

PULSE WAVE VELOCITY

1. 0 Background and Rationale

The aorta and other major arteries are normally very compliant conduits. These flexible tubes facilitate the movement of oxygenated blood and nutrients from the left ventricle of the heart to all areas of the body. In healthy subjects these arteries prove a very low resistance path for the distribution of blood. With each contraction of the heart, a flow wave is generated which travels the length of the arterial system. The physical properties of the arteries can dramatically influence the ways in which these flow waves travel. Pulse wave velocity (PWV) is the measurement of the speed at which a flow or pressure wave travels the length of an artery.

Certain diseases, like diabetes, atherosclerosis, and hypertension can dramatically alter the physical and elastic qualities of the arterial tree. These alterations have many adverse effects on the heart and predispose to premature heart disease. Pulse wave velocity is a non-invasive means to measure the speed of a flow wave in centimeters per second (cm/sec). The speed of the flow wave is proportional to the stiffness of the arterial tree. Older subjects who have very stiff arteries may have a PWV of approximately 1000-1300 cm/sec. Younger subjects may have a PWV around 500-600 cm/sec. The non-invasive measure of PWV provides some of the information that is obtained during cardiac catheterization in a very safe and simple fashion. The measurement of age-related stiffening of the vascular tree, as measured by PWV, is included in Health ABC to complement measures of clinical and subclinical cardiovascular disease.

2. 0 Equipment and Supplies

- Burdick EK-10 ECG System
- Digital Computer Acquisition System
- Parks Doppler Flowmeters Model 810-A
- Transmission Jel (01-08)

2.1 Use of Equipment

Parks Doppler Model 810-A

1. THE PROBE. The probe consists of two crystals; one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. This resin is attacked by any gel or liquid containing the

chloride ion. Therefore you must NOT use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASONIC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. Remove the gel after use with a soft tissue. If you should find the probe with dried gel on it, wash it off under running water. Do NOT scrape off the gel because you may damage the epoxy coating. Do NOT autoclave the probe. Gas sterilization is OK.

2. POSITION OF THE PROBE: The best testing ground is in your particular area of interest. It takes some practice in order to be able to do this. The arm is a good and convenient limb for you to learn on-to learn the basics of how to hold the probe depending on the depth of the artery and vein. The area about 6 inches each side of the elbow is a good place to start.

First, put some gel on the tip of the probe. The gel squeeze-bottle must be shaken downward and then gently squeezed to get the gel to come out. Pile up about a quarter of an inch of gel on the probe, making certain there are no large air bubbles in the pile because ultrasound does not go readily through air. It needs a continuous conducting medium, and the gel is ideal.

Turn the VOLUME control fully down (counter clockwise) and turn the instrument on. Gradually turn up the volume. You should hear a rumbling sound if you are holding the probe. This is caused by the vibration of the gel due to tremor in your arm. Now place the probe over an artery in the arm about half way between the elbow and the wrist. Tilt the back of the probe toward the hand at an angle of about 45 degrees, making certain there is gel in the pathway between the probe and the skin. Move the probe and the skin sideways to try to find the center of the artery and the hissing noise at heart rate, which is the doppler sound for an artery. If the sounds you hear are more or less continuous, that is simply the background noise of the instrument and it means that you are not over the artery. The main energy of the beam is only about as wide as the crystals in the probe, so there isn't much room for error in aiming the probe. For this reason you must always search the area of the artery and tilt the probe for best doppler sounds.

When you are looking for deep arteries, or for small or obstructed arteries, you will have to turn the VOLUME control near maximum. This also means that every time you move the head of the probe you are going to get some pretty big thumping noises in the speaker. Therefore you want to avoid moving the head of the probe with respect to the skin as much as possible. That is why you place the probe over the area where you think the artery is and then you search for the exact point by moving the skin with the probe and changing the angle of the probe with respect to the skin. You might wonder why these big transient noises can't be filtered. We do limit their intensity, but we do

not filter. The reason is that in the search for low-velocity blood flow, such as in occluded arteries and in the veins, the pitch of the doppler sounds associated with the blood flow are very low. Any filtering to eliminate or minimize the sounds accompanying movement of the probe would also reduce the response to low-velocity blood flow sounds, and of course this is undesirable.

Battery Replacement

Turn the screw on the back of the Doppler Box until the back cover will fold down. The Doppler uses 8 alkaline D-cell batteries. Ensure that the new batteries are placed in the holder in the same direction that the original batteries were before they were removed.

Settings on the Parks Doppler Flowmeter (810-A)

The Parks Medical Doppler Flowmeter Model 810A is set up for subject testing as follows:

- 1) Meter Multiplier 2
- 2) Output Filter 3
- 3) Output Level Fullscale (9)
- 4) Input Level Minimum setting for good signal (1-3)

The probe is plugged into the RCA phono jacks that mate with the connectors on the probe cable. The computer is connected to the proper recorder output jack connected to the computer's daughter board.

The Doppler boxes are matched to the particular probe that was shipped with that box.
DO NOT INTERCHANGE THE PROBES!

Off-On-Battery Check. This is the power switch to the doppler which has an extra position on it for checking the condition of the internal batteries. A new set of flashlight cells will cause the meter to indicate full scale or a little higher. If the battery voltage is down by 20% the meter will read about 0.8. When the batteries are weak (**below 0.8**), the sensitivity of the instrument is somewhat reduced, but the calibration of the meter and the accuracy of the recorded flow signal will remain the same until battery voltage falls to a value indicated by about 0.7 on the meter.

Burdick EK10 ECG

Setting up the ECG

All analysis of the wave forms is based on the ECG. If the signal is noisy or the R wave amplitude is too small, then the recorded file is of no value. The vascular measurements are to be performed prior to the exercise treadmill test (ETT). For the

ETT, we assume, a standard 10 electrode chest distribution will be used (RA, RL, LA, LL, V1-V6).

Place the subject on the exam table after the leads have been placed on the chest. Do not use electrodes on the arms or legs. They should be moved to the chest, as is routinely done during treadmill testing. Electrodes on the limbs can be easily dislodged during the process of flow wave form recording. Attach **all four** of the limb lead cables to the subject (RA, RL, LA, LL). This will ensure an adequate ground and reduce the noise of the signal. Next attach lead V4, V5 and V6 cable to the corresponding electrodes.



Turn the EK10 unit on using the switch on the back.

Push the **ON/OFF** button on the front panel. The LCD display will demonstrate the first screen.

