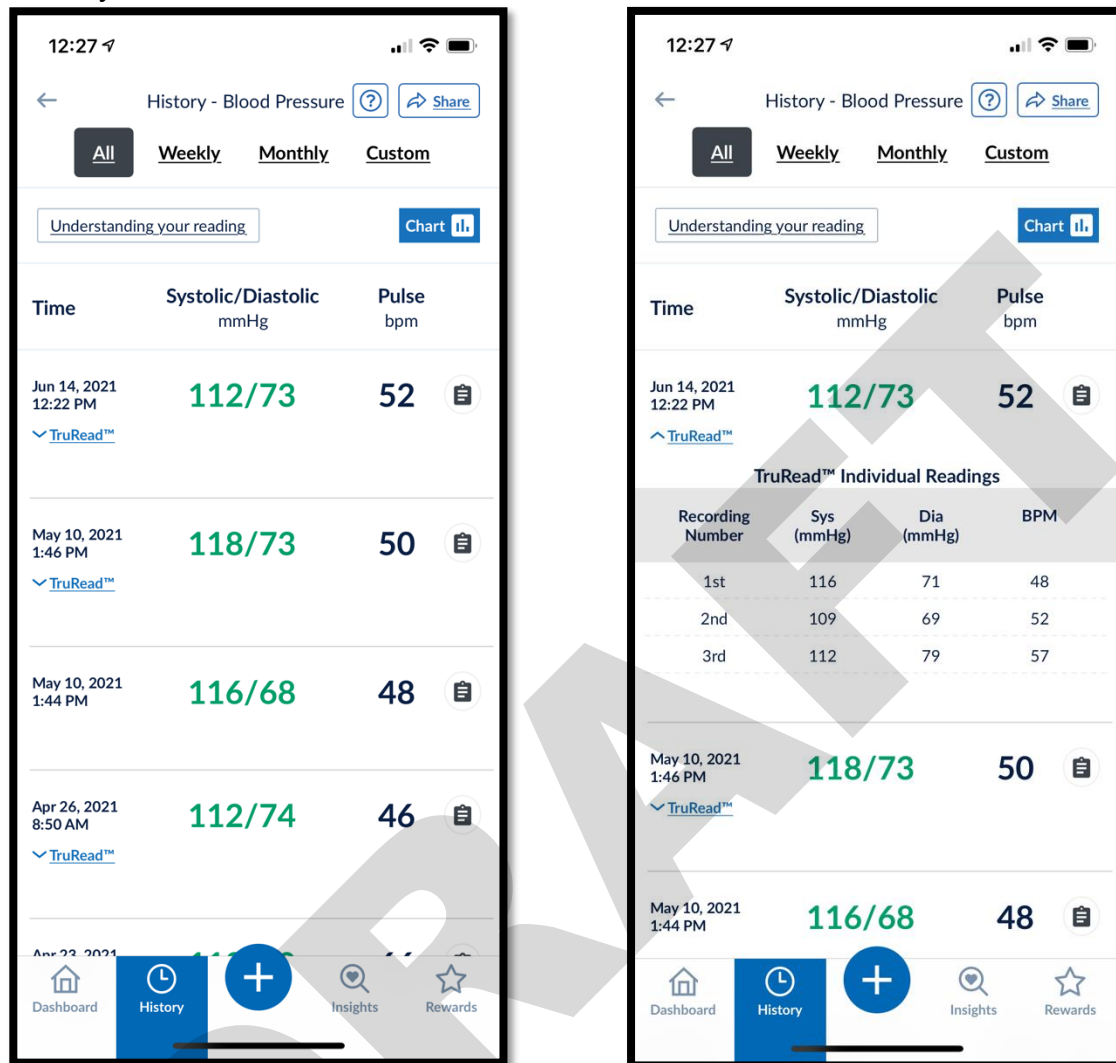
- Once the tablet or smartphone is paired to the OMRON Connect app, all blood pressure measurements stored in the monitors history can be securely transferred to the OMRON app.
- Place the tablet or smartphone next to the monitor and open the OMRON app. Within seconds, the measurements will transfer automatically. If they do not transfer, make sure all other applications are closed.
- If data does not transfer, close the app and let the monitor turn off. Push the “Document” icon button above the arrows and open the Omron app. When the blue tooth symbol flashes on the Omron monitor screen the data is transferring.
- All blood pressure history will be stored in the history portion on the app once synced.

OMRON Dashboard:



Dashboard will display the most recent reading (click on “[TruRead Individual Readings \(3\)](#)” to see all three

All blood pressure measurements from the 8-day HBPM period will appear under the “History” tab:



- Once all measurements have been transferred to the OMRON Connect app, a report can be sent to any email address:
 - History
 - Share (top right corner in app)
 - Blood pressure
 - Select format → **Excel (or CSV in a new version of the app)**
 - Send to Other
 - Enter in preferred email

12:28

Share Report

Blood Pressure

Activity

Weight

Select period

Start Date:

May 14, 2021

End Date:

Jun 14, 2021

Select format

Excel

PDF

Send to me

Send to Other

Email address:

jwood3@bidmc.harvard.edu

Notes:

0/300

Send

Dashboard

History

Insights

Rewards

Manual 38: ARIC Ambulatory and Home BPM MOP

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- Reports should be sent as CSV files.

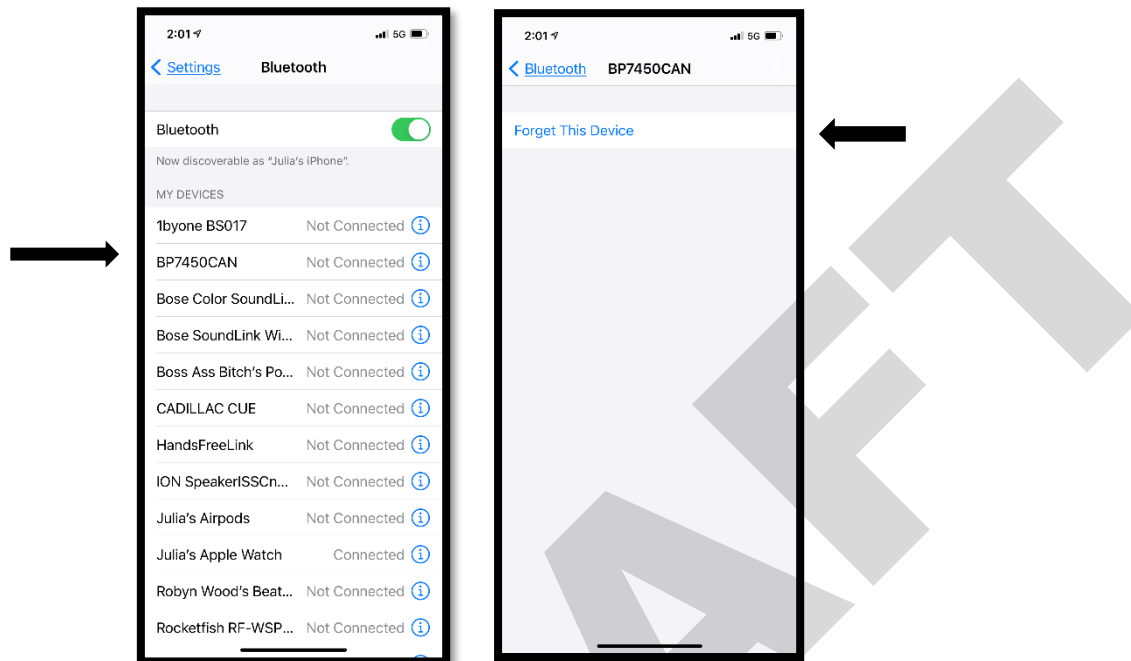


- Once the file is downloaded and opened, you will see columns with the Date, Time, Systolic reading, Diastolic reading, pulse, and any notes included (TruRead).

