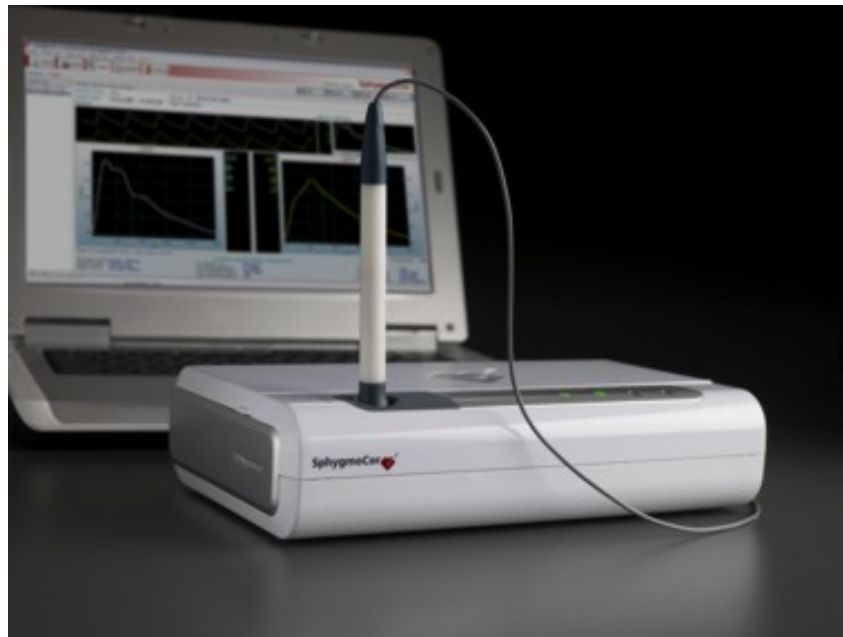# SEARCH 4 MOP

Section 13 - Cohort Visit - SphygmoCor Procedures

HEART RATE VARIABILITY (HRV) THEORY OVERVIEW

- HRV analysis is the ability to assess overall cardiac health and the state of the autonomic nervous system responsible for regulating cardiac activity
- We analyze HR because during normal sinus rhythm HR varies from beat to beat as a result of multiple physiologic mechanisms
- One of these mechanisms, the autonomic nervous system, influences short-term HR regulation
- HRV examines the balance of the sympathetic and parasympathetic nervous systems
- The ECG signal is analyzed to determine the difference in timing from beat by beat (R to R intervals).
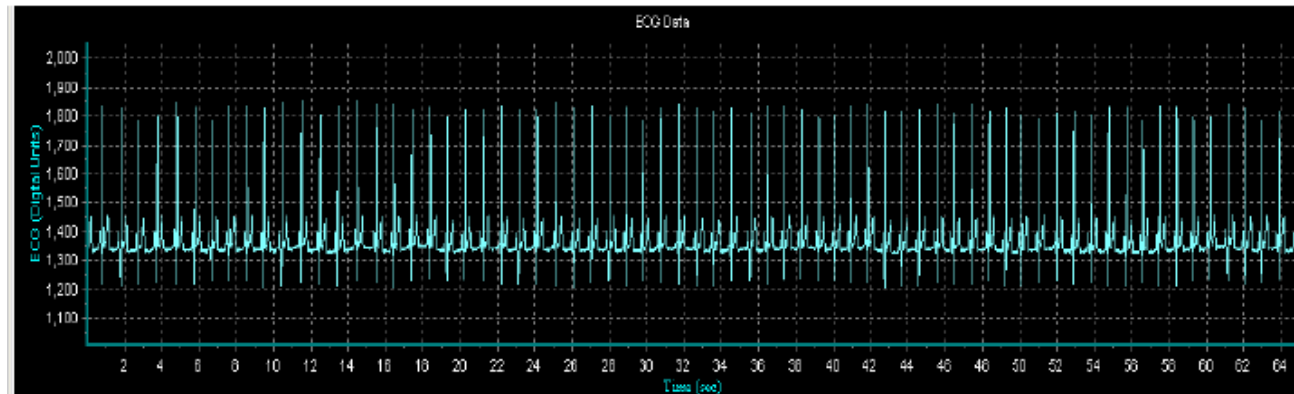

- HRV assessments can be performed over a short period of time (10 minutes) or a longer period such as 24 hours.
- Since HRV is governed by the sympathetic and parasympathetic systems, HRV analysis helps to provide a window to observe the state and integrity of the Autonomic Nervous System (ANS).
- Heart rate variability measures the time delay between sequential QRS complexes in the ECG.

- The SphygmoCor system uses these time delays to determine the normal-to-normal (NN) interval time.
- Once all of the intervals are obtained, the results can be analyzed in the:
  - Time-domain: analysis with respect to time (statistical analyses including standard deviation - variability)
  - Frequency domain: analysis with respect to frequency of HR oscillations (changes).

Time Domain HRV Measures

- <u>SDNN</u>: The standard deviation of all of the R-R or Normal-to-Normal (NN) intervals is calculated.
- It reflects all the cyclic components responsible for variability in the period of the recording.
- It is an estimate of <u>overall</u> HRV
- <u>SDANN</u> is the standard deviation of the average of the NN intervals calculated over short periods (5 minutes)
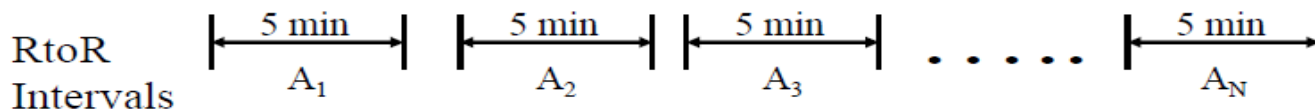

$$SDANN = STD(A_1, A_2, \ldots, A_N)$$

Where A is the average R to R values of the 5 minute period

- It is an estimation of the changes in heart rate due to cycles longer than five minutes
- It reflects circadian rhythmicity of autonomic function.
- A decreased SDNN has been associated with sudden cardiac death and is associated with LV dysfunction after acute MI.
- PNN50 is the proportion of successive R-R Intervals with a difference greater than 50 msec.
- Reflects alterations in autonomic function that are primarily vagally (parasympathetic) mediated.
- It is virtually independent of circadian rhythms.
- RMSSD: The root mean squared successive difference is the square root of the mean squared differences of successive NN intervals
- RMSSD is an estimate of the short-term components of HRV
- It also reflects vagal tone.

Geometric HRV Measures
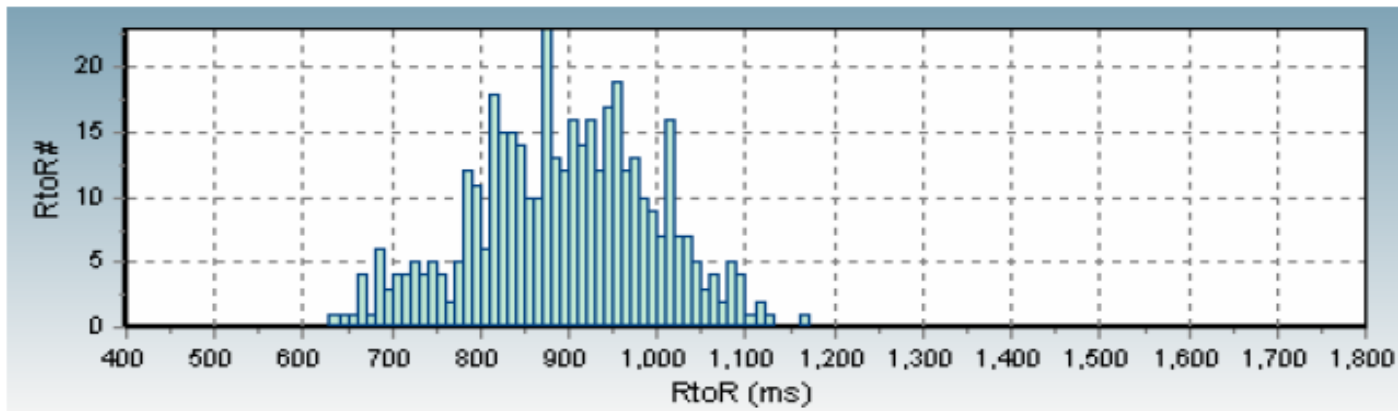
- Triangular Index = the integral of the density distribution divided by the maximum of the density distribution and given in msec
- It is an estimate of the overall HRV

Frequency Domain HRV Measures

- Also called 'Spectral Analysis' or 'Fast Fourier Analysis'
- Frequency of oscillations in HR are defined as:
  - Low Frequency = 0.04-0.15 Hz
    - influenced by both <u>sympathetic</u> and <u>parasympathetic</u> activity
  - High Frequency = 0.15-0.4 Hz
    - corresponds to <u>parasympathetic</u> activity
    - considered to be a marker of vagal activity
- The ratio of LF/HF represents the balance of parasympathetic and sympathetic activity
- More appropriate for short-term recordings (2-5 minutes)
- In patients surviving an acute MI, there was a reduction in total and individual power of spectral components
- In diabetic autonomic neuropathy you will find:
  - Reduced power in all spectral bands
  - Failure to increase LF on standing
  - Abnormally reduced total power with unchanged LF/HF
  - A leftward shift in the LF central frequency

Types of HRV Measurements

- Resting
  - Time Domain
  - Frequency Domain
  - Geometric Measures
  - Poincare plots

- Stress
  - Orthostatic (standing manoever)
  - Valsalva
  - Controlled breathing: since one of the main drivers of HRV is respiration.

SEARCH 3 is only collecting data at rest

GENERAL INFORMATION

The SphygmoCor test is not a clinical or diagnostic test. The research team members are not trained to interpret the tracing or the results of the SphygmoCor test. However, if the research team member notes a concern on the SphygmoCor tracing and the participant does not experience or spontaneously report any symptoms (dizziness, lightheadedness, shortness of breath, fainting), the research team member will save a screen shot and send the screen shot by email to Elaine Urbina for review and interpretation. Further action will be dictated by Elaine's interpretation. See page 54 for an explanation of the procedure for exporting screen shots.

Subjects will be asked to refrain from using vaso-active drugs the AM of the test (tobacco, caffeine, decongestants, asthma medications). Prior to beginning the SphygmoCor testing, ask the participant questions 1. thru 3. on the SEARCH SphygmoCor form and record their responses. If the subject responded "yes" to any of these questions, the test may still be performed (see Appendix A).

Order of Testing
- HRV
  - *1 recording of exactly 10 minutes will be collected while resting*
  - Must be resting (at least 5 minutes)
  - Can measure distances for PWV during rest (remember to put towel on foot to keep it warm)
  - Can't press on carotid artery (changes autonomic function)
- PWV
  - *3 readings each of carotid - femoral, carotid - foot then carotid - radial will be obtained in that order*
  - Can convert to PWA if good quality tracing

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- PWA
  - *3 readings will be obtained,* but if high quality carotid-radial tracings obtained from PWV can skip PWA

Prepare the Device

Connect the Type B Plug to the rear of the Electronics Module labelled
Connect the Type A Plug to the computer, at USB port indicated by label.

Connect the Type B plug to the rear of the Electronics Module

Connect the Type A plug to the computer

- The device should be locked in a secure location after use.
- The room should be maintained at a normal ambient temperature.
- Use the USB Cable supplied with your system. It is a special cable that provides the power to the Electronics Module and the means for the computer to communicate with the Module.
- Connect the type B plug to the Electronics Module.
- Note the labels on your notebook computer and connect the type A plug to the specified USB port, failure to do so will result in an error and the computer will not recognize your module.

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- Attach the ECG cable to the side of the module
- Turn on the PC.
- The Standby/Ready indicator will be orange.
- Open the SphygmoCor software by double clicking the icon on the desktop.
- The Standby/Ready indicator will turn green (ready to take a measurement).
- If the module has any errors it will change to red.

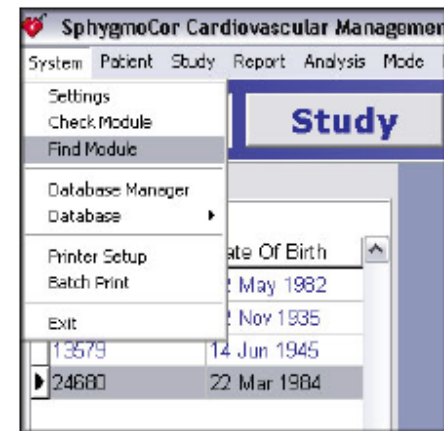## Communication Errors

- If a COMMUNICATIONS ERROR appears it is because either:
    - (a) The electronics module is not connected to the computer
    - (b) The electronics module is not switched on
    - (c) The selected computer communications port is incorrect.
- Click YES if you wish to try detecting the module again.

- If the module is not detected on its second attempt a message window will appear prompting you if you wish to change the configuration settings.
- If you click YES the SphygmoCor Configuration Window will appear, allowing you to change the computer communications port to which the electronics module is connected.
- If you only connect the device to the specified USB port on your laptop, you will avoid this problem.
- For help with determining the number for your USB ports on your computer, contact the Ohio or Colorado study sites.
- You can also try to automatically find correct communication port.
- 'Find Module' assists in detecting the SphygmoCor System communications port

- Accessed by clicking 'System,' then selecting 'Find Module'
- Pop-up box will appear confirming that the search is about to begin
- After searching all available COM ports, the software automatically selects the appropriate COM port
- Results will be displayed

Select SEARCH 4 Database
- Select the correct database for the study
- Click on System then Database manager and a list of databases appears
- Use the up/down arrows to scroll to and highlight the SEARCH 3 database
- Click on Select (lower left hand corner) and OK.

