

III. 24 Hour Ambulatory Blood Pressure Study

(1) Data Management

There are several forms used in tracking the data from scheduling all the way through to giving a data set to the database administrator to be statistically analyzed:

- a) **BP Hookup Volunteer List:** This is a master list that shows everyone who is scheduled for a study, who canceled, rescheduled, showed up, etc. It helps you know what your schedule looks like, and helps you write the end of the month summary for Linda.
- b) **24 Hour Ambulatory BP Study Progress Sheet:** This sheet lists every volunteer that was seen for a study *with a successful hookup*. This lists tracks when the unit is downloaded, when the data are edited, and when the result letter is sent to the volunteer. One full sheet lists 48 studies, completing one full data set.
- c) **Data Folder Coversheets:** These sheets are found on each volunteer's file and are filled out as the data are entered, reviewed by Dr. Mae Hla, and saved to disk.
- d) **Spreadsheet:** The spreadsheet is located on the hard drive of the Reviewer computer, and is used in making the monthly summaries and generally keeping track of the data in the study. It is not used as much on a daily basis, but it a required part of managing the data.

General Schedule for Record Keeping:

- a) Approximately once every week or two, the BP Hookup Volunteer List should be filled out with the future BP appointments according to the Sleep Cohort Study wall calendar. As studies are canceled, rescheduled, or completed, this list should be updated accordingly. *This is the only document that is completed BEFORE a study is done.*
- b) After a hookup is completed, the corresponding Accutracker II Use Log should be filled out, and an entry should be made in the 24 Hour Ambulatory BP Study Progress Sheet. If the study failed and the participant did not wear the equipment home, no entry should be made on the Progress Sheet, and it should be noted on the Use Log sheet if the equipment was to blame for the fail.
- c) After the unit has been returned and downloaded, the Use Log and the Progress Sheet should be updated.
- d) Every few weeks, information from the Progress Sheet can be entered into the spreadsheet on the Reviewer computer. Again, only studies where the volunteer wore the equipment home should be included in the spreadsheet (even if a fail occurred only a short time after the hookup).
- e) At the end of every month, the spreadsheet, Progress Sheet, and Volunteer list are used to prepare a monthly summary to file and give to Linda
- f) After one Progress Sheet is filled with 48 studies, the spreadsheet should be updated in full to include all of the information needed by the database administrator for data analysis. A data file is created with these data and sent to the database administrator along with a floppy containing the data.

(2) 24 Hour Blood Pressure Study Protocol

I. Before the Volunteer Arrives

- a) Preparation of the participant charts:
 1. Fill in the volunteer's name (last, first), cohort ID (with no extensions), BP ID number, address, telephone numbers, and date of birth on the front of the chart using the MSLT intake for as a reference
 2. Date and volunteer name should be filled in on the calibration data sheet stapled to the inside of the chart. **IT IS VERY IMPORTANT TO NOTE ON THIS SHEET WHICH ACCUTRACKER DEVICE IS USED!**
- b) Arrange the following items in the workspace before the start of the hook-up:
 - ✓ one regular and one large Accutracker cuff
 - ✓ one case and one belt
 - ✓ ultrasound unit
 - ✓ sphygmomanometer and stethoscope
 - ✓ one volunteer procedure kit (place informational stickers in the first two pages, fill out front)
 - ✓ Transpore® tape
 - ✓ tape measure
 - ✓ green marker
 - ✓ ultrasound gel

✓ 4" gauze

- c) Chose an Accutracker unit to use from the bottom shelf of the nurse server
1. Using adhesive remover, clean the three ECG leads and the microphone pad, and any other area on the cable that has tape residue on it. Repeat using alcohol.
 2. Ensure that there is tape around the ECG leads where they plug into the patient cable.
 3. Place four new batteries into the Accutracker unit, and secure the battery compartment with tape.
 4. Turn the Accutracker unit power on by holding down the "NO" key and switching the power switch to on. Push "NEXT" when prompted to do so by the unit.