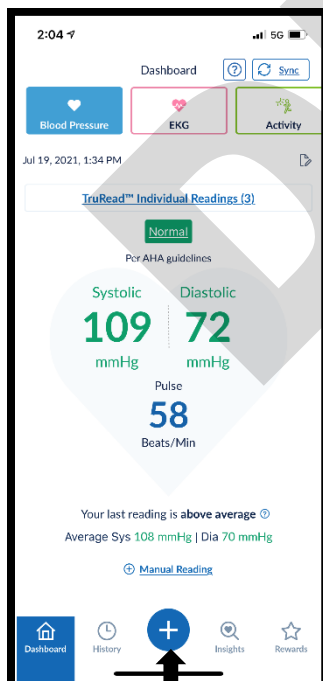
	A	B	C	D	E	
1	Date	Time	Systolic (mm	Diastolic (mr	Pulse (bpm)	Notes
2	June 14, 202	12:25 PM	112	79	57	TruRead
3	June 14, 202	12:23 PM	109	69	52	TruRead
4	June 14, 202	12:22 PM	116	71	48	TruRead
5						
6						
7						
8						
9						

Syncing a different monitor with the same tablet or smartphone

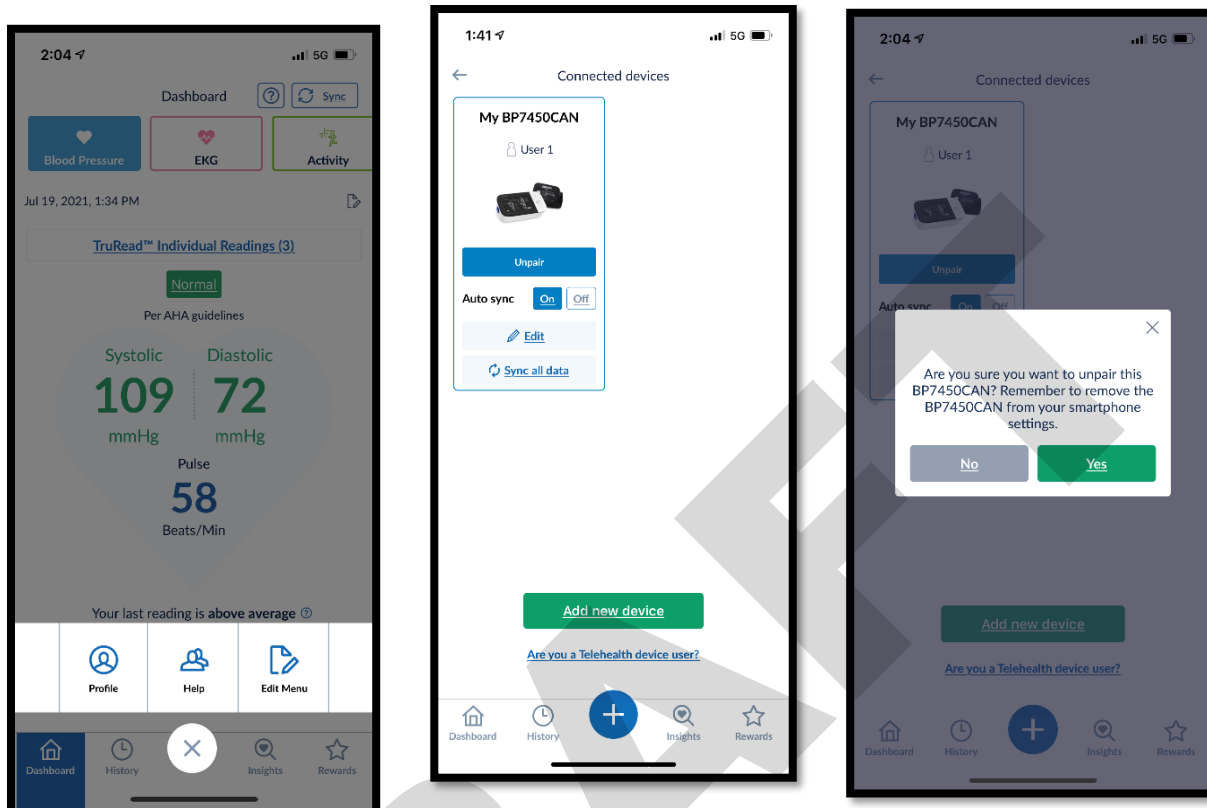
- Make sure you first disconnect the previous monitor from the tablet or smartphone you connected it to, by going into **Settings** → **Bluetooth** → **“Forget this device”**



- Go into the OMRON app
 - Click the blue + button at the bottom of the screen



- Click Profile → Connected Devices
 - Unpair → Yes, you are sure you want to unpair



- Now, Add new device
 - See notes above regarding which device to use.
- Press the Bluetooth button on the back of your device until you see a flashing P on the screen

2.3.2 Manual Data Collection

If data syncing via Bluetooth cannot be used or if data are missing from the data file, you will need to manually enter results from the monitor's history into the HBPR form. Please record the date and time and systolic, diastolic, and HR for readings 1-3 within the HBPR form.

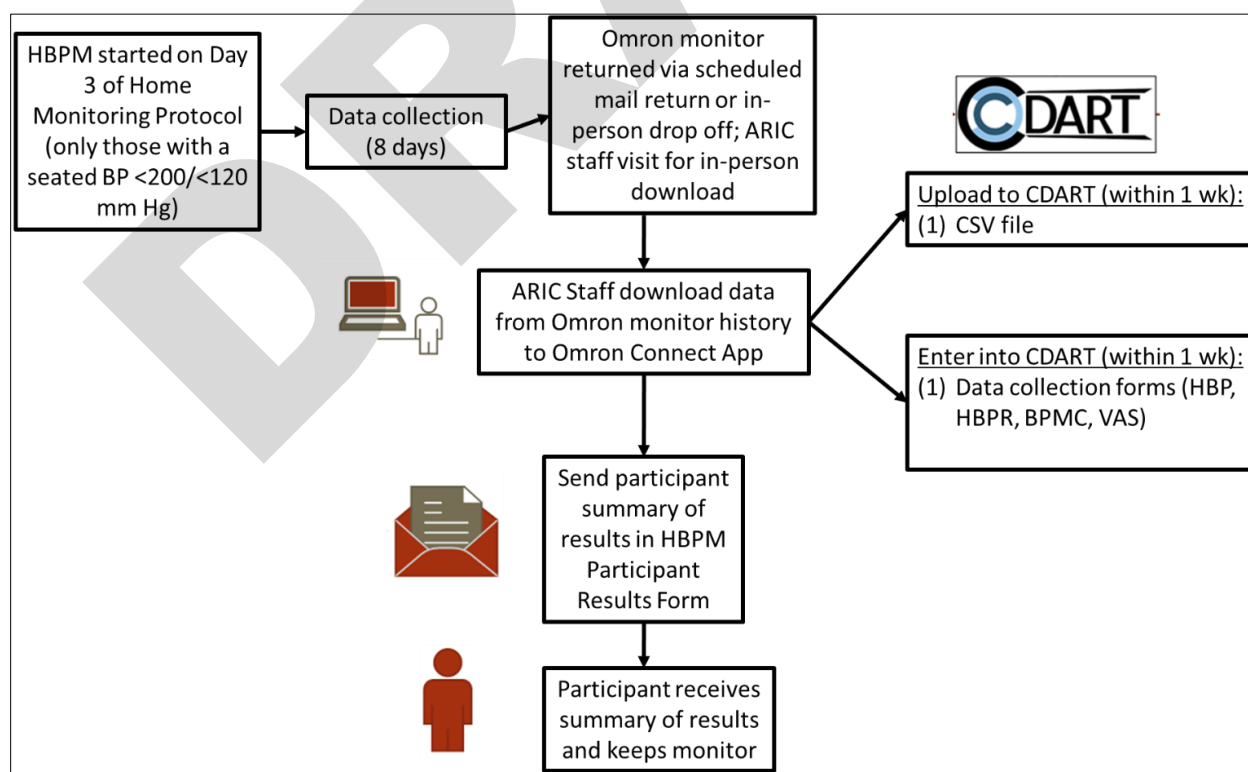
2.3.3 Data Transmission

- Review CSV file for completeness

Example CSV file:

