

Revo®

Operator's Manual



(This page intentionally left blank.)

TABLE OF CONTENTS

INTRODUCTION, INTENDED USE, ENVIRONMENTAL CONDITION, SYMBOLS, WARNINGS AND CAUTIONS	4
CHAPTER 1: GETTING STARTED – UNPACKING AND ASSEMBLING	7
CHAPTER 2: SYSTEM OPERATION.....	14
Initial Setup	14
Start Screen	15
Main Menu.....	16
Options	18
Temp Files	21
VascuLink™	22
CHAPTER 3: PATIENT POSITIONING AND CUFF APPLICATION.....	23
CHAPTER 4: PATIENT STUDIES	26
CHAPTER 5: ABI WITH ANKLE DOPPLER WAVEFORMS STUDY	27
Completed Report	35
CHAPTER 6: ABI WITH ANKLE PVR WAVEFORMS STUDY	36
Calibrated Pulse Volume Recording (C-PVR™).....	37
Completed Report	40
CHAPTER 7: QUICK ABI WITH ANKLE PVR STUDY	41
Completed Report	46
CHAPTER 8: PPG TOE WAVEFORMS AND PRESSURES STUDY.....	47
Completed Report	51
CHAPTER 9: QUICK STRIP STUDY	52
Completed Report	53
CHAPTER 10: INDICATION QUESTIONS	54
CHAPTER 11: PATIENT STUDY NOTES	55
CHAPTER 12: EDIT, VIEW, PRINT, SAVE OR DELETE PATIENT STUDIES	56
Viewing Your Patient Study	56
Editing Patient Studies.....	57
Printing Reports.....	58
Saving Patient Studies.....	58
Deleting Patient Studies	59
CHAPTER 13: VASCULINK™ OPTION	60
Enabling Vasculink™.....	60
Disabling Vasculink™.....	61
Sending Studies	61
Successful Transmission	62
Failed Transmission.....	63
Setting up Vasculink™ (technical).....	63
CHAPTER 14: THEORY OF OPERATION	66
PPG	66
DOPPLER PROBE	66
PVR Cuff.....	67
CHAPTER 15: CARE, MAINTENANCE, WARRANTY AND SERVICE	68
Care and Preventative Maintenance	68
Troubleshooting	68
Cleaning.....	68
Limited Warranty.....	69
Service	69
GLOSSARY OF TERMS	70

Introduction

Thank you for choosing The Unetixs Revo™ 1100 with Vasculink™ (Here in after referred to as Revo™) for your PAD assessment needs. The Revo™ was designed to quickly evaluate your at-risk patients accurately and easily. The Revo™ builds upon Unetixs' reputation for building the finest vascular instrumentation for the most demanding applications and with proper care will give you many years of exceptional service.

Intended Use and Misuse

The Revo is intended for use as a non-invasive diagnostic device by trained medical personnel following physician orders. This device is intended for the detection of obstruction to blood flow in human arteries and veins as an aid for the diagnosis of disease in the peripheral vascular system. IT IS NOT INTENDED FOR MONITORING PATIENT VITAL SIGNS OR TO ADVISE IN THE ADMINISTRATION OF ANY DRUG.

NOTE: The accuracy of non-invasive vascular diagnostic studies depends on the knowledge, skill and experience of the technologist and the physician performing the interpretation of the study. This operator's manual is intended to be used as a guide to instrument operation only, and as such, should not be viewed as a substitute for formal clinical vascular education.








NOTE: The manufacturer and its agents cannot accept liability for loss, indirect or consequential damages resulting from misuse of or modification to the device or from operator negligence.

Because the results of the studies are dependent upon operator skill, procedures and interpretation beyond the manufacturer's control, the manufacturer or its agents cannot accept any liability arising from operator error or Physician misinterpretation.

It is recommended, in the event of an uncertain diagnosis following a primary testing with the system, that the patient be referred to an expert vascular practitioner and/or laboratory for further evaluation.

Specified Environmental Conditions for use of Revo

1. Indoor use ONLY.
2. 68 – 78 Degrees Fahrenheit (20 – 25.5 Celsius)

Symbol	Definition
	Refer to Operator's Manual for Information
	Do not dispose of in municipal waste. Wheeled bin symbol indicates separate collection for electrical and electronic equipment (WEEE Directive 2002/96/EEC)
IP20	Identifies the degree of protection against Fluid & Dust.
	Direct Current (DC)
	Do not re-use
	Type BF Equipment
	Class II
	Technical Support Phone Number



- Before operating please go through the Operator's Manual which contain theory of operation, setup, operation, and Warnings to minimize the risk of improper usage and application of the device.
- All the cables and tubing should be carefully routed to avoid the possibility of patient entanglement and strangulation with an active, semi-conscious patient, nor should patient be left unattended.
- Inspect for damage! User should inspect the system for signs of damage. Do not use the system if damage is evident or failure is evident or suspected.
- The device should not be used in MRI environment.
- The device is to be operated by trained medical personnel only.
- People who are suffering from Deep Vein Thrombosis (DVT, i.e., blood clot in the veins of the legs) should not undergo an ABI test.
- Do not connect luer or bayonet fittings into any other equipment.
- Do not connect cuffs with luer lock or bayonet connectors to intravenous fluid systems or air may enter the patient. Immediately consult a physician if this occurs.
- When inflated above 10mmHg, make sure the cuffs will not remain on patient for more than 10 minutes, which may lead to patient distress, disturbance in blood circulation and injury to the peripheral nerves.
- Cuffs should not be wrapped on patient where skin is delicate or damaged.
- Cuffs should not be wrapped very tightly, at least a space of 1 finger must be allowed between the patient and the top of the cuff.
- The Doppler probes are not intended to be used on open skin. Disinfect the probe before using it again in case of open wound contamination.
- The Doppler probes are not intended to be used on or near the eyes.



- The Doppler probes are not intended for fetal use.
- Do not use the system in the presence of, or in rooms with access to, gas mixtures which may be flammable and flammable anesthetic agents.
- Operators not to leave the patient unattended in between testing.
- Do not re-use accessories labeled as single use.



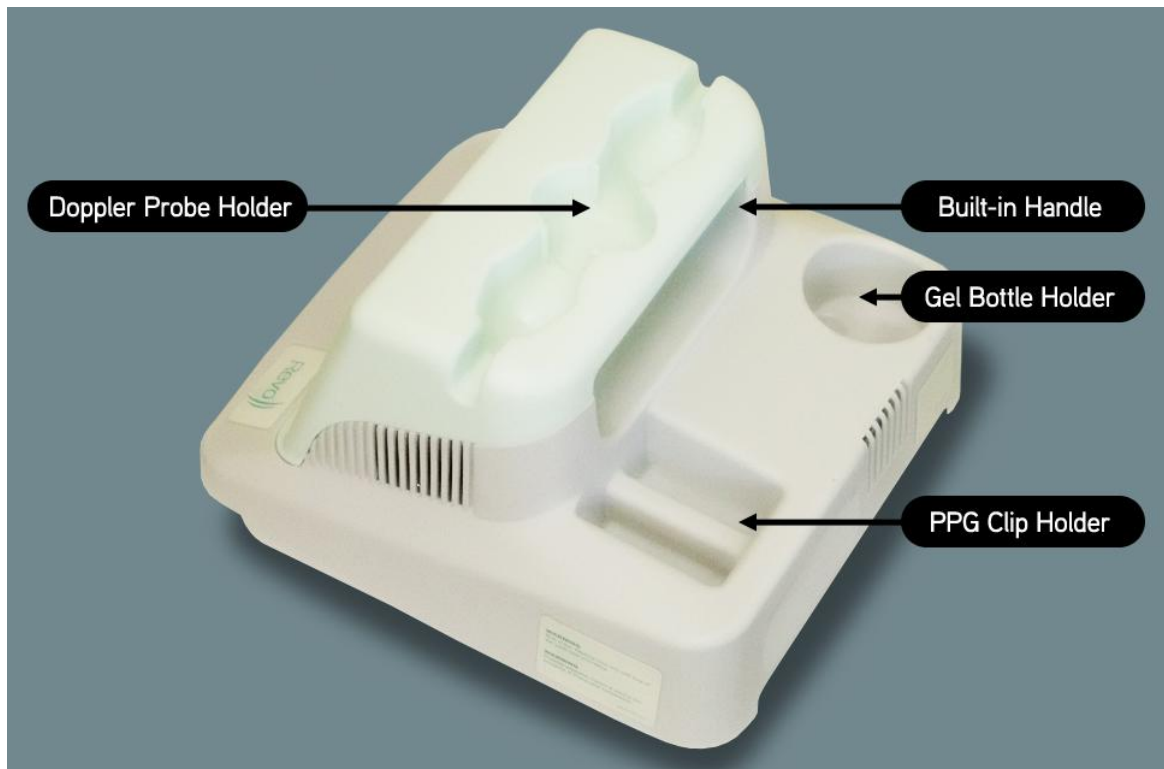
- Revo™ is non – invasive vascular diagnostic equipment and not for monitoring the patient's vital sign and not for use in ICU or in operating theater, administering or advise for administering any kind of drugs.
- Testing to be performed by trained medical personnel in a separate room where care against fluid ingress has been taken.
- Doppler and PPG connectors are push/pull connectors ONLY for easy detachment. Any attempt to twist or “screw” these cables in or out will result in damage to the cables.
- Use the equipment only with recommended accessories! Use of unapproved accessories may cause inaccurate readings.
- Do not store equipment at extreme temperatures. Temperatures exceeding specified storage temperatures (-5 to 50 °C) could damage the system and accessories
- Use the power supply (10378-0001-01) which was provided with the unit.
- The system is not intended for continuous or unattended monitoring.
- During the study when the patient feels discomfort during the cuff inflation, cuff can be deflated by pressing the deflate button on the Revo™ screen or easily disconnect from the hose.
- Unit to be operated in an un-interrupted power supply environment.
- Do not use devices, like USB memory sticks, with the system without first scanning them for virus or malware bytes. UNETIXS, Inc. assumes no responsibility if the user chooses to leave the system unprotected.
- Do not use the Ethernet port for internet access, other than for a device application such as Vasculink™. If Ethernet port must be used, use of firewalls and/or virus protection scanning software is recommended.
- Unit is to be serviced by UNETIXS trained service personnel only. There are no user serviceable parts in the unit. Changes or modifications, not expressly approved by UNETIXS, Inc., may cause unexpected results (hazards to the patient or the operator), and may also void the warranty.
- Do not press on the keys and screen with surgical instruments or other tools. Sharp or hard objects could damage the keys and screen. Use only your fingertips to press on the keys and screen.
- U.S. Federal law restricts this device to sale by or on the order of a physician
- When products and accessories are near expiry dates and/or require disposal, these items must be processed in accordance with relevant product processing regulations. For further information, please contact UNETIXS, Inc., or its representative agencies.
- Avoid placing the device near diagnostic or therapeutic equipment like X-ray machines, ultrasound machines, electrically operated beds, etc.
- Do not operate the system on an unstable cart or stand. The system may fall causing injury. Use the system with a cart approved or supplied by the manufacturer.
- Use only in specified environmental conditions.

Chapter 1: Getting Started – Unpacking and Assembling

STEP 1: Unpacking and Mounting on Pedestal

Your Revo™ with Vasculink™ will arrive in 2 boxes: one for the Revo™ unit and its accessories, and one for the pedestal, pre-attached power supplies and printer. You will find the **System Component Checklist** inside the Revo™ box. While unpacking, check contents against the list. Call Unetixs immediately in the unlikely event that anything is missing.

- 1) When lifting the Revo™ unit, use the built in handle:

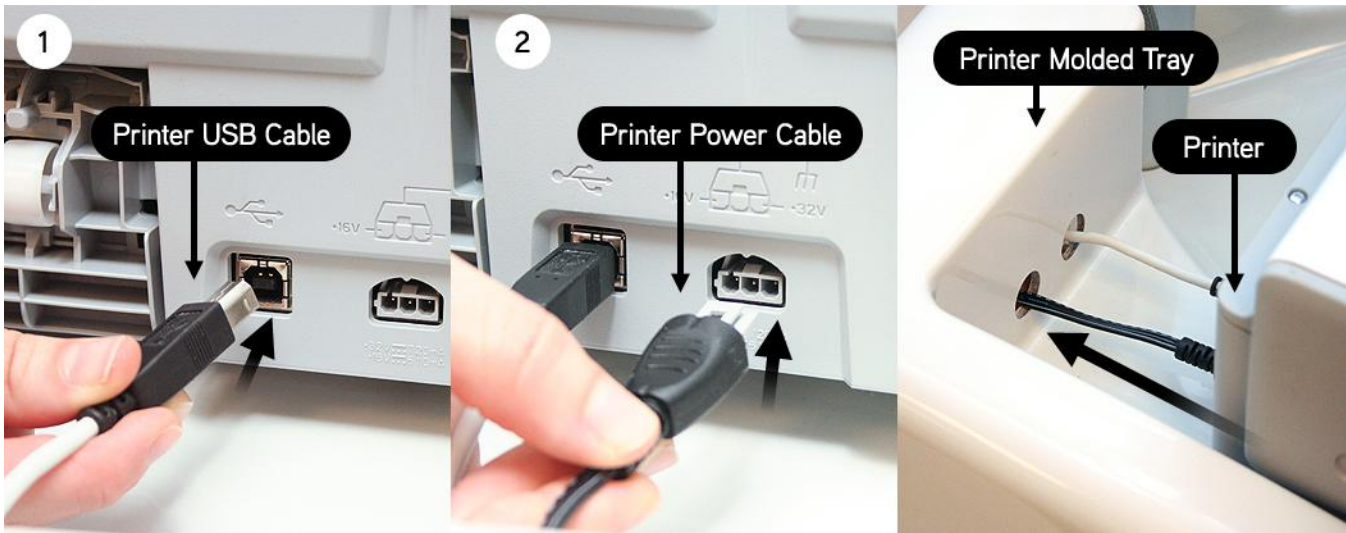


- 2) If you purchased the cart option, please refer to the Revo™ Cart Assembly Instructions (10307-0001-01).
- 3) Retain all shipping boxes for future use.
- 4) Adjust the pedestal height by loosening the black knob. The gas assisted cylinder will rise. Tighten knob to hold it in place.



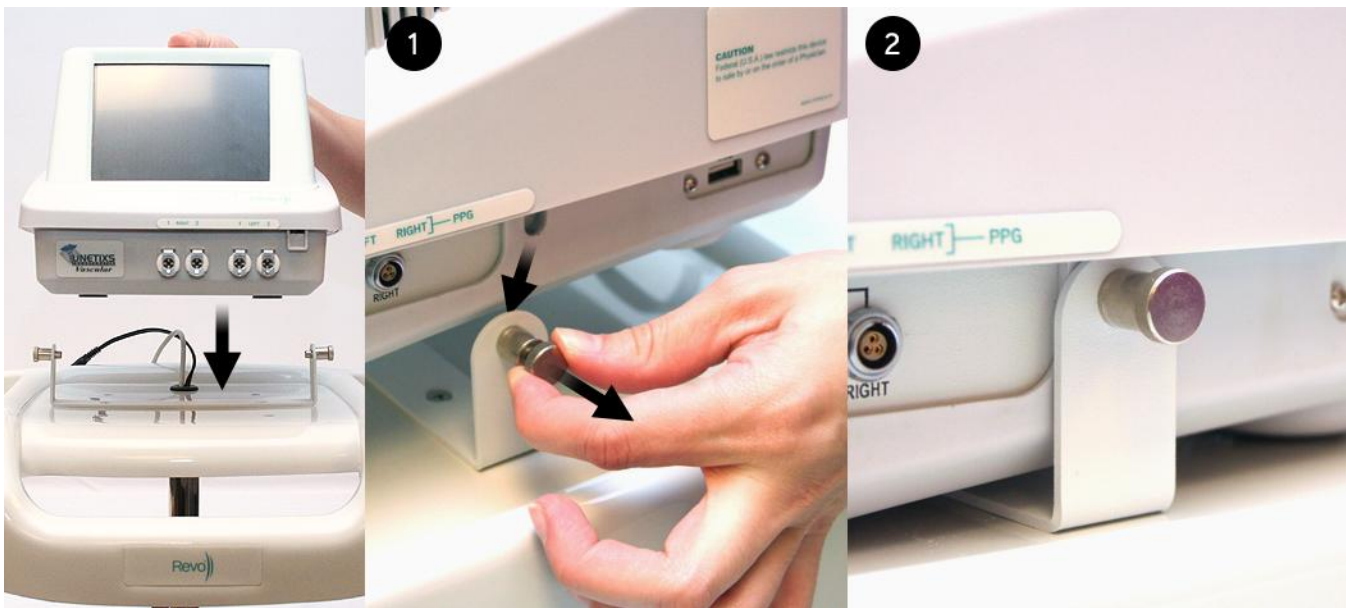
- 5) Unpack the printer according to manufacturer's directions, and place the printer on its shelf.

6) Connect the printer's power cord and USB cable as shown (due to their shape, you cannot insert them incorrectly):



7) Later, when you have power connected to the system and it's turned on, install the printer ink cartridges according to the manufacturer's directions.

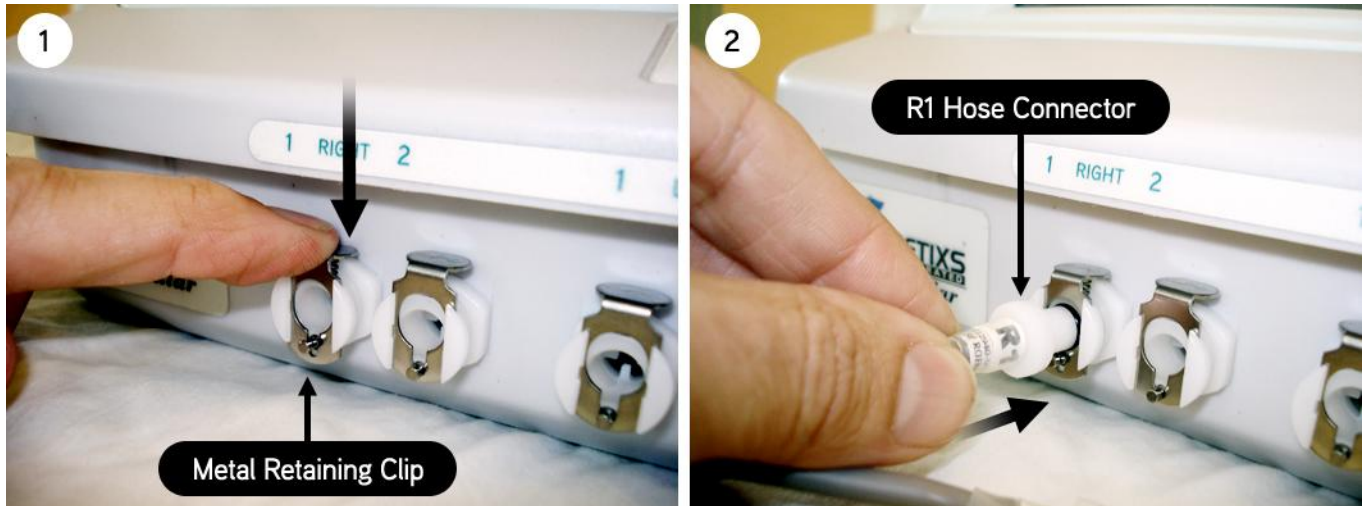
8) Place the Revo™ unit on top of the pedestal. There are two spring loaded pins located on either side. Pull the pins out and let them slide into the receptacles on the Revo™ - these will hold the unit securely in place:



Once your Revo™ system is on the pedestal, install probes and pneumatic hoses.

STEP 2: Pneumatic Hose Installation

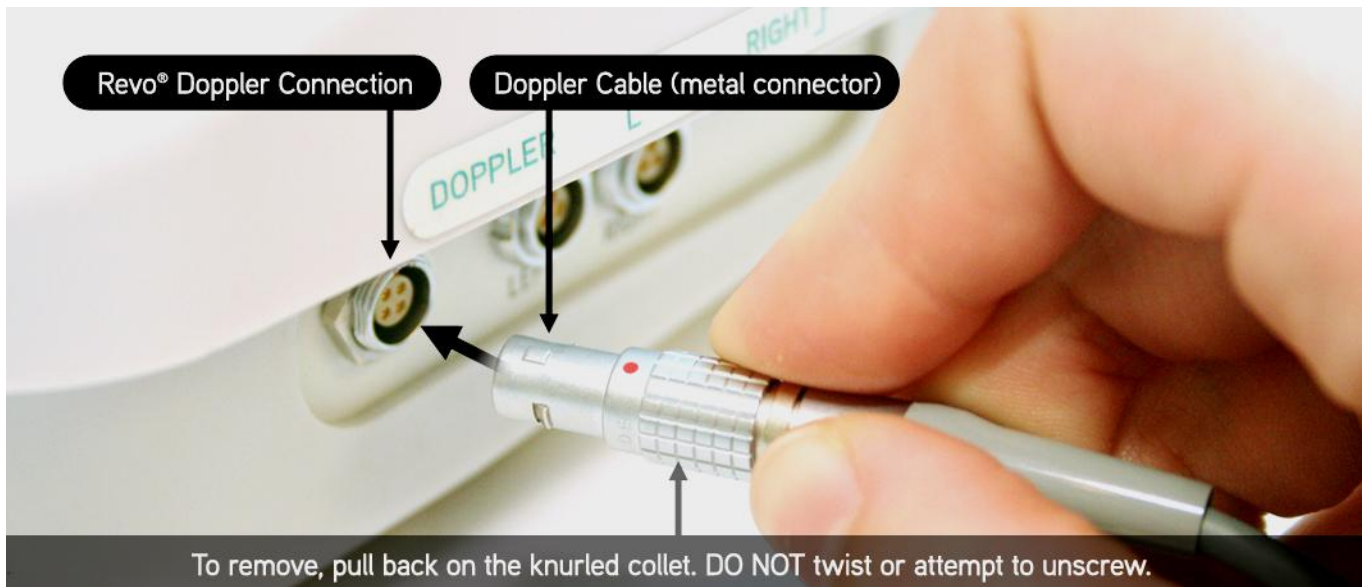
- 1) Install pneumatic hoses by pressing down on the metal retaining clip as shown below.
- 2) Insert the RIGHT pneumatic hose (R1) into the inlet port. The retaining clip will make a “snap” sound when hose is completely inserted.



- 3) Insert hoses R2, L1 and L2 in the same manner.