II. After the Volunteer Arrives

- a) Introduce yourself and invite the volunteer to be seated. Close the door.
1. Have the volunteer read and sign the consent form. Sign a second copy of this form and set it aside for the volunteer to keep.
- b) Explain the general instructions, using the instruction sheet for a guide:
- ✓ No bath or shower for 24 hours
 - ✓ No vigorous arm movements
 - ✓ Be careful when changing clothes
 - ✓ Cuff will inflate every 20 minutes from 6:00 am to 11:00 pm with one possible retry, and every 30 minutes from 11:00 pm to 6:00 am with no retry
 - ✓ Try to keep arm relaxed while cuff inflates
 - ✓ Diary is to be completed after each measurement
 - ✓ Unit may be taken off the belt at night and placed in bed
 - ✓ After 24 hours have passed, turn off the monitor and remove the electrodes, microphone, and cuff
 - ✓ Fill out the evaluation sheet
 - ✓ Return equipment to the UW Hospital and Clinics main information desk
- c) Explain the diary in greater detail
1. If a primary technician is on backup, explain that the volunteer can page him or her if any problems arise. **IF THE PRIMARY TECHNICIAN IS NOT AVAILABLE, BE SURE TO CROSS OFF THE PAGER INFORMATION WITH YOUR MARKER!** Explain to the volunteer that they may contact Dr. Hla if any problems should arise.
 2. Explain each of the error codes and what should be done if they appear.
 3. Instruct the volunteer to fill in sleep and wake times on page two.
 4. Explain to the volunteer when to push the start button: just before falling asleep and just after waking up.
 5. Time on the display should be recorded after each measure, and the "Where are you?", "What are you doing?", and "Any Symptoms?" questions should be answered on the subsequent pages. Further explain that more than one box may be checked, and that additional comments are helpful and may be written in.
 6. Explain that the diary should not be a concern when the volunteer is driving or trying to sleep.
- d) Collect information from the volunteer
1. Verify the volunteer's social security number, address, and daytime and evening telephone numbers.
 2. Ask for the volunteer's height, weight, and age and record this information on the inside page of the chart.
 3. Ask which is the volunteer's dominant arm (cuff will be placed on the opposite arm).
 4. Find out if the volunteer is currently being treated for hypertension; if so, record medications and dosages on the inside sheet.
 5. Measure the volunteer's arm to determine which cuff size to use.
 6. Take the volunteer's blood pressure to note a baseline reading.
- e) Begin the hook-up of the Accutracker Unit (explain each step to the volunteer as you proceed)
1. Ask the volunteer to remove his or her shirt(s). Women may leave bras on.
 2. Place some ultrasound gel on the Doppler unit and listen from the area along the brachial artery with the loudest signal. Mark this area with the green marker.

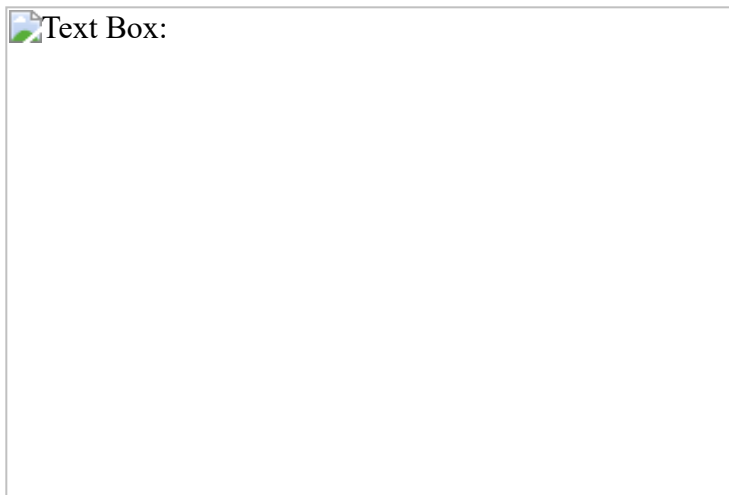


Figure 3. The brachial artery can be found as it travels across the antecubital region and up the medial side of the upper arm.