	A	B	C	D	E	F	
1	Date	Time	Systolic (mm)	Diastolic (mm)	Pulse (bpm)	TruRead	Notes
2	7/22/2021	5:35 AM	104	74	69	TruRead	
3	7/22/2021	5:34 AM	108	72	68	TruRead	
4	7/22/2021	5:33 AM	107	74	66	TruRead	
5	7/21/2021	10:51 PM	107	67	67	TruRead	
6	7/21/2021	10:50 PM	103	67	69	TruRead	
7	7/21/2021	10:49 PM	110	76	72	TruRead	
8	7/15/2021	8:27 AM	110	72	82	TruRead	
9	7/15/2021	8:25 AM	111	71	87	TruRead	
10	7/15/2021	8:24 AM	117	73	88	TruRead	
11	7/14/2021	11:27 PM	121	75	76	TruRead	
12	7/14/2021	11:26 PM	110	71	74	TruRead	
13	7/14/2021	11:25 PM	114	73	75	TruRead	
14	7/14/2021	10:24 PM	117	78	78	TruRead	
15	7/14/2021	10:23 PM	114	75	72	TruRead	
16	7/14/2021	10:22 PM	120	78	76	TruRead	
17							
18							

- Attach CSV to HBPR form CDART. Please refer to the "Appendix E. Attaching Data to a CDART Form" instructions for details.
- Enter data into the HBPR form in CDART.
 - Data from the HBPM participant experience form will be entered into the HBPR form.
- Data download and transmission should occur within 1 week of the device being returned. Preferably sooner to avoid accidental data deletion with next use.



2.3.4 Safety

There are no alerts as the data are not available in real-time and the data collected are not clinically actionable at the time of the data download. Seated blood pressure is already reported to participants as part of the parent ARIC NCS protocol.

2.3.5 Results Reporting

Results will be provided to participants using a CDART reported based on the HBPM results report template.

During the course of the HBPM protocol, it is possible to encounter clinically concerning blood pressure measurements. Response to blood pressure measurements should be based on average readings at the end of the 8-day period (not based on individual readings) and need to be confirmed in a clinic setting by the participant's healthcare provider. See Table 1 for details related to results reporting.

2.4 TRAINING AND CERTIFICATION

Training webinars will be held prior to the ancillary study start date. After the initial training webinars, study coordinators are responsible for training new staff using certified examiners based on standardized MOP and QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual.
- Attend ARIC training session on administration techniques (or observe administration by experienced examiner).
- Practice on other staff or volunteers.
- Discuss problems and questions with local expert or QC officer.

Certification will include:

- Complete training requirements.
- Recite exclusions.
- Conduct exam on two volunteers according to protocol, as demonstrated by a completed HBPM Certification Checklist.

3 APPENDIX MATERIALS

APPENDIX A. ABPM INITIALIZATION (SCREENSHOTS)

CONFIGURE THE ABP RECORDER

We are using the 90227 OnTrak ABP recorder for these instructions.

Place 2 fresh AA batteries in the recorder (optional: one piece of yarn tied around a battery to aid removal).

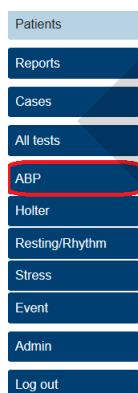




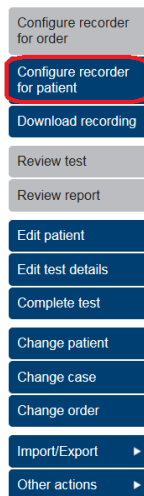
The back cover of can be secured over the piece of yarn.

Connect one end of the USB interface cable to the computer, the other end to the 90227 OnTrak ABP recorder, and turn the recorder on. The recorder display will show a self-test, then *connected to host*, then *Connected to PC*.

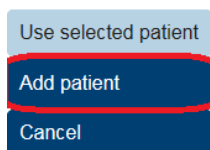
Log into Sentinel, and click on *ABP*.



Click on *Configure recorder for patient*.

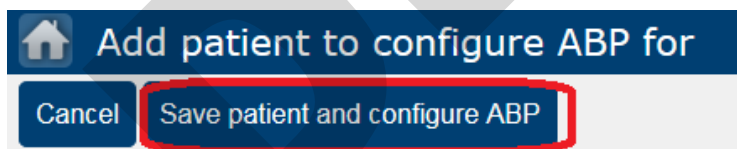


Click on *Add patient*.



Either scan the ID barcode or copy and paste the ARIC cohort ID into the Patient ID field. If you want the participant's name to appear on the graphical results, you will need to key in the participant's first and last name into the respective fields.

Click on *Save patient and configure ABP*.

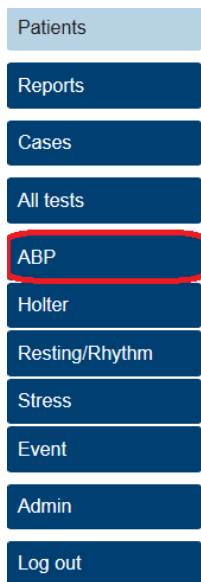


Under protocol change from default to “ARIC ABPM” protocol. (To set up “ARIC ABPM” protocol, see below)

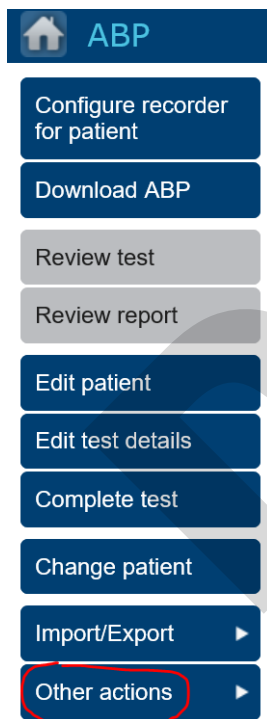
Confirm that the default *Intervals* are correct (these should be pre-programmed in the “ARIC ABPM” protocol).

Follow these steps to create the “ARIC ABPM” protocol. You only have to do this step **once**. After you do this step, you will see “ARIC ABPM” as an option in the drop-down menu under Protocol. (These instructions can also be found in the Sentinel Ops Manual, Section 8.5, that came on the flash drive with your Sentinel software.

On the *Home* screen, click *ABP*.



Click on *Other actions*.



Click on *Protocols*.