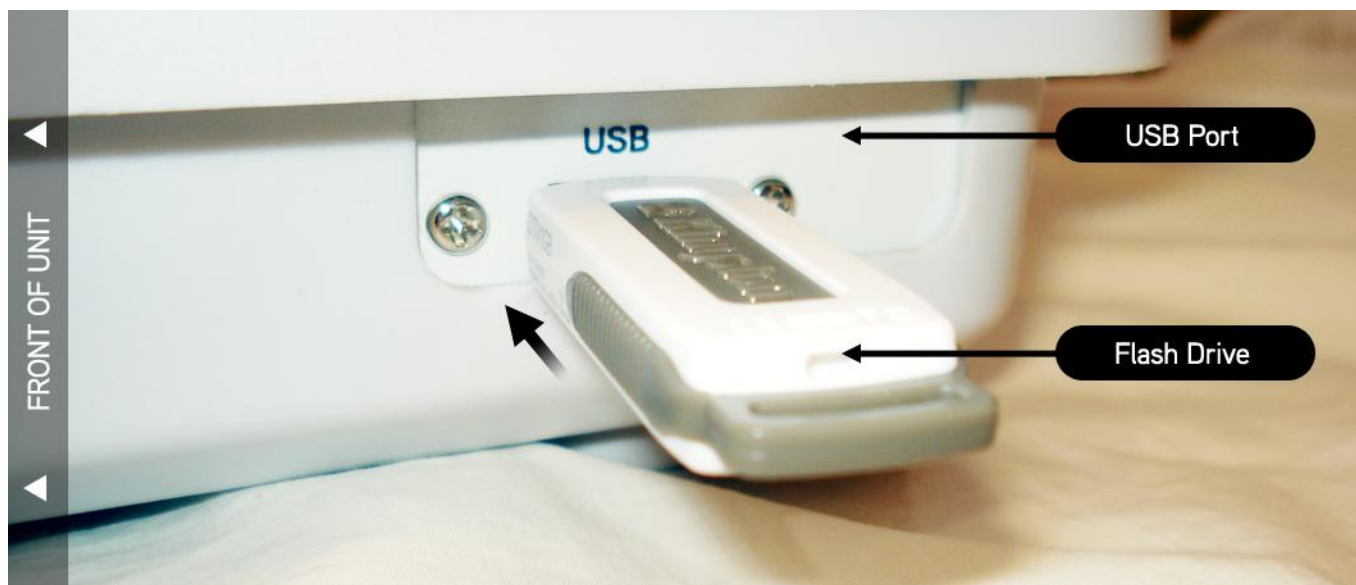
STEP 3: Inserting the Doppler Cable

Insert the Doppler cable into the Revo™ unit, by positioning the red dot on the metal connector with the red dot on the Doppler cable port, and pushing straight in:



CAUTION: The Revo™ Doppler and PPG connectors are push/pull connectors ONLY. Any attempt to twist or “screw” these cables in or out will result in damage to the cables, or the Revo™ unit.

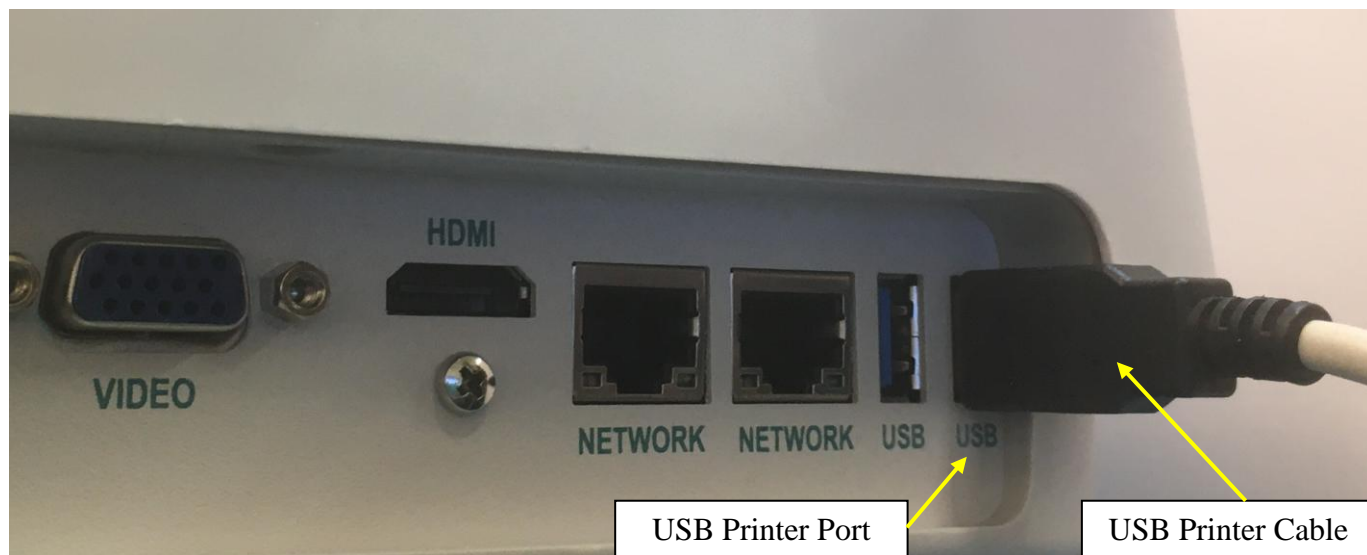
Plug the USB flash drive into the USB port on the SIDE of the Revo™ unit as shown:



NOTE: The USB port on the BACK of the Revo™ unit is for the supplied USB color page printer.

STEP 6: Inserting the Printer Cable

Insert the USB printer cable connector into the USB port on the back panel of the Revo™ unit as shown:



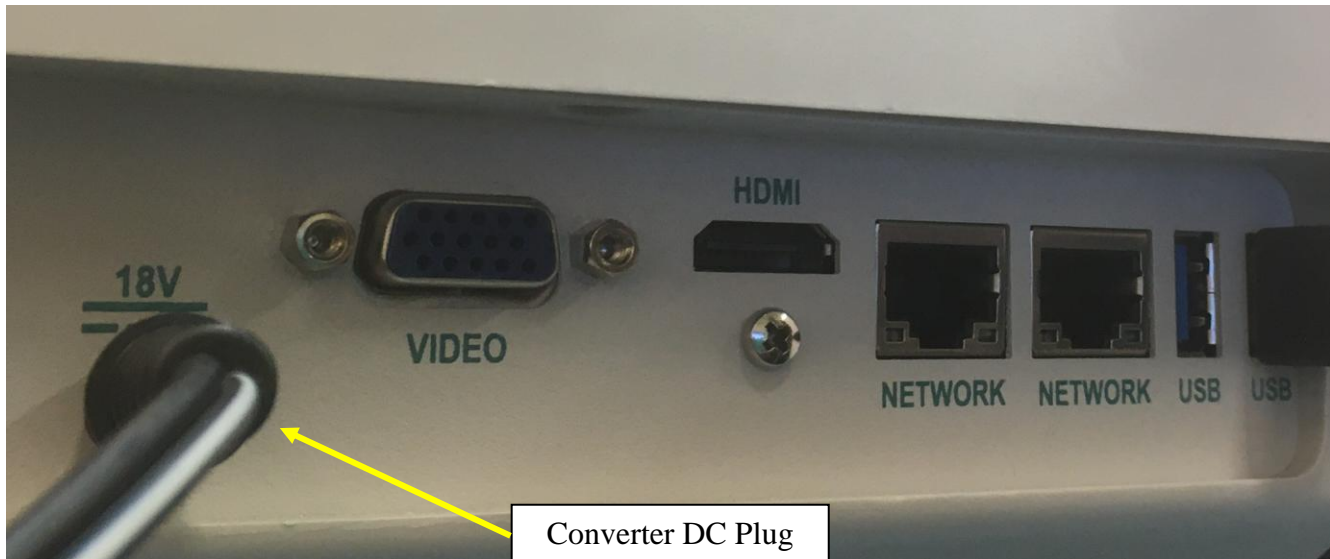
STEP 7: Inserting the Power Cable

The power to the Revo™ comes from an 18 volt AC (110v or 220v) converter:



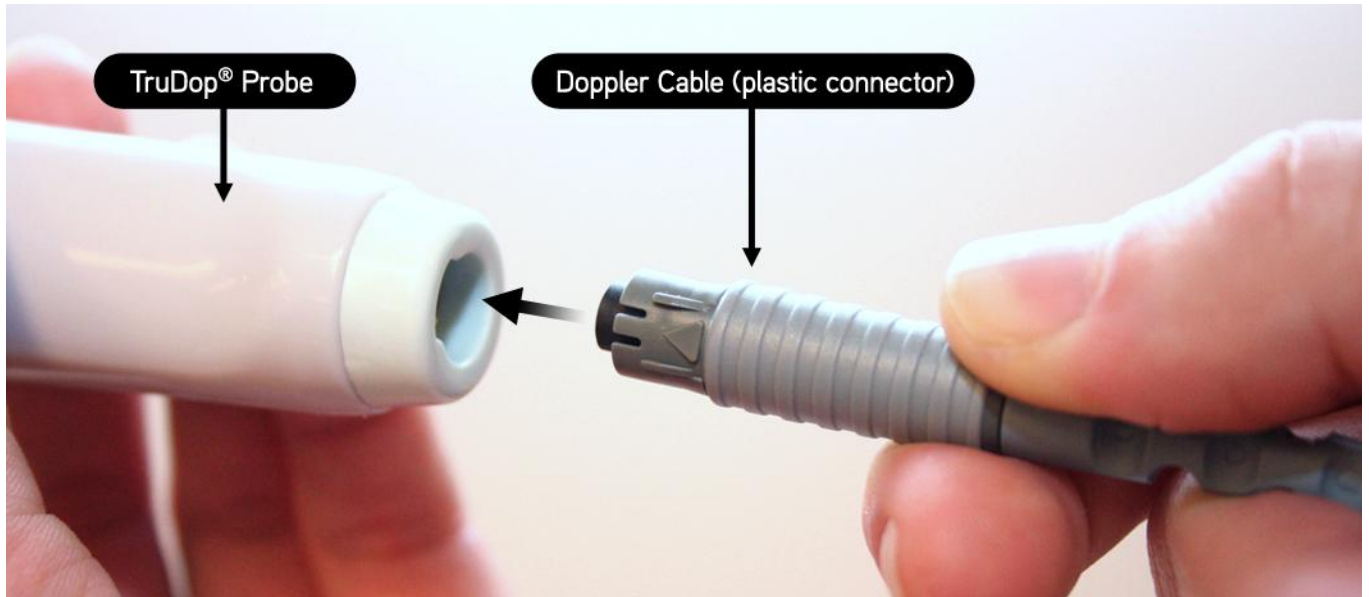
NOTE: If you purchased your Revo™ system with the optional cart, the converter will be preinstalled into the cart prior to shipment.

The multi-prong cable connects to the wall power socket, and the small round connector fits into the back of the Revo™ as shown:

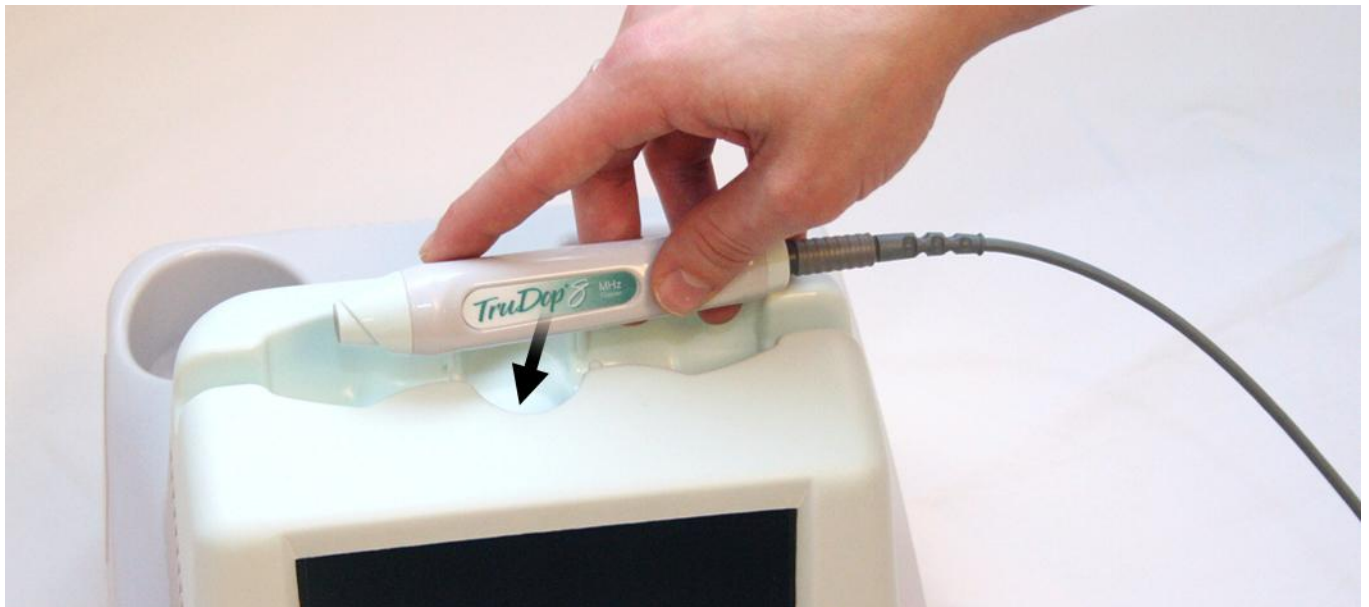


STEP 8: Attaching the Doppler Probe to the Cable

The cable connector that attaches to the Unetixs TruDop™ probes, is made of molded plastic, and has an arrow to designate proper probe connection. The Unetixs TruDop™ probe has a notch in the base of the probe to accept the arrow in the cable. Line-up the arrow in the cable with the notch in the probe base, and push straight in. Make sure the cable connector is firmly seated:

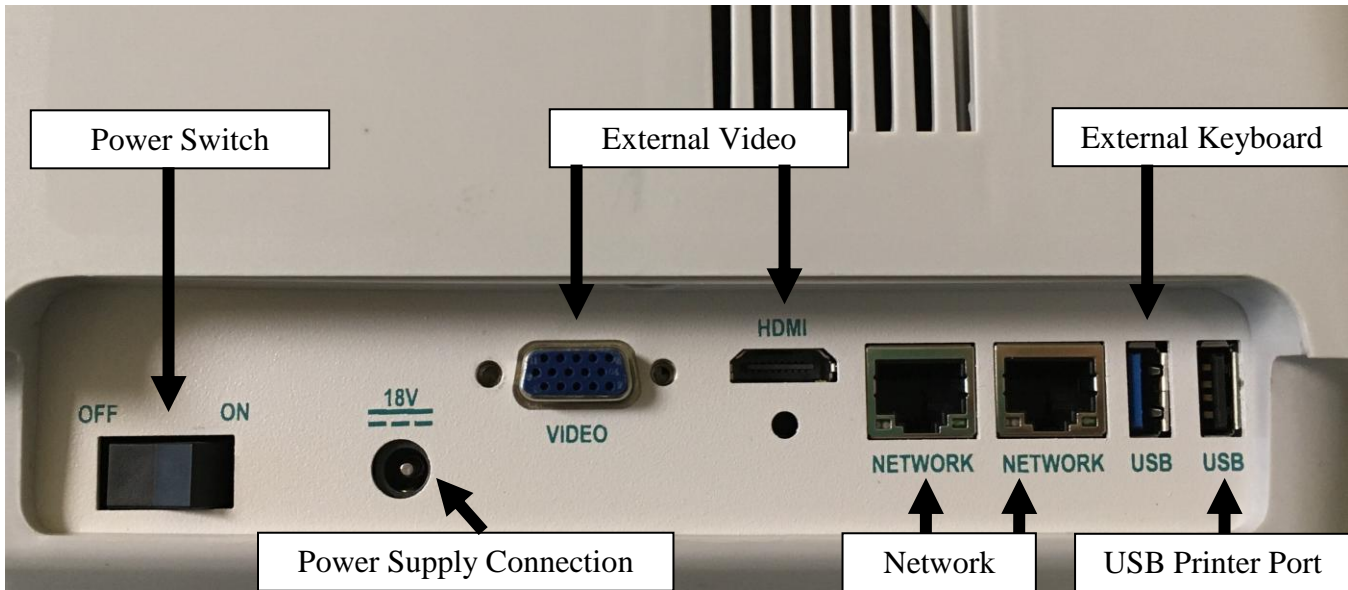


When cable and probe are connected, place the Doppler probe into the Doppler holder on top of the Revo™ unit:



Chapter 2: System Operation

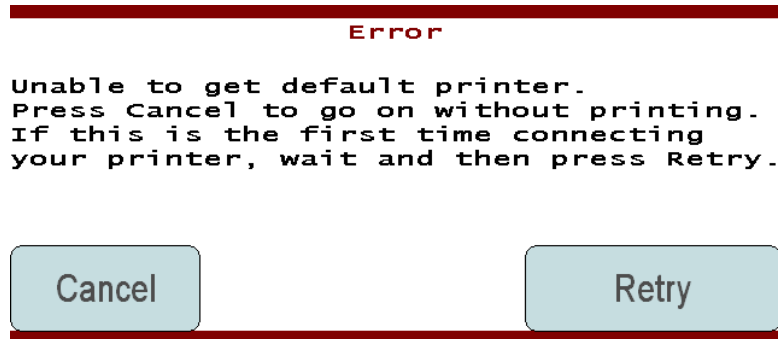
To turn on your Revo™ system, use the power switch on the back of the instrument as indicated below:



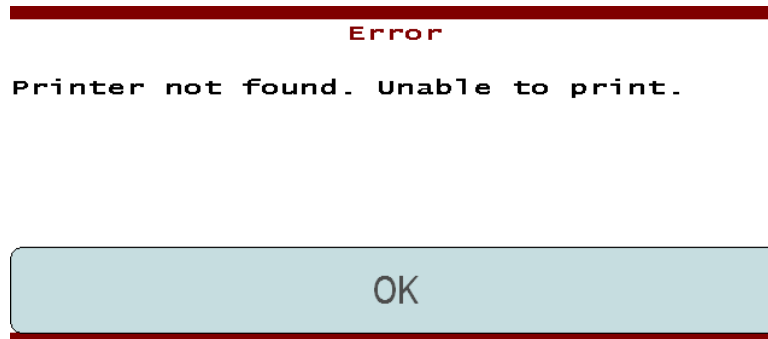
Initial Setup

Default Printer and Printer Not Found Messages

If this is the first time you are turning on your Revo™, you may see the following screen:



This just means that the system needs some more time to install the printer driver. The best solution is to keep **“Retrying”** for a couple of minutes to allow the default driver to load. If you press **“Cancel”** you will see the following screen:



This message alerts you that there is no printer recognized by the system. The Revo™ will still operate, but you will not be able to print. You can still save your studies to a thumb drive (see **Chapter 12: Saving Patient Studies**).

Start Screen

When the Revo™ is ready for operation, you will see the Revo™ Start Screen.

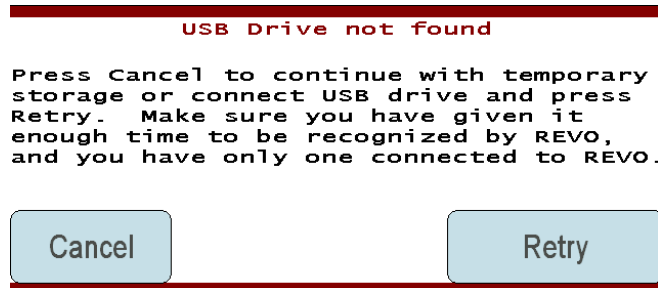


“Shutdown,” at the lower left of the screen, shuts down the operating system. This is recommended to do before turning your Revo™ off.

“Start,” at the lower right of the screen, will allow you to begin using your Revo™. If a USB storage drive has already been connected, Revo™ will automatically begin using the USB storage mode (see **USB Storage Mode** below).

USB Drive Not Found Message

If a USB drive is not found, you will see the following screen:



Depending upon your selection here, the Revo™ will operate in **Temporary Storage Mode** or **USB Storage Mode**.

Temporary Storage Mode

Pressing cancel on the screen shown above will allow the Revo™ to operate, but **patient data will be erased when the system is started or shutdown**. Completed studies can still be saved as a PDF to a USB thumb drive, or they may be printed.

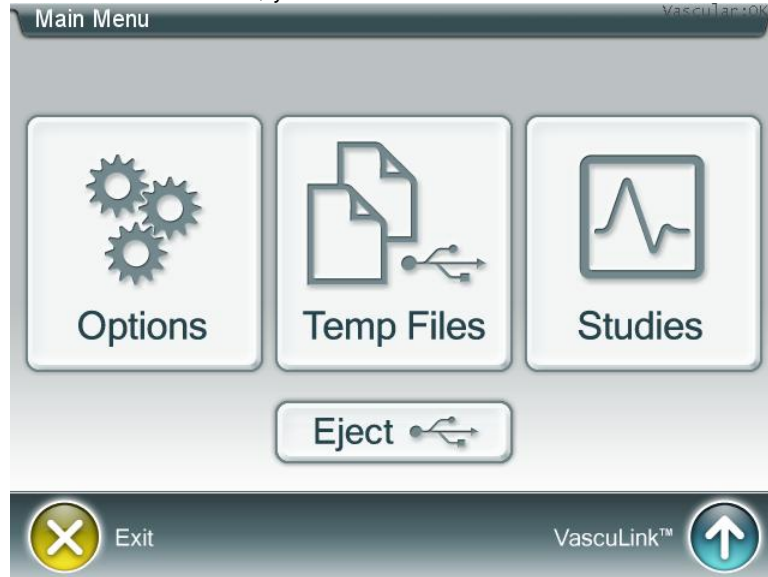
USB Storage Mode

You may press “Retry” as many times as necessary as you wait for the system to recognize the USB storage device. The recognition process may take a minute or so (especially for a new USB device), but you can retry every 10 seconds or so as desired. When operating in this mode, the Revo™ will save all patient information in USB storage, even through a power down and system restart. The user will have to explicitly delete patient studies (see **Chapter 12: Deleting Patient Studies**) from the USB storage device. Note that the USB storage is not tied to the exact Revo™ where the data was captured (i.e. you can perform the study on one Revo™, and then edit, print, and save the studies on a different Revo™).

TECHNICAL NOTE: The files stored in the USB Storage Mode will be found in the “UNETTEMP” folder on the USB device. If the folder does not exist, Revo™ will attempt to create it. This must succeed before USB Storage Mode is allowed. The files in this folder contain information in a format only understood by the Revo™ itself. Attempts to use other programs to view this data will likely fail (i.e. using Adobe® Acrobat® Reader to view the “.pdf” files).

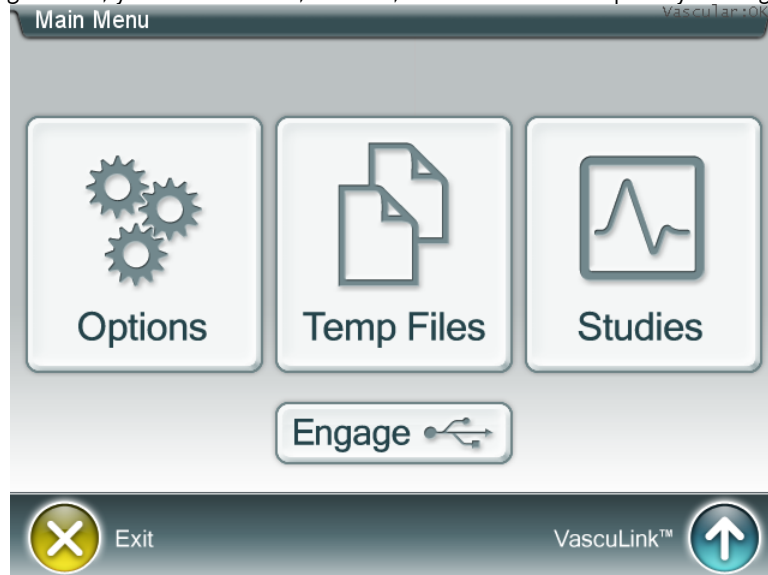
Main Menu

After pressing “Start” from the Revo™ **Start Screen**, you will then see the Revo™ **Main Menu** screen (USB Storage mode):



Note the USB symbol on the Temp. Files button.

If you are in Temporary storage mode, your screen will, instead, look like this (Temporary Storage mode):



Pressing “Exit” will return you to the **Start Screen**. This can be useful if you want to return to USB Storage mode when you are in Temporary Storage Modes (see **Temporary Storage Mode** and **USB Storage Mode** in the **Start Screen** section above). If you have used the **Temporary Storage Mode** you will get the following warning if the **Temp. Files** area is not empty when you attempt to “Shutdown” from the Start Screen:



Pressing “Cancel” aborts the exit process and returns you to the **Start Screen**, so you can return to the temp files. Then you can save or print as desired (see **Temp Files** below).

