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

Version 2.3 – 10/13/2023

Ambulatory and Home Blood Pressure Monitoring

Manual of Procedures

Table of Contents

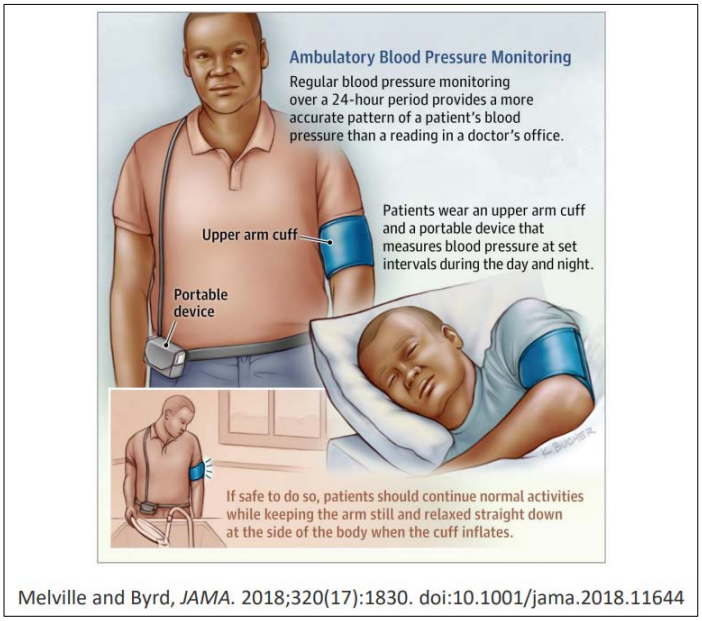
MANUAL REVISIONS

Date	Version	Section	Revision Summary
2/10/2023	1.6	2.2.7	Updated information for HBPM report download to specify the end date should be the day after the end date of the wear period.
2/9/2023	1.6	Appendix P	Specified the dates that must be entered when completing HBPM data download and saving as a .csv file. Start date must be date of clinic visit to include in-clinic measure, and end date must be day after actual end date of wear period to capture last PM measurement. Updated image to reflect the inclusion of correct dates.
2/9/2023	1.6	Table 1 (ABPM), Table 2 (HBPM)	Updated blood pressure triggers and their corresponding interpretations for results letters.
2/28/2023	1.7	Table 1, Table 2, Appendices	Removed ABPM and HBPM results letter templates, ABPM and HPBM threshold values and interpretations, and ABPM and HBPM participant handouts from the Manual. These will now appear in separate documents on the ARIC website. Renumbered appendices.
4/18/2023	2.0	Appendix V	Added information about the Blood Pressure Stand Alone Visit to Appendix V.
5/8/2023	2.1	1.3.1	Added info/screenshot about how to save the full ABPM report when using Microsoft Edge
8/11/2023	2.2	Appendix W, X, Y	New appendices added (W-Y) with instructions for completing accuracy checking on the ABPM device with the SimCube.
10/13/2023	2.3	1.2.2	Added troubleshooting instructions for when the Sentinel desktop icon/shortcut is not working.

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 measurements over the course of 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.
  - Legally Authorized Representative (LAR) may provide consent for participants (e.g., participants with dementia are eligible if their LAR can consent and confirm they will assist with the home protocol).
- Visit 10 protocol
  - Near the end of Visit 10.
  - Participants will be asked to participate in the ABPM protocol during their in-person visit. Staff will explain the ABPM protocol in-person and the participant will leave with the cuff and monitor on them.

1.1.3 Who

- 1 physical examiner for ABPM instructions, placement, device tracking, and data download
  - Components of the protocol can be done by different staff members, as long as they are trained and certified on that specific component (i.e., one staff member may place the ABPM cuff and monitor on the participant in-

clinic, and another staff member may download the ABPM report after the monitoring period is complete).

1.1.4 Equipment, Materials, and Supplies

- 1 Spacelabs OnTrak 90227 ABPM device monitor with reusable pouch
- 1 computer or laptop with Spacelabs Sentinel software
- 1 appropriately sized blood pressure cuff
- 1 USB cable (comes with ABPM device)
- 2 AA batteries
- ARIC ABPM travel bag
- String for helping with battery removal (optional)
- FedEx Small Box (S2: Rectangular and deep) and pre-paid label for device return (see **Appendix S. Device Return Guide** for detailed instructions). An alternative is using the USPS shipping method.

1.1.5 Forms, Logs, and Scripts

- Printed Participant Checklists, Forms, and Logs
  - ABPM Participant Checklist and Replacing the Cuff Instructions
  - 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. A Legally Authorized Representative (LAR) may provide consent for participants. This will be noted on the standard ARIC consent form.
- 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).
- Health proxies, caregivers, or LARs may assist with filling out forms and replacing cuff on the arm if it was removed during the assessment, but may not

be required if the participant intends to keep the cuff on or demonstrates an ability to put it back on independently.

1.1.7 Inclusion and Exclusion Criteria

Inclusion Criteria

- All participants who provide informed consent are eligible to participate in ABPM.
- If the participant has a Legally Authorized Representative (LAR), they are still eligible to participate in the ABPM protocol with the consent of their LAR.
- If the LAR cannot help with filling out forms at home, such as the ABPM Participant Activity Log (ABPM_PL) or ABPM Participant Experience Form, this does not exclude the participant.
    - However, a participant will be excluded if staff foresees issues with wearing the ABPM monitor at home (see exclusion criteria below).

Exclusion criteria:

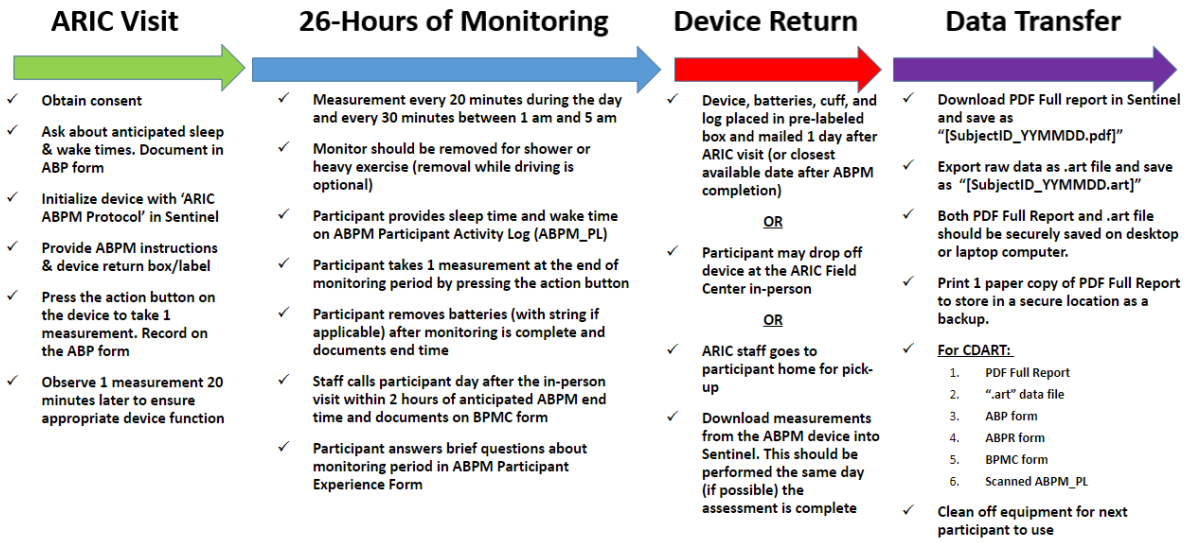
- Participants who are physically unable to perform assessments at home or return the ABPM device will be excluded.
- Participants (or their LAR) who do not provide consent
- The LAR, caregiver, or proxy is unable to assist with home protocol.
    - Note: This can be up to staff discretion. For example, if the proxy, LAR, or caregiver is unsure whether they will be able to assist the participant with keeping the ABPM cuff on, correctly repositioning the cuff should it become loose or slip beneath their elbow, or removing the cuff after 26 hours, staff can determine that the participant is ineligible.
- A participant or their LAR, caregiver, or proxy is unable to select a device return method or is unable to assist with device return to ensure timely data transmission after ABPM completion.
- If a participant has an average seated Systolic Blood Pressure ≥200 mm Hg or Diastolic Blood Pressure ≥120 mm Hg measured during the ARIC visit.
    - Note: If this does occur, the exam will be stopped for the participant to receive urgent care. The participant will be ineligible for the ABPM protocol. This protocol will directly follow ARIC Sitting Blood Pressure (SBP) so that staff can determine a participant's eligibility at that time.
- Arm circumference > 50 cm (i.e., if a participant has an arm circumference that is outside the acceptable range of cuffs.
    - Note: In borderline cases staff may round to 50 cm; (e.g., for a participant with an arm circumference of 50.1 – 50.5 cm, staff can round down to 50 cm to err on the side of including the participant and use the XL cuff). See arm cuff sizes and arm circumference ranges below:

Spacelabs Reusable Cloth ABPM Cuffs

015-0067-04Q	Cloth cuff, metal quick disconnect	small adult	17 - 26 cm
015-0068-05Q	Cloth cuff, metal quick disconnect	adult	24 - 32 cm
016-0077-05Q	Cloth cuff, metal quick disconnect	large adult	32 - 42 cm
016-0109-04Q	Cloth cuff, metal quick disconnect	XL adult	38 - 50 cm

- Be sure that the participant's arm circumference fits within the appropriate cuff size. If the participant has an arm circumference directly on the border size choose the **larger size** (i.e. for an arm circumference of 26 cm, use an adult small, or for an arm circumference 32 cm, use a large adult).
    - Note: If the cuff is too small, pressure readings may be falsely high; a cuff that is too large produces a falsely low reading.

1.1.8 Timeline Schematic



1.2 STUDY PROCEDURES

1.2.1 Prior to Visit 10 (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 loose, long-sleeve shirt over the cuff after it has been placed.

- Have Sentinel 11 or 11.5 installed on a desktop or laptop computer. Note: **Internet Explorer** or **Microsoft Edge** are the compatible browsers for the Sentinel software and must be used in order to prevent errors in configuration of participants.
    - Note: See **Sentinel Workstation Installation Guide** that came with your ABPM devices. This is an electronic file that came in both PDF and a word file.
- Within your Sentinel software, add a new protocol called **"ARIC ABPM Protocol** and a new statistic called **"ARIC Report".** Both of these steps are only done **ONCE** and should be done before the first participant in-person visit.
    - See **Appendix A. Create ARIC ABPM Protocol**
    - See **Appendix B. Create ARIC Statistics Report**

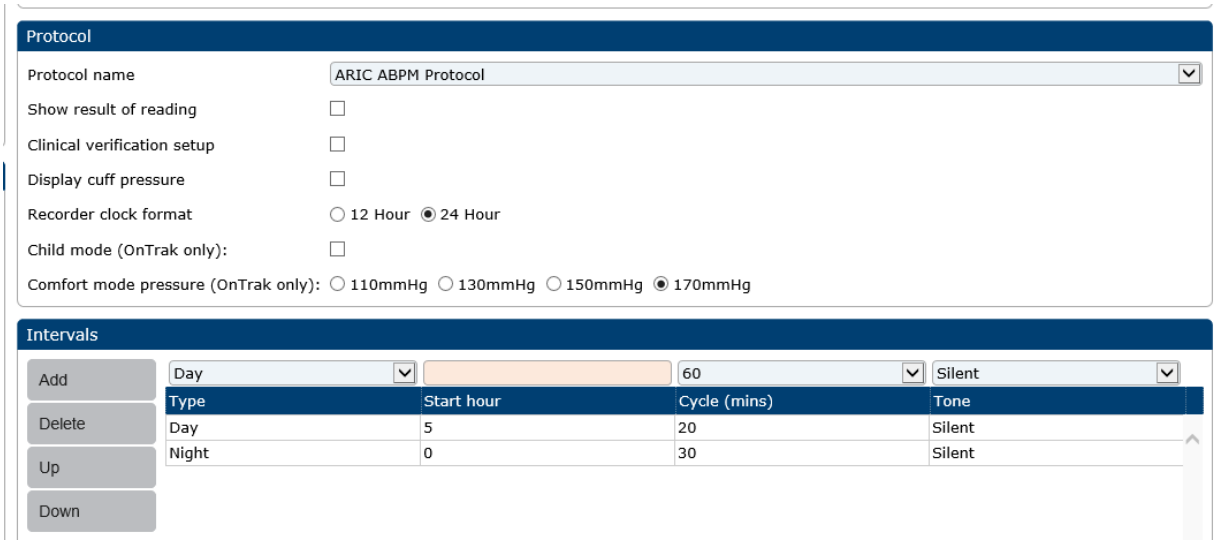
1.2.2 Set-up of Monitor [**See Appendix C. ABPM Configuration** for detailed instructions]

- Start desktop or laptop computer with the software installed on it, and click on the icon for the Sentinel 11 or Sentinel 11.5 (the version depends on when the software was purchased, but either is fine).
- Verify participant ID and consent.
- Affix participant-specific label onto the ABP and ABPR forms.
- Place new batteries (AA size) in the back of the monitor. It is recommended to tie a piece string or ribbon around one of the batteries to assist with battery removal after ABPM completion. Replace the monitor cover once batteries are correctly placed in the device.

- Plug the monitor into the computer using the monitor cable. Connect one end of the USB cable into the appropriate port on the computer, and the other end of the cable to the ABPM device.
- Turn on the monitor by pressing the action button on the front of the monitor. You will hear a beep as it powers on.
    - [Note: if the ABPM device was previously used by a different participant, a box will appear on the screen and as "Do you want to end current test?" Use the down arrow to move to "Yes" and press the action button to end the current test.

- The device will then say “Connected to PC.”

- Click “ABP”
- Click “Configure recorder for patient.”
- Click “Add patient” and enter the ARIC Participant ID in the “Patient ID” line. This field is mandatory and you will not be able to move forward until the ID has been entered. Click “Save patient and configure ABP”
- Under Protocol next to Protocol name, select “ARIC ABPM protocol.” This will change the protocol from the “Default” setting.
- Verify that the intervals are correct. Intervals should be as follows:
  - Day: Start hour=5. Cycle (mins) =20. Tone=silent
  - Night: Start hour should be 0. Cycle (mins) =30. Tone=silent

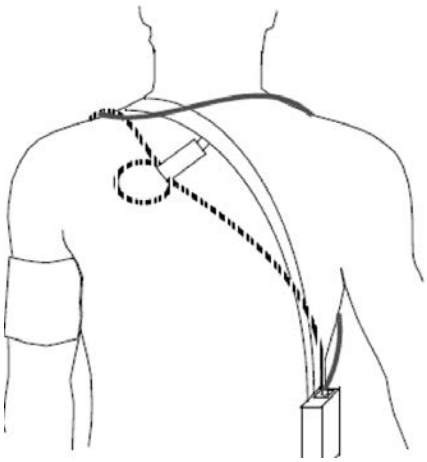


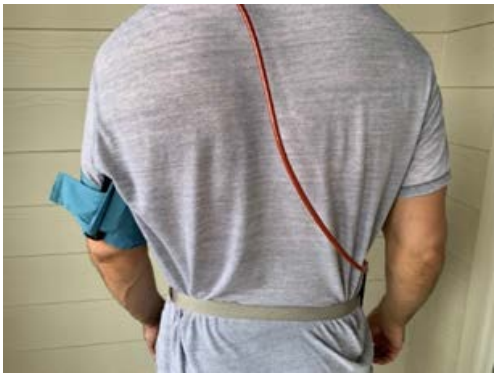
  - [Note this should reflect the pre-programmed “ARIC ABPM Protocol” with Day starting at 5:00 (5am) and Night starting at 00:00 (midnight). TIME IS MILITARY TIME. **See Appendix A Create ARIC ABPM Protocol** for more detailed instructions on how to set up the ARIC ABPM Protocol]. Note that for “Night” Sentinel will treat the 00:00 as a 1:00 am start time.
  - Blood pressure measurements will be made as follows:
    - Between 5:00 am and 1:00 am [Day], every **20 minutes**
    - Between 1:00 am and 5:00 am [Night], every **30 minutes**
    - In the event of an unsuccessful measurement the device with attempt a second time within 2 minutes
- Click “Configure recorder”
- The Configuration Confirmation window will confirm the patient details. Select Configure.
- When complete, your new participant will be displayed in the *Configured* or *All* tabs.
- Click on the Home button.
- Click on *Log out.*
- It is best to keep the device plugged into the computer until you are ready to connect it to the cuff and place on the participant.
  - When the device is plugged into the computer, it will not inflate. The inflation intervals will begin once the device is disconnected from the computer.
- Follow the instructions in section 1.2.2 to prepare the participant for the ABPM protocol.
  - Note: If you are preparing the device prior to the participants arrival (morning of the visit is appropriate), you can disconnect the monitor from the computer, but remove one of the batteries and put it in backwards. This will disrupt the electric current and the device will not inflate.
  - Once the participant arrives, you can switch the battery back. You will still need to press the action button to take 1 manual measurement, and then wait to make sure the device inflates automatically within 20 minutes. If it does not, you will need to re-configure the device and repeat this process.

- In the event where the Sentinel desktop icon is not working:
  - Open a browser (any browser, it does not matter).
  - In the address bar, type http://localhost/sentinel and press enter.
  - The Sentinel log-in screen will appear. Continue with the rest of the steps above.
  - To fix the Sentinel desktop icon, open Microsoft Edge and run the http://localhost/sentinel. Create a shortcut or bookmark it for future use.

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 in as well as on the individual ABPM device (on the back of the device). See **Appendix H ABPM Device Serial Number and Tracking (Screenshots)** for more information.
  - Be sure to scan the barcode with app or scanner and record the barcode on the ABPM initialization form (ABP) and the ABPM return form (ABPR) to appropriately track devices.
- Identify the correct ABPM cuff size for participant. If needed, measure participant arm circumference according to proper ARIC technique.
  - Proper cuff size is essential for accurate blood pressure measurement. There are four ABPM cuff sizes available (**See page 7**).
- Place ABPM cuff on participant with the tubing going up towards the shoulder. (For ABPM, it may be easier to place the cuff while the participant is standing, but this is not necessary.
  - Cuff placement should be performed following similar practices as performed for seated BP.
    - Use prior arm measurements to select appropriate cuff size if needed. Ideally use the same arm 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 BP would be ideal).
    - Cuff should be positioned over <u>bare skin</u>.
    - Staff should feel for brachial artery (just medial to and above the cubital fossa) and wrap the cuff over the artery at least 1” above the crease of the participant’s elbow. The cuff should be snug enough to fit 2 fingers just underneath both ends of the cuff.
      - Check the fit of the cuff to ensure that it is secure, but not too tight. The cuff should be of uniform pressure against the arm.
  - 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 or tucking underneath clothing.
- Review and provide the **ABPM Participant Checklist and Replacing the Cuff Instructions** with the participant
- Ask the participant to demonstrate removing the cuff and appropriately repositioning it back on their arm. If the participant has a healthcare proxy, LAR, or caregiver, consider having them demonstrate removing the cuff and repositioning it back on their arm.

Note: Should the participant need to take their cuff off at any time, or should the cuff become loose, the ABPM Participant Checklist and Replacing the Cuff Instructions can be used to show them how to correctly reposition the cuff back on their arm.

- Driving with the ABPM cuff on is optional.
  - If the participant will be driving home, they may slide the cuff off. If the Velcro is loosened during this process, it may need to be tightened when placed back on the arm.
  - Participants may also keep the cuff on while they drive. Staff can use discretion for safety purposes.
  - Ask the participant to record anytime they drive or are a passenger in a vehicle on the ABPM Participant Activity Log.
- The participant should remove the cuff when heavily exercising or when taking a bath/shower to avoid getting it wet.

- Explain that the blood pressure readings are visible at first but hidden after the initial readings, so there is no need to check the device during the monitoring period.
- Ask each participant about anticipated **sleep and wake times and record in the ABP form** (this is critical for data interpretation that the Coordinating Center will do).
  - If a participant has a healthcare proxy or LAR, ask them for this information.
- Complete the ABP form in CDART

- Provide the participant the ABPM_PL and the Participant Experience Form to take home. The log should include sleep time, wake time, and end of study time filled out. Participant should return the ABPM_PL and experience form in the mail with the device.
  - For participants with LARs, healthcare proxies or caretakers, encourage them to assist with keeping the ABPM device on. Encourage them to help record sleep and wake times and fill out the log throughout the 26-hour period.
    - Note: As mentioned in the inclusion/criteria, if a proxy, LAR, or caregiver cannot assist with keeping the ABPM on and returning the ABPM device, the participant can be excluded. Staff can use their discretion with this.
  - 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 a string or ribbon 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 string or ribbon when explaining battery removal to the participant. (See figure in Appendix C).
- Unplug the monitor from the USB port and connect it to the tubing attached to the cuff already on the participant. Place the monitor in the reusable pouch. The monitor in the reusable pouch can also be zipped into the ARIC ABPM travel bag, which can be fastened around the participant's waist **(see images below)**.

Reusable Pouch

ARIC ABPM Travel Bag

- Press the action button to begin first measurement. **Document time, SBP, DBP, and HR from the first measurement on the ABPM Initialization Form (ABP). Record the participant's anticipated sleep and wake times.**
- Remind participants not to touch any buttons once the ABPM device is placed. The only thing participants should do is press the action button (the circular button on the front of the device) at the end of the 26-hours.
- Remind the participant to complete the ABPM_PL throughout the next 26-hours, specifically noting their sleep and wake times.
- Remind participants to place their monitor and BP cuff into the pre-paid FedEx overnight box with their ABPM_Participant Log and ABPM Participant Experience Form after the monitoring is complete.
- The participant may proceed with their ARIC visit, but they should be observed undergoing at least **one** successful, spontaneous second BP measurement before going home (*this is to ensure appropriate and automatic firing frequency every 20 minutes*).
  - It is possible for the ABPM device to display an error message and not take a reading after 20 minutes. If there is an error (most common error is due to movement) and the ABPM cannot get a successful measurement, it will automatically wait 2 minutes, and attempt the measurement again. If it is still unable to obtain a reading, it will move onto the next measurement at the original time interval.
  - If the ABPM device does not spontaneously take a measurement, staff will need to re-configure the device and repeat the process to ensure appropriate firing every 20 minutes.
  - If the ABPM stops taking readings completely while the participant is home, the participant may remove the cuff, take the batteries out, and mail the device back to the clinic.
    - Note: There is also an option to have the participant use another monitor. In this case, it would require participants to return to the field center for staff to configure the second monitor and place on the participant.
- Remind the participant you will call them the next day (Day 2 of wearing the ABPM) to ensure they have completed the assessment or are about to complete the assessment, and that they have plans for device return in addition to their participant log and participant experience form.
  - Note: The participant must have at least 14 successful daytime readings OR at least 7 successful nighttime readings to be included in study analyses for day or night blood pressure, respectively.

1.2.4 First Check-in Call (See Appendix R. BP Monitoring 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 anticipated end time. Note, it is preferred to call the participant after the assessment has ended; however, if this time falls outside of normal business hours (e.g., after 5pm), it is acceptable to call the participant anytime within the 2 hours of anticipated end time.
- Ask if they encountered any difficulty wearing the device or with device measurement, document these responses on the Blood Pressure Monitor Check-in Call Form (BPMC).
- Review plans for returning the ABPM device and encourage mailing that day (or remind participant of when the FedEx pick-up is scheduled)
- Remind participants to remove the batteries before returning the device. (Use string if appropriate)
- Use this call to remind the participant about HBPM starting the following morning and to review procedures.
- Enter this information on the BPMC form.

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 in as well as on the individual ABPM device (on the back of the device). See **Appendix H. ABPM Device Serial Numbers and Tracking** for detailed instructions.
- 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 the ABP form).
- In the case of a mismatch, the serial number should be reconciled with the serial number recorded on the ABP form and the Coordinating Center should be notified with any discrepancies.

1.2.6 Device Return

Please adapt and follow the instructions below, according to the device return method that works best for your field center and based on each participant's preference:

Schedule FedEx pick-up from the participant's home and drop off at ARIC Field Center with FedEx Express. See https://www.fedex.com/en-us/home.html. An alternative is using the USPS shipping method. See https://www.usps.com/.

OR

Participant returns ABPM device in-person to the ARIC Field Center at _____.

OR

ARIC staff pick-up at participant's home

Be sure to record date of scheduled return and device return method on the ABP form.

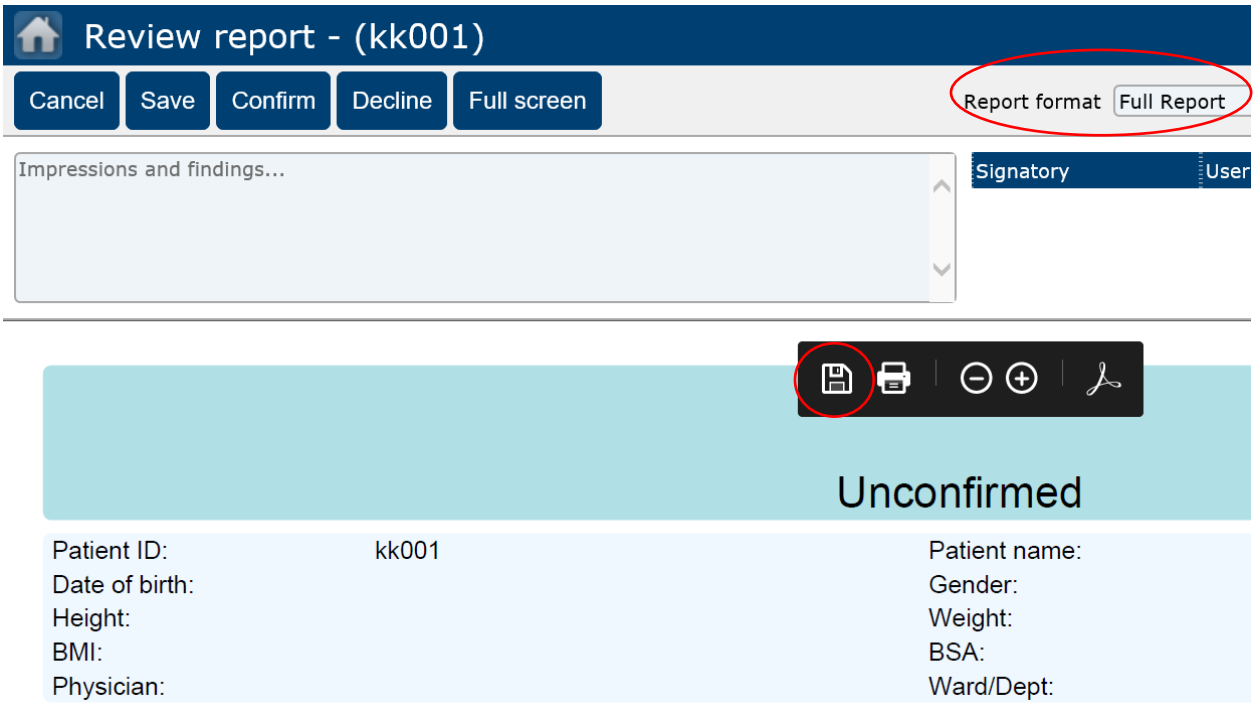
For FedEx Express (see **Appendix S. Device Return Guide** for detailed instructions).

- Create and print out shipping label. Schedule FedEx Express pick-up at participant's home for the day after ABPM completion.
    - *Ex.* ABPM is fitted with participants on Monday April 18, 2022. Schedule pick-up for Wednesday April 20, 2022 (or closest available date)
    - Choose 2-day shipping
    - Be sure to confirm with participant that they will be home to bring out the package or leave it on the doorstop.
- Send participant home with the FedEx Small Box, shipping label (attached to the box).
    - Remind them to include the ABPM Participant Log and Participant Experience Form in the box to be returned to the field center.

1.3 DATA AND RESULTS REPORTING

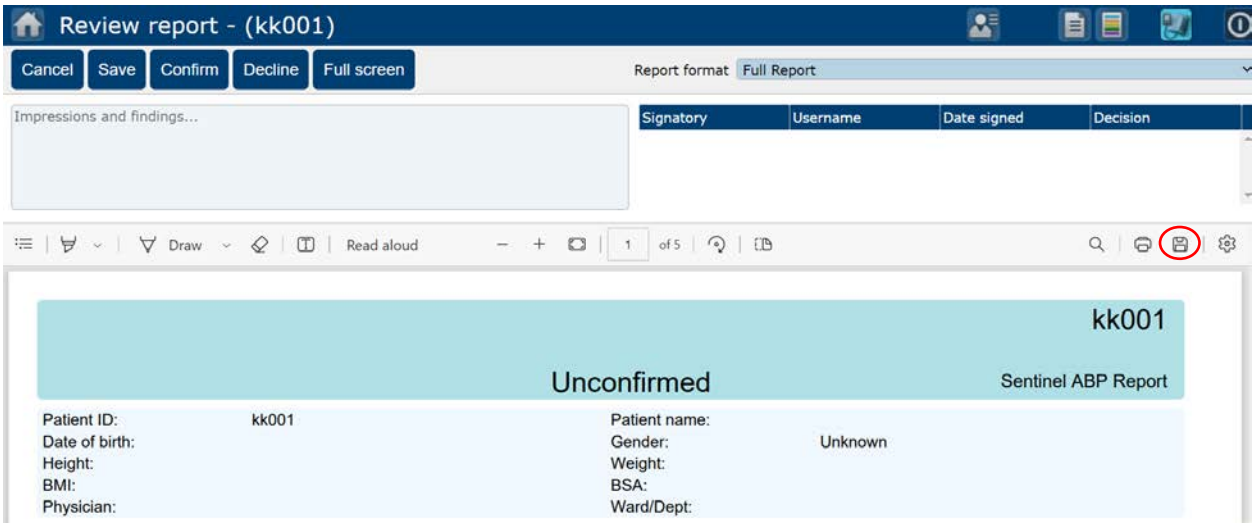
1.3.1 Data Download Instructions (see Appendix B. Download the ABP Recorder with screen shots)

- Log into Sentinel 11 or 11.5.
- Connect the monitor to the computer using the USB cable.
- Turn the monitor, "On" (it is recommended to use fresh batteries).
- The device will display 'Do you want to end current test?'
- Use the arrows on the device to toggle between the options and select 'Yes'
- Click, "ABP" on the Sentinel software
- Select "Download ABP" then confirm participant ID.
- Click Ok.
- A Confirmation window will appear to let you know the Download is complete.
- Click Ok.
- Select "Review Test" enter settings then under "configured statistics" select pre-programmed "ARIC Report."
- Select "OK" and then "Save"
- Select "Review Report".
- Select Report Format (top right drop down menu), **"Full Report"**
- A small window will appear, click the save icon and save file as participant's ARIC Subject ID and date of ABPM completion: "[SubjectID_YYMMDD.pdf]".



Alternatively, if using **Microsoft Edge** as a default browser:

- After clicking on Report Format (top right drop down menu), and selecting "Full Report", click the save icon on the tab above the patient ID and save file as participant's ARIC subject ID and date of ABPM completion: "[SubjectID_YYMMDD.pdf]".



- In Sentinel, click on admin, and "Export files", then "Export to ART". Please refer to the "**Appendix E. ABP Export from Sentinel 11 or 11.5**" instructions with screenshots for details.

- Save raw data as an .art file as “[SubjectID_YYMMDD].art” onto the desktop or laptop computer (e.g., W123456_220613.art).
    - Note: The date used should be the **date of ABPM completion**. For example, if a participant ends their ABPM on June 13, 2022, the file will be saved using the ARIC Subject ID and 220613 (YYMMDD).
- 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 reusable pouch.

1.3.2 Data Transmission

- Attach the “.art” file with raw data **and** the .pdf file to the ABPR form in CDART. Please refer to **Appendix F. Attaching ABPM Data to a CDART Form** for more detailed.
- 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 data download.
- Seated blood pressure is already reported to participants as part of the parent ARIC NCS protocol.
    - If average SBP during ARIC Sitting Blood Pressure is ≥200 or DBP ≥120 mmHg: STOP exam for urgent care. [If this were to happen, the participant will not have been eligible for the ABPM Protocol].
- Staff will generate a several page Full 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 location. In addition, the PDF report will be uploaded to CDART for the Coordinating Center to calculate results for each participant’s Summary of Results.

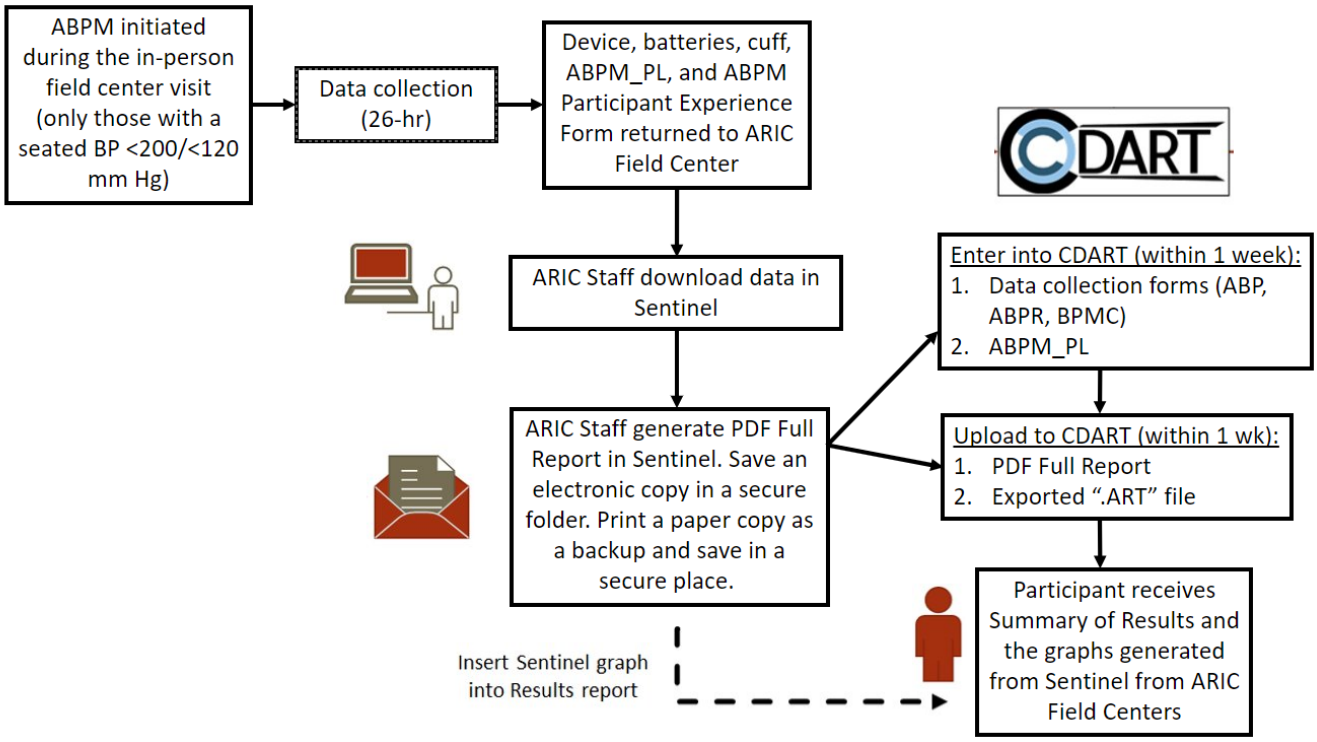
1.3.4 Results Reporting

- Results will be provided to participants using a CDART report 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 daytime 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.

- ABPM threshold values for results are reported as normal, abnormal, or alerts and interpretations are included in the report to study participants/their healthcare provider. See **MOP 38 Results Letter Templates** (on the ARIC website) for specific details related to results reporting.
- ARIC staff will upload ABPM reports including the participant graph, which will be mailed to the participant from the field centers as part of the full visit 10 results report prepared by the Coordinating Center.

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.

All staff performing ABPM must be trained and certified by ARIC in the Seated Blood Pressure (SBP) technique.

Training will include:

- Read and study the manual, forms, and QxQs.
- Attend ARIC training sessions on administration techniques (or review the training video).
- Practice on other staff or volunteers.
- Discuss problems and questions with the local field center expert or QC officer.

Certification will include:

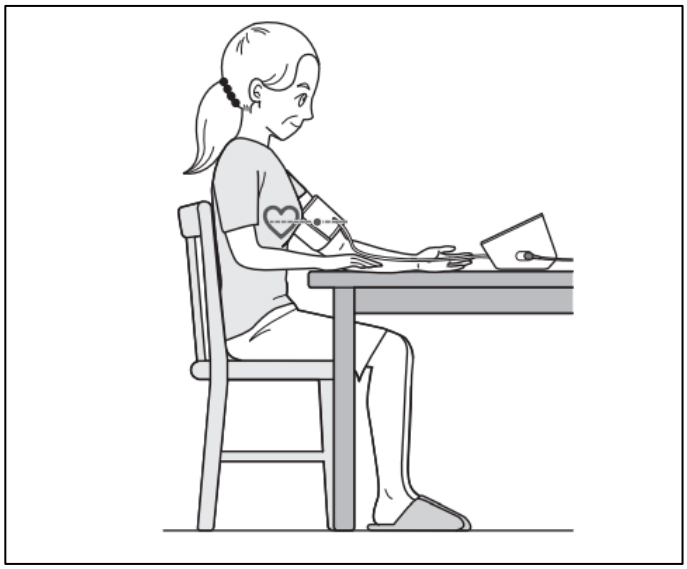
- Complete training requirements.
- Recite exclusions.
- Conduct exam on two volunteers according to protocol, as demonstrated by a completed ABPM Certification Checklist (Appendix T).
- The administration of the ABPM protocol (including device set-up, using the in-clinic scripts, and completing the in-clinic measurement) must be observed **one time** by Stephen Juraschek. There are two acceptable methods of completion:
    - Record administration of the ABPM protocol and upload the video to your institution's file share program (e.g., OneDrive, Dropbox). Notify Stephen Juraschek (sjurasch@bidmc.harvard.edu) and Fredrick Larbi Kwapong (flarbikw@bidmc.harvard.edu) via email that a file is ready for their review. Note: before recording, ensure that the volunteer participant consents to being filmed for training purposes.
    - Schedule a virtual certification session with Dr. Juraschek and complete the observation in real time

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 8-days to perform additional blood pressure measurements at home.
        - A Legally Authorized Representative (LAR) may provide consent for participants (e.g., participants with dementia are eligible if their LAR can consent and confirm they will assist with the home protocol).
- Visit 10 protocol
    - End of visit after the other ARIC ancillaries are complete.
    - The participant will leave Visit 10 wearing the ABPM monitor, NOT the HBPM monitor. The following protocol will instruct staff on how to set up the Omron Series 10 HBPM monitor and how to take 1 validation measurement in-clinic.
        - Note: The **same** arm should be used for ARIC SBP, ABPM, and HBPM.

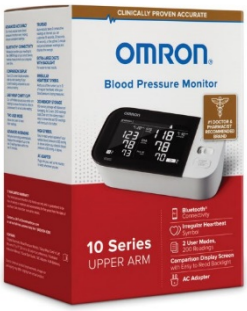
- Staff will instruct participants on proper technique for taking their blood pressure at home with the Omron Series 10 monitor. Participants will begin home monitoring <u>one day after the ABPM protocol is complete.</u>
    - <u>Note:</u> If a participant is not taking part in the ABPM protocol, staff can instruct them to begin their home monitoring with the Omron Series 10 monitor <u>one day after their in-person visit.</u>

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.
- Easy Wrap ComFit Cuff HEM-FL31-B (22-42 cm or 9-17 inches) (included in monitor box)
- 4 AA batteries (for Omron) and AC power adapter (included in box)



- FedEx Large Box (L2: Square and deep) and pre-paid label for device return for those returning their monitor in this fashion (see **<u>Appendix S. Device Return Guide</u>** for detailed instructions)

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 ARIC consent form. A Legally Authorized Representative (LAR) may provide consent for participants, and this will be noted on the standard ARIC consent form. 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' records.

