



INSTRUCTIONS FOR THE HOME BLOOD PRESSURE MONITOR RETURN FORM

I. General Instructions

This form is completed for all participants who agree to take part in the Home Blood Pressure Monitor (HBPM) ancillary study. This form should be completed once the HBPM device has been returned to the clinic.

II. Administrative Information

- 0a. Enter the date the form was completed.
- 0b. Enter the staff code of the person who completed this form.

A. HBPM Participant Experience Form

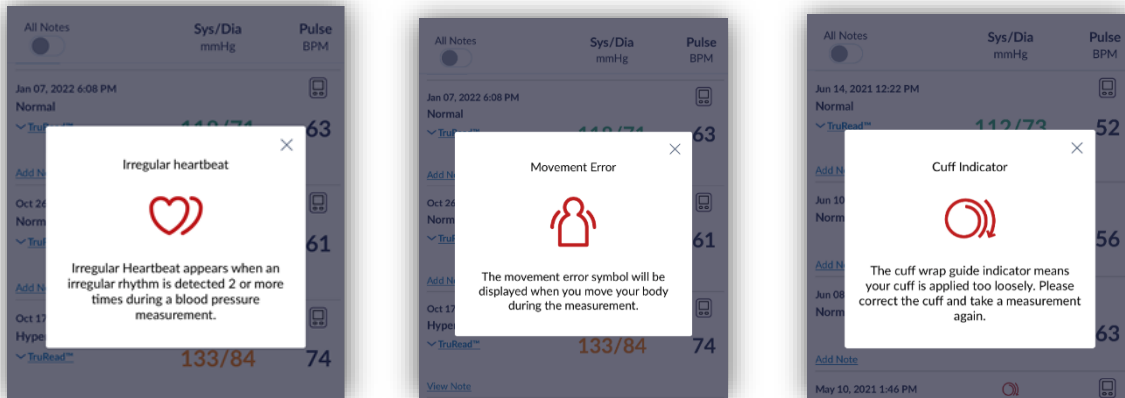
1. Record how the information from the Participant Experience Form was collected. If no form was received and/or no data were captured, go to item 5.
 - 1a. Record the date the Participant Experience Form was received.
2. Record the HBPM end date that the participant recorded on the HBPM Participant Experience Form.
3. Record whether the monitor was used by anyone other than the participant.
4. Using the information from the HBPM Participant Experience Form, select whether the patient had more or less of the following things during their 8 days of blood pressure monitoring (on a scale of 1-5, with 1 being 'much less' and 5 being 'much more'):
 - 4a. Stress
 - 4b. Pain
 - 4c. Time Sleeping
 - 4d. Physical Activity
 - 4e. Feeling light-headed or dizzy
 - 4f. Number of headaches
 - 4g. Time feeling sick

B. HBPM Device

5. The 31-digit HBPM serial number will be automatically prefilled here from the HBP form. When the device is returned to the clinic, the HBPM serial number found on the device should be verified against the serial number that is automatically applied in the HBPR 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 of any

discrepancies.

6. Record how the device was accessible to staff. If the device was not accessible, save and close the form.
7. Record the date the device was accessed by staff.
8. Record whether all the blood pressure readings are on User 1.
9. Open the Blood Pressure History in the Omron app. Scroll through the measurements to check and see if there are any alerts present. Alerts will appear as the following symbols:



If you see any of these symbols in the blood pressure measurements, select Yes, and continue to 9a. These alerts will need to be added as Notes in the Omron app to ensure the alerts will appear in the .csv file. Use the following letter/number combinations for the above alerts:

Irregular heartbeat = IH1
Movement error = ME2
Cuff indicator = CI3

See MOP38 Appendix P for more information about alert symbols and how to add the alerts as a Note.

- 9a. Record whether the alerts were added as a note to the Omron app.
10. Record if the data was successfully downloaded from the device. If No, save and close the form. If Yes, record the date of data download in 10a.

Open the Omron device history by pressing the button with the notepad and pencil on the front of the device. Scroll through the data file and the data recorded in the device. If there are any measurements that are recorded on the device but are not present in the raw data file, these will need to be entered into CDART manually.

Look at the raw data file and see how many rows of data were present in the data file. Less than 52 rows of data indicates that there are missing blood pressure measurements. This

could mean that a participant did not take all measurements per protocol or that the data file does not match the data on the Omron device. It will be important to understand why there are less than 52 rows of data in the file so that you can accurately respond to question 10. A complete HBPM report will consist of **52 rows of data**. If the participant measures their BP with 1 TruRead measurement in the morning and 1 TruRead measurement in the morning, they will obtain 48 measurements in total, plus 3 readings from their in-clinic visit, and 1 row accounting for the titles of each column.

Example of a participant who has their visit 10 on 10/7/21 (first 2 days of home monitoring after the APBM is complete):

	A	B	C	D	E	F
1	Date	Time	Systolic (mmHg)	Diastolic (mmHg)	Pulse (bpm)	TruRead
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

If there are less than 52 rows of data in the raw data file, then it is ok to proceed, however, be extra careful to verify that there are no additional measurements on the Omron device that are not contained in the raw data file. Any differences will need to be manually recorded in CDART.

If there are more than 52 measurements on the device, and the extra measurements are not recorded in the raw data file, then these measurements will also need to be manually recorded in CDART.


11. After scrolling through the data file and the device history, record whether the data file contains the same data as recorded in the device. If Yes, skip to item 29. If No, continue with items 11-28. **All measurements that are missing from the raw data file will need to be recorded in this next section.**

12-28. If all or some measurements are missing from the data file, record the date and time of measurement for all systolic, diastolic, and heart rate values that are missing from the data file. (Questions 12-28 depending on how many missing measurements there are). If there are any alerts present in the data, these will also need to be entered here using the following Alert Code options:

No Alert
IH1- Irregular Heartbeat
ME2 – Movement Error
CI3 – Cuff Indicator

29. Record if the exported HBPM data file was successfully attached to the HBPR form in CDART.

To attach the data file using the iPad, staff will need to complete the following steps:

- Open CDART and the file explorer on the iPad at the same time.
- Click the three dots at the top of the iPad screen. ...
- Tap the Split View button. 
- Use your finger to drag the data file over to the file drop location in the HBPR form in CDART.

29a. Record the staff ID of the person who attached the data file to CDART.