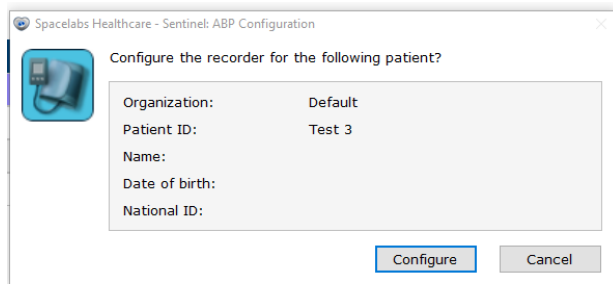
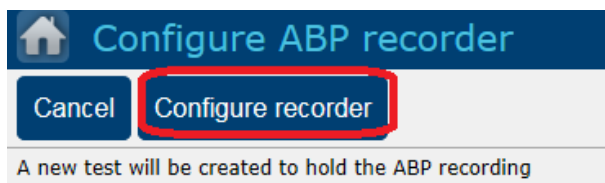
Click on *Add Protocol* and enter “ARIC ABPM” in the line next to *Protocol name*. Make sure the information under *Recorder* and *Intervals* are correct. (The intervals for this protocol will instruct the monitor to inflate every 20 minutes during the day and every 30 minutes while the participant sleeps from midnight (0:00) to 5 am (05:00). These are the correct intervals:

Name		Intervals			
* Protocol name ARIC ABPM		Add	Day	60	Silent
Recorder		Type	Start hour	Cycle (mins)	Tone
Show result of reading	<input type="checkbox"/>	Day	5	20	Silent
Clinical verification setup	<input type="checkbox"/>	Night	0	30	Silent
Display cuff pressure	<input type="checkbox"/>				
Recorder clock format	<input type="radio"/> 12 Hour <input checked="" type="radio"/> 24 Hour				
Child mode (OnTrak only):	<input type="checkbox"/>				
Comfort mode pressure (OnTrak only):	<input type="radio"/> 110mmHg <input type="radio"/> 130mmHg <input type="radio"/> 150mmHg <input checked="" type="radio"/> 170mmHg				

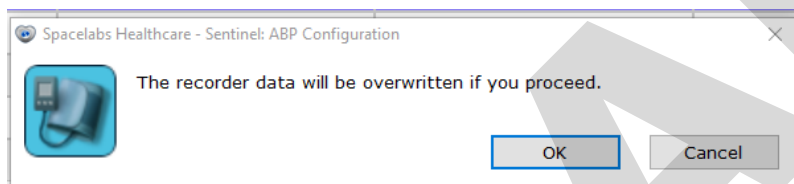
Click *Save*.

Name		Intervals			
* Protocol name ARIC ABPM		Add	Day	60	Silent
Recorder		Type	Start hour	Cycle (mins)	Tone
Show result of reading	<input type="checkbox"/>	Day	5	20	Silent
Clinical verification setup	<input type="checkbox"/>	Night	0	30	Silent
Display cuff pressure	<input type="checkbox"/>				
Recorder clock format	<input type="radio"/> 12 Hour <input checked="" type="radio"/> 24 Hour				
Child mode (OnTrak only):	<input type="checkbox"/>				
Comfort mode pressure (OnTrak only):	<input type="radio"/> 110mmHg <input type="radio"/> 130mmHg <input type="radio"/> 150mmHg <input checked="" type="radio"/> 170mmHg				

Click on *Configure recorder*.



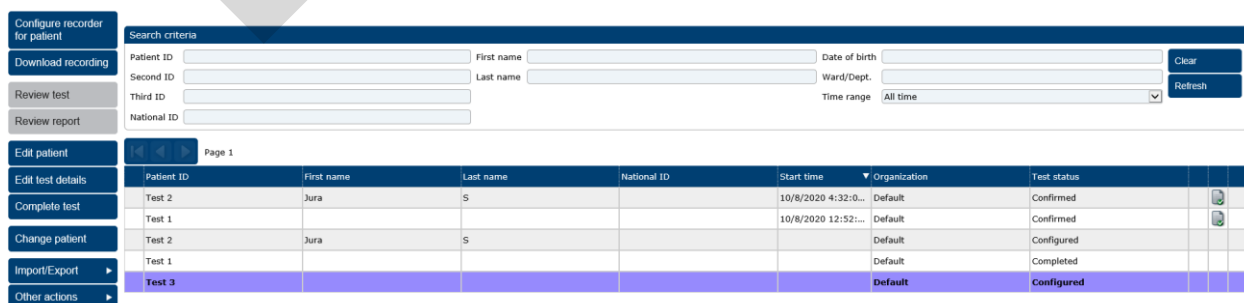
If the recorder has information from a previously downloaded participant, the following window will appear. Click on OK to erase device.



Click *OK*.



When complete, your new participant will be displayed in list with the “Test Status” reading “Configured”.

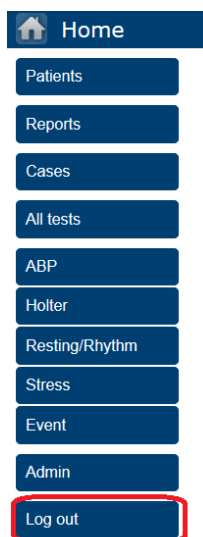


Click on the Home button.



Place cuff on participant.

Click on *Log out*.

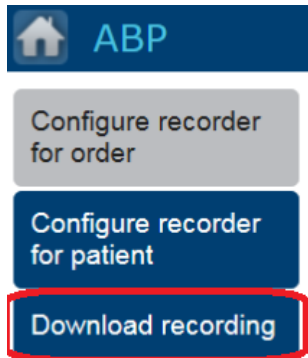


Disconnect the ABP monitor from the computer. Check position of cuff (should be over bare skin over brachial artery on upper arm). Press action button to record first measurement. **Document time, SBP, DBP, and HR for first measurement in the ABP data collection form.** Place the monitor into Velcro holder. Secure tubing if needed. Will need to wait for 20 minutes to observed second measurement. Participant can be doing other things during this time.

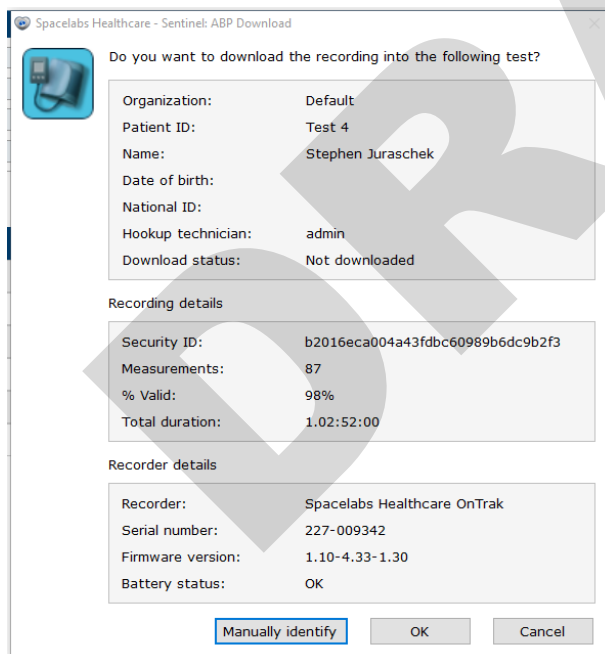
APPENDIX B. DOWNLOAD THE ABP RECORDER

When the participant returns the recorder replace the battery and push the round action button on the recorder, and it will say *End Test* on the screen and ask “*Do you want to end the current test?*” Arrow down once, so that *Yes* is highlighted and hit the round action button to select. It will then connect to the PC.

To Download a recorder, turn on and plug in the recorder. Log into Sentinel and at the Home page, click on *ABP*, *Download recording*.



It will search the recorder for the data that was initially programmed, and the participant details will appear with the number of readings and the recorder information.



Click *Manually identify*.

Click **OK**.

The screenshot shows the ARIC Ambulatory and Home BPM MOP interface. A dialog box titled "Speculato Healthcare - Sentinel ABP Download" is displayed in the center, with the message "Recording has been downloaded. Please wait for identify web page to appear." and an "OK" button. The background interface includes a "Use selected patient" button, a "Cancel" button, and a table of recording details. The table has columns for Organization, Patient ID, National ID, Last name, First name, Date of birth, and Gender. The row for Patient ID "Test 4" is highlighted in purple.

Organization	Patient ID	National ID	Last name	First name	Date of birth	Gender
Default	Test 4		Juraschek	Stephen		Unknown

Click **Use selected patient**. **OK**.