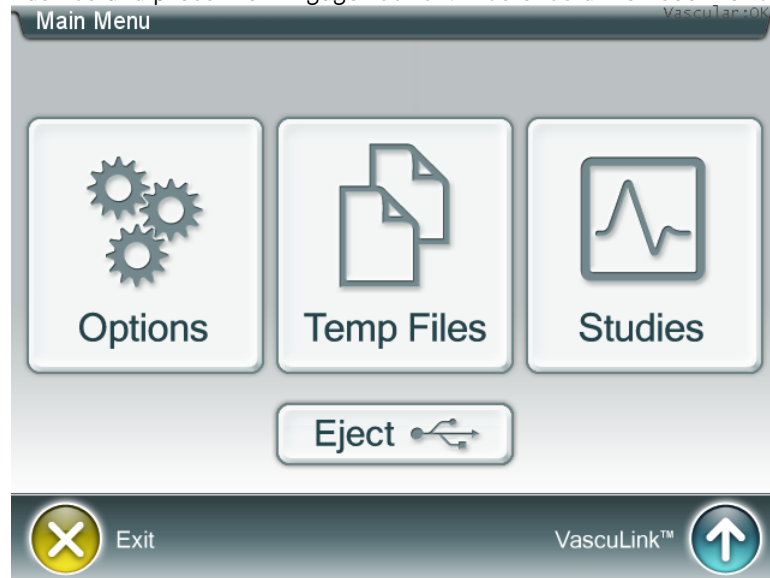
Pressing “OK” will delete all of the patients in the **Temporary File** (again, only for **Temporary Storage Mode**) and will shut down the Revo. After shutting down the operating system, the screen may say “it is now safe to turn off your computer” or screen may go blank. You can then power off the Revo™ with the power switch in the back of the system.

Switching between Storage Modes

If you are in USB Storage mode, simply press the “Eject” button on the main screen to switch to Temporary Storage Mode. To get to USB Storage Mode from Temporary Storage Mode, First press the “Engage” button to engage the USB Device; then press “Exit” to return to the Start Screen; from the Start Screen press “Start” to re-enter the Main Menu.

Saving data to the USB device while in Temporary Storage Mode

If no USB device is present, the “Save” buttons (see Editing Patient Studies in chapter 12 or Temp. Files in this chapter) will be disabled. Simply insert a USB device and press the “Engage” button. You should then see the follow screen:



At this point the “Save” buttons will be enabled.

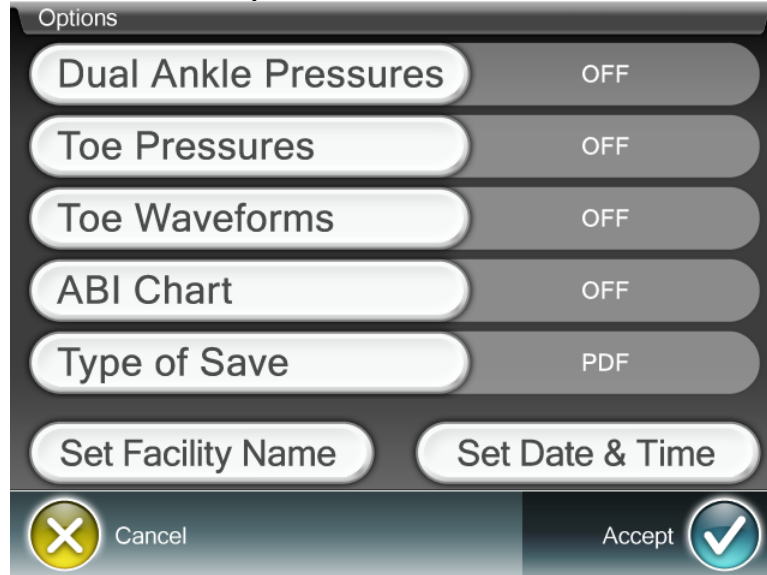
Proper Removal of the USB Device

If, after saving a patient study, you wish to remove the USB device to review what was saved, **you must first press the “Eject” button from the Main Menu.** Failure to do this may result in lost or corrupted data on the USB device.

When your review of the data is complete you may re-insert the USB device. You can then select your Storage mode (see Switching between Storage Modes above) after pressing the “Engage” button on the Main Menu screen.

Options

Pressing the “Options” button on the **Main Menu** screen will give the user the opportunity to change certain settings on the vascular studies that are preloaded from the factory.



NOTE: Settings cannot be changed during an exam. Settings must be set prior to starting a new study.

The options are:

Dual Ankle Pressures

Applies to: ABI w/ Ankle Doppler Waveforms Study and ABI w/ PVR Ankle Waveforms Study

Revo™ has the ability to take blood pressures utilizing the Doppler probe in a **single channel** format or in a **dual channel** format utilizing the two PPG sensors and clips.

- ON** In this position, the user will be prompted to take ankle pressures with the Doppler probe at both the Dorsalis Pedis and the Posterior Tibial arteries on the right and left ankles. On the **ABI with Doppler Waveforms** study, the user will also be prompted to obtain Doppler waveforms at both arteries on each ankle.
- OFF** In this position, the user will be prompted to take a single ankle pressure at each ankle. The user may choose either the Dorsalis Pedis or Posterior Tibial artery. The user may also choose to use the PPG probe to obtain the pressure.

Toe Pressures

Applies to: ABI w/ Ankle Doppler Waveforms Study, ABI w/ Ankle PVR Waveforms Study, Quick ABI w/ Ankle PVRs Study, and PPG Toe Waveforms and Pressures Study

Revo™ has the ability to take **dual channel toe pressures** in order to determine the Toe Brachial Index (TBI).

- ON** In this position, the user will be prompted to obtain 2 toe pressures in all applicable studies except **PPG Toe Waveforms and Pressures** where 10 (instead of 2) toe pressures may be obtained.
- OFF** In this position, the user will not be prompted to take toe pressures in any of the applicable studies except **PPG Toe Waveforms and Pressures** where only 2 toe pressures may be obtained.

Toe Waveforms

Applies to: ABI with Doppler Waveform Study, ABI with PVR Waveform Study, Quick ABI study, and PPG Toe Waveforms and Pressures Study

Revo™ has the ability to take **dual channel toe waveforms** utilizing the PPG clips and sensors.

- ON** In this position, the user will be prompted to obtain 2 toe waveforms in all applicable studies except **PPG Toe Waveforms and Pressures** where 10 (instead of 2) toe waveforms may be obtained.
- OFF** In this position, the user will not be prompted to take toe waveforms in any of the applicable studies except **PPG Toe Waveforms and Pressures** where only 2 toe waveforms may be obtained.

ABI Chart

Applies to: ABI with Doppler Waveform Study, ABI with PVR Waveform Study, Quick ABI study

Revo™ has the ability to include an **ABI chart** in the final report, depicting normal and abnormal values for quick reference. Two charts are offered.

- CHART 1** The following chart is included in the final report^[1]:

Ankle/Brachial Index (ABI)	
.97 - 1.25	NORMAL
.75 - .96	MILD
.50 - .74	MODERATE
<.50	SEVERE

- CHART 2** The following chart is included in the final report^[2]:

Ankle/Brachial Index (ABI)	
0.90- 1.30	NORMAL
0.70- 0.89	MILD
0.40- 0.69	MODERATE
<0.40	SEVERE

- OFF** No chart is displayed.

[1] Scissons, R., RVT, FSVU. Jobst Third Vascular & Endovascular Interventions Symposium, April 29, 2004.

[2] Olin JW. Clinical Evaluation and Office-Based Detection of Peripheral Arterial Disease contained in Primary Care Series: Peripheral Arterial Disease and Intermittent Claudication; Hirsch AT (Ed), Excerpta Medica, Inc., 2001.

Type of Save

Applies to: 'Save' buttons on the End of Study and Temp. Files screens

Revo™ has the ability to save either PDF files (suitable for printing) or BMP files (suitable for viewing).

- PDF** In this position, pressing the save button will save a PDF file of the patient report to the USB drive. The files will be located in the UNETPDF folder on the USB drive.
- BMP** In this position, pressing the save button will save a BMP file or files of the patient report to the USB drive. The files will be located in the UNETBMP folder on the USB drive.

Set Facility Name

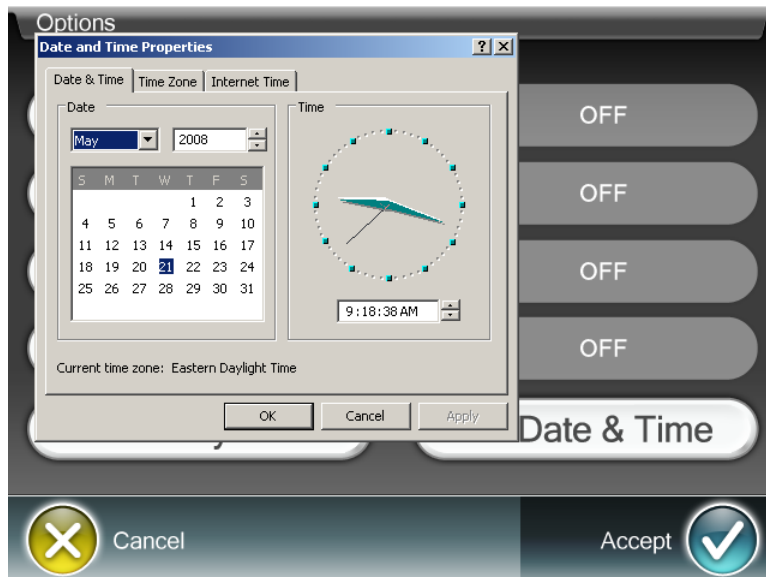
Applies to: All Studies

This sets the **facility name** that is printed at the top of all Revo™ reports. When activated, an on-screen keyboard will appear to enter the name of your facility. Note: After pressing “Accept” on this screen, you must also press “Accept” on the Options screen.



Set Date & Time

Pressing “Set Date & Time” will bring up the operating system’s control panel for setting the Date and Time.

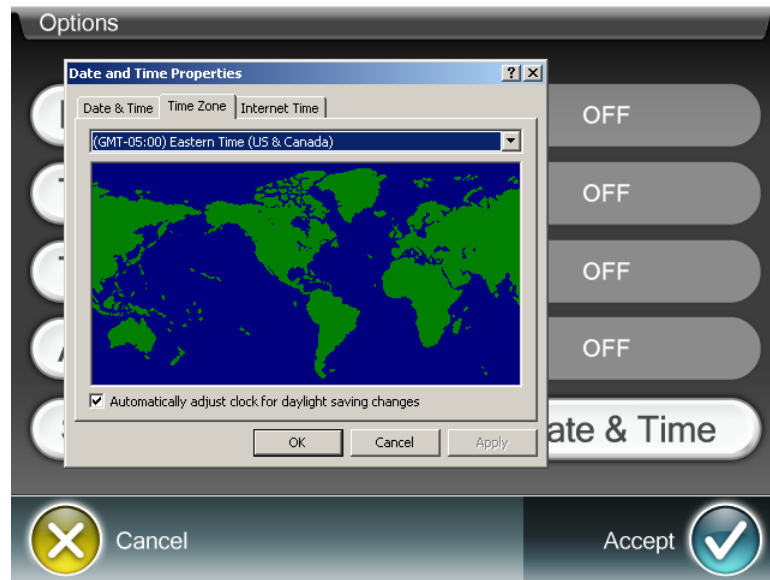


NOTE: Due to the small size of the touch targets in the operating system’s control panel, it may be advisable to use a fingernail or other small non-metallic object on the touch screen. Another option is to temporarily connect a USB mouse to the Revo™.

Change the Year, Month and Day using the controls on the left side of the “Date and Time Properties” panel.

To change the Hours, Minutes and Seconds, first touch the value you wish to change. A cursor will be placed next to the value or the value will be highlighted. Then use the up and down arrow keys to change the value.

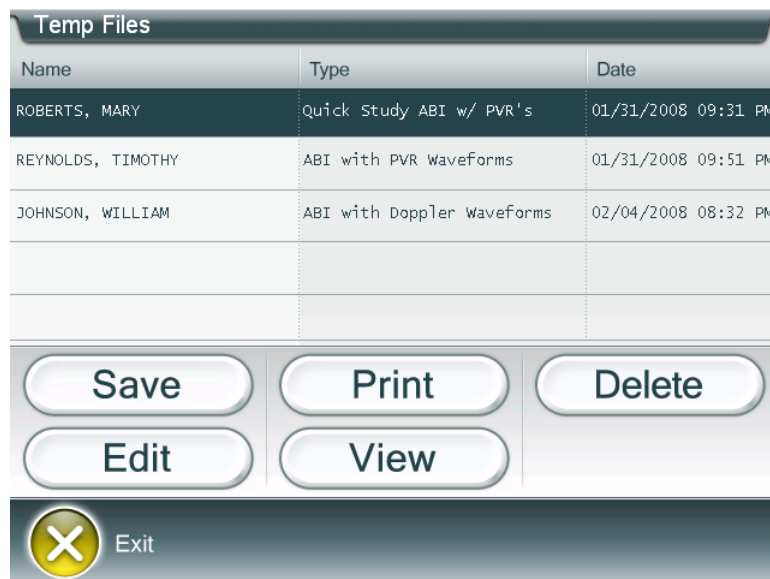
To set the Time Zone, touch the “**Time Zone**” tab at the top of the panel to change the screen as follows:



You may now change the **Time Zone** as needed.

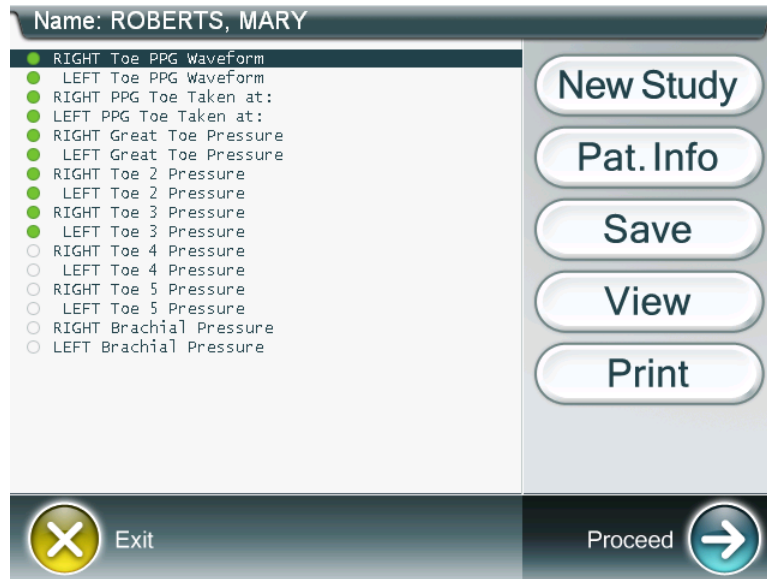
Temp Files

The Revo™ has built-in protection against power outages or user errors. If the USB flash drive is left in the Revo™ unit, it can store **up to five temporary studies**. These temporary files can be edited, changed, printed or saved to the USB flash drive. If the USB flash drive is removed when the system is powered on, the user should immediately exit to the **Start Screen** to reset the Storage Mode (see Switching between **Storage Modes**, p. 15). The EJECT button on the main menu should be pressed before removing the USB flash drive. When you touch the “**Temp Files**” button from the Main Menu (p. 16) screen, you will see the contents of the Temporary File folder:



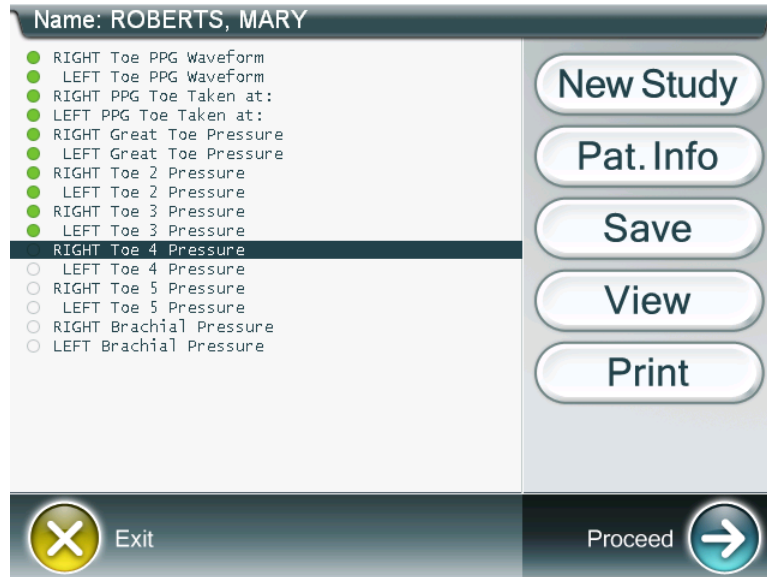
Recovering from a Power Outage or Operator Error (USB storage mode only)

Press the “Temp Files” button, and then touch the patient exam you were performing. Touch the “Edit” button. The following screen will appear:



Any exam step that has a green dot next to it has already been captured.

Touch the first “open” site as shown:



Press the “Proceed” arrow to continue your exam.

Vasculink™

Pressing the Vasculink™ button will attempt to enable an optional data networking system. With Vasculink™ enabled, the ‘Save’ buttons are changed to ‘Send’ buttons as the normal PDF or BMP saves are disabled. Note that the USB drive does not need to be inserted for Vasculink™ to function... thus Vasculink™ works in either USB or Temporary storage modes. You can disable Vasculink™ by simply returning to start screen. See chapter 13 for more information. Once Vasculink™ is enabled, the button is dimmed and does not need to be pressed again.

Chapter 3: Patient Positioning and Cuff Application

Unetixs recommends the following to ensure accuracy:

1. Room temperature

The temperature in the examination room should be 76 – 80 degrees F. Colder room temperatures can result in vasoconstriction, which can render inaccurate results in the “Quick ABI” study, and any study incorporating toe waveforms or pressures.

2. Patient positioning

Gravity affects arterial pressure. It is best to have the patient supine for vascular studies. A flat exam table with a small pillow to support the head is ideal. Some patients cannot tolerate this position due to obesity, back problems, etc. If necessary, elevate the table section supporting the back to the minimum degree to make the patient comfortable.

3. Cuff Application

For Blood Pressure measurements, proper cuff application will speed the exam. For PVR (Pulse Volume Recording) waveforms, proper cuff application will produce consistent and accurate waveforms.

Wrap cuffs at the following locations:

Size	Location
10cm	Right and Left Arm – As high as possible
10cm	Right and Left Ankle – Above the Medial Malleolus (Ankle) Bone
1.9cm	Great Toes – At the base of each great toe, as proximal as possible.

For best results, wrap the cuffs snugly and uniformly as shown below:



Incorrect ankle cuff application:



Cuffs should be wrapped snugly with looseness not exceeding “1-finger width” of the technologist. Wrinkles should be avoided. A poorly wrapped cuff will adversely affect PVR testing results.

When wrapping, place the tubing connector of the cuff on the medial side of the limb, this will insure that the bladder of the cuff is covering the area where the vessels are anatomically located. The non-bladder portion of the cuff should be away from this area.

Lift the patient’s limb when applying a cuff. If the patient “tries to help you” by lifting their limb, tell them to relax, a contracted muscle during cuff application will usually result in a loose cuff when patient relaxes limb.

The patient should be supine or with head elevated (semi-Fowler) on padded exam table. Avoid having the limb or cuff rest on the edge or crease of stretcher, cot or bed since this will cause an uneven pressure within the cuff.

Cuffs should not be inflated to a pressure of greater than 250mmHg. If occlusion does not occur, “Capture” the pressure reading, and using the “Set Output” function, enter the value as “CNO”, “250+” or “>250” to avoid erroneous reporting of indices, and to signify limb segment was still pulsatile at that pressure to interpreting physician.

A patient complaint of severe pain during a pressure examination is sufficient reason to terminate the test on that particular cuff. Press “NEXT” and skip to the next segment. Do not press “CAPTURE”.

IMPORTANT: DO NOT APPLY BRACHIAL CUFFS IN THE FOLLOWING CONDITIONS:

- Over a “PICC” line, or venous access port.
- On an arm that is swollen, hot or hard (possible DVT).
- On female mastectomy patients as advised by their physician.

Digital cuffs should be applied with the bladder surrounding the fleshy part of the digit and not toward the bony side or nail bed side. Be cautious of connector hose kinking on these cuffs.

A properly wrapped toe cuff:



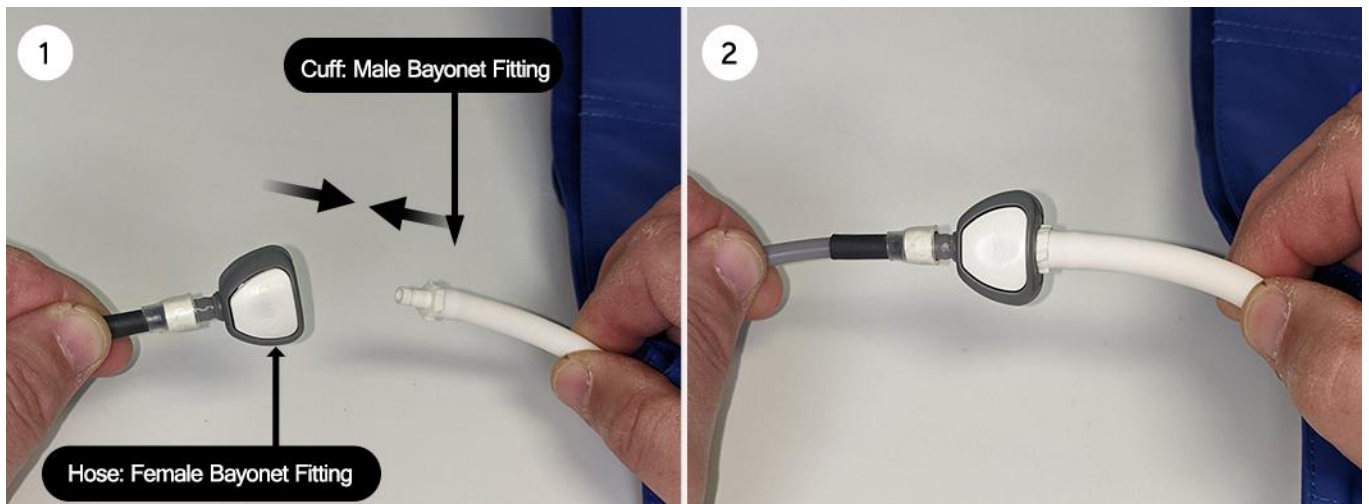
4. Hooking up the hoses

The Revo hoses are color-coded, and labeled.

RT-ARM	Insert into Cuff Located on the Right Arm
LT-ARM	Insert into Cuff Located on the Left Arm
RT-ANK	Insert into Cuff located on the Right Ankle.
LT-ANK	Insert into Cuff located on the Left Ankle

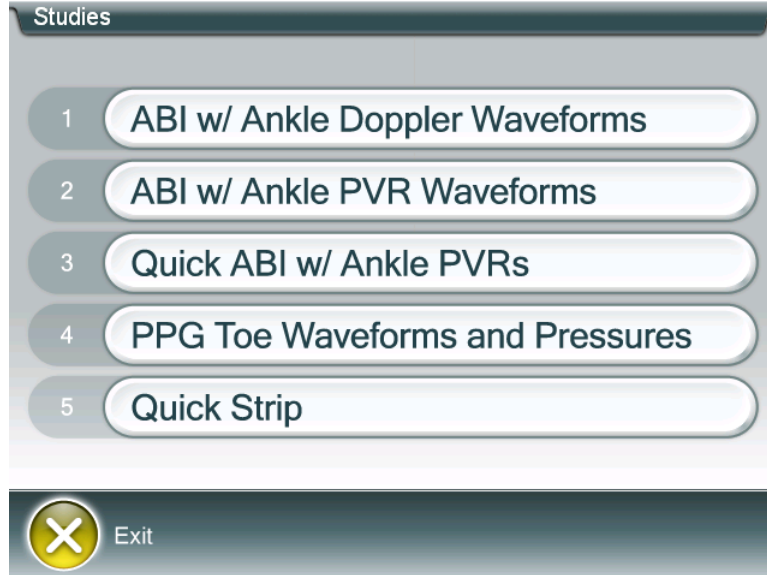
NOTE: RT-ANK and LT-ANK are also to be used with the 1.9cm toe cuffs when obtaining toe pressures.