Warning Communication Error (#504)

The Communications Port specfied is in use by the System or does not exist. PortID = 1

OK

SphygmoCor Cardiovascular Managemen

System Patient Study Report Analysis Mode

Settings
Check Module
Find Module

Database Manager
Database ▶

Printer Setup
Batch Print

Exit

Study

ate Of Birth
May 1982
Nov 1935
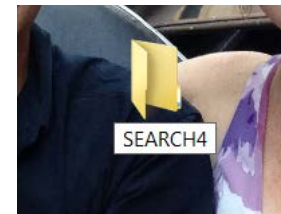13579   14 Jun 1945
▶ 24680   22 Mar 1984

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SphygmoCor: *Creating a New Database*

- Click on *System* (upper L toolbar)
- In drop-down, select *Database Manager*
- Enter SEARCH4 for Name & description
- Click on *Create New* lower left corner
- Click *OK* to open
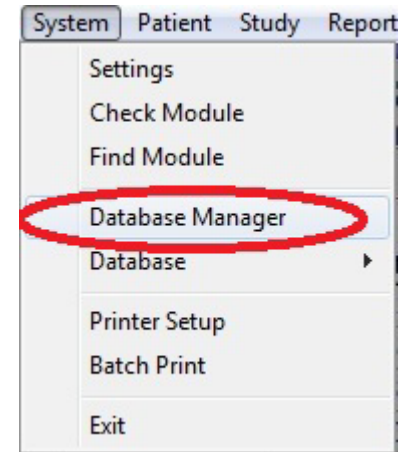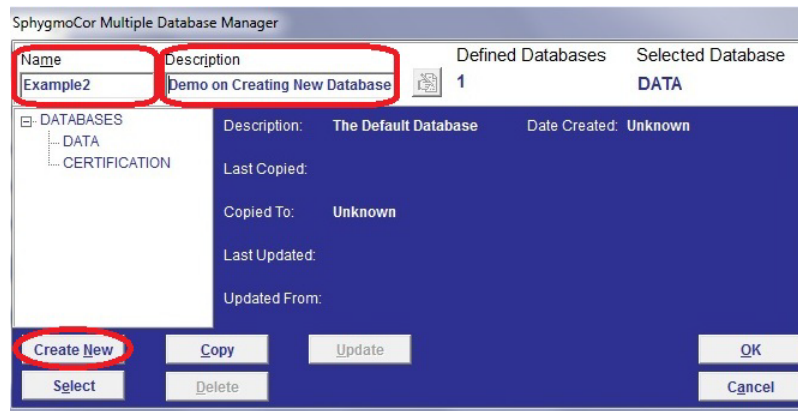
- Create Folder on Laptop Desktop
- R click on Desktop and scroll to New then Folder.
- Name the new Folder SEARCH4

PREPARE THE SUBJECT

- Offer the subject a Nutrigrain bar and water (standard snack). If the participant has celiac disease, you may offer a Glutino bar as a gluten-free alternative. Record what the subject ate on the SEARCH SphygmoCor form, question 4 (see Appendix A).

- Obtain (3) BP measurements using the SEARCH protocol.

- Have the subject lie down with their arms alongside their body and their RIGHT palm facing upwards.

- Be sure that the patient is positioned so that both the patient's and operator's complete forearm can rest on a firm surface.

- Enter (3) BPs obtained previously into the SphygmoCor worksheet. Save the worksheet with SEARCH4 ID number.

- For a copy of the worksheet see Appendix B.

Apply ECG Leads

ECG leads can be applied to the Chest or the Limbs. The advantage of using the chest is that signals may be stronger when using the chest than when using the limbs. Using the chest, however, can be more invasive to the participant's privacy. In some cases, chest placement may require chest hair to be shaved. For taller participants the lead wires may not be long enough for limb lead placement.
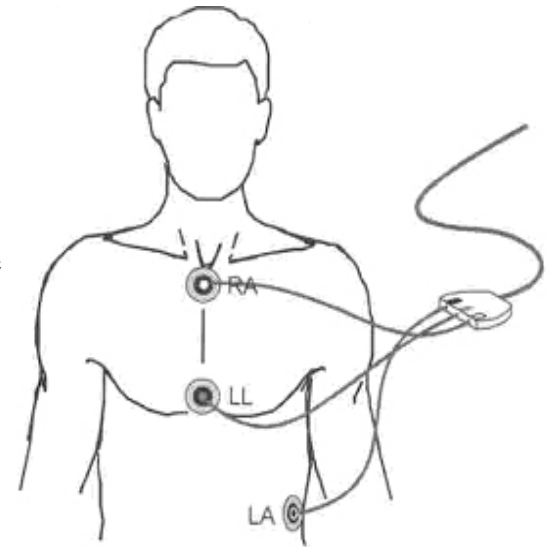
Before applying the ECG leads, use alcohol swabs to remove skin oils/creams. If tracing is poor then try re-prepping the skin and consider using abrasive ECG prep paste. Try changing the ECG leads (they may get dry).

Chest placement of Electrodes:

- White ECG (RA) on top of sternum
- Black ECG (LA) on left side of abdomen
- Red ECG (LL) on bottom of sternum

Limb Placement of Electrodes:

- White ECG (RA) on the right arm
- Black ECG (LA) on left arm
- Red ECG (LL) on the left leg
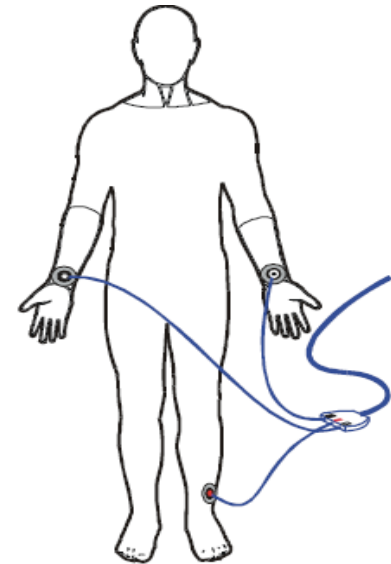
Electrodes on Peripheral Limbs

ENTER SUBJECT DATA

- Click on NEW Enter subject ID number
- Enter X for LAST name
- Enter X for FIRST name
- Leave DATE of BIRTH at January 1, but change to 1950. The software will not allow PWA on kids less than 18 years.
- Enter GENDER.
- Click SAVE and YES when it asks if you want to accept the changes.

Patient Button to go to Patient Screen

Patient Browser lists all subjects in active database

Create New Button

Fields requiring information to be entered

Save button will be active in 'Create New' patient mode

PERFORMING THE HRV TEST

- Select HRV from the right of the screen.
- Click on STUDY and patient screen appears.
- Enter the staff ID number in the OPERATOR box.
- Enter DBP & MAP.
- Be sure HRV calculation is selected.
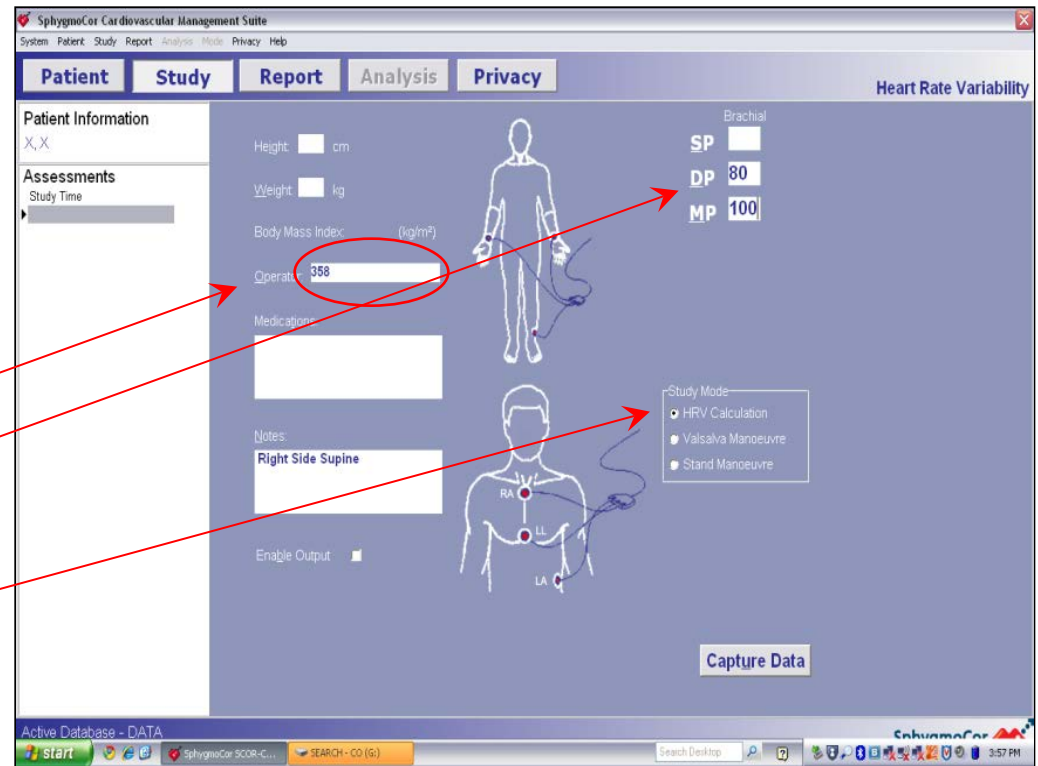
- Tell the subject to lie still as the test is about to begin.
- Press the capture button. During the capture, the blue ECG indicator labeled on the front panel will be illuminated.

ECG Data

Beat to beat R-R intervals

'Start Session' and 'Calculate' buttons for HRV measures

- You will see a horizontal trace of ECG in the <u>ECG Data Capture </u>Window. Ensure that a quality ECG trace is seen but the beat to beat R to R intervals chart is not yet activated.
- When you are satisfied with the quality of the signals, start recording by pressing the <u>Start Session</u> button on the top right of the screen.
- The <u>beat to beat R to R intervals chart</u> will now be activated and updated every 5 seconds.
- Values relating to Elapsed Time, Number of Pulses, Average R to R Interval and Average Heart Rate will also be updated every 5 seconds.

Check ECG Leads

- If tracing poor (irregular baseline or T waves that are as tall as the QRS), place new leads closer to the R & L shoulder and on the L side of the abdomen.
- If this does not improve the tracing, use chest placement.
  - WHITE ECG (RA) on top of sternum.
  - BLACK ECG (LA) lead on the L side of abdomen.
  - RED ECG (LL) on the bottom of sternum.
- If no improvement:
  - re prep the skin and consider using abrasive ECG prep paste
  - Change ECG leads (get dry).

Alternate ECG Placement on Chest

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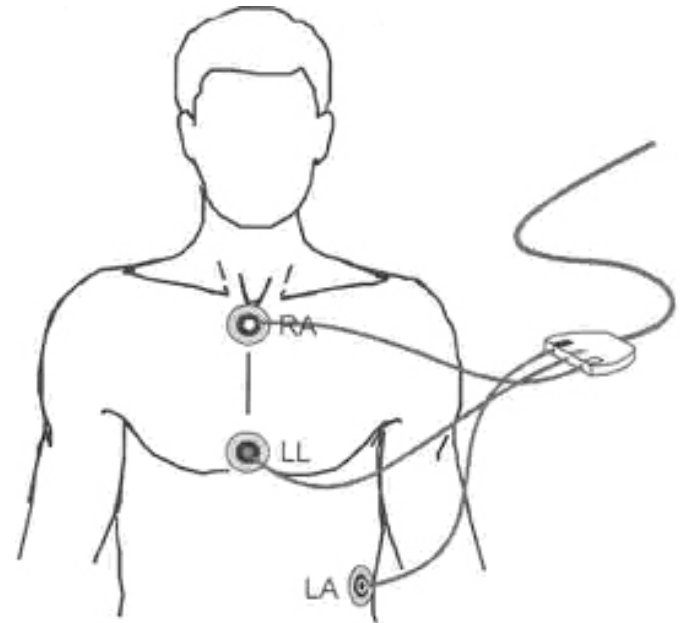
Generate Report

- After 10 minutes of good quality data, press the Calculate button in the top right of the capture screen or press the Footswitch. (The foot pedal may not work as well as the spacebar, but it will not result in invalid data.)
- The HRV Report Screen will be displayed.
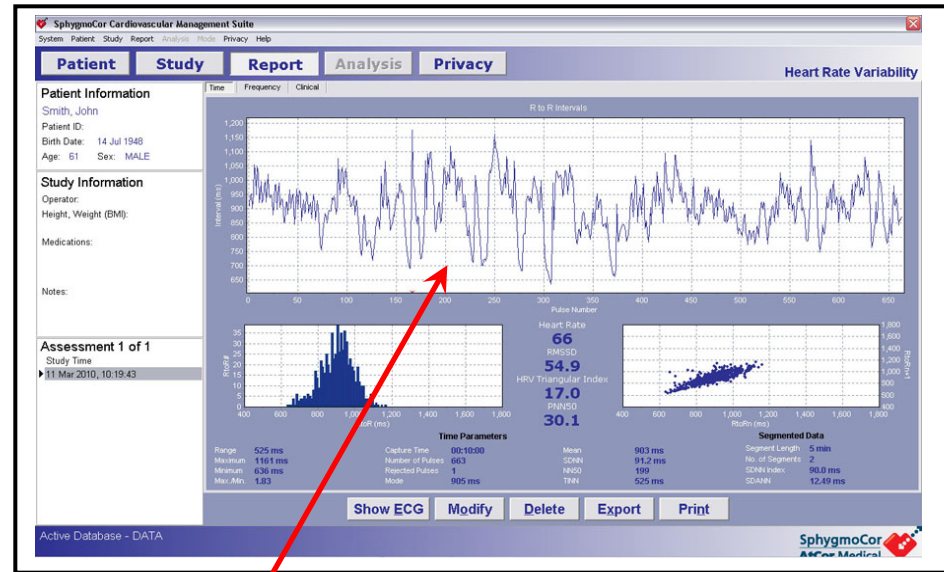
- Examine the report for quality: the plot shows beat to beat R to R intervals of the whole recording. An interval marked with a red star indicates that it had been rejected and it will not be used in the HRV calculation. An interval will be rejected when it is uncharacteristically too high or too low compared to previous intervals.
- Ectopic beats are automatically discarded from the ECG. Ectopic beats are defined as significant changes to the R-to-R intervals from the previous beat. As long as the number of ectopic beats is <35% of the total number of beats, the HRV calculation will be deemed acceptable.