Select the manual mode by pressing the large **MANUAL** selection button on the upper right hand side of the panel. This will allow you to review the selected leads, so you can select the lead with the largest R wave as possible. Typically **V4, V5 or V6** will provide a large R wave amplitude needed for analysis. As you switch from V4 to V6, you should see it displayed on the computer screen in real time.

If the signal is noisy you should reattach the limb lead cables to the electrodes or replace the actual electrodes.

The alligator clips provided with the system can be attached to any electrode or disposable sensors that are used in the clinic.

There is no need to enter ID numbers into the EKG.

Disable ECG Timeout

The Burdick EK10 ECG machine has a built in timeout function that is in the system to save the operator from endlessly running paper by leaving the ECG machine on. With the system we fielded, this is not a necessary function because we have disabled the printers. However, the timeout function will still cause a problem. It turns off the real-time output that we need for the Pulse Wave Studies.

Burdick built into the machine a method to disable this timeout. It is done by pressing the following keys:

Press V4 and V6 simultaneously
Press V4 again.

Once this series of keys are pressed, the ECG timeout is disabled until the machine is turned off or placed in standby mode.

2.2 Maintenance and Calibration

2.21 Parks Model 810-A Doppler Flowmeter

CARE OF THE PROBE AND STERILIZATION

The Doppler probes are easily ruined through misunderstanding and neglect, Over 90% of the failures of the Doppler are due to failure of the probe in some way. It will pay you to read what follows and transmit this information to any person using the Doppler.

ABOUT THE PROBE: The active part of the probe consists of two rectangular crystals. One transmits the ultrasonic waves and the other receives them. Each crystal can serve either function so it makes no difference how you plug in the probe to the panel connectors. The crystals are held in place by an epoxy resin. This resin protects the crystals and the tiny wires soldered to them. The resin is attacked by heat and alcohol. We recommend an ultrasonic gel but in an emergency, use any surgical jelly. Bubbles in the gel make popping noises. Don't use ECG paste.

After use, the probe should be gently wiped clean of the Aquasonic or other acoustical coupling gel with a soft tissue. If the gel has dried on the probe, put it under running tap water (not hot) to soften the gel and permit you to wipe it off.

If someone takes a sharp instrument and tries to scrape off the dried gel he may succeed in also scraping off the epoxy resin and sometimes the tiny wires and crystals as well. We speak from long experience. Such probes cannot be repaired, and in fact any probe with a broken or cracked crystal cannot be repaired. You must order a replacement, specifying the frequency marked on the connector (something like 9.2, 8.1, etc.).

BE SURE THE PROBE FREQUENCY MATCHES THE TUNING OF THE INSTRUMENT. The frequency of the probe is marked on the connector end of the cable or engraved on the metal of a pencil probe. The tuning of the instrument is marked with an embossed stick-on label near the probe connectors.

DISCONNECTING THE PROBES from the instrument should be minimized. Don't do it unless you need to, for two reasons. First the connectors wear and make erratic contact after many disconnects. Simple repairs for this wear are described in the maintenance section of this manual. Second, people have a tendency to pull on the cable instead of the connectors themselves and they break the soldered connection inside the cable connector.

THE COUPLING GEL which we furnish is called Aquasonic, made by Parker Laboratories. This gel or a similar ultrasonic gel (not runny) will usually be available from one of your surgical supply dealers. Other makes of gel may work as well, though the dispenser may not be as convenient.

STERILIZATION: Sterilization of the probes is **NOT REQUIRED**.

A PROBE EXTENSION CABLE may be purchased which allows you to keep the Doppler out of the sterile field when the probe is to be used intraoperatively. This cable is about four feet long and costs very little.

GENERAL MAINTENANCE OF THE DOPPLER

NOTES FOR THE SERVICE TECHNICIAN

Information that follows is for doppler instruments of our manufacture in general, and not all of the notes below will apply to the doppler described in this operating manual.

In addition to true service problems which will be described later, you will frequently encounter "operator trouble". **Things to watch out for are:**

1. The doppler is tuned to a frequency which is different from that marked on the probe. This occurs in hospitals which have dopplers and probes of more than one frequency. The probes and instruments get mixed up. We try to circumvent this by sending a particular hospital dopplers and probes of the same frequency. The probe frequency is marked on its connector and the doppler frequency is marked with a stick-on embossed tape next to the probe connectors or on a label somewhere on the instrument. A variation of .1 MHz. is not significant at around 5 or 10 MHz. but it is around 2 MHz.
2. On a doppler that is dual-frequency (two dopplers in one box), the probes are either interchanged or connected improperly. Dry batteries installed are either the wrong type or they're put in backwards or they were shorted while they were being installed. Shorting during installation occurs mostly with the round 9-volt batteries and the result is diminished battery life.

3. On dopplers that have a recorder output, the complaint may be that the recording is too small. This is a problem that may be caused by incompatibility of the recorder. The doppler output is designed to work with the d.c. input of an electrocardiograph which has a high input impedance (usually 100K or more) and deflects the stylus 1 cm. for a 50 mv. input. Most research recorders are compatible with the high-impedance single-ended output of our doppler, but some require a low impedance signal of around 0.1 volt for a cm. of deflection and they just won't work with the doppler without a pre-amplifier.

4. An attempt is made to feed the signal from the earphone plug on the doppler to another device for either amplification or processing and it doesn't work. The most likely reason for this is that a single ended plug has been used which shorts out the stereo-type jack in the doppler. You must use a tip-ring-sleeve-type plug (stereo) to take off the audio signal.

True service problems can be broken down into the following general categories which are listed in the approximate order of their occurrence.

1. Failure of the probe. This accounts for about 90% of all the service problems. The user should keep a spare probe of the proper frequency on hand if he depends on the doppler.
2. Probe connectors or panel jacks are making poor contact and there is "static". The center pin wiping on the panel jack is usually at fault. A sharp tool can be used to bend the wiping sleeve inward and stop the noise.
3. Failure of the meter, battery or plastic case because the instrument was dropped. Battery bracket is sprung so that a good end contact is not made with zinc-carbon cells.
4. Leaking zinc-carbon batteries have corroded battery brackets so that good end contact is not made or corrosive fluid has penetrated end insulators causing electrical leakage to ground,
5. Component failure, un-soldered joint or poorly soldered joint, wire to battery or connector broken (perhaps only internally). Look for broken resistors around the edge of the circuit board. They may be broken inadvertently during the process of changing the batteries.