The Bayonet fittings offer a positive, airtight connection. Insert the hose tip from the cuff into the inlet on the hose. It will snap when fully inserted. The fitting should be able to be disconnected with one hand. To disconnect the bayonet, depress the button on the hose and pull away from the cuff.



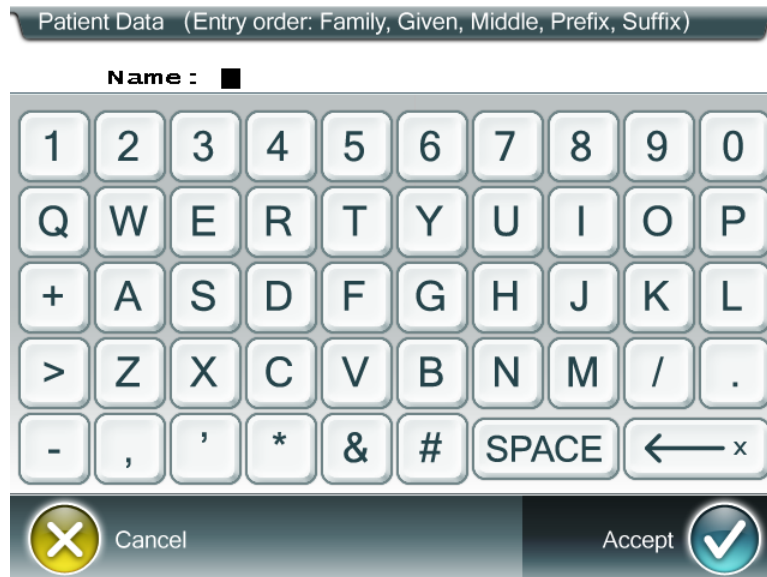
Chapter 4: Patient Studies

The Revo™ is designed to perform basic PAD evaluation studies. When you press the “**Studies**” (see p. 16, Main Menu) button, you will see the Study Menu screen as shown:



Entering Patient information

When you select a Revo™ study, you will see the following screen, and be prompted to enter patient information.



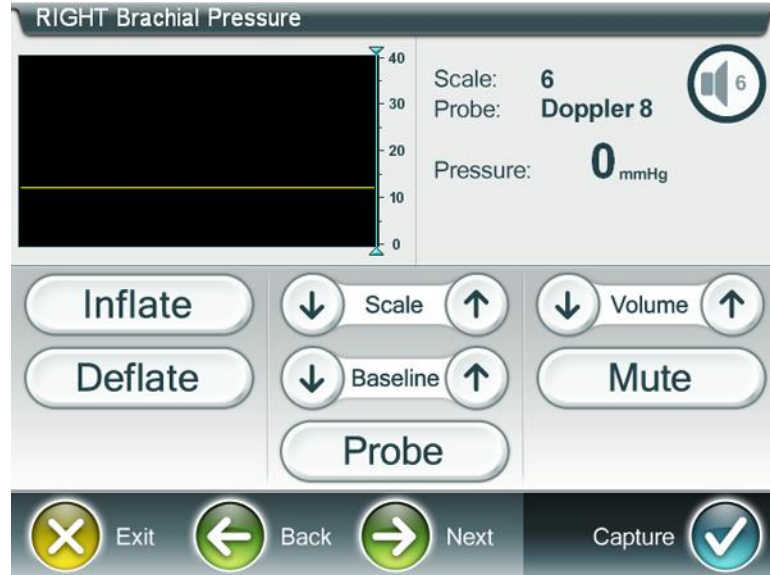
Use the on-screen keyboard to type in the information as prompted.

Press the “**Accept**” button to continue. If you do NOT want to enter certain patient information, press the “**Accept**” button to bypass. For certain information, such as name and date of birth, you may be asked to enter the information in a special way as prompted at the top of the screen. These special entries are required if you are using the Vasculink™ option (see chapter 13).

Chapter 5: ABI with Ankle Doppler Waveforms Study

Preparation

- 1) Apply Blood Pressure Cuffs as described **Chapter 3: Patient Positioning and Cuff Application.**
- 2) Touch the **“Studies”** Button and then **“ABI w/ Ankle Doppler Waveforms.”**
- 3) Enter Patient information and press the **“Accept”** button. After patient information has been entered or skipped, you will see the following screen:

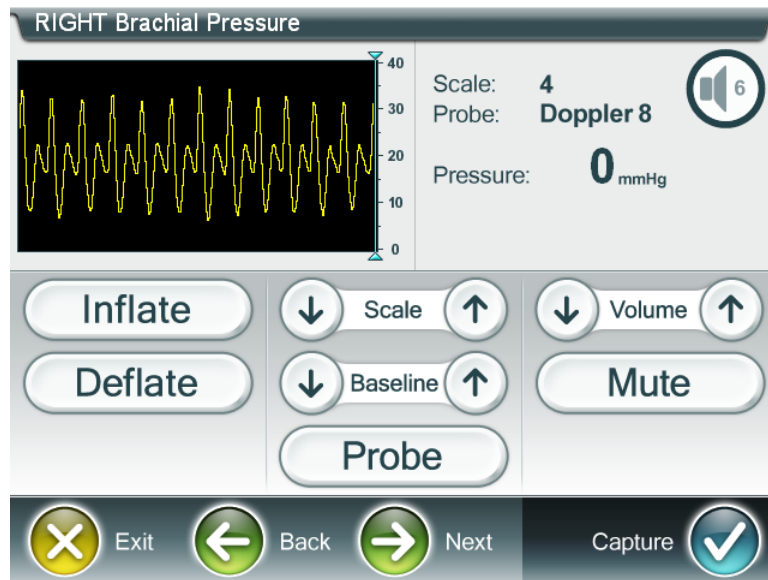


STEP 1: Taking Brachial Pressures with the Doppler Probe

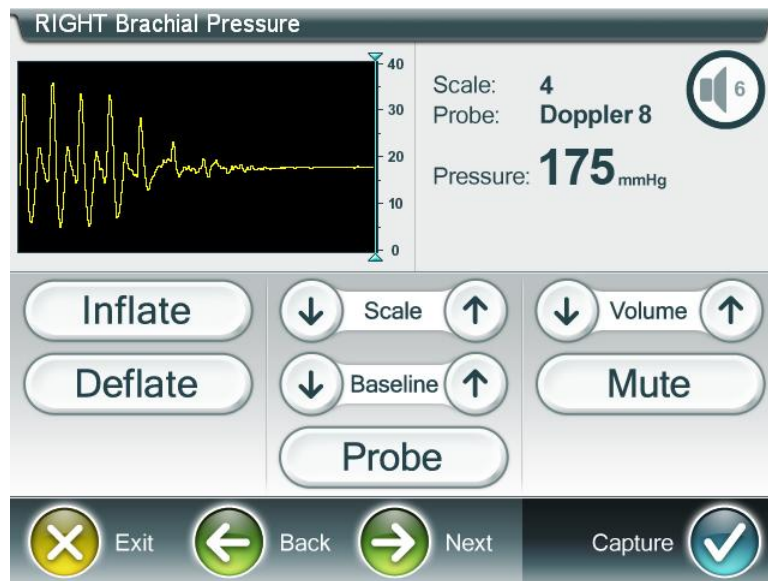
- 1) Apply ultrasound gel to brachial artery with palm facing up.
- 2) Position Doppler probe to patient's right arm at a 45 degree angle as shown:



- 3) Start in the center of the arm, at the elbow level, and move probe slowly in straight line towards body (medially). The radial or ulnar arteries can be used as alternative sites.
- Listen for strongest Doppler signal (loudest audible sound and largest possible waveform)
 - Once the signal is acquired do not move probe
 - User must stay on the artery throughout the inflation/deflation cycle
 - The Revo™ screen will look like this:



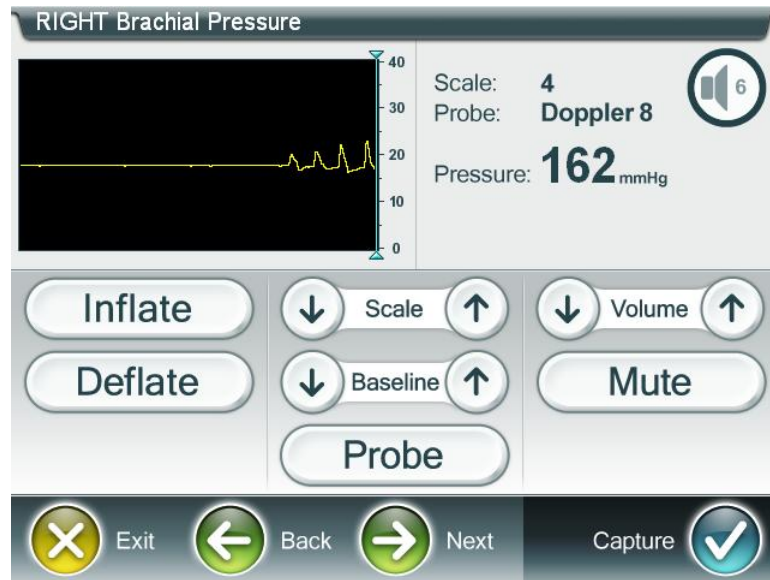
- 4) Press the “Inflate” button to begin cuff inflation.
- The right brachial cuff will automatically inflate to 175mmHg.
 - Hold Doppler probe still. Doppler sound will stop and waveform will become flat as shown:



NOTE: If blood flow is still present, touch and hold “Inflate” button until signal is obliterated. DO NOT EXCEED 250mmHG.

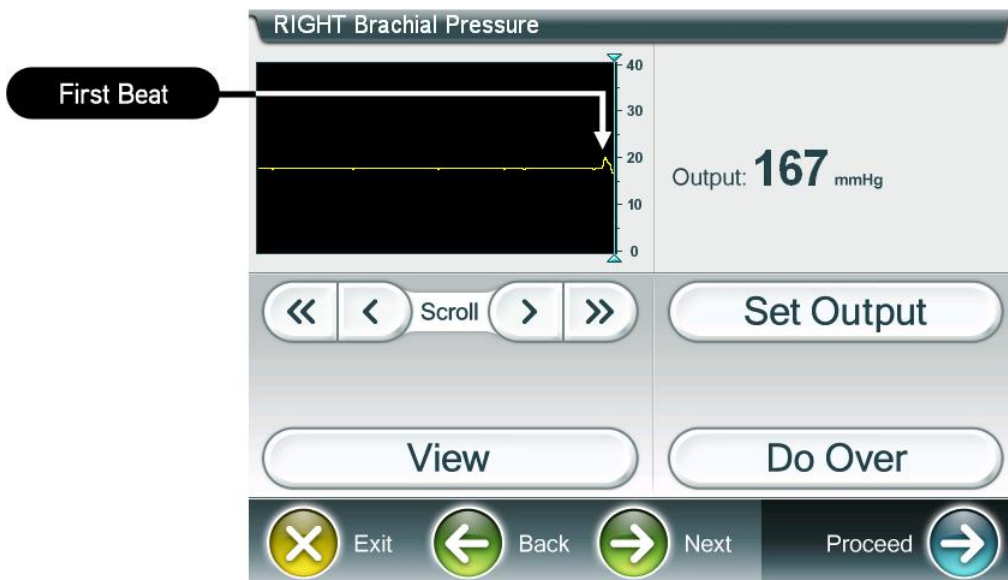
- 5) Touch “Deflate” to begin deflation cycle, while holding Doppler probe still.

- 6) Press the “**Capture**” button when Doppler sound returns, and flat line begins to “pulse.”



Note: Let 3 or 4 beats pass prior to “**Capture**”, making sure that beats are regular and consistent with patient’s heart rate. Do not confuse “artifact” (patient arm movement) with return of blood flow.

- 7) Touch the left “**Scroll**” button (<< fast and < slow), and scroll the first beat back to the blue line on right side of waveform box:



- 8) Press the “**Proceed**” or “**Next**” button to proceed to left arm pressure, and repeat the above steps.
- 9) After you obtain the left arm pressure, the Revo™ will prompt you to take a Doppler waveform tracing at the right Dorsalis Pedis artery.

Step 2: Obtaining Doppler Waveform at Dorsalis Pedis Artery

1) The Dorsalis Pedis artery can usually be found in one (or more) of the following locations:

A. Mid Foot: Move the Doppler slowly in a horizontal line across the top of the foot.



B. Between the great toe and second toe:

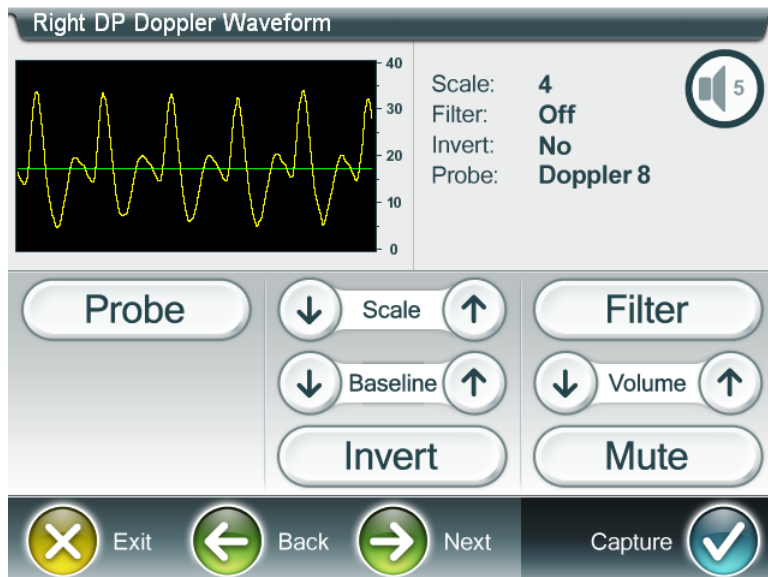


C. Between the tendons:



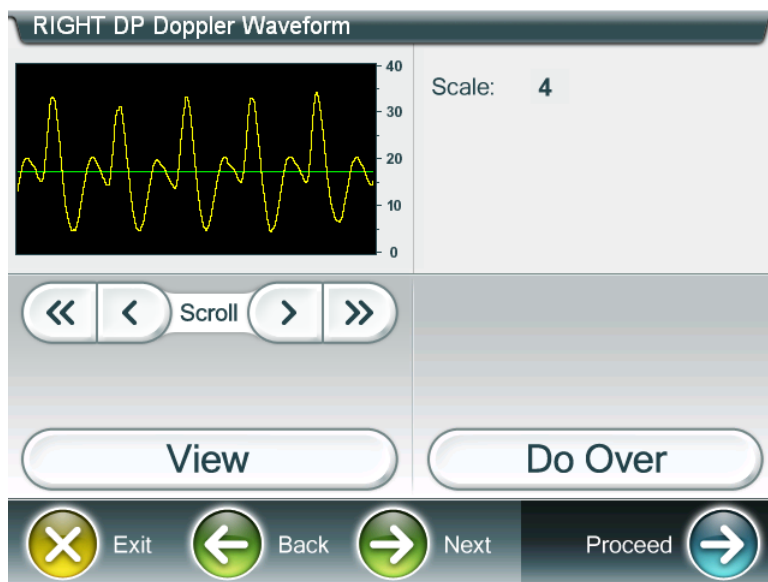
- Use a very light touch as the vessel can easily be compressed.

- 2) Once located, briefly try slight probe movement or slight changes in the angle of approach to improve signal quality (loudest audible sound and largest possible waveform).



- Use the “Baseline”, “Scale”, “Invert” and “Filter” buttons to adjust the waveform if necessary.

When optimum Doppler signal is displayed, press the “Capture” button and KEEP DOPPLER PROBE ON VESSEL.

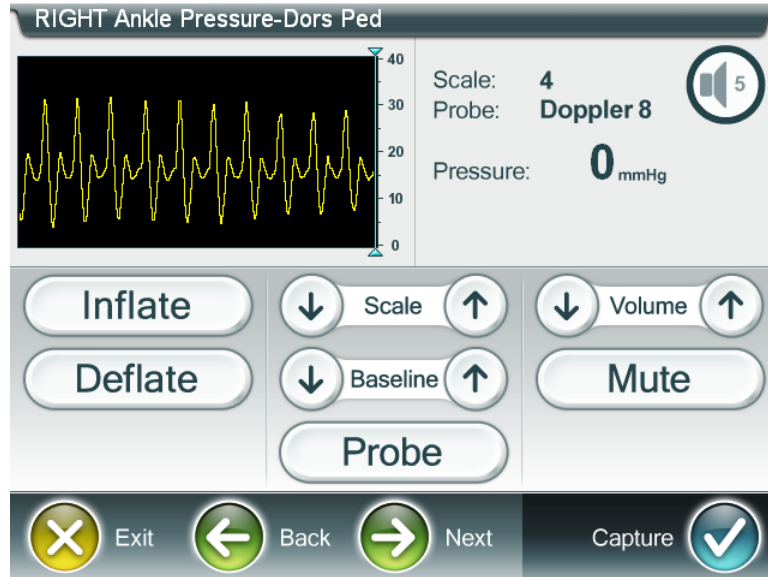


- 3) Use the “Scroll” buttons (if necessary) to display desired waveforms. The Revo™ can scroll back 30 seconds of recorded waveforms. Press “Proceed” or “Next” to continue.

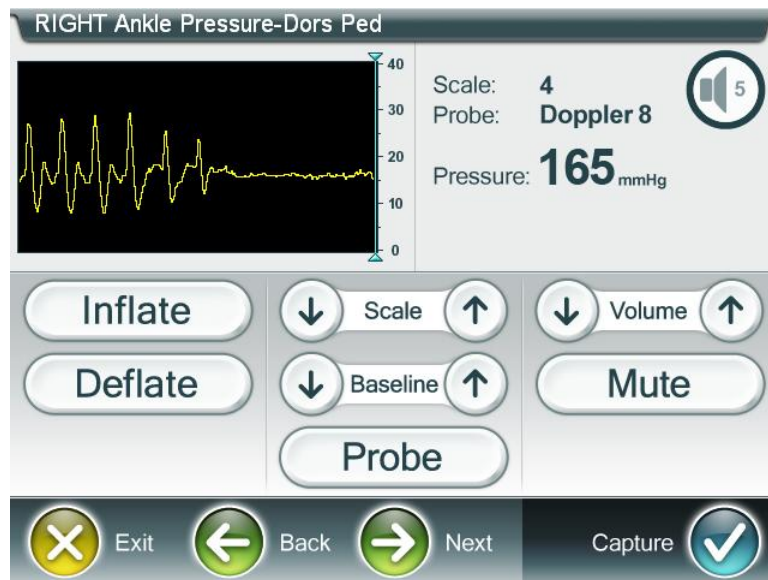
By keeping Doppler probe on vessel, you are now ready for the next step.

STEP 3: Taking an Ankle Pressure Using the Dorsalis Pedis Artery

- 1) Your Revo™ screen should look like this (reposition probe if necessary):



- 2) Press the “**Inflate**” button and the ankle cuff will inflate to 165mmHG.
- Doppler sound will become quiet, and waveform on screen will become flat:



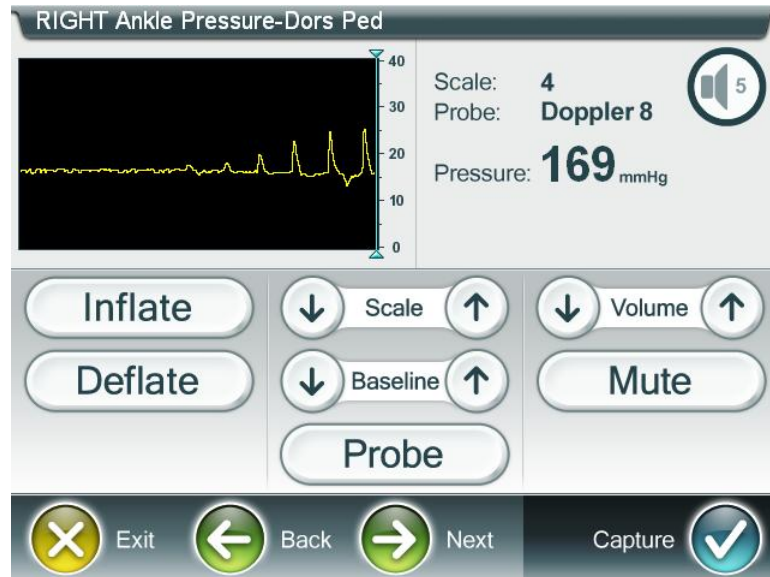
Note: If blood flow is still present, touch and hold “**Inflate**” button until signal is obliterated. DO NOT EXCEED 250mmHG.

Note: If the patient is still pulsatile at 250mmHg, press “**Capture**” and then press “**Set Output.**” Enter text and symbols such as >250 or CNO (Could Not Occlude) on the on-screen keyboard, so the reader will know that the artery is incompressible.

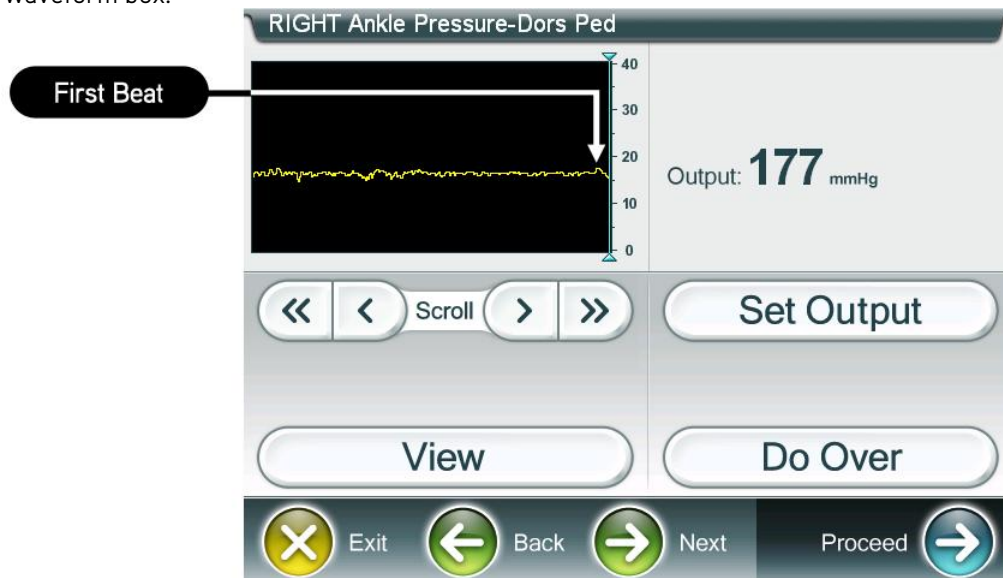
- 3) Touch “**Deflate**” to begin deflation cycle, while holding Doppler probe still.

- 4) Press the “Capture” button when Doppler sound returns, and flat line begins to “pulse.”