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Check Data Quality

- Click on CLINICAL Tab
- Look for inconclusive label.
- An 'Inconclusive' label appears when one of the following parameters is too large.
- The report should be discarded and measurement repeated.
- Items judged:
  - Percentage of rejected pulses (pulses with very high or very low R to R values) compared to accepted pulses
 - RMSSD & PNN50
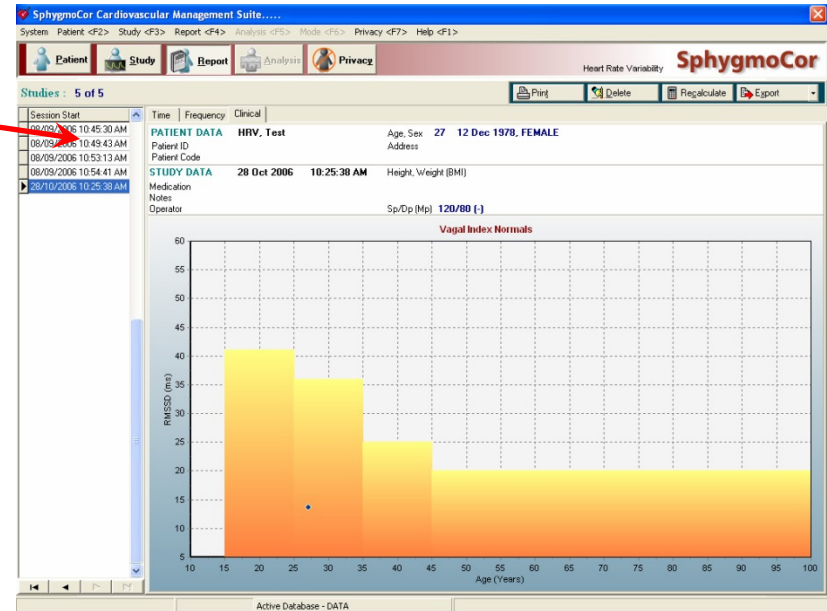
Protocol Deviations

- Record any problems/protocol deviation in the protocol deviation log (Appendix C)

SEARCH4 Protocol Deviation Log

SEARCH ID	Date	Measure Time	SEARCH Staff ID No/Initials	Study Type (HRV, PWA, PWV, Other)	Protocol deviation

Unable to Get HRV Measurements

- Participants with erratic, accelerated, irregular or mechanically controlled (paced) heart rhythms.
- Participants with the following conditions:
    - Atrio-ventricular block, 2nd or 3rd degree (there are more P waves than QRS complexes or Ps and QRSs don't match up correctly on the ECG)
    - Pacemakers
- Bradycardia (HR < 40 beats/min) or tachycardia (HR >160 beats/min)
- Atrial fibrillation or flutter (abnormal p waves and irregularly, irregular rhythm will be seen on ECG)
- Mentally disoriented or unaware patients who are unable to follow instructions.
- Severe HTN (SBP $\geq$160 mmHg) or those who have proliferative retinopathy or who have had laser treatment for retinopathy in the past 3 months should not perform the Valsalva maneuver (risk for retinal rupture).
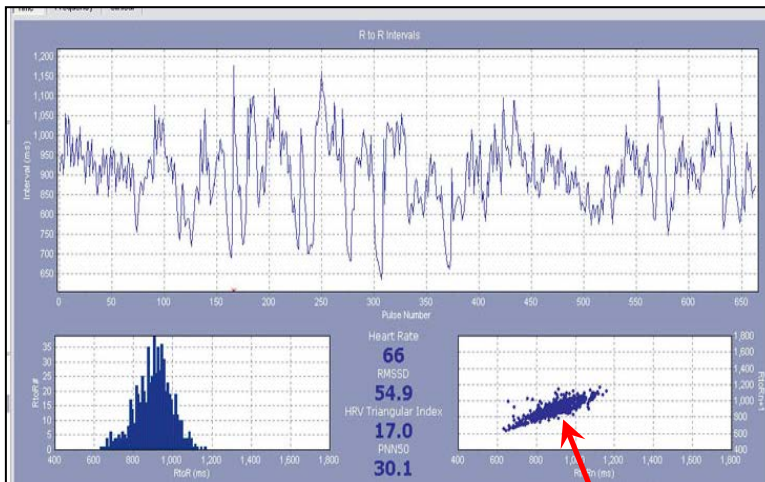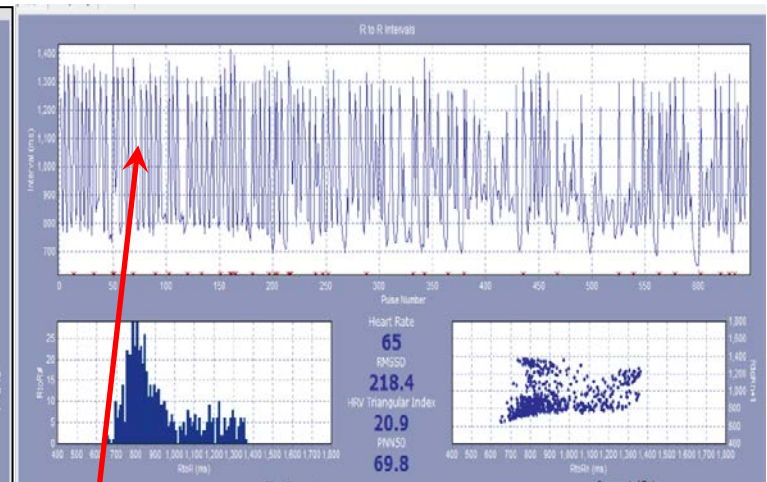

**GOOD**   **ARTIFACT**

- **Examine the report for quality: Very large narrow spikes may be artifact.**
    - **Poincaré plot should look like a comet.**

PERFORMING THE PWV

- Have the patient lie down in a comfortable position. Let them know they will be lying down for awhile.
- It is best to keep the head flat, not on a pillow. One may place a small roll under the neck if the patient is uncomfortable.
- *Allow tape measure to rest lightly on body. Do not stretch 'as the crow flies.'*
- All measurements to be performed 3 times and recorded in the SphygmoCor Excel spreadsheet in cm to the nearest 0.1 cm.
- Record in CM (worksheet will convert to mm: 1 cm = 10 mm).
- Each measurement should differ by no more than 1 cm (i.e. 9.5, 8.9, 9.7 is ok but 8, 9.5, 10 is not, re-measure 3 more times)
- For a copy of the worksheet, see Appendix B
- Part A (SSN to Umbilicus):
  - Have the patient lie down
  - Locate their Umbilicus
  - Measure Part A DISTAL distance from the SUPRA STERNAL NOTCH to the Umbilicus 3 times.
  - Record in the Excel worksheet in CM (worksheet will convert to mm).

Site A - Carotid Artery

Suprasternal Notch

Site B - Femoral Artery
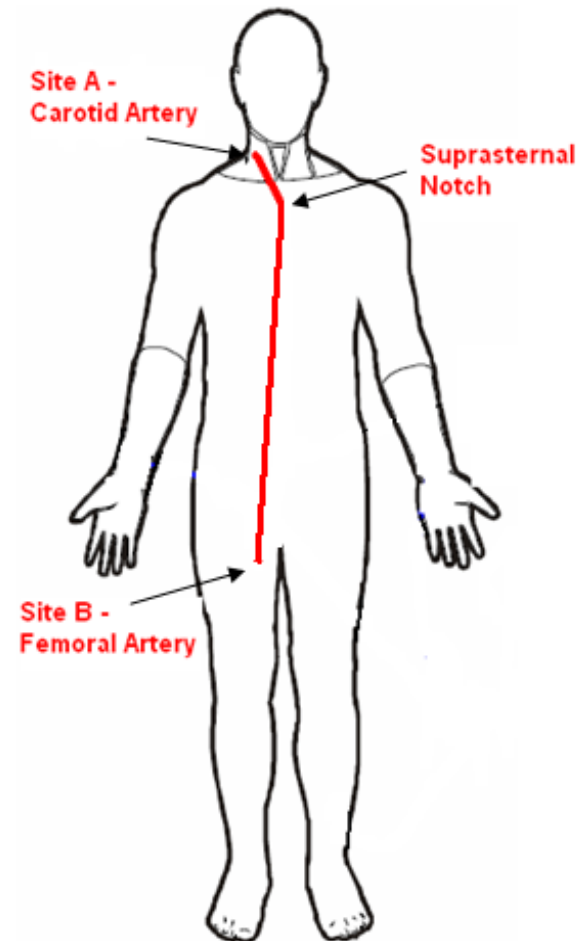
- Distal distance Part B (Umbilicus to Femoral)
- Find the location of the strongest pulse at the FEMORAL artery and mark with a washable marker. Find by placing your index and middle fingers of the hand just below the inguinal ligament in the groin.
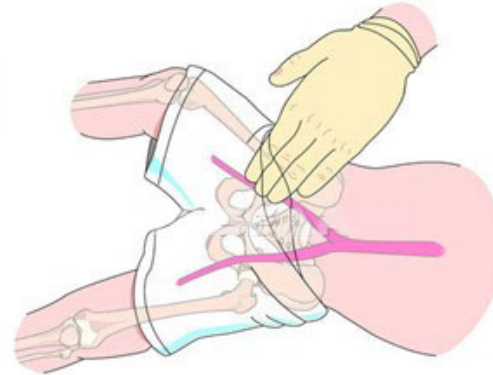
- Placing a roll under the hips helps to bring the artery to the surface.
- Measure DISTAL distance Part B from the Umbilicus to the mark with a tape measure 3 times. Record each value in the SphygmoCor Excel worksheet in CM (worksheet will convert to mm). Excel will calculate the total DISTAL FEMORAL.
- *Keep the tape measure flat.* Do not stretch the tape measure in the air over the area.

- Distal distance Part C (Femoral to Foot)
- Find the location of the strongest pulse at the FOOT and mark.
- Prefer the Dorsalis Pedis (top of the foot).
- If using Posterior Tibial (behind inner ankle 'medial malleolus'), use tape measure to transfer the mark to the corresponding spot on the front of the ankle for ease of measurement.
- Measure DISTAL distance Part C from the FEMORAL mark to the FOOT mark with a tape measure 3 times.
- Record in the Excel worksheet in CM (worksheet will convert to mm).

- *Keep the tape measure flat on the subject's clothing/skin. Do not stretch the tape measure in the air over the area (less reproducible).*
- Excel will calculate the total DISTAL FOOT.
- Place towel on the foot to keep it warm while doing other pressure recordings so that foot does not get cold (makes pulse hard to find).

- Distal Distance for RADIAL PWV.
- Find the location of the strongest pulse at the radial artery by placing your index and middle fingers of the hand on the thumb's side of the patient's wrist.
- Mark this spot with a washable marker.
- Have the subject extend their arm to the side and rest on a surface (table or bed).
- Measure the PROXIMAL distance from the SUPRA STERNAL NOTCH to the mark on the radial artery with a tape measure 3 times to the nearest 0.1 cm recording each value in the SphygmoCor Excel worksheet in CM (worksheet will convert to mm).
- Excel will calculate the average.

- Proximal distance (Carotid to SSN):
- Find the strongest pulse at the PROXIMAL site (always carotid artery) by placing your index and middle fingers of the hand on the right side of the patient's neck up near jaw.
- Best to have patient's head flat (not on a pillow), or extended slightly backward by placing a roll under the shoulders (similar to positioning for an arch view for echo). Mark this spot with a washable marker.
- Place a mark in the center of the SUPRA STERNAL NOTCH.
- Measure from the CAROTID to SSN 3 times to the nearest 0.1 cm recording each value in the SphygmoCor Excel worksheet in CM (work sheet will convert to mm).
- Excel will calculate the average.

Select Database for PWV

Distances

- Select PWV from the right of the screen.
- Click on STUDY and patient screen appears.
- Enter the staff ID number in the OPERATOR box.
- Enter DBP & MAP.
- Enter Distal distance in mm from excel (differs by distal type)
- Enter Proximal distance in mm from excel.

- Be sure site A set to Carotid.
- Click on Radial, Femoral or Distal for arm, groin, foot for Site B.
- Leave the time 10 seconds for both sites (this is the capture time).
- Leave the PWV algorithm on Intersecting tangents.
- Click on Capture data.