The screenshot shows the ARIC Ambulatory and Home BPM MOP interface. A dialog box titled "Sentinel" is displayed in the center, with the message "This will assign the following recording:" and a list of recording details. The background interface includes a "Use selected patient" button, a "Cancel" button, and a table of recording details. The row for Patient ID "Test 4" is highlighted in purple.

Organization	Patient ID
Default	Test 4

Sentinel

This will assign the following recording:

Patient ID: Test 4
 Last name: Juraschek
 First name: Stephen
 Date of birth:
 Test type: ABP
 Start time: 10/11/2020 11:13:00 AM
 Serial number: 227-009342

to patient:

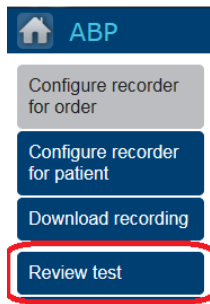
Organization: Default
 Patient ID: Test 4
 Last name: Juraschek
 First name: Stephen
 Date of birth:
 Gender: Unknown

This action will create an unordered test.

OK **Cancel**

Make sure the participant is highlighted (indicated by a purple row) and use the menu buttons on the left to select the task you wish to complete.

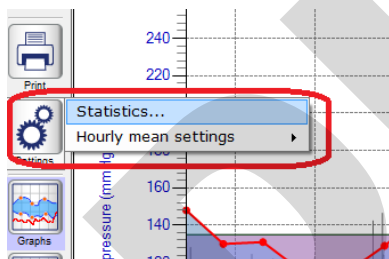
Click on *Review Test*.



Click on *Settings*.



Then, click on *Statistics*.



In the *Statistics* window, change the “Configured statistics:” field to the preprogrammed “ARIC Report.” Confirm the correct settings auto-populated:

Start hour: 7, 23.

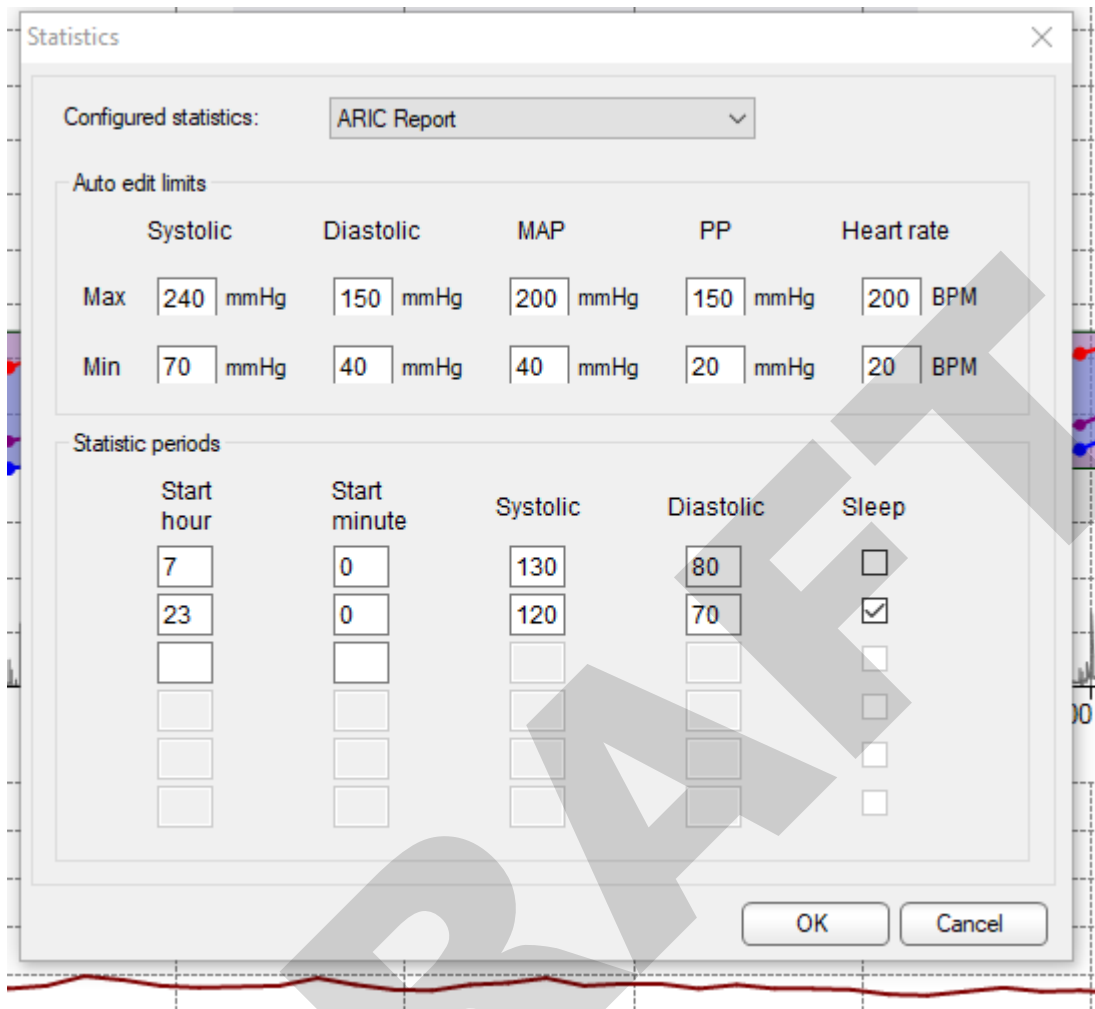
Start minute: 0, 0.

Systolic 130, 120.

Diastolic, 80, 70.

Sleep: unchecked, checked.

Click OK.



The 'Statistics' dialog box is shown with the 'Configured statistics' dropdown set to 'ARIC Report'. The 'Auto edit limits' section contains input fields for Systolic, Diastolic, MAP, PP, and Heart rate, with 'Max' and 'Min' values. The 'Statistic periods' section contains input fields for Start hour, Start minute, Systolic, Diastolic, and Sleep, with values for the first two periods. The 'OK' and 'Cancel' buttons are at the bottom right.

Configured statistics:		ARIC Report				
Auto edit limits						
	Systolic	Diastolic	MAP	PP	Heart rate	
Max	240 mmHg	150 mmHg	200 mmHg	150 mmHg	200 BPM	
Min	70 mmHg	40 mmHg	40 mmHg	20 mmHg	20 BPM	
Statistic periods						
Start hour	Start minute	Systolic	Diastolic	Sleep		
7	0	130	80	<input type="checkbox"/>		
23	0	120	70	<input checked="" type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		

Click Save (note if you want the report to save "Confirmed" click Confirm first, but this step is not required).



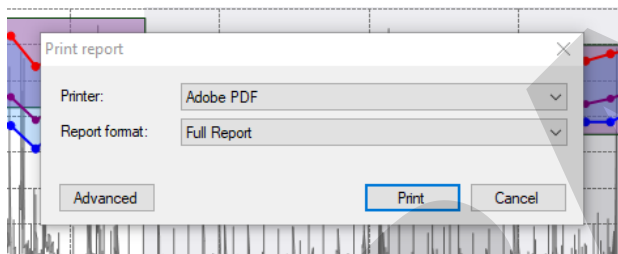
The confirmation dialog box shows four options: Confirm, Decline, Save, and Cancel. The 'Save' option is highlighted with a red box.

<input checked="" type="checkbox"/>	Confirm
<input type="checkbox"/>	Decline
<input checked="" type="checkbox"/>	Save
<input type="checkbox"/>	Cancel

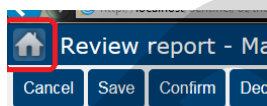
To print, with the appropriate participant ID highlighted, click *Review Test*. Click *Print*.