In general we suggest you return the unit to us for service that might be complicated or that may require transistors. The reason is that transistors are often selected for low noise or their d.c. operating characteristic. Customers in the U. S. (except Oregon,

Alaska and Hawaii) can call us free on our inward WATS line by dialing **800 547-6427**. Our regular business phone is **503 649-7007**.

2.22 Burdick EK10 Maintenance

There is no required operator maintenance or adjustment procedures for the EK10. In the event of a malfunction, or the need for an adjustment becoming evident, contact your Burdick dealer or service representative.

3. Safety Issues and Exclusions

None.

4. Participant and Exam Room Preparation

The examination room should be equipped with:

- standard examination table or hospital bed
- footstool for climbing on and off the table
- carts or tabletops for placement of the doppler and ECG equipment
- cart or tabletop area for computer equipment and monitor

The participant shall be dressed in a hospital examination gown.

5. Detailed Measurement Procedures

5.1 General issues, description

Before the test note whether or not there is a carotid bruit:

Carotid Bruit: Before palpating the artery, place the bell of a stethoscope over the artery close to the angle of the jaw. If a bruit is noted (the rushing sound produced by the turbulent blood flow) there is a distinct likelihood that there is a significant carotid plaque impairing blood flow. Note whether or not there is a carotid bruit on the Pulse Wave Velocity Tracking form in the Baseline Clinic Visit Workbook and proceed with the test.

During the testing procedure you will measure the following:

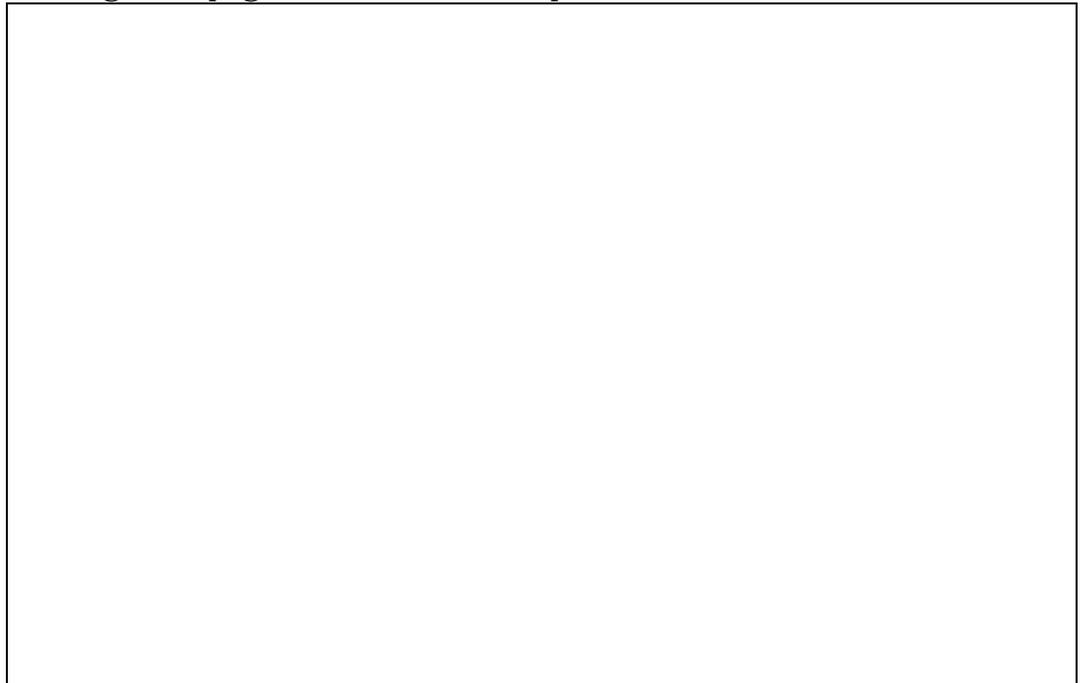
- a) A good quality EKG with a large R-wave amplitude.
- b) Doppler flow waves from the right common carotid and femoral artery.

- c) The distance from the mid-portion of the manubrium to the sampling site on the right common carotid.
- d) The distance from the mid-portion of the manubrium to the lower edge of the umbilicus.
- e) The distance from the lower edge of the umbilicus to the femoral artery sampling site.
- f) The systolic and diastolic blood pressure from the right arm, using standard techniques after 10 minutes of rest and before measuring the flow velocity.

The technique of pulse wave velocity measurement is straight forward and painless. As with any measurement, it must be done in a consistent fashion, making every effort to obtain the most exacting and detailed signals. You will record a doppler flow signal from the right common carotid and right femoral artery simultaneously.

A doppler probe is positioned proximally, on the carotid artery. Simultaneously, a second probe is placed on the right femoral artery. Ultrasound beams emitted by the probes will reflect off the moving column of blood. The reflected sound waves return to the probe with a different frequency. The shift in frequency or "doppler shift" is used to generate a visual flow wave signal (Figure 2). Figure 2 shows the approximate area for the placement of the probes. See Figure 3, page 9, for the proper placement of the carotid probe, and Figure 7, page 10, for the femoral probe.

If you then measure the arterial distance between the probes in centimeters and divide this value by the time in milliseconds, you obtain the velocity in cm per second. Again the stiffer the



arterial tree, the faster the PWV.

All measurements are done supine.

The blood pressure is taken during the early part of the subject's visit. Since you will need to place the ECG leads on the patient's chest, it is best to have them in a hospital gown. Use standard techniques to obtain the ECG signal and the systolic and diastolic blood pressures. The computer will need a good ECG signal from a standard ECG for analysis of the flow wave.

5.2 Administration of Test

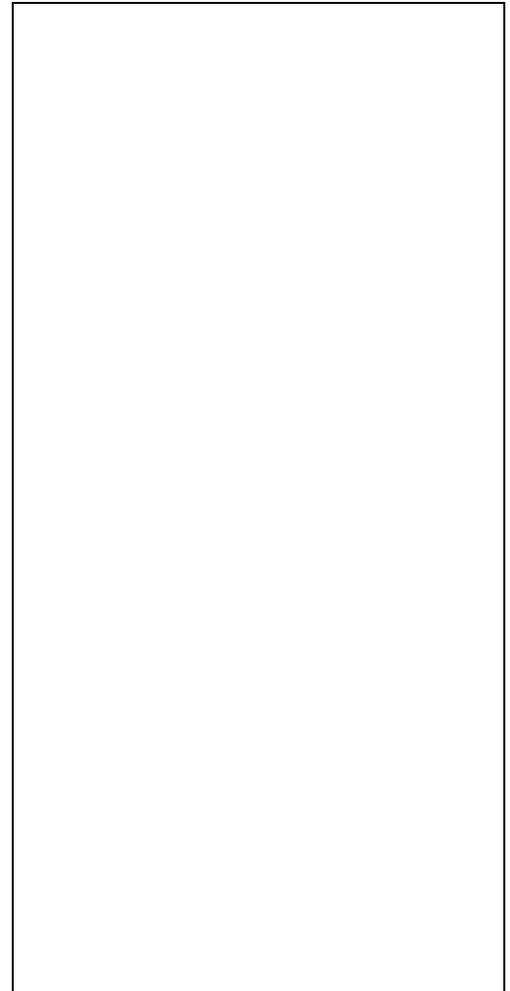
5.21 Placement of the Continuous Wave Doppler Probes