Note: Let 3 or 4 beats pass prior to CAPTURE, making sure that beats are regular and consistent with patient’s heart rate. Do not confuse “artifact” (patient leg movement) with return of flow.



- 5) Touch the left “Scroll” button (<< fast and < slow), and scroll the first beat back to the blue line on right side of waveform box:



- 6) Touch “Proceed” to continue to the next step.

STEP 4: Obtaining Doppler Waveform at the Posterior Tibial Artery

- 1) The Posterior Tibial artery can usually be found in the following three positions:
A. Close to Medial Malleolus (inside ankle bone):



B. Proximal to the Medial Malleolus (inside ankle bone):



C. Distal to the Medial Malleolus (inside ankle bone):



- 2) Once the best signal is obtained (loudest amplitude, and largest on-screen waveform) capture waveform by following instructions of **STEP 2**, above.

STEP 5: Obtaining Ankle Pressures at Posterior Tibial Artery

Keep Doppler probe on the Posterior Tibial Artery after obtaining waveform, and repeat procedure as outlined in **STEP 3**.

STEP 6: Optional Toe Waveforms and Pressures

If the **Toe Waveforms and Pressures** option is turned on, you may be prompted to obtain toe waveforms and/or pressures. If so, refer to **Chapter 8** for instructions.

STEP 7: Indication Questions

After all the measurements are taken, you will be prompted to answer indication questions. See **Chapter 10: Indication Questions** for instructions.

STEP 8: Patient Study Notes

Notes: After all the indications are entered, you will be prompted to add notes to the report. See **Chapter 11: Patient Study Notes** for instructions.

Completed Report

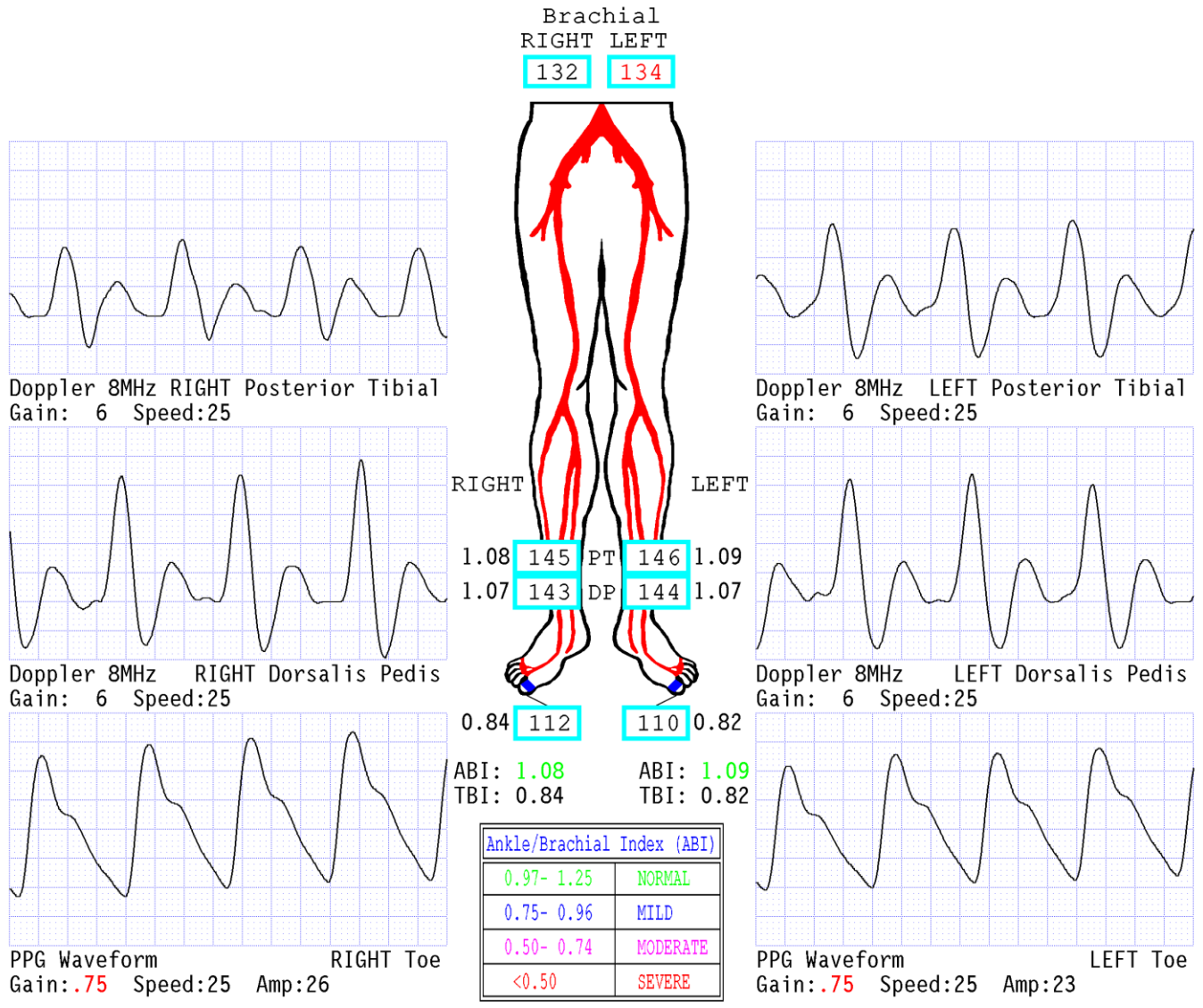
Name: DOE, JANE
 ID #: 1234GSH
 Exam Date: 06/24/2010 12:26 PM
 D.O.B.: 12/22/1947

UNETIXS VASCULAR LAB
 Vascular Tech: JP
 Ref.Phys.: ALFREDSON

MultiLab^{Series II}

Claudication: YES	Rest Pain: YES	Ulcerations: YES
Coronary Disease: YES	Tobacco: YES	Diabetes: YES
Hypertension: YES	High Cholesterol: YES	Loss of Pulses: YES

Diagnostic ABI & TBI with Doppler Waveforms and Digit Waveforms



NOTES

(*) Indices use highest brachial pressure.
 (*) VESSEL CALCIFICATION MAY CAUSE FALSELY ELEVATED PRESSURES

Chapter 6: ABI with Ankle PVR Waveforms Study

This study is similar to the previous study (**ABI with Doppler Waveforms**), in that it takes pressure measurements using the Doppler probe, but instead of taking Doppler Waveforms at the ankles, this study takes two PVR (Pneumoplethysmography) waveform tracings at both ankles simultaneously.

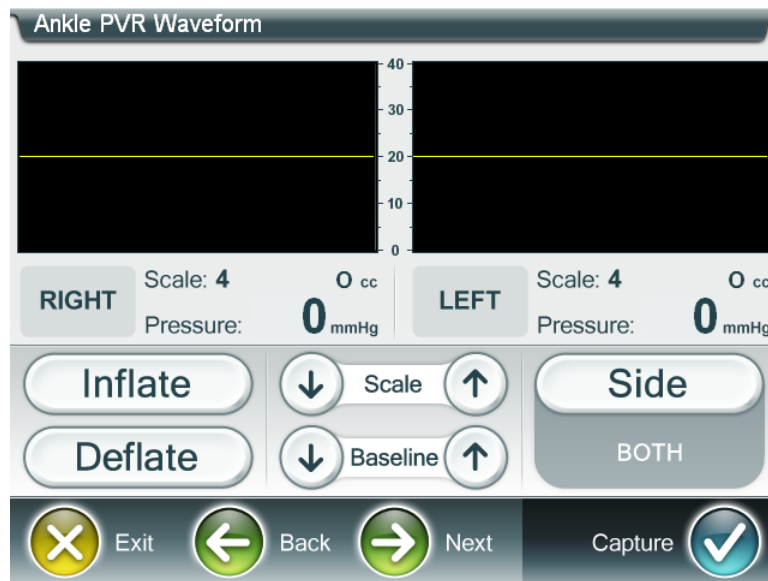
Preparation

- 1) Apply blood pressure cuffs as described in **Chapter 3: Patient Positioning and Cuff Application**.
- 2) Touch the **“Studies”** button and then **“ABI with PVR Waveforms.”**
- 3) Enter patient information as described in the **Chapter 4: Patient Studies**.

STEP 1: Obtain brachial pressures using the Doppler probe.

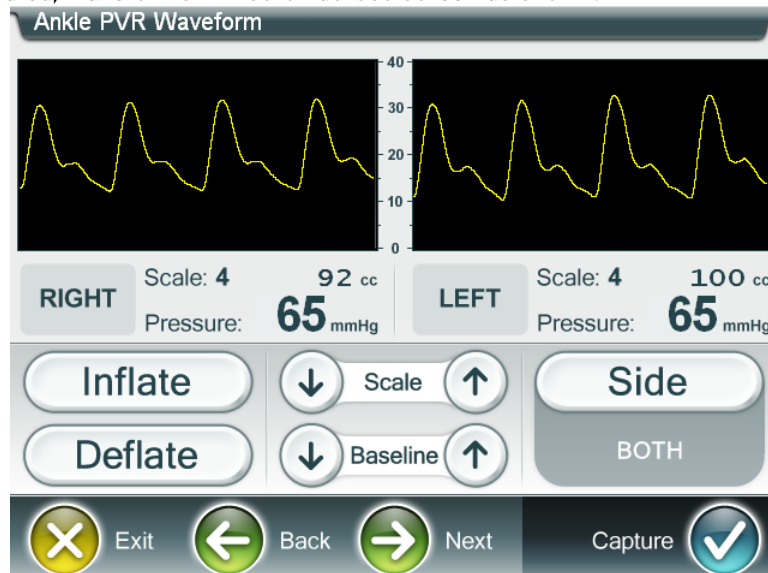
(See: **STEP 1** in **Chapter 5: ABI with Doppler Waveforms Study**)

- After obtaining both brachial pressures, and pressing **“Accept”**, you will see the following screen:



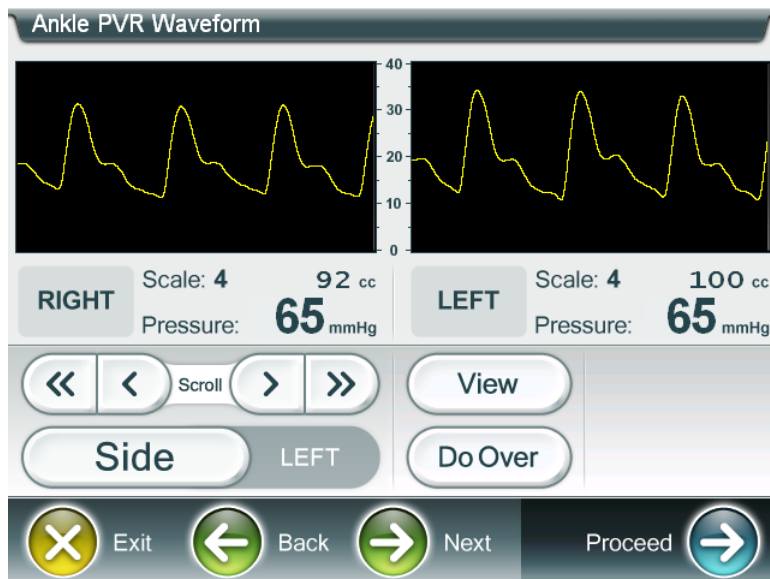
STEP 2: Obtain PVR Waveform tracings at both ankles

- 1) Touch **“Inflate”** to inflate both ankle cuffs to 65mmHg.
- When cuffs are inflated, waveforms will scroll across screen as shown:



- The PVR cuff pressure should be between 62 – 68 mmHg, and the entire waveform must be visible on the screen.

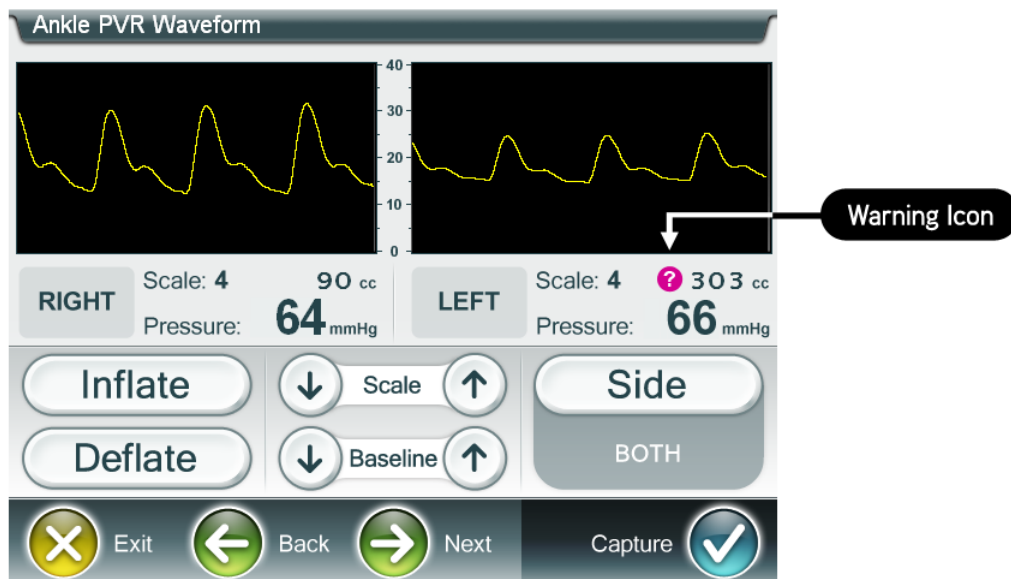
- Use the “Scale ↓” button, if the waveform is too large to fit on the screen. You may also use the Scale ↑ button to make the waveform larger if needed.
 - Make sure the Scale is set at the same setting for right and left ankle cuffs, and use the “Baseline ↑ or ↓” button to center the waveform on the screen.
- 2) Press the “Capture” button when you see three or four consistent waveforms on each side.



- 3) Scroll waveforms back together (“Side” BOTH), or independently (using “Side” button to select) if necessary, and press the “Proceed” button when finished.

Calibrated Pulse Volume Recording (C-PVR™)

The Revo™ utilizes Calibrated PVR to ensure accuracy and consistency. If one of the ankle cuffs has been improperly wrapped, you will see a warning icon as shown below:



The left ankle cuff has been applied too loosely, resulting in a PVR tracing that is markedly diminished compared to the right ankle, due to the difference in cuff air volume (90cc vs. 303cc).

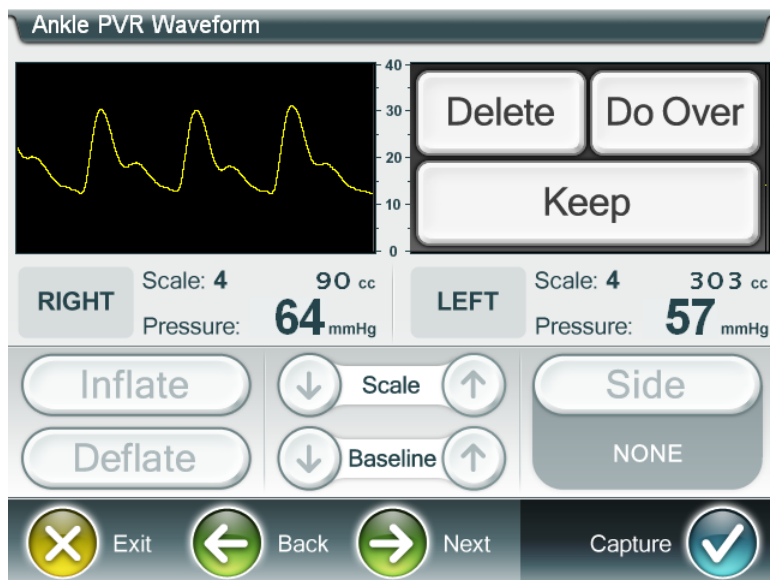
Should this occur, press “Capture” and then “Do Over.”

STEP 3: Ankle PVR Waveform Do-Over (if necessary)

- 1) When you press the “Do Over” button during a PVR Waveform, you will see this screen:

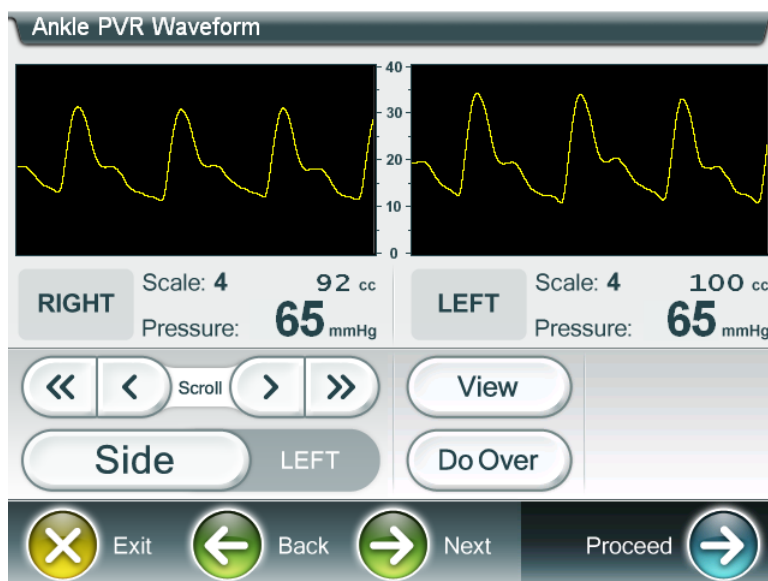


- 2) Press the “Keep” button on the side with the LOWER air volume (90cc), and press the “Do Over” button on the side with HIGHER (303cc) air volume.



- 3) Unplug the pneumatic hose from the left ankle cuff, and remove the left ankle cuff.
 4) Reapply the cuff more snugly, reinsert the pneumatic hose, and press the “Inflate” button.

- 5) If the warning indicator light does not appear, press **“Capture.”**



NOTE: If patient presents with swollen ankle/s do not be concerned with PVR “warning” light, as limb segments will be of different diameters. Wrap cuffs as snugly as possible.

- 6) Scroll waveforms if necessary, and press **“Accept”** to continue.

STEP 4: Optional Toe Waveforms and Pressures

If the **Toe Waveforms and Pressures** option is turned on, you may be prompted to obtain toe waveforms and/or pressures. If so, see to **Chapter 8** for instructions.

STEP 5: Indication Questions

After all the measurements are taken, you will be prompted to answer indication questions. See **Chapter 10: Indication Questions** for instructions.

STEP 6: Patient Study Notes

After all the indications are entered, you will be prompted to add notes to the report. See **Chapter 11: Patient Study Notes** for instructions.

Completed Report

Name: DOE, JANE
 ID #: 1234GSH
 Exam Date: 06/24/2010 12:14 PM
 D.O.B.: 12/22/1947

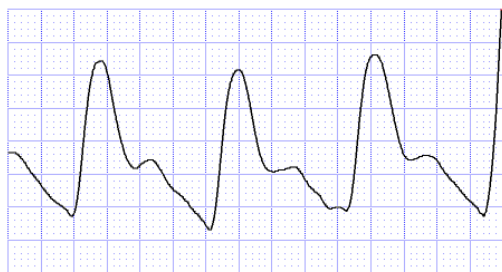
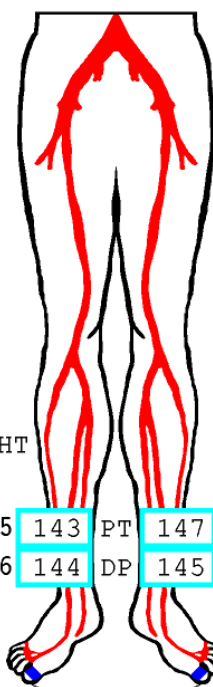
UNETIXS VASCULAR LAB
 Vascular Tech: JP
 Ref.Phys.: ALFREDSON



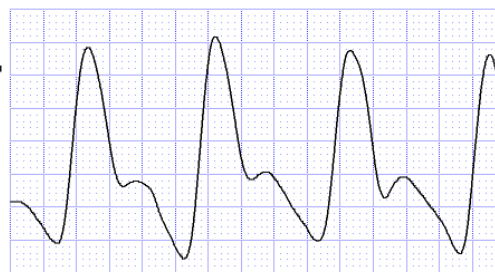
Claudication: YES	Rest Pain: YES	Ulcerations: YES
Coronary Disease: YES	Tobacco: YES	Diabetes: YES
Hypertension: YES	High Cholesterol: YES	Loss of Pulses: YES
BMI >30 - Obese: YES		History of PAD: YES

Diagnostic ABI & TBI with C-PVR Waveforms and Digit Waveforms

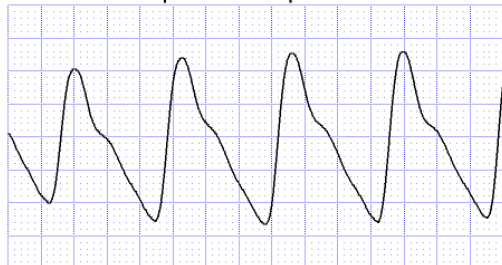
Brachial
 RIGHT LEFT
 132 136



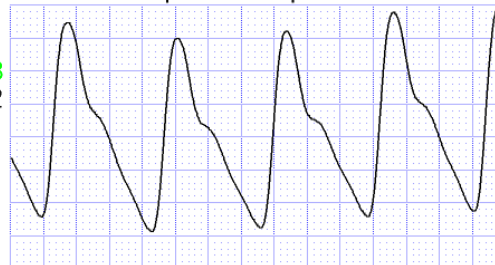
PVR 67mmHg 76cc RIGHT Ankle
 Gain: 8 Spd:25 Amp:31



PVR 66mmHg 76cc LEFT Ankle
 Gain: 8 Spd:25 Amp:34



PPG Waveform RIGHT Toe
 Gain:.75 Speed:25 Amp:26



PPG Waveform LEFT Toe
 Gain:.75 Speed:25 Amp:31

RIGHT LEFT
 1.05 143 PT 147 1.08
 1.06 144 DP 145 1.07

0.80 109 111 0.82
 ABI: 1.06 ABI: 1.08
 TBI: 0.80 TBI: 0.82

Ankle/Brachial Index (ABI)	
0.97- 1.25	NORMAL
0.75- 0.96	MILD
0.50- 0.74	MODERATE
<0.50	SEVERE

NOTES

(*) Indices use highest brachial pressure.
 (*) VESSEL CALCIFICATION MAY CAUSE FALSELY ELEVATED PRESSURES

Chapter 7: Quick ABI with Ankle PVR Study

The Quick ABI study is different than the previous two studies in that it uses the PPG sensors (instead of the Doppler probe) to take the arm and ankle pressures, and as such, can perform both arm pressures at the same time, as well as both ankle pressures at the same time.

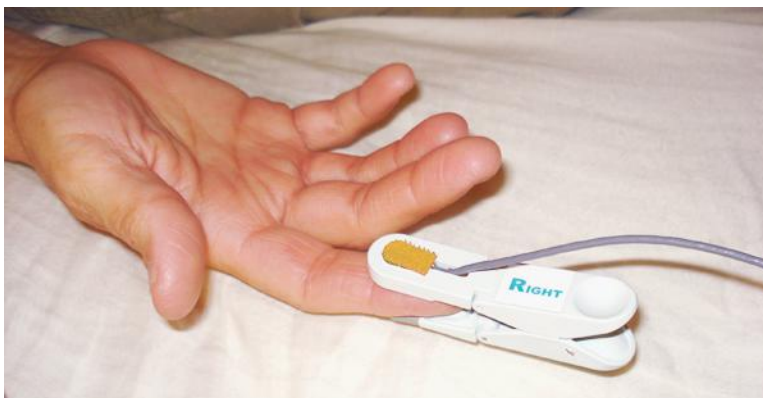
This study also incorporates PVR waveform tracings at the ankles as described in **Chapter 6: ABI with PVR Waveforms Study**.