Capture Proximal (carotid)

- Place your index and middle fingers of the hand not holding the tonometer on the right side of the patient's neck over the previously placed mark.
- Place the tonometer between the two fingers and compress it gently.
- The best results are obtained if the head is flat on the bed and turned away slightly.
- Use your fingers to prevent the artery from rolling.

Signal Detail Area

Site B Waveform & ECG   **Patient/Study Data**

- The Signal Detail area is the large area in the middle of the screen. The Signal Detail area is refreshed and re-scaled every five seconds. The software will auto scale and zoom to make the waveform large enough to fill the window. When the horizontal grid lines appear farther apart, the signal strength is better.

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- The Signal for Processing area will display the entire waveform & ECG that will be processed.
- Make sure that you can see the BOTTOM & TOP OF EACH WAVE IN THIS AREA and that the WAVES FILL THE WINDOW CONSISTENTLY.

Signal Detail Area

SphygmoCor: Pulse Wave Velocity
Press [ESC] or Click <Cancel> To Abort Data Capture

SphygmoCor Pulse Wave Velocity Data Capture PWV, Test   CAROTID 10

Site B Waveform & ECG

Patient/Study Data

- The Signal Statistics are on the bottom right
- Capture time is the time over which you have been capturing a signal.
- Signal Strength is the strength of the signal you are capturing (both ECG & Pressure waves). This should be NO LESS THAN 100. Usually between 300 and 500 can be achieved.

Identifying Quality Tracing

- If the tracing is off the top or bottom of the screen, the operator is pressing too hard or not hard enough respectively.
- Adjust the tonometer slightly backwards and forwards across the artery. As you move away from the center of the artery, the pulse waveform will become smaller.
- Once you have obtained a good waveform, you will notice that it is consistent, large, and moving across the screen in a steady vertical position.
- Look for a steady vertical waveform position
- A constant pulse height
- Consistent waveform profiles for two complete screens (at least 10 seconds).

Capture Data

- When in the Capture screen, press the spacebar or use foot pedal to activate the capture request in any mode (PWA, PWV or HRV).
- Remember, the last 2 seconds of displayed pulse waveform is discarded when data is captured. This allows the user up to two seconds between removing the tonometer from the artery and pressing the space bar or foot pedal.
- A message box will pop up stating "Site A data captured successfully. Would you like to continue and capture site B data?"
- Click the YES button to proceed. The Data Capture Screen will appear again indicating readiness to capture DISTAL data.

Capture Distal (radial, femoral, foot)

- Capture DISTAL data (FEMORAL or FOOT or RADIAL).
- Place your index and middle fingers of the hand not holding the tonometer on the mark previously placed in the groin (or foot or radial).
- Place tonometer between the 2 fingers and press gently.
- Best results obtained if the leg is bent outward slightly.

Signal Detail Area

Site B Waveform & ECG   Patient/Study Data

- Keeping towel on the foot to keep it warm while doing other pressure recordings is helpful.
- Identify quality data.
- Press spacebar or use foot pedal. The report screen will open.
- <u>Replace the tonometer in the tray immediately after capturing data</u>.

Check for Quality

- R wave on the ECG should be easily recognized. The device is using only the R waves with a green dot on them. Red dot ECG waves were rejected. Visually inspect to be certain the appropriate ECG spike is indicated by a green dot.

- It is important that the foot of the wave is easily identified. The device indicates good wave forms with a green dot and rejected waves with a red one. Visually inspect to be certain that only good waves are indicated with a green (not red) dot. Usually the green dot is slightly higher than the lowest part of the wave tracing.

- The software requires a minimum of 3 pairs of data to calculate a result.
- If it rejects too many pairs the software will not calculate a PWV.
- If you have been careful to make sure that the tracing does not go off the top or bottom of the screen this should not be an issue.

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- SD of the first two values (ECG-CAR and ECG-FEM) should be $\leq 6\%$ (ignore CAR-FEM).
- Be sure NUMBERS ARE **GREEN** not **RED**.

Site A-B	MeanT(ms)	SD(ms)	N	HR(bpm)
ECG-CAR	62.2	2.1	11	78
ECG-FEM	113.1	0.8	9	79
CAR-FEM	50.9	2.2		

CAR-FEM PTT SD 4.4 %

Pulse Wave Velocity (m/s) 10.8 ± 0.5

- PTT SD should be ≤ 10%.
- *Also NOTE*: Difference in HR between Proximal and Distal should be ≤ 5 BPM (may be hard in younger kids).
- If your final recording position is > 1 cm from your original mark: re-measure 3 times and enter into spreadsheet to get average.   Click on modify, enter new data, click on modify.
- The software does not actually show the % for the standard deviation, it shows the actual standard deviation. The % SD = the SD (ms) divided by the MeanT (ms). For example, if ECG – FEM is 6.8 ms, the SD is 6.8/178.7 x 100 = 3.8%. So, the value for the ECG-FEM is within the 6% limit and it is not flagged by the software as a red number. In this example the SD for ECG-Car = 2.1/62.2 x 100 = 4.4%.

THEREFORE: PTT SD should be in GREEN, but not specific number.

Must start with Carotid (cannot do Femoral then Carotid):
1) **Pressure on carotid body may change HR/BP, want all sites to have the same influence on PWV**
2) **Makes difficulties for CoC when uploading, sorting and analyzing the data.**

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PWV: *Good Quality Study*

- **Notice relatively even pulse traces with little waver in the baseline and similar shapes throughout.**
- **PWV is 4.5 m/sec**

PWV: *POOR STUDY*

- **Pulses for Carotid are very uneven pulse and there is a lot of waver in the baseline and change in size/shapes.**
- **PWV is 6.0 m/sec**
- **NEED TO REPEAT**
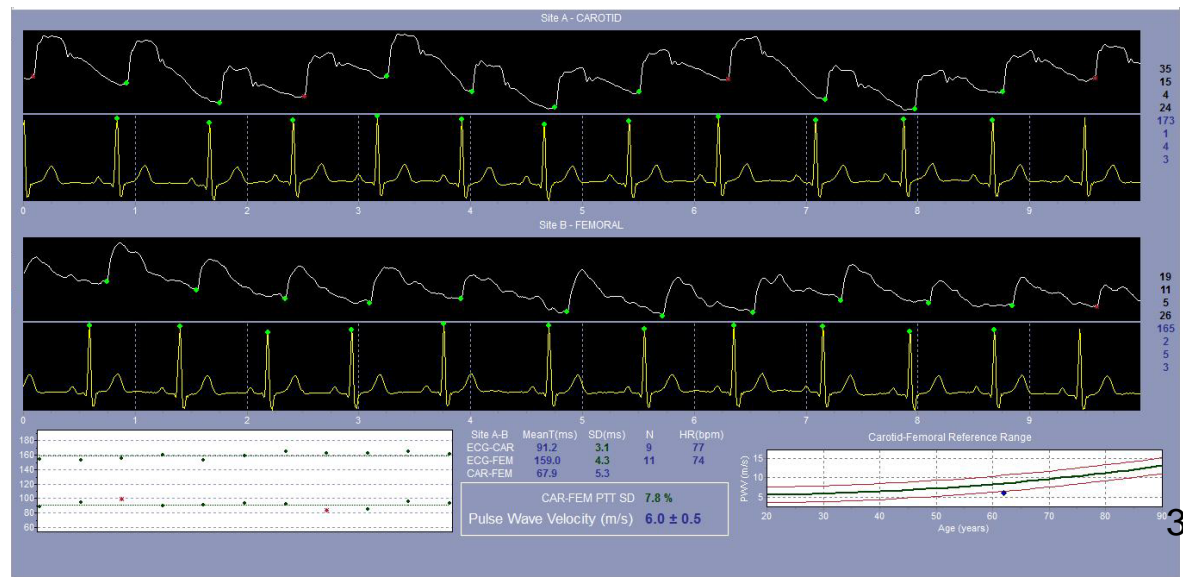
Calculate PWA from Carotid – Radial PWV

- Try to get good quality Radial tracings to convert to PWA.
- Check the Quality Control Area of the report screen FOR THE DISTAL (radial) site for the Pressure tracing (not ECG).
- Look at the top 3 numbers only (PH, PHV, DV)
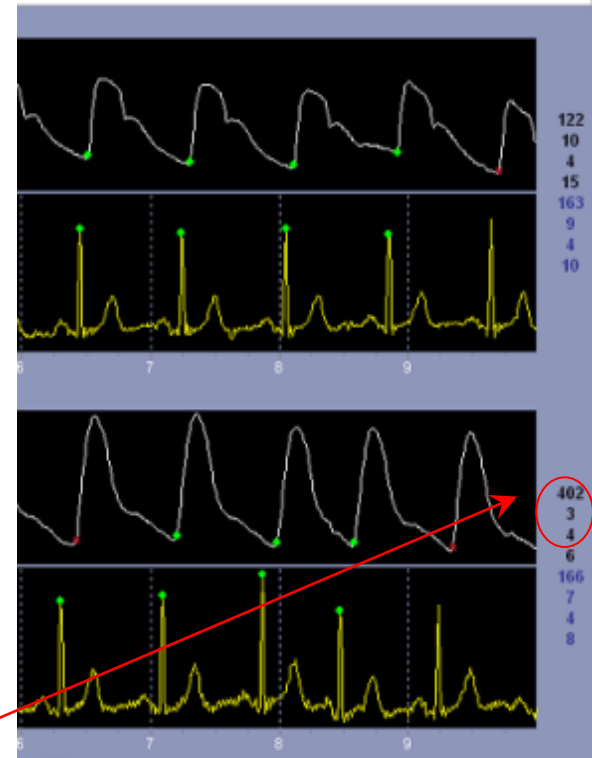
- Average Pulse Height: must be $\geq$ 80 (100 is even better).
- Pulse Height Variation: should be less than 5%
- Diastolic Variation: should be less than 5%.
- If values are outside of acceptable limits, you will have to repeat a separate PWA (see section PWA).

- If QC indices are within acceptable range, press the Create PWA button on bottom.
- At the question "Would you like to create a Pulse Wave Analysis Report for LAST, First using RADIAL pressure wave form of Site B," click YES. Be sure it states RADIAL.
- A box will appear stating "PWA Report created." Click OK.
- When it asks "Would you like to create a Pulse Wave Analysis Report for LAST, First using CAROTID pressure wave form of Site A," click NO.

- Verify the PWA
- Go to the PWA report created by clicking on PATIENT, changing to PWA and clicking on REPORT.
- Review the PWA created.
- If Not Validated is displayed you may ignore this notation. The transfer function has only been validated in adults.
- Inconclusive may be displayed if the dP/dt is large such as in a healthy teenager with good cardiac contractility. Sometimes the Aortic or Radial T1 (time to first peak) will be out of range.
- Re-evaluate the waveforms. If the waveforms appear acceptable and the other quality controls have been met you can retain the reading. If unsure, delete and obtain another PWA reading.

PWV Time Considerations

- Always obtain FEMORAL first (most important).
- If a subject cannot stay still very long, the observer should obtain 3 FEMORAL, then 3 FOOT, then 3 RADIAL and repeat until the subject is unable to tolerate additional study time or 3 of each measure have been obtained.
- You may have to accept (leave data missing if cannot reach these more 'relaxed' QC guidelines).
  - SD of the first two values (ECG-CAR and ECG-FEM) should be 6 -10% PTT SD should between 10 - 15%.
  - Difference in HR Proximal - Distal 5-10 BPM
- No more than 3 readings per site should be saved.

Protocol Review: *Deleting Poor Quality Studies*

- Open the SphygmoCor program and select the appropriate database.
- Click on the patient of interest to highlight it. Select PWA, PWV, HRV.
- Click on REPORT
- Find the study to be deleted from the STUDY TIME list on the left hand column and click once to highlight it.
- Click the DELETE button on bottom to delete. You will get a message 'This will delete the Measurement for patient LAST, FIRST are you sure? Click Yes.

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PERFORMING PULSE WAVE ANALYSIS (PWA)

Pulse Wave Analysis is also known as Augmentation Index (AIx).

Select Database for PWA

- Click PWA along the right side of the screen.
- Click on STUDY (upper left).
- Enter the staff ID number in the OPERATOR box.
- Enter the DBP & MAP data.
- Be sure RADIAL is selected.
- Click on CAPTURE DATA (bottom right) and the DATA CAPTURE SCREEN OPENS.

Capture Data

- Place your index and middle fingers of the hand not holding the tonometer on the wrist near the base of the RIGHT thumb.
- Place the tonometer between the two fingers and press down gently.
- The best results are obtained if the wrist is bent outward (dorsiflex position).
- The RIGHT wrist should be supported by using a small cushion or the operator's hand.

