

17. Blood Pressure/Omron Device

Archiving Note: See Nocturnal Trial analysis document named 'Explanation of Data from Home Blood Pressure (BP) Forms (F213-F215).'

17.1 Development of the blood pressure measurement schedule

Blood pressure can be affected by numerous factors, including volume status, time of day the reading is made and whether the blood pressure reading is made at home or in a medical setting (“white-coat hypertension”). In order to be able to compare blood pressures in the in-center conventional arm with the home nocturnal arm, blood pressures will be measured at home in both arms of the study using an automated Omron blood pressure cuff.

Since blood pressure can be affected by volume status, blood pressure readings will be obtained both midweek and over a weekend. The weekend blood pressure measurements will allow for the measurement of blood pressure at the time when the patients will have the longest interdialytic period, and thus most likely to have a higher level of volume overload compared to midweek.

Blood pressures will be routinely obtained at the start and end of hemodialysis sessions; thus, the major use of the Omron automated blood pressure monitor will be to obtain blood pressures in the interdialytic period. None of the interdialytic blood pressure readings should be obtained within 2 hours of either the start or conclusion of a hemodialysis session.

A blood pressure schedule will be generated by the DCC to assist the study coordinator in developing a schedule for blood pressure readings for study participants. Information needed to generate this schedule will include the treatment arm (conventional versus nocturnal), the type of collection (midweek or weekend) and the usual start and end times for the hemodialysis session.

In general, for the conventional arm, the midweek blood pressure readings will be obtained between the end of a dialysis session on a Wednesday or Thursday and the start of a dialysis session on a Friday or Saturday. The weekend blood pressure readings will be obtained between the morning after the Friday or Saturday dialysis session and the start of the next dialysis session on the following Monday or Tuesday.

For the nocturnal arm, the midweek blood pressure readings will be obtained from the end of a dialysis session on a Wednesday or Thursday morning, to the start of the dialysis session on Friday or Saturday evening. Blood pressure readings will not be obtained by the Omron device during the dialysis session that occurs about 18 hours after the start of the blood pressure monitoring period. The weekend blood pressure readings will be obtained from the end of the dialysis treatment on Sunday morning to the start of the next dialysis treatment on Monday evening.

For both arms of the study, blood pressures will not be recorded from 12 midnight to 6 am. Blood pressures will be measured three times per day; thus blood pressure measurements will be obtained at 4 to 6 hour intervals. Since the interdialytic period in the nocturnal arm is shorter than for the conventional arm; the time interval available for interdialytic blood pressure readings will of necessity, be shorter in the nocturnal arm than in the conventional arm.

17.2 Use of the Omron device

Setting Up and Choosing Blood Pressure Monitor for Participant

1. To set up the blood pressure monitor, plug the arm cuff into the main unit of the blood pressure machine (outlet is located on the left side of the unit).
2. Choose the proper cuff size: measure the participant's arm circumference (the upper part of the arm at the midpoint). Use a large cuff if the circumference of the upper part of the arm at the midpoint is > 31 cm (12.2 inches).

How to Apply the Arm Cuff When Teaching Participant How to Use Machine

1. Put the participant's arm through the cuff loop. The bottom of the cuff should be approximately ½" above their elbow. The Green Marker on the cuff should lie on the inside of the arm, over the brachial artery (see instructions on the cuff for locating your brachial artery). The tube should run down the center of their arm, approximately even with their middle finger.
2. Pull the cuff so that the top and bottom edges are tightened evenly around their arm.
3. When the cuff is positioned correctly, press the sewn hook material **FIRMLY** against the pile side of the cuff.
4. Make sure the cuff fits snugly around their arm. The cuff should make good contact with the skin. You should be able to fit your index finger between the cuff and their arm easily; this insures that the cuff is not too tight.
5. Insure their arm is relaxed with the palm facing upwards. Their arm should be resting on/supported by something.
6. Ensure that there are no kinks in the air tubing.