3. Wipe the area dry with gauze and clean with alcohol. Place the cable around the back of the volunteer's neck, leading toward the non-dominant arm, **REMEMBERING TO PLACE ALL WIRES UNDERNEATH UNDERCLOTHS (BRAS) SO THE VOLUNTEER CAN LATER REMOVE THIS CLOTHING!**
4. Place the blue microphone into the adhesive pad and place it diagonally over the marked area. Follow with Transpore® tape.
5. Using the proper size cuff, align the "artery" mark with the microphone. Explain to the volunteer how to readjust the cuff if necessary. Attach the cuff to the cable.
6. Attach each electrode: white to the collar bone opposite the cuff arm, red on a rib on the left side, and black on a rib on the right side. Adjust the electrode position as necessary to accommodate for excess skin or fat.
7. Before applying the electrode, prep the skin with alcohol and dry with gauze. Snap wire onto the ECG electrode, place the pad on the area that has been prepped, press down to assure a proper hold, and secure the electrode contact using the Transpore® tape.

f) Perform the Accutracker calibration

1. Instruct the volunteer to relax their arm.
2. At the "Begin Office Run?" prompt push "YES". The cuff should inflate. Explain to the volunteer that the machine is calibrating itself their body and that the first few inflations will be especially tight. Push "YES" again when prompted to begin the second calibration reading. *It is normal to see R's and K's flashing on the screen during the calibration.*
3. Attach the sphygmomanometer to the Accutracker using the 3-way connector. Make sure the bulb is closed tightly.
4. At the "Another Test Run?" prompt, push "YES." Listen as the cuff inflates, and record manual versus Accutracker readings in the volunteer's chart. Systolic readings should be within ten points and diastolic within five points. Repeat.
5. Have the volunteer stand for two more test runs. Raise the table so that the sphygmomanometer is vertically level with the volunteer's heart. Push "YES" at the "Another Test Run?" prompt for two more test readings. If all readings are accurate, begin the study.

g) Begin the study

1. At the "Another Test Run?" prompt, press "NO". At the "Begin BP Study?" prompt, push "YES".
2. Attach a snap sticker to the volunteer's shoulder and snap the cuff to it. Check to see if anymore tape should be applied to the neck or torso to help hold the cable in place.
3. Put the Accutracker in the leather pouch, and help the volunteer put it around his or her waist. Use a nylon belt if the volunteer is not wearing one of their own.
4. Have the volunteer put his or her shirt back on.
5. Place the volunteer's paperwork and extra tape in the Accutracker box. Remind the volunteer about returning the unit to the UW Hospital and Clinics main information desk inside the main hospital entrance.
6. When the cuff inflates for the first time, go over the diary with the volunteer, reminding them to fill in bed and wake times. If the Accutracker shows no errors, the volunteer is ready to go! **THANK THE VOLUNTEER FOR THEIR PARTICIPATION.** Inform them that the results will be sent in three to four weeks.

III. After the Volunteer Leaves

- a) Place the completed chart in the nurse server to the right of the green files.
- b) Return all supplies to the nurse server and straighten-up the room.
- c) **IF THE PRIMARY TECHNICIAN IS GONE FOR AN EXTENDED PERIOD OF TIME (VACATION, etc...)** you may run out of Accutacker units. If this happens:
 1. Go down to the main information desk located just inside the main hospital entrance and collect the Accutacker units that may have been left there by volunteers
 2. In the sleep lab, download the data from the Accutacker unit as follows:
 - ✓ Open the Accutacker program on the C-Drive of the “Sleeper” computer. The program is called “Accuwin” and has a brows icon that looks like a circular saw blade.
 - ✓ Click on the “Download” square on the main page. The computer is now ready to accept data from the Accutacker unit.
 - ✓ Turn on the Accutacker unit. Push “NEXT” when prompted. At “DOWNLOAD BP DATA” select “YES.”
 - ✓ At “ENTER SLEEP TIMES” push “NEXT”
 - ✓ At “IS THE DATA CABLE INSERTED?” plug the data cable into the back of the Accutacker unit. The cable is hooked to the “Sleeper” computer and is stored behind the computer. Push “YES”.
 - ✓ The computer screen should now show the information from the unit is being downloaded. When the download is complete, the volunteer’s Social Security number should be displayed. You will need to enter the volunteer’s name (last, first) where prompted (the name can be found on the diary that was returned with the equipment).
 - ✓ Replace the data cable, turn off the Accutacker unit, and place the dairy and any other paperwork to the right of the green files in the nurse server.
 3. Return the Accutacker unit to the bottom shelf of the nurse server. It is now ready to be used again.