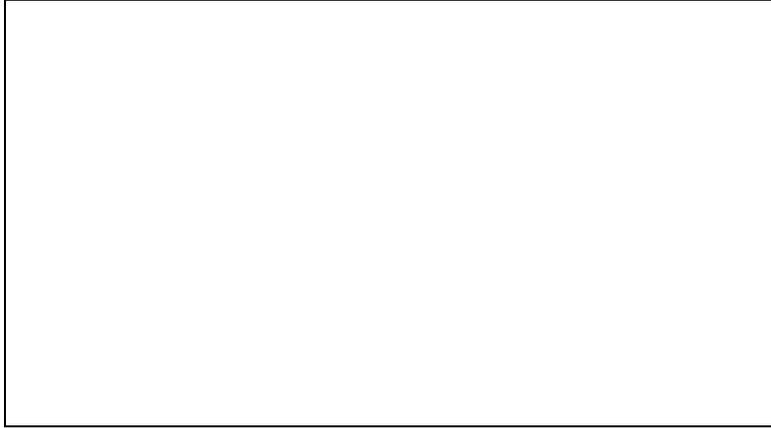
Carotid Artery:

The right common carotid artery originates directly from the arch of the aorta, by way of the innominate artery. Doppler flow wave forms are obtained from the point of the maximal palpable impulse along its course through the neck. (I on Figure 3)

Place the patient in the supine position with the chin elevated and the head moderately rotated to the left. To help assure the subject's comfort a small pillow or towel is rolled and placed under the nap of the neck to facilitate the comfortable extension of the head (Figure 4).

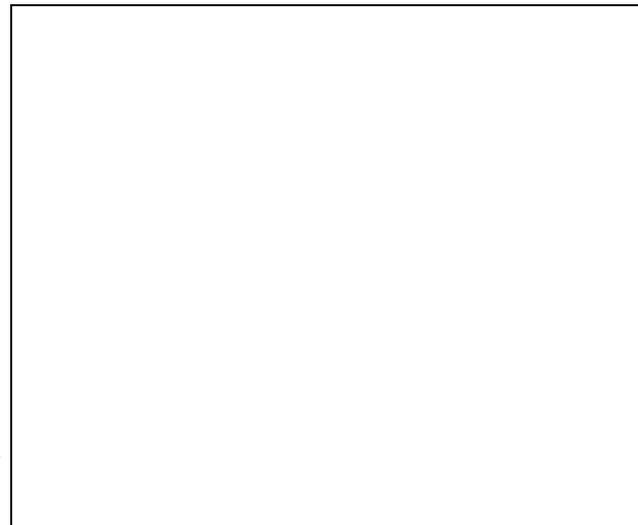
Before palpating the carotid artery, place the bell of a stethoscope over the artery close to the angle of the jaw. If a bruit is noted (the rushing sound produced by the turbulent blood flow) there is a distinct likelihood that there is a significant carotid plaque impairing blood flow. Note carotid bruit on Pulse Wave Velocity Tracking Form.





Carefully palpate the artery to find the maximal point of its pulse. This will be the place to sample the artery to achieve the highest fidelity recording. Mark this site with a tissue pen. You will need to know this site later to measure the distances.

Your primary goal is to obtain the most defined wave form to facilitate data analysis. Apply a liberal amount of ultrasonic gel to the skin. Carefully apply the probe (8.0 MHz) with a comfortable amount of pressure on the artery to achieve the maximal intensity of the flow wave signal. Generally, in a normal sized neck, very little downward pressure is needed because the sound wave penetrates the tissue so well. The wave should have minimal background noise, a stable baseline, **and a sharp foot at the onset of the upstroke of the flow wave** (Figure 5). The audible signal from the doppler probe will be loudest when



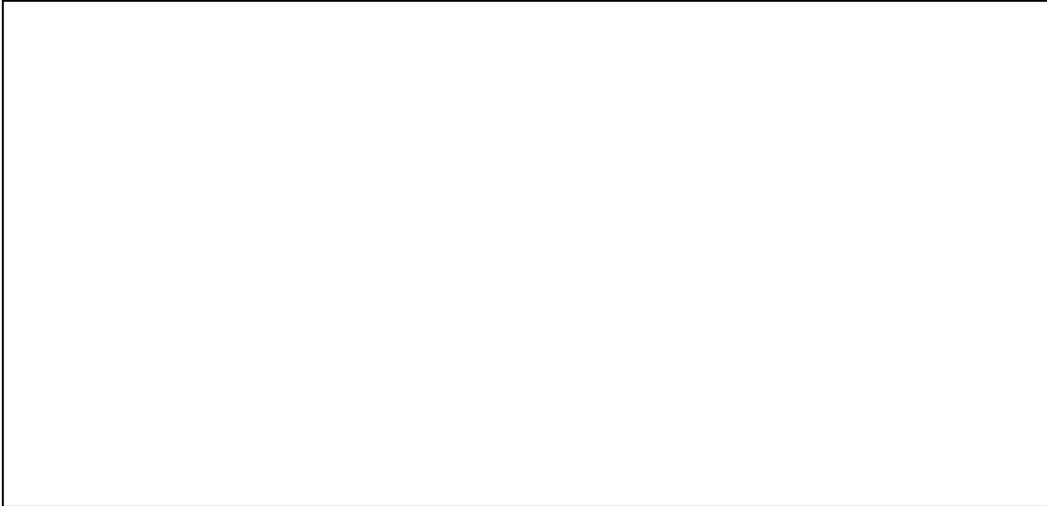
the wave form is most desirable. Adjust the angle of the probe on the carotid to provide the best wave form with the sharpest foot at the beginning of the upstroke.