2.1.7 Inclusion and Exclusion Criteria

Inclusion criteria:

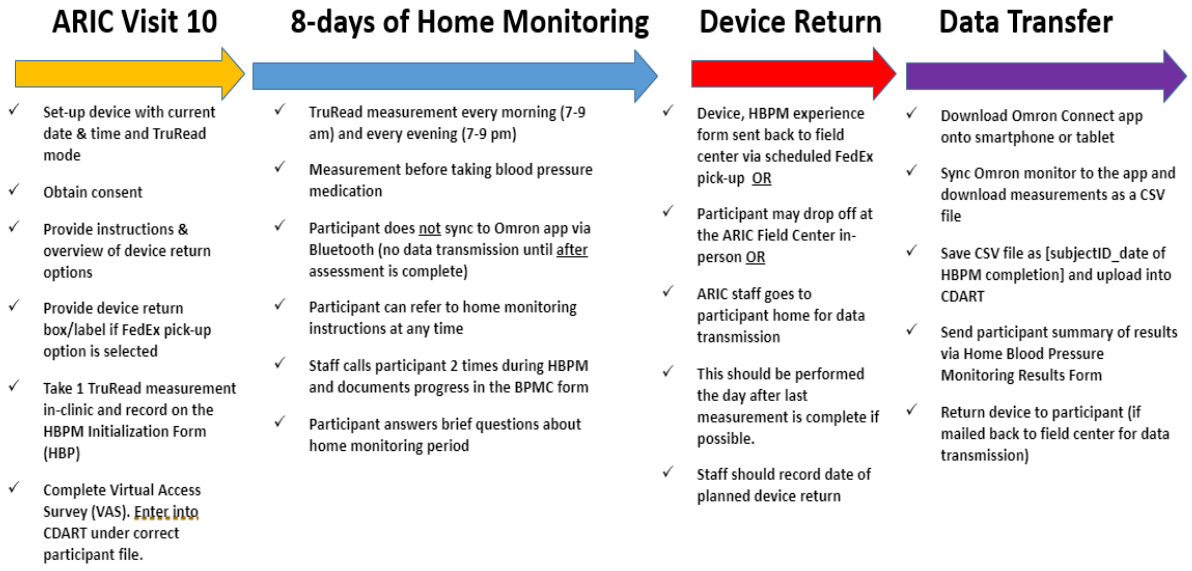
- All participants who provide informed consent are eligible to participate in HBPM.
- If the participant has a LAR, they are still eligible to participate in the HBPM protocol with the consent of their LAR.
- If the LAR cannot help with filling out forms at home, such as the HBPM Participant Experience Form, this does not exclude the participant from participating in the HBPM ancillary as long as they are able to perform HBPM according to the protocol's schedule.
    - Note: a participant will be excluded if staff foresees issues with measuring their blood pressure twice a day at home (see exclusion criteria below).

Exclusion criteria:

- Failure to receive consent from the participant or their LAR
- The LAR, proxy, or caregiver is unable to assist with the home protocol. Note: this can be up to staff discretion.
    - For example, if they are unsure whether they will be able to assist the participant with appropriately monitoring their blood pressure at home in the morning and evening for 8 days, staff can determine that the participant is ineligible.
- The healthcare proxy, LAR, or caregiver is unable to select a device return method and is unable to assist with device return to ensure data transmission.
- If a participant has an average Systolic Blood Pressure ≥200 mm Hg or Diastolic Blood Pressure ≥120 mm Hg, the exam will be stopped for the participant to receive urgent care. The participant will be ineligible for the HBPM protocol. This protocol directly aligns with ARIC Sitting Blood Pressure (SBP) safety parameters for continuing the ARIC visit.
- Arm circumference <22 cm (i.e.,ComFit cuff that comes with the monitor due to their arm circumference being less than 22 cm; note in borderline cases that may round to 22 cm; err on the side of including the participant).

- Arm circumference >42 cm (i.e., if a participant is unable to use the Easy-Wrap ComFit cuff that comes with the monitor due to their arm circumference being greater than 42 cm.
    - Note: This cuff is designed for an upper arm circumference of 22-42 cm; however, in borderline cases staff may round to 42 cm; (e.g., for a participant with an arm circumference of 42.1 – 42.5 cm, staff can round down to 42 cm to err on the side of including the participant and use the XL cuff). See arm cuff size and arm circumference range below:
    -

2.1.8 Timeline Schematic

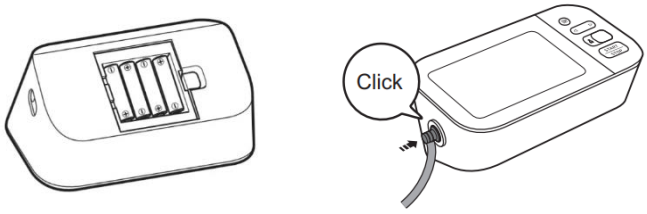


2.2 STUDY PROCEDURES

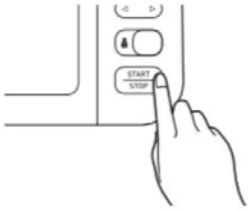
2.2.1 Set-up of Omron Series 10 (complete prior to visit)

Monitor should be set up morning of participant visit (if possible). No more than 1 week prior to visit (to save battery life). Note: All devices come with a plug that could be used to power the monitor in case batteries run out.

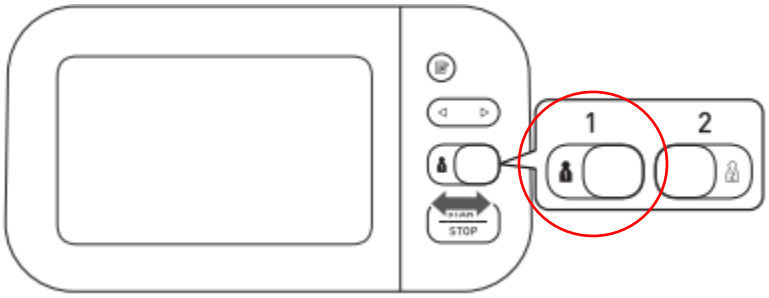
- Open Omron box and insert batteries. Affix arm cuff into monitor using the air ply to ensure a secure connection. Listen for a “click”.



- Press START/STOP to turn device on. 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 **Appendix I. HBPM Configuration** for detailed instructions



- Check that the Omron is programmed to TruRead Mode to obtain 3 blood pressure measurements separated by 60 seconds each (see page 18, 26 in Omron Manual). **See Appendix J. TruRead Mode Configuration** for more detailed configuration instructions.
- Select **User ID 1** (when participant arrives, explain that this User should not be changed during the study protocol).
  - Place an ARIC sticker or tape over User 2 to prevent user changes during the protocol.

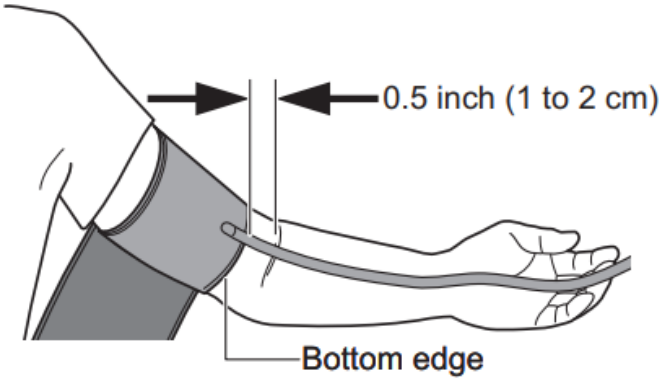


- Do not turn on Bluetooth or sync monitor to any device. Re-emphasize to participant that they should not pair any personal device with the monitor via Bluetooth.
  - All BP measurements will be downloaded after the 8 days of monitoring. Research technician or ARIC staff will pair smartphone or tablet with the BP monitor once all BP readings are completed.
- Affix participant-specific label onto the HBP and HBPR forms.

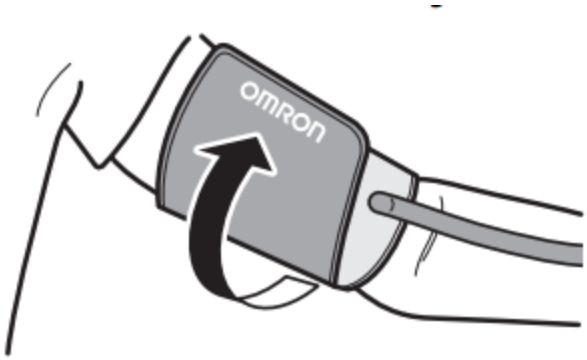
2.2.2 In-Clinic Procedures

- 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 (**See Appendix J. TruRead Mode Configuration)**
- Confirm the participant's arm circumference is within the range of the Omron cuff (22-42 cm). If it is outside of the cuff range (i.e. their arm circumference is greater than 42 cm), then the participant is not eligible to participate in the study (note: in borderline cases that may round to 42 cm; err on the side of including the participant).

- 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 Q. HBPM Device Serial Number and Tracking.**
    - This 31-digit serial number will be recorded on both the HBPM initialization (HBP) form and HBPM return form (HBPR) for tracking purposes.
- Allow the participant to rest quietly for 5 minutes before taking the in-clinic measurement.
- Place the cuff on the same arm the participant used for the in-clinic, seated blood pressure.
- Press START/STOP to perform a single TruRead measurement for comparison with the in-clinic measurement. Record SBP, DBP, and HR from Measurement 1, 2, 3, & the average on the HBP form in *Section B. Clinic Assessment.* (See **Appendix K. Using TruRead Mode** for detailed instructions on using TruRead mode and viewing readings)
    - Note: Use this TruRead measurement to demonstrate the measurement process to the participant. 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.
    - If the participant has a LAR, healthcare proxy, or caregiver, be sure they understand the protocol and can provide assistance if needed.
    - Note: participants may have atypical sleep patterns. It is okay if the measurements fall outside of the 7-9a window, but the two sets of measurements should be roughly 12 hours apart; adhering to the recommended time windows are encouraged
- Advise participant on how to correctly position the cuff on their arm at home:
    - Use the same arm that was used in clinic.
    - Apply the cuff on a bare arm, approximately ½ inch above elbow.
    - Cuff should neither be too tight or too loose. The cuff should be snug enough to fit 2 fingers just underneath both ends of the cuff.



    - The air tube should run down towards hand and not be coiled. Be sure to not rest elbow on the cuff.



- Advise the participant on sitting correctly while they take their blood pressure at home:
    - Sit in a comfortable chair that supports the participant's back and the arm being used for blood pressure measurement.
    - Keep feet flat on the floor and legs uncrossed.
    - Rest arm with the cuff comfortably on a table at heart level.

- Advise the 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.
- After, in-clinic measurements are complete, complete the Virtual Access Survey (VAS) using the instructions script.
- Provide each participant with the ARIC HBPM Participant Checklist and HBPM Participant Experience Form.
    - Note: If the participant has a LAR, healthcare proxy, or caregiver, they are encouraged to assist with filling out the HBPM Participant Experience Form.
- Provide the participant with the plug so they have the option of charging the device at home.

- Call participants on Days 4, and 8 of the HBPM protocol (3, and 7 days after the completed in-person visit) to address any concerns and ensure compliance. See **Appendix R. Blood Pressure Monitoring Check in Call Schedule**. Refer to the delayed start plan if needed.
- Before the participant leaves, ensure that if you will be utilizing FedEx for device return, you print out a pre-paid label that has the scheduled pick-up for **1 day after the participant is due to finish their 8-day HBPM period** and you provide the appropriate box (Large Box: L2) (See Appendix S for example).
- Note that the participant has to have a minimum of 12 consecutive measurements completed to be included in the study (i.e., at least 1 TruRead measurement for 3 days in a row).

Some helpful videos for HBPM:

- 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 R. BP Monitoring Check-In Call Schedule** for more details)

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. You will record this information in Section C of the BPMC form ("HBPM delayed start add-on call")
    - If they did start, confirm the date they started and record on the BPMC form.
- Enter this information on the BPMC form in Section B.

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, in-person participant drop-off at field center).
- Enter this information on the BPMC form in Section D.

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 Q. HBPM Device Serial Number and Tracking** for more details.

Be sure to scan the QR code and record this 31-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 the 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 and follow the instructions below, according to what method of returning works best for your field center and based on the participant's preference.

Schedule pick up from the participant's home / drop off at ARIC Field Center with FedEx Express. See https://www.fedex.com/en-us/home.html. An alternative is using the USPS shipping method. See https://www.usps.com/.

***If you are using FedEx pick-up, the pick-up must be scheduled for 1 day after HBPM expected completion. The participant must go home with the correct box and pre-paid label. ***

OR

[Participant] Return in-person to the ARIC Field Center at _____.

OR

ARIC staff pick-up at participant's home

Be sure to record date of scheduled return and device return method on BPMC form in Section D.

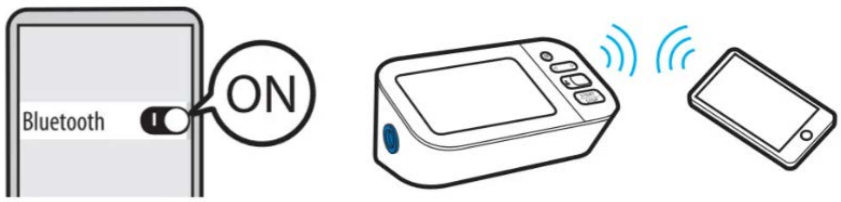
For FedEx Express (see **Appendix S. Device Return Guide** for detailed instructions).

- Create and print out shipping label. Schedule FedEx Express pick-up at participant's home for day **after** HBPM completion.
    - *Ex.* Participant begins HBPM protocol on Tuesday April 19, 2022.
    - Following proper HBPM protocol, the participant will monitor their blood pressure at home for the next 8 days, which means they will should complete HBPM on Tuesday April 26, 2022.
    - Schedule pick-up for Wednesday April 27, 2022 (or closest available date)
    - Choose 2-day shipping.
    - Be sure to confirm with participant that they will be home to bring out the package or leave it on the doorstop for pick-up.
- Send participant home with the FedEx Large Box, shipping label (attached to the box).
    - Remind them to include the monitor, cuff, and HBPM participant experience form in the box to be returned to the field center.

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

2.2.6 Smart Device Pairing with Omron Connect App

- Open and sign into the Omron Connect app on your smart device (suggestion: app is compatible with Apple products including iPad 6th generation and up). (See **Appendix L. Omron Connect App Download and Smart Device Pairing** for more detailed instructions).
- Make sure the Bluetooth on the iPad or smart device is on, and connect the iPad to the Omron Series 10 Monitor via Bluetooth.

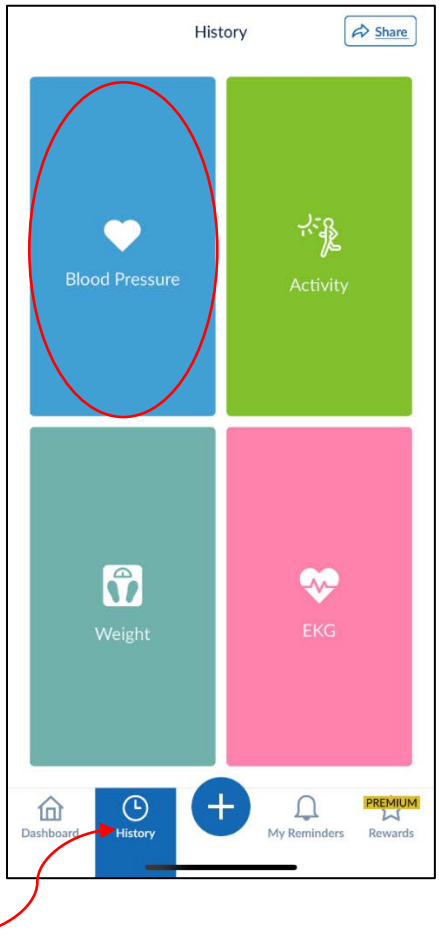


- For detailed instructions and screenshots on how to download the Omron Connect app and pair the Omron series 10 BP7540 blood pressure monitor via Bluetooth, see **Appendix L**.

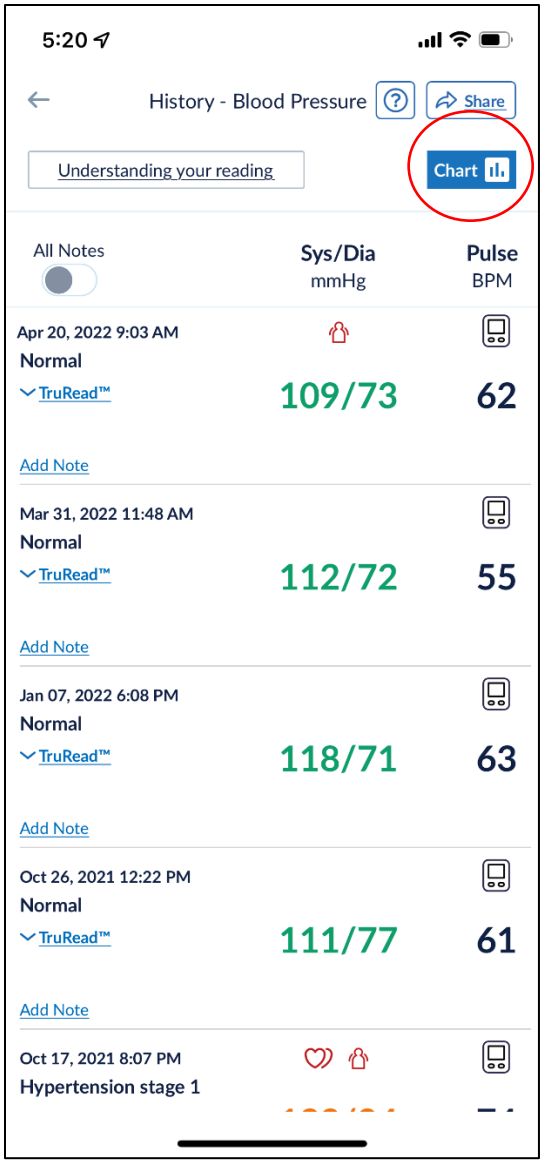
2.2.7 Data Transmission

- Once the tablet or smartphone is paired to the OMRON Connect app, all blood pressure measurements stored in the monitor's history can be securely transferred to the app.

- Place the smart device next to the monitor and open the 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 “Bluetooth” icon on the monitor for about 3 seconds and press the sync button on the Omron App at the upper right corner. 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.
- Navigate to “History” and select “Blood Pressure”:



- To see all blood pressure measurements and any alerts, make sure the view is shown as “List” not “Chart”
    - You may have to click “List” to change the view.

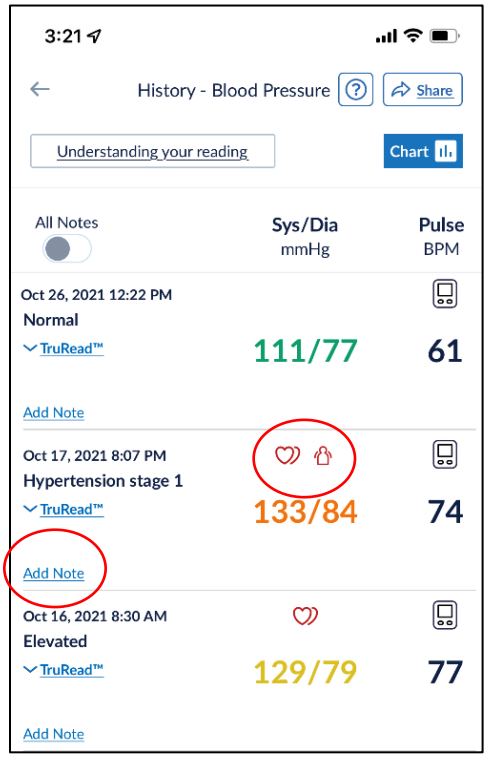


- Briefly scroll through the measurements in the app and look for any alerts.
    - If you see any alerts, be sure to document them as a "Note" in the app, under the measurement. (See **Appendix M. HBPM Download** for more instructions). Adding the alerts in the "Note" section will ensure that alerts are included in the csv file that will be exported.
    - Under the measurement that the alert appears next to.
        - Click "Add Note"
        - Enter **IH1** for irregular heartbeat, **ME2** for movement error, or **CI3** for cuff indicator (these are the only three alerts you may see). See **Appendix N** for more detailed instructions.
            - See the table below for alert symbol full name, abbreviation for HBPR form, and alert symbol icon:

Table. Omron Series 10 Alert Symbols

Alert Symbol Full Name	**Abbreviation**	**Alert Symbol Icon**
Irregular Heartbeat	IH1	
Movement Error	ME2	
Cuff Indicator	CI3	

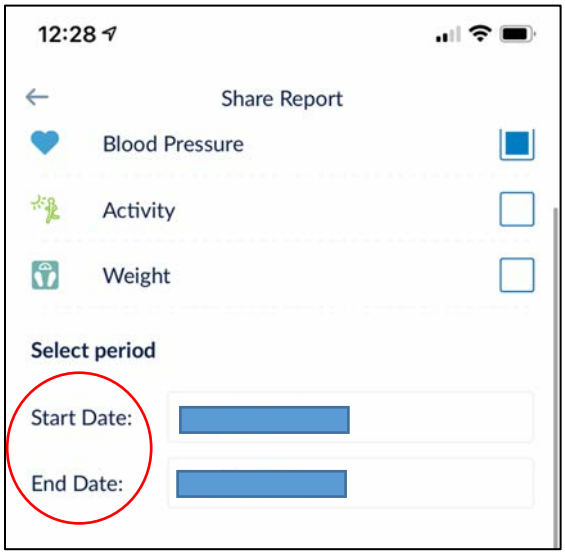
- For measurements with more than 1 alert, type the letter/number combination with **1 space only** in between (i.e. “IH1 ME2):
- See example below:



Once all alerts have been entered into the Omron app, navigate to the “Share” button and select the appropriate dates to include in the csv report. **Make sure to**

include the in-person visit date and the date of the day <u>after</u> HBPM completion.

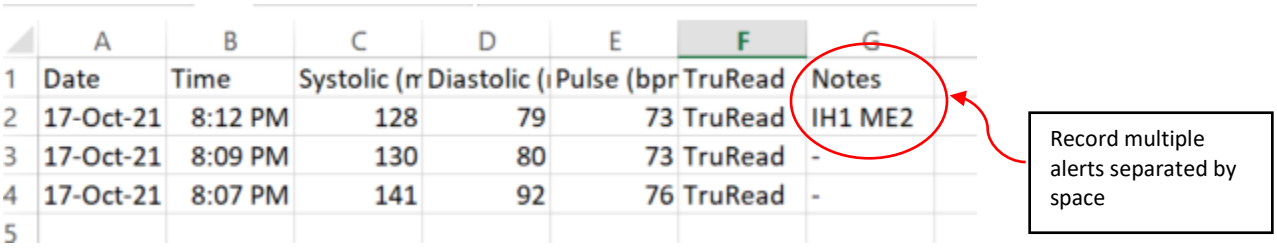
- For example, if a participant has their visit 10 on 10/7, they are expected to start HBPM on 10/9 and expected to end on 10/16. Staff will choose a Start date of 10/7 and an end date of 10/17 on the Omron App (see Appendix N for details).



- Review CSV file for completeness.
  - *A complete HBPM report will consist of **<u>52 rows of data.</u>*** The first row will contain each column title “Date, Time, Systolic, Diastolic, Pulse, TruRead, Notes.” There will be 3 rows from the TruRead measurement in-clinic during V10.
  - *Example HBPM Report (CSV file):*

	Date	Time	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	TruRead	Notes
2	21-Sep-22	8:33 PM	123	67	66	TruRead	-
3	21-Sep-22	8:32 PM	145	67	76	TruRead	-
4	21-Sep-22	8:31 PM	134	68	64	TruRead	-
5	21-Sep-22	8:26 AM	135	71	75	TruRead	-
6	21-Sep-22	8:25 AM	129	68	75	TruRead	-
7	21-Sep-22	8:24 AM	141	76	73	TruRead	-
8	20-Sep-22	9:06 PM	134	75	67	TruRead	-
9	20-Sep-22	9:05 PM	128	79	70	TruRead	-
10	20-Sep-22	9:04 PM	127	74	71	TruRead	-
11	20-Sep-22	9:02 AM	131	88	70	TruRead	IH1
12	20-Sep-22	9:01 AM	135	76	71	TruRead	-
13	20-Sep-22	9:00 AM	147	81	75	TruRead	-
14	19-Sep-22	8:45 PM	122	76	72	TruRead	-
15	19-Sep-22	8:44 PM	134	74	77	TruRead	-
16	19-Sep-22	8:43 PM	135	79	66	TruRead	-
17	19-Sep-22	8:23 AM	134	84	65	TruRead	-
18	19-Sep-22	8:22 AM	122	81	63	TruRead	-
19	19-Sep-22	8:21 AM	132	85	60	TruRead	-
20	18-Sep-22	9:12 PM	133	78	67	TruRead	-
21	18-Sep-22	9:11 PM	143	74	71	TruRead	-
22	18-Sep-22	9:10 PM	146	72	73	TruRead	-
23	18-Sep-22	9:05 AM	148	69	70	TruRead	-
24	18-Sep-22	9:04 AM	121	65	59	TruRead	-
25	18-Sep-22	9:03 AM	137	68	69	TruRead	-
26	17-Sep-22	10:20 PM	133	77	73	TruRead	-
27	17-Sep-22	10:19 PM	144	74	68	TruRead	-
28	17-Sep-22	10:18 PM	126	69	60	TruRead	-
29	17-Sep-22	10:08 AM	129	61	71	TruRead	-
30	17-Sep-22	10:07 AM	124	64	75	TruRead	-
31	17-Sep-22	10:06 AM	130	66	68	TruRead	-
32	16-Sep-22	9:50 PM	131	70	64	TruRead	IH1 ME2
33	16-Sep-22	9:49 PM	128	79	67	TruRead	-
34	16-Sep-22	9:48 PM	128	75	72	TruRead	-
35	16-Sep-22	9:30 AM	122	67	70	TruRead	-
36	16-Sep-22	9:29 AM	124	64	56	TruRead	-
37	16-Sep-22	9:28 AM	122	65	55	TruRead	-
38	15-Sep-22	8:27 PM	135	71	67	TruRead	-
39	15-Sep-22	8:26 PM	137	75	64	TruRead	-
40	15-Sep-22	8:25 PM	134	70	69	TruRead	-
41	15-Sep-22	8:30 AM	130	76	71	TruRead	-
42	15-Sep-22	8:29 AM	136	75	78	TruRead	-
43	15-Sep-22	8:28 AM	131	72	76	TruRead	-
44	14-Sep-22	9:12 PM	126	64	69	TruRead	-
45	14-Sep-22	9:11 PM	122	68	63	TruRead	-
46	14-Sep-22	9:10 PM	129	63	66	TruRead	-
47	14-Sep-22	9:05 AM	143	81	78	TruRead	-
48	14-Sep-22	9:04 AM	141	79	75	TruRead	-
49	14-Sep-22	9:03 AM	140	78	73	TruRead	-
50	12-Sep-22	12:09 PM	133	76	69	TruRead	-
51	12-Sep-22	12:08 PM	132	72	72	TruRead	-
52	12-Sep-22	12:07 PM	129	75	65	TruRead	-

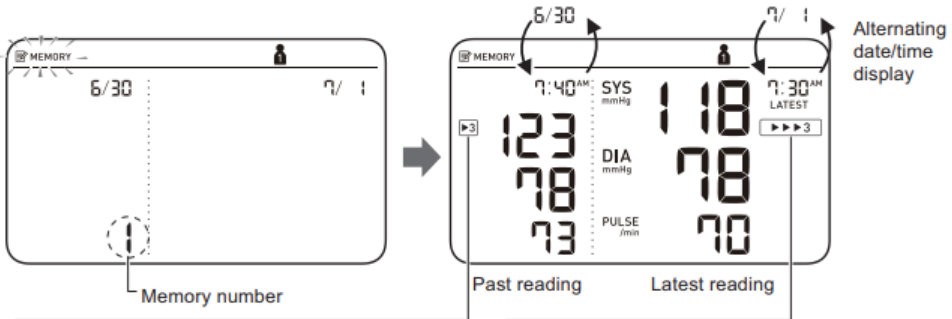
- If any alerts were recorded in the Notes section, they will appear in the Notes column of the CSV file:



	A	B	C	D	E	F	G
1	Date	Time	Systolic (m	Diastolic (I	Pulse (bpr	TruRead	Notes
2	17-Oct-21	8:12 PM	128	79	73	TruRead	IH1 ME2
3	17-Oct-21	8:09 PM	130	80	73	TruRead	-
4	17-Oct-21	8:07 PM	141	92	76	TruRead	-
5							

- Regardless of number of rows (so even if the csv has 52 rows), briefly check the monitor's history to ensure all measurements on the monitor were downloaded into the app.
    - Best practice would be to confirm the date/time of the first measurement, and date/time of the last measurement in the monitor history. Scroll through the monitor history to confirm this.
    - Do this by pressing the notepad & pencil symbol and then the left arrow to repeatedly scroll through the previous readings.
    - The screen will split to show the latest reading and past reading.
    - The date/time will be alternating in the top right hand corner of each reading.

Press the button.



If the past reading was taken in TruRead mode, the "▶3" symbol appears and the reading shown on the left is the average of 3 measurements.

If the latest reading was taken in TruRead mode, the "▶▶▶3" symbol appears and the reading shown on the right is the average of 3 measurements.

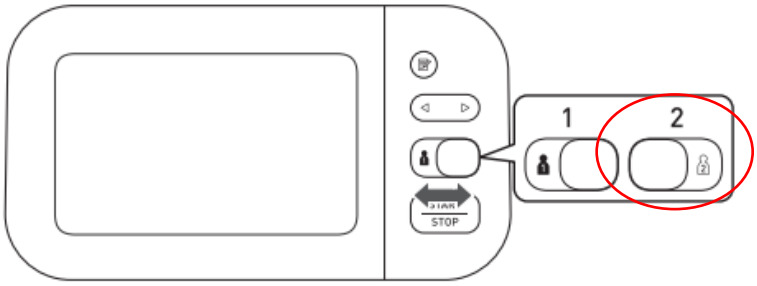
After a memory number appears, the latest reading will appear with a past reading. A past reading will appear in the comparison display on the left.

Press the ◁ or ▷ button repeatedly to scroll through the previous readings stored in the memory.

◁ : To view the older readings

▷ : To view the more recent readings

o Repeat this process for User 1 and 2. There should only be readings on User 1, but confirm that there are no readings on User 2, by sliding the button so that User 2 appears.

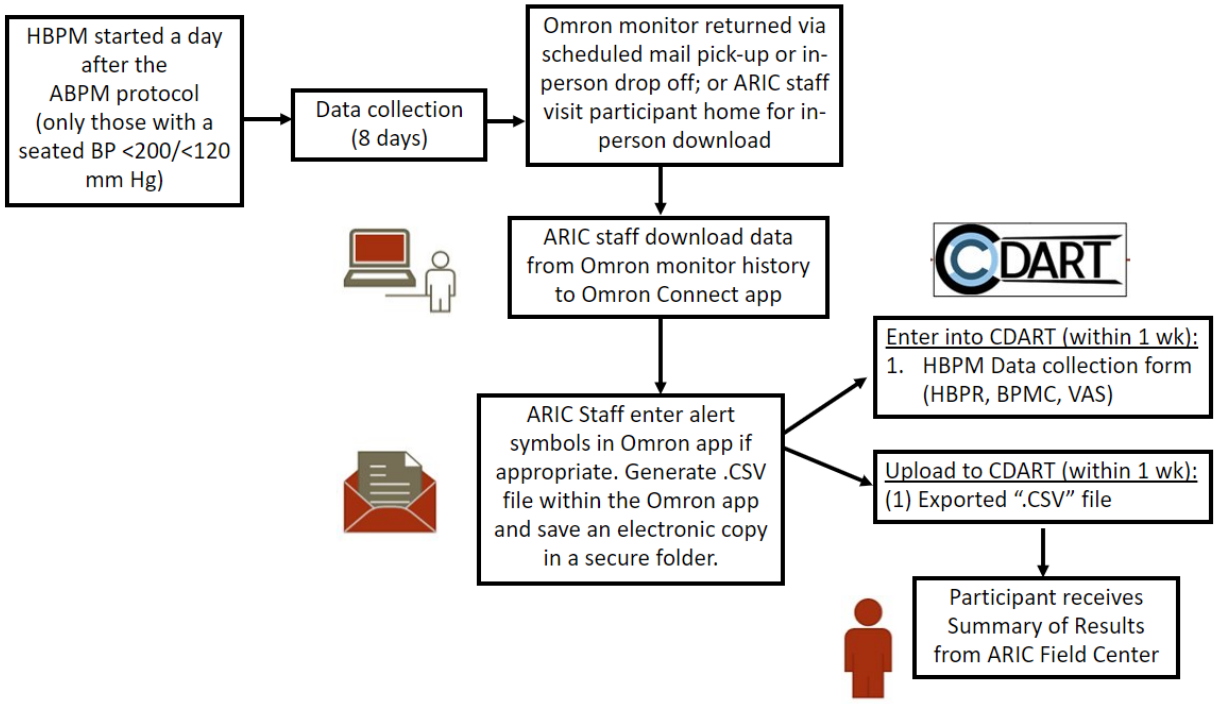


- Once all measurements in the device history have been confirmed to be displayed in the CSV file, move forward with saving the data file.
- Save the CSV file as [SubjectID_YYMMDD.csv] in a secure folder. The date used should be the date of HBPM completion.
- Attach the CSV file to the HBPR form and upload to CDART within 1 week. Please refer to the "**Appendix O. Attaching HBPM 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.

2.2.8 Manual Data Collection

- If data syncing via Bluetooth with the Omron Connect App 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 in Q11-27d.
    - Note: A common reason for not being able to sync the BP monitor with the Omron connect app is if the device has already been paired to the app on a different device (e.g., the participant paired the monitor with their smartphone or tablet).
    - Instruct participants to refrain from connecting the HBPM device with their smart device until after the study.

Figure. Summary of data collection and results reporting for HBPM



2.2.9 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.

2.2.10 Results Reporting

Results will be provided to participants using a CDART report 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 **MOP 38 Results Letter Templates** (on the ARIC website) for details related to HBPM results reporting.

2.2.11 Unpairing HBPM Device

After confirming successful .csv download, all measurements should be deleted from the Omron App and the device should be unpaired in preparation for the next participants. (See **Appendix N** for more detailed instructions)

To confirm a successful .csv download, be sure you check the HBPM raw data file (.csv) for 52 rows. Additionally, all staff should check device history on both User 1 and 2 of the HBPM monitor. **Refer back to section 2.2.7.**

Staff should unpair the Omron Series 10 from the iPad or smart device used for data transmission. The monitor cannot be given back to the participant until this step has occurred.

> Note: The Omron Series 10 will be given to each participant that participates in HBPM. If the monitor is returned via FedEx, once all of the data has been downloaded from the device, it can be mailed or returned to the participant.

2.3 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.

All staff performing HBPM must be trained and certified by ARIC in the Seating Blood Pressure (SBP) technique.

Training will include:

- Read and study the manual, forms and QxQs.
- Attend ARIC training session on administration techniques (or review the training video).
- Practice on other staff or volunteers.
- Discuss problems and questions with local field center 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 (Appendix U).
- The administration of the HBPM protocol (including device set-up, using the in-clinic scripts, and completing the in-clinic measurement) must be observed **one time** by Stephen Juraschek. There are two acceptable methods of completion:
    - Record administration of the HBPM protocol and upload the video to your institution's file share program (e.g., OneDrive, Dropbox). Notify Stephen Juraschek (sjurasch@bidmc.harvard.edu) and Fredrick Larbi Kwapong (flarbikw@bidmc.harvard.edu) via email that a file is ready for their review. Note: before recording, ensure that the volunteer participant consents to being filmed for training purposes.
    - Schedule a virtual certification session with Dr. Juraschek and complete the observation in real time

3 APPENDIX MATERIALS

3.1 AMBULATORY BLOOD PRESSURE (ABPM) PROTOCOL

APPENDIX A. CREATE ARIC ABPM PROTOCOL (THIS STEP IS ONLY DONE ONCE)

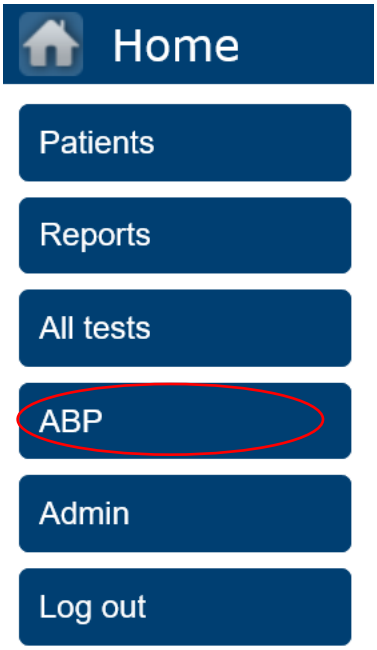
Follow these steps to create the “ARIC ABPM Protocol.” You only have to do this step **one time.**

After you do this step, you will see “ARIC ABPM Protocol” as an option in the drop-down menu under Protocol and you will choose this option each time you configure an ABPM device instead of “Default.”

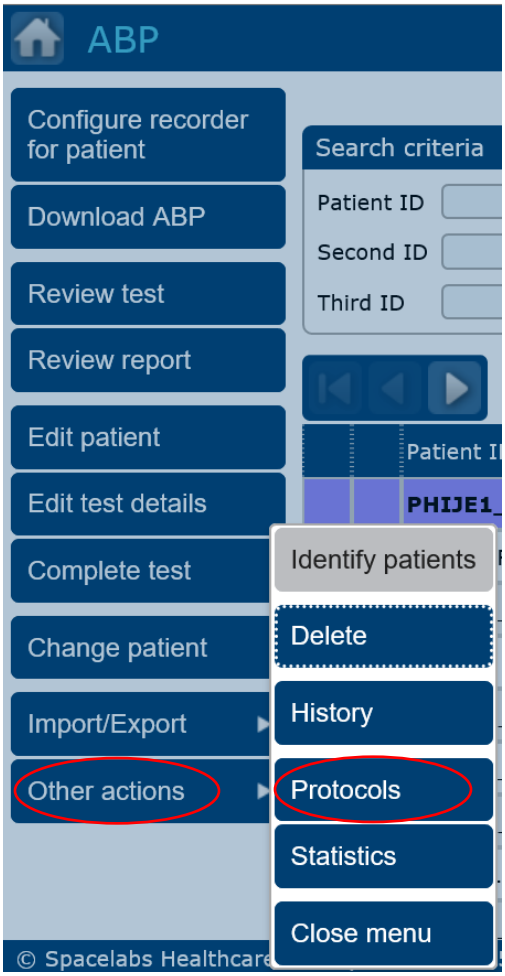
[Note: These instructions can also be found in the Sentinel Ops Manual, **Section 8.5**, which came on the flash drive with your Sentinel software. It can also be found in the Sentinel ABP Ops Manual in **Section 3.4.6,** which also came on that same flash drive.]

Log into Sentinel 11 or 11.5

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



Click on *Other actions,* then *Protocols.*



Click on *Add Protocol*

Type “ARIC ABPM” in the line next to *Protocol name.*

Under *Recorder,* select **170 mmHg** next to *comfort mode pressure (OnTrack only)*.

Under *Intervals*, add Day and Night Intervals.

Next to Day, type **5** above start hour. Select **20** above Cycle (mins). Keep **Silent** above Tone. (This means there will be no sound when the monitor begins to inflate. This will minimize participant burden).