Selected printer or PDF. Select “Full Report” (Note: you do not need to print all pages, only the graph for participants). Click *Print*. When saving as a PDF label: “[subjectID].pdf”



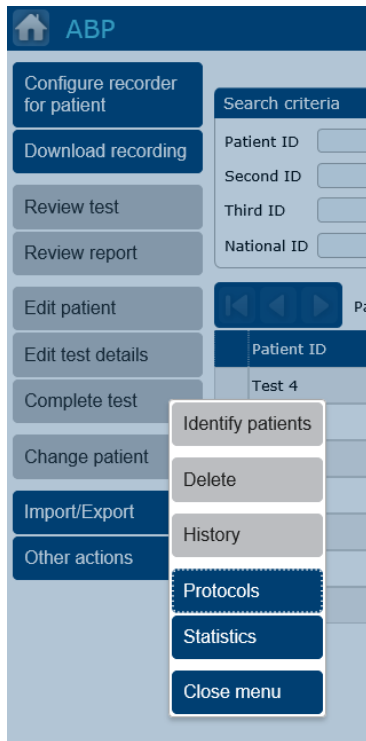
When you finished with the report, “x” out of the report screen and click the *Home* button.



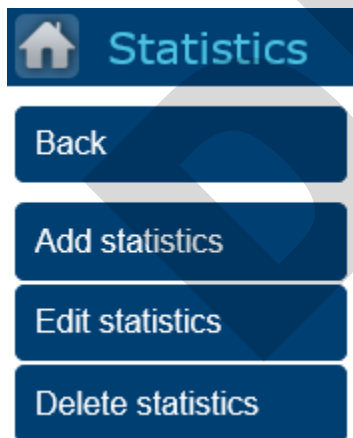
Then click on *Log out*.

APPENDIX C. CREATE STATISTICS REPORT (THIS STEP IS PERFORMED ONLY ONCE)

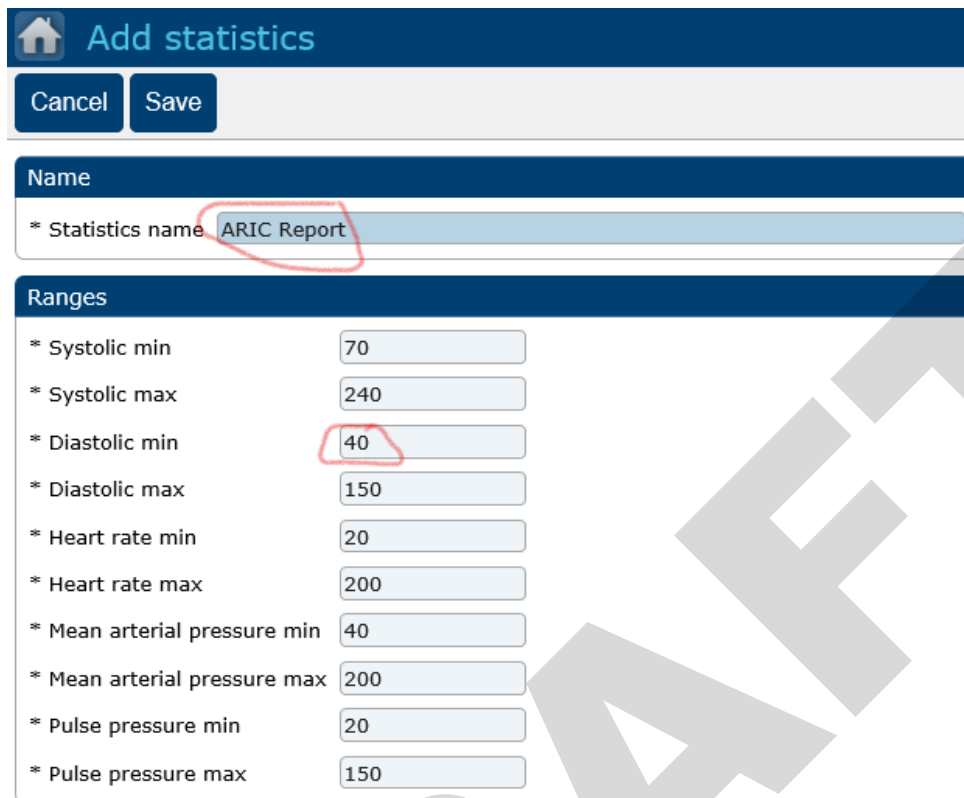
In the Home menu, select *ABPM*. Click *Other actions*. Select *Statistics*.



Select *Add statistics*.



In the “Statistics name” field add the name: “ARIC Report”. Use the default ranges but note that the **diastolic min should be changed to 40**.



Add statistics

Cancel Save

Name

* Statistics name ARIC Report

Ranges

* Systolic min 70

* Systolic max 240

* Diastolic min 40

* Diastolic max 150

* Heart rate min 20

* Heart rate max 200

* Mean arterial pressure min 40

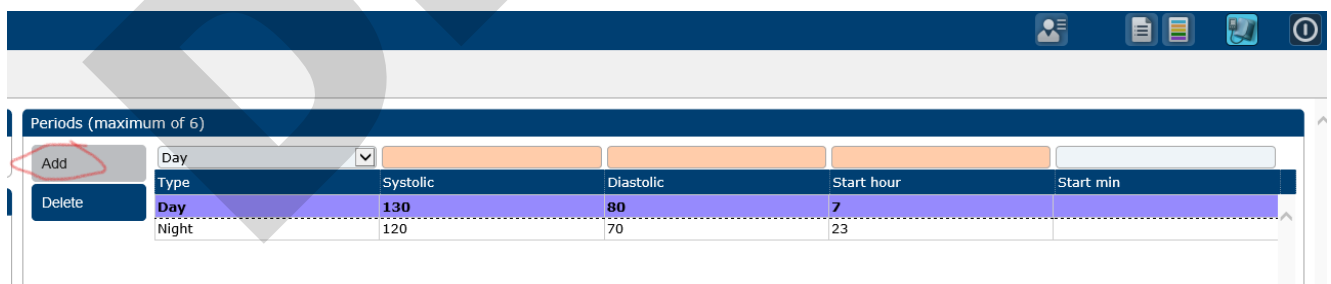
* Mean arterial pressure max 200

* Pulse pressure min 20

* Pulse pressure max 150

Add two cycles:

- Day with Systolic 130, Diastolic 80, and Start hour 7
- Night with Systolic 120, Diastolic 70, and Start hour 23



Periods (maximum of 6)

Add

Delete

Type	Systolic	Diastolic	Start hour	Start min
Day	130	80	7	
Night	120	70	23	

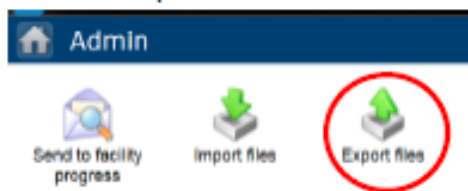
Click Save. Click “Home” icon to return to main menu.

APPENDIX D. ABP EXPORT FROM SENTINEL 11

1. Log into Sentinel and at the home page, select Admin



2. Select the Export Icon

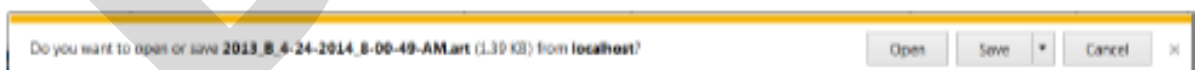


3. Highlight the participant record you wish to export. Double check this step.

4. Select Export to ART



5. Save the .art file to a shared folder



Save .art file as “[subjectID].art” onto the desktop or laptop computer.

NOTE: The first time you complete this process you will need to create a directory folder on the computer called “ABPM Raw Data Files”.

Save the each .art file in the folder on the computer called “ABPM Raw Data Files.” In this example, the raw .art file should be saved as **W123456.art**.