Note the relationship of the flow wave signal and the respiratory cycle of the patient. If the signal increases in noise or intensity with inspiration you are likely getting some measurement of the jugular vein's blood flow which lies parallel to the common carotid. This is easily corrected by repositioning the probe either to the right or left to achieve a true arterial flow wave form. Be patient and remember that small changes in the angle or position of the probe can result in significant changes in the flow wave contour.

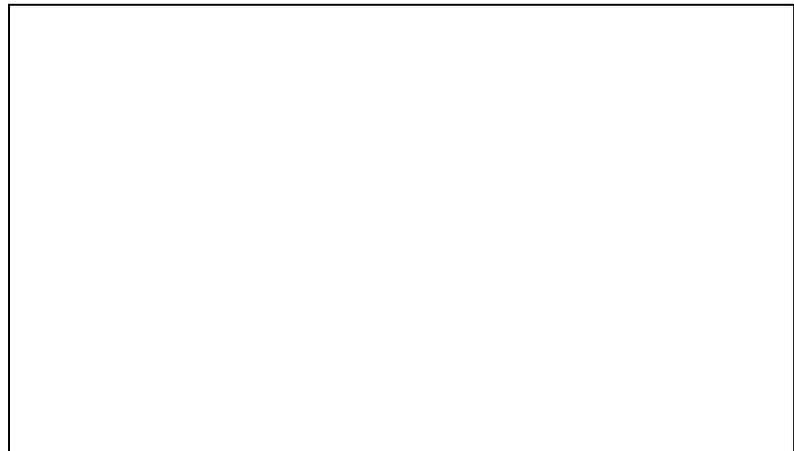
Do not stop measuring the proximal site in the carotid until your assistant has obtained a reliable femoral blood flow tracing. Once both probes are recording good quality signals, record several samples for the permanent record, by activating the foot pedal.

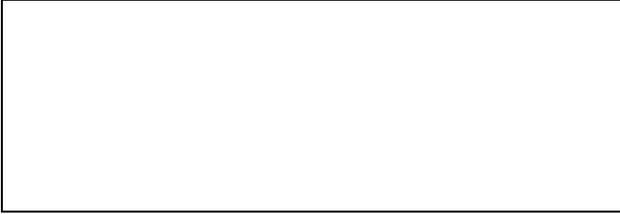
Femoral Artery

The right femoral artery is easily measured (III on Figure 3). This artery comprises the distal site and the signal is recorded simultaneously with the proximal site in the carotid.



The femoral artery is typically a large vessel with a strong pulse. It is normally used for cardiac catheterization. It is located below the inguinal ligament in the skin crease between the abdomen and the leg that diagonally crosses the groin (Figure 6).





Identify the inguinal ligament and palpate the femoral artery below the level of this ligament. Mark the skin with a marker in a manner similar to the carotid artery. With the second Doppler flow probe (9.5 MHz) and a generous

amount of ultrasound gel, find the maximal flow signal of the artery simultaneously with the carotid recording. **Remember to keep the angle between the probe and the course of the artery to less than 60°** (Figure 7). You may have problems with the femoral vein signal. As with the jugular vein signal it will fluctuate with respiration. The artery typically is found lateral to the vein or outside the femoral vein. Therefore, if the signal is noisy, try carefully moving the probe to the lateral aspect of the leg. Remember to always stay over the maximal point of the arterial impulse.

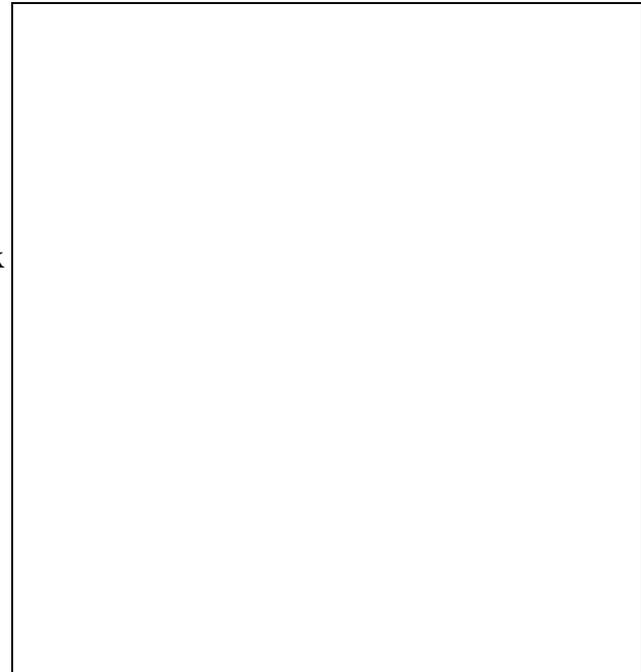
5.2.2 Measure the Distances

Three specific distances need to be measured. 1) The distance from the mid-portion of the manubrium to the sampling site on the right common carotid artery. 2) The distance from the mid-portion of the manubrium to the inferior edge of the umbilicus. 3) The distance from the umbilicus to the sampling site on the right common femoral artery.

The breast bone in the center of the anterior chest wall is composed of three bones (Figure 9). The uppermost is the manubrium, the middle and longest bone is the sternum, and the smallest and most inferior is xiphoid. You must first find the mid-portion of the manubrium. First, make a mark on the skin at the sternal notch. Then carefully feel along the manubrium to the level of the joint between it and the body. This is called the sternal angle or Angle of Louis and typically is raised. Measure this distance between these two points and make a mark at the midpoint. The mid-point of the manubrium is the key location for the other measurements.

a) Manubrium to Carotid Distance (MCD)

The MCD is measured from the previously marked sampling site of the right common carotid to the mid-point of the manubrium. Record this distance in centimeters. [Maintain measurement head position.]



b) Manubrium to Femoral Distance (MFD)

The MFD is comprised of **two** measurements. First, the distance from the mid-point of the manubrium to the inferior edge of the umbilicus. Second, the distance from the inferior portion of the umbilicus to the sampling site on the right common femoral artery. These two distances are added to give the MFD. For example the MFD = 36 + 12 (48). The software has two boxes that these two measurements should be entered into, and it will do the summing of the distance.

5.25 Blood Pressure Measurement

There are a few key points needed to make accurate measurements of systolic and diastolic blood pressure. The right arm is used for all patients. The proper cuff size is selected for the dimensions of the arm. The right arm should be bare from the shoulder to the wrist, as with a hospital gown. The pressure must be taken in the supine position with the forearm horizontal and relaxed.