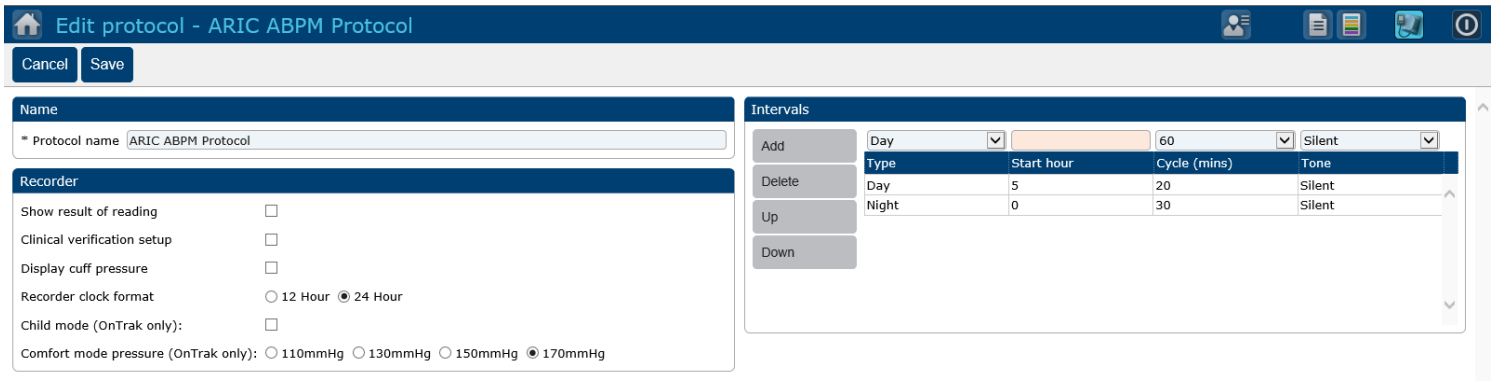
Click *Add*.

Click the drop-down menu next to “Day” to switch to “Night.” Type **0** for above start hour. Select **30** above Cycle (mins). Keep “Silent” for Tone.

Click *Add*.

Click *Save*.

Make sure the information under *Recorder* and *Intervals* are correct:

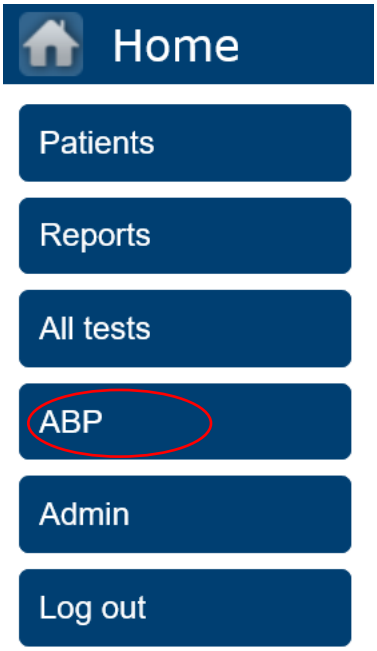


Note: The intervals for this protocol will instruct the monitor to inflate every 20 minutes during the day from 5:00 am to 1:00 am and every 30 minutes while the participant sleeps from 1:00 am to 5:00 am. This protocol will be selected at the time of ABPM Configuration (See **Appendix C**).

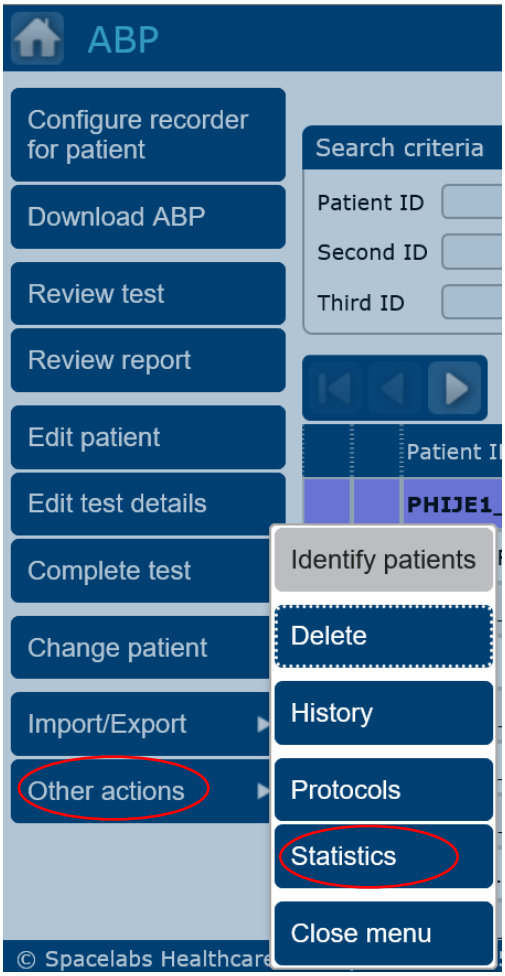
APPENDIX B. CREATE ARIC STATISTICS REPORT (THIS STEP IS PERFORMED ONLY ONCE)

Log into Sentinel 11 or 11.5

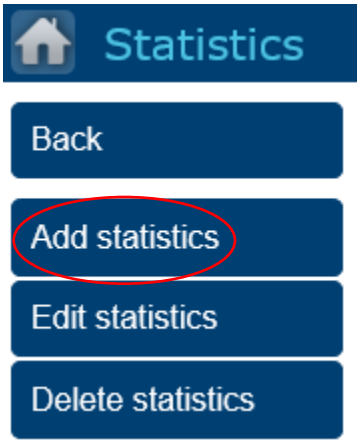
On the *Home* screen, click *ABP.*



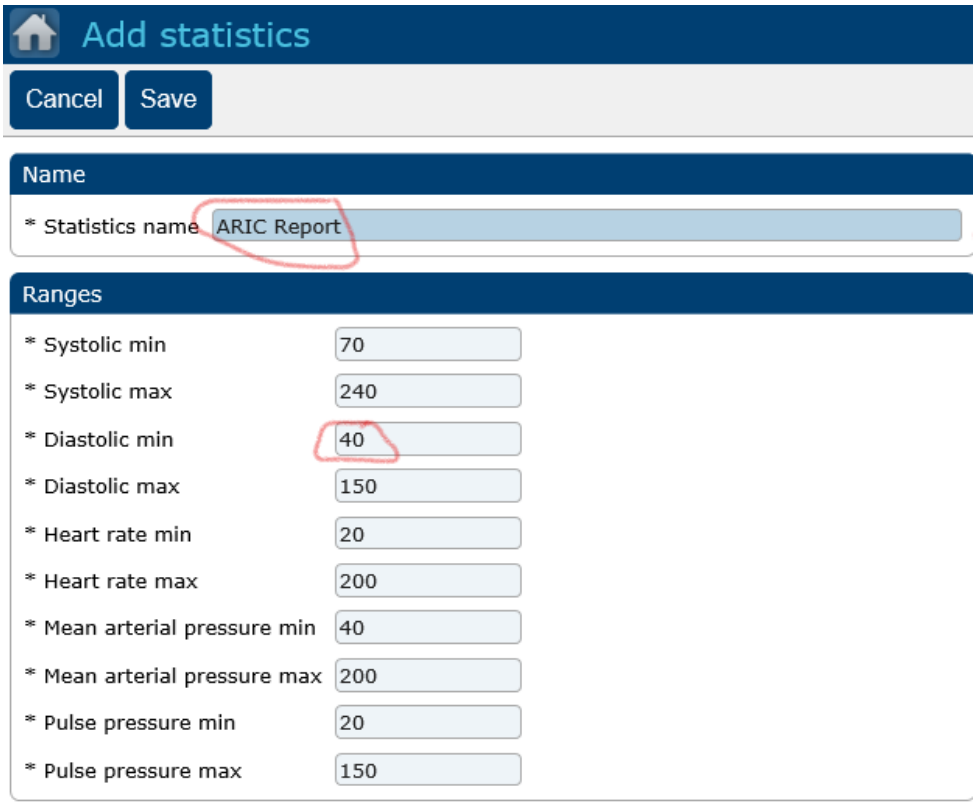
Click *Other actions*, then *Statistics*.



Select *Add statistics*.

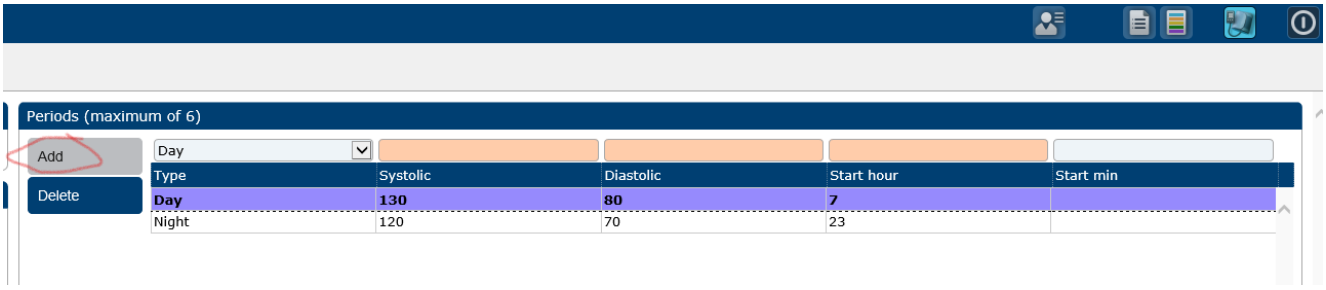


In the “Statistics name” field add the name: “ARIC Report”. Use the default ranges but note that the **diastolic min should be changed to 40**.



Add two cycles under *Periods (maximum of 6)*:

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



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

Note: This statistics report will be selected at the time of ABPM download (see **Appendix D**) to generate a full PDF report of all the participants' results. These limits allow the device to determine which elements of the patient's data are considered abnormal when the program performs its initial analysis of the patient data.

APPENDIX C. ABPM CONFIGURATION (SCREENSHOTS)

CONFIGURE THE ABP RECORDER

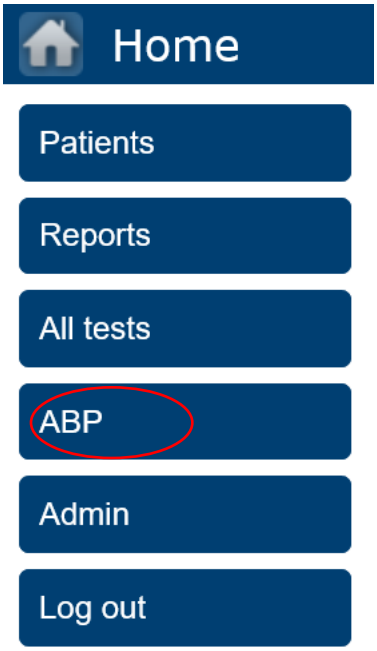
We are using the 90227 OnTrak ABP recorder for these instructions.

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

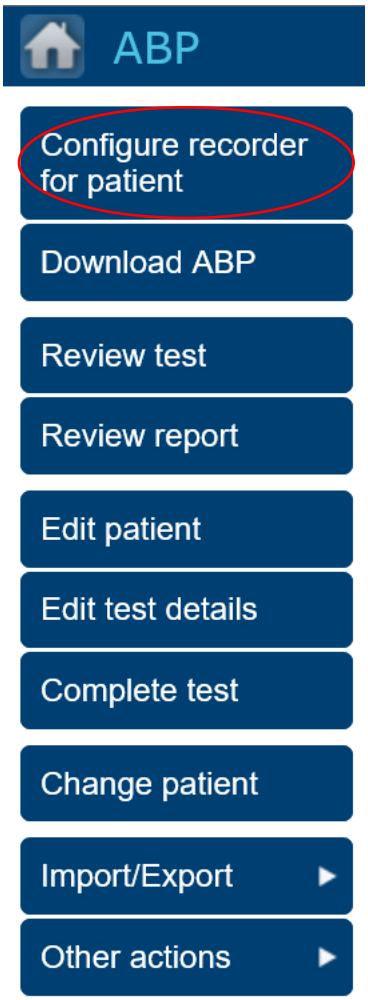
The back cover can be secured over the piece of string or ribbon.

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 (press the white circular button, called the action button, on the device). The recorder display will show a self-test, then *connected to host,* then *Connected to PC.*

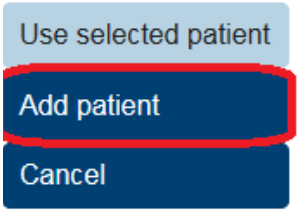
Log into Sentinel, and click on *ABP.*



Click on *Configure recorder for patient.*

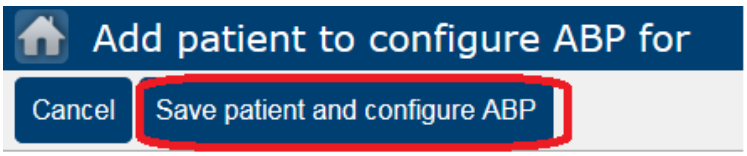


Click on *Add patient.*

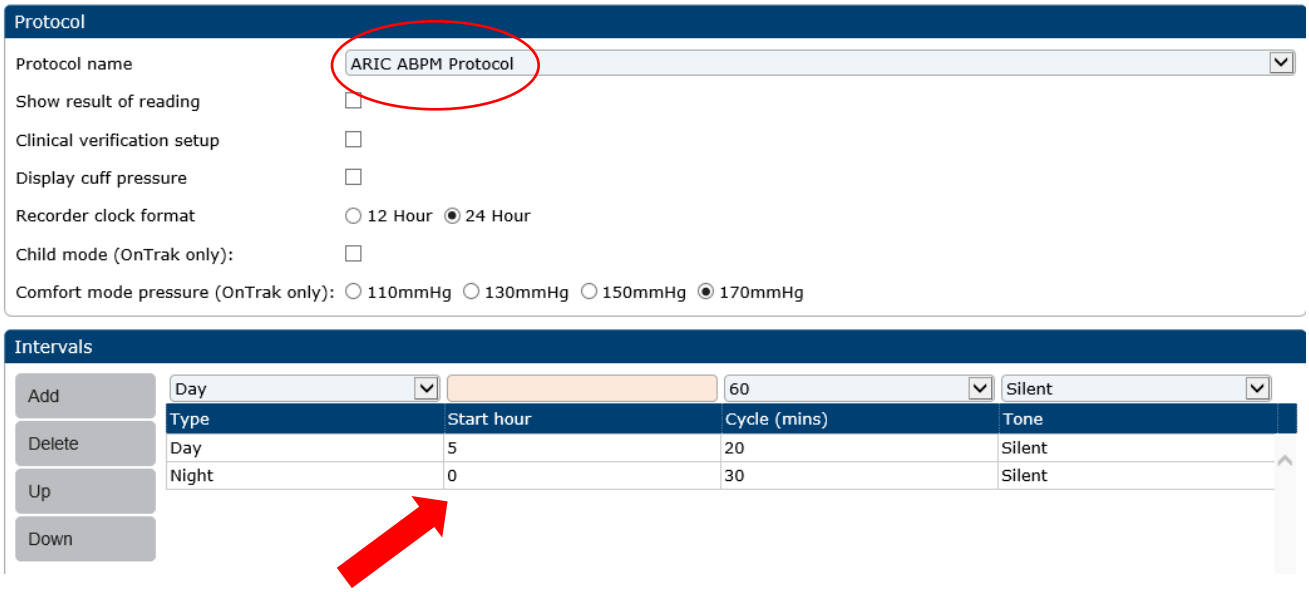


Enter ARIC Participant ID into the Patient ID field. If you want the participant's name to appear on the graphical results, you will need to enter in the participant's first and last name into the respective fields.

Click on *Save patient and configure ABP.*

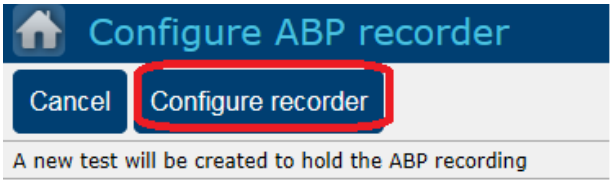

Add patient to configure ABP for
Cancel
Save patient and configure ABP

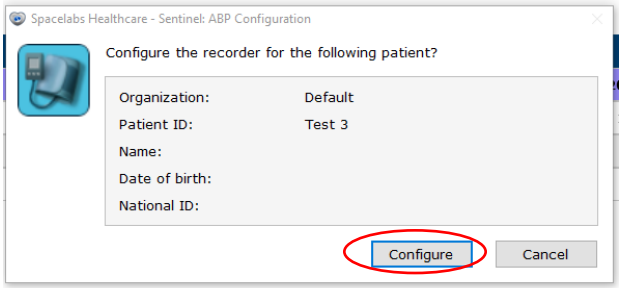
Under Protocol, select “ARIC ABPM Protocol.” This will change the protocol from Default to the ARIC ABPM Protocol (For detailed instructions on creating the ARIC ABPM Protocol, see **Appendix A**).



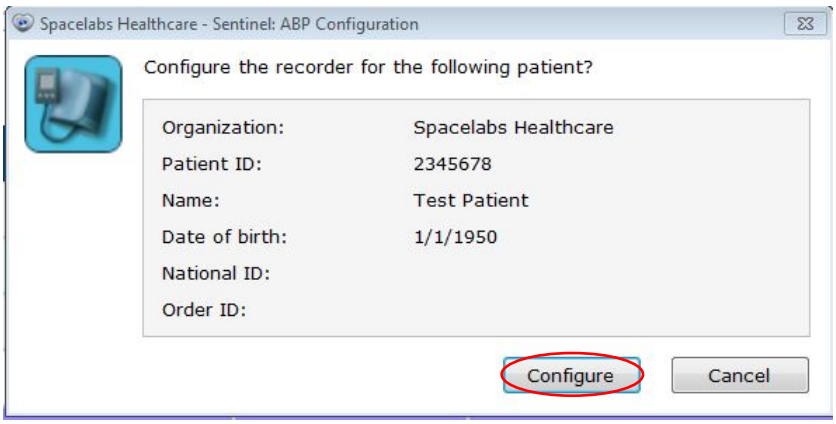
Confirm intervals are correct.

Click on *Configure recorder.*



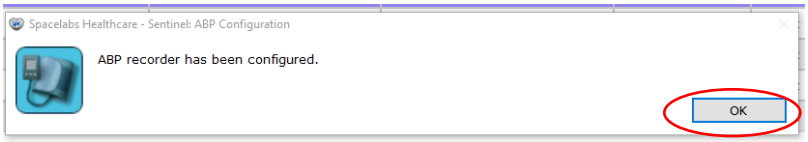


The Configuration Confirmation window will confirm the patient details. Select Configure.

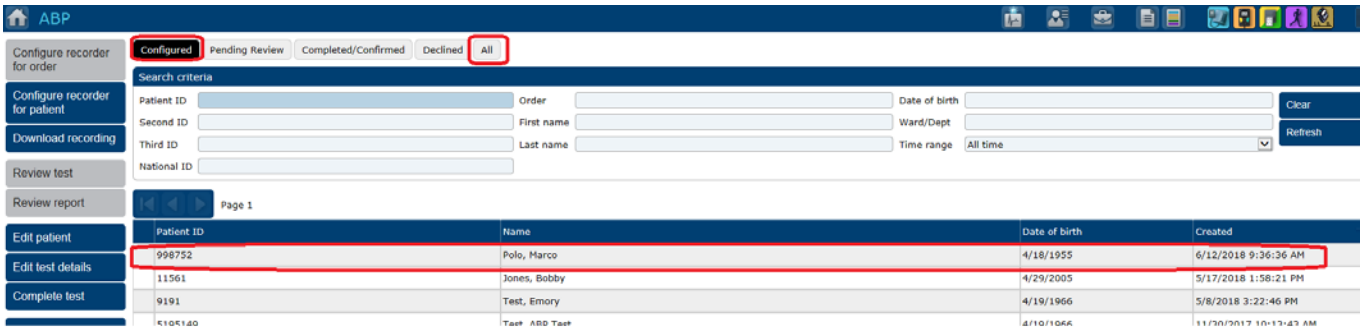


The following window will be shown to confirm that your monitor has been configured:

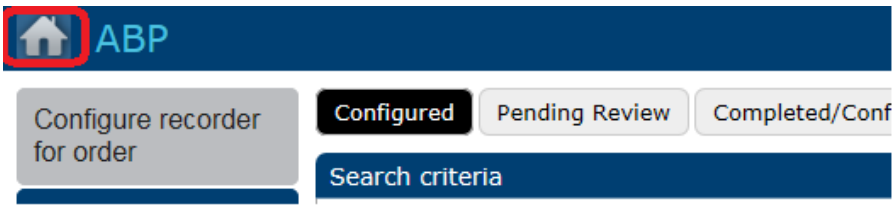
Click *OK*.



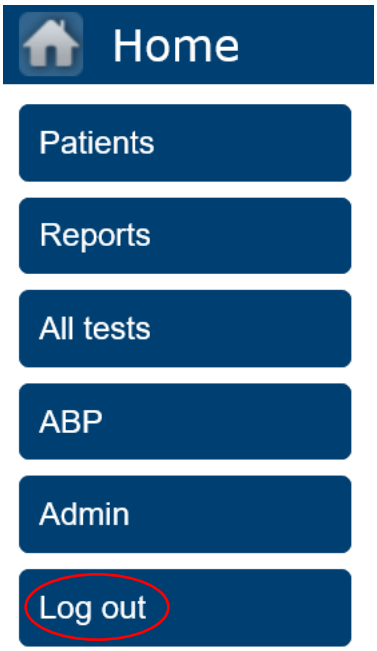
When complete, your new patient will be displayed in the *Configured* or *All* tabs.



Click on the Home button.



Click on *Log out.*



At this point, we suggest already having the cuff properly placed on the participant. (See section 1.2.1 and 1.2.2).

Disconnect the ABP monitor from the computer. Check the position of cuff (should be over bare skin over the brachial artery on the upper arm). Place the monitor into the reusable ARIC pouch.

Secure tubing if needed (this can be important for safety as the tube can catch on objects like door knobs or drop into stovetops). Connect the device to the cuff and press the action button to take 1 measurement. **Document time, SBP, DBP, and HR for first measurement on the ABP form.**

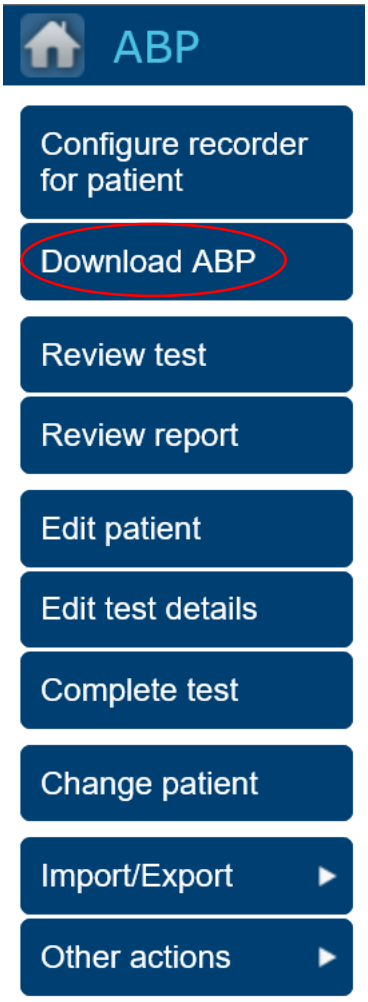
After the measurement is complete, you will need to wait to observe an automatic inflation to ensure proper interval settings. This may take up to 20 minutes. The participant will need to wait for 20 minutes for the observed second measurement.

Participant can be doing other things during this time, but when the cuff starts inflating, the participant should not move or talk.

APPENDIX D. ABPM DOWNLOAD (SCREENSHOTS)

When the device is returned, replace the batteries and push the action button on the device. 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 ABP*.



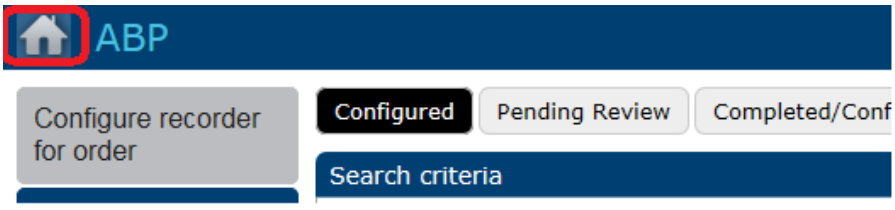
It will search the recorder for the data that was initially programmed, and the participant details will appear with the number of readings and the recorder information.

Click *OK*.

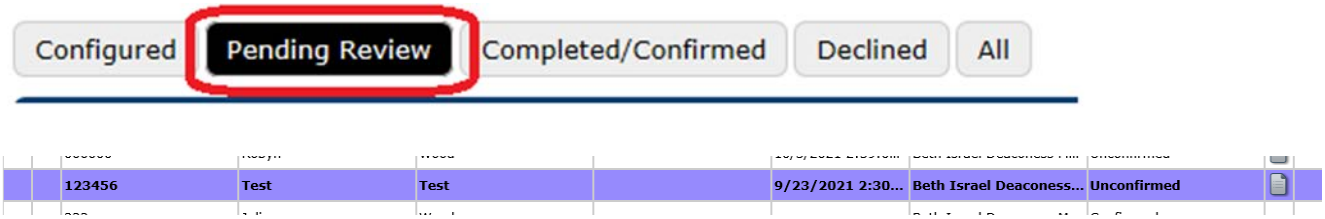
A Confirmation window will appear to let you know the Download is complete:

Click *OK*.

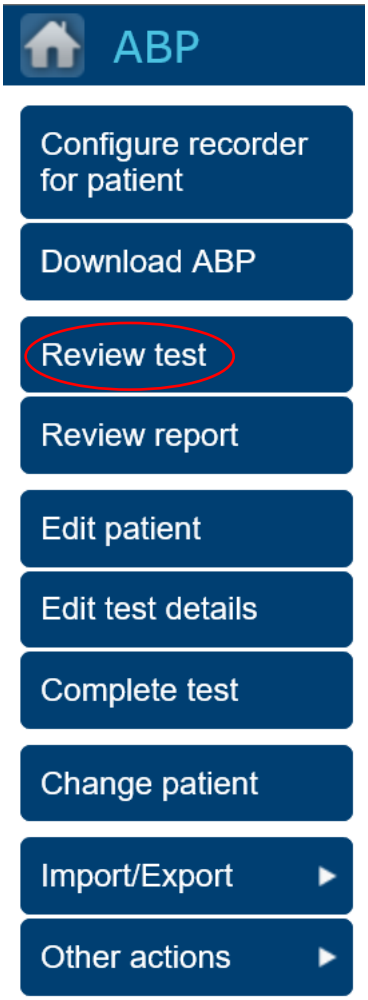
Click on the Home button. Then click ABP.



You can find the participant's test in the *Pending Review* tab. 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.

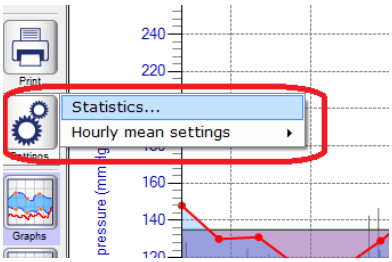


Once the participant ID is highlighted, click on *Review Test.*



Click on *Settings.*

Then, click on *Statistics.*



In the *Statistics* window, change the “Configured statistics:” field to the pre-programmed “ARIC Report.” For details on how to program the ARIC Report, see Appendix B. Confirm the correct settings auto-populated:

Start hour: 7, 23.

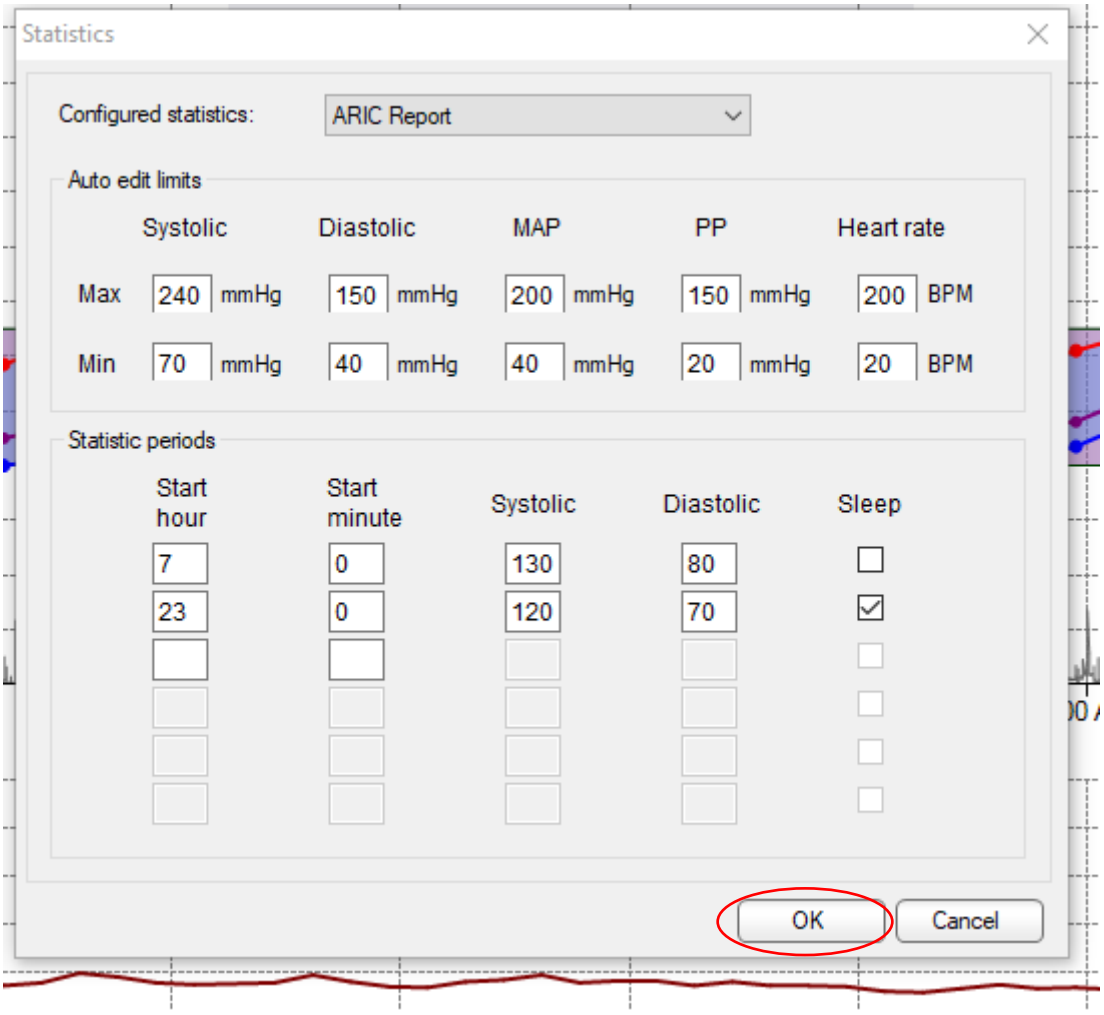
Start minute: 0, 0.

Systolic 130, 120.

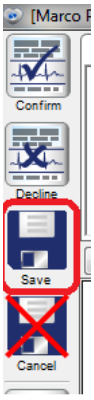
Diastolic, 80, 70.

Sleep: unchecked, checked.

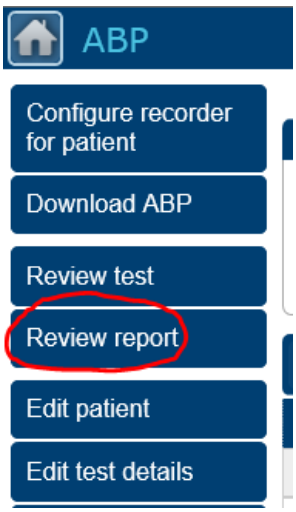
Click *OK*.



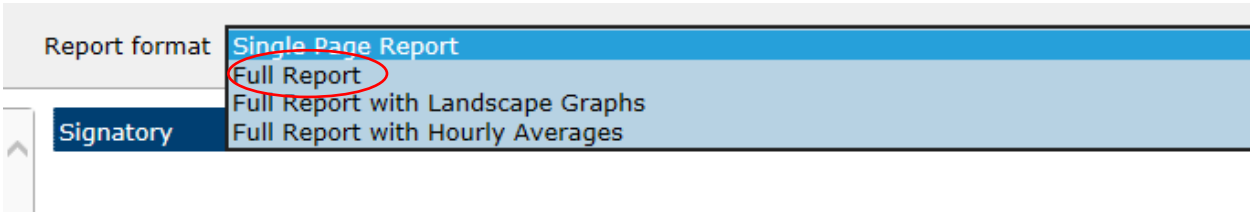
Click *Save* (note if you want the report to save “Confirmed” click Confirm first, but this step is not required).



To save and print, with the appropriate participant ID highlighted, click *Review Report*.

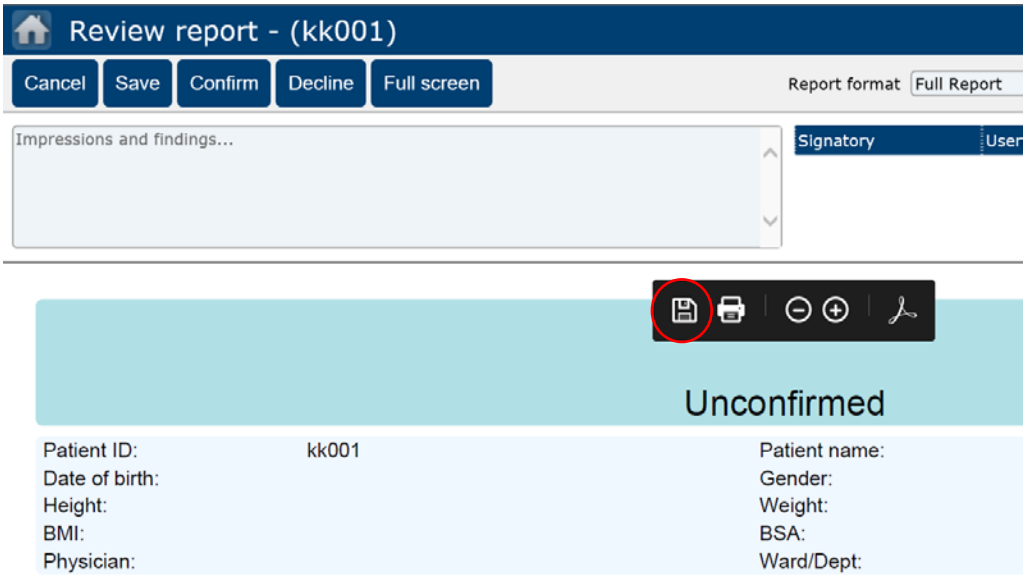


In the top right corner, select **“Full Report”** next to Report Format.



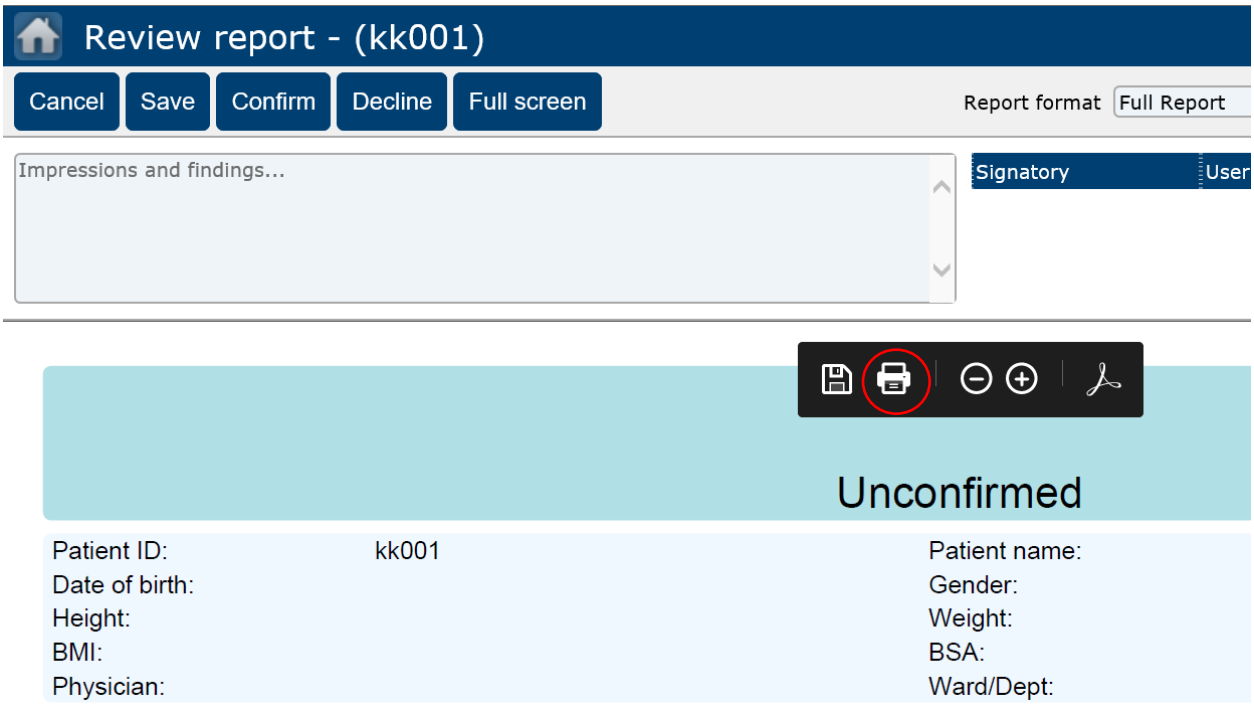
A small window will appear. Click the save icon to save file as a PDF in a secure folder. When saving as a PDF label: “[SubjectID_YYMMDD].pdf”

Note: The date used will be the ABPM date of completion. If a participant ends their ABPM on May 23, 2022, the date would be 220523.



Upload this saved PDF Full to CDART in the correct participant file within 1 week.

Print out 1 paper copy to store in a secure location as a backup. Click the print icon to print the report. (Note: the length of a report will depend on the number of measurements, but is typically anywhere from 3-6 pages).