Applanation Tonometry

Sensor

Artery

Bone

Sensor

Artery

Bone
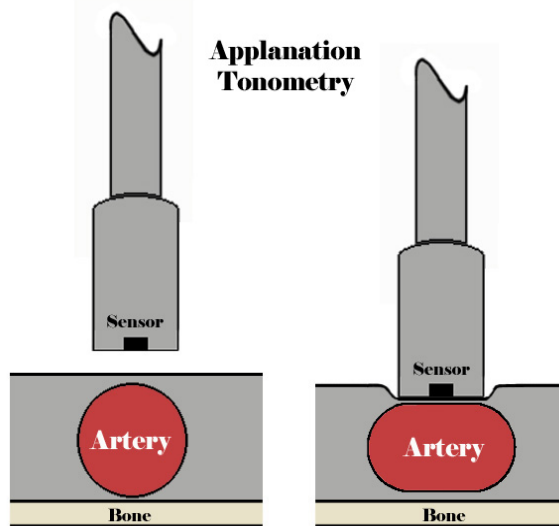
- The tonometer should be held at the base so that the operator's fingertips make contact with the patient's skin.
- Holding the tonometer higher on the shaft will allow less control and makes data capture more difficult.
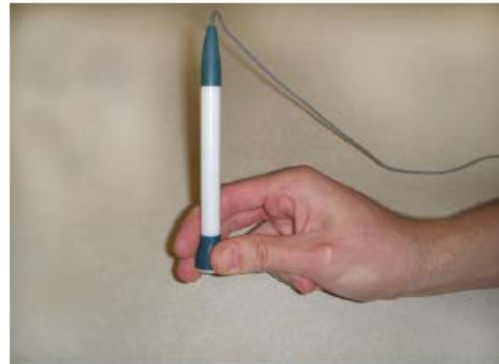
Correct Grip
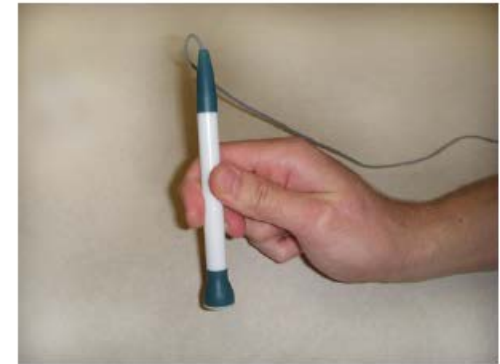
Incorrect Grip
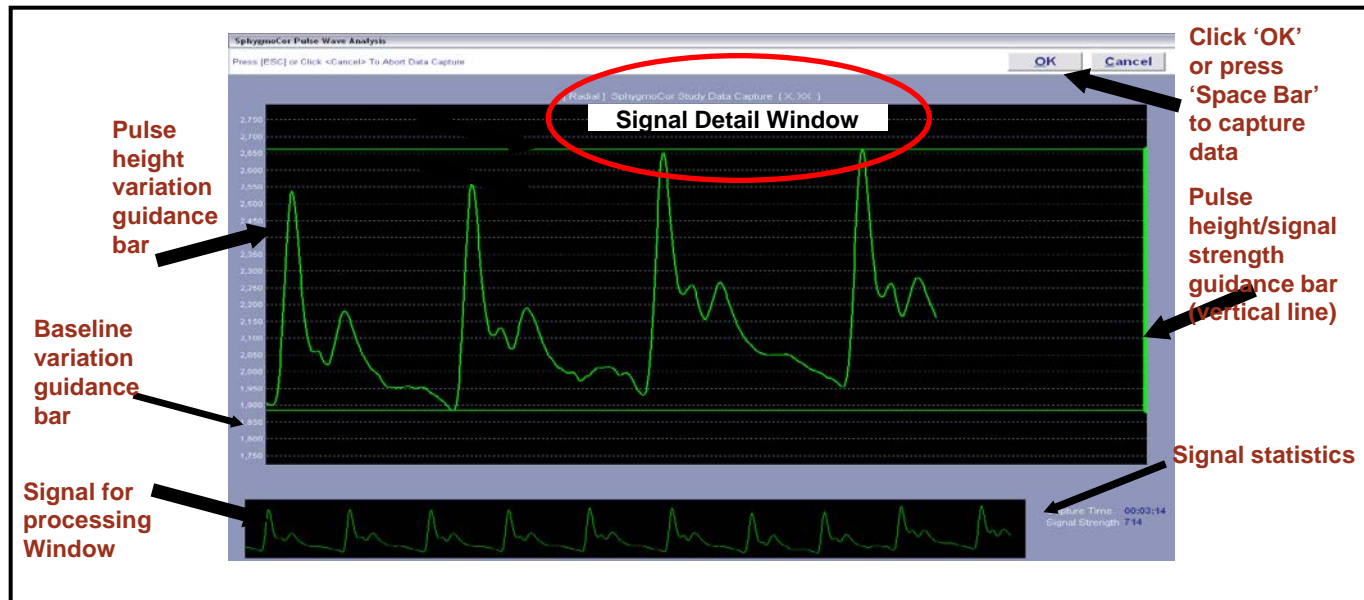
Pulse height variation guidance bar

Baseline variation guidance bar

Signal for processing Window

Signal Detail Window

Click 'OK' or press 'Space Bar' to capture data

Pulse height/signal strength guidance bar (vertical line)

Signal statistics

- The Signal Detail area is the large area in the middle of the screen.
- The Signal Detail area is refreshed and re-scaled every 5 seconds.
- The software will auto scale and zoom to make the waveform large enough to fill the window.
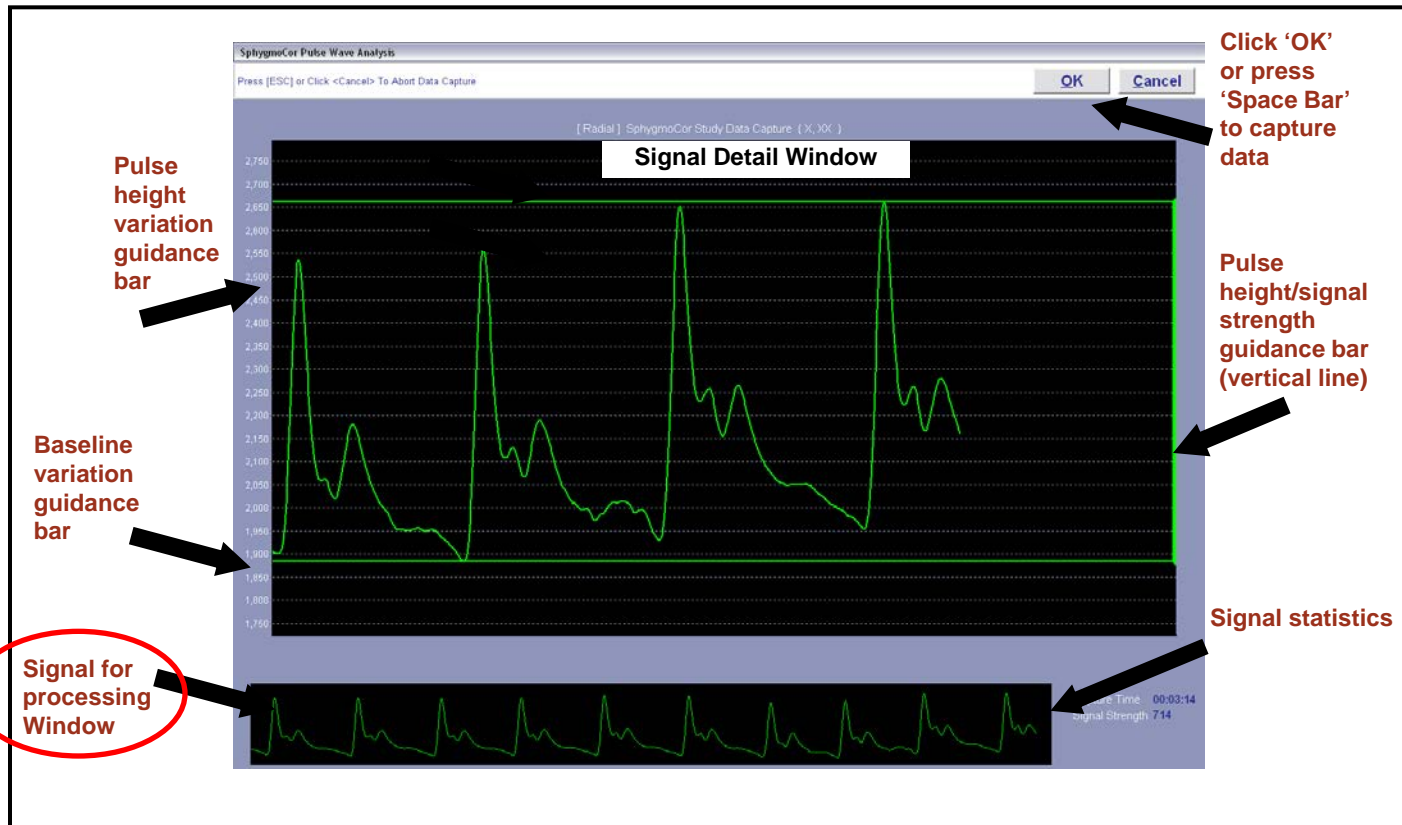
- The Signal for Processing area will display the entire waveform that will be processed.
- Make sure that you can see the BOTTOM AND TOP OF EACH WAVE IN THIS AREA and
- The WAVES CONSISTENTLY FILL THE WINDOW.

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SphygmoCor Pulse Wave Analysis

Press [ESC] or Click <Cancel> To Abort Data Capture

OK   Cancel

[Radial] SphygmoCor Study Data Capture { X, XX }

Signal Detail Window

Click 'OK' or press 'Space Bar' to capture data

Pulse height variation guidance bar

Pulse height/signal strength guidance bar (vertical line)

Baseline variation guidance bar

Signal statistics

Signal for processing Window

Capture Time 00:03:14
Signal Strength 714

- The Signal Statistics are on the bottom right.
- Capture time is the time over which you have been capturing a signal.
- Signal Strength is the strength of the signal you are capturing.

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Check Quality

Identify high quality PWA signal.

- Adjust the tonometer slightly backwards and forwards across the artery. As you move away from the center of the artery, the pulse waveform will become smaller. Once you have obtained a good waveform, you will notice that it is consistent, large and moving across the screen in a steady vertical position.

- If tracing is off the top or bottom of the screen, the operator is pressing too hard or not hard enough respectively. Look for a steady vertical waveform position
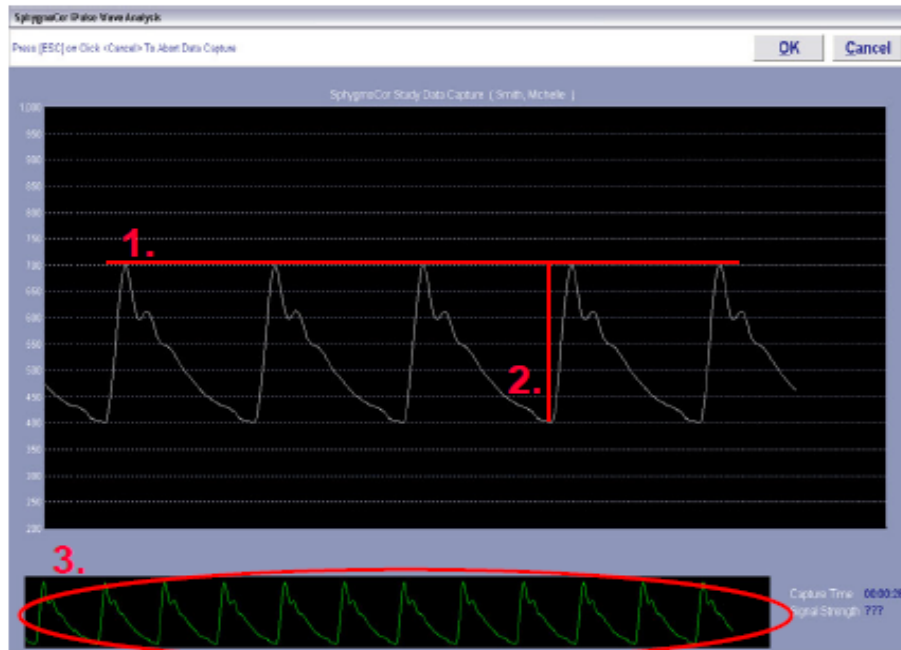
High quality data requires that the following conditions be satisfied:

1. Consistent Pulse Height

2. Large Waveform Amplitude (filling as much of the screen as possible)

3. Consistent waveform shapes for ten seconds

Note the lack of artifact and "noise" in the signal

Pulse Height Variation

Pulse Height

Baseline Variation

Reduce Pulse Height Variation   Reduce Baseline Variation

Increase Pulse Height
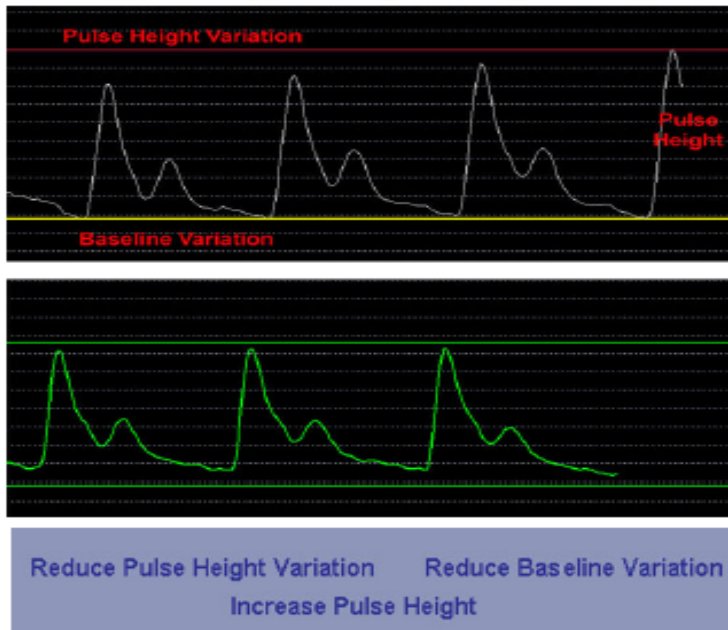
- The bars are color-coordinated using red, yellow and green