After saving the file, go to the “ABPM Raw Datafiles” folder on your local computer and confirm that the file has been saved.

WARNING: We recommend that you do not click the file to open it as it may automatically open in Excel or another default program that could change the file formatting. If the file needs to be opened for some reason, a text editor should be used.

6. Attach the “.art” file to the ABPR form in CDART as described in Appendix E.

DRAFT

APPENDIX E. ATTACHING DATA TO A CDART FORM

Use the following instructions to attach the participant raw data files to the CDART return forms.

Raw .art data files for ABPM

1. After filling out relevant data in the ABPR form, use the dropbox (labeled “Files”) at the bottom of the form to attach the .art participant data file to the ABPR form. To be able to see the dropbox, the tab with “Event” will need to be highlighted (this is the default). Files can be attached by dragging the file from the folder on your computer into the box with the “+” (Note, you must save the form before the “+” will appear on the dropbox). This dropbox can be accessed from any tab within the form.

The screenshot displays the CDART form interface. At the top, there are tabs labeled 'CGR 0a-9', '9-15', and '16'. Below these, the 'ADMINISTRATIVE INFORMATION' section includes fields for '0a. Completion Date:' and '0b. Staff ID:'. A link '[Click here to open the QoQ for this form]' is visible. Instructions state: 'Instructions: This form is completed when a Continuous Glucose Monitoring Libre Pro sensor is returned to the clinic. All results and data files obtained from the CGM sensor should be attached to this form using the following standard naming format: CSV files: "[ARIC subjectID]"_"[sensor serial number]"_csv PDF files: "[ARIC subjectID]"_"[sensor serial number]"_results.pdf If the participant had a replacement sensor, wait to send results until both sensors have been returned.'

The 'A. CGM Sensor Return Information' section contains several questions with dropdown menus and checkboxes:

- 1. Sensor Serial Number: [text input]
- 2. Was the CGM sensor returned to the clinic? [checkbox]
- 3. Date CGM sensor returned to clinic: [date picker]
- 4. Was the data successfully downloaded from the sensor? [checkbox]
- 4a. Why not? [dropdown]
- 4a1. If other, please specify: [text input]
- 5. Was the exported .csv file successfully attached to this form? [checkbox]
- 6. Was the .pdf results file successfully attached to this form? [checkbox]
- 7. Did the participant wear the sensor for the full 14-day wear period? [checkbox]
- 7a. How many days did the participant wear the sensor? [text input]
- 8. Did the participant have the sensor replaced? [checkbox]

A note states: 'Do not send participant results until the replacement sensor has been returned to the clinic.'

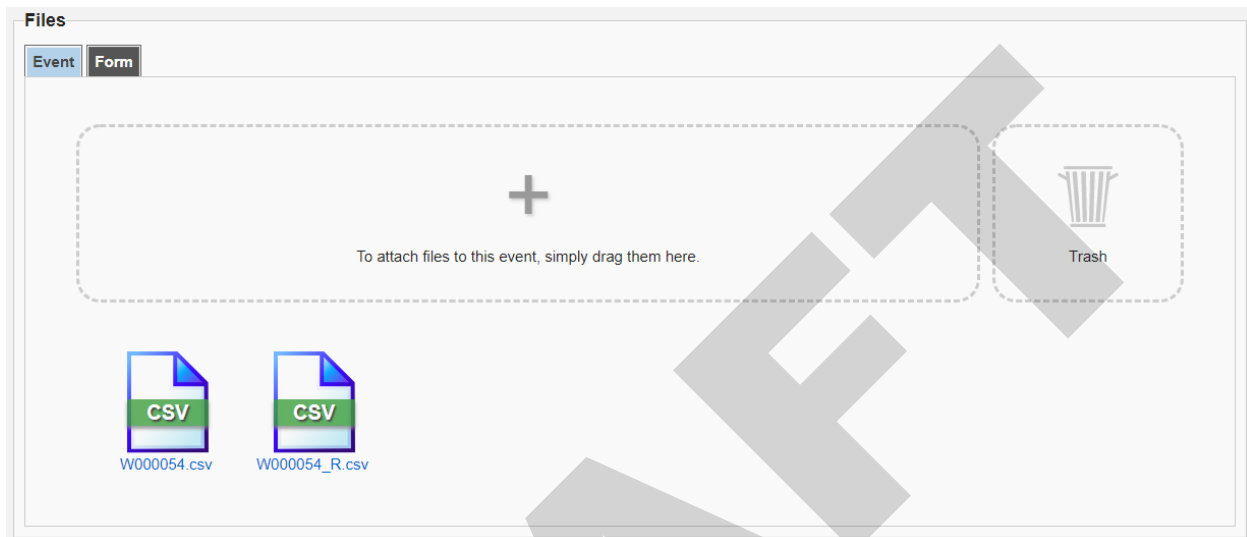
At the bottom, there are buttons for 'Print Form', 'Save and Close', 'Save and Reload', 'Save', and 'Next Page'.

The 'Files' section at the bottom has two tabs: 'Event' (selected) and 'Form'. Below the tabs is a large dashed box with a '+' icon and the text 'To attach files to this event, simply drag them here.' To the right of this box is a 'Trash' icon.

2. Attach one .art file for each monitor worn by the participant. Be sure that the filenames match the specified convention.

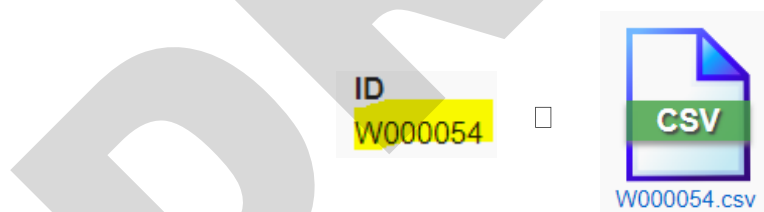
Participant data filename convention: '[subjectID].art'

Participant replacement data filename convention: '[subjectID]_R.art'



If the wrong file was attached, you can drag the file to the trash area of the dropbox to remove the file from the form.

3. Ensure that the ARIC subjectID in the filename matches the ARIC subjectID on the form.



4. Finally, after attaching all necessary files, be sure to save the form.



Raw .csv data files for HBPM

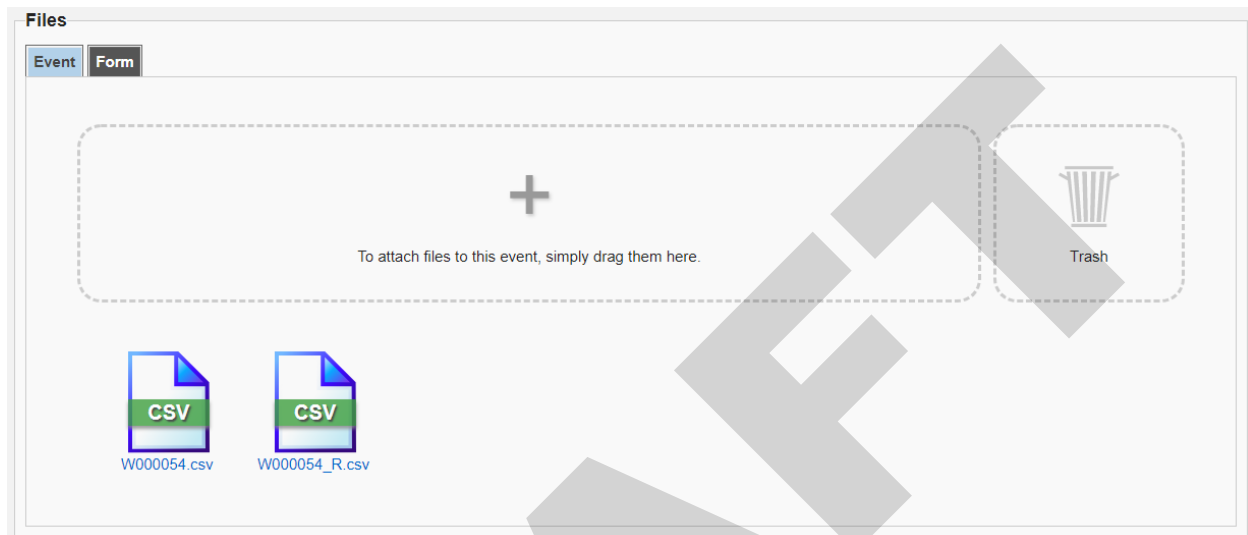
1. After filling out relevant data in the HBPR form, use the dropbox (labeled “Files”) at the bottom of the form to attach the .csv participant data file to the HBPR form. To be able to see the dropbox, the tab with “Event” will need to be highlighted (this is the default). Files can be attached by dragging the file from the folder on your computer into the box with the “+” (Note, you must save the form before the “+” will appear on the dropbox). This dropbox can be accessed from any tab within the form.

