



INSTRUCTIONS FOR THE HOME BLOOD PRESSURE MONITOR INITIALIZATION FORM

I. General Instructions

This form is completed for all participants who agree to take part in the Home Blood Pressure Monitor (HBPM) ancillary study. If a participant has a healthcare proxy, Legally Authorized Representative (LAR) or caregiver, be sure to discuss the HBPM protocol with them, and encourage them to assist with the home protocol, the HBPM Participant Activity Log, the HBPM Participant Experience Form, and the device return process. They may also assist with the completion of this questionnaire.

If the participant's arm circumference does not fit the Omron Series cuff range, then the participant is not eligible to participate. The first blood pressure measurement should be taken with the Omron Series 10 home device while in the clinic and can be recorded from the HBPM onto the paper form or directly into the CDART form.

II. Detailed Instructions for Each Item

0a. Enter the date the form was completed.

0b. Enter the staff code of the person who initialized the HBPM device and completed the in-clinic blood pressure measurements.

0c. Record whether the participant is interested in participating in the HBPM ancillary study. If the participant is not interested in the HBPM study, select No and do not open or complete the other forms for the HBPM ancillary. It is not necessary to mark those forms as Permanently Missing. Continue with item 0c1. If they are interested in participating, select Yes and skip to item 1.

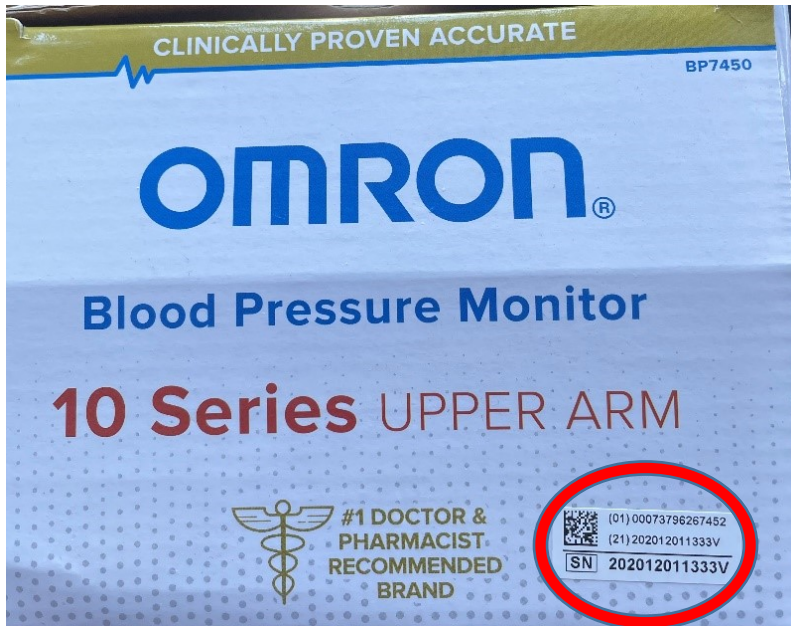
0c1. If the participant indicates that they are not interested in participating in the HBPM ancillary study, record the reason why not. Save and close the form.

A. Visit Details

1. Record if the participant's arm circumference is within the range of the Omron Series. The participant's arm circumference can be found on the V10 Snapshot Report and in the SBP Form. If the participant's arm circumference does not fit the range, they are not eligible for the HBPM protocol. Save and close the form.
2. Record the arm being used for blood pressure monitoring.
3. Record the participant's dominant arm.
4. Record the device serial number. The HBPM device serial number includes 31 characters. Staff should scan the QR code that can be found on the box and on the bottom of the Omron monitor directly into CDART in order to avoid transcription errors.

4. HBPM device serial number:

010007379626745221202012011333V



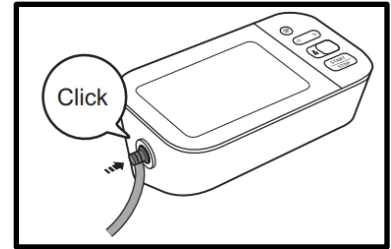
The 31-character serial number and QR code can be found on the box and on the back of the device.



*HBPM Device Initialization Information

The monitor should be set up the morning of the participant visit (if possible), and no more than 1 week prior to the visit (to save battery life). If for any reason the monitor has not been set up prior to the participant visit, follow these instructions for the correct set-up of the Omron Series 10 BP7540 or BP7540CAN.

These instructions also describe how to obtain 1 TruRead measurement in-clinic.



- Open Omron box and insert batteries. Affix the arm cuff into a monitor using the air ply to ensure a secure connection. Listen for a “click”.
- Press START/STOP to turn on the device. Set **current** Date and Time. Use the arrows to move between numbers, and the Bluetooth button on the rear surface as an “enter or OK” button once you’ve selected the correct number. See MOP38 Appendix J for detailed instructions.
- Check that Omron is programmed to obtain 3 blood pressure measurements separated by 60 seconds each (see pages 18, 26 in the Omron Device Manual); this is referred to as a “TruRead” mode. (See **Omron series 10 configuration** below).
- Select user ID 1 (explain to the 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 the 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. The research technician or ARIC staff will pair a smartphone or tablet with the BP monitor once all BP readings are completed.
- Affix participant-specific labels 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:

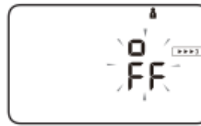
2.4 Setting the TruRead Mode

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.

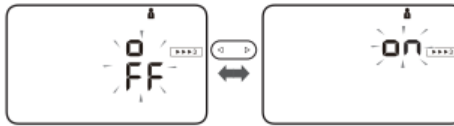
After it is completed, the "▶▶▶3" symbol appears on the display.



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.



B. Clinic Assessment

Make sure the date and time are set correctly and the monitor is configured to "TruRead" Mode. Place the cuff on the participant's arm and perform a single triplicate measurement. The device will take three measurements, each separated by 60 seconds. It will also display a reported average for SBP, DBP, and HR from the three measurements.

5. Record the time of the first measurement.

6 – 8c. Record Measurement 1 (SBP, DBP, and HR) in 6a-6c, Measurement 2 in 7a-7c, and Measurement 3 in 8a-8c.

9. Record the reported average for systolic blood pressure, diastolic blood pressure, and heart rate from the 3 measurements. These averages come from the Omron device and should NOT be calculated by hand.

10 – 10b. Record the expected start and end dates for Home Blood Pressure Monitoring. Once the expected start date is entered into CDART, save the form and click the arrows in the field in 10b. CDART will calculate the expected end date.