- Pulse Height Variation & Baseline Variation
  - Red indicates a variation greater than 10%
  - Yellow indicates a variation between 5 – 10%
  - Green indicates a variation less than 5%

- Pulse Height:
  - Red indicates a height less than 75
  - Yellow indicates a height between 75 – 85
  - Green indicates a height greater than 85

- Messages regarding tonometer adjustment are also displayed at the bottom of the screen
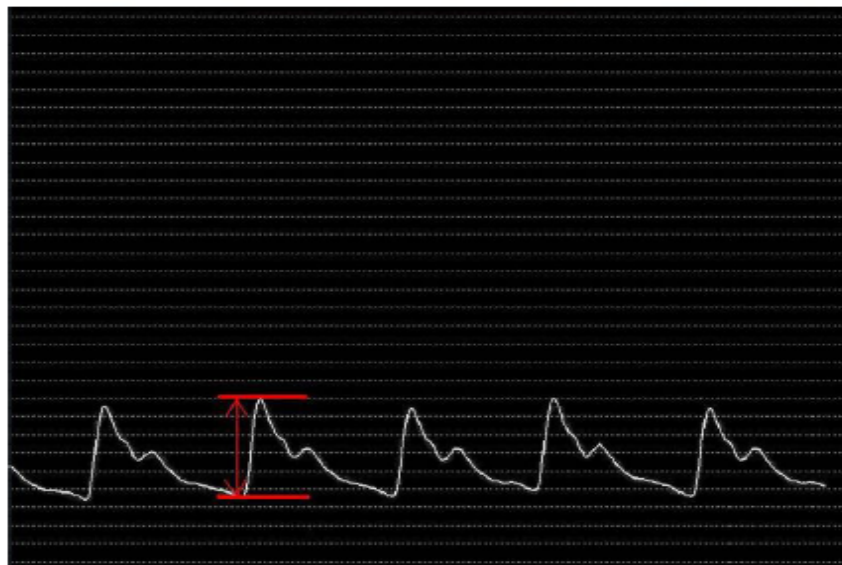
If the waveforms appear small:

- Wait until the signal scale is amplified as the signal reaches the right side of the screen

- Press slightly harder to induce stronger signal

- Adjust the tonometer positioning slightly so that the tip is over the strongest pulse point

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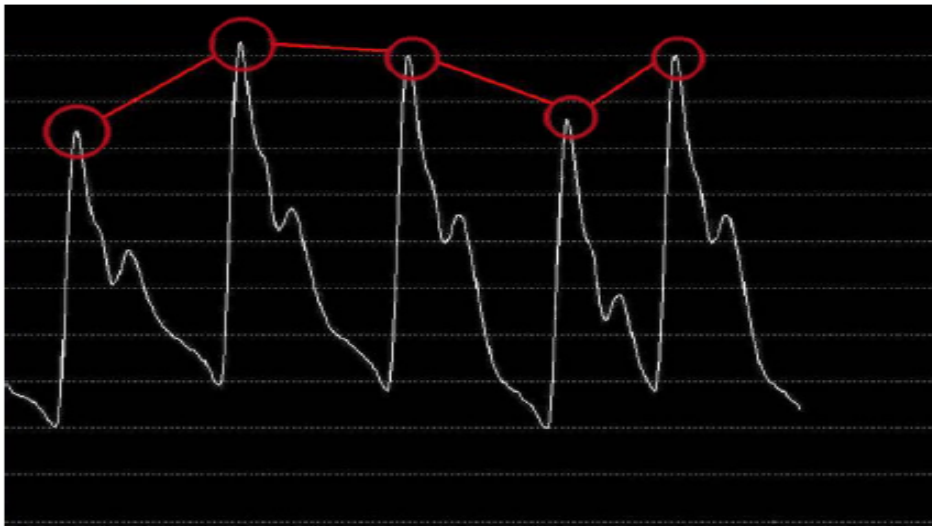
Pulse height inconsistency is most commonly caused by either inconsistent hold-down pressure or respiratory variation.

- Hold tonometer at the base with fingers touching the patient's skin
- Ensure hand positioning is stable to maintain consistent hold-down pressure
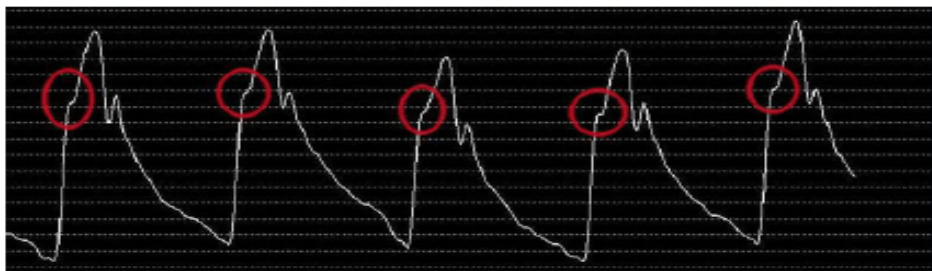
The initial upstroke of the waveform signal should be sharp from base to peak.

Improper tonometer positioning creates an inflection in the upstroke.

- Change the angle at which tonometer is held over the patient's pulse
- Adjust the location of the tonometer's tip

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Look For:

- Signal Strength should be NO LESS THAN 100. Usually 300 - 500
- Look for a steady vertical waveform position, with all pulses visible in signal for processing screen
- A constant pulse height
- Consistent waveform profiles for two complete screens (at least 10 seconds).

Troubleshooting Poor Waveforms

Bump in Ascending Radial Waveform
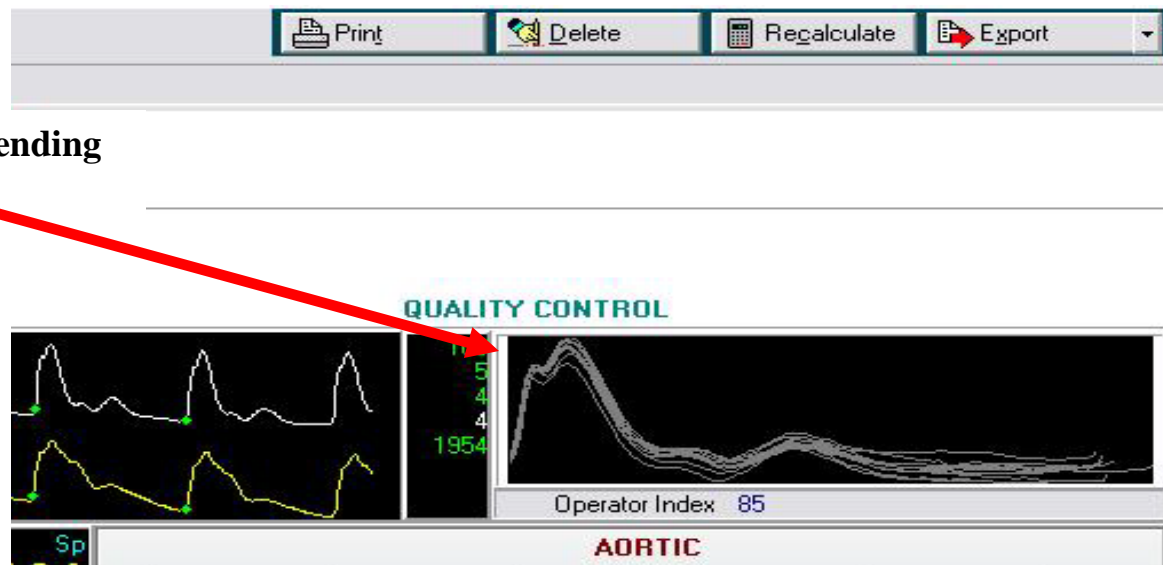
- The tonometer is not directly on top of the radial artery.

Noisy Signal
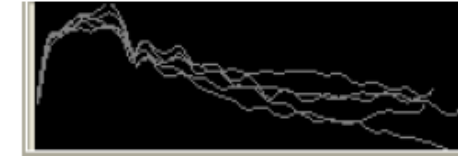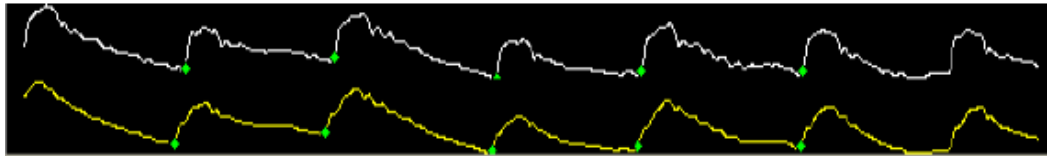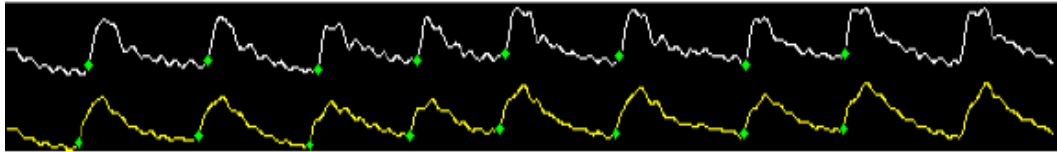
Vary in Baseline

• The tonometer is not directly on top of the radial artery.

Flat Diastolic Part
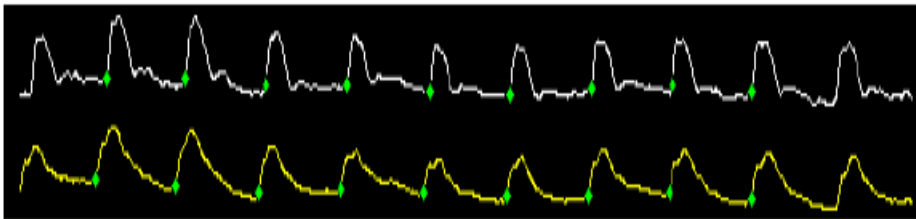
• Variation in the peaks/troughs = change in P applied, need to hold steady
• May also be an unavoidable respiratory artifact
• Diastolic part of wave flat = hold-down P too high, artery is being occluded.

- When in the Capture screen, if the horizontal lines going across both turn green, then the tracing is good and the Autocapture mode will take the data to process. You may also press the spacebar or use the foot pedal to active the capture request in any mode (PWA, PWV or HRV).
- Remember, the last 2 seconds of displayed pulse waveform is discarded when data is captured. This allows the user up to two seconds between removing the tonometer from the artery and pressing the space bar or foot pedal.
- After you have captured data successfully the REPORT screen will appear.
- Replace the tonometer in the tray immediately after capturing data ($3000 to replace).

Review the Detailed Screen

- Device defaults to the CLINICAL screen
- Click on DETAILED to go to that screen

Sample of What the Detailed Screen Looks Like

45
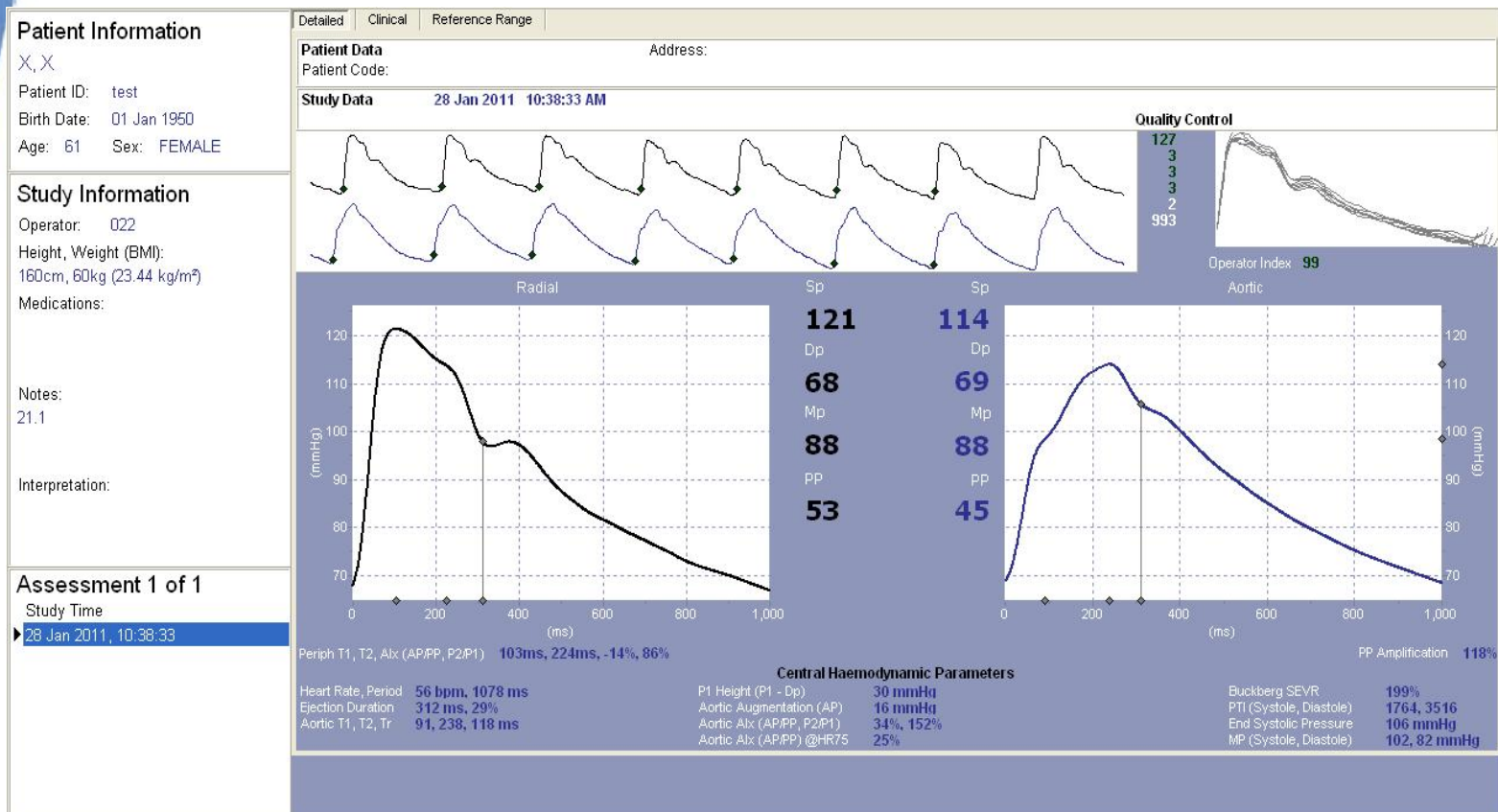
Generate Report
Check Report for Accuracy

- If the patient data is incorrect, click the Patient tool-bar button (top left) to return to the patient screen and update patient details. Then click on report to return to report.