There are three basic cuff sizes used: Adult (22.6-30.0 cm), Large Arm (30.1-37.5 cm), Thigh (37.6-43.7 cm). Each cuff has a distance range to indicate weather it fits. Too small a cuff will result in over estimation of the pressures, too large a cuff will underestimate the pressures. The mid portion of the cuff should be over the brachial artery. The lower edge should be 1 inch above the crease of the elbow.

To accurately measure systolic pressure inflate the cuff while palpating the radial pulse. Note the pressure in the cuff that causes the radial pulse to disappear. Deflate the cuff completely. Re-inflate the cuff to a pressure that is 20 mmHg higher than the pressure needed to occlude the radial artery. Systolic blood pressure is noted where the first of 2 or more sounds are heard in appropriate rhythm (1st phase). The diastolic blood pressure is recorded where the last of the rhythmic sounds are heard (5th Phase). A single sound heard in isolation before the first sound (SBP) or after last sound (DBP) does not meet criteria.

Two supine blood pressure measurements are taken early during the subject's visit, and they are entered in the patient information screen. Enter one on the **1st BP** line, and the second on the **2nd BP** line. The computer will average these two readings and enter them in the proper unlabeled line on the patient information screen.

Summary Table**Essentials for the proper measurement of the blood pressure****2 blood pressure readings than average the values****Systolic BP is the first sound****Diastolic BP is the last sound**

**Deflate at a rate of 2 mm per second.
Have the proper cuff size.**

5.2.3 Data Acquisition

System Startup

Startup of the PulseWave Study system involves turning on the computer and the letting it boot into windows. At the time of shipment, the system booted with the **PWV Stuff** group present in the Windows screen. A sample

Program Manager Screen is shown as Figure 9. This screen shows the **PWV Stuff** group shown as the active group on top of the Main program group. This is the way one system boots, and the way that the system was configured when it was shipped from Gerontology Research Center, NIA.

The system could possibly come up with the **PWV Stuff** hidden from the operators view. In the case of a "missing"**PWV Stuff** group, click on the Windows Program Manager Bar selection **Window**, shown in Figure 10. This can be done either by clicking the mouse on the **Window**, or holding down the Alt key and pressing

the **W** key. This will bring down the Window menu, which includes some of the following items (not necessarily in this order).

Cascade
Tile
Arrange Icons
1 Main
2 Accessories
3 Applications
4 StartUp
5 Games
6 Microsoft Tools
7 Visual Basic 3.0
8 PWV Stuff
More Windows



If the **PWV Stuff** group shows in the list, click on the listing, and the computer will bring that group to the foreground in the Program Manager window. If you do not see the **PWV Stuff** listed in the Window list, click on the **More Windows** line. This will bring up the **Select Window**, as shown in Figure 11. The **Select Window** shows that **PWV Stuff** is highlighted. This is not necessarily what you will see on your computer. You may have to press either the up or down arrow on the right hand side of the box to display additional windows. When you have **PWV Stuff** highlighted, press on the **OK** button, and the **PWV Stuff** window will become the active group. The size of this display may vary.



System Functions

Once the **PWV Stuff** is the active group, you will have five selections. These five selections are shown in Figure 12. The selections are:

Acquire
Archivp
Archivf
Review
Edit PWP.INI

Double-clicking on the icons will result in the following actions:

- Acquire** The Acquire program will run to take data from the subject. The program will run continuously displaying data until the **Done This Session** button is pressed. This program will run without having either a floppy or a PCMCIA drive present.
- Archiv*** The **Archivp** and **Archivf** Programs are run to archive data that has been taken at the site. It is automated to write data to either a floppy disk (**Archivf**) or the PCMCIA disk (**Archivp**). The program automatically locates files on the hard drive, loads the file names into a list, displays the list on the screen, and waits instructions. When selected, it checks the data, copies the data files, and verifies that a valid copy was made. It then moves the data from the data file to a backup directory, maintaining a second copy in the event that the disk(s) get lost by the shipping organization.
- Review** This program enables the investigators to review data taken at the site. It will draw the screen, and enable the investigator/program coordinator to personally 'grade' the operator's work.
- Edit PWP** The Edit PWP.INI icon is present to make editing the Pulse Wave Program initialization file easy. This is not normally necessary, and should only be done on instructions from one of the Pulse Wave Study coordinators located in Baltimore.

Acquire Program

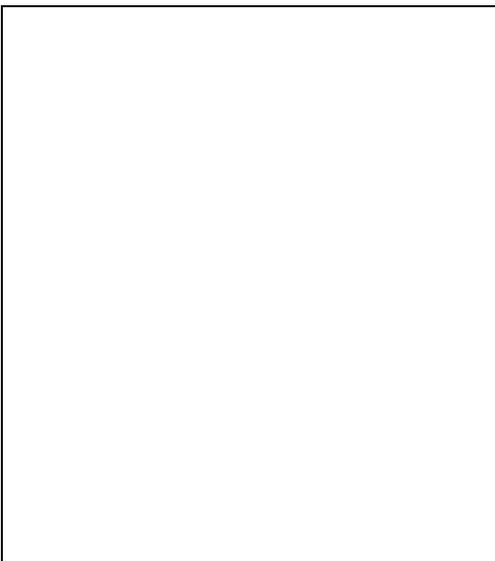
Figure 13 is a copy of the Acquire screen in operation. It is mandatory that you start the **Acquire** program to fill out the patient information. Once started, all data recording operations must first be preceded by pressing the **Patient Information** button on the **PWV Data Recorder** screen.



Patient Information Screen

The first thing that should be done from the **PWV Data Recorder** screen is to press the **Patient Information** button on the bottom of the screen. When this button is pressed, Figure 14 will be superimposed over the PWV Data Recorder screen. Once the data fields are filled in, you are ready to begin to locate the signals.

The **Patient information** screen is used to enter data about the subject into the data file header. Fill in the Patient ID block with the proper numeric identification that identifies the patient to be tested. Operator Identification numbers are entered into the blocks for Operator1 and Operator2.



Enter the distance measured (in Centimeters) from the mid portion of the manubrium to the common carotid reading point in the box labeled Sternum to Carotid. Enter the distance measured (in Centimeters) from the mid portion of the manubrium to the femoral reading point in the box labeled Sternum to Femoral. Blood pressure systolic readings are placed in the left hand boxes

labeled **1st BP:**, the diastolic is placed in the right hand boxes. Pressing **TAB** will cause the two BP's to be averaged and place in the boxes below the **2nd BP**. Once the data is **properly entered**, press the **OK** button at the bottom of the screen. If you have made mistakes, and want to start over, press cancel. Then press the Patient Information button on the PWV Data Recorder screen to begin the entry of patient information again.