The first page of the ABPM report will look like this:

kk001

Unconfirmed

Sentinel ABP Report

Patient ID:	kk001	Patient name:	
Date of birth:		Gender:	Unknown
Height:		Weight:	
BMI:		BSA:	
Physician:		Ward/Dept:	

Recording information

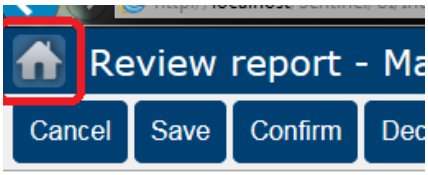
Start:	9/4/2022 1:16:00 PM	Ambulatory Arterial Stiffness Index (AASI):	0.13
End:	9/5/2022 3:52:00 PM	Morning Surge Index (MSI):	19.01 %
Duration:	1.02:36:00	Comfort mode max. pressure:	170
Successful readings:	64 (83.12 %)	Child mode:	Disabled
Systolic > limits:	100.00 %	Serial number:	227-013581
Diastolic > limits:	95.31 %		

MBP 6:00 AM-10:00 AM: Systolic 160 mmHg, Diastolic 100 mmHg, MAP 116 mmHg, PP 61 mmHg; HR 68 BPM

Summary of entire recording - Successful: 83.12 % (64 of 77), Avg.: 156/97 mmHg

	Hourly avg.	Std. dev.	Min.	Max.	Dipping
Overall summary - Successful: 83.12% (64 of 77), Avg: 156/97 mmHg					
Systolic above limits: 100.00%, Diastolic above limits: 95.31%					
Systolic (mmHg)	156	9.10	132 (16:15 Sun)	182 (08:35 Mon)	4.33%
Diastolic (mmHg)	97	10.32	75 (23:55 Sun)	123 (11:55 Mon)	11.16%
MAP (mmHg)	114	9.42	92 (16:15 Sun)	136 (08:35 Mon)	8.89%
Pulse pressure (mmHg)	59	6.65	43 (18:35 Sun)	79 (23:55 Sun)	
Heart rate (BPM)	69	7.11	52 (02:45 Mon)	85 (13:55 Sun)	
Wake periods summary - Successful: 77.19% (44 of 57), Avg: 159/101 mmHg					
Systolic > 130 mmHg: 100.00%, Diastolic > 80 mmHg: 93.18%					
Systolic (mmHg)	159	9.51	132 (16:15 Sun)	182 (08:35 Mon)	
Diastolic (mmHg)	101	9.59	75 (13:15 Mon)	123 (11:55 Mon)	
MAP (mmHg)	117	9.10	92 (16:15 Sun)	136 (08:35 Mon)	
Pulse pressure (mmHg)	58	5.95	43 (18:35 Sun)	70 (17:55 Sun)	
Heart rate (BPM)	71	6.49	60 (15:35 Sun)	85 (13:55 Sun)	
Sleep periods summary - Successful: 100.00% (20 of 20), Avg: 151/89 mmHg					
Systolic > 120 mmHg: 100.00%, Diastolic > 70 mmHg: 100.00%					
Systolic (mmHg)	151	6.03	139 (05:55 Mon)	158 (00:35 Mon)	
Diastolic (mmHg)	89	7.45	75 (23:55 Sun)	105 (03:15 Mon)	
MAP (mmHg)	106	5.49	95 (23:35 Sun)	116 (03:15 Mon)	
Pulse pressure (mmHg)	61	7.27	45 (03:15 Mon)	79 (23:55 Sun)	
Heart rate (BPM)	64	6.51	52 (02:45 Mon)	82 (23:55 Sun)	

When you finished with the report, click on the *Home* button,



Then click on *Log out.*

APPENDIX E. ABPM EXPORT AS .ART FROM SENTINEL 11 OR 11.5

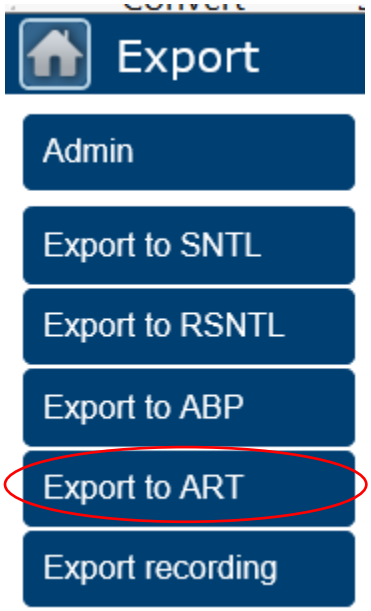
Log into Sentinel and click *Admin.*

Click Export Files

Highlight the participant report you wish to export. The selected report will be highlighted in purple. Double check this step.

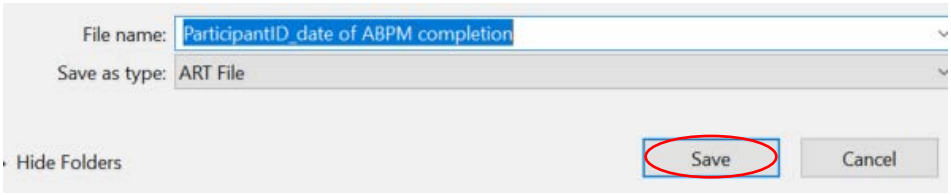
Beth Israel Deaconess...	AKQ001				9/23/2022 2:57:00 PM	
Beth Israel Deacone...	**kk001**				**9/4/2022 1:16:00 PM**	
Beth Israel Deaconess...	kwa001				7/24/2022 10:01:00 PM	

Select Export to *ART*.



Click the small arrow next to save and select “save as”

This will all you to save the report as an .art file as “[ParticipantID_date of ABPM completion.art”] onto the desktop or laptop computer in a secure folder.



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_220523.art** where

W123456 is the participant ID and 220523 (YYMMDD) is the ABPM date of completion (May 23, 2022).

After saving the file, go to the “ABPM Raw Data files” 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.

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

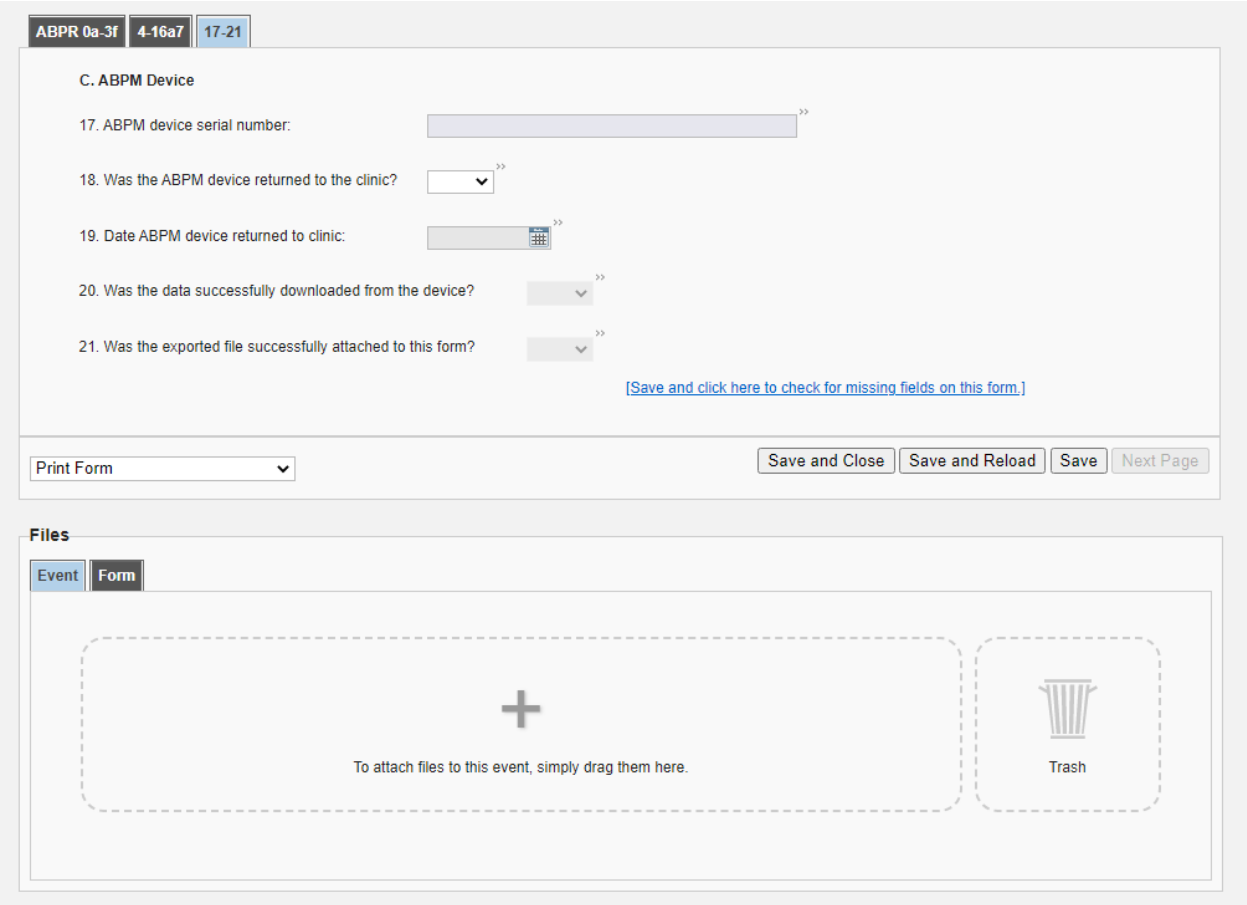
APPENDIX F. ATTACHING ABPM DATA TO A CDART FORM

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

Raw .art data files for ABPM

After filling out relevant data in the ABPR form, use the drop box (labeled “Files”) at the bottom of the form to attach the .art participant data file to the ABPR form.

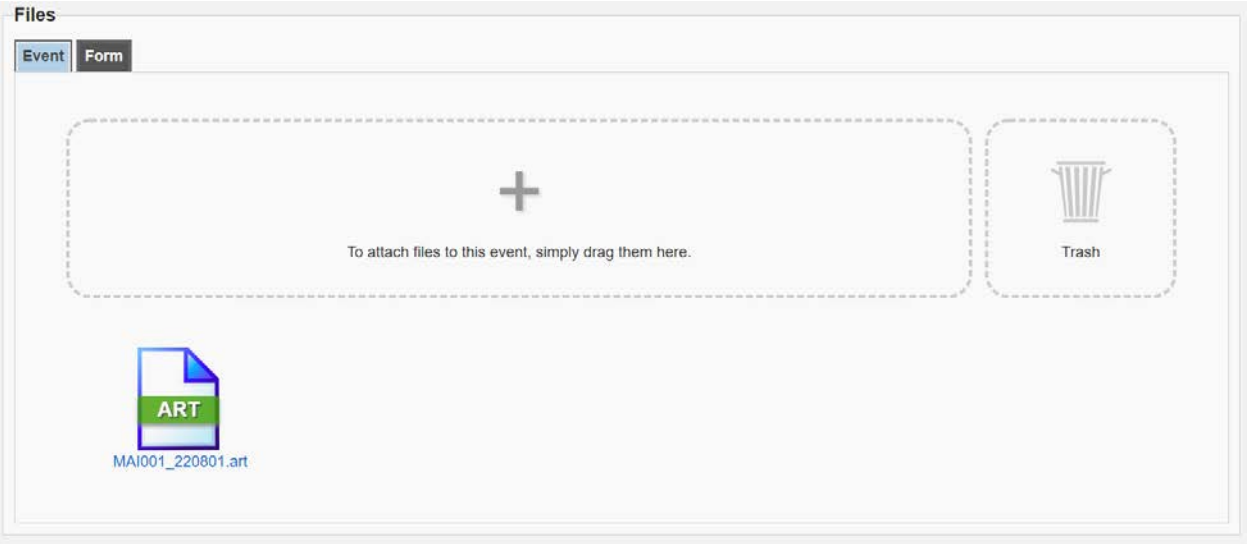
To be able to see the drop box, the tab with “Event” will need to be highlighted (this is the default). Files can be attached by dragging the file from the folder on your computer into the box with the “+” (Note, you must save the form before the “+” will appear on the drop box). This drop box can be accessed from any tab within the form.



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

Participant data filename convention: ‘[SubjectID_YYMMDD.art]’

Participant replacement data filename convention: '[SubjectID_YYMMDD.art]'

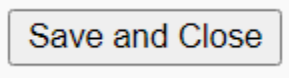


If the wrong file was attached, you can drag the file to the trash area of the drop box to remove the file from the form.

1. Ensure that the ARIC Subject ID in the filename matches the ARIC Subject ID on the ABPR form.

ID
MAI001_220801 =

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



APPENDIX G. ABPM EVENT CODES

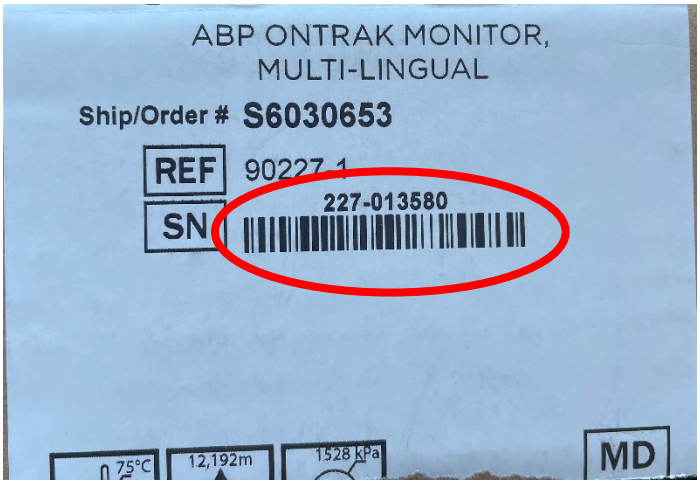
Report	Condition
EC03	Patient cancelled reading by pressing ACTION key. No retry attempt is made following an EC03 code.
EC04	Blood pressure measurement not completed in the maximum time allowed. Occasional EC04 messages may result from excessive patient movement. Frequent EC04 messages would indicate an improperly applied cuff or a monitor malfunction which requires return to Spacelabs for service
ECn4	(where n = 1 to 9) Indicates that one or more of the blood pressure results have been corrupted and subsequently recovered. Frequent occurrence of this message would indicate a malfunction that requires return to Spacelabs for service.
EC10	Excess movement artifact. Frequent EC10 messages may indicate an air leak and unit need to be returned to Spacelabs for service
EC11	Did not pump above the mean arterial level.
EC16	Low battery detected prior to start of measurement.
EC18	Too few data entries to accurately determine blood pressure. This message may indicate that the cuff is not being worn by the patient (taken off but left connected to the monitor). The message may also indicate that motion artifacts cause the majority of the incomplete data.
EC20	A) A very large number of movement artifacts B) Heart rate arrhythmia
EC21	Did not pump above systolic pressure.
EC22	Overpressure.
EC26	Low battery detected after measurement started. Usually caused by the pump drawing enough current to lower the battery voltage.
EC28	Diastole above 200mmHg.
EC32	Overpressure.
EC38	Pulse pressure less than 16mmHg.
EC40	A) Movement artifact at systole B) Heart rate arrhythmia
EC42	No cuff attached.

EC45	Invalid bleed size. The monitor has automatically changed the bleed size to 8mmHg.
EC48	A) Movement artifact at mean arterial pressure B) Heart rate arrhythmia
EC50	A) Movement artifact at diastole B) Heart rate arrhythmia
EC52	Kinked hose.
EC55	An unexpected loss of power possibly caused by: a) removal of the batteries during a blood pressure measurement, b) hardware overpressure, or c) a hardware timeout. Frequent EC55 messages would indicate a malfunction which requires the unit to be returned to Spacelabs for service.
EC58	A) Movement artifact at diastole B) Heart rate arrhythmia
EC62	Cuff applied too loosely.
EC70	Systole was found to be above the highest cuff pressure. However, this result appears to be an error caused by motion artifact. Therefore, the cuff will not be inflated to a higher pressure on the next measurement attempt
EC75	Equipment malfunction. Return to Spacelabs Healthcare for service.
EC78	Blocked connector filter. Return to Spacelabs Healthcare for service
EC80	A) Movement artifact B) Heart rate arrhythmia
EC85	The Time and Date are corrupted. Update them to continue with normal operation.
EC90	A) Movement artifact B) Heart rate arrhythmia
EC91	Systole appears higher than the selected maximum cuff pressure limit.
EC95	Cuff pressure baseline is out of limits. The monitor should correct the baseline

Note: To fix the EC85 code, simultaneously press and hold the up and down buttons on the OnTrak monitor for 3 seconds. When prompted, enter the correct date and time. Select OK.

APPENDIX H. ABPM DEVICE SERIAL NUMBER AND TRACKING (SCREENSHOTS)

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.



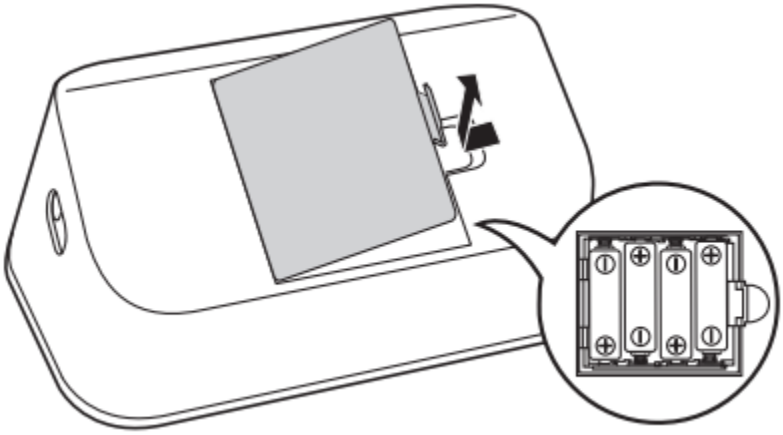
This serial number and barcode on the box matches the serial number and barcode on the back of the ABPM device.

3.2 HOME BLOOD PRESSURE MONITORING (HBPM) PROTOCOL

APPENDIX I. HBPM CONFIGURATION

This step can be done prior to participant arrival; however, it is recommended to not perform this step more than 1 week prior to participant visit to save battery life.

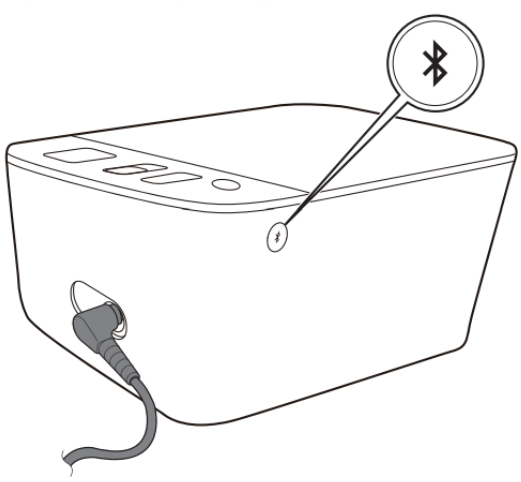
Push down on the hook of the battery cover and pull down. Insert 4 AA batteries into the back of the Omron Series 10 monitor in the battery compartment.



Close the battery cover. Consider taping the back of the device to prevent batteries coming out if the monitor is dropped.

As soon as batteries are correctly installed, the year flashes on the display screen.

Press the Bluetooth button on the back of the monitor to change the year. If the correct year is already displayed, skip this step.

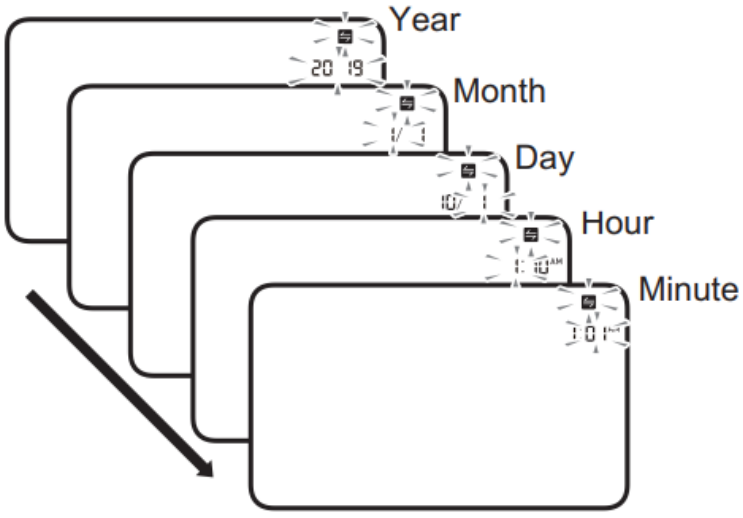


Press the ▷ or ◁ button to adjust the year.

Press and hold the ▷ button to quickly advance the years.

Press and hold the ◁ button to quickly go backwards through the years.

Press the ✱ button to confirm the year, then the month will flash. Repeat the same steps to adjust the month, day, hour, and minute.



Note: Set the **CURRENT** date and time.

Press the Bluetooth button to save the settings. If you need to reset the date and time at any point, replace the batteries or press the Bluetooth button, then follow the steps above.

Once you save the settings, the TruRead Mode setting will be displayed. For this HBPM protocol, you will set-up TruRead mode for each monitor. See Appendix K for TruRead mode instructions.

APPENDIX J. TRUREAD MODE CONFIGURATION

2.4 Setting the TruRead Mode

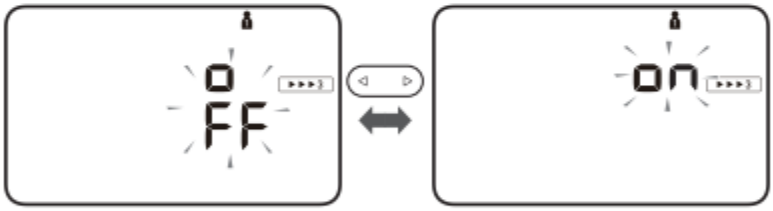
The TruRead mode takes 3 consecutive measurements. The monitor will inflate, take a measurement, and deflate - 3 times, separated by a short interval between each measurement.
The TruRead mode is set to “oFF” by default.

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).

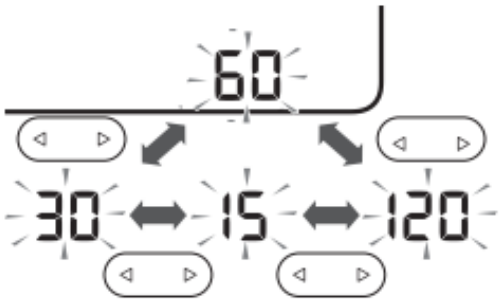


3. Press the ✱ button to confirm.

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.

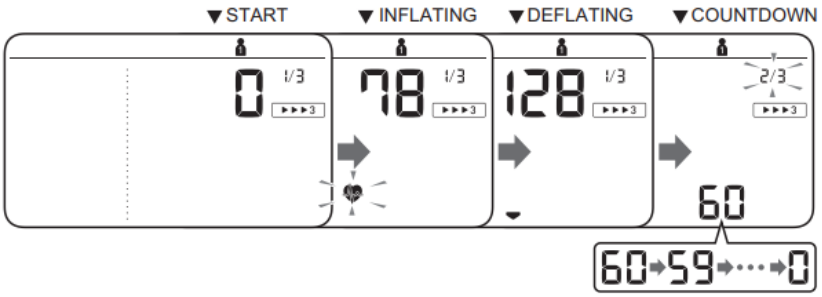
Note, the TruRead interval for the HBPM protocol is 60 seconds.

APPENDIX K. USING TRUE READ MODE

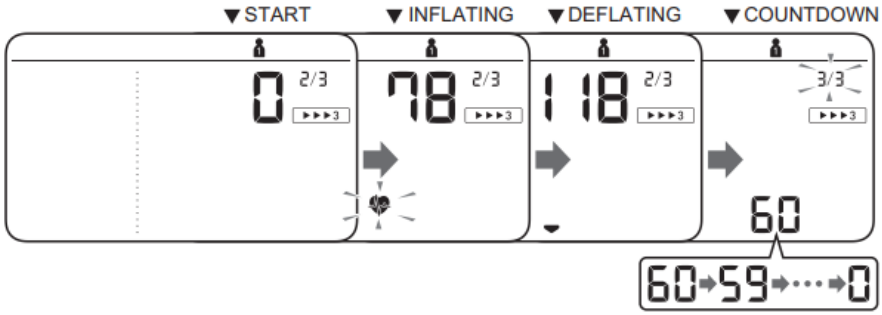
1. Select your user ID.

2. Press the [START/STOP] button.

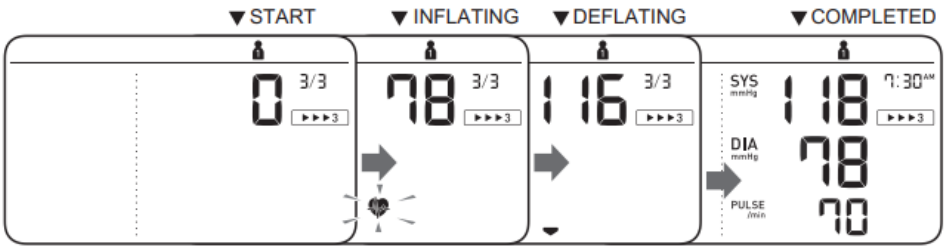
The arm cuff starts to inflate automatically.
After the first measurement is complete, wait for the next measurement to start.
The interval you selected during TruRead settings will appear on the display.



After the second measurement is complete, wait for the next measurement to start.
The interval you selected during TruRead settings will appear on the display.



After the third measurement is complete, the average for the 3 measurements appears on the display.



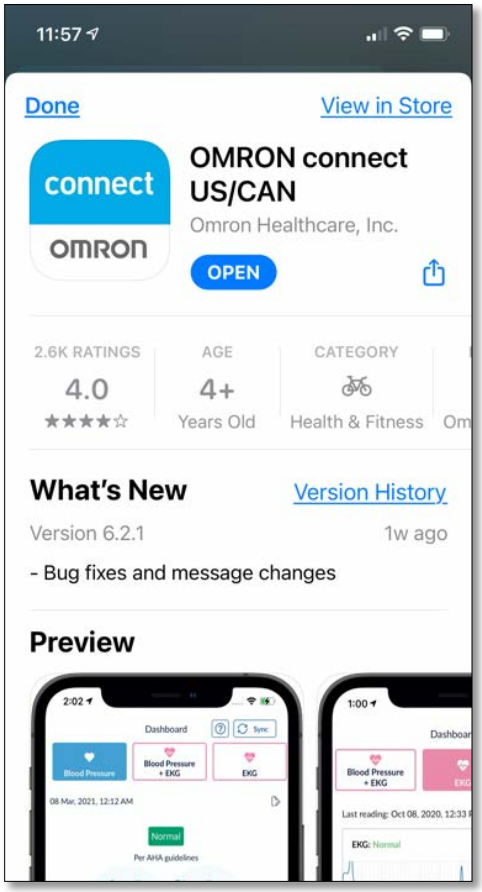
APPENDIX L. OMRON CONNECT APP DOWNLOAD & SMART DEVICE PAIRING

This step is done by ARIC Staff only. Remind each participant at their visit and during check-in calls that they do not need to pair this device with their phone or tablet. All they will do is take their blood pressure measurements at home each morning and evening.

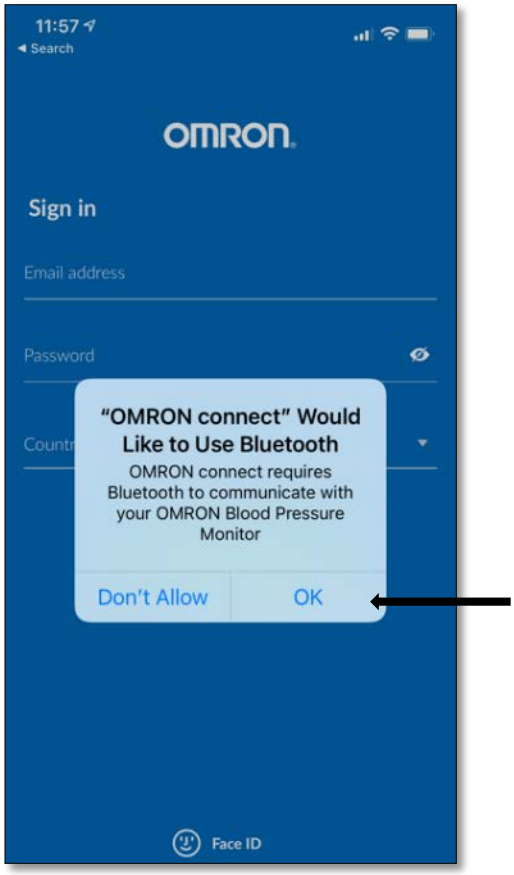
App download and smart device pairing will occur after participant completes the 8-day HBPM protocol and the HBPM device is returned.

Note: Screenshots are from iPhone 12. Instructions may need to be adjusted accordingly based on what smart device is being used. **An iPad 6th generation or higher is preferred.**

1. Download Omron app

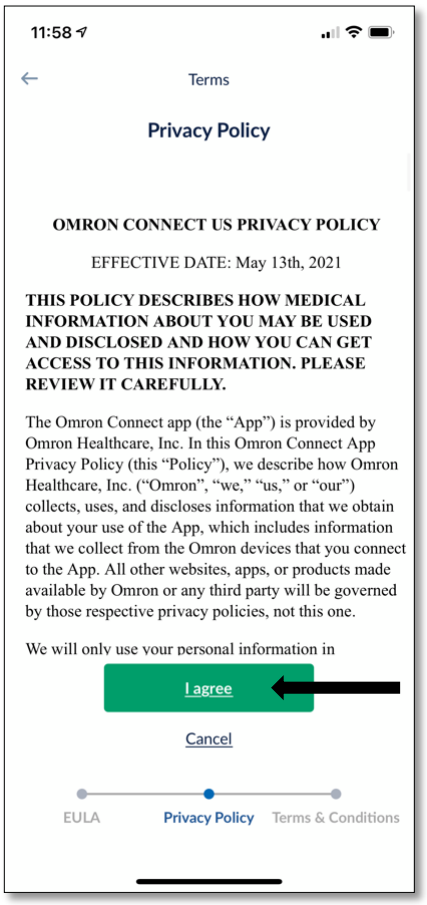


2. Allow Bluetooth and sync with device



Note: ARIC staff who are downloading the HBPM measurements will need to create an account to sign into the Omron Connect App. Follow the steps within the app to do this.

3. Agree to Privacy Policy / Terms & Conditions



4. Choose the correct device

BP7450

OR

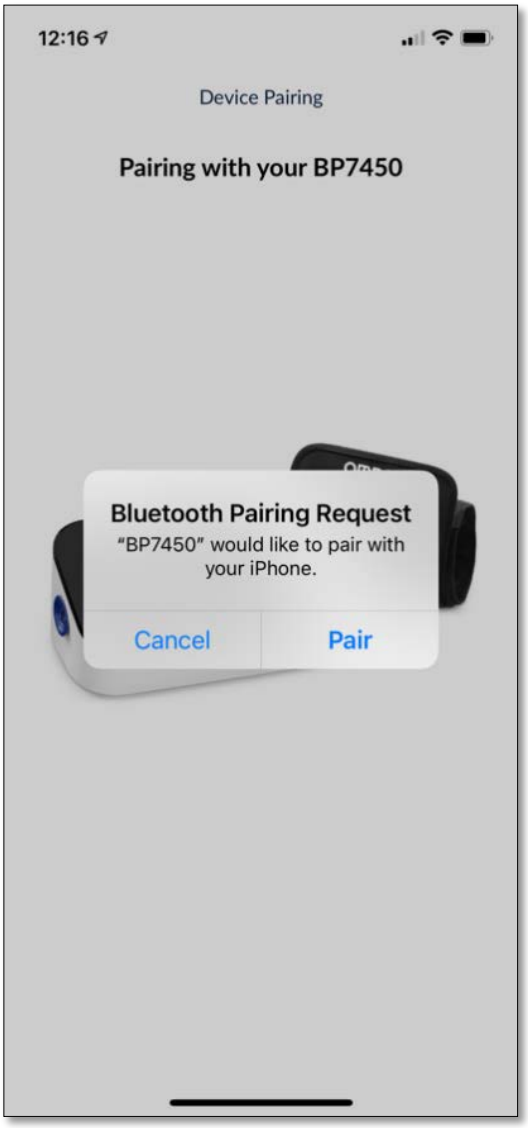
BP7540 CAN

5. Connect via Bluetooth

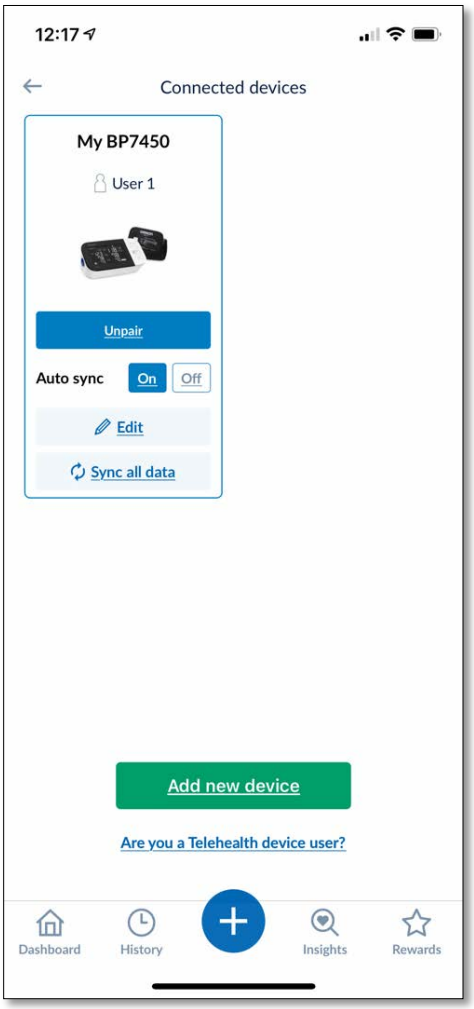
Make sure Bluetooth is turned on (device and monitor)

6. Select the device when it appears

7. Pair device with BP monitor



8. Select **User 1** (or whichever User the respective ARIC participant used for the 8-day HBPM – it is recommended that this always be **User 1**). An ARIC sticker or piece of tape will have been placed over the user **not** being used.



Select *Confirm*.

APPENDIX M. HBPM DOWNLOAD

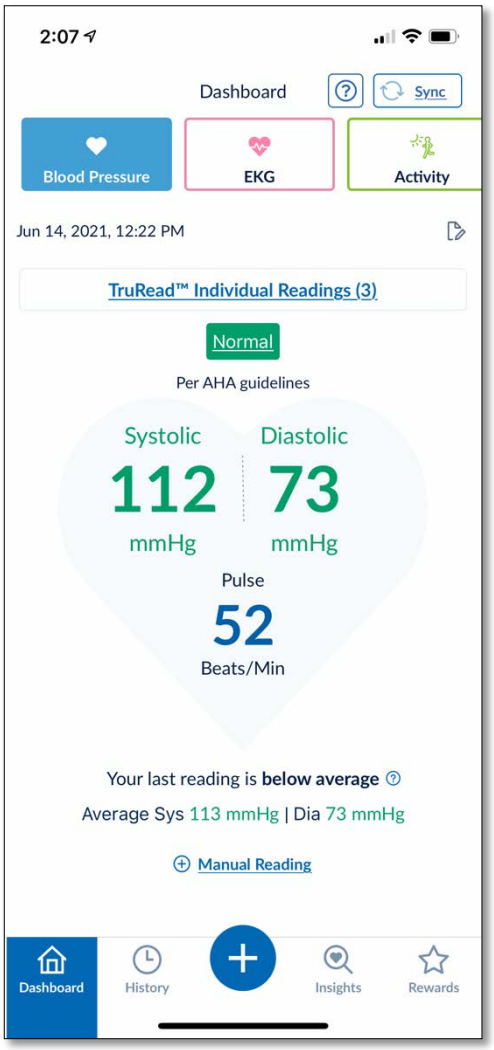
Once the tablet or smartphone is paired to the OMRON Connect app, all blood pressure measurements stored in the monitors history can be securely transferred to the OMRON app.

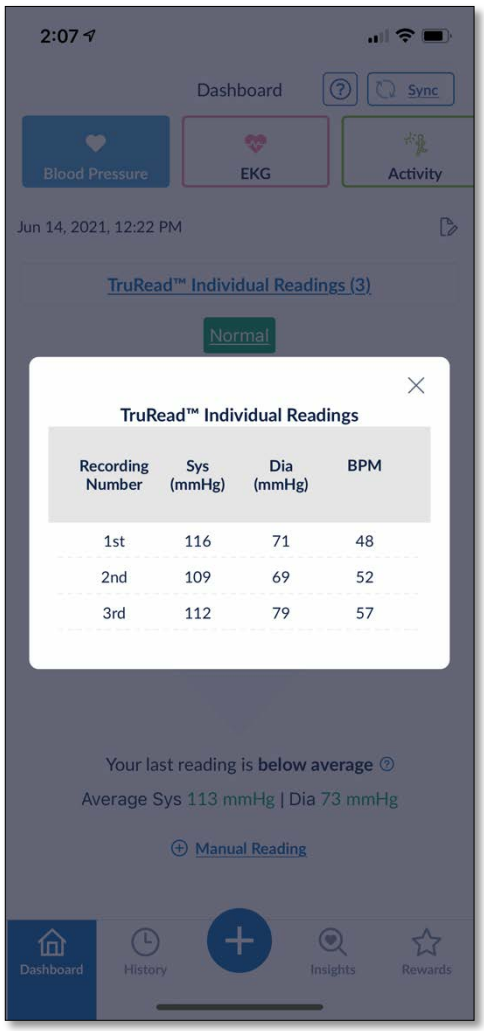
Place the tablet or smartphone next to the monitor and open the OMRON app. Within seconds, the measurements will transfer automatically. If they do not transfer, make sure all other applications are closed.

If data does not transfer, close the app and turn the monitor off. Push the “Note” 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.

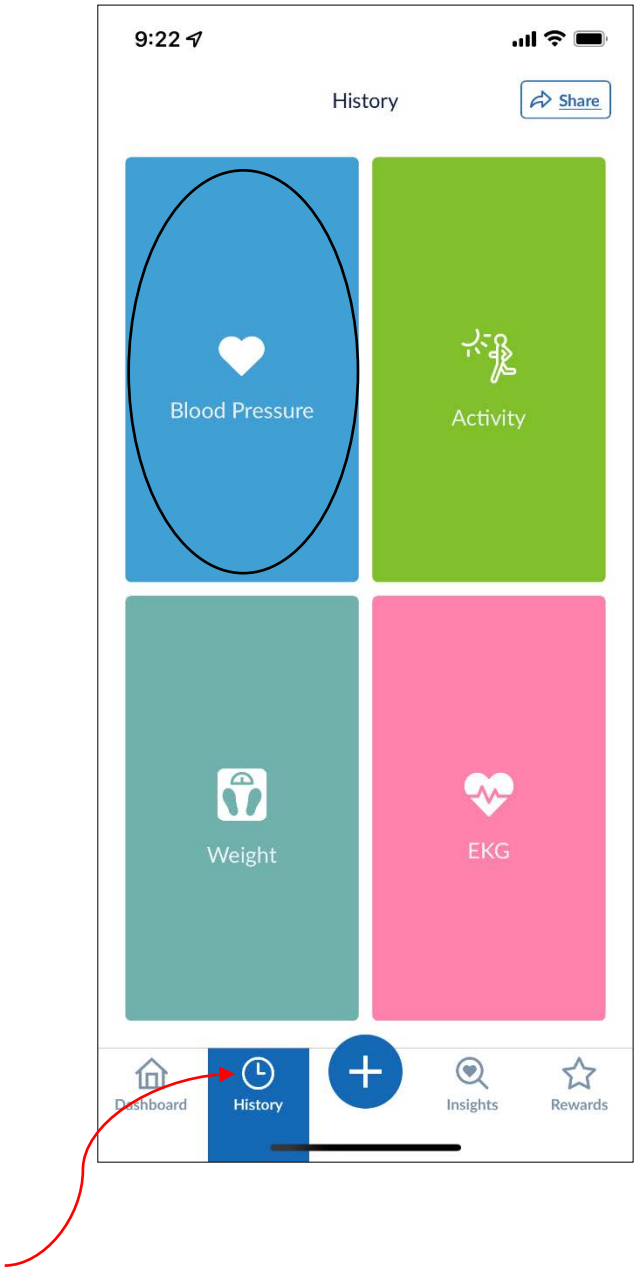
OMRON Dashboard:

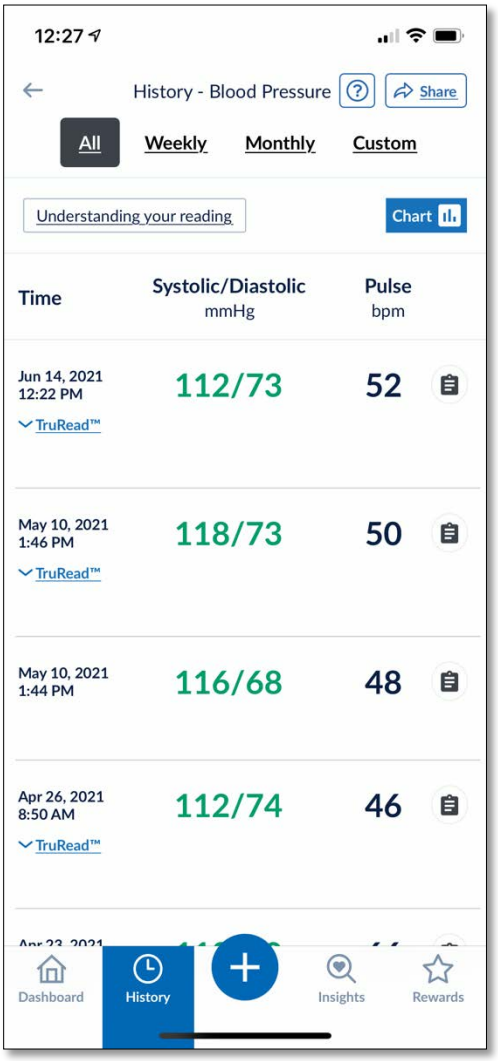


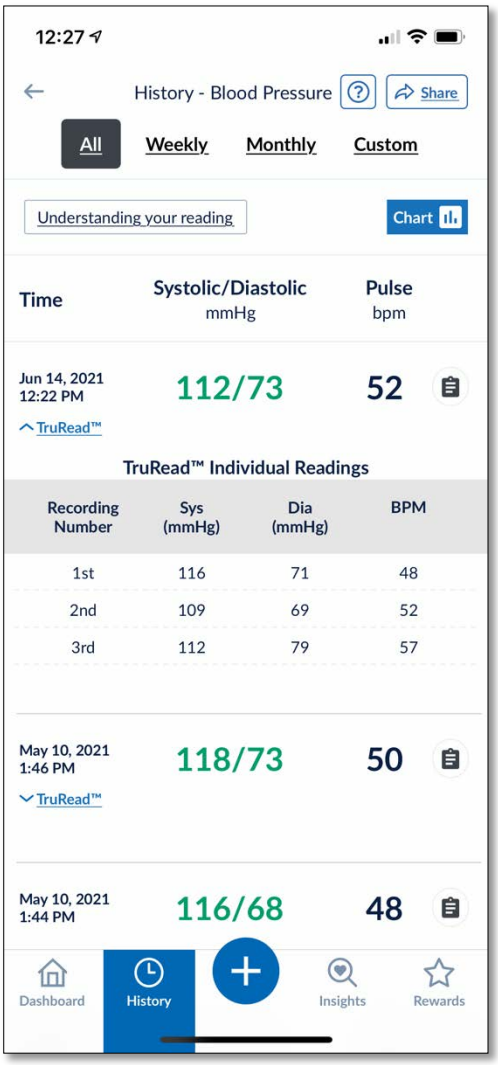


Dashboard will display the most recent reading (click on **"TruRead Individual Readings (3)"** to see all three measurements.