Detailed Report Tab

SphygmoCor Cardiovascular Management Suite

System Patient Study Report Analysis Mode Privacy Help

| Patient | Study | Report | Analysis | Privacy |

Pulse Wave Analysis

Patient Information
X, XX
Patient ID:
Birth Date: 26 Feb 1977
Age: 33   Sex: MALE

Study Information
Operator: RAH
Height, Weight (BMI):

Medications:

Detailed Clinical Reference Range

Patient Data   Address:
Patient Code:

Study Data   19 Oct 2010 5:08:54 PM

Quality Control
135
3
4
3
4
649

Operator Index: 96

Quality Control Indices

- If the study data is incorrect, click the MODIFY button. Change the incorrect details (i.e., wrong BP) in the Study Screen and click on MODIFY again.

Check Quality

- Check the Quality Control area. GOOD READINGS are in **GREEN**. There should be NO NUMBERS in **RED**.

Pulse Wave Analysis

Quality Control
135
3
4
3
4
649

Operator Index 96
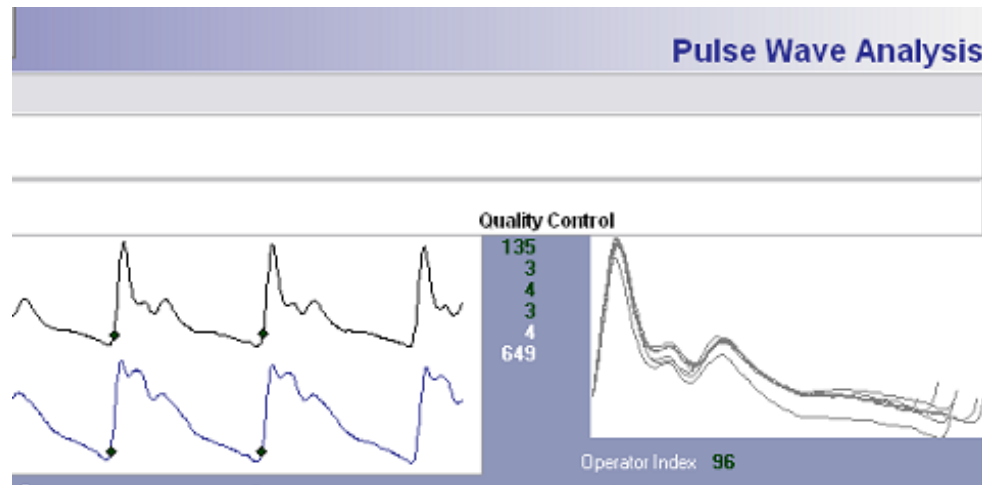
1) Average Pulse Height: must be ≥ 80 (100 is even better).

2) Pulse Height Variation: should be ≤ 5%

3) Diastolic Variation: should be ≤ 5%. High value occurs with inconsistent pressure applied to the tonometer during the measurement.

4) Shape variation should be ≤ 4%.

5) Ignore Pulse Length Variation (it is related to HR)

6) Ignore the Max dP/dt (diastolic P change over diastolic time change)

Detailed Report Tab
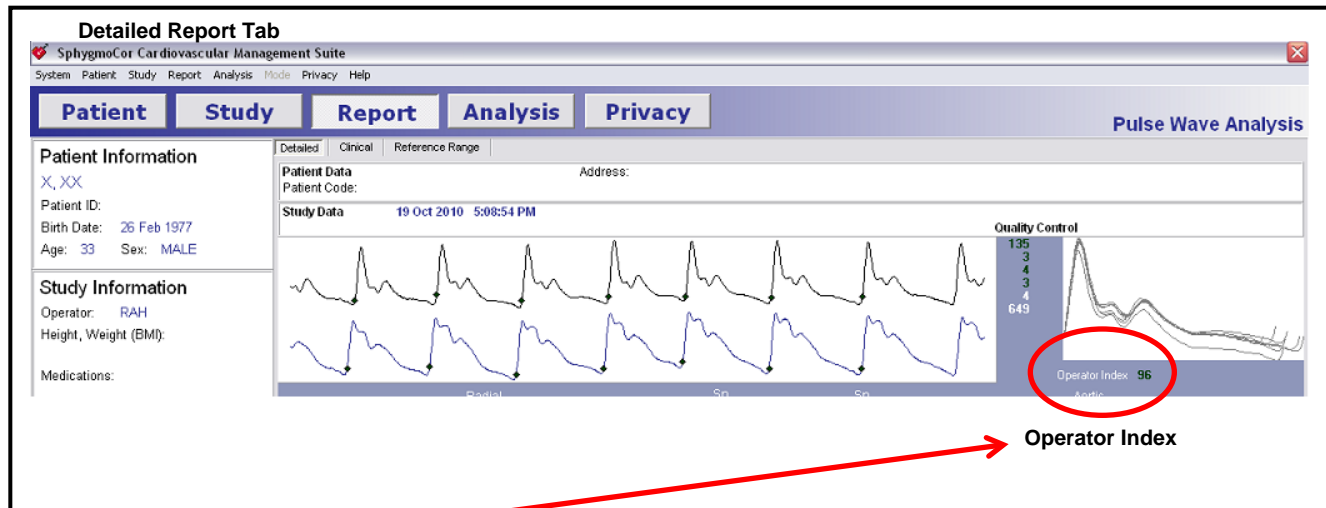
Operator Index

- Operator index: MUST be ≥ 75. It's a 'weighted' value calculated from the other indices above.

    Excellent = 95-100%
    Good = 90-94%
    Acceptable = 85-90%
    Borderline = 75-84%
    Unacceptable = ≤ 74%

Pulse Wave Analysis
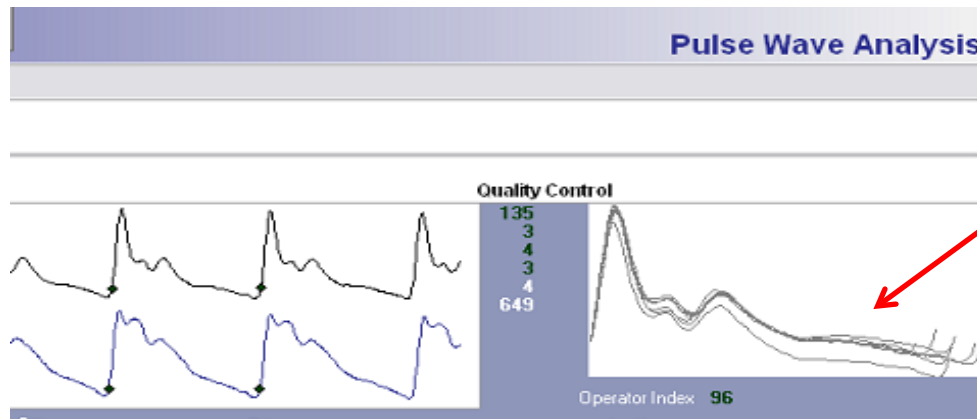
Overlay data

- Check to see that the <u>overlay</u> recorded data is visually coherent. That is, the waveform pulses should overlay with minimal spread.

- If values are outside of acceptable limits, delete the study by clicking on the DELETE button on the bottom of the REPORT Screen. When it asks if you are sure you want to delete the data, click YES. Then Click the STUDY Tool-bar button (or press F3) to return to the Study Screen.

- If an "n/c" shows up on the detailed screen, repeat measurement.

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Periph T1, T2, Aix (AP/PP, P2/P1)   116ms, 220ms, -52%, 48%

Central Haemodynamic Parameters

Heart Rate, Period	78 bpm, 773 ms	
Ejection Duration	295 ms, 38%	
Aortic T1, T2, Tr	151, 210, 184 ms	

P1 Height (P1 - Dp)	31 mmHg
Aortic Augmentation (AP)	-1 mmHg
Aortic Aix (AP/PP, P2/P1)	-4%, 96%
Aortic Aix (AP/PP) @HR75	-3%

Buckberg SEVR
PTI (Systole, Diastole)
End Systolic Pressure
MP (Systole, Diastole)

Note:
Waveform Timing out of Range. [Aortic T1]

- **If Waveform Timing out of Range, delete and repeat.**

PWA: Time Considerations

- If the study is taking too long, you may have to accept data with an Operator Index >75 and reasonable wave form overlay, but with one of the QC numbers in red.
- You may accept:
    1) Average Pulse Height: Really must be ≥ 80
    2) Pulse Height Variation: between 5-10%
    3) Diastolic Variation: between 5-10%
    4) Shape variation between 4-8%
    5) Ignore Pulse Length Variation
    6) Ignore max dP/dt .
- Leave data missing if cannot reach 'relaxed' QC guidelines.
- No more than 3 readings per site should be saved.
- Delete additional studies by going to the report page and clicking on the Delete button.
  You may not be able to get an acceptable PWA for participants who have significant arrhythmia

CONCLUDE THE STUDY

- Exit SphygmoCor Software FIRST
- Then turn off the PC
- *TURN OFF PC PRIOR TO DEVICE*
- *Then disconnect cables if need to dis-assemble the device*
- Compete the remainder of the SEARCH SphygmoCor form – questions 5. thru 8. (see Appendix A).   50
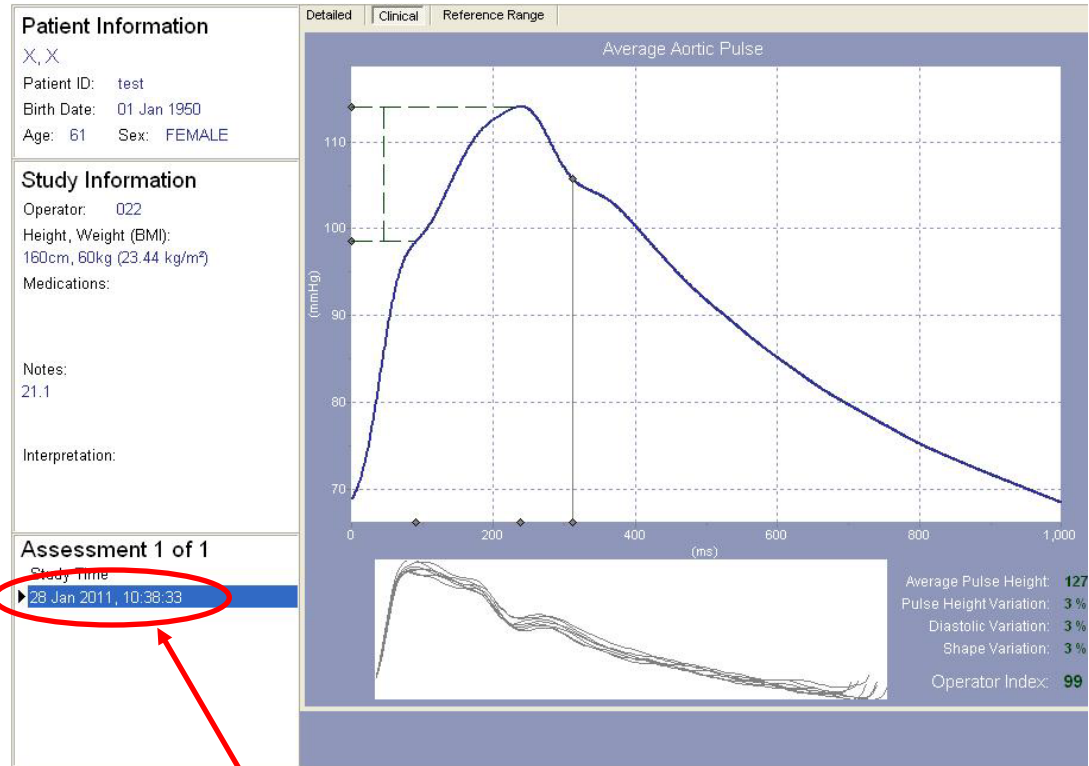
DELETING POOR QUALITY STUDIES

- Open the SphygmoCor program and select the appropriate database.
- Click on the patient of interest to highlight it. Select PWA, PWV, HRV.
- Click on REPORT
- Find the study to be deleted from the STUDY TIME list on the left hand column and click once to highlight it.
- Click the DELETE button on bottom to delete. You will get a message 'This will delete the Measurement for patient LAST, FIRST are you sure? Click Yes.