How To Take A Reading With OMRON

1. Press the blue on/off button on the top of the monitor
 - a. All display symbols will appear for approximately 1 second.
 - b. When the monitor becomes ready to measure, the Heart Symbol appears on the larger display in the right upper corner.
2. Press the start button
 - a. As the cuff begins to inflate, the monitor automatically determines their ideal inflation level. Because this monitor detects the pulse even during inflation, the participant must remain still until the entire measurement completes.
3. Inflation stops automatically and measurement is started
 - a. As the cuff slowly deflates, decreasing numbers appear on the display and the Heart Symbol flashes at every heart beat. In rare circumstances, a higher inflation may be necessary. In those cases, the monitor re-inflates

- the cuff up to 30mmHg higher than initial inflation and restarts the measurement.
4. When the measurement is complete, the arm cuff completely deflates and the blood pressure and pulse rate are displayed.
 - a. NOTE: The monitor automatically stores blood pressure and pulse rate into the memory.
 5. Press the ON/OFF button to turn the monitor off.
 - a. NOTE: If you forget to turn the monitor off, it will automatically shut itself off after five minutes.

17.3 Recording of blood pressure readings by the patient

Although the Omron device has the ability to store blood pressure readings, there is the possibility that the readings could be erased or that the machine is used by other family members or friends during the blood pressure measurement period. Thus, all study participants will be encouraged to record their blood pressures as they are obtained. The study coordinator will provide a spreadsheet to the patient (Form 213) that will have the days and approximate times that each of the blood pressure readings should be obtained. The patient will return this form after the blood pressure readings are obtained and the study coordinator will review the spreadsheet to ensure that the blood pressures were obtained at the appropriate days and times. If more than 20% of the blood pressure readings are missing, the patient will be asked to repeat the blood pressure measurements for that part of the study (baseline, F5 or F14).

17.4 How to Generate a Patient Blood Pressure Worksheet

To generate a patient blood pressure worksheet form 214, go to the FHN data entry menu and enter a "Nocturnal Study: Generating Patient Home BP Worksheet" - Form 213. When Form 213 has been entered and saved, you will need to click on the button at the bottom of the report, "Save and Generate Report" and the database will generate a Patient Home BP Collection Worksheet - 214. There can be anywhere from 3-5 worksheet pages produced. This worksheet is created specifically for the patient and you will need to review the worksheet with the him/her instructing them on how to complete it. *Note: The worksheet "pops up," so if you have a pop-up blocker on, turn it off during the worksheet generation process.*

Instructions for completing the Form 214 are on the form and in preceding sections of this Manual of Operations.

The patient should complete the Worksheet# 214 as instructed and return the completed worksheet to the study coordinator. The study coordinator should then compare the BP measures printed from the Omron home BP device to the data collected on Worksheet #214, making sure that the Worksheet #214 does not contain any data that was not printed from the Omron device. (If the Omron printout includes extra data - which may be a result of family members trying out the Omron machine - these can be disregarded. The purpose of the comparison is to make sure there are no data on Worksheet #214 that were not truly measured on the Omron device.)

After the comparison, data should be entered following the instructions on Form 215 "Nocturnal Study 2-Day Home Blood Pressure Form #215." You will first need to query the patient identification number and date or the blood pressure tracking number previously assigned to bring up the correct record in order to enter the data. Once the data are entered and saved, a box in the upper right hand corner of the database form will populate with "Adequate" or "Inadequate". This will identify whether or not you need to have the patient recollect another set of the same type of measures (midweek vs. weekend). You can click on the "Print Report" button at the top of the database form and the database will generate a detailed report identifying any errors incurred. You can use this report to counsel the patient on his/her next collection of BP measures. *Note: The report "pops up," so if you have a pop-up blocker on, turn it off during the report generation process.*

If for any reason the blood pressures could not be done as scheduled by the worksheet, Form 215 can also be used to identify the reason why the test was not done as scheduled by the worksheet. This will "close out" the worksheet and a new worksheet can be generated for a different set of days.

Keep in mind that whenever the study requires home blood pressure measurements, two two-day measures are done for for each patient: one for two consecutive mid-week days and one for two consecutive weekend days.

Appendix 1

Written Instructions Which Can Be Given To Participants

Please read the following instructions carefully before you begin to take your blood pressure measurement.

- Please do not smoke, drink caffeine or exercise for at least 30 minutes before measuring your blood pressure as these activities will affect your blood pressure measurement making it inaccurate.
- You will need to take the blood pressure readings as scheduled on the recording sheet provided to you.
- Please record both numbers that are displayed in the large box on the machine. For example, if the machine reads 140 on the top and 90 underneath, then record 140/90.
- Please do not let other people use this blood pressure machine. This machine has a built in memory function and will record all measurements taken.