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


9:22
History
Share
Blood Pressure
Activity
Weight
EKG
Dashboard
History
Insights
Rewards



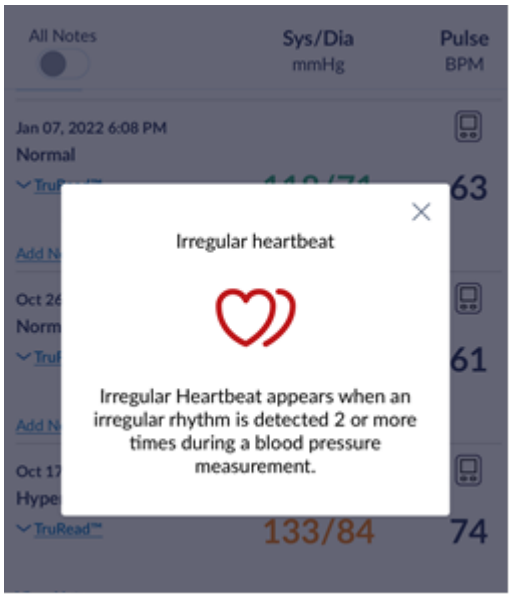


- Once all measurements have been transferred to the OMRON Connect app, scroll through the app and look for any alert symbols that may appear.

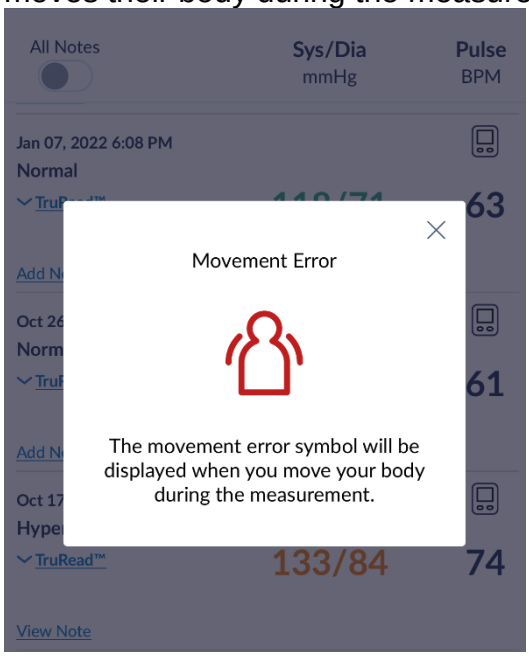
APPENDIX N. OMRON CONNECT APP SYMBOLS

- Alert codes/symbols that will appear in the Omron Connect app once all measurements have been downloaded from the monitor. These symbols include:

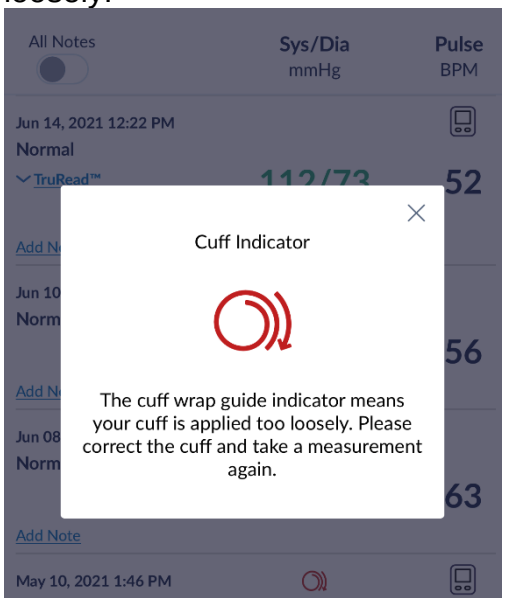
    - o <u>Irregular heartbeat symbol</u>
        - Irregular heartbeat appears when an irregular rhythm is detected 2 or more times during a blood pressure measurement.



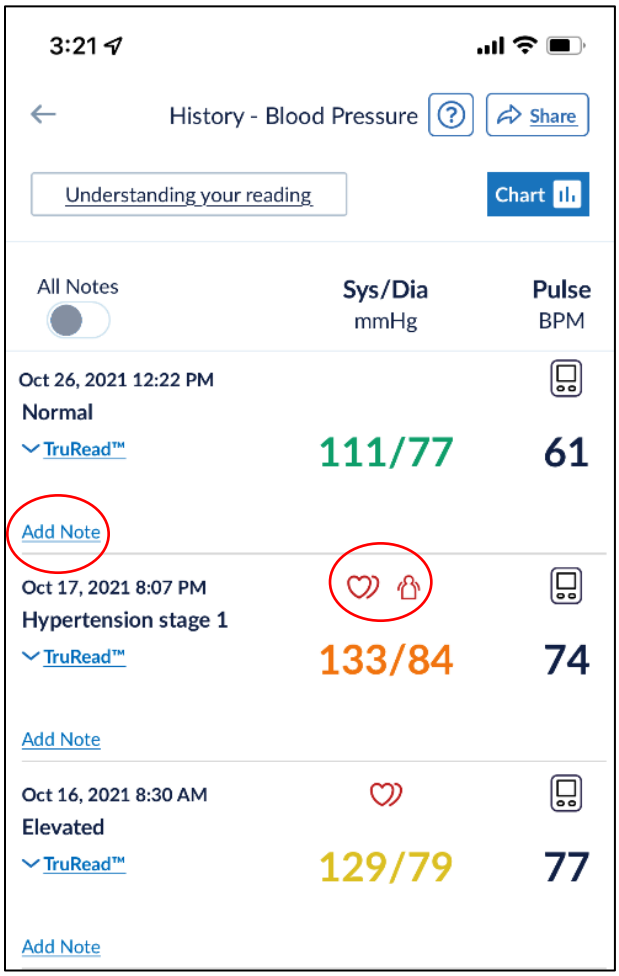
    - o <u>Movement Error Symbol</u>
        - The movement error symbol will be displayed if the participant moves their body during the measurement



- Cuff indicator symbol
  - The cuff wrap guide indicator means your cuff is applied too loosely.



- To ensure that an alert will appear in the csv file, use the following letter/number combination to add “note” in the Omron app, under the measurement that the alert appears next to.
  - Click “Add Note”
  - Enter IH1 for irregular heartbeat, ME2 for movement error, or CI3 for cuff indicator.
  - For measurements with more than 1 alert, type the letter/number combination with **1 space** in between (i.e. “IH1 ME2):



- With the addition of this note, alerts would appear in the downloaded HBPM csv report, under the “Notes” column:

	A	B	C	D	E	F	G
1	Date	Time	Systolic (m	Diastolic (i	Pulse (bpr	TruRead	Notes
2	17-Oct-21	8:12 PM	128	79	73	TruRead	IH1 ME2
3	17-Oct-21	8:09 PM	130	80	73	TruRead	-
4	17-Oct-21	8:07 PM	141	92	76	TruRead	-
5							

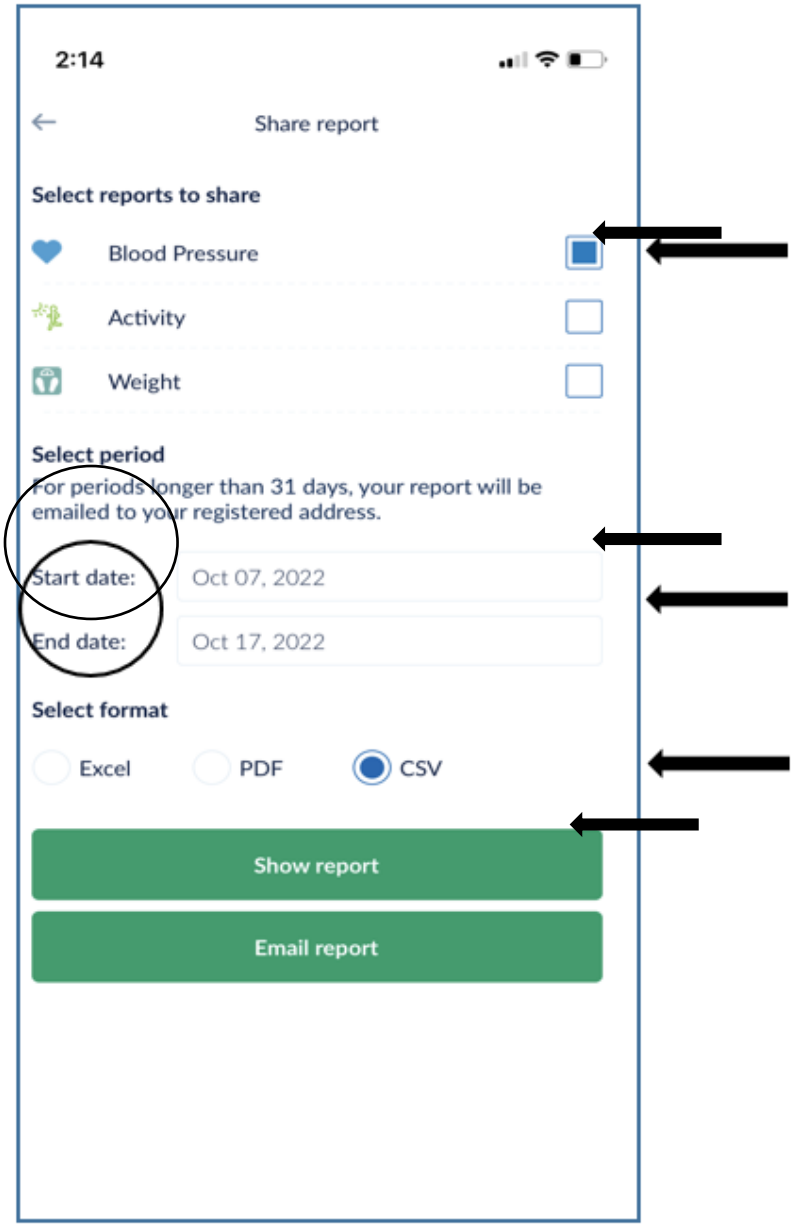
Record multiple alerts separated by space

- A report can be sent securely via email or saved to any file on the device.
  - Go to History > Blood Pressure
    - Select Share (in the top right corner in app)
    - Select reports to share:
      - Blood Pressure should already be selected (but select this if not)

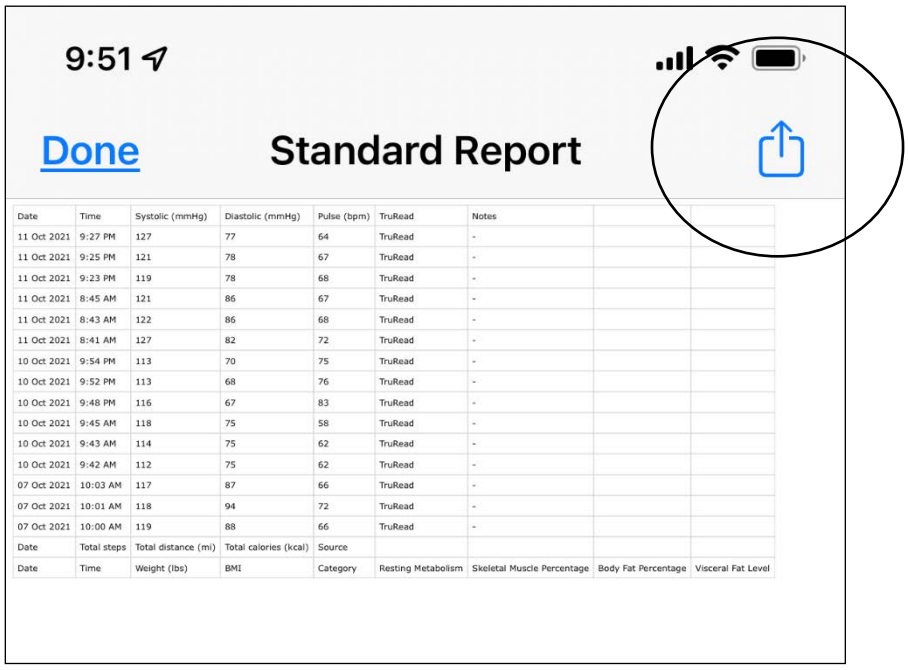
- Select period
  - Enter start and end date of HBPM

__IMPORTANT__: you must mark the start date as the day of the clinic visit in order to capture the in-clinic measurement. You must also mark the end date as the day __after__ the actual end date. This is necessary to avoid losing the PM data on the last day of the HBPM wear period.

- Select format → **CSV**
- Click show report

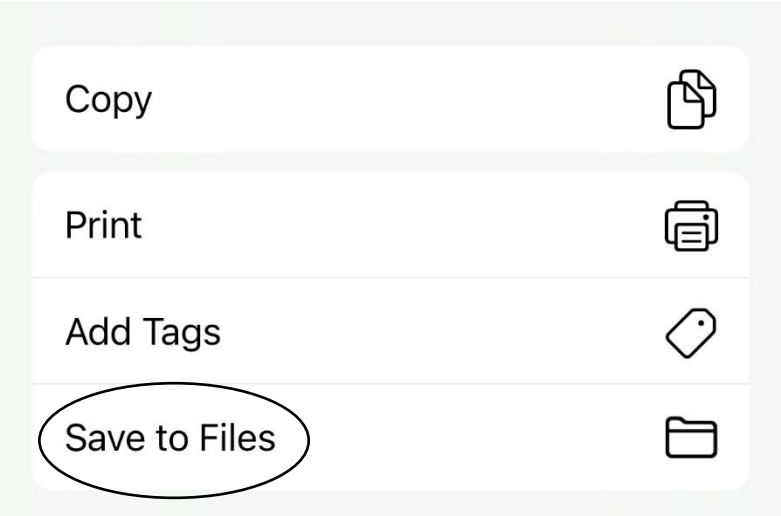


- A “Standard Report” will show on the screen.
- In the top right corner, click the up arrow to save the report.



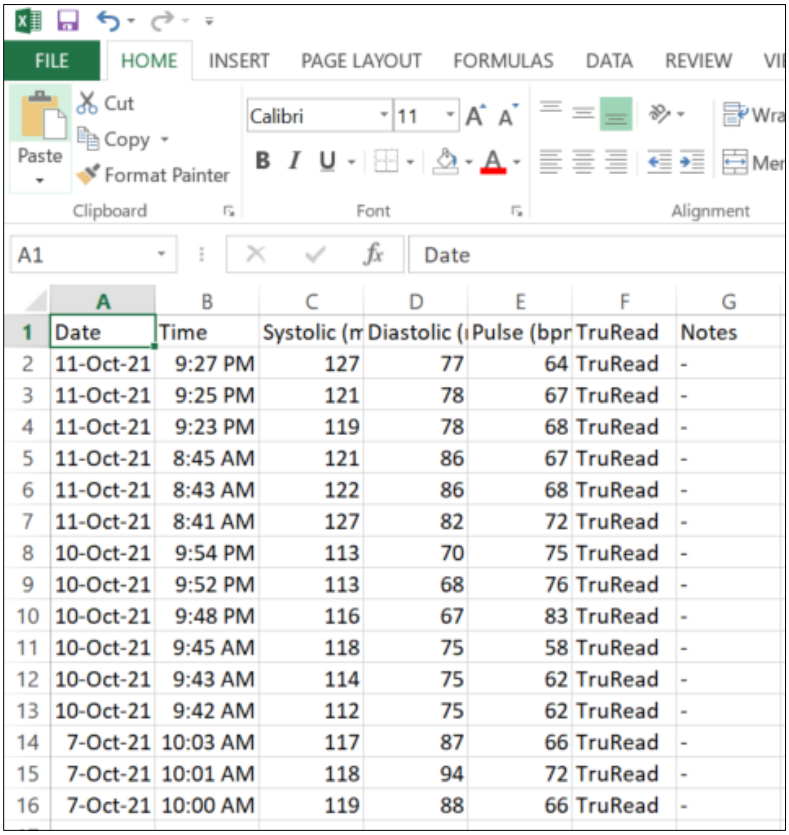
Date	Time	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	TruRead	Notes		
11 Oct 2021	9:27 PM	127	77	64	TruRead	-		
11 Oct 2021	9:25 PM	121	78	67	TruRead	-		
11 Oct 2021	9:23 PM	119	78	68	TruRead	-		
11 Oct 2021	8:45 AM	121	86	67	TruRead	-		
11 Oct 2021	8:43 AM	122	86	68	TruRead	-		
11 Oct 2021	8:41 AM	127	82	72	TruRead	-		
10 Oct 2021	9:54 PM	113	70	75	TruRead	-		
10 Oct 2021	9:52 PM	113	68	76	TruRead	-		
10 Oct 2021	9:48 PM	116	67	83	TruRead	-		
10 Oct 2021	9:45 AM	118	75	58	TruRead	-		
10 Oct 2021	9:43 AM	114	75	62	TruRead	-		
10 Oct 2021	9:42 AM	112	75	62	TruRead	-		
07 Oct 2021	10:03 AM	117	87	66	TruRead	-		
07 Oct 2021	10:01 AM	118	94	72	TruRead	-		
07 Oct 2021	10:00 AM	119	88	66	TruRead	-		
Date	Total steps	Total distance (mi)	Total calories (kcal)	Source				
Date	Time	Weight (lbs)	BMI	Category	Resting Metabolism	Skeletal Muscle Percentage	Body Fat Percentage	Visceral Fat Level

- Save to files. This can be a specific, secure folder on your device or tablet (preferably an iPad), which can be directly uploaded to CDART.
- Rename the file to ensure it is appropriately saved with correct participant information. Save as [**SubjectID_YYMMDD.csv**].



  - ***NOTE: The first time you complete this process you will need to create a directory folder on the device/tablet called “HBPM Raw Data Files”.***

- Once the file is saved and opened as a CSV, you will see columns with the Date, Time, Systolic reading, Diastolic reading, Pulse, TruRead, and Notes (if any, such as irregular heartbeat or movement error).
    - **NOTE: the "Notes" column will remain empty if not added directly through the Omron Connect App.**

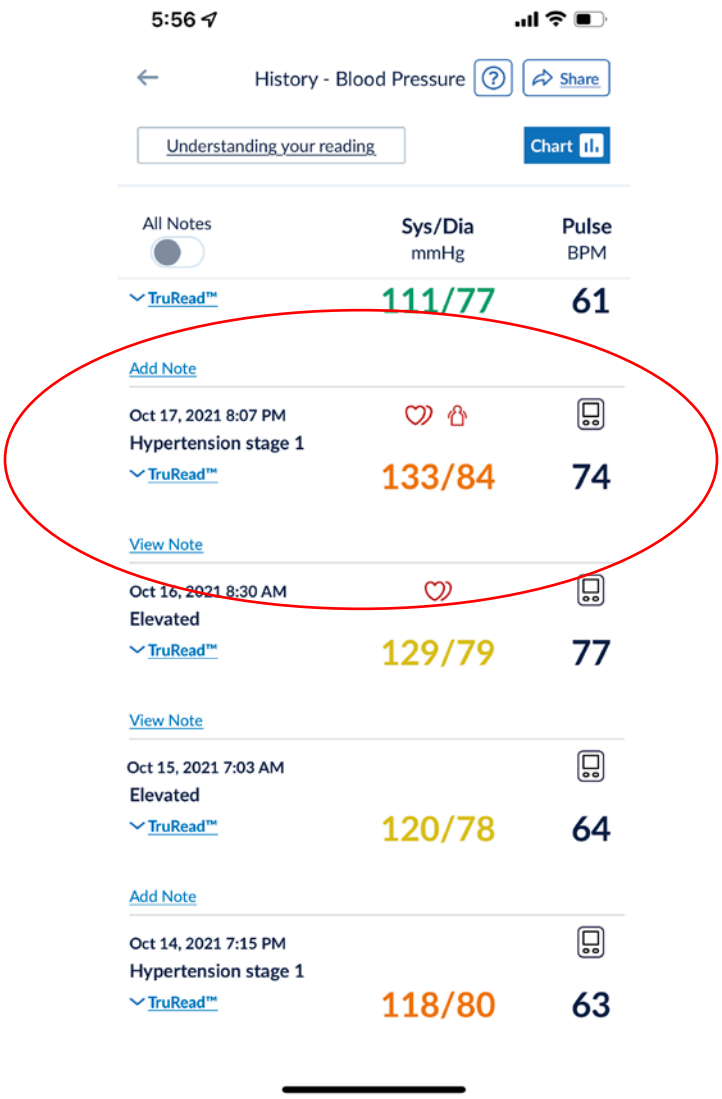


	A	B	C	D	E	F	G
1	Date	Time	Systolic (m	Diastolic (i	Pulse (bpr	TruRead	Notes
2	11-Oct-21	9:27 PM	127	77	64	TruRead	-
3	11-Oct-21	9:25 PM	121	78	67	TruRead	-
4	11-Oct-21	9:23 PM	119	78	68	TruRead	-
5	11-Oct-21	8:45 AM	121	86	67	TruRead	-
6	11-Oct-21	8:43 AM	122	86	68	TruRead	-
7	11-Oct-21	8:41 AM	127	82	72	TruRead	-
8	10-Oct-21	9:54 PM	113	70	75	TruRead	-
9	10-Oct-21	9:52 PM	113	68	76	TruRead	-
10	10-Oct-21	9:48 PM	116	67	83	TruRead	-
11	10-Oct-21	9:45 AM	118	75	58	TruRead	-
12	10-Oct-21	9:43 AM	114	75	62	TruRead	-
13	10-Oct-21	9:42 AM	112	75	62	TruRead	-
14	7-Oct-21	10:03 AM	117	87	66	TruRead	-
15	7-Oct-21	10:01 AM	118	94	72	TruRead	-
16	7-Oct-21	10:00 AM	119	88	66	TruRead	-

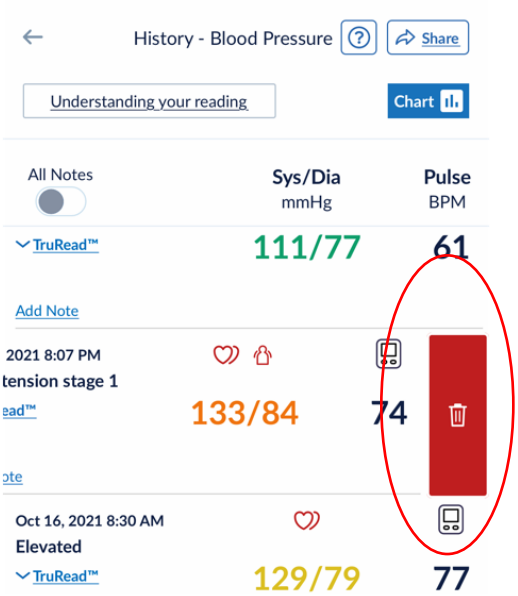
- Remember to save this report with the correct ARIC Study ID.
- Save each CSV file in the folder on the computer (or iPad or mobile device) called "HBPM Raw Data Files." In this example, the raw .csv file should be saved as [SubjectID_YYMMDD.csv].
- After saving the file, go to the "HBPM Raw Data Files" folder on your device/tablet and confirm that the file has been saved.

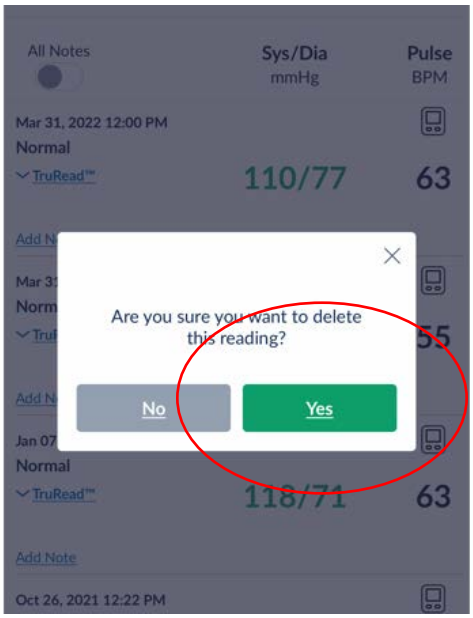
Syncing a different monitor with the same tablet or smartphone

- In the Omron app, be sure to delete all measurements from the previous participant.
- You can delete each TruRead measurement by swiping left on the screen and pressing the red button with the trash bin. This must be done for **each** measurement individually.

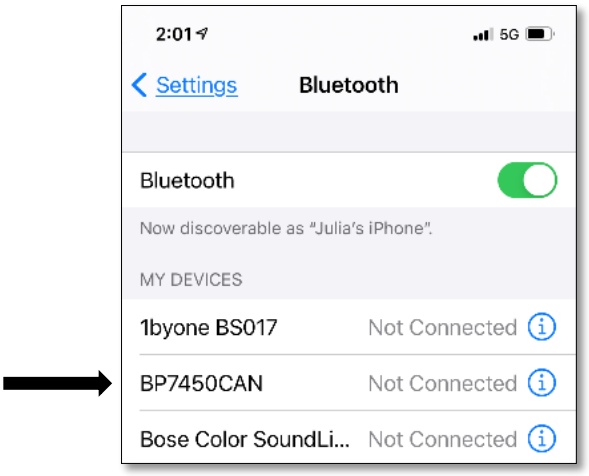


Use your finger to swipe left on the measurement.

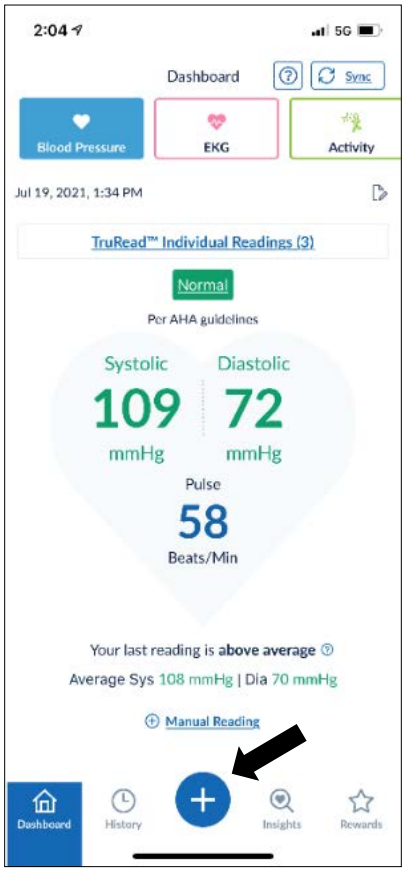




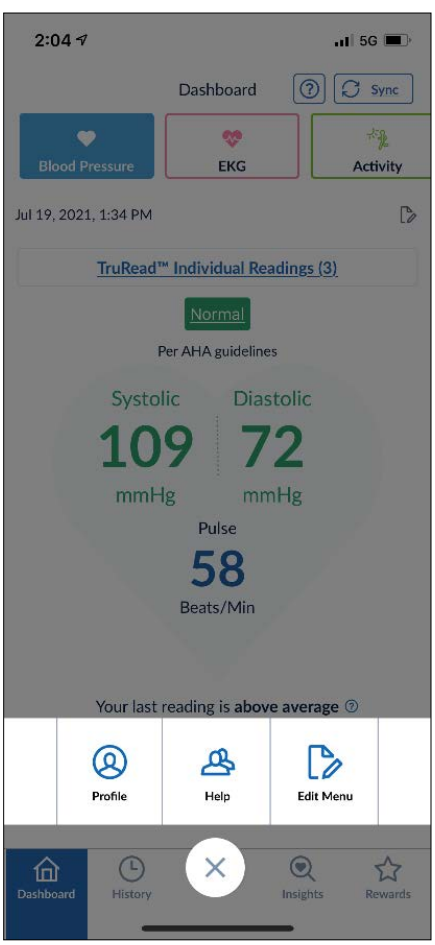
- Press “Yes” you want to delete the measurement to permanently delete it.
    - Note: Be sure the CSV file is saved in a secure place with the ARIC Study ID and date of HBPM completion before you delete measurements off of the app.
    - Confirm all measurements have been deleted.
- Disconnect the previous monitor from the tablet or smartphone you connected it to, by going into **Settings” → “Bluetooth” → “Forget this device”**

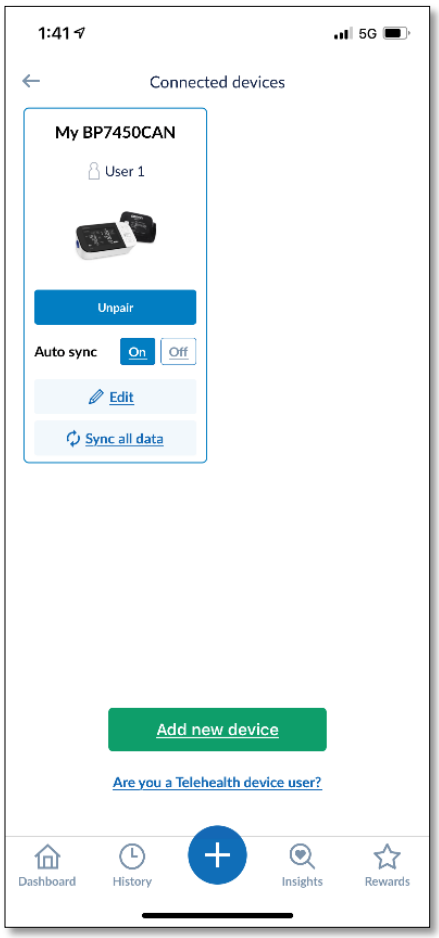


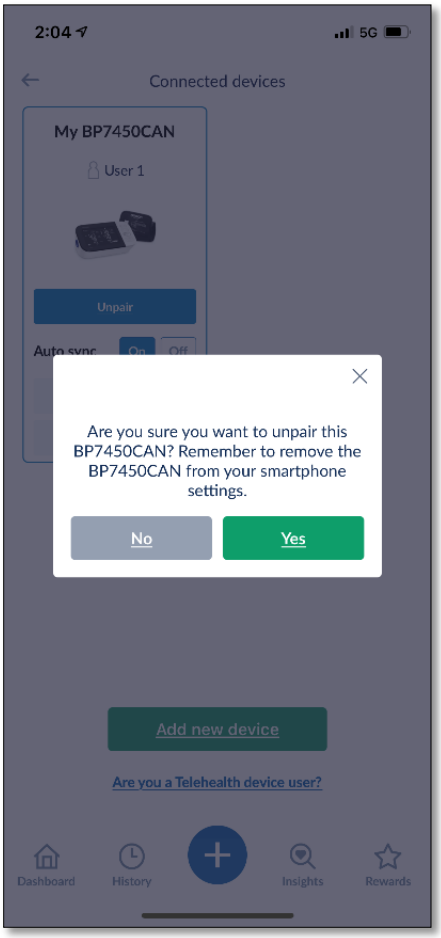
- Go into the OMRON app
    - Click the blue + button at the bottom of the screen



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





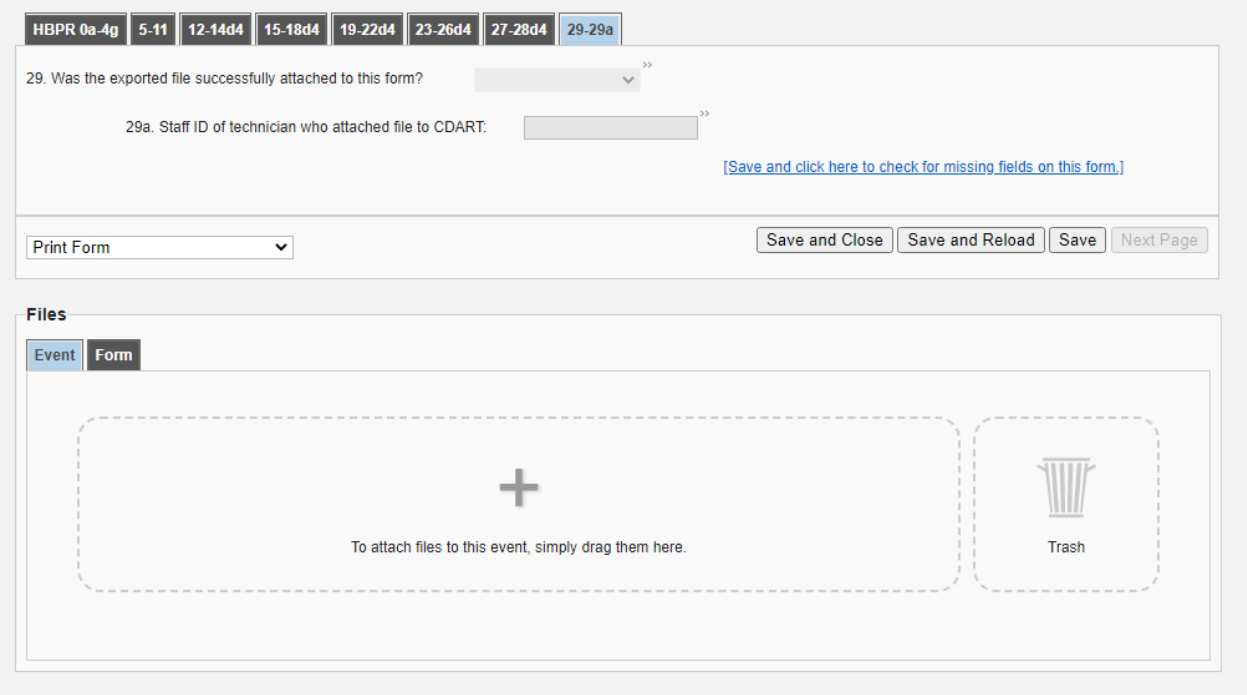


- Now, Add new device
    - See notes above regarding which device to use.
- Press the Bluetooth button on the back of your device until you see a flashing P on the screen

APPENDIX O. ATTACHING HBPM DATA TO A CDART FORM

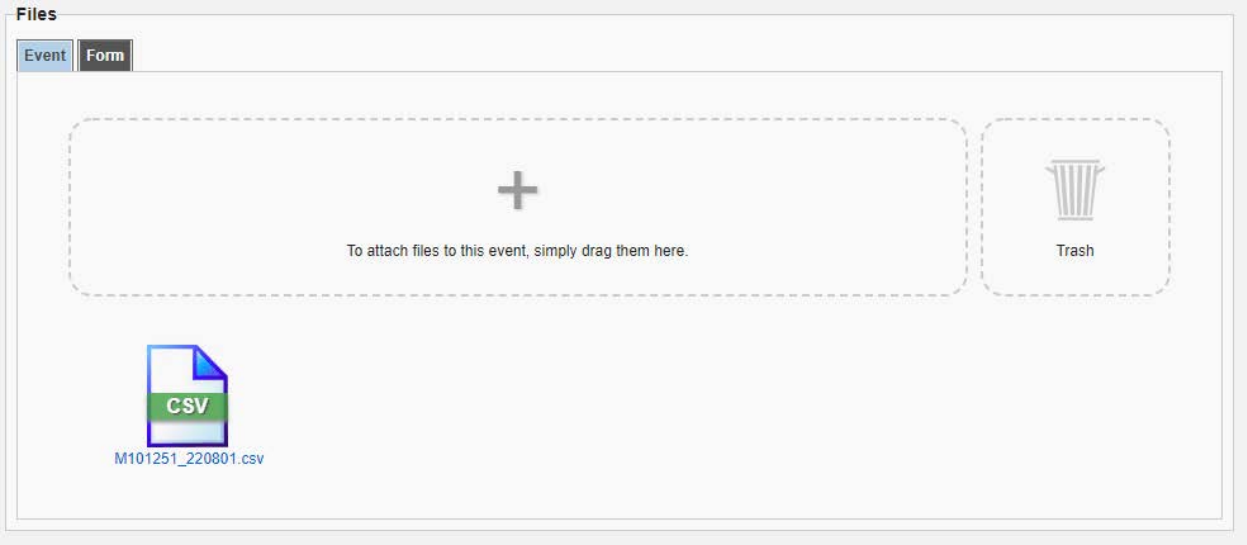
Raw .csv data files for HBPM

1. After filling out relevant data in the HBPR form, use the drop box (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 drop box, 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 drop box). This drop box can be accessed from any tab within the form.



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

Participant data filename convention: '[SubjectID_YYMMDD.csv]'
Participant data filename convention if data for **User 2**: '[SubjectID_2_YYMMDD.csv]'

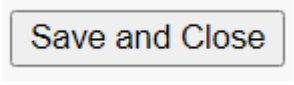


If the wrong file was attached, you can drag the file to the trash area of the drop box to remove the file from the form.

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

ID
M101251_220801 =

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



APPENDIX P. OMRON SERIES 10 MONITOR 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.

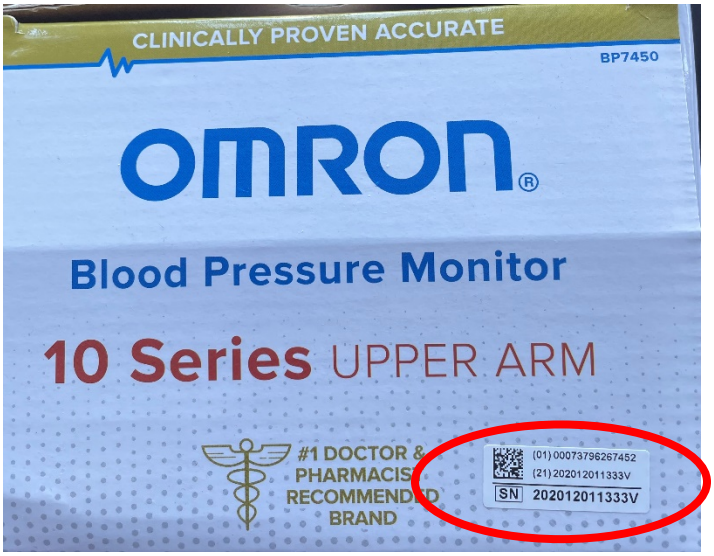
Display/ Problem	Possible Cause	Solution
E1 appears or the arm cuff does not inflate.	Air plug is not completely plugged into the monitor.	Insert the air plug securely. Refer to sub-section 2.6.
	The arm cuff is not applied correctly.	Apply the arm cuff correctly, then take another measurement. Refer 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
E3 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.
E4 appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
E5 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		
Er 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
E rr 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.
P 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.
0 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.	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.
	The date and time is not set.	
 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 Q. HBPM DEVICE SERIAL NUMBERS AND TRACKING (SCREENSHOTS)

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



3.3 BOTH PROTOCOLS

APPENDIX R. BLOOD PRESSURE MONITORING CHECK-IN CALL SCHEDULE FOR IN-CLINIC VISIT, ABPM AND HBPM PROTOCOL

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 starting ABPM on Fridays so ABPM end / check-in call 1 do not fall on a weekend.