QUALITY CONTROL STUDIES

- 'QC' repeat studies to assess variability between visits will not be performed since between visit variability in Search3 was acceptable and within visit variability in Search 3, which can be assessed more frequently, was sufficient to identify observers needing retraining.

EXPORTING STUDY MEASURES

Export on first screening day of every calendar month.
- If you do not have direct e-mail capabilities, insert a thumb drive into the USB port of the laptop
- From the Patient window, select study to be exported (HRV, PWV, PWA)
- Click on System (top left corner) and then Database and scroll to the right to click on Export as text
- The SphygmoCor Export window will be displayed
- Click on SELECT & then locate the drive where you would like to save the file. Open the SEARCH export file folder by double clicking on it. Click on Open (bottom right) and this window will close.
- Click on export (bottom left) and the entire HRV database file will be sent as a text file to the drive you selected for saving
- When 'successfully exported xx of xx records' message appears, click close.
- Repeat the same procedures for PWV and PWA. Thus all three (HRV, PWA, PWV should now be saved on the selected drive)
- Close the program
- If you saved the information to be exported on a thumb drive, remove the thumb drive
- Upload the 3 text files to the new Search web site as instructed by Ken Wilson (Kwilson@wakehealth.edu).
- As of July 15, 2016, files will no longer be uploaded to Intelemage.

CERTIFICATION PROCEDURES

- Perform one 10-minute HRV measure and 3 resting PWV (carotid-femoral only) and 3 resting PWA measures on 3 volunteers on both a 'True' visit and a repeat 'blind duplicate' visit.
- Use the default database (not SEARCH4) to keep the data separate.
- Assign one of the volunteer ID's (provided by the CoC) to each volunteer (the ID consists of a seven-digit number followed by a V). When the volunteer comes for the second visit add "QC" to the end of the ID to indicate it is a repeat 'blind duplicate' visit.
- Fill out the Certification log (see Appendix D). When saving this file, please be sure to indicate who the staff member is within the name of the file.
- Export study measurements:
  - If you do not have direct e-mail capabilities, insert a thumb drive into the USB port of the laptop.
  - From the Patient window, Select HRV (for HRV).
  - Click on System (top left corner) and then Database and scroll to the right to click on Export as text.
- The SphygmoCor Export window will be displayed.
- Click on SELECT & then locate the drive where you would like to save the file. Open the SEARCH export file folder by double clicking on it. Click on Open (bottom right) and this window will close.
- Click on export (bottom left) and the entire HRV database file will be sent as a text file to the drive you selected for saving.
- When 'successfully exported xx of xx records' message appears, click close.
- Repeat the same procedures for PWV and PWA. Thus all three (HRV, PWA, PWV) should now be saved on the selected drive.

- Export screen shots of PWA
- Open patient screen for first volunteer
- Click on type of study (PWA)
- Click on the first PWA reading (on the left hand side)
- Click on report
- Click on the detailed report tab
- Click on Export, SphygmoCor Export window will be displayed
- Click on SELECT & then locate the drive where you would like to save the file. Open the export file folder by double clicking on it. Click on Open (bottom right) and this window will close.
- Click on export (bottom left) and the screen will be exported as a picture (*.jpeg)
- Repeat this process for each PWA for each volunteer
- Click on close
- If you saved the information to be exported on a thumb drive, remove the thumb drive.
- Send an email to Ken Wilson (kwilson@wakehealth.edu) including the certification log. Then, upload the three text files to the CoC as done with real patient data for SEARCH3 and SEARCH4.
- The CoC will determine:
- within-visit reproducibility for the 'True' visit (CV among the 3 readings for PWA and PWV only)
- and between-visit reproducibility between the mean True measure and the mean Blind Dup measure (CV between the means on the 2 separate days for PWA, PWV, HRV).
- Send an email to Dr. Urbina (Elaine.urbina@cchmc.org) and attach the screen shots.
- Dr. Urbina will communicate with Carrie Williams(ccwillia@wakehealth.edu) and Scott Isom (sisom@wakehealth.edu) at the CoC to confirm certification status.

EXPORTING SCREEN SHOTS FOR REVIEW

If you are having difficulties in obtaining acceptable measures or if you have questions regarding a specific participant's waveforms or ECG tracing, it may be useful to save a screen shot so it can be sent to Dr. Urbina along with your questions. The following is a description of the procedure for exporting screen shots for review:

- If you do not have direct e-mail capabilities, insert a thumb drive into the USB port of the laptop.
- Turn on your device and laptop and open SphygmoCor program
- Open database where questionable study is located
- Open patient with questionable study
- Click on type of study (PWA, PWV, HRV)
- Click on the time the questionable reading was performed
- Click on report
- Click on Export, SphygmoCor Export window will be displayed
- Click on SELECT & then locate the drive where you would like to save the file. Open the SEARCH export file folder by double clicking on it. Click on Open (bottom right) and this window will close.
- Click on export (bottom left) and the study will be exported as a picture (*.jpeg)
- Click on close
- If you saved the information to be exported on a thumb drive, remove the thumb drive.
- Send an email to Dr. Urbina (Elaine.urbina@cchmc.org) and attach the screen shots.

ARTERIAL STIFFNESS FLAG PROTOCOL

For all vascular and HRV measures

1. A 'flag procedure' is the protocol used to notify the Principal Investigator of an abnormal study. The PI will determine if the abnormality requires additional evaluation or treatment.

2. Criteria to flag a study:
   a. Abnormal BP, very high (>160/100) or very low (<80/50)
   b. Abnormal HR
      i. Very fast or slow HR (HR > 150 or < 50)
      ii. Very irregular HR
      iii. Abnormal beats (arrhythmia) - any very unusual ECG tracing
      iv. Any study that makes you feel 'uncomfortable'

3. Each site will report the 'flagged' procedure to their site-specific PI and to Dr. Urbina in Cincinnati (elaine.urbina@cchmc.org).

4. If abnormality is deemed 'Urgent:'
   a. Urgent = Abnormal BP or HR associated with dizziness, shortness of breath, chest pain or other symptoms
   b. Page your site-specific PI.

5. If 'routine,' download a 'screen shot' of the image of reading from the device as per protocol and email with a description of what you suspect is abnormal to your site-specific PI and to Dr. Urbina in Cincinnati (elaine.urbina@cchmc.org).
   a. Dr. Urbina will also contact your PI within 1 to 2 weeks with an interpretation.
   b. She will contact the site coordinator to let them know if they need to delete the reading.

ARTERIAL STIFFNESS Contact Information

- Technical questions about the device:
    - Bobby Stutz (engineer at Atcor): b.stutz@atcormedical.com
- Performing SphygmoCor:
    - Mary James (CV tech): mary.james@cchmc.org
- Abnormalities in studies:
    - Elaine Urbina (PI): elaine.urbina@cchmc.org
- Transfer of data, contact data manager:
    - Thompson, Diana Diana.Thompson@cchmc.org

Chapter 15 - SphygmoCor

Appendices

Appendix A- SphygmoCor Form

Appendix B- SphygmoCor Worksheet

Appendix C- Protocol Deviation Log

Appendix D- Certification Log

SEARCH SphygmoCor Form

Ask the participant questions 1 thru 3:

1. Have you had any caffeine this morning?

   1☐ No
   2☐ Yes
       If Yes, please list:_____

2. Have you smoked or used anything with nicotine this morning?

   1☐ No
   2☐ Yes
       If Yes, please list:_____

3. Have you taken any decongestants or asthma medications this morning?

   1☐ No
   2☐ Yes
       If Yes, please list:_____

 If the participant answered yes to questions 1, 2, or 3 above, you may still conduct the SphygmoCor.

To be completed by study personnel:

4. What did the participant eat/drink prior to testing other than water?
   1☐ Nutrigrain bar (standard snack)
   2☐ Glutino bar (standard snack for celiac disease)
   3☐ Nothing (refused standard snack)
   4☐ Other
       If Other, please list (indicate nutrient content for protein, carbs, and fat if available):

       _____

5. Was the examination room unusually hot or cold?

   1☐ No
   2☐ Yes – very hot
   3☐ Yes – very cold

6. Were all SphygmoCor measurements obtained?

    1❑ Yes, all measurements obtained

    2❑ Partial measurements obtained (check all measurements obtained)

        1❑ <u>Heart Rate Variability</u>

        2❑ <u>Pulse Wave Velocity</u> – **femoral**:
          1❑ 1 measurement   2❑ 2 measurements   3❑ 3 measurements
        3❑ <u>Pulse Wave Velocity</u> – **radial**:
          1❑ 1 measurement   2❑ 2 measurements   3❑ 3 measurements
        4❑ <u>Pulse Wave Velocity</u> – **foot**:
          1❑ 1 measurement   2❑ 2 measurements   3❑ 3 measurements

        5❑ <u>Pulse Wave Analysis</u>
          1❑ 1 measurement   2❑ 2 measurements   3❑ 3 measurements

    3❑ No measurements obtained

7. Comments regarding difficulties with measurements or missed measurements?

    1❑ Yes (*if Yes, describe)* :

    2❑ No comments

FOR STUDY USE ONLY

	Month	Day	Year		
Date Completed	☐☐	☐☐	☐☐☐☐	Completed by	☐☐☐
Date Reviewed	☐☐	☐☐	☐☐☐☐	Reviewer Code	☐☐☐
Date Entered	☐☐	☐☐	☐☐☐☐	Data Entry Code	☐☐☐

SphygmoCor Worksheet SEARCH4

Subject ID Number		*SAVE SPREADSHEET WITH ID Number*

Summary	
Ave SBP	#DIV/0!
Ave DBP	#DIV/0!
MAP	#DIV/0!
Distal Femoral	#DIV/0!
Distal Foot	#DIV/0!
Distal Radial	#DIV/0!
Proximal Carotid	#DIV/0!

Staff ID Number or initials:			
ARM Used for BP:		Right (1)	Left (2)
Side used for PWV:		Right (1)	Left (2)
Pulse used for foot:		Dorsalis Pedis (1)	Posterior Tibial (2)
Deviation from protocol		Yes (1)	No (2)
Type of deviation			

SBP (mmHg)	Value	AVG SBP	1/3 SBP
Measurement #1			
Measurement #2		#DIV/0!	#DIV/0!
Measurement #3			

DBP (mmHg)	Value	AVG DBP	1/3 SBP	**MAP** = 1/3 SBP + 2/3 DBP
Measurement #1				
Measurement #2		#DIV/0!	#DIV/0!	#DIV/0!
Measurement #3				

A = SSN to Umbilicus: Distal for Femoral & Foot (convert cm to mm)	Value	AVG Fem-Foot (mm) [Avg ÷3 then x 10]	
Measurement #1			
Measurement #2		#DIV/0!	
Measurement #3			

B = Umbilicus To Femoral: Distal for Femoral and Foot (convert cm to mm)	Value	AVG Umb-Fem (mm) [Avg ÷3 then x 10]	Total Distal Femoral [A+B]
Measurement #1			
Measurement #2		#DIV/0!	#DIV/0!
Measurement #3			

C = Femoral To Foot: Distal for Foot (convert cm to mm)	Value	AVG Fem-Foot [Avg ÷3 then x 10]	Total Distal Foot [A+B+C]
Measurement #1			
Measurement #2		#DIV/0!	#DIV/0!
Measurement #3			

SSN to Radial: Distal for Radial	Value	AVG Distal Radial
Measurement #1		
Measurement #2		#DIV/0!
Measurement #3		

CAROTID to SSN: Proximal for all (convert cm to mm)	Value	AVG Proximal Carotid
Measurement #1		
Measurement #2		#DIV/0!
Measurement #3		

SEARCH4 Protocol Deviation Log

SEARCH ID	Date	Measure Time	SEARCH Staff ID No/Initials	Study Type (HRV, PWA, PWV, Other)	Protocol deviation

rev 07DEC2015

SEARCH4 SphygmoCor Certification Log

Site:	
Staff initials	

PWV (carotid-femoral only)

Subject	True or QC	Volunteer ID No.	Last Name	First Name	Measure No.	Date	Time	Notes (any problems or protocol deviations)
1	TRUE		Cert1	True	1			
					2			
					3			
	QC		Cert1	QC	1			
					2			
					3			
2	TRUE		Cert2	True	1			
					2			
					3			
	QC		Cert2	QC	1			
					2			
					3			
3	TRUE		Cert3	True	1			
					2			
					3			
	QC		Cert3	QC	1			
					2			
					3			

PWA

Subject	True or QC	Volunteer ID No.	Last Name	First Name	Measure No.	Date	Time	Notes (any problems or protocol deviations)
1	TRUE		Cert1	True	1			
					2			
					3			
	QC		Cert1	QC	1			
					2			

Subject	True or QC	Volunteer ID No.	Last Name	First Name	Measure No.	Date	Time	Notes (any problems or protocol deviations)
					3			
2	TRUE		Cert2	True	1			
					2			
					3			
	QC		Cert2	QC	1			
					2			
					3			
3	TRUE		Cert3	True	1			
					2			
					3			
	QC		Cert3	QC	1			
					2			
					3			

HRV								
Subject	True or QC	Volunteer ID No.	Last Name	First Name	Measure No.	Date	Time	Notes (any problems or protocol deviations)
1	TRUE		Cert1	True	1			
	QC		Cert1	QC	1			
2	TRUE		Cert2	True	1			
	QC		Cert2	QC	1			
3	TRUE		Cert3	True	1			
	QC		Cert3	QC	1			