A properly completed Patient Information screen is attached as Figure 15.

Operation of the Patient Information button follows this explanation of the controls on the **Data Recorder** screen.

During the operation of the **Data Recorder**, there is a need to understand the controls that we have built into the operation of this program. In order to 'simulate' the EKG machine speed controls you may or may not be familiar with, we have included different display speeds. Normal use is in the **1 inch per second**, but you can select either **2 or 3 inches per**

second. This will give you a more **detailed display** of the data you are taking. This does not effect data acquisition.

There are two buttons on the screen **Start Recording** and **Stop Recording**. These buttons enable you to start or stop the recording cycle. However, we have learned with our original system, the operator has his/her hands full when he/she is taking readings, so it is very much of a problem to get to a mouse or keyboard when holding doppler probes. As a result, we have included a foot pedal switch which duplicates the **Start Recording** button.

The **Reset Traces** button is the most important button we have on the screen. This button serves to set/reset the gain of the display on the screen. In the initial setting, it sets the ADC (analog/digital input card) between 0 and the maximum the card can sample. As you get the display drawing traces that are coming from the proper signal transducers, you will find you will have to press the **Reset Traces** button multiple times to get the traces to display properly on the screen. If any trace looks like a straight line or appears very noisy, it may be necessary to press **Reset Traces** one or more times. Data is recorded independent of what is displayed on the screen. (This will be necessary

to get the normal drift and/or **gain** set up for the instruments as you begin a study.) The **New Patient** button on the **PWV Data Recorder** screen resets the Patient Information to blank data. This is to simplify entry of a new subject. The blank record forces the operator to enter all data, and, hopefully, prevents a record from being created with the wrong information in it.

In addition to the **Reset Traces** button, we have added an **AutoReset** button. This button is a toggle that turns on or off an automatic **Reset Traces** routine. This has been done to free up the hands on requirement to get the trace back into the center of the screen. When it is activated, there is a little red box next to the toggle. While not recording, the program will automatically run the **Reset Traces** routine every 5 seconds. When you start recording, the reset is turned off, but reactivated when the recording is finished.

Inverted Traces appear periodically on the Doppler traces. We have simplified the method to reverse the direction of the trace with the stroke of a key on the Number Pad on the computer keyboard. If the first doppler trace has inverted, press the 1 key on the number pad. The computer will respond with a beep and the trace will begin to be drawn in the reverse direction. If the second doppler trace is reversed, the 2 key is pressed, the computer will beep and reverse the direction of that trace. Pressing either 1 or 2 will toggle the direction again if necessary.

Once you get the traces properly and the patient information entered, press the footpedal switch to cause the computer to start taking data. You can take multiple records on the **SAME PATIENT** by pressing either the **footswitch** or the **Start Recording** button on the screen. The label at the top of the screen will change to **RECORDING** and the computer will capture the data that is displayed on the screen.

Upon completion of the testing with this subject, you can either press the **Done This Session** button to return to Windows Program Manager (if you are finished for the day), or you can press **New Patient** to clear the patient information and start to input information about your next patient.

Review Data Program

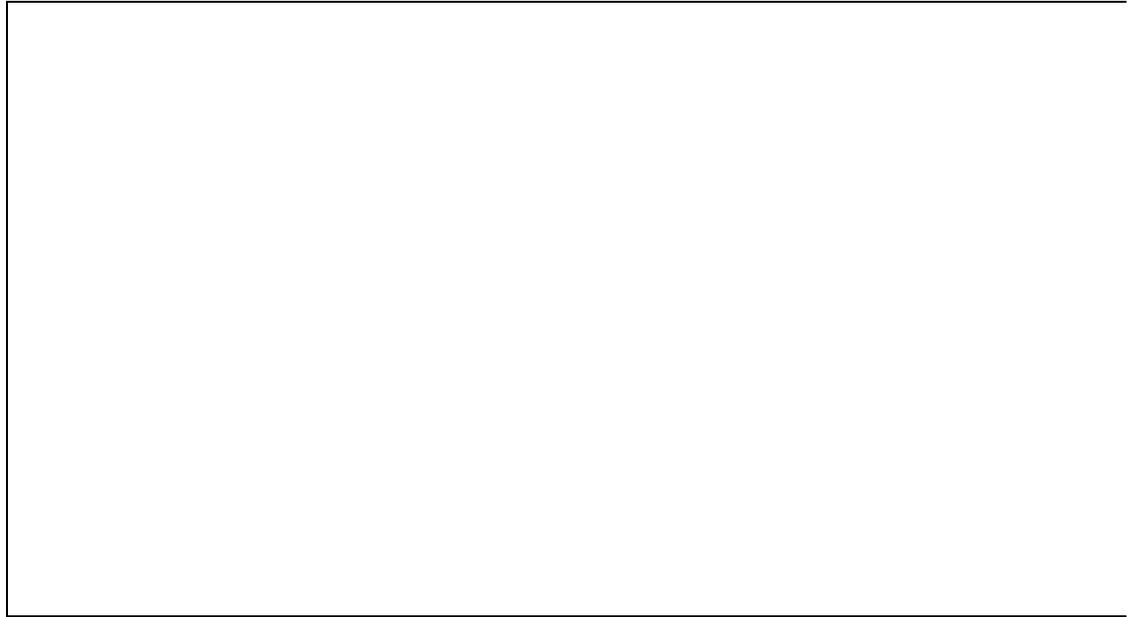


Figure 16 is the **Review Data** screen. It is powered by the Review Program and is used to review data that has previously been captured by the acquire program. It gives the reviewer-operator the ability to review data and classify the quality of the data being returned to NIH. The **Review** program can be used by either the operators themselves, or the Principal Investigator, to check on the quality of the data taken before it is transferred to Baltimore. The program requests that the reviewer sign himself/herself on by using the Reviewer Checkbox if the person wants to assign quality or review the patient data. Once again, if you are reviewing, select only the reviewer number or operator number that you were assigned for this study. Do not use any reviewer number that is assigned to someone else. The button to **Review Patient Info** will present the **Patient Information** screen over top of the **Review Data** screen.