** Preference for check-in call 2 is Day 4; however, this call can take place on Day 3 or Day 5 should Day 4 fall on a weekend.

APPENDIX Rb. BLOOD PRESSURE MONITORING CHECK-IN CALL SCHEDULE FOR PARTICIPANT WHO OPT FOR HBPM ONLY

In-clinic during v10	**First Day of HBPM**	**Check-in Call 1***				**Check-in Call 2****		**Last Day of HBPM**
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday
Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

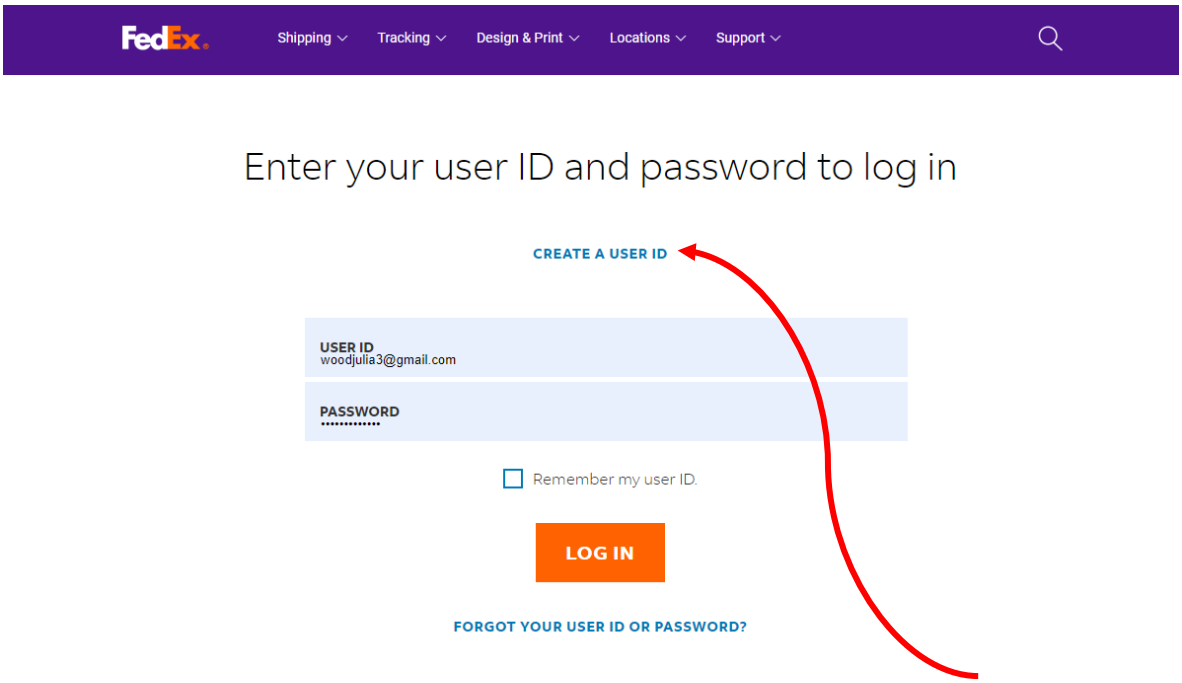
* Preference for check-in call 1 for Thursday and Friday is Day 3; however, this call can take place on Day 2 and Day 4 respectively since Day 3 fall on a weekend.

** Preference for check-in call 2 for Monday is Day 7; however, this call can take place on Day 8 since Day 7 falls on a weekend.

APPENDIX S. DEVICE RETURN GUIDE

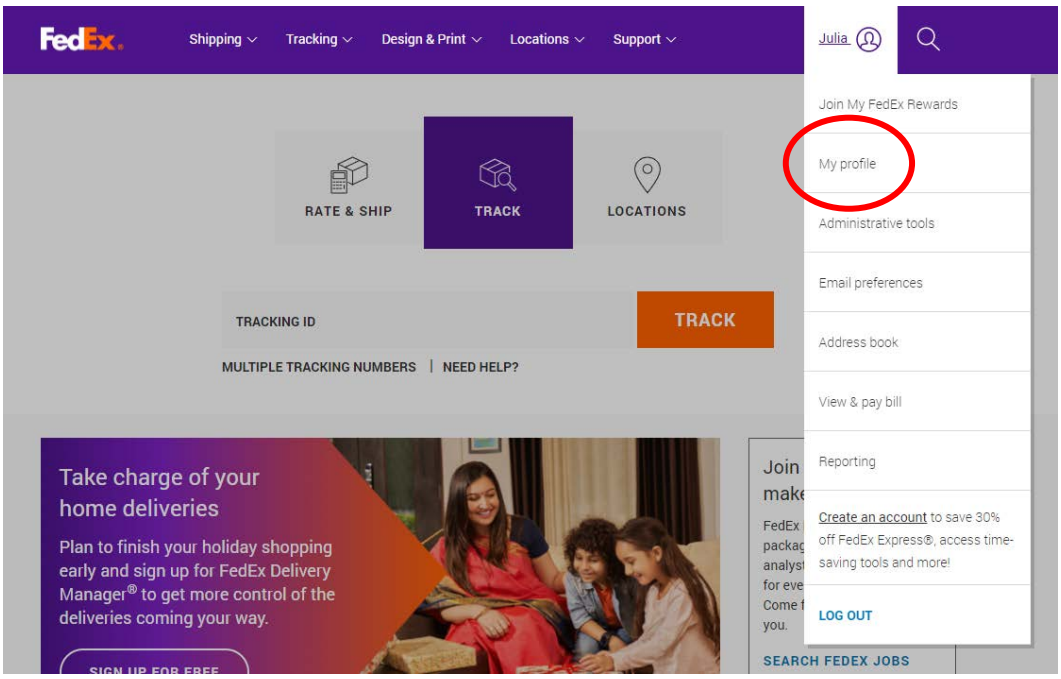
Instructions for ordering FedEx Express boxes

1. Sign into FedEx

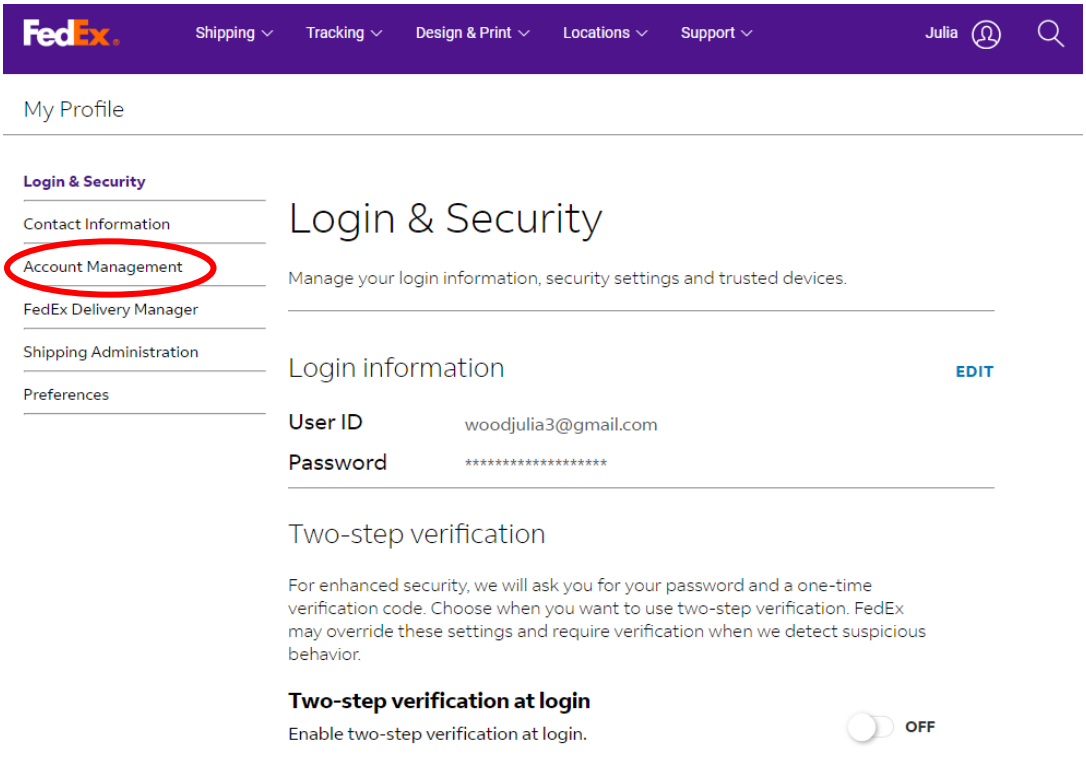


*If your site does not have an account, this can easily be done by clicking Create a user ID.

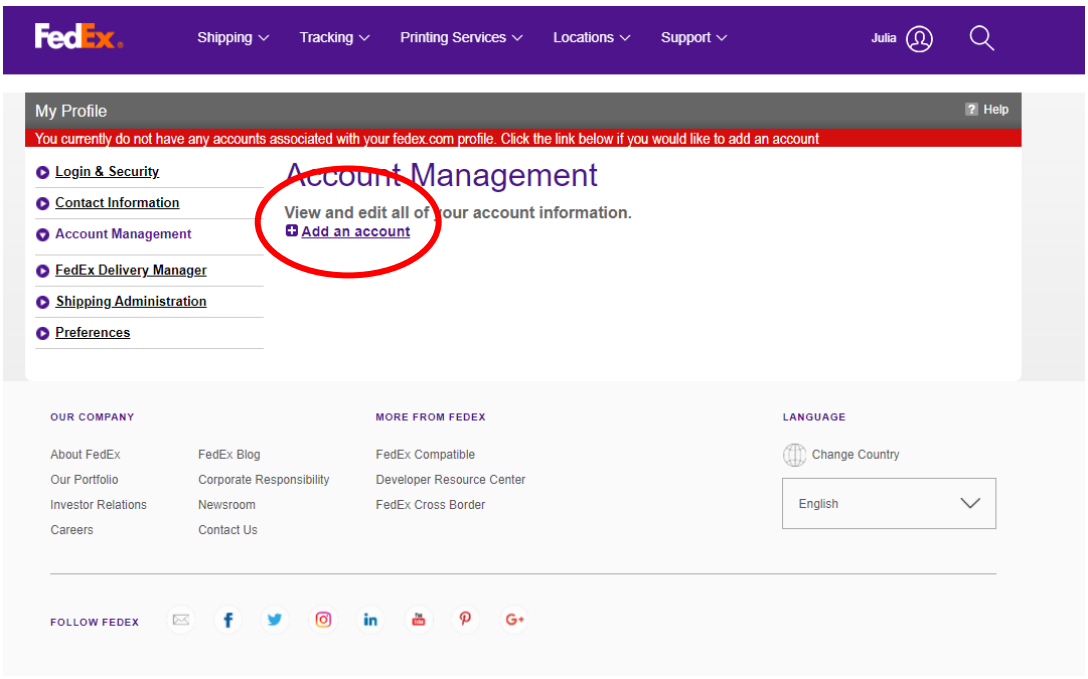
2. If this is a new FedEx account, add a payment account so you can order supplies and shipping labels. First go to My profile.



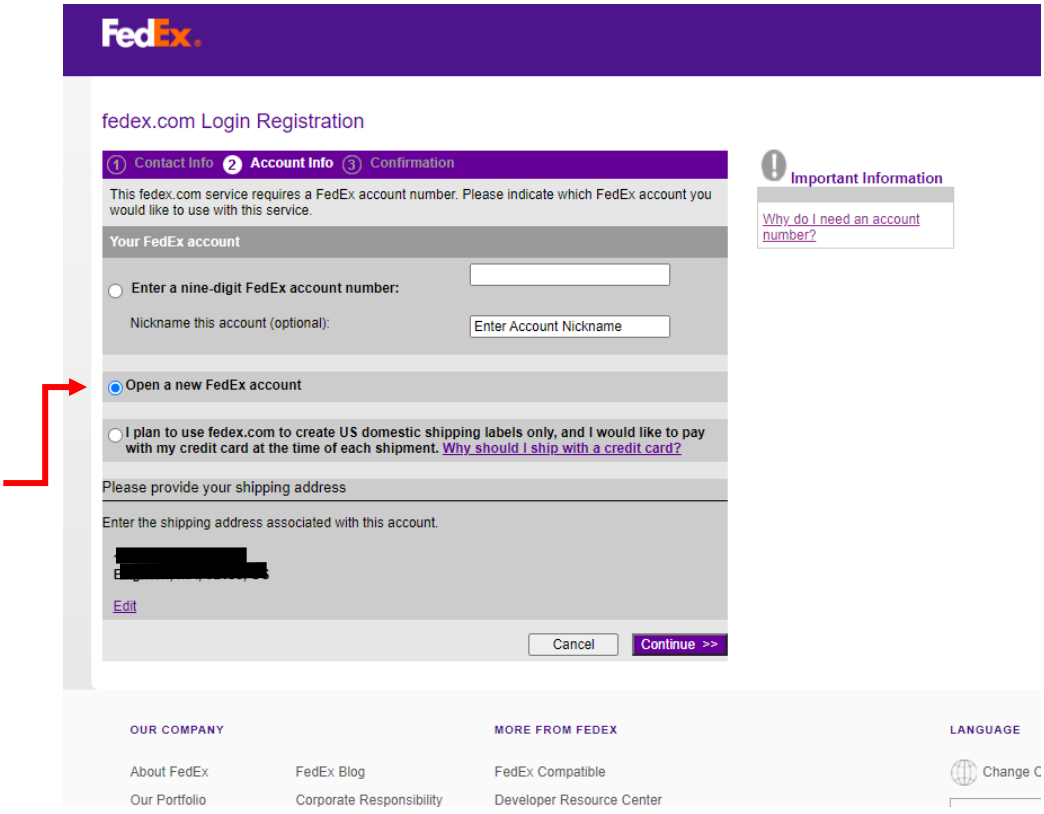
Go to Account Management:



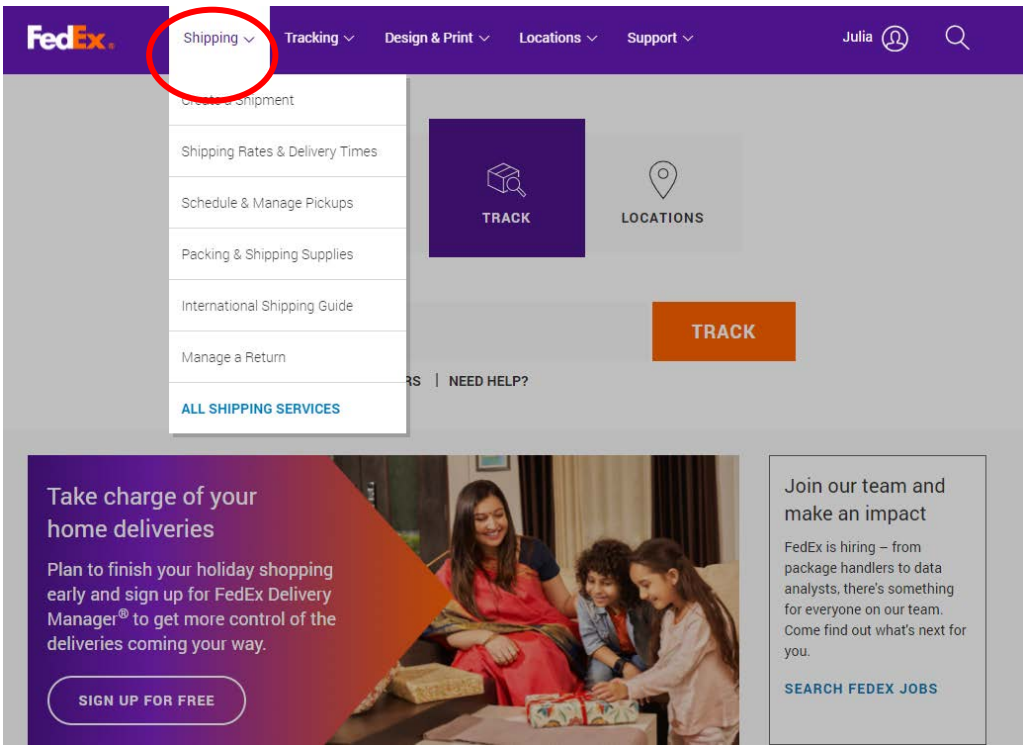
Add an account:



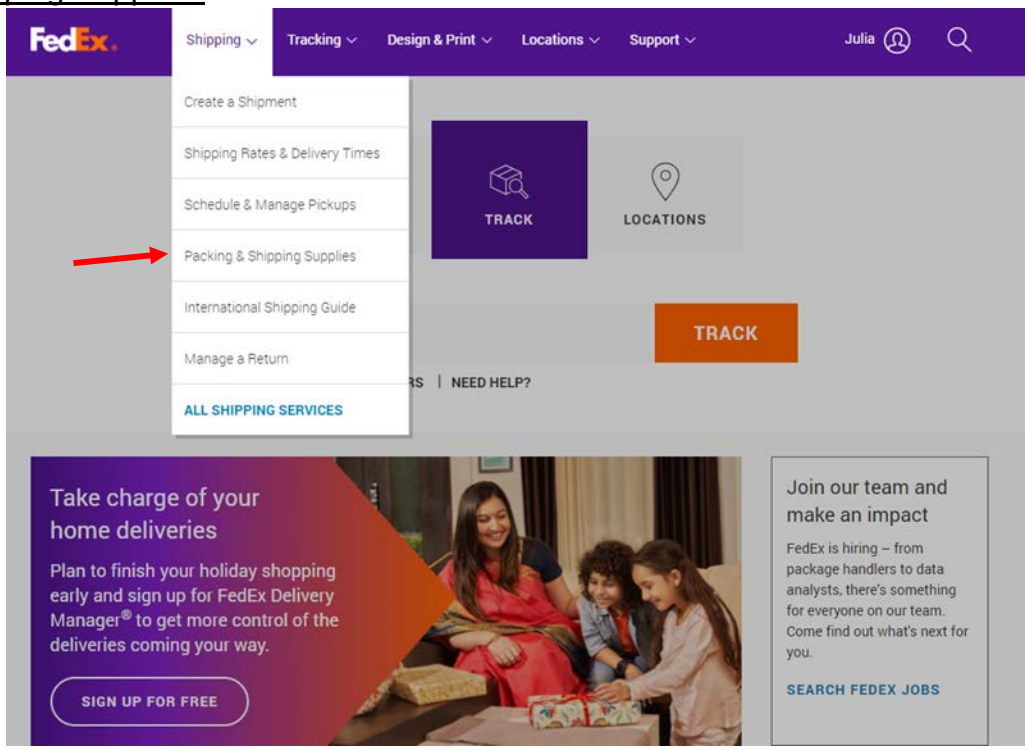
Open new account:



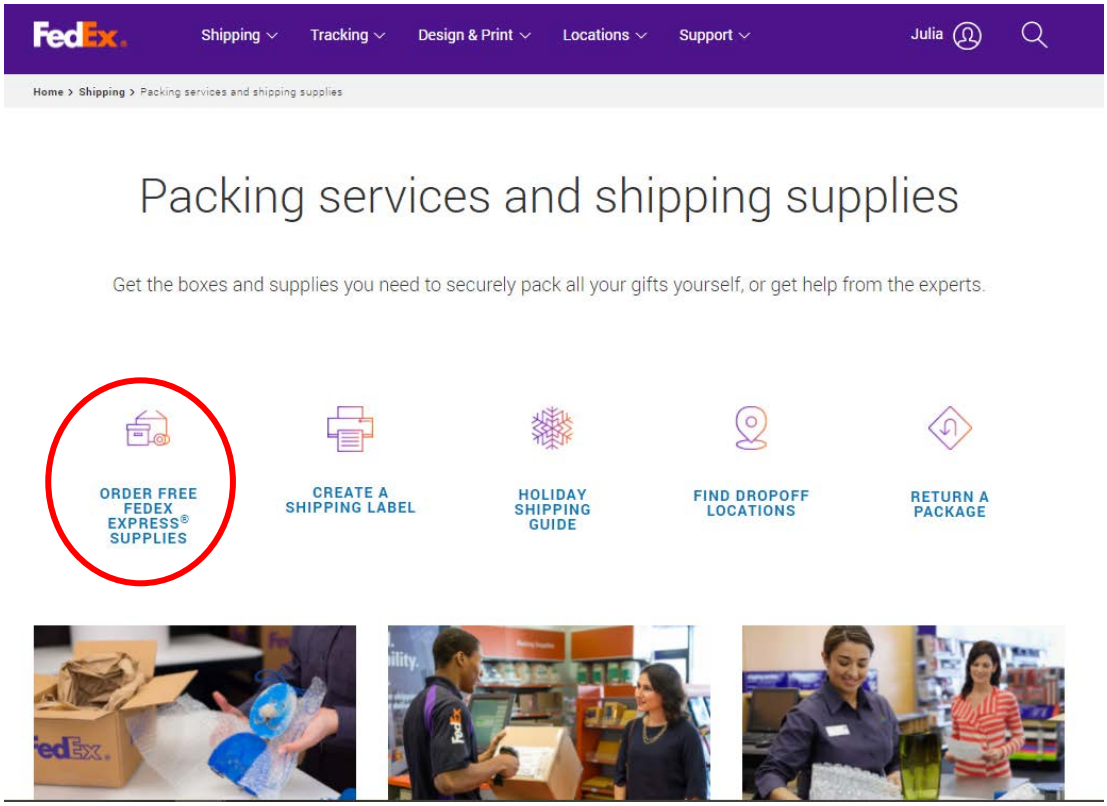
3. Once logged in and the account is added, navigate to Shipping



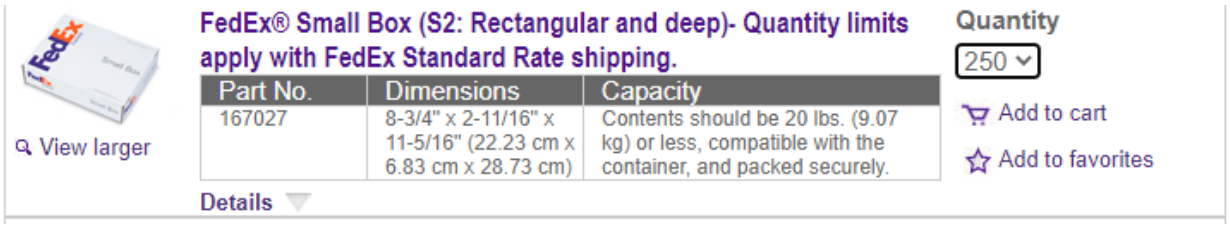
4. For ABPM device return (and HBPM device return if appropriate) you can order packing and shipping supplies directly on the FedEx website. Click Packing & Shipping Supplies.



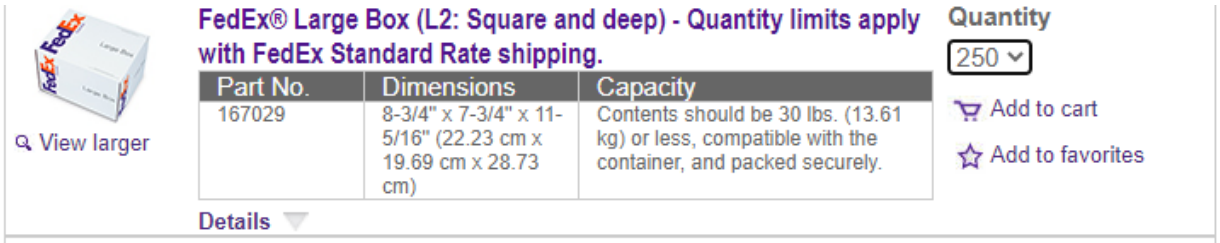
5. Select Order Free **FedEx Express** Supplies



The ABPM (Spacelabs OnTrak 90227) device can be returned in a **Small Box** (S2: Rectangular and deep)

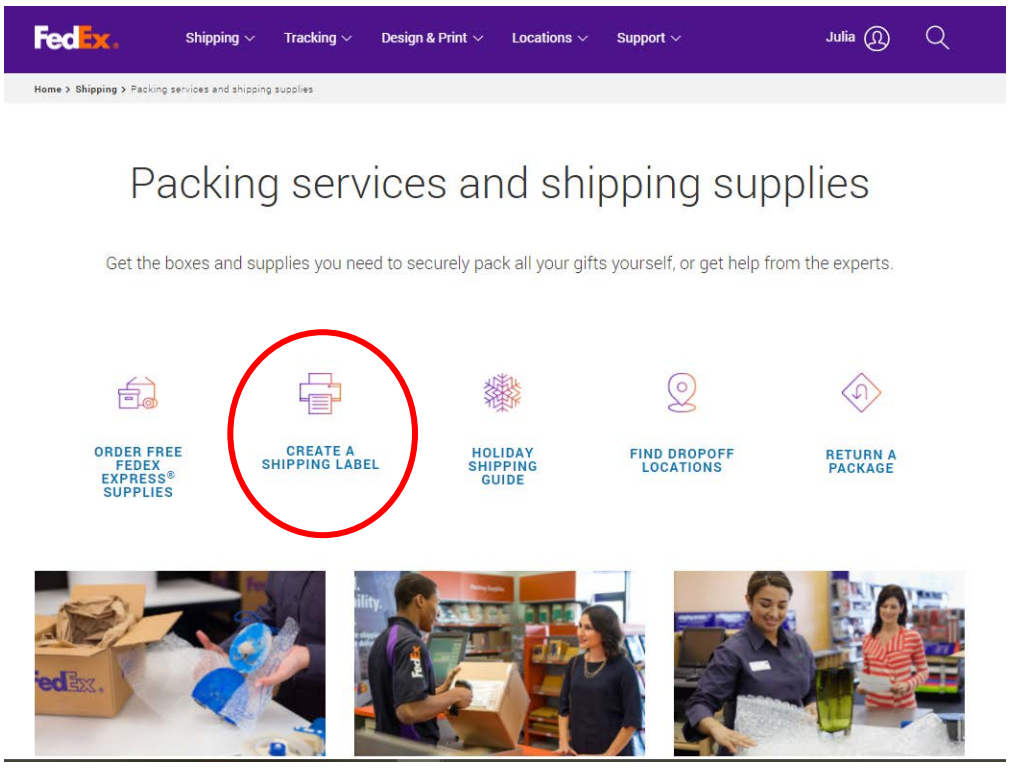


The HBPM device (Omron Series 10 BP7450 or BP7450CAN) can be returned in a **Large Box** (M2: Rectangular and deep)

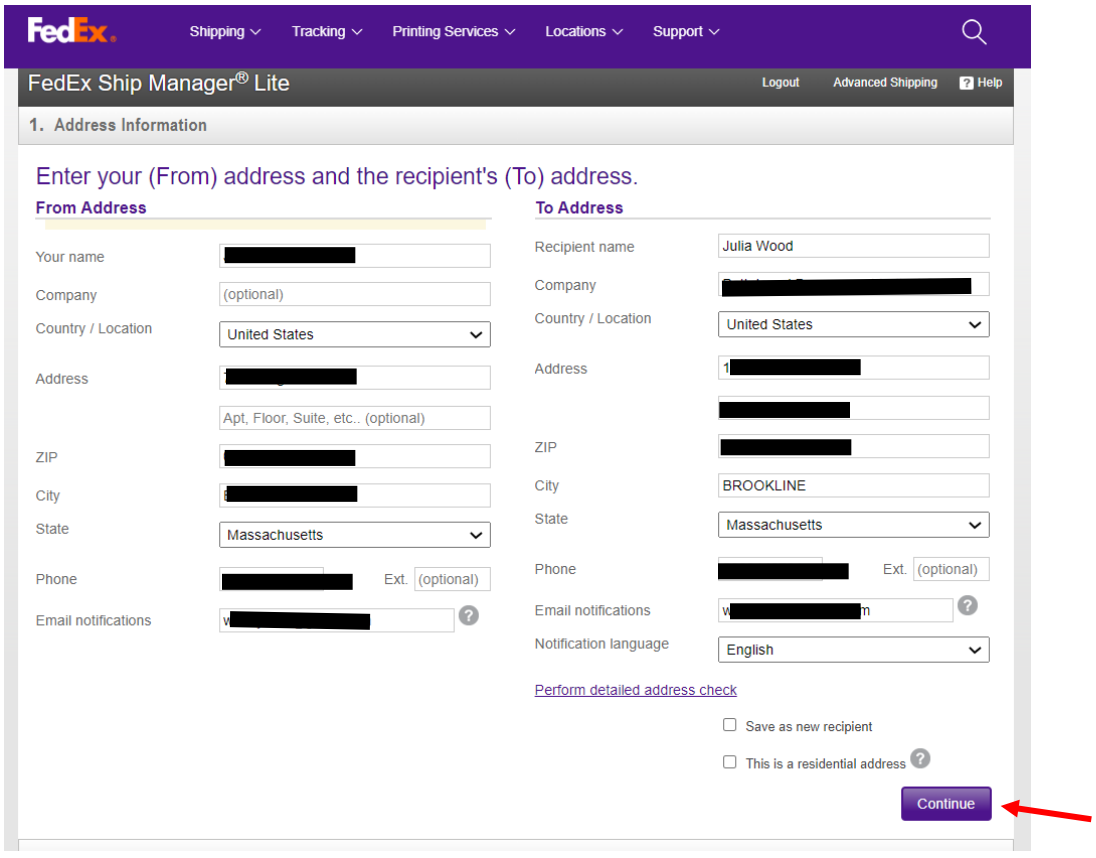


Instructions for creating a shipping label

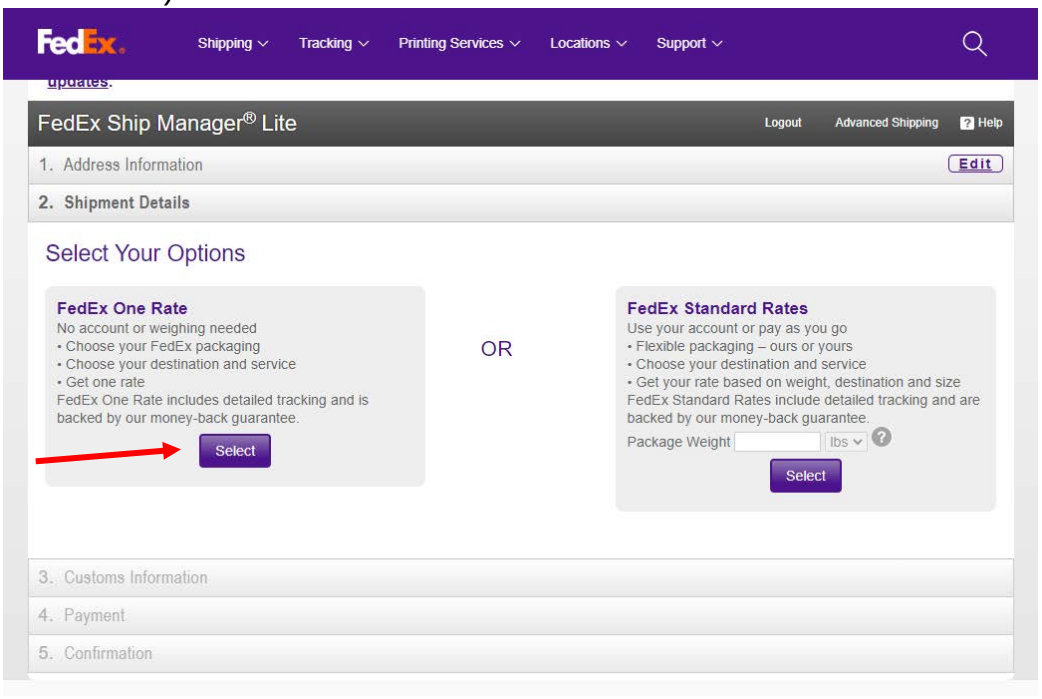
1. Before the participant leaves with the ABPM/HBPM devices, create a shipping label to send home with them.

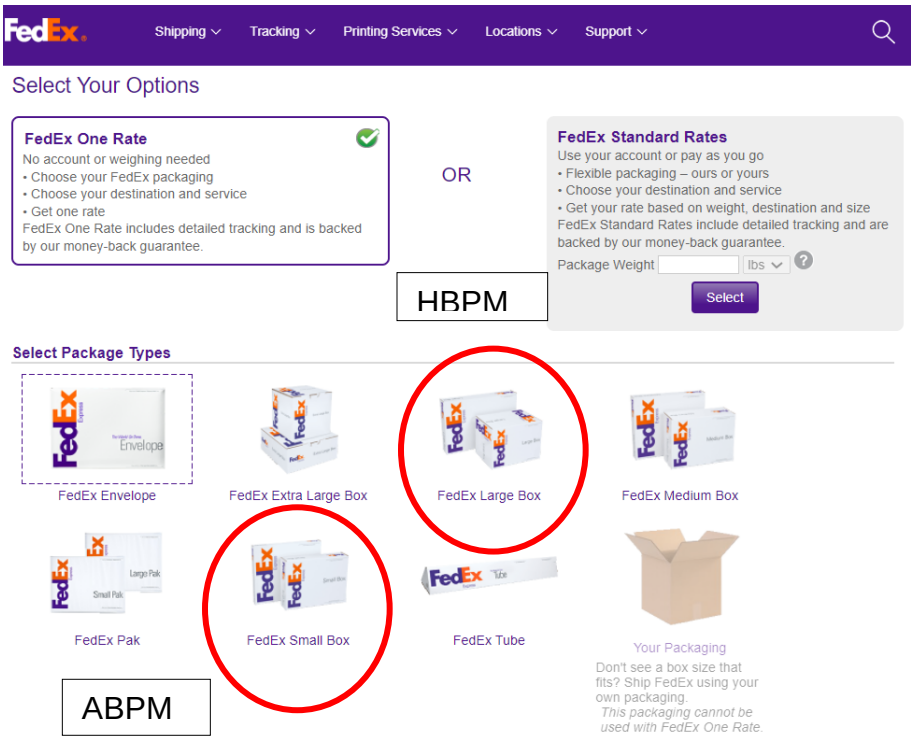


2. Enter in the participant's information in the "From Address" and your field center information in the "To Address" and click continue.



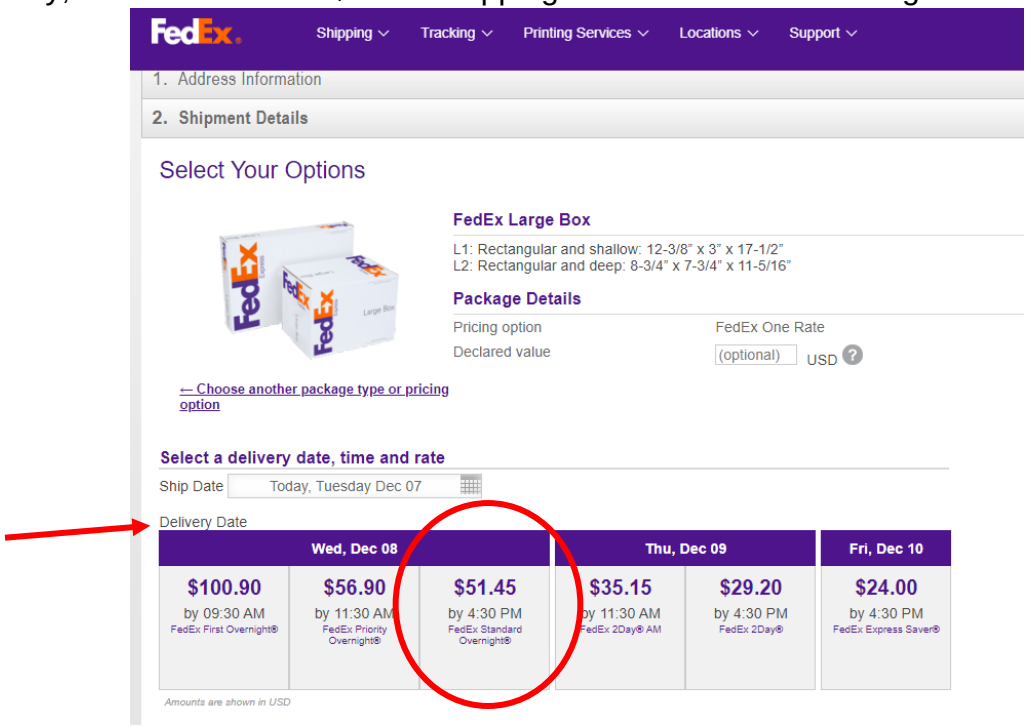
3. Select **FedEx One Rate** and specify the size of the box (small for ABPM and/or large for HBPM).

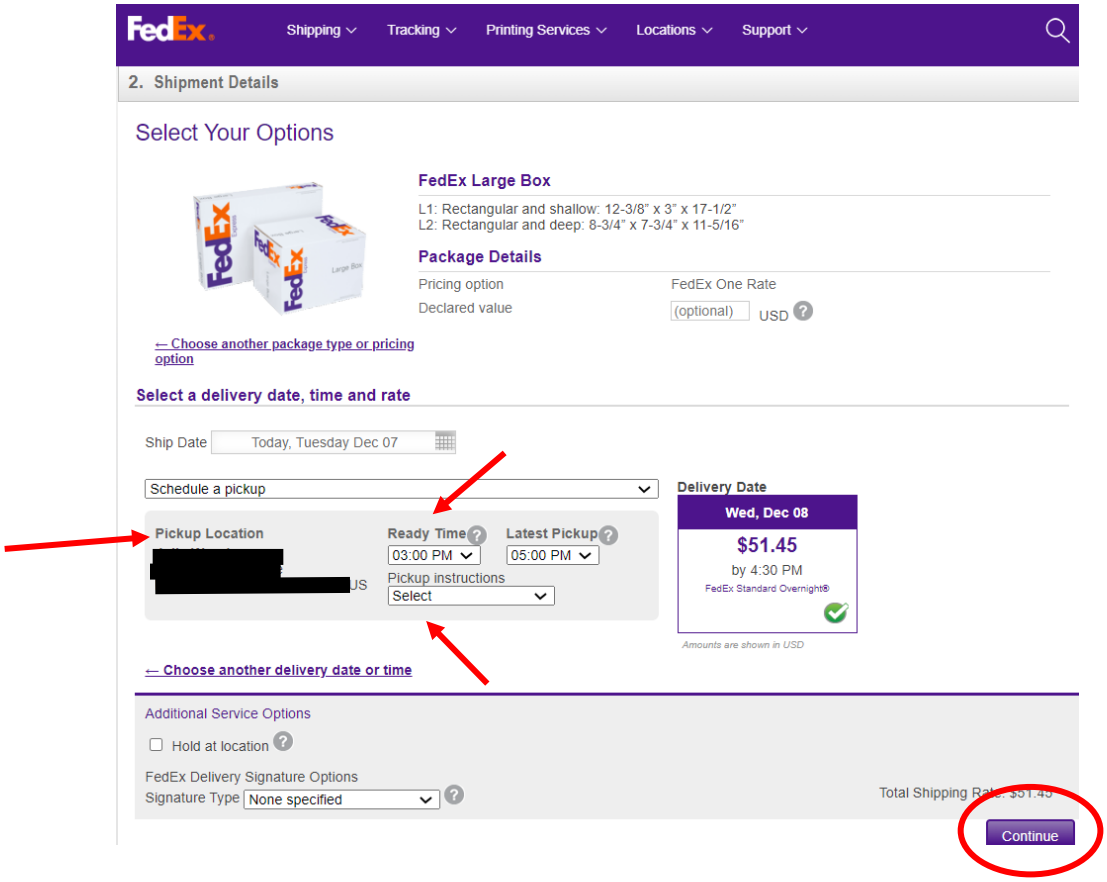




4. Schedule the ABPM device (along with the cuff, batteries, ABPM Participant Log, and ABPM Participant Experience form) same day or one after the participant is due to finish ABPM (e.g. ABPM is placed on 12/6 at 10 am, will finish on 12/7 at 12 pm,

so you would schedule pick up for 12/7 after 12 pm for delivery of 12/8). Prices will vary, but we estimate ~$50 for shipping FedEx Standard Overnight.