The screenshot displays the HBPR form interface. At the top, there are tabs for 'CGR 0a-8', '9-15', and '16'. The 'ADMINISTRATIVE INFORMATION' section includes fields for '0a. Completion Date' and '0b. Staff ID'. Below this, instructions state: 'Instructions: This form is completed when a Continuous Glucose Monitoring Libre Pro sensor is returned to the clinic. All results and data files obtained from the CGM sensor should be attached to this form using the following standard file naming format. CSV files: {ARIC subjectID}_{sensor serial number}.csv PDF files: {ARIC subjectID}_{sensor serial number}_results.pdf If the participant had a replacement sensor, wait to send results until both sensors have been returned.' Section 'A. CGM Sensor Return Information' contains questions 1 through 8, with input fields for sensor serial number, date, and days worn. A 'Print Form' dropdown is located below the questions. At the bottom, there is a 'Files' section with 'Event' and 'Form' tabs. The 'Event' tab is active, showing a large dashed box with a '+' icon and the text 'To attach files to this event, simply drag them here.' To the right of this box is a 'Trash' icon.

2. Attach one .csv file for each monitor worn by the participant. Be sure that the filenames match the specified convention.

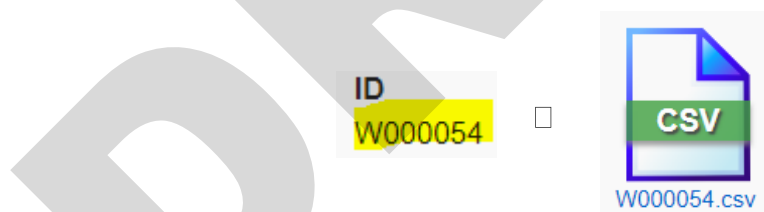
Participant data filename convention: '[subjectID].csv'

Participant data filename convention if data for user 2: '[subjectID]_2.csv'



If the wrong file was attached, you can drag the file to the trash area of the dropbox to remove the file from the form.

3. Ensure that the ARIC subjectID in the filename matches the ARIC subjectID on the form.



4. Finally, after attaching all necessary files, be sure to save the form.



APPENDIX F. BLOOD PRESSURE MONITORING CHECK-IN CALL SCHEDULE

Start ABPM (In-clinic during V10)	End ABPM/ Check-in Call 1	First Day of HBPM	Check-in Call 2**				Check-in Call 3		Last Day of HBPM
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday
Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Friday*	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday









* Try to avoid Fridays







** Preference is Day 4, but can be Day 3 or Day 5

APPENDIX G. HOME OMRON ERROR CODES

If any of the below problems occur during measurement, check to make sure that no other electrical device is within 12 inches (30 cm). If the problem persists, refer to the table below.

Display/ Problem	Possible Cause	Solution
E1 appears or the arm cuff does not inflate.	Air plug is not completely plugged into the monitor.	Insert the air plug securely. Refer to sub-section 2.6.
	The arm cuff is not applied correctly.	Apply the arm cuff correctly, then take another measurement. Refer to sub-section 2.6.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 9.
E2 appears or a measurement cannot be complete after the arm cuff inflates.	You move or talk during a measurement and the arm cuff does not inflate sufficiently.	Remain still and do not talk during a measurement. If "E2" appears repeatedly, inflate the arm cuff manually until the systolic pressure is 30 to 40 mmHg above your previous readings. Refer to sub-section 3.1.
	The systolic pressure is above 210 mmHg and a measurement cannot be taken.	Inflate the arm cuff manually until the systolic pressure is 30 to 40 mmHg above your previous readings. Refer to sub-section 3.1.

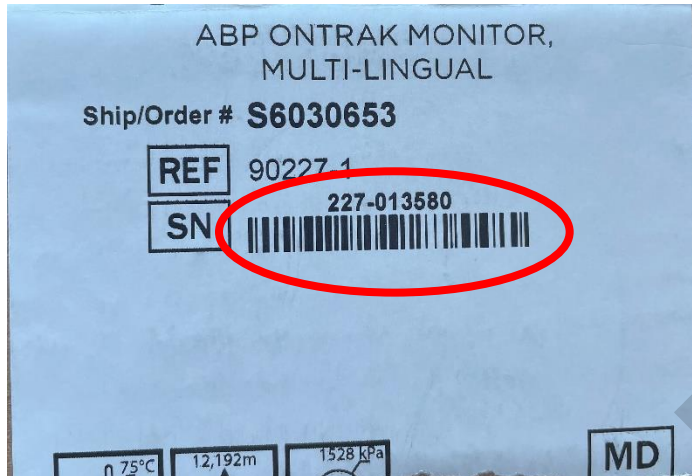
Display/ Problem	Possible Cause	Solution
 appears	The arm cuff is inflated exceeding the maximum allowable pressure.	Do not touch the arm cuff and/or bend the air tube while taking a measurement. If inflating the arm cuff manually, refer to the end of sub-section 3.1.
 appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
 appears	The pulse rate is not detected correctly.	Apply the arm cuff correctly, then take another measurement. Refer to sub-section 2.6. Remain still and sit correctly during a measurement. If the "  3 " symbol continues to appear, we recommend you to consult with your physician.
 /  3 appears		
 does not flash during a measurement		
 appears	The monitor has malfunctioned.	Press the [START/STOP] button again. If "Er" still appears, contact customer service. Refer to section 12.

Display/ Problem	Possible Cause	Solution
 appears	The monitor cannot connect to a smart device or transmit data correctly.	Follow the instructions shown in the "OMRON connect US/CAN" app. If the "Err" symbol still appears after checking the app, contact customer service. Refer to section 12.
 flashes	The monitor is waiting for pairing with the smart device.	Refer to sub-section 4.1 for pairing your monitor with your smart device, or press [START/STOP] button to cancel pairing and turn your monitor off.
 flashes	The monitor is ready to transfer your readings to the smart device.	Open the "OMRON connect US/CAN" app to transfer your readings.
 flashes	There are more than 80 readings in memory to be transferred. The date and time is not set.	Pair or transfer your readings to the "OMRON connect US/CAN" app so you can keep them in memory in the app, and this error symbol disappears.
 appears	There are 100 readings in memory to be transferred.	
 flashes	Batteries are low.	Replacing all 4 batteries with new ones is recommended. Refer to sub-section 2.1.

APPENDIX H. DEVICE SERIAL NUMBERS AND TRACKING (SCREENSHOTS)

ABPM

You can find the serial number for each ABPM device on the box and the individual device itself. There is a barcode and a QR code that can be scanned.



This serial number and barcode on the box matches the serial number and barcode on the back of the ABPM device.



HBPM

There is a QR code with a serial number on the OMRON box and on the bottom of the Omron monitor.