Preparation

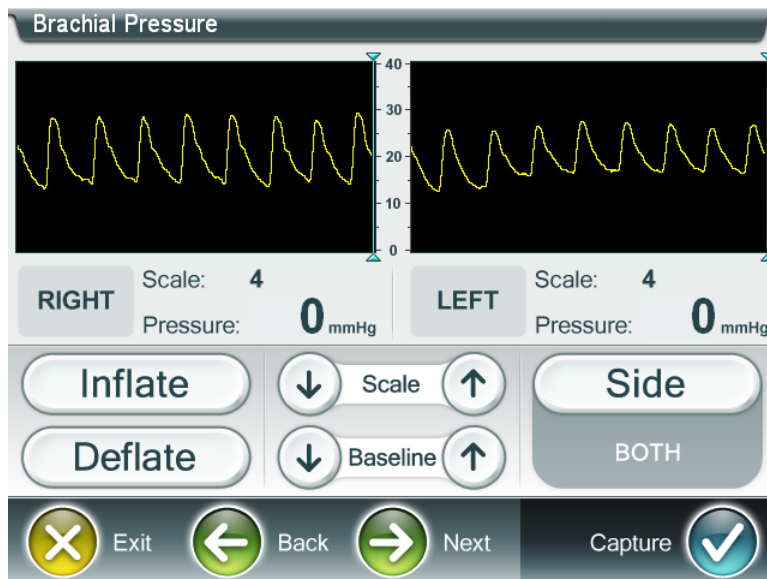
- 1) Apply blood pressure cuffs as described in **Chapter 3: Patient Positioning and Cuff Application**.
- 2) Touch the “**Studies**” button and then “**Quick ABI with PVR Waveforms.**”
- 3) Enter patient information as described in **Chapter 4: Patient Studies**.

STEP 1: Obtain Brachial Pressures Using the PPG Sensors

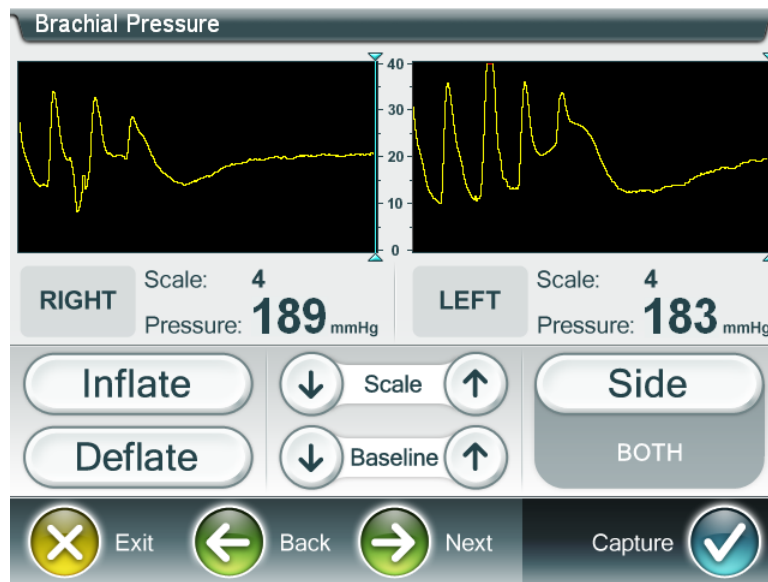
- 1) Place the right and left PPG sensors and clips on the right and left index or middle fingers as shown:



- On the Revo™ you will see the following screen:



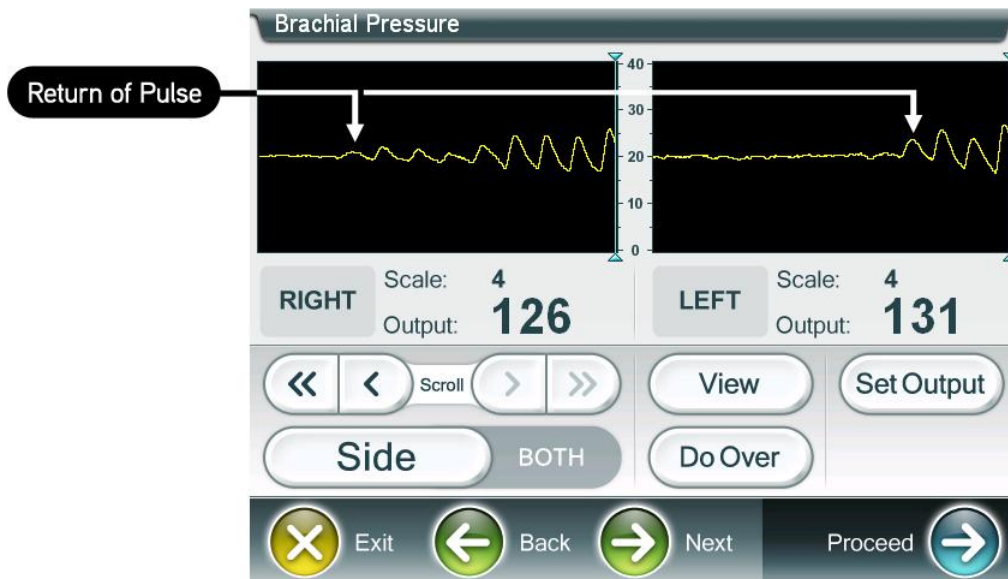
- 2) Press the “Inflate” button to inflate both pressure cuffs. The Revo™ will automatically inflate the arm pressure cuffs to 175mmHg.
 - In most patients, this will cause the PPG waveforms to flat-line like the photo below:



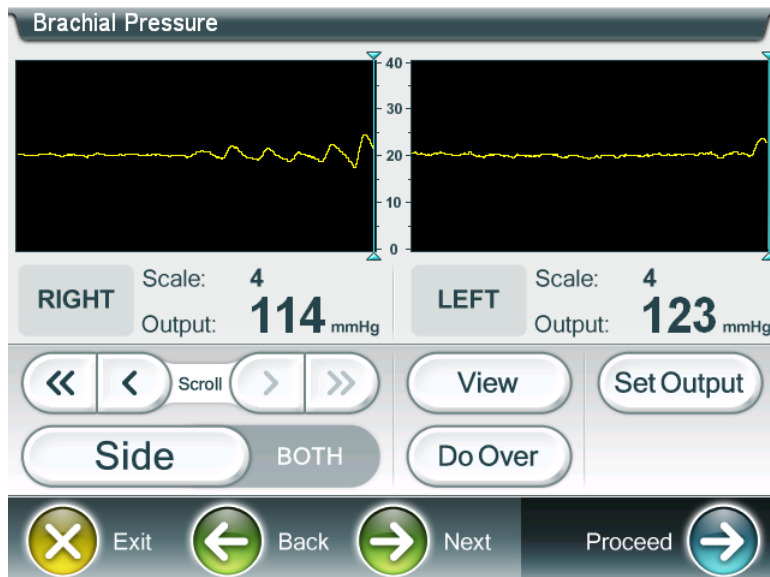
- 3) When finger pulses become flat, press “Deflate” to start cuff deflation cycle.

NOTE: If waveforms are still present after pumps shut off (very hypertensive patient), press and hold the “Inflate” button until the waveforms flat-line (DO NOT EXCEED 250mmHg). Once the pulses disappear, press the “Deflate” button, to begin cuff deflation.

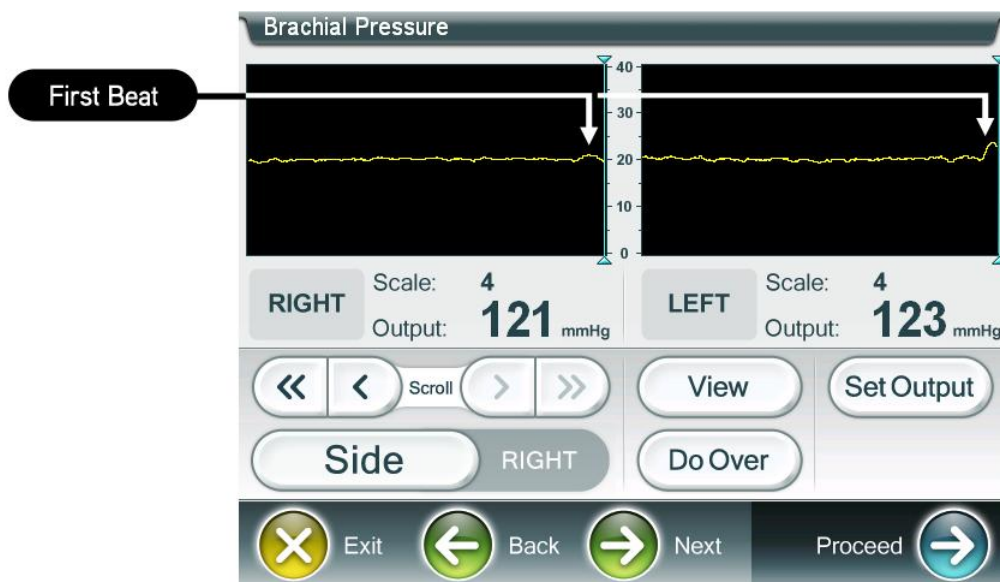
- 4) Once both pulses reappear, press the “Capture” button. Wait until you see several waveform pulses in both Revo™ waveform boxes as shown below:



- Use the fast (<<) or slow (<) scrolling buttons, and scroll both pulses back until the first pulse lines up with the blue pressure indicator line on the right of the Revo™ pressure box as shown below:



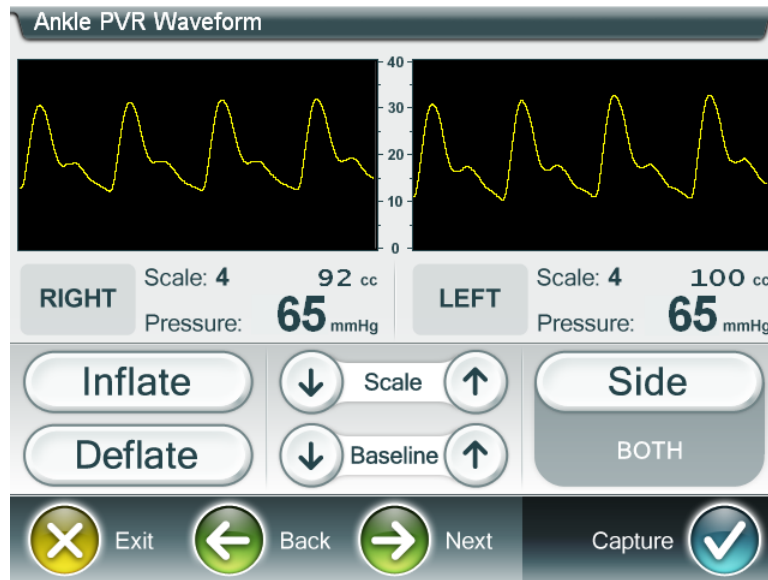
- Press the “Side” button on the Revo™ screen to select the side that needs to be scrolled back further. Use the scrolling buttons again to line the first pulse on that side with the pressure indicator line, as shown below:



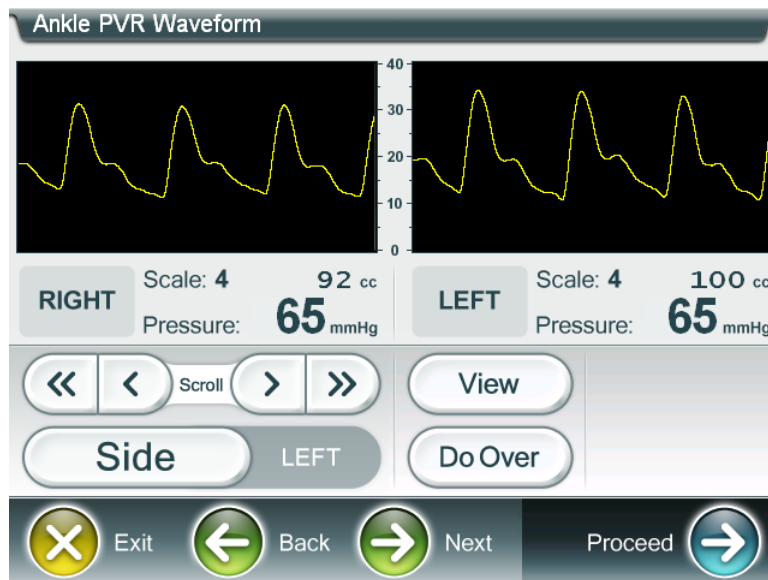
- Press “Proceed” to save and continue.

STEP 2: Obtain PVR Waveform tracings at both ankles

- 1) Touch **"Inflate"** to inflate both ankle cuffs to 65mmHg.
 - When cuffs are inflated, waveforms will scroll across screen as shown:



- The PVR cuff pressure should be between 62 – 68 mmHg, and the entire waveform must be visible on the screen.
 - Use the **"Scale ↓"** button, if the waveform is too large to fit on the screen. You may also use the **"Scale ↑"** button to make the waveform larger if needed.
 - Make sure the Scale is set at the same setting for right and left ankle cuffs, and use the **"Baseline ↑ or ↓"** button to center the waveform on the screen.
- 2) Press the **"Capture"** button when you see three or four consistent waveforms on each side.



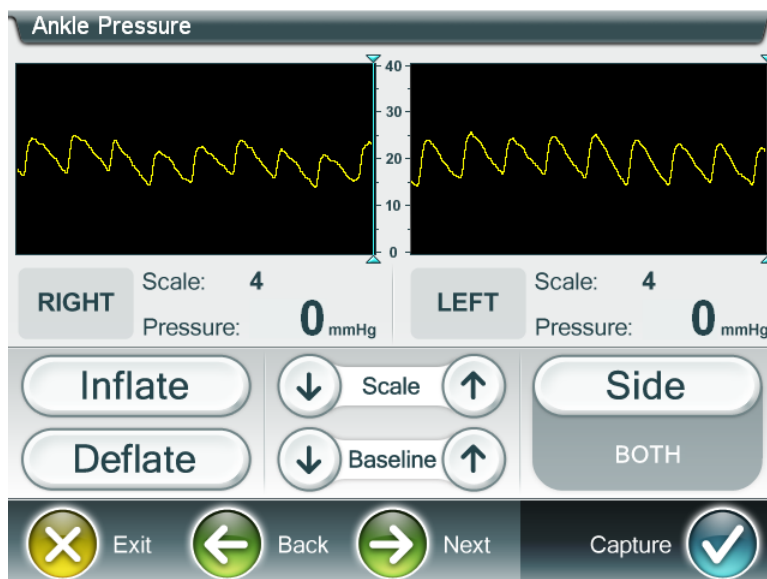
- 3) Scroll waveforms back together (**"Side" BOTH**), or independently (using **"Side"** button to select) if necessary, and press the **"Proceed"** button when finished.

STEP 3: Obtain Ankle Pressures Using the PPG Sensors

- 1) Remove the PPG clips and sensors from the fingers and apply to the patient's toes as shown:



- You will now see the following screen:



- 2) Follow the instructions in **STEP 1** for inflating, deflating and capturing pressures at both ankles.

NOTE: If the patient is still pulsatile at 250mmHg, press “Capture” and then press “Set Output”. Enter text and symbols such as >250 or CNO (Could Not Occlude) on the on-screen keyboard, so the reader will know that the artery is incompressible.

STEP 4: Optional Toe Waveforms and Pressures

If the **Toe Waveforms and Pressures** option is turned on, you may be prompted to obtain toe waveforms and/or pressures. If so, see to **Chapter 8** for instructions.

STEP 5: Indication Questions

After all the measurements are taken, you will be prompted to answer indication questions. See **Chapter 10: Indication Questions** for instructions.

STEP 6: Patient Study Notes

After all the indications are entered, you will be prompted to add notes to the report. See **Chapter 11: Patient Study Notes** for instructions.

Completed Report

Name: DOE, JANE
 ID #: 1234GSH
 Exam Date: 06/24/2010 12:01 PM
 D.O.B.: 12/22/1947

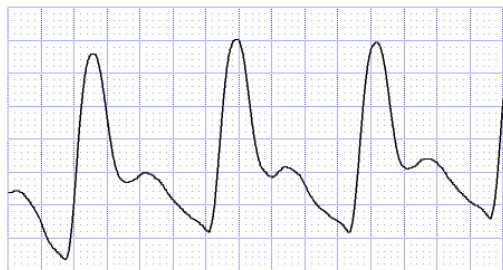
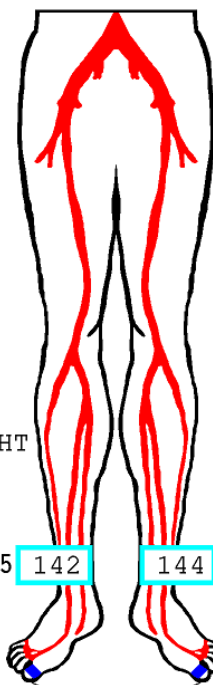
Your Facility's Name Here
 Vascular Tech: JP
 Ref.Phys.: ALFREDSON

MultiLab Series II

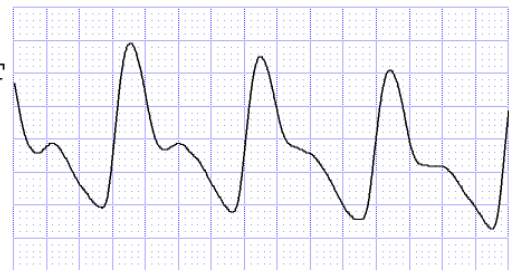
Claudication: YES	Rest Pain: YES	Ulcerations: YES
Coronary Disease: YES	Tobacco: YES	Diabetes: YES
Hypertension: YES	High Cholesterol: YES	Loss of Pulses: YES
BMI >30 - Obese: YES	Family History PAD: YES	History of PAD: YES

Diagnostic ABI & TBI with C-PVR Waveforms and Digit Waveforms

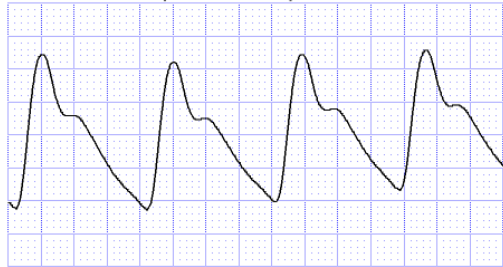
Brachial
 RIGHT LEFT
 132 135



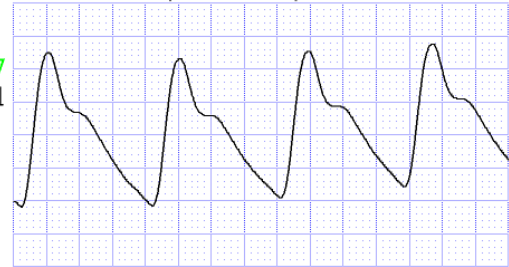
PVR 68mmHg 92cc RIGHT Ankle
 Gain: 8 Spd:25 Amp:29



PVR 64mmHg 96cc LEFT Ankle
 Gain: 8 Spd:25 Amp:24



PPG Waveform RIGHT Toe
 Gain:.75 Speed:25 Amp:21



PPG Waveform LEFT Toe
 Gain:.75 Speed:25 Amp:22

RIGHT 1.05 142 144 1.07
 LEFT 0.84 113 110 0.81
 ABI: 1.05 ABI: 1.07
 TBI: 0.84 TBI: 0.81

Ankle/Brachial Index (ABI)	
0.97- 1.25	NORMAL
0.75- 0.96	MILD
0.50- 0.74	MODERATE
<0.50	SEVERE

NOTES

(*) Indices use highest brachial pressure.
 (*) VESSEL CALCIFICATION MAY CAUSE FALSELY ELEVATED PRESSURES

Chapter 8: PPG Toe Waveforms and Pressures Study

This study will take toe waveforms and toe pressures using the PPG sensors and toe cuffs. Brachial pressures can be performed at the end of the study, to derive a TBI (Toe/Brachial Index)

Preparation

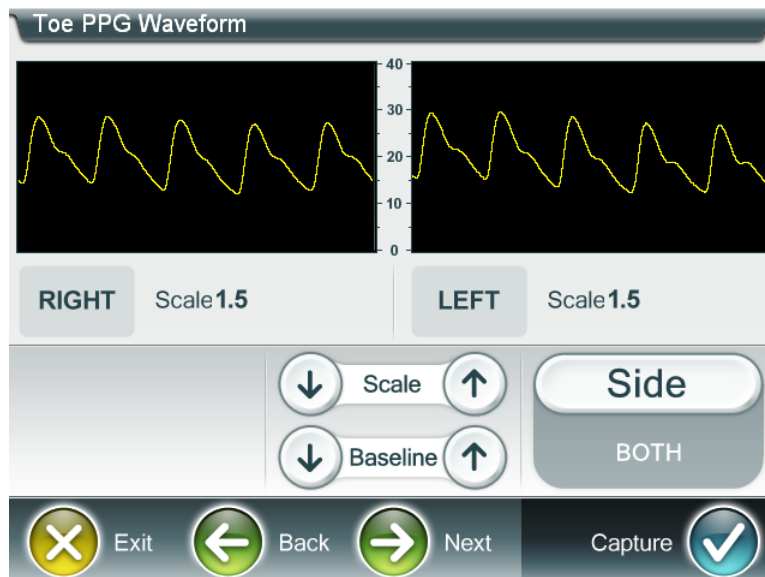
- 1) Patient should be supine with DC-1.9 cuffs around base of great toes. Insert right and left ankle hoses into the right and left digit cuffs, and apply PPG sensors to the toes, distal to the cuff as shown:



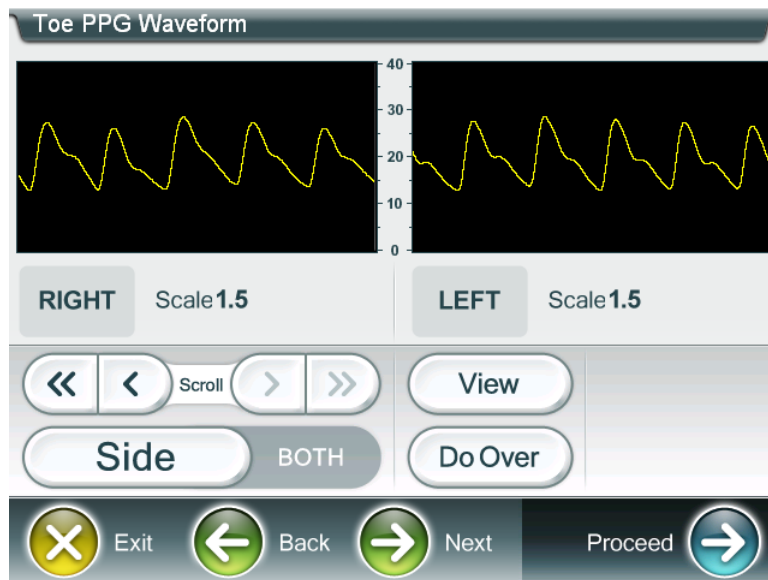
- 2) Touch "Studies" then "PPG Toe Waveforms and Pressures."