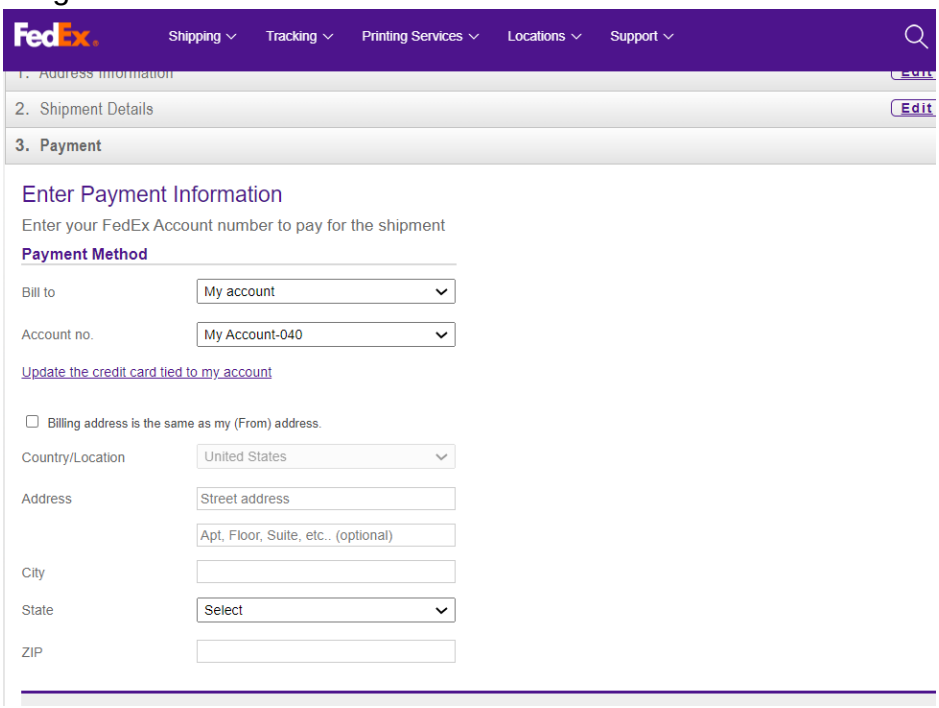


5. Make sure to choose “schedule a pick up” and confirm the participant’s address.

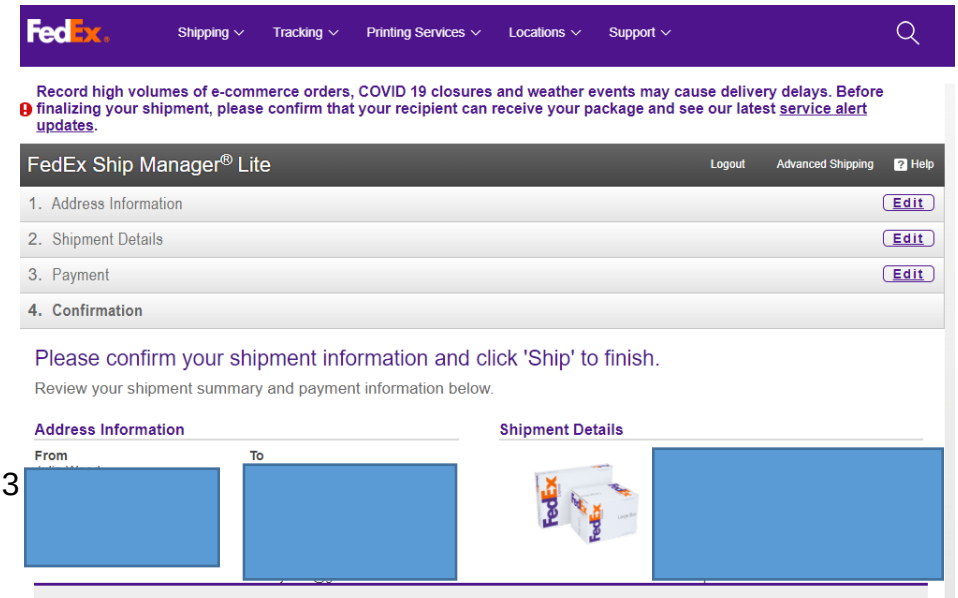
6. Choose “Ready Time” for after the participant is due to finish the 26 hour monitoring. The latest ready time you can choose is 4:30 pm, so if the participant is not due to finish their ABPM, for example, until 5:30 pm, it may be best to wait until the next day to schedule the pickup.

7. Select pick-up instructions that works best for the participant (e.g. front door, side door, back door, garage, etc.). Press Continue.

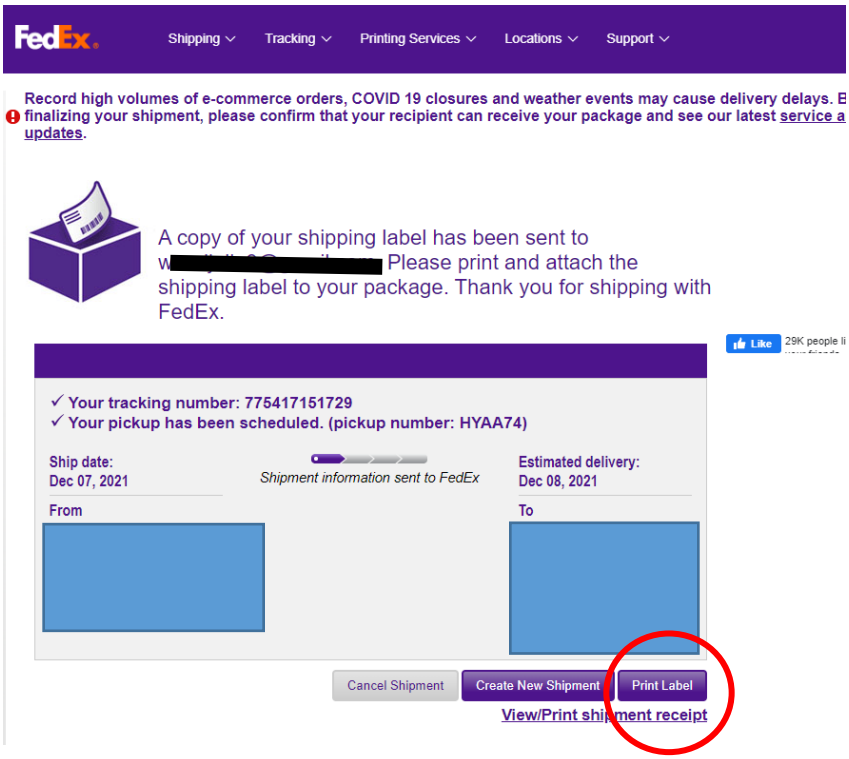
8. Payment will be billed to your account. Billing address is not the same as the “From” address since you are shipping from the participant’s home. You will have to fill in your billing address.



9. Confirm shipment information and click ‘Ship’ to Finish. You can include a copy of shipping label to participant’s email address if desired. Click Ship.



10. Print label and tape onto the box to send home with participant.



11. If your site chooses this method of device return for HBPM, or if this process works best for the participant, repeat the same process, ensuring you use the large FedEx box

    Note: The Omron Series 10 box will fit perfectly in this FedEx box).

    Scheduled pick-up at the participant home should be **1 day after the participant is due to finish HBPM.**

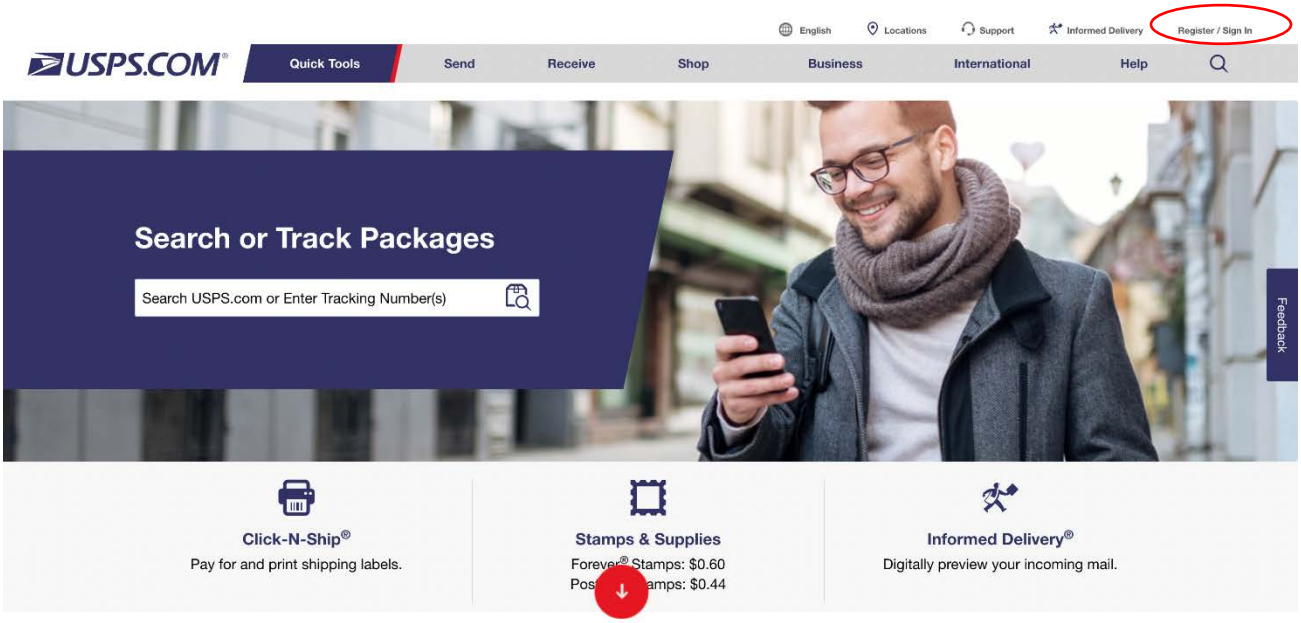
    Note: This is important since the HBPM protocol has participants finishing in the evening between 7-9 pm).

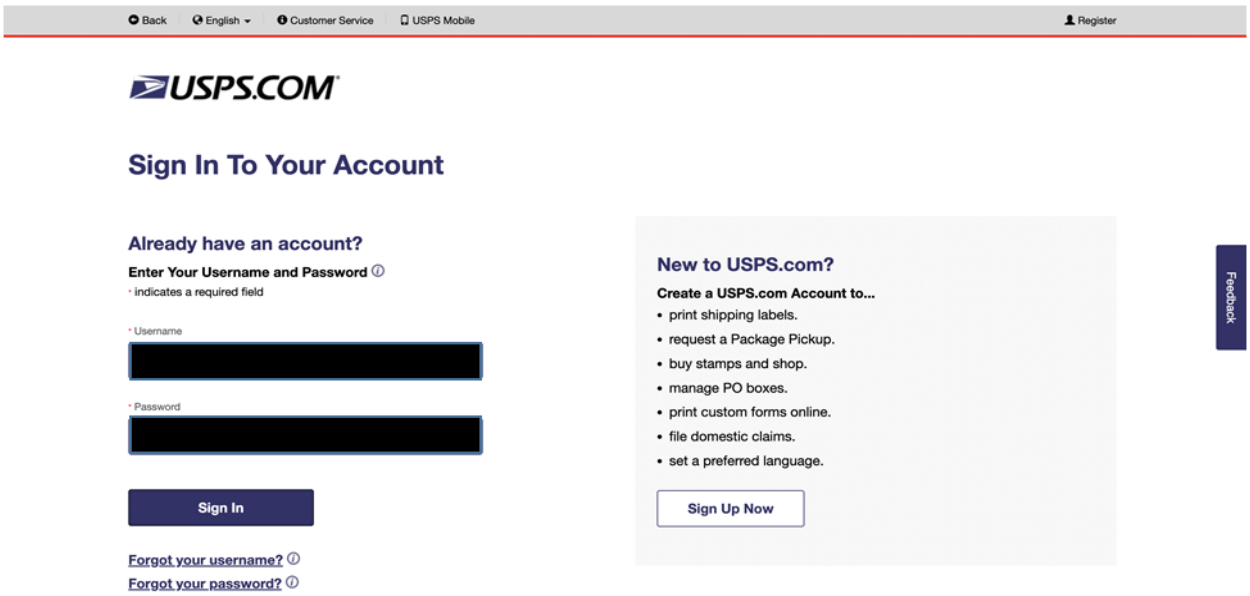
    - Example: Participant is seen in-clinic for V10 on 12/6
        - ABPM placed 12/6 (at 10 am)
        - Participant will complete ABPM 12/7 (at noon)
        - FedEx express pick-up is scheduled for any time after noon on 12/7 (pick-up can be scheduled 12/8 – ideally pick-up is 1-2 days after ABPM placement)
        - Participant begins HBPM on 12/8
        - Participant will complete HBPM on 12/15
        - **FedEx express pick-up scheduled for 12/16**

ALTERNATIVE TO FEDEX DEVICE RETURN: USPS DEVICE RETURN

Instructions for ordering USPS boxes

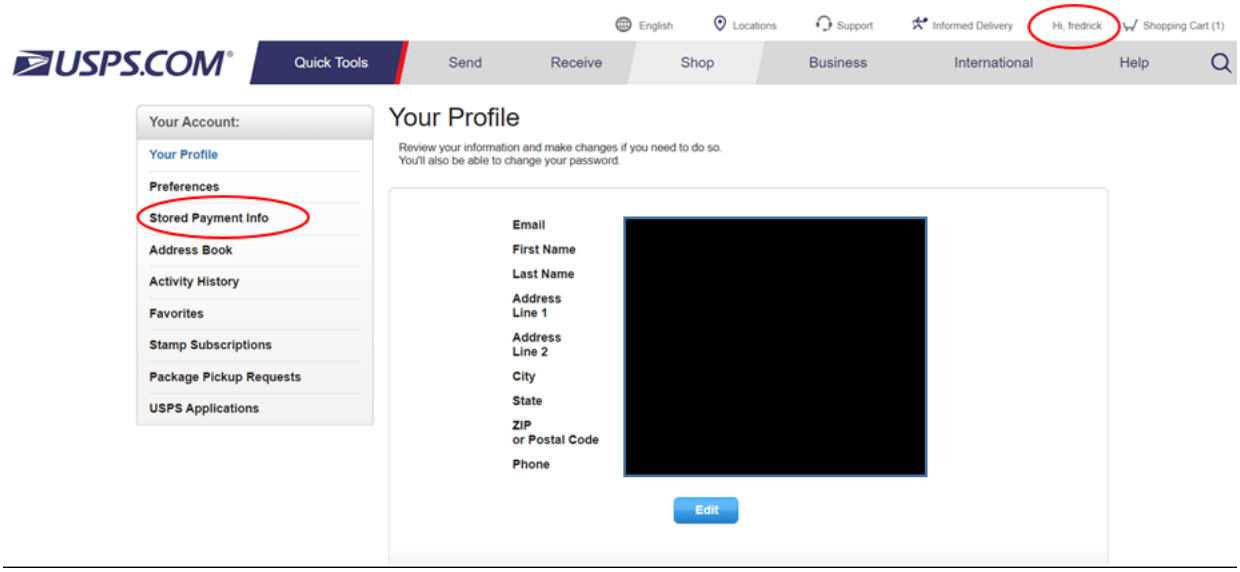
1. Sign into USPS.



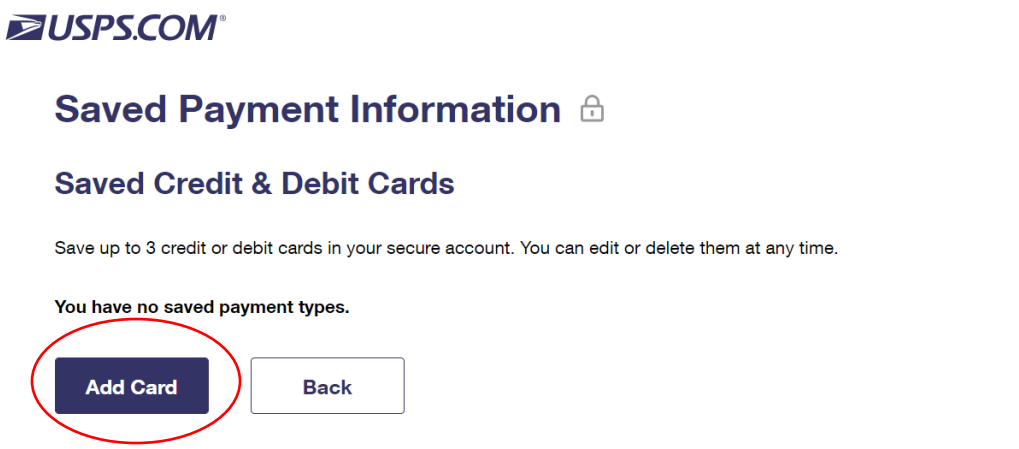


If your site does not have an account, this can easily be done by clicking **Register/sign in.**

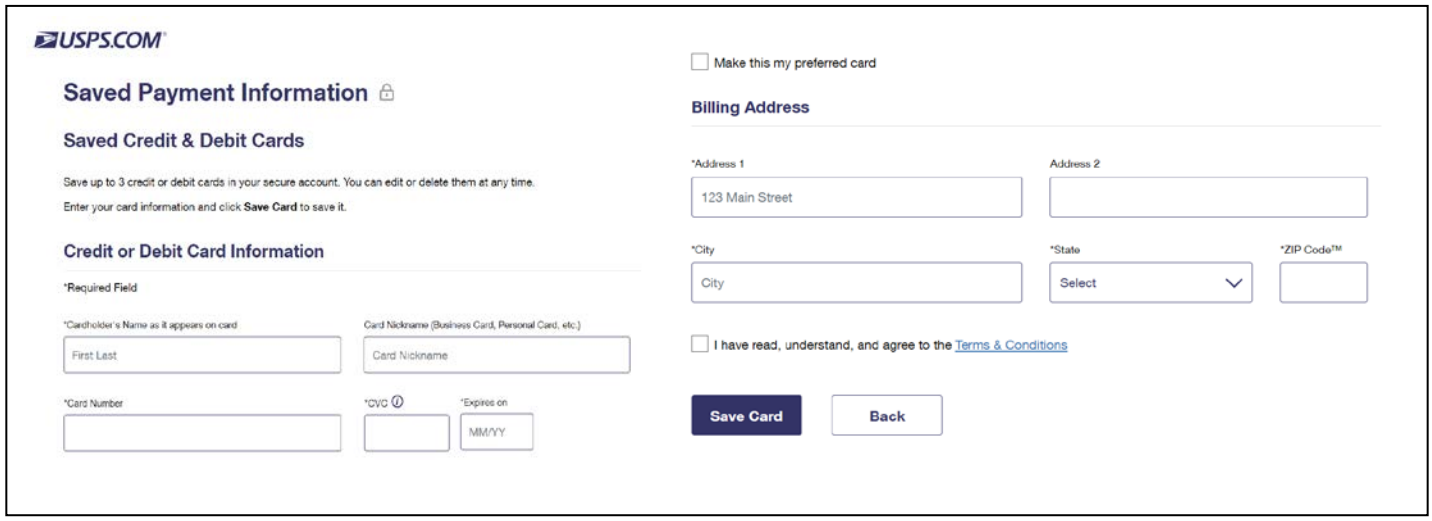
2. If this is a new USPS account, add a payment account so you can order supplies and shipping labels. First click on the account name to display your profile. **Select Stored Payment Info.**



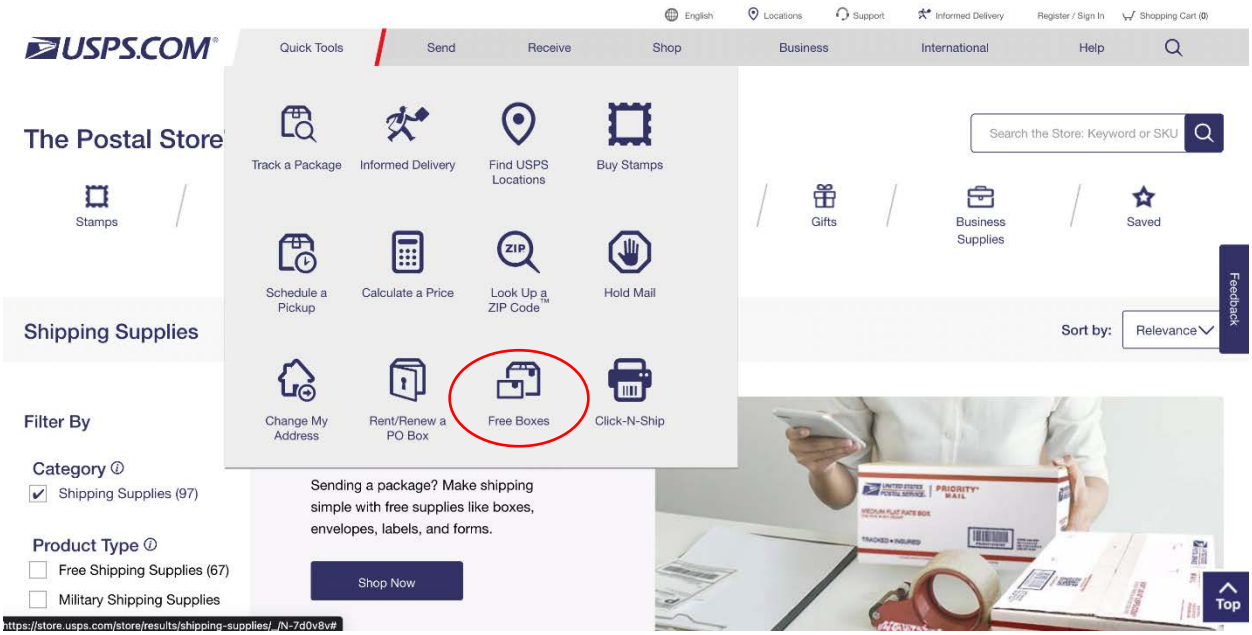
Click on Add Card



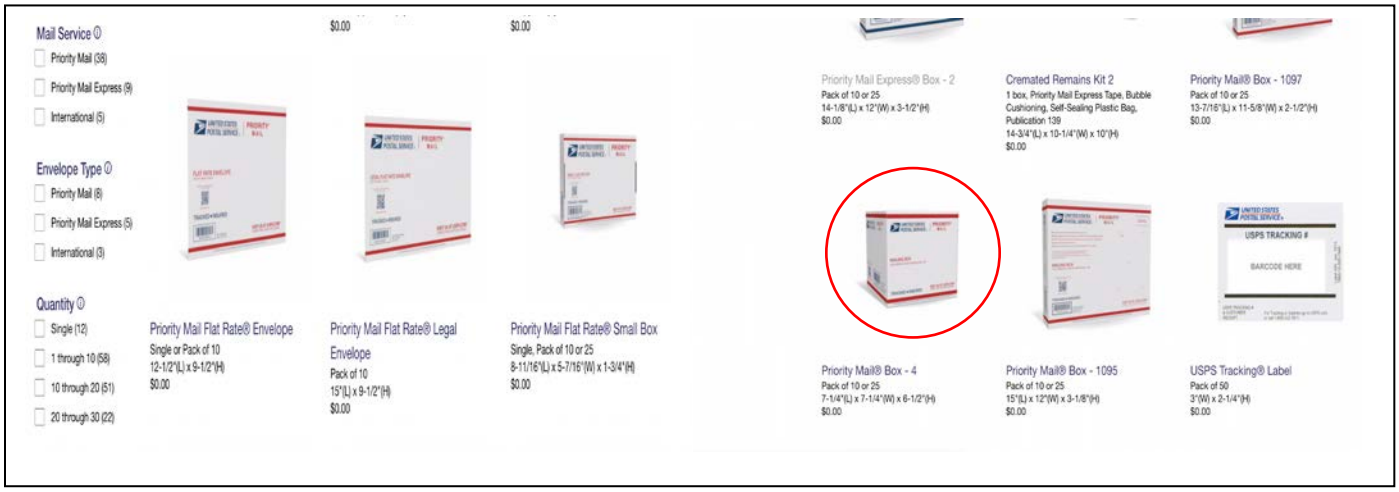
Save Payment information



3. For ABPM device return (and HBPM device return if appropriate), you can order packing and shipping supplies directly on the USPS website. Click on **Free boxes**.

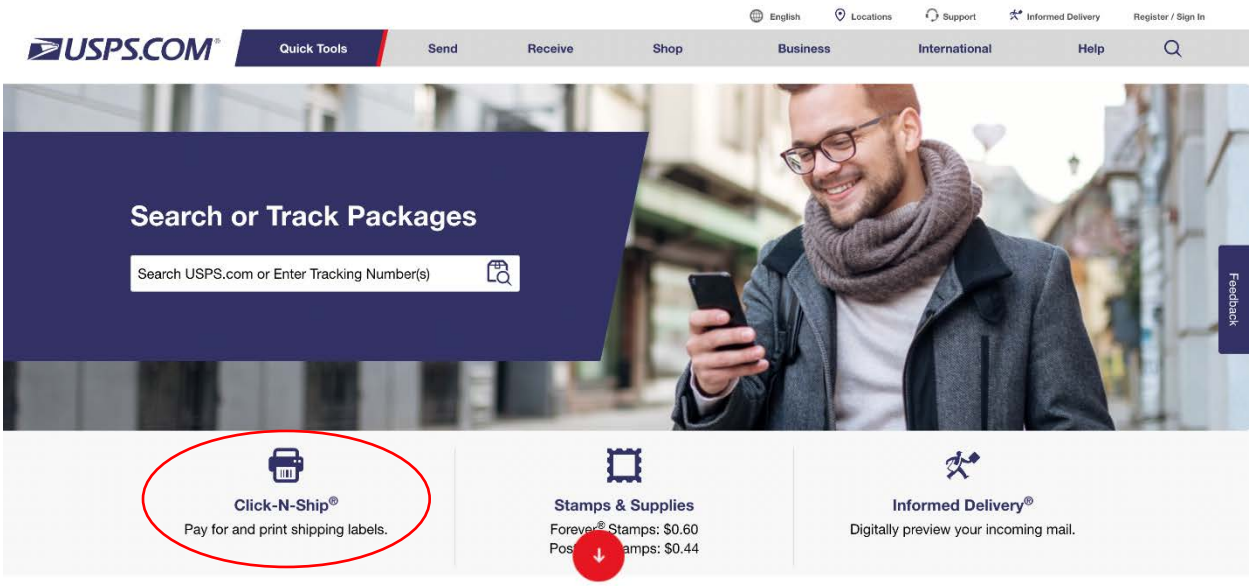


Select Priority **Flat Rate Small Box** for ABPM and **Priority Mail Box- 4** for HBPM.

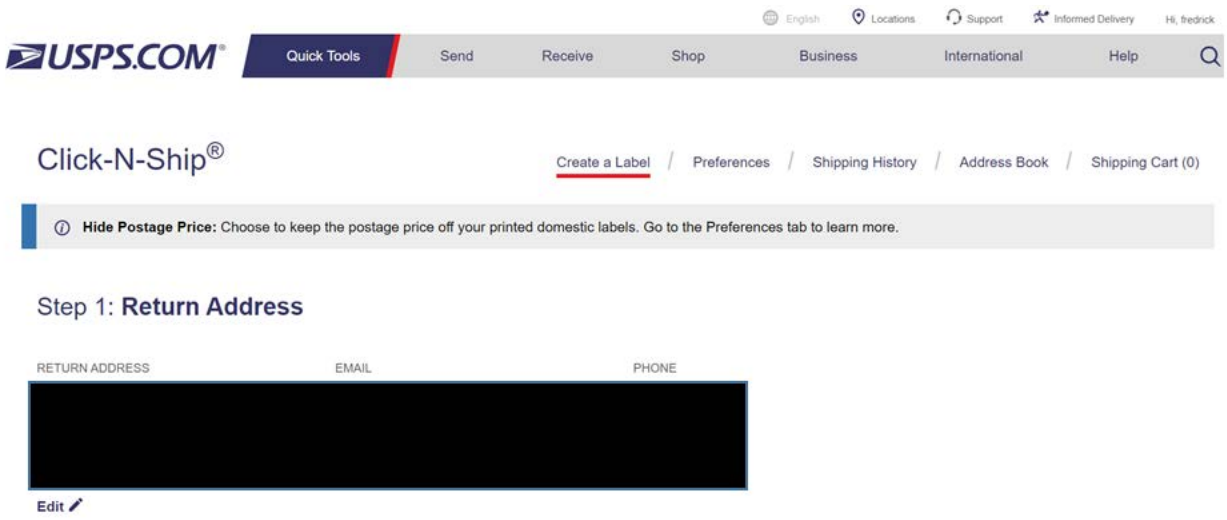


Instructions for creating a shipping label

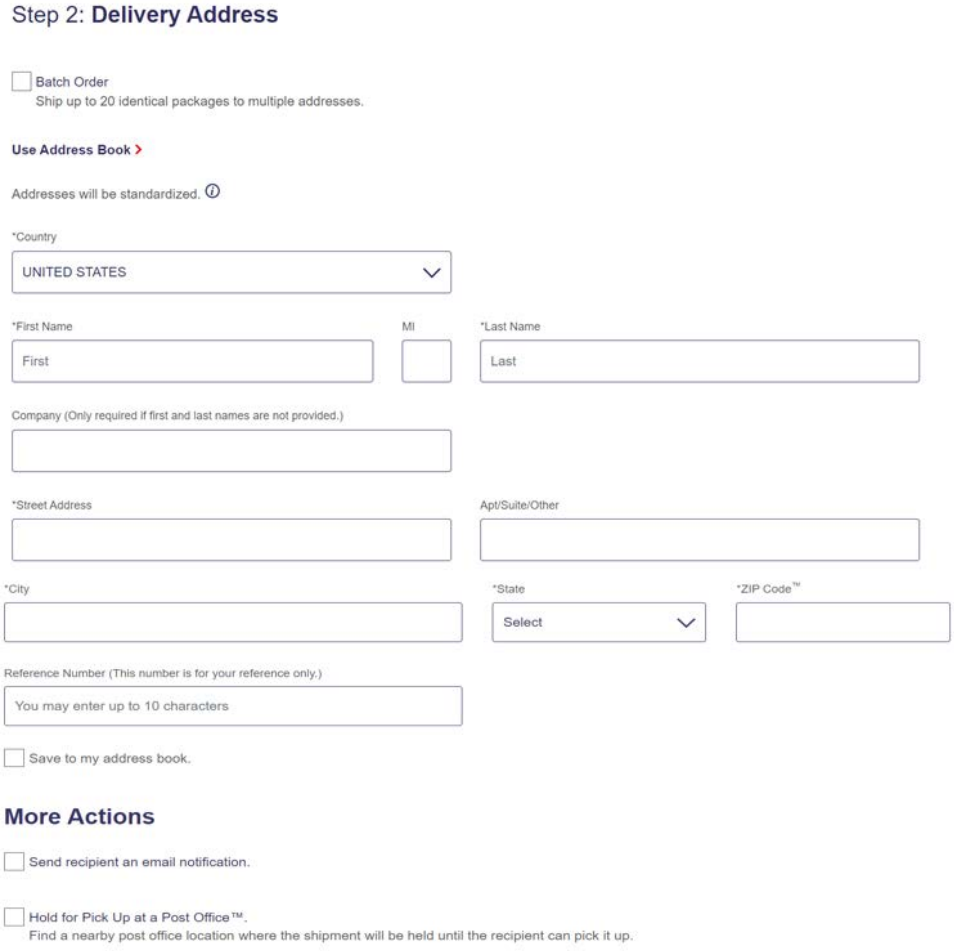
1. Before the participant leaves with the ABPM/HBPM devices, create a shipping label to send home with them. **Select Click-N-Ship.**



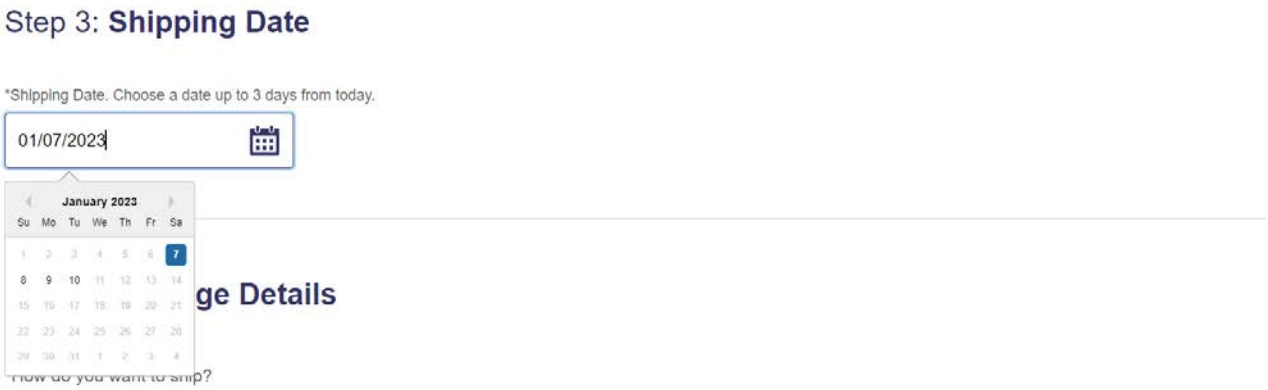
2. Edit details for Return Address (Enter the participant's information).



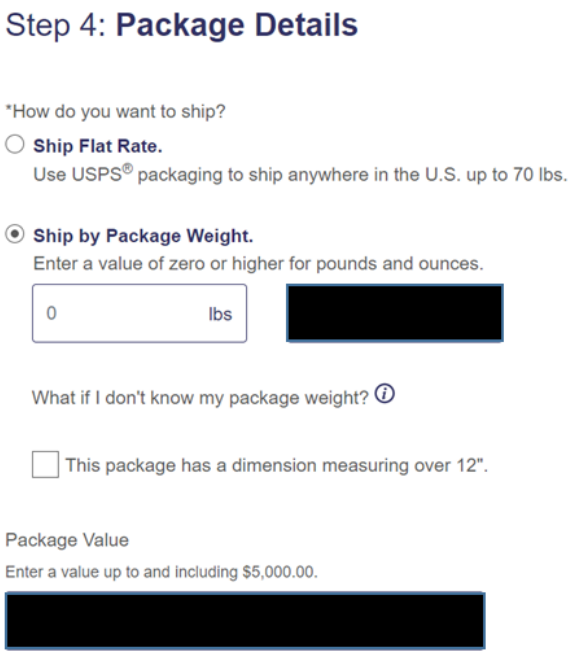
3. Enter details for Delivery Address (this is the information of the field center).



4. Choose a shipping date.



5. Enter Package details.



6. Select Service Type. Click on the drop down menu to select **Priority Mail**. Select the option Priority Mail (Choose your own box). You could select an insurance option for this package. Choose No selection for Signature services. Then click on **Add to Cart**.

Step 5: **Service Type**

Selecting a Priority Mail Flat Rate® product or a Priority Mail Express® Flat Rate product requires USPS® provided packaging.

If you plan to ship live animals, please go to your local Post Office™ ›

*Service

Priority Mail®

Select Service and Packaging

Select a Service: Priority Mail® Priority Mail Express®

View as: List Grid

Package Type	Expected Delivery	Price
◉ Priority Mail® (Choose your own box)	January 11, 2023 // 1-Day Delivery	$9.00
○ Priority Mail® Flat Rate Envelope 12-1/2" x 9-1/2"	January 11, 2023 // 1-Day Delivery	$9.90
○ Priority Mail® Small Flat Rate Box 5-3/8" x 8-5/8" x 1-5/8"	January 11, 2023 // 1-Day Delivery	$10.40
○ Priority Mail® Medium Flat Rate Box 11" x 8-1/2" x 5-1/2 13-5/8" x 11-7/8" x 3-3/8"	January 11, 2023 // 1-Day Delivery	$17.05
○ Priority Mail® Padded Flat Rate Envelope	January 11, 2023 // 1-Day Delivery	$10.60

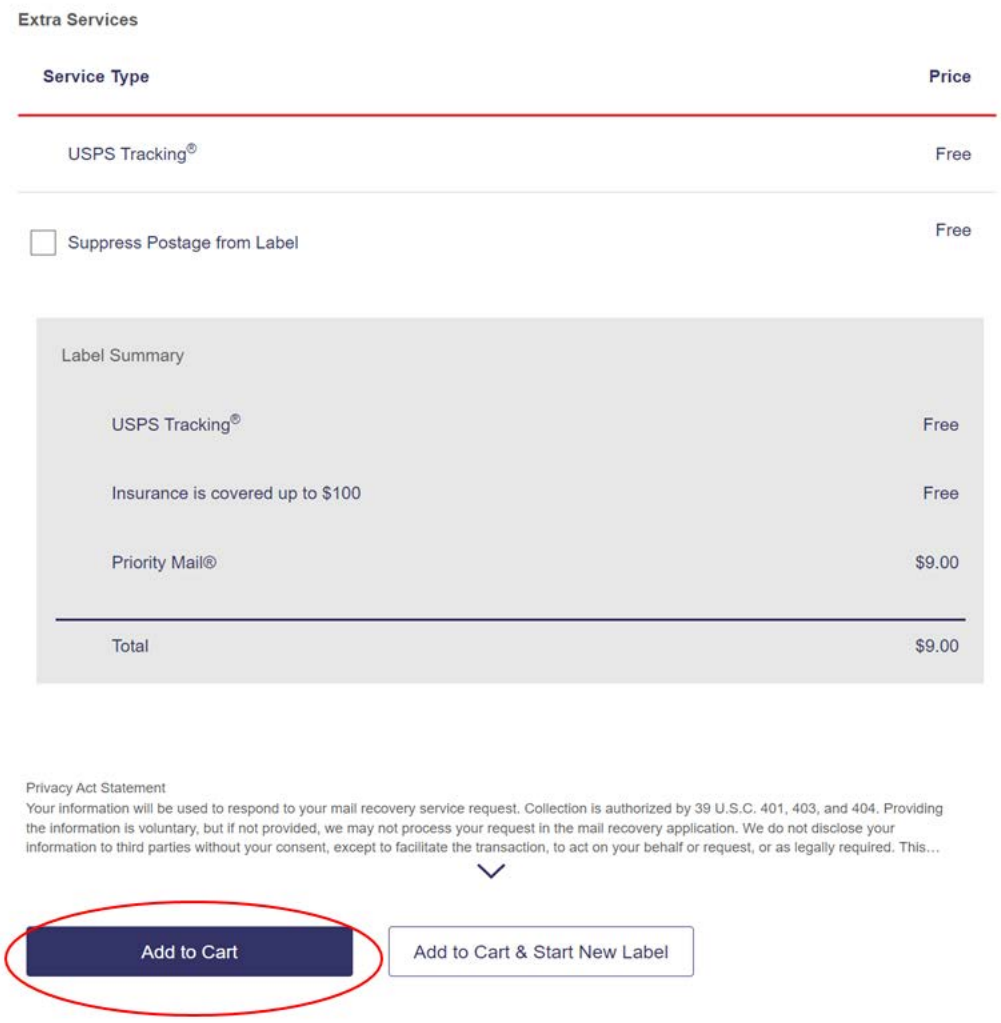
Insurance

Priority Mail® covers up to $100 of package value. For packages with a value over $100, additional insurance can be purchased to cover the balance.