This enables you to check the information that has been entered into the original data information screen. The **Assign Quality** checkbox will present the following choices for the reviewer to assign quality to a trace:

- 0 - **NO GOOD!**
- 1 - Marginal Quality
- 2 - } Acceptable Quality
- 3 - } Acceptable Quality
- 4 - } Acceptable Quality
- 5 - } Acceptable Quality

Assigning quality appends several bits of information into the header block written to the data and transferred to Baltimore. This data is that the run's quality was checked by the personnel at the site,

and that the site reader's subjective reading states that the quality of the recording is X, where X can equal 0, 1, 2, 3, 4 or 5. While 2, 3, 4, and 5 all represent **ACCEPTABLE QUALITY**, you can further grade this quality with 5 representing the best trace ever seen!

An additional feature of the **Review Data** screen is the adjustable gain controls that are on the right hand side of the screen. (This option is not currently available in the **Acquire** software.) A sample of one of these gain controls is shown in Figure 17. These gain bars are used by placing your mouse pointer on either the top or the bottom line, pressing the left mouse button, and pulling down or pushing up. The bar will either get longer or shorter, and when you release it, the trace of matching color will have its gain recalculated with its top and bottom limits being either end of the gain bar. There is one gain bar for each trace on the computer display.

Copy Program

The **Copy Screen** (Figure 18) is used in conjunction with either of the archive programs, **Archivf** or **Archivp**. The main difference between these two programs is the ultimate destination of the archived data. **Archivf** writes the data to a floppy disk drive, and **Archivp** writes its data to the PCMCIA drive. This program automatically checks the data directory, finds all files that are available for transfer and archiving. It will list the file number in the left most column under **Run**. When the **Do 'em** button is pushed, the program processes the data files in the data directory. Each file is opened prior to copy to verify that it is a valid file, the header is checked by being read, the correct site information is present, and the length of the file is verified. The computer will then copy the file from the data directory to the

archive directory. The makeup of both data directory and archive directory are compared, and if they are the same, the file in the data directory is deleted. The



Crash button is designed to be able to stop the copy backup while it is running. It gives

a clean way to exit from the operation. The **Ok** button exits the program and returns you to the Windows Program Manager.

7. Alert Values/reporting to participants

The measurements made at the time of the visit are raw values and must be reviewed by the reading center. No direct clinical information is provided by these measures or needs to be reported to the patient at the time of the test. Pulse wave velocity readings generated at the reading center are experimental numbers. The clinical significance of these values is hypothesized but not clearly determined. Therefore, even if the values are outside of normally distributed values, they will not be reported to the patient.

The blood pressure measurements obtained at the time of the test are often helpful. Values for the SBP and DBP greater than acceptable clinical values should be reported to the subject per previously defined Health ABC protocols.

8.1 Training and Certification

Qualifications

The measurement system has incorporated many tools to make it as simple as possible to run. Individuals who will make these measurements should have some clinical background and prior patient testing experience.

Certification is granted to the user when the user demonstrates that he/she can capture the proper signals from the carotid and femoral arteries.

9. DataTransfer Instructions

The method of handling the Pulse Wave Velocity data transfers from the HealthABC sites to Baltimore should be handled bi-monthly and are as follows.

1. Use the ArchivP icon on the computer to locate and copy the files to the PCMCIA disk drive. When the archive of data is complete, put the PCMCIA disk in its carrier, and package in a Federal Express or UPS envelope for shipment.
2. The ship to address is as follows:

Paul Pullen
Gerontology Research Center/NIA/NIH
4940 Eastern Avenue, Box 13
Baltimore, MD 21224-2780

3. Drop the disk at your local FEDEX/UPS pickup location.

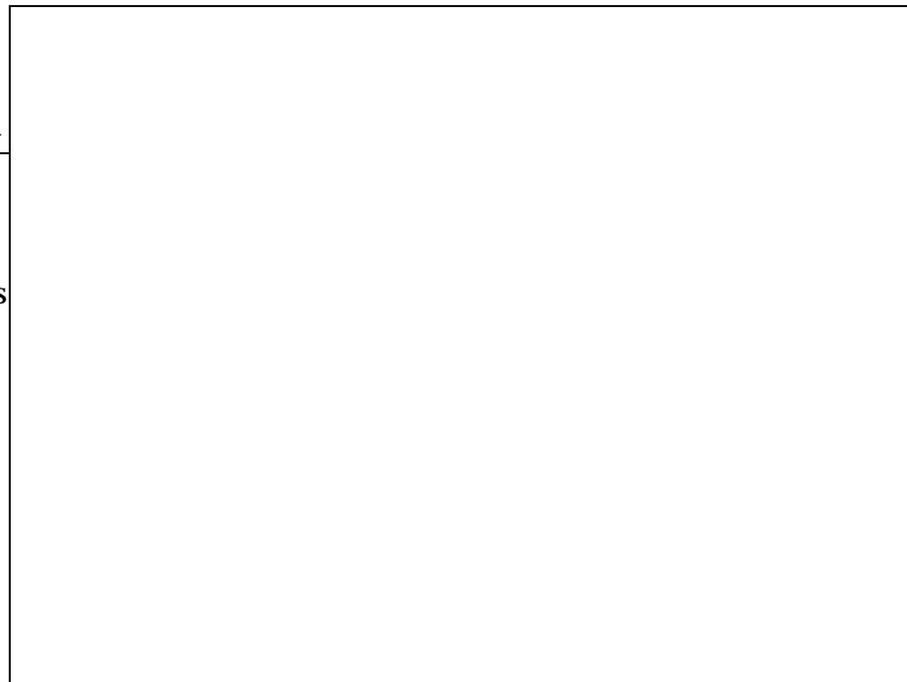
When we receive the disk, we will extract the files and archive them on our network drive where we have the Not Reviewed data. The drive will then have the transferred, datafiles deleted and be processed for return to the site by FEDEX. (NIA has a contract with FEDEX, and we cannot use UPS as our shipping company.)

Any questions/problems, please feel free to contact Paul Pullen at (410)558-8646 or by e-mail as pullenp@grc.nia.nih.gov for assistance.

Appendix: Examples of acceptable and unacceptable PWV Curves

Example of a GOOD Pulse Wave Velocity curve:

In each case, the top curve is ECG, and the next two are assumed to be neck and femoral pulsewave curves, although we sometimes note that the



probes have been reversed (as evidenced by the arrival or the pulse at the femoral before it arrives at aortic arch!). The second “bump” in the lower trace isn’t ideal but does not interfere with assessment of the initial upstroke of this channel. There is no ambiguity in determining where the initial upstroke begins for either trace in beats 1 thru 8. Beat 9, and the start of beat 10 off the tracing to the right are not usable because of the movement artifact at the start of the upstroke, but sufficient beats were good in this curve for analysis. We seldom see a perfect trace for an entire record!