Step 1: Obtain PPG Waveform Tracings of the Great Toes

- 1) After entering patient information as outlined in [Chapter 4: Patient Studies](#), you will see the following screen:



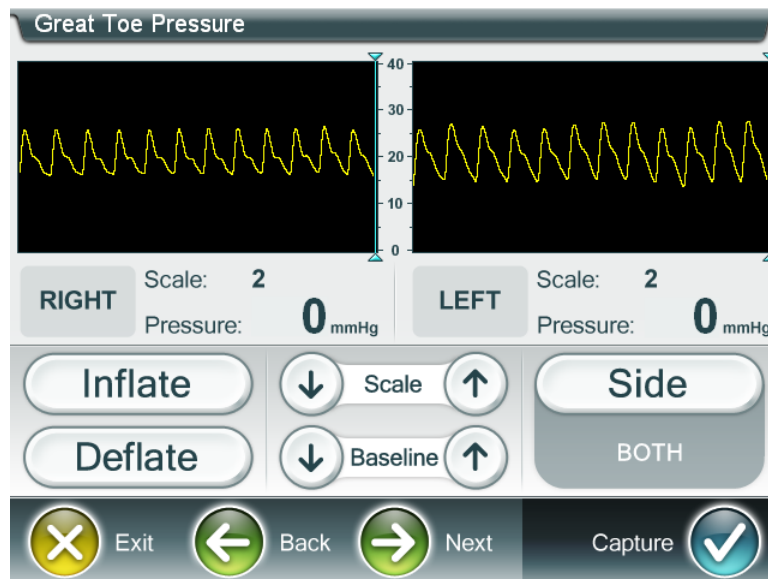
- When you see three or four consistent waveforms, press the **“Capture”** button to bring up the following screen:



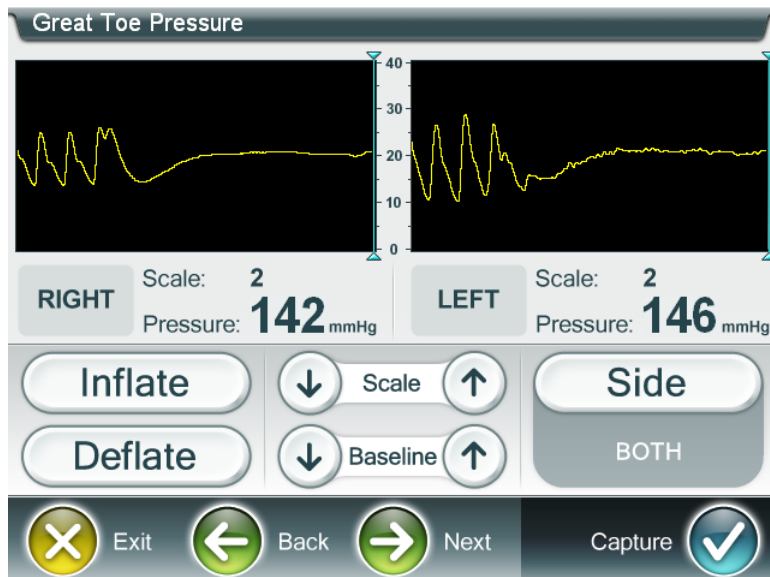
- Use the fast (<<) or slow (<) scrolling buttons to scroll waveforms back together (**“Side” Both**), or independently (using **“Side”** button to select) if necessary, and press the **“Proceed”** button when finished.

Step 2: Obtaining Toe Pressures

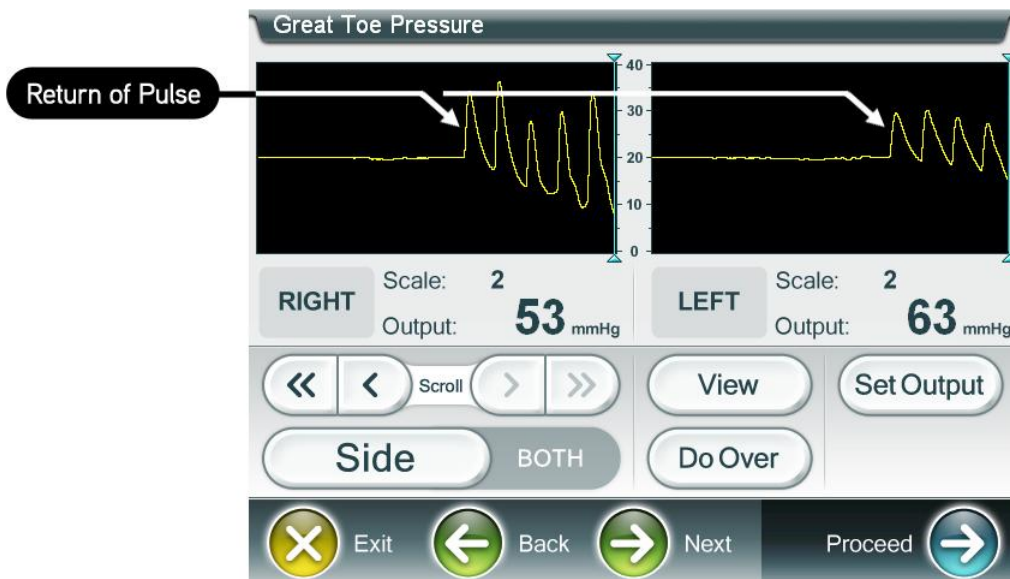
- After you obtain the PPG waveforms at the great toes, you will see this screen:



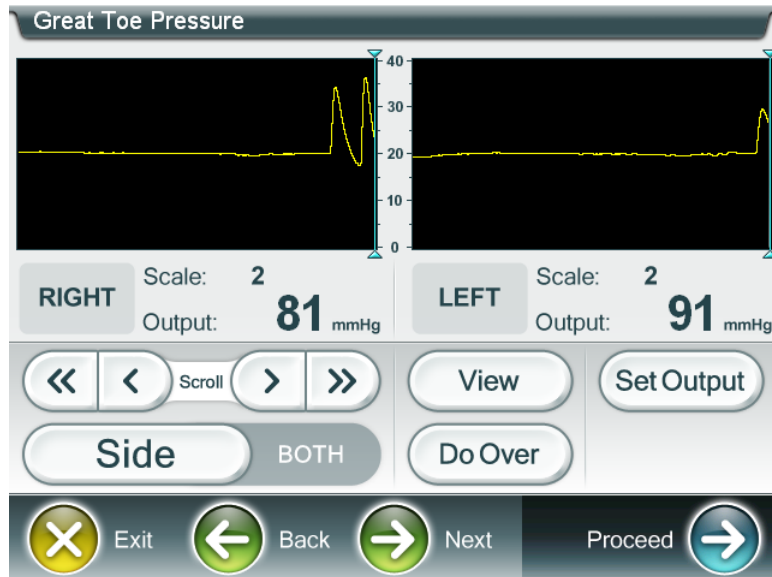
- 2) Press the **"Inflate"** button. Toe cuffs will automatically inflate to 145 mmHg.
- When pressure in the toe cuffs exceeds toe systolic pressure, the PPG waveforms will become flat:



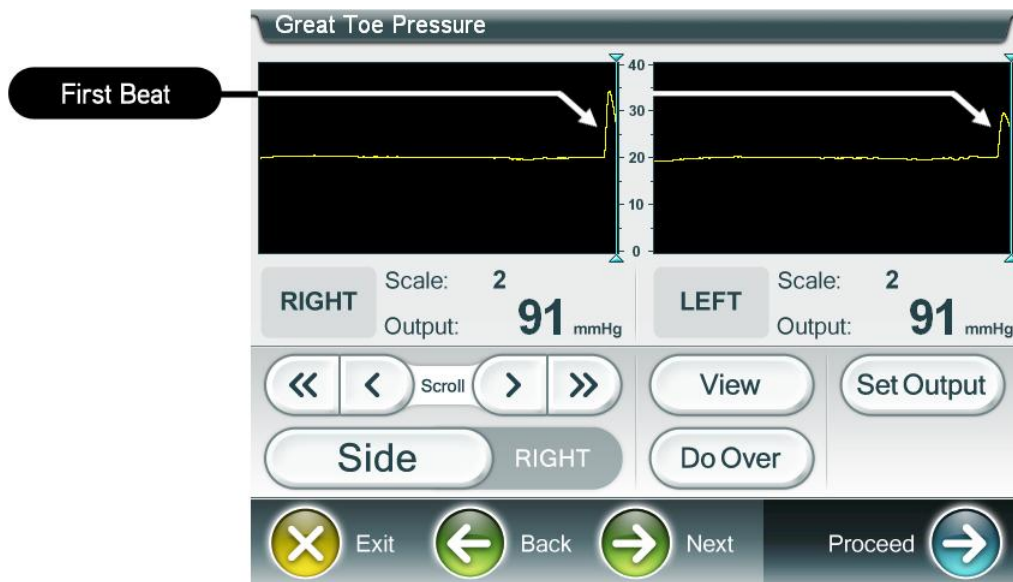
- When both waveforms become flat, press the **"Deflate"** button to begin the deflation cycle.
- 3) Once both pulses reappear, press the **"Capture"** button. Wait until you see several waveform pulses in both Revo™ waveform boxes as shown below:



- 4) Use the fast (<<) or slow (<) scrolling buttons, and scroll both pulses back until the first pulse lines up with the blue pressure indicator line on the right of the Revo™ pressure box as shown below:



- 5) Press the “Side” button on the Revo™ screen to select the side that needs to be scrolled back further. Use the scrolling buttons again to line the first pulse on that side with the pressure indicator line, as shown below:



- 6) Press the “Proceed” button to save pressures and continue.

NOTE: If the “Toe Pressure” option is “ON” (see Chapter 2 – Revo™ System Operation), you will be prompted to repeat Step 2 (toe pressures) on toes 2, 3, 4 and 5. In this instance, move both the digit cuff and PPG sensor and clip.

NOTE: If the “Toe Waveform” option is “ON” (see Chapter 2 – Revo™ System Operation), you will be prompted to repeat Step 1 (waveform tracings) at toes 2, 3, 4 and 5. In this instance, simply move the PPG sensors and clips from toe to toe and follow the instructions outlined in Step 1.

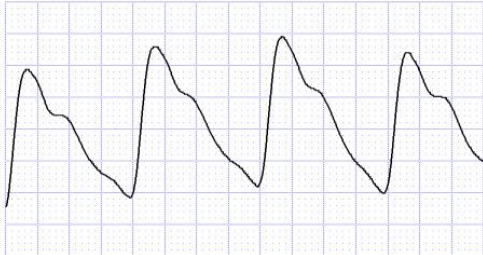
Step 3: Obtaining Brachial Pressures (Optional)

If you wish to derive a TBI (Toe Brachial Index), you will need to take arm pressures. See: **STEP 1** in **Chapter 5: ABI with Doppler Waveforms Study** or press “NEXT” button to skip.

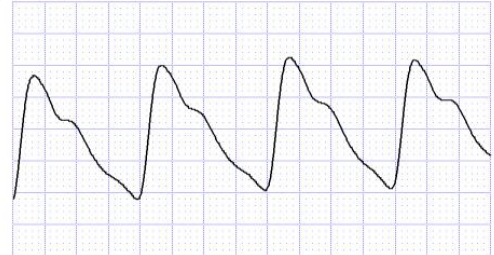
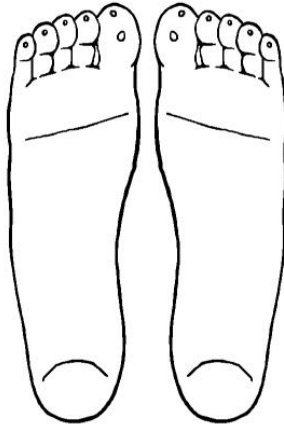
Completed Report

Name: DOE, JANE
 ID #: 1234G5H
 Exam Date: 06/09/2008 09:57 PM
 D.O.B.: 12/22/47

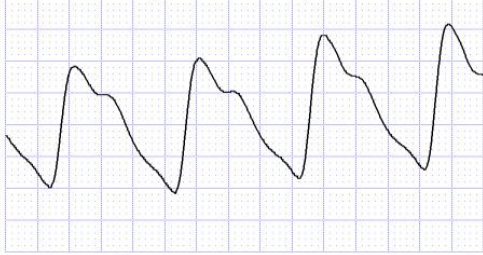
UNETIXS VASCULAR
 Vascular Tech: MT
 Ref.Phys.: JASONER



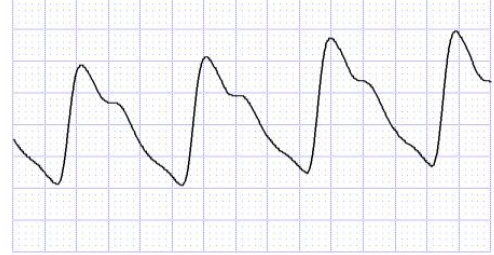
PPG Waveform RIGHT Great Toe
 Gain: .75 Speed:25 Amplitude:24mm



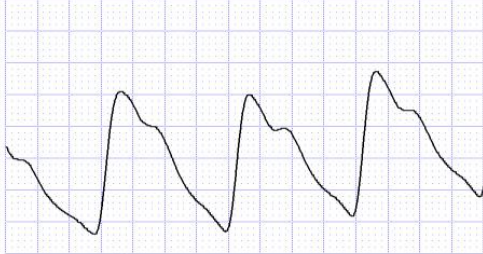
PPG Waveform LEFT Great Toe
 Gain: .75 Speed:25 Amplitude:21mm



PPG Waveform RIGHT Toe 2
 Gain: .75 Speed:25 Amplitude:23mm

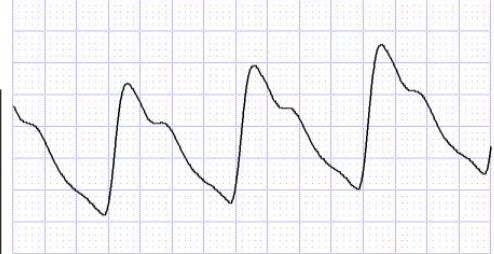


PPG Waveform LEFT Toe 2
 Gain: .75 Speed:25 Amplitude:21mm

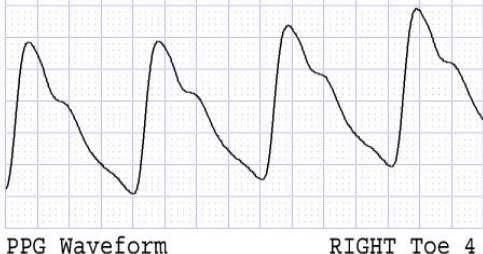


PPG Waveform RIGHT Toe 3
 Gain: .75 Speed:25 Amplitude:23mm

RIGHT PRESSURES & TBI		
Brachial	123	
Great Toe	117	0.95
Toe 2	109	0.89
Toe 3	108	0.88
Toe 4	106	0.86
Toe 5	98	0.80

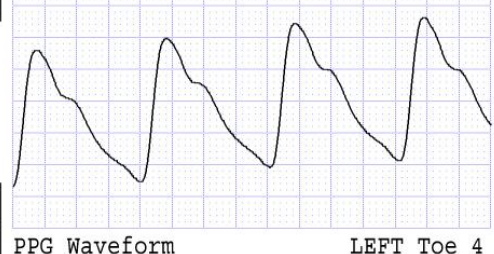


PPG Waveform LEFT Toe 3
 Gain: .75 Speed:25 Amplitude:23mm



PPG Waveform RIGHT Toe 4
 Gain: .75 Speed:25 Amplitude:25mm

LEFT PRESSURES & TBI		
Brachial	119	
Great Toe	112	0.91
Toe 2	113	0.92
Toe 3	114	0.93
Toe 4	105	0.85
Toe 5	102	0.83



PPG Waveform LEFT Toe 4
 Gain: .75 Speed:25 Amplitude:23mm



PPG Waveform RIGHT Toe 5
 Gain: .75 Speed:25 Amplitude:25mm



PPG Waveform LEFT Toe 5
 Gain: .75 Speed:25 Amplitude:24mm

Chapter 9: Quick Strip Study

The quick strip can be used to capture single waveforms at any point on the body. The report printout has room for 4 Doppler waveforms, 4 PVR waveforms (done as 2 pairs), and 2 PPG waveforms (done as 1 pair). No pressures can be taken with this protocol. After taking each waveform measurement, you must use the "Notes" text entry to manually label the captured waveform for the report (see: **Chapter 11: Patient Study Notes**).

To facilitate the entry of waveform labels, some of the text has been pre-entered for you. You may override this text by hitting the backspace button as necessary. You may also keep the pre-entered text, and add your own text to it. Following is an ordered list of the waveforms you may capture, along with their pre-entered text:

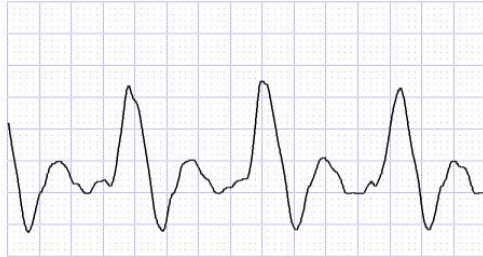
Waveforms	Pre-entered Text
RIGHT PRE – Doppler waveform	"RIGHT PRE-"
LEFT PRE – Doppler waveform	"LEFT PRE-"
RIGHT POST – Doppler waveform	"RIGHT POST-"
LEFT POST – Doppler Waveform	"LEFT POST-"
RIGHT PRE PVR Waveform	"RIGHT PRE-"
LEFT PRE PVR Waveform	"LEFT PRE-"
RIGHT POST PVR Waveform	"RIGHT POST-"
LEFT POST PVR Waveform	"LEFT POST-"
RIGHT PPG Waveform	"RIGHT Toe"
LEFT PPG Waveform	"LEFT Toe"

- For help on performing Doppler waveforms, see **Chapter 5: ABI with Ankle Doppler Waveforms Study**, steps 1, 2, and 4.
- For help on performing PVR waveforms, see **Chapter 6: ABI with Ankle PVR Waveforms Study**, step 2.
- For help on performing PPG waveforms, see **Chapter 8: PPG Toe Waveforms and Pressures Study**, step 1.

Completed Report

Name: DOE, JANE
 ID #: 1234G5H
 Exam Date: 06/09/2008 10:01 PM
 D.O.B.: 12/22/47

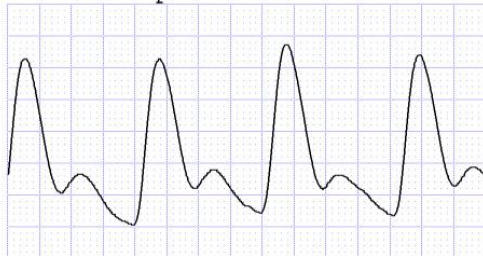
UNETIXS VASCULAR
 Vascular Tech: MT
 Ref.Phys.: JASONER



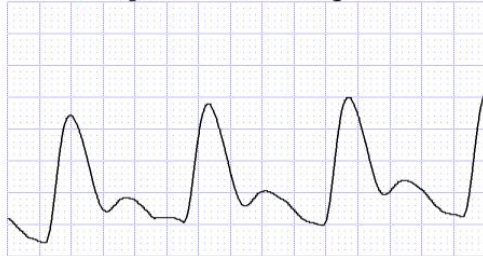
Dop 8Mhz YOUR LABEL
 Gain: 4 Speed:25



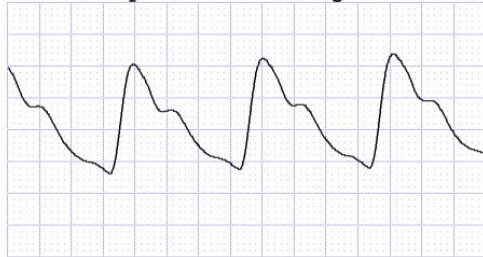
Dop 8Mhz YOUR LABEL
 Gain: 4 Speed:25



PVR YOUR LABEL
 Gn: 6 Sp:25 Pr: 65mmHg V1:189cc



PVR YOUR LABEL
 Gn: 4 Sp:25 Pr: 67mmHg V1:173cc



PPG YOUR LABEL
 Gain:.50 Speed:25



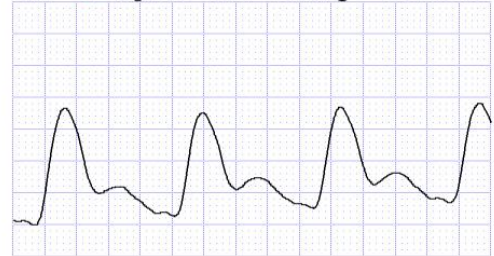
Dop 8Mhz YOUR LABEL
 Gain: 4 Speed:25



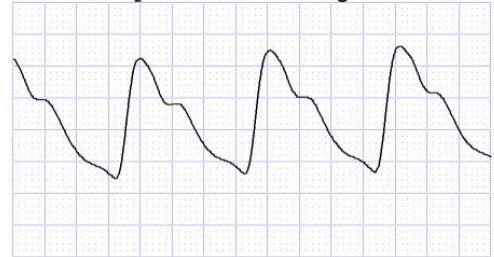
Dop 8Mhz YOUR LABEL
 Gain: 4 Speed:25



PVR YOUR LABEL
 Gn: 6 Sp:25 Pr: 63mmHg V1:203cc



PVR YOUR LABEL
 Gn: 4 Sp:25 Pr: 66mmHg V1:180cc



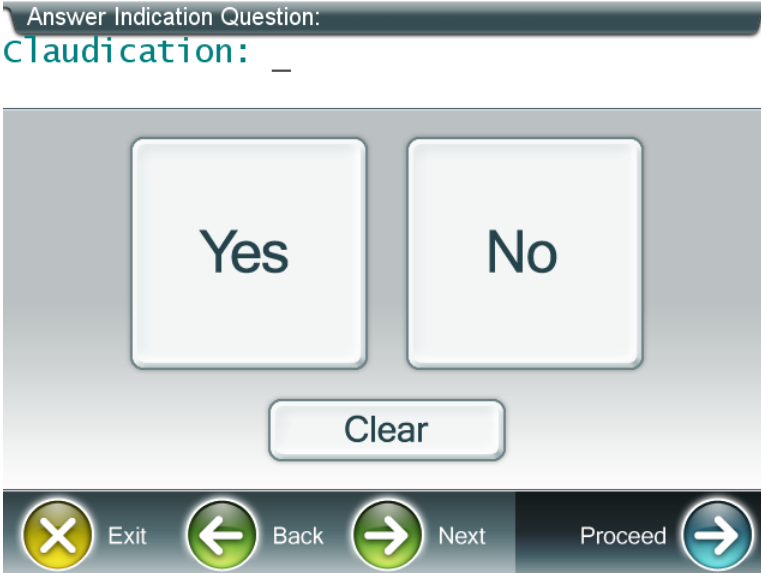
PPG YOUR LABEL
 Gain:.50 Speed:25

Chapter 10: Indication Questions

Indication questions are asked to give the reading physician insight into why the test was performed. If an indication is not provided in the list, you can add your own in the Notes section (see chapter 11). Near the end of some exams you may be asked some or all of the following indication questions:

- Claudication
- Rest Pain
- Ulcerations
- Coronary Disease
- Tobacco
- Diabetes
- Hypertension
- High Cholesterol
- Loss of Pulses
- BMI > 30 – Obese
- History of P.A.D.
- Family History

This screen prompts you answer an indication question:



Answer Indication Question:
Claudication: _

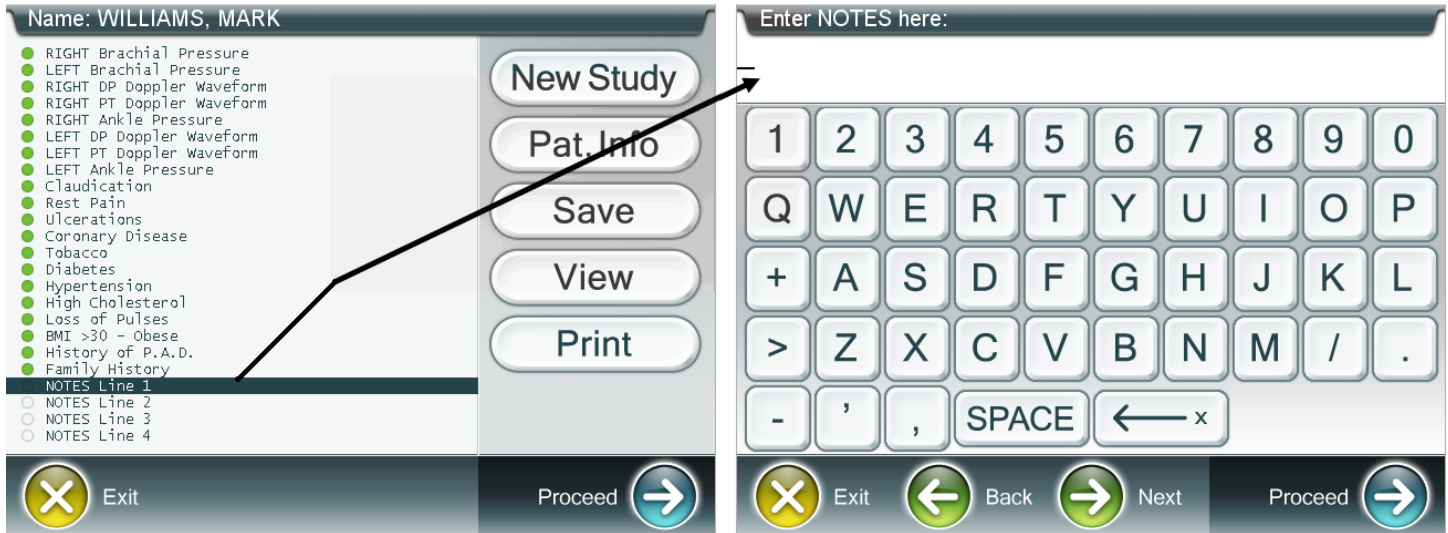
Yes No

Clear

Exit Back Next Proceed

Press 'Yes' or 'No' to answer the question and move on. Press the 'Next' or 'Proceed' button to skip answering the question. Questions that are not answered will not appear on the final report. Press the 'Clear' button to remove an answer from a question.