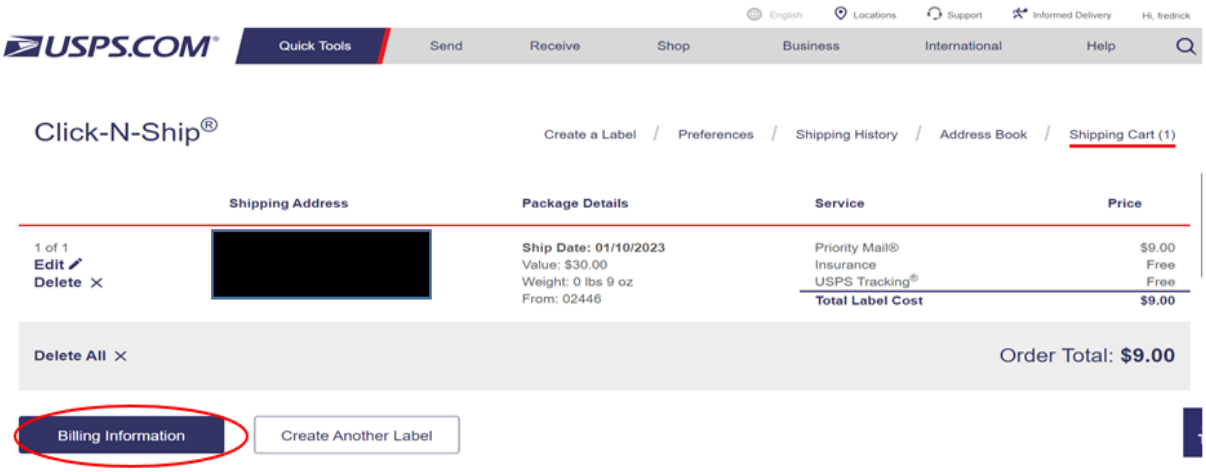
Service Type	Price
◉ Insurance for packages valued up to $100	Free

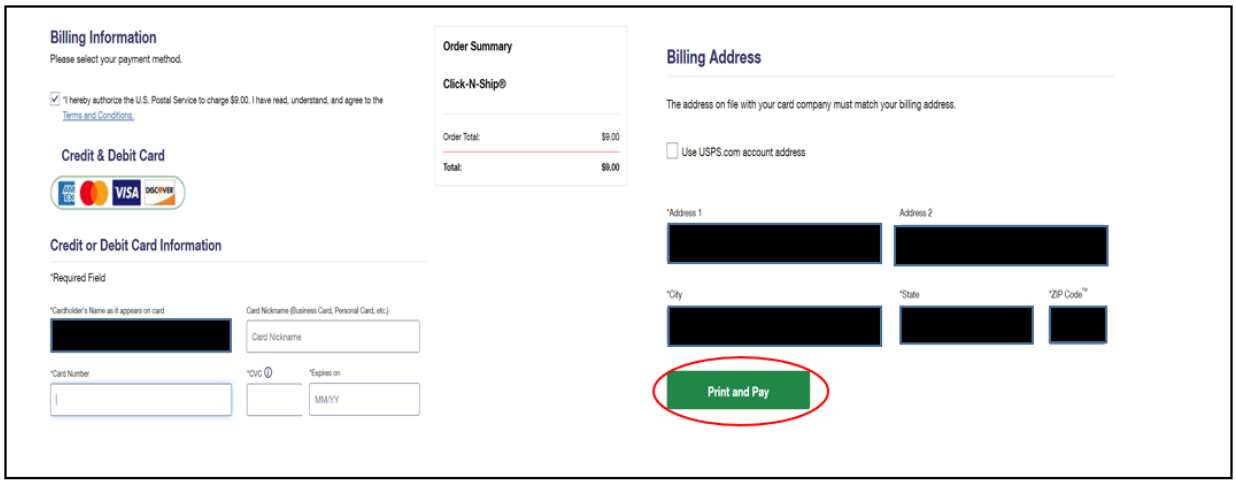
Signature Services

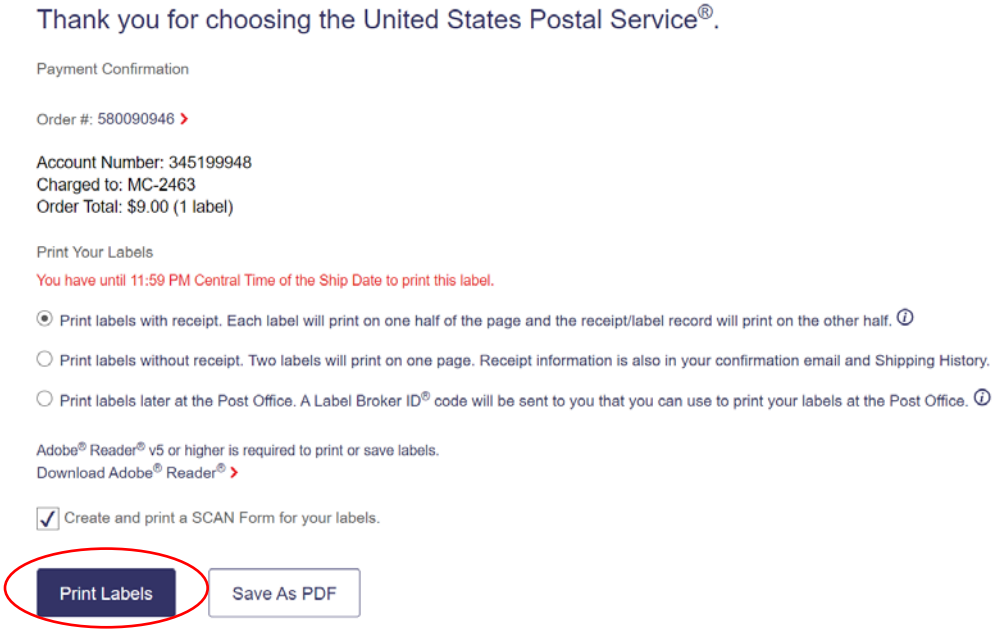
Service Type	Price
◉ No Selection	
○ Signature Confirmation™	$3.10
○ Adult Signature Restricted Delivery 21 or Older ⓘ	$8.75
○ Signature Confirmation™ Restricted Delivery	$9.35
○ Adult Signature Required 21 or Older ⓘ	$8.50



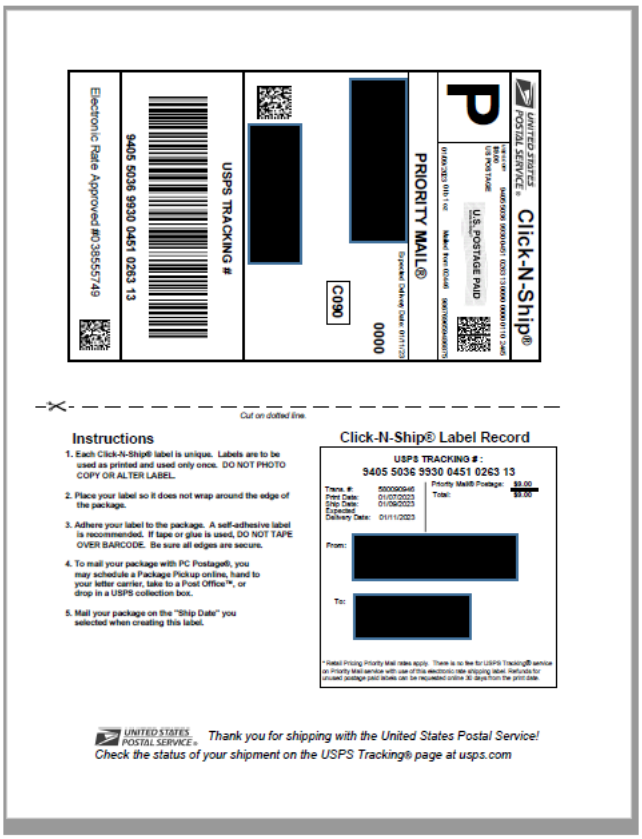
7. Click on the Billing Information and add the details required. Click on Print and Pay. Finish by clicking on Print label.





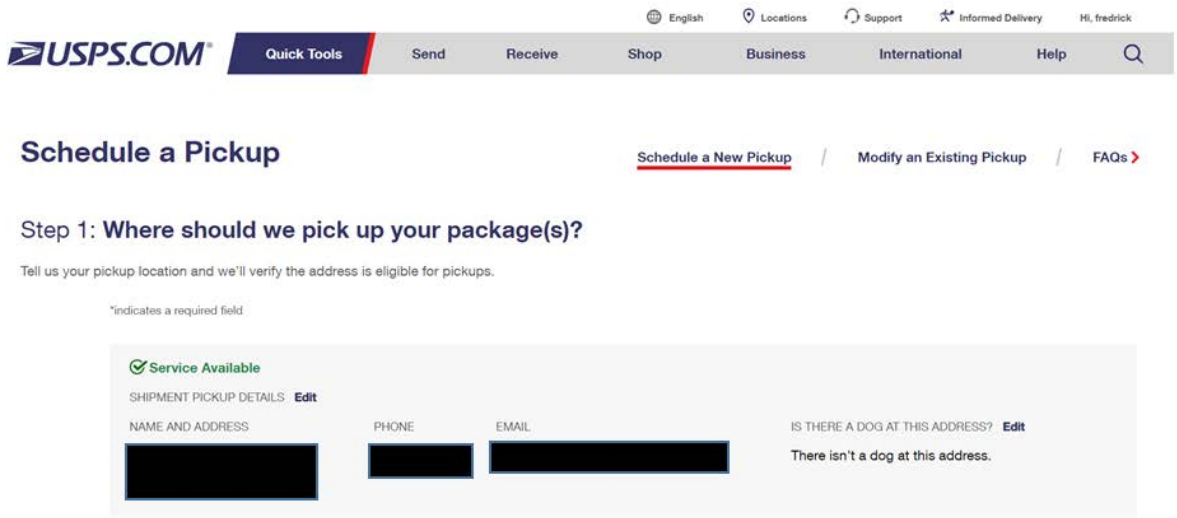


8. Example of shipping label.

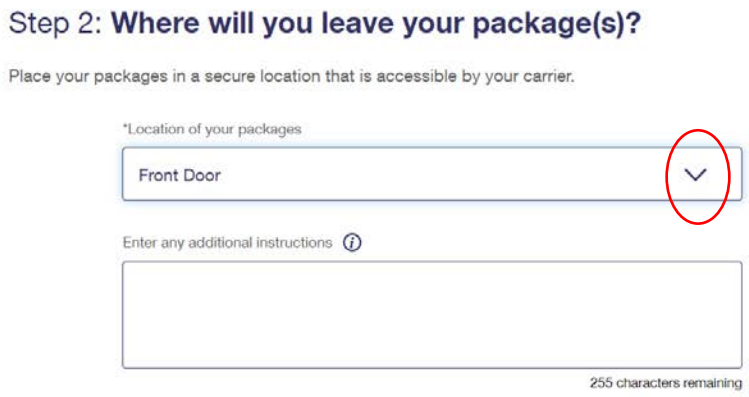


Instructions for scheduling a pickup:

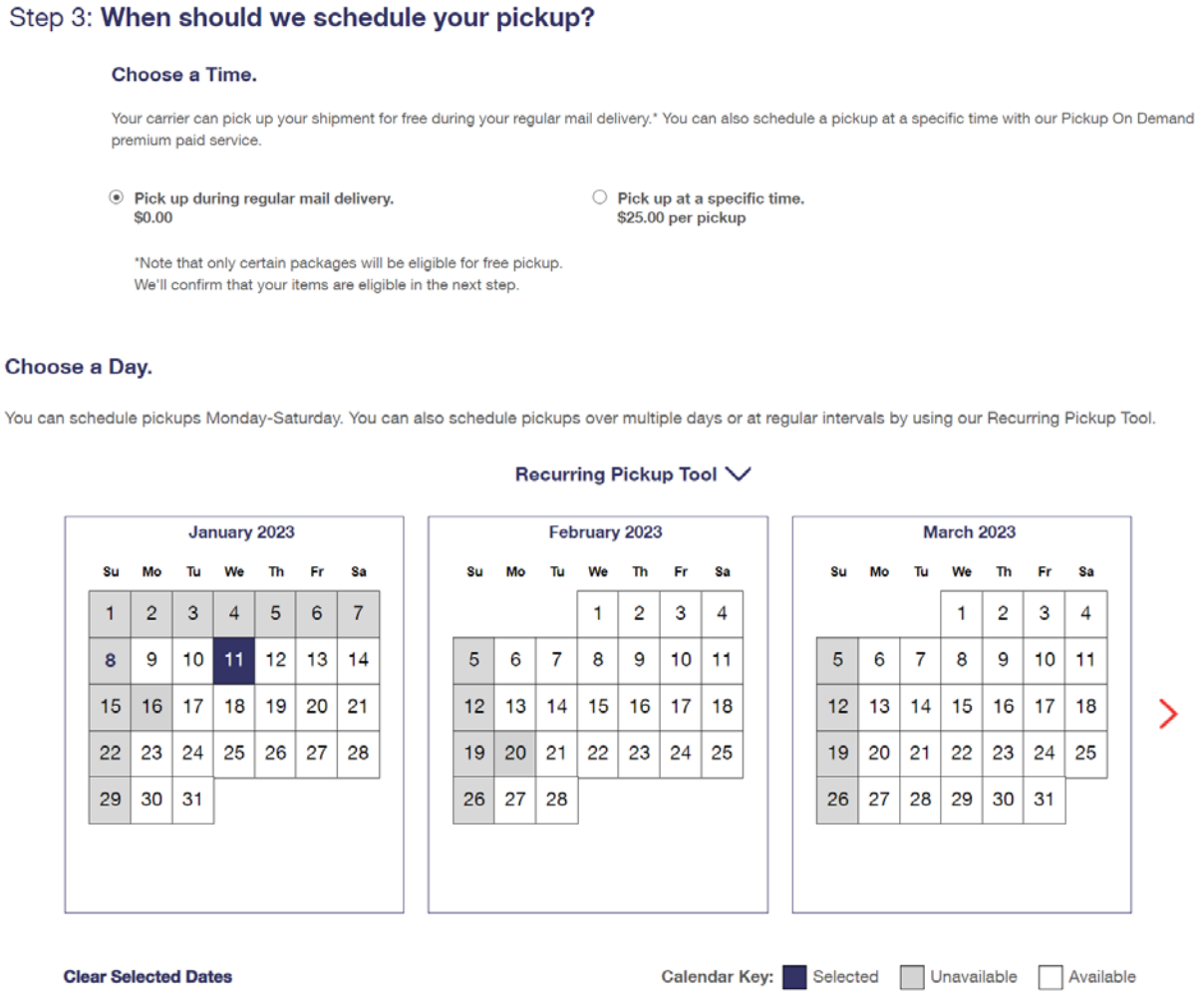
1. Enter a valid address where package could be picked up.



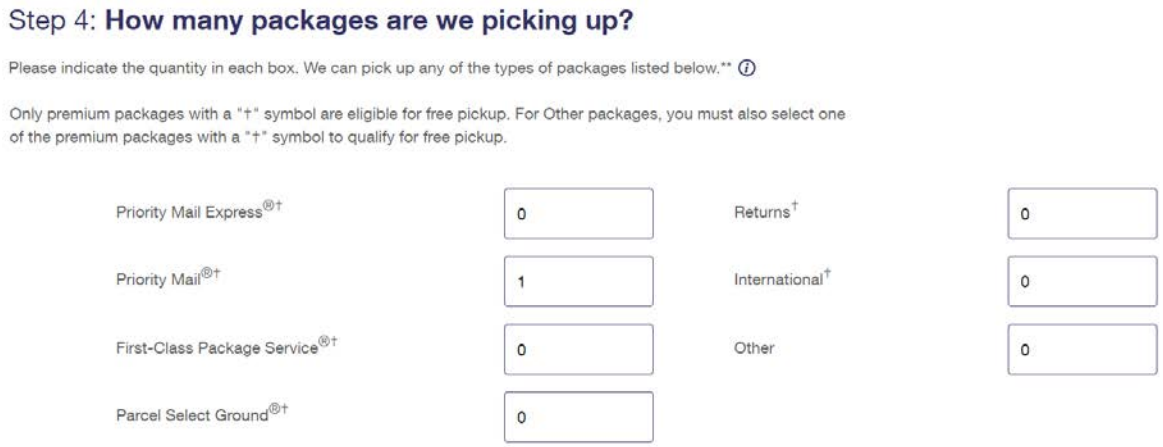
2. Indicate where you would leave the package by clicking on the drop down menu.



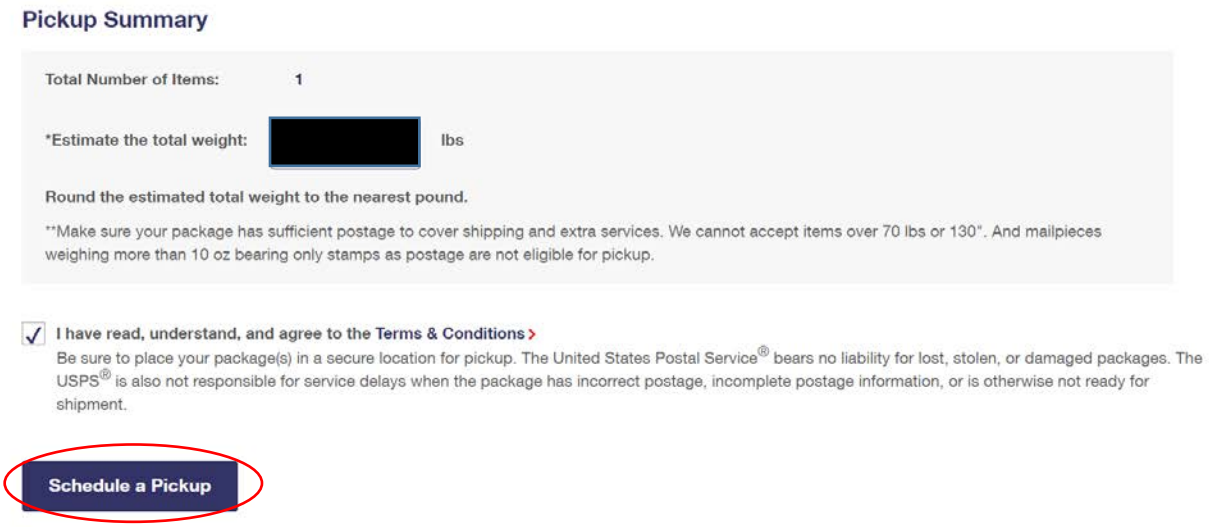
3. Pick a day for delivery of your package, which should correspond with the date for the label you created.



4. Indicate how many packages will be ready for pickup.



5. Confirm Pickup summary and agree to terms and conditions. Click on **Schedule a Pickup**



APPENDIX T: ABPM CERTIFICATION CHECKLIST

Date: _____

Name of staff member(s) being observed:

_____

_____

Name of staff member observing:

_____

First Steps

- ☐ Review MOP38
- ☐ Review ABP, ABPR, and BPMC forms and QxQs
- ☐ Complete in-person training. Staff hired after the training should view the video recording of the training

Set up:

- ☐ Set up video recording device (if recording for certification)
- ☐ Verifies participant ID and confirms consent.
- ☐ Has **Ambulatory Blood Pressure Monitor Initialization Form (ABP), ABPM Participant Activity Log** (each with the correct participant label), and the **ABPM Protocol Instruction Script**.
- ☐ Makes sure computer with the Spacelabs Sentinel 11 or 11.5 software is turned on and the application is open, ready for use.
- ☐ Places new batteries in the OnTrak ABPM device monitor.
- ☐ Plugs monitor into the computer using the provided USB cable.
- ☐ Turns on the monitor and wait for the screen to say "Connected to PC".
- ☐ Follows Sentinel 11 or 11.5 /OnTrak instructions
  Verifies correct settings are selected (this should reflect the pre-programmed "ARIC ABPM" protocol with Day starting at 05:00 and Night starting at 00:00)

ABPM Placement / Protocol:

- ☐ Confirms which arm the participant prefers for blood pressure cuff placement.
- ☐ Uses appropriate size blood pressure cuff and place on same arm as used for the seated BP.
- ☐ Places cuff over bare skin.
- ☐ Makes sure the attached tube runs up the arm and around the back of the participant. (Participant can clip this onto their clothing if preferred).
- ☐ Explains to participant that blood pressure readings are visible at first, but then hidden after the initial reading.

- ☐ Asks participant about their anticipated sleep and wake times. **Record** both answers on the ABP Form.
- ☐ Provides participant their labeled **ABPM Participant Activity Log**, **ABPM Participant Experience Form,** and **ABPM Participant Checklist and Replacing the Cuff Handout** to take home with them.
- ☐ Instructs participant that they must log their **sleep time, wake time, and end of study time.**
- ☐ Informs participant they may remove the monitor to shower, for heavy exercise, or while driving, but instruct them to **NOT** turn off the monitor.
- ☐ Shows participant how to properly replace the blood pressure cuff if they remove it for any of the reasons explained.
- ☐ Informs patient that after they have completed 26 hours of blood pressure monitoring, they should do **one** manual measurement. To do this, instruct them to push the "action button" on the device.
- ☐ Once the manual measurement is completed, instructs participant they can remove the monitor.
- ☐ Instruct participant to remove batteries from the monitor and record the time on the ABPM log.

To initiate ABPM:

- ☐ Unplugs monitor from USB port / computer and presses action button to begin first measurement.
- ☐ Documents time, systolic blood pressure, diastolic blood pressure, and heart rate from the first measurement on the ABP Form **AND** the start time on their ABPM log.
- ☐ Scans device barcode directly into ABP Form in CDART to record serial number
- ☐ Records anticipated end time for the participant on their log (to help facilitate the correct end time entry).
- ☐ Explains to participant that they may proceed with their ARIC visit, however they should undergo at least one successful second BP measurement before they leave (to ensure the device is correctly firing every 20 minutes).
- ☐ Reminds patient once ABPM is completed, to send back monitor and BP cuff, along with their log, via pre-paid label and envelope (specific to each field center).

***Data download to begin once the device, bp cuff, and ABPM log are mailed back to the field center. ***

ABPM Data Download:

- ☐ Logs into Sentinel 11 or 11.5
- ☐ Connects monitor to computer using provided USB cable
- ☐ Places batteries in device to turn it on

- ☐ Clicks ABP
- ☐ Confirms participant ID and ensures the device serial number matches the serial number expected for that participant ID
- ☐ Selects “Download recording”
- ☐ Manually identifies the participant using the correct ID
- ☐ Selects “Review Test” under settings
- ☐ Selects “pre-programmed ARIC Report” under statistics
- ☐ Clicks “Save”
- ☐ Selects “Review Report”
- ☐ On the top right drop down menu, select “Report Format”, then “Full Report”
- ☐ Prints one copy of the report which includes the graph
- ☐ When a small window appears, save the file at “PARTICPANTID_YYMMDD.pdf”
- ☐ In Sentinel, clicks on “admin” and then “Export to ART” (refer to Appendix E for more details)
- ☐ Saves .art file as “PARTICIPANTID_YYMMDD.art” onto desktop
- ☐ Makes sure to properly wipe down bp cuff and ABPM monitor for next participant using disinfectant wipe.

Data Transmission:

- ☐ Attaches full report to ABPR form in CDART
- ☐ Attaches .art file with raw data to ABPR form in CDART
- ☐ Ensures that data download and transmission occurs within **one** week of the device being returned.

Video Upload and Sharing

- ☐ Upload the video recording of the HBPM assessment to your institution’s file share program (e.g., OneDrive, Dropbox).
- ☐ Notify Stephen Juraschek sjurasch@bidmc.harvard.edu and Fredrick Larbi Kwapong flarbikw@bidmc.harvard.edu via email that a file is ready for their review.

To be completed by staff member observing the ABPM assessment:

What did they do well?

_____

_____

How could they improve their skills?

_____

_____

Do they need additional training and support? ☐ Yes ☐ No

If so, we will meet on _____ to review

_____ and then another QC will occur on

_____.

Reviewer's signature: _____

Observed staff signature: _____

APPENDIX U: HBPM CERTIFICATION CHECKLIST

Date: _____

Name of staff member(s) being observed:

_____

Name of staff member observing:

_____

First Steps

- ☐ Review MOP38
- ☐ Review HBP, HBPR, and BPMC forms and QxQs
- ☐ Complete in-person training. Staff hired after the training should view the video recording of the training

Prior to the participant arriving:

- ☐ Set up video recording device (if recording for certification)
- ☐ Sets up Omron BP7450 / BP7450CAN:
  - ☐ Presses "START/STOP" to turn on device
  - ☐ Sets correct date and time
  - ☐ Turns on "TruRead" mode to ensure that the monitor will take 3 blood pressure measurements each separated by 60 seconds
- ☐ Does not turn on Bluetooth or sync the monitor to any smart device

In-clinic with participant:

- ☐ Confirms consent
- ☐ Documents participant ID, arm used, dominant arm, and any blood pressure medications taken the day of the visit on the Home Blood Pressure Monitor Initialization Form (HBP) in CDART
- ☐ Records HBPM device serial number on HBP form by scanning the barcode directly into CDART
- ☐ Records anticipated start and end date on the HBP Form
- ☐ Reads HBPM script to participant
- ☐ Educates participant on appropriate technique and instructions for the 8-day monitoring

- ☐ Asks participant if he/she has any questions or concerns
- ☐ Asks participant to rest for 5 minutes before the measurement of the blood pressure
- ☐ Confirms appropriate placement of the cuff over bare skin on the same side used for the seated blood pressure measurement
- ☐ Performs single triplicate measurement
- ☐ Records triplicate measurement and reported average on the HBP form
- ☐ Provides participant with HBPM Participant Experience Form, HBPM Participant Checklist, and mailer for sending the device back to the field center (if applicable)

HBPM Tracking

- ☐ Calls participant 3 times during the 10-day home blood pressure assessment (see home monitoring check-in schedule for reference if needed); *for certification purposes, the check in calls may or may not align exactly with the days required for the protocol*
    - ☐ Records date of *check-in call 1* (Day 2): calls to check that participant has finished ABPM, plans to return it, and will start HBPM with the Omron BP7450/ BP7450 CAN the next day
    - ☐ Records date of *check-in call 2* (~Day 4): calls to check that participant has started HBPM and is not having any issues monitoring twice a day (morning and evening).
        - ☐ **Records participant reported start date on the BPMC Form in CDART**
    - ☐ Records date of *check-in call 3* (Day 8)
        - ☐ **Records participant's data transmission plan (and date) on the BPMC Form**

Downloading blood pressure data (Data Tracking)

- ☐ Downloads OMRON connect app on smartphone or tablet
- ☐ Records date of data download on the Home Blood Pressure Monitor Return Form (HBPR)
- ☐ If monitor cannot be synced to smartphone or tablet, then records blood pressure measurements on the manual home data collection form (all data can be found in the history of the Omron Series 10 BP7450/ BP7450CAN)
- ☐ Records alerts (if any) as notes in the app and on the HBPR Form using the appropriate abbreviations
- ☐ Downloads the .csv file from the Omron app and saves the file in a secure folder on the iPad (8th generation or above)

☐ Attaches the .csv file to the HBPR Form in CDART using the correct naming convention (SubjectID_YYMMDD.csv)

Video Upload and Sharing

- ☐ Upload the video recording of the HBPM assessment to your institution's file share program (e.g., OneDrive, Dropbox).
- ☐ Notify Stephen Juraschek sjurasch@bidmc.harvard.edu and Fredrick Larbi Kwapong flarbikw@bidmc.harvard.edu via email that a file is ready for their review.

To be completed by staff member observing the HBPM assessment:

What did they do well?

_____

_____

How could they improve their skills?

_____

_____

Do they need additional training and support? ☐ Yes ☐ No

If so, we will meet on _____ to review _____ and then another QC will occur on _____.

Reviewer's signature: _____

Observed staff signature: _____

THANK YOU FOR YOUR PARTICIPATION IN ARIC.

APPENDIX V: BLOOD PRESSSURE STAND-ALONE VISIT

In order to provide participants with additional flexibility, field center staff may offer participants the option of returning to the ARIC clinic for a stand-alone blood pressure visit. This visit is entirely optional and should only be offered to participants who voluntarily express interest in completing the blood pressure ancillary protocols (ABPM, HBPM, OH). The intention of the BP stand-alone visit is to provide accommodation for participants who may not have the time or ability to complete these protocols during the regular ARIC Visit 10 clinic exam. This visit **must be completed within 4 months of ARIC Visit 10.**

The BP Stand-Alone visit consists of the following protocols that should be completed in the listed order:

- ARIC Sitting Blood Pressure (SBP)
- Orthostatic Hypotension (OSQ, OBP)
- Home Blood Pressure Monitoring (HBP, HBPR, VAS)
- Ambulatory Blood Pressure Monitoring (ABP, ABPR)

When completing the seated blood pressure for the stand-alone visit, **staff must utilize the SBP form in the Visit Ancillaries form group**. Do not use the SBP form in the V10 / NCS form group. Please note that there will be no alerts or results reporting generated from the SBP form collected for this separate visit; field center staff should reference the alert values indicated in the SBP form itself and follow the standard ARIC protocol for any concerning blood pressures.

The Blood Pressure Stand-Alone Visit Checklist can be found on the ARIC website at the following location: V10 / NCS Forms and QxQs (unc.edu) [Cohort > Current Visit Forms, QxQs, and Manuals > V10 / NCS Forms and QxQs]

APPENDIX W ACCURACY CHECK PROTOCOL FOR ABPM

Purpose:

SimCube simulation system provides non-invasive blood pressure (NIBP) simulation in a small, portable, easy to use package. In addition to the NIBP simulation, optional ECG, respiration and invasive blood pressure simulation are available. For the purpose of our ancillary study, the SimCube simulation system will be used for accuracy check for the Spacelabs 90227 OnTrak Ambulatory Blood Pressure Monitoring (ABPM) device and the Omron HEM-907XL device. Accuracy checking for the ABPM device will be reviewed here; information on accuracy checking for the Omron HEM-907XL, used for the Orthostatic Hypotension (OH) protocol, can be found in MOP 37.

When:

Accuracy checks for the ABPM device will be conducted semiannually and documented on the ABPM Device Maintenance and Accuracy Check Log (Appendix X).

Who:

Technicians will maintain all blood pressure equipment used in their clinic.

Device:

Supplies:

- SimCube NIBP simulator
- Power Supply (6V DC)
- NIBP adapters
- Battery Boost Converter
- Carrying case for the device
- Cuff Jacket

SimCube NIBP simulator

NIBP Adapter Set

Battery Boost Option

Cuff Jacket

Setup Procedure:

- Plug the SimCube power supply into an AC outlet
  - You should use only the power supply provided with your SimCube system. The power supply provided is 6V DC, 1.8amp, center positive, 2.1mm jack.
- Connect the power jack into the SimCube power receptacle.

Note: Many power supplies use the same plug, and connecting the SimCube simulator to the wrong power supply may damage it. Be sure to use the original plug from the manufacturer.

- Wait for the power-up sequence to complete. When this step is complete, the display will show 0.0 on the simulator. During the power-up sequence, the simulator will zero its pressure, so please remove all connections from the NIBP bulkhead to allow the SimCube to accurately zero to atmosphere. This step may take up to 15 seconds to complete.
- Select the desired mode by pressing the Yellow Mode button. Each time the mode button is pressed, the mode will be changed and the LED indicating the new mode will be lit.

Note: if the SimCube transitions into sleep mode (after approximately 30 seconds of non-use) to conserve power, the first press of the mode button will illuminate the display and a second press will be required to move to the next mode. The mode desired for this accuracy check is **NIBP Adult (120/80).** This simulates a patient with blood pressure of 120/80 mm Hg, heart rate of 70 bpm, mean pressure of 97 mm Hg, and pulse volume of 1 ml.

- Start the accuracy check by connecting the SimCube simulator in line with the monitor's cuff and hose as shown in Figure 1. Different monitors will require different adapters. Using a SimCube cuff jacket can improve reading capture and consistency. Generally, the smaller cuff jacket sleeve volume is best for most monitors. To use the cuff jacket, wrap the cuff and insert into the desired sleeve. If not using the cuff jacket, wrap the cuff snugly around itself or around a solid object and place in an area safe from accidental motion.

Figure1

Insert the cuff (small cuff size) into the cuff sleeve. Connect the ABPM device to the simulator and the cuff using the appropriate adapter. Plug the SimCube power supply into an AC outlet

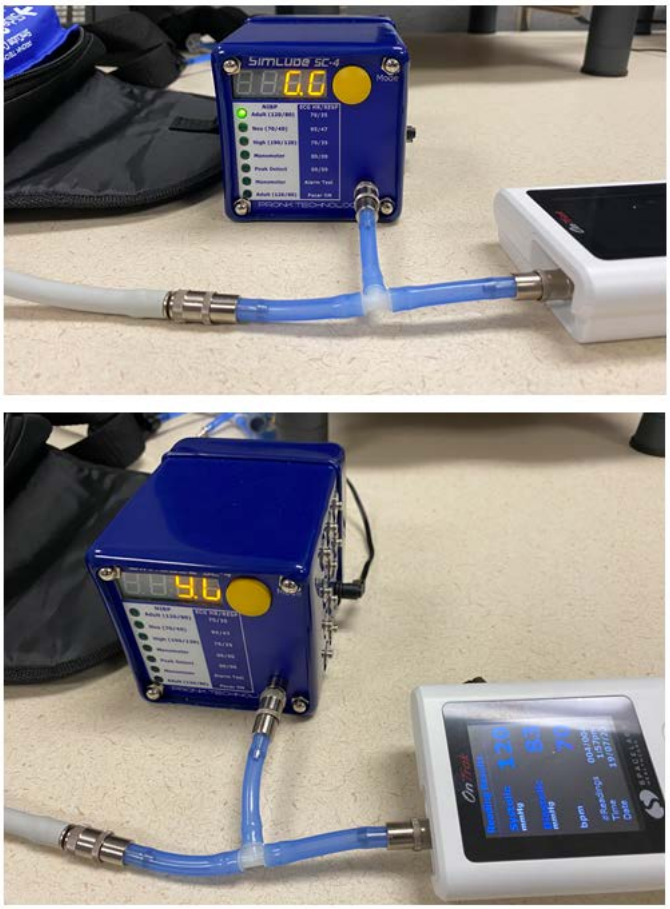
Action button

Accuracy Check for ABPM:

- Insert batteries into the ABPM device.
- Push the mode button on the simulator to select NIBP Adult (120/80).
- Push on the action button of the ABPM to start the reading. The ABPM device will measure above 160 mm Hg.
- You should expect a gradual decrement in the mm Hg from both the ABPM device and the SimCube simulator till it measures 120/80 mm Hg +/- 3 mm Hg on the ABPM device.

Note: if final measurement on the ABPM device is greater than or less than +/- 3 mm Hg of the simulated value of 120/80, run the accuracy check 2 additional times. If you continue to get higher or lower readings, document the result in the ABPM device maintenance and accuracy check log as failed and arrange for shipment to the Spacelabs Company for troubleshooting.

Figure 2



The LED on the simulator should read 0.0 before you start the reading. Push the action button and wait for the reading to complete.

Leak Testing Cuff Sizes for ABPM:

For leak testing, connect the SimCube simulator and the manual pump bulb in line with the monitor's cuff (placed in the sleeve) as shown in Figure 3. Manually pump the bulb to >/= 150 mm Hg and observe a gradual decrement in the reading on the simulator. A sudden drop in the reading indicates leakage in cuff bladder, cracking or holes in the tube. Document the result in the device maintenance and accuracy check log as failed and arrange for shipment to the Spacelabs Company for troubleshooting.

Figure 3

The LED on the simulator should read 0.0 before you begin to manually pump the bulb. You should expect an increase in size of the cuff with every pump of the bulb. When you reach 150mmHg on the simulator, observe for a gradual decrement in the mmHg.

Battery Operation:

SimCube SC-4kit may be operated on battery power using the battery boost option. The battery boost allows the user to switch between AC power and four "AA" batteries and it easily integrates with the SimCube padded carrying case. The battery boost is designed to operate with alkaline batteries for simplicity and convenience, however, please note that using NiMH batteries will provide the highest battery performance. While

rechargeable batteries may be used, an external charger is required to recharge these batteries. When the batteries are depleted, the battery level indicator on the battery boost will illuminate a red LED and the SimCube may re-boot to further indicate the need to replace the batteries.

Note: When the battery level indicator lamp is red, your simulator may continue to operate, but values should not be trusted. Always confirm battery level LED is green when doing simulation on battery power. When your simulator is not in use, switch the battery boost to the “Batt OFF” position to avoid draining the batteries.

APPENDIX X: ABPM DEVICE MAINTENANCE AND ACCURACY CHECK LOG

Instructions: This checklist documents the semiannual checks for the ABPM device. One log should be completed for each semiannual check. If there is more than one ABPM device used, indicate the checks with a separate log for each device.

TECH ID NUMBER: | | | | FIELD CENTER | | DATE: ☐☐/☐☐/☐☐☐☐
Month Day Year

Blood Pressure Measurement **ABPM SERIAL #:**_____

	Y/N	**If YES, action**
Availability of all sizes of cuffs		
Cracking		
Holes		
Worn out cloth of Velcro		
Leakage of cuff bladder		
Accuracy Check with SimCube SC-4kit ***(Observe a gradual decrement in the mmHg from both the Omron device and the SimCube SC-4kit till it measures 120/80 mm Hg +/- 3 mm Hg)***		

Comments:

_____

_____

APPENDIX Y: SIMCUBE TROUBLESHOOTING TIPS

SYMPTOM	SOLUTION
Readings inconsistent or no reading at all	If using Battery Boost, be sure the Batt On/Off switch is ON and the Batt Level LED is green. If the Level LED is Red or dark, replace the batteries with a fresh set.
Readings inconsistent, error message (C05) on Welch Allyn 52000	Reduce/Control cuff volume and movement by inserting the cuff into the small sleeve of the Pronk Cuff Jacket Duo.
During NIBP simulation, monitor continually inflates cuff without reading	Check for leak in hose and cuff. Use standard adult size cuff only for adult and hyper modes. Neo mode requires size 3 or 4 (8-13cm) cuff to be effective. Reduce/Control cuff volume and movement by inserting either adult or neo size cuff into the small sleeve of the Pronk Cuff Jacket Duo.
Alaris / IVAC 4410 does not get readings	This device calculates diastolic during inflation. Wait until it is done with its first inflation cycle; it will automatically restart inflation and will get reading.
IVAC 4200 does not get readings	The IVAC 4200 is primarily an auscultatory blood pressure monitor, in fact there is a microphone built into the cuff itself. However, these monitors also have an oscillometric algorithm and will get consistent readings if you remove the cuff from the hose and connect the hose directly to the SimCube simulator.
Can't get RESP waveform on Datascope	Reconfigure snaps to the following: black lead to white RA, red lead to black LA and white lead to green RL.
Battery Boost Option does not charge batteries	This is by design. In order to allow customers to use off the shelf alkaline batteries, no charge current is applied to the batteries being used.
Readings are always high/low on specific model/manufacturer	Each model of monitor has a different algorithm for calculating NIBP values; therefore different models, even from the same manufacturer, can yield different results. Use the SimCube Sample Reading Chart as a reference.
Respiration does not count	The amplitude of the respiration signal was carefully selected to ensure that monitors will not count if 60hz noise is present. Some monitors may require an adjustment to increase resp size in order to get an accurate respiration rate.

SimCube won't read 0 (shows ––) at power up	During power on initialization, SimCube auto zeroes pressure itself. Therefore, vent circuit to atmosphere at power up and wait 15 seconds for auto zero to complete, signified by 000.0 on display of SimCube models SC-1, SC-2, SC-3 and SC-4 and SC-5 SW version up to 4.5. SC-5 version 5.0 or higher will display 0.0 when zeroed to atmosphere.
Can't connect 12 Leads to snaps	Order ECG snap extender, part number ECG EXTEND.
No heart rate on EASI configured Telemetry	When viewing AVR or V2 lead, change the V lead to V6 snap.
ECG is Noisy	The noise may point to a ground loop issue. Check for ground loop noise by running the SimCube on battery power to see if the noise still exists. If it is present, check to see that the monitor under test has its A/C filter(s) enabled. Please note that monitors may have more than one filter that filter out of different frequencies.
Unable to resolve problem	**Contact Pronk Technologies' Technical Support at:** (800) 541-9802