Instructions for Taking Your Blood Pressure Measurement

Getting Started

Included in this blood pressure monitor you should have 2 separate parts. You should have the main blood pressure unit and the gray arm cuff. You will need both of these in order to take your blood pressure reading.

Setting Up Blood Pressure Monitor

3. To set up the blood pressure monitor, plug the arm cuff into the main unit of the blood pressure machine (outlet is located on the left side of the unit).

How to Apply the Arm Cuff

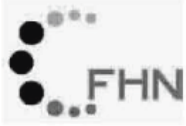
7. Put your arm through the cuff loop. The bottom of the cuff should be approximately ½" above your elbow. The Green Marker on the cuff should lie over the brachial artery on the inside of the arm (see instructions on cuff for locating your brachial artery). The tube should run down the center of your arm, approximately even with your middle finger.
8. Pull the cuff so that the top and bottom edges are tightened evenly around your arm.
9. When the cuff is positioned correctly, press the sewn hook material **FIRMLY** against the pile side of the cuff

10. Make sure the cuff fits snugly around your arm. The cuff should make good contact with the skin. You should be able to fit your index finger between the cuff and your arm easily.
11. Relax your arm and turn your palm so it is facing upwards. Your arm should be resting on/supported by something.
12. Ensure that there are no kinks in the air tubing.

How To Take A Reading

6. Press the blue on/off button on the top of the monitor
 - a. All display symbols will appear for approximately 1 second.
 - b. When the monitor becomes ready to measure, the Heart Symbol appears on the larger display in the right upper corner.
7. Press the start button and remain still
 - a. As the cuff begins to inflate, the monitor automatically determines your ideal inflation level. Because this monitor detects the pulse even during inflation, do not move your arm and remain still until the entire measurement completes.
8. Inflation stops automatically and measurement is started
 - a. As the cuff slowly deflates, decreasing numbers appear on the display and the Heart Symbol flashes at every heart beat.. In rare circumstances, a higher inflation may be necessary. In those cases, the monitor re-inflates the cuff up to 30mmHg higher than initial inflation and restarts the measurement.
9. When the measurement is complete, the arm cuff completely deflates and your blood pressure and pulse rate are displayed.
 - a. NOTE: The monitor automatically stores blood pressure and pulse rate into the memory.
10. Press the ON/OFF button to turn the monitor off.
 - a. NOTE: If you forget to turn the monitor off, it will automatically shut itself off after five minutes.

Appendix 2:



Frequent Hemodialysis Network
Patient Home Blood Pressure Collection Worksheet

07/30/2008 11:23 AM
Worksheet #214
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Treatment Type: **Conventional** Collection Period: **Midweek**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX	ML				
Participant ID#	Alpha Code	Visit Type	Visit Number	XXXXX	BP Worksheet Tracking Number

Collection Day 1 (Expected - Wednesday, March 19th)

____/____/____
actual date: dd/mon/yyyy

BP Session 1: End of Dialysis

Time when dialysis session ends? (expected end time is 01:30 PM) _____:_____
AM or PM (circle one)

End of dialysis BP: (NOT from Omron: ask your dialysis nurse or technician to provide)

BP: _____/_____
Time: _____:_____
AM or PM (circle one)

BP Session 2: between 03:30 PM to 06:00 PM

***In case your dialysis session ends later than anticipated, remember to measure these BPs at least two hours after dialysis ends.

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
_____/_____	_____:_____ AM or PM (circle one)	_____/_____	_____:_____ AM or PM (circle one)
_____/_____	_____:_____ AM or PM (circle one)	_____/_____	_____:_____ AM or PM (circle one)

BP Session 3: between 06:00 PM to MIDNIGHT

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
_____/_____	_____:_____ AM or PM (circle one)	_____/_____	_____:_____ AM or PM (circle one)
_____/_____	_____:_____ AM or PM (circle one)	_____/_____	_____:_____ AM or PM (circle one)



Frequent Hemodialysis Network Patient Home Blood Pressure Collection Worksheet

Treatment Type: **Conventional** Collection Period: **Midweek**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX	ML			XXXXX
Participant ID#	Alpha Code	Visit Type	Visit Number	BP Worksheet Tracking Number

Collection Day 2 (Expected - Thursday, March 20th)

____/____/____
actual date: dd/mon/yyyy

BP Session 1: between 06:00 AM to NOON

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)

BP Session 2: between NOON to 06:00 PM

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)

BP Session 3: between 06:00 PM to MIDNIGHT

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)