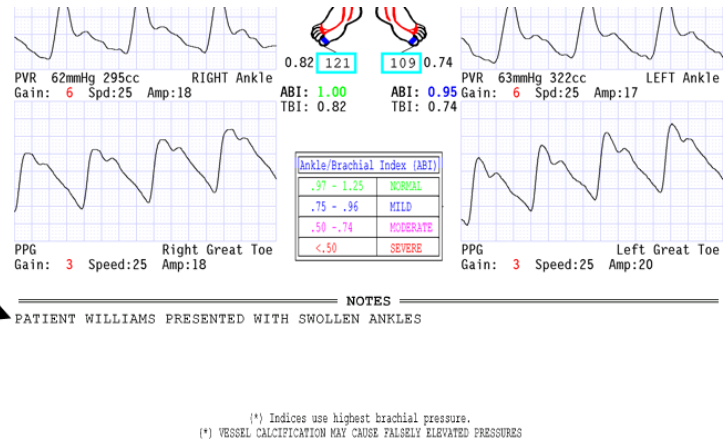
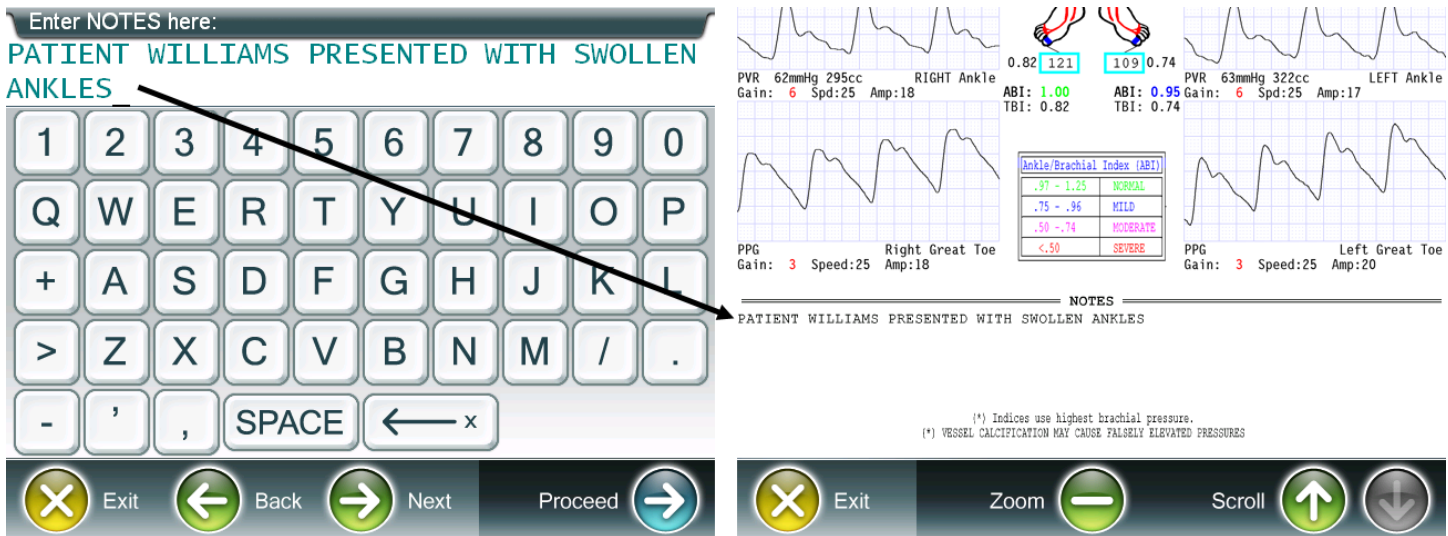
Chapter 11: Patient Study Notes



This screen prompts you to enter a line of text. This line will show up on the bottom of the report under the label "NOTES". You may enter up to 4 lines of text; each line consists of 80 characters. Use the "Next" and "Back" buttons on the bottom of the screen to switch between the different lines of text.

The text on the screen is divided into two lines of 40 characters each. After you have entered the first 40 characters, the next characters will show up on the next line as shown below.

NOTE: Although you see two lines on screen, only one line will be shown on the printout:



NOTES

PATIENT WILLIAMS PRESENTED WITH SWOLLEN ANKLES

(*) Indices use highest brachial pressure.
(*) VESSEL CALCIFICATION MAY CAUSE FALSELY ELEVATED PRESSURES

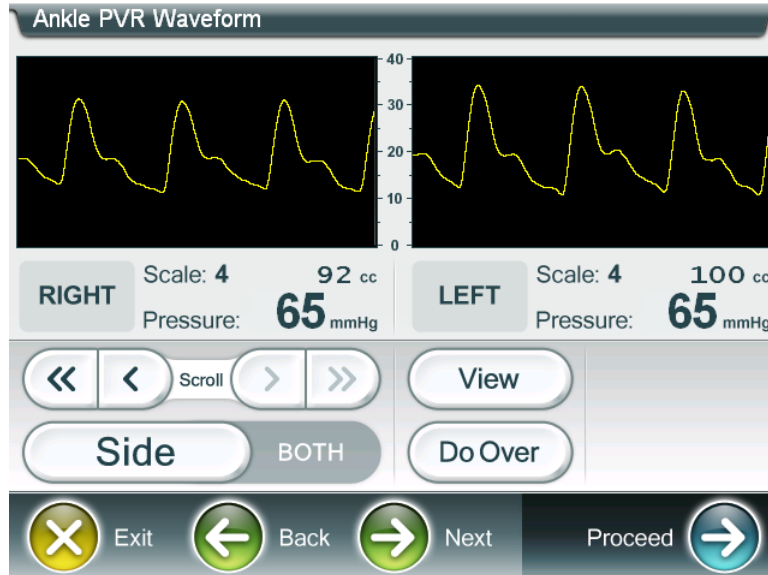
It may be necessary to edit text that has already been entered. The cursor usually indicates the point at which text is either inserted or deleted. To move the cursor, simply touch where you would like the cursor to be placed. After touching, you may also drag your finger to more accurately position the cursor.

Chapter 12: Edit, View, Print, Save or Delete Patient Studies

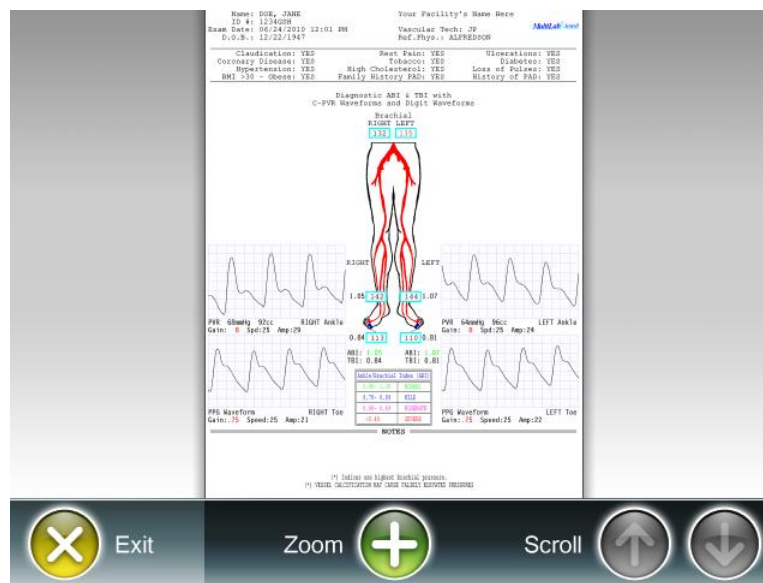
Once you have finished your desired Revo™ study, you have a number of options.

Viewing Your Patient Study

From any of the Revo™ “Capture” screens, you will see a button labeled “View”:



- Pressing the “View” button will display all the waveform and pressure data that has been captured during that particular examination. The initial view screen will look as follows:



- Press the “Zoom+” button to enlarge the page display.


- You can then use the “Scroll ↓” button to display the rest of the contents of the page, or press the “Zoom ⊖” button again to display the entire page on the Revo™ screen:

Name: DOE, JANE	Your Facility's Name Here	
ID #: 1234GSH	Vascular Tech: JP	<i>MultiLab[®] Serost</i>
Exam Date: 06/24/2010 12:01 PM	Ref.Phys.: ALFREDSON	
D.O.B.: 12/22/1947		

Claudication: YES	Rest Pain: YES	Ulcerations: YES
Coronary Disease: YES	Tobacco: YES	Diabetes: YES
Hypertension: YES	High Cholesterol: YES	Loss of Pulses: YES
BMI >30 - Obese: YES	Family History PAD: YES	History of PAD: YES

Diagnostic ABI & TBI with
C-PVR Waveforms and Digit Waveforms

Brachial
RIGHT LEFT
132 135



Exit Zoom Scroll

It is a good idea to use the “View” function, before printing or saving the Patient Study. If you see something that doesn’t look correct, you can edit the study before printing or saving it.

Editing Patient Studies

You can make changes to your existing study, or any study in your “Temp Files” (p. 21).

To edit your current study, press the “Exit” button at any point during the examination. This will bring up the “Edit” screen:

Name: ROBERTS, MARY

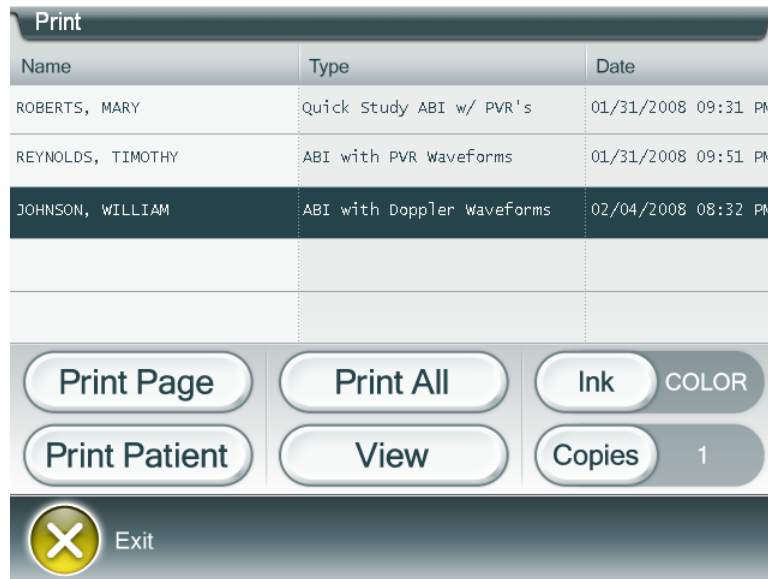
<input checked="" type="checkbox"/> RIGHT Toe PPG Waveform	<p>New Study</p> <p>Pat. Info</p> <p>Save</p> <p>View</p> <p>Print</p>
<input checked="" type="checkbox"/> LEFT Toe PPG Waveform	
<input checked="" type="checkbox"/> RIGHT PPG Toe Taken at:	
<input checked="" type="checkbox"/> LEFT PPG Toe Taken at:	
<input checked="" type="checkbox"/> RIGHT Great Toe Pressure	
<input checked="" type="checkbox"/> LEFT Great Toe Pressure	
<input checked="" type="checkbox"/> RIGHT Toe 2 Pressure	
<input checked="" type="checkbox"/> LEFT Toe 2 Pressure	
<input checked="" type="checkbox"/> RIGHT Toe 3 Pressure	
<input checked="" type="checkbox"/> LEFT Toe 3 Pressure	
<input type="checkbox"/> RIGHT Toe 4 Pressure	
<input type="checkbox"/> LEFT Toe 4 Pressure	
<input type="checkbox"/> RIGHT Toe 5 Pressure	
<input type="checkbox"/> LEFT Toe 5 Pressure	
<input type="checkbox"/> RIGHT Brachial Pressure	
<input type="checkbox"/> LEFT Brachial Pressure	

Exit Proceed

- The left side of the screen will display the protocol steps of the exam, and a green dot will appear adjacent to any of the sites where information (waveforms or pressures) has been captured.
- Use your finger to touch any of the sites you want to change, and then press the “Proceed” button. This will take you back to that site, where you can press the “Do Over” button to obtain another reading at that site.

Printing Reports

When you want to print your report, pressing the “Print” button on the “Edit” screen, will bring up the “Print Menu”:



- If you have more than one Patient Study in the “Temp Files” you will see the other studies, as well. Select the study you want to print by touching it with your finger.
- The “Print Page” button will print just the highlighted Patient Exam.
- The “Print Patient” button will print all studies with the same Patient Name.
- The “Print ALL” button will print all studies in the “Temp Files.”
- The “Ink” button allows printing in color or black and white. The default setting is “Color.”
- The “Copies” button will allow you to print multiple copies of the same study. Each touch will add one more copy up to a maximum of 9. If you need to reset the number of copies to 1, press the “Exit” button and then press the “Print” button again.

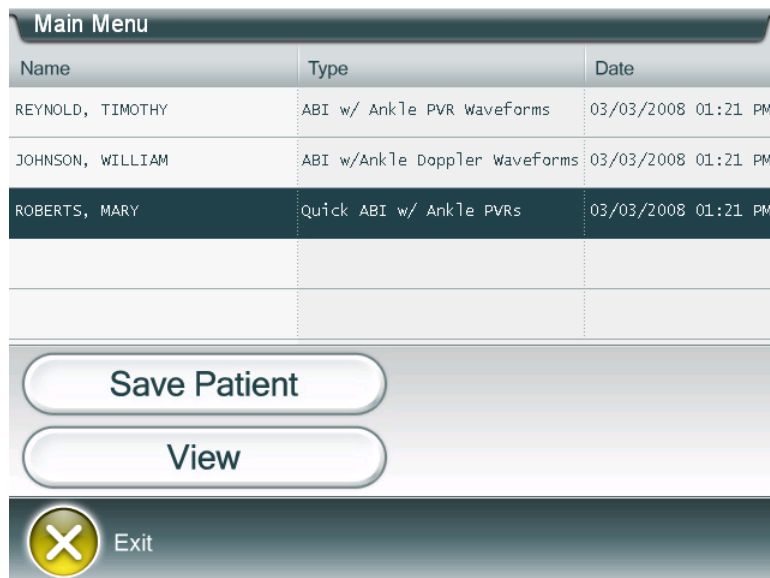
Saving Patient Studies

The Revo™ comes with a 1 GB (minimum) USB flash drive (p. 11).

With the USB flash drive installed, the Revo™ can keep up to 5 Patient studies in the “Temp Files”, and store up to 5,000 patient studies on the flash drive in .PDF format for permanent storage, or transferring to another computer, network or other storage media.

Note: On the USB drive, the UNETTEMP folder contains the “Temp. Files” and the UNETPDF folder contains the saved PDF files. The folders will be created if they do not exist.

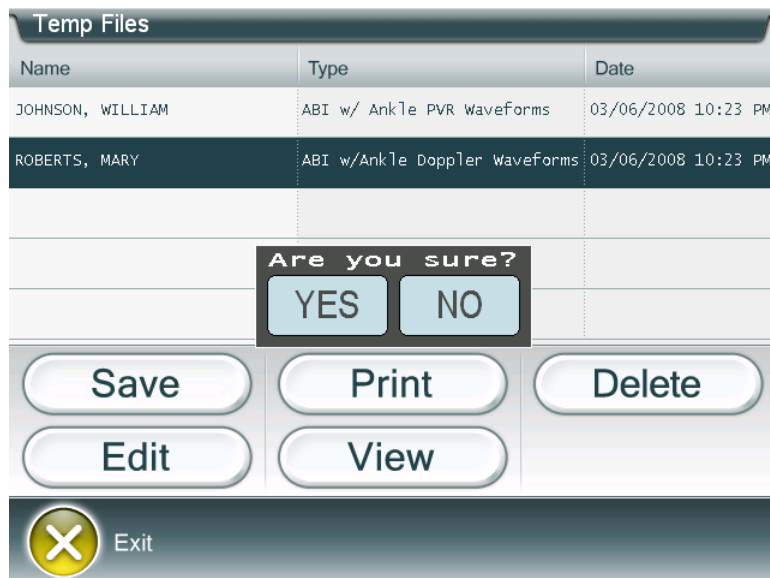
To save a Patient Study to the flash drive, press **“Save”** from the **“Edit”** screen or from the **“Temp Files”** menu.



- Pressing **“Save Patient”** will save all studies with the same patient name to the flash drive.

Deleting Patient Studies

To delete a Patient Study from the **“Temp Files”**, press the **“Temp Files”** button, touch the Patient Study you want to delete, then press the **“Delete”** button. A box will pop up asking **“Are you sure?”** Press **“YES”** to **permanently delete** the Patient Study, or **“NO”** to cancel the deletion.



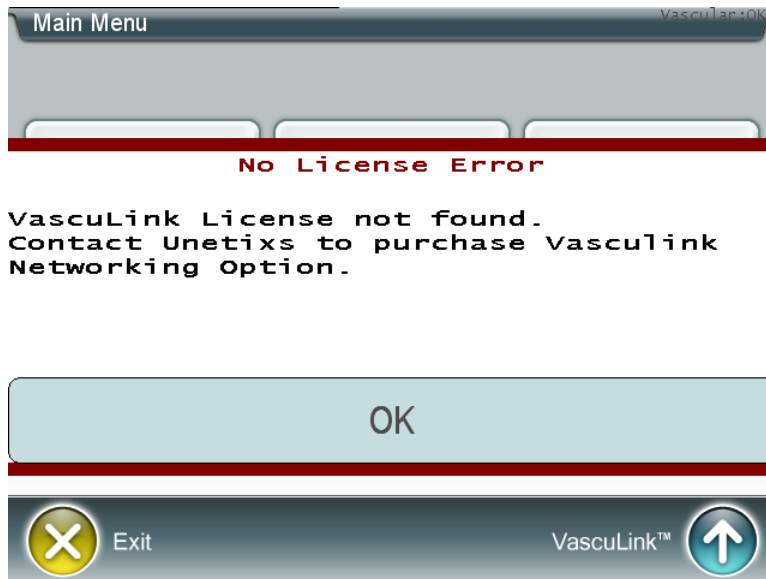
- Remember, pressing **“YES”** will **permanently delete** the Patient Study.

Chapter 13: Vasculink™ Option

The Vasculink™ option allows you to use the 'Network' port on the back of your Revo® to send completed studies to remote network locations.

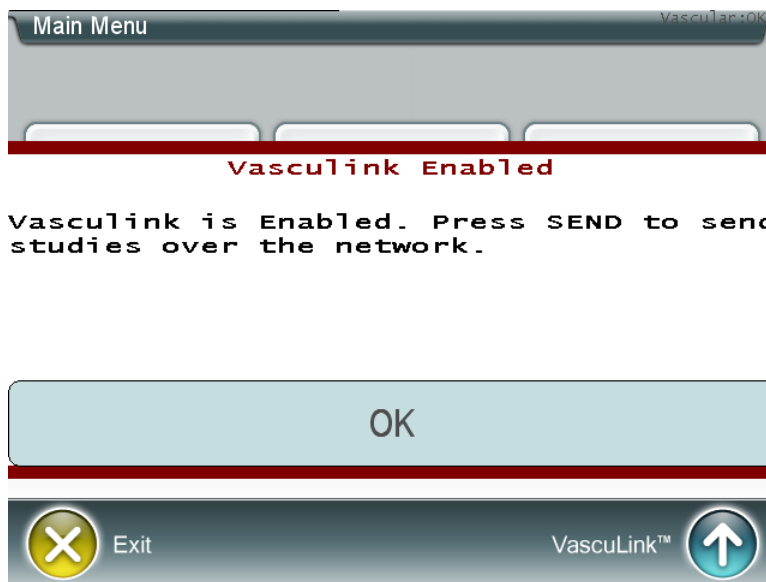
Enabling Vasculink™

Vasculink™ mode is enabled by pressing the Vasculink button on the Main Menu (see Chapter 2, Main Menu). If your Revo® doesn't have a license to use Vasculink™ you will see the following screen:



Contact the Sales Department at Unetix Vascular to purchase a license and go over your networking options.

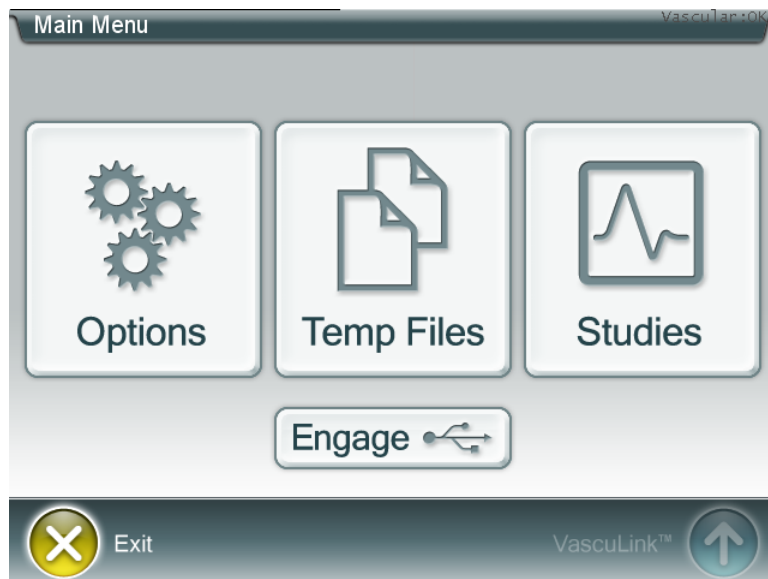
If the enabling of Vasculink™ was successful, you will see the following screen:



At this point, just press the 'OK' button and proceed to use the Revo® as you would normally. When an exam is complete, you will notice that the 'Save' buttons have been changed to 'Send' buttons.

Disabling Vasculink™

