

Frequent Hemodialysis Network NOCTURNAL STUDY 2-DAY HOME BLOOD PRESSURE – FORM #215

Instructions: The patient should have recorded his or her blood pressures over two days (approximately), using the patient-specific generated Blood Pressure Measurement Worksheet - Form 214. The study coordinator should review the completed worksheet with the patient and compare the BP measures printed from the Omron device to the data captured on F214. *(If the patient recorded dates differently from 'expected' dates, please contact the DCC before proceeding.)* Following the review, data on this form (215) should be entered.

Schedule: This form will be completed twice, once each for **midweek** and **weekend** sessions. Nocturnal v3.0: Baseline, F-4 and F-12. *(Nocturnal v2.1: Baseline, F-5 and F-14).*

1. Participant ID #	2. Alpha Code	3a. Visit Type	3b. Visit Number	BP tracking number							

5. Date when techniques for self-measurement of blood pressure were reviewed between the patient and the study coordinator (dd/mon/yyyy)? _____/_____/_____
(Date should fall within 2 weeks prior to patient self-assessment.)

6. a. Did the patient complete home BP measurements according to the schedule provided? _____
0=No, complete Question 6b.
1=Yes, skip to Q7.

- b. Identify reason why patient did not attempt test or failed to complete the home BP tests: _____
(After completing this question, skip to question 200.)
- 1=The study site was unable to provide patient with a machine.
 - 2=Machine unable to accurately measure patient's blood pressure.
 - 3=Measurements recorded but lost.
 - 4=Patient unable to understand instructions.
 - 5=Patient, even with family member assistance, was physically unable to perform measurement
 - 6=Patient collected BP measures from the wrong days.
 - 7=Patient needed an extra dialysis session so the schedule would not work.
 - 8=Patient changed dialysis schedule for that week.
 - 9=Study Staff error
 - 10=Arrhythmia requires use of different model of Omron device.
 - 11=Patient forgot to take measurements.
 - 12=Fall 2006 database freeze.
 - 13=Patient was unexpectedly not available on the dates planned.
 - (If there was some other reason, contact the DCC and a new code will be provided)*
 - 14=Pt. received transplant or died before BP measures could be completed.**

7. Model of Omron device used to collect home blood pressure measurements _____
1=705CP, 2=711AC (for patients with arrhythmias)

Reminder: The patient needs to collect blood pressure measurements for midweek and weekend. Please remind the patient if one collection period is still pending.

200. Date this form completed (dd/mon/yyyy) _____/_____/_____
201. Username of person reviewing completeness of this form _____

For Clinical Center Use Only:
202. Username of person entering this form: _____
203. Date entered: (dd/mon/yyyy) _____/_____/_____

Data Entry Instructions For BP Worksheet Section of Form 215

After completing page 1, continue to the next section titled "BP Worksheet". Here you will need to enter the patient's collected blood pressures directly from Form 214. The dates and times appearing on this Form 215 have been set up to match those on the BP Worksheet (#214) so data entry should be more straight forward. Please double-check the collection day number and the date to make sure you are entering the data in the correct BP session.

A patient can record up to 4 BP measures per session. The data entry person should enter all data as recorded on the worksheet.

Collection Day #: Note that this date will change according to the patient's generated schedule. The patient will need to enter the actual date when the measurements were taken. The expected and actual dates should be the same. If the patient recorded data from different days, please contact the DCC before proceeding.

Entering Times: Form 214-BP Worksheet times were captured using AM/PM instead of the 24-hour clock to make it easier on the patient. You will need to enter the time as HH:MM and must also include the 'AM' or 'PM' otherwise a warning box will pop-up.

Actual Dialysis End Time: This box may be greyed out to show that you cannot enter anything in it. The box will change to a white background when the database needs to have a time entered

Actual Dialysis Start Time: Same as above.

BP Measures: Entering systolic BP measure first followed by the diastolic BP measure. The database will then skip to the time box. Enter the time as recorded on the form (see instructions above). If a time or time-frame differs from what the database expects, a warning box will appear. This warning box is meant to prevent you from key entering incorrect times by mistake. Click on the 'ok' button and re-enter the time as recorded on the worksheet.

The database will prompt you with next set of blood pressure measurements. Continue entering until you get no further prompts from the database. The data entry person should enter the BP measures as seen on the worksheet.

Once all data are entered and saved, a database program will check to see whether the patient completed the BP measurements (midweek/weekend) and will notify the study coordinator and PI if the patient successfully or unsuccessfully completed the task. The collection period will have to be repeated if unsuccessful.

	Blood Pressure (systolic/diastolic)	Time of Measurement (HH:MM AM/PM)
BP measure 1:	___ ___ / ___ ___	Time 1: ___ ___ : ___ ___
BP measure 2:	___ ___ / ___ ___	Time 2: ___ ___ : ___ ___
Optional BP Measure 1	___ ___ / ___ ___	Time 3: ___ ___ : ___ ___
Optional BP Measure 2	___ ___ / ___ ___	Time 4: ___ ___ : ___ ___