Frequent Hemodialysis Network
Patient Home Blood Pressure Collection Worksheet

Treatment Type: **Conventional** Collection Period: **Midweek**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX
Participant ID#

ML
Alpha Code

Visit Type

Visit Number

XXXXX
BP Worksheet Tracking Number

Collection Day 3 (Expected - Friday, March 21st)

____/____/____
actual date: dd/mon/yyyy

BP Session 1: between 06:00 AM to 07:30 AM

***If you anticipate your dialysis will start earlier than usual, remember to measure these BPs at least two hours before you believe your dialysis will start

BP Measures
____/____
____/____

Times
____:____
AM or PM (circle one)
____:____
AM or PM (circle one)

Optional BP Measures
____/____
____/____

Times
____:____
AM or PM (circle one)
____:____
AM or PM (circle one)

BP Session 2: Beginning of Dialysis

Time when dialysis session begins? (expected start time is 09:30 AM) ____:____
AM or PM (circle one)

Start of dialysis BP: (NOT from Omron: ask your dialysis nurse or technician to provide)

BP: ____/____

Time: ____:____
AM or PM (circle one)

Important:

Have you collected blood pressures for the Weekend period during this point in the study? If you are unsure, please check with your study coordinator.



Frequent Hemodialysis Network Patient Home Blood Pressure Collection Worksheet

07/30/2008 11:24 AM

Worksheet #214

Page 1 of 3

Treatment Type: **Conventional** Collection Period: **Weekend**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX
Participant ID#

ML
Alpha Code

Visit Type

Visit Number

XXXXX
BP Worksheet Tracking Number

Collection Day 1 (Expected - Saturday, March 22nd)

___/___/___
actual date: dd/mon/yyyy

BP Session 1: between 06:00 AM to NOON

BP Measures

Times

Optional BP Measures

Times

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

BP Session 2: between NOON to 06:00 PM

BP Measures

Times

Optional BP Measures

Times

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

BP Session 3: between 06:00 PM to MIDNIGHT

BP Measures

Times

Optional BP Measures

Times

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)

___/___

__:__:__
AM or PM (circle one)



Frequent Hemodialysis Network Patient Home Blood Pressure Collection Worksheet

Treatment Type: **Conventional** Collection Period: **Weekend**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX	ML			XXXXX
Participant ID#	Alpha Code	Visit Type	Visit Number	BP Worksheet Tracking Number

Collection Day 2 (Expected - Sunday, March 23rd)

____/____/____
actual date: dd/mon/yyyy

BP Session 1: between 06:00 AM to NOON

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)

BP Session 2: between NOON to 06:00 PM

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)

BP Session 3: between 06:00 PM to MIDNIGHT

<u>BP Measures</u>	<u>Times</u>	<u>Optional BP Measures</u>	<u>Times</u>
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)
____/____	____:____ AM or PM (circle one)	____/____	____:____ AM or PM (circle one)



Frequent Hemodialysis Network
Patient Home Blood Pressure Collection Worksheet

Treatment Type: **Conventional** Collection Period: **Weekend**

Study Period: **Baseline**

Instruction:

Please provide blood pressures and times in the required blanks below. Blood pressures should be taken close to 5 minutes apart within each BP session.

Note: Contact your coordinator if a dialysis session is moved to a different time.

900XXX

Participant ID#

ML

Alpha Code

Visit Type

Visit Number

XXXXX

BP Worksheet Tracking Number

Collection Day 3 (Expected - Monday, March 24th)

____/____/____

actual date: dd/mon/yyyy

BP Session 1: between 06:00 AM to 07:30 AM

***If you anticipate your dialysis will start earlier than usual, remember to measure these BPs at least two hours before you believe your dialysis will start

BP Measures

Times

Optional BP Measures

Times

____/____

____:____
AM or PM (circle one)

____/____

____:____
AM or PM (circle one)

____/____

____:____
AM or PM (circle one)

____/____

____:____
AM or PM (circle one)

BP Session 2: Beginning of Dialysis

Time when dialysis session begins? (expected start time is 09:30 AM) ____:____
AM or PM (circle one)

Start of dialysis BP: (NOT from Omron: ask your dialysis nurse or technician to provide)

BP: ____/____

Time: ____:____
AM or PM (circle one)

Important:

Have you collected blood pressures for the Midweek period during this point in the study? If you are unsure, please check with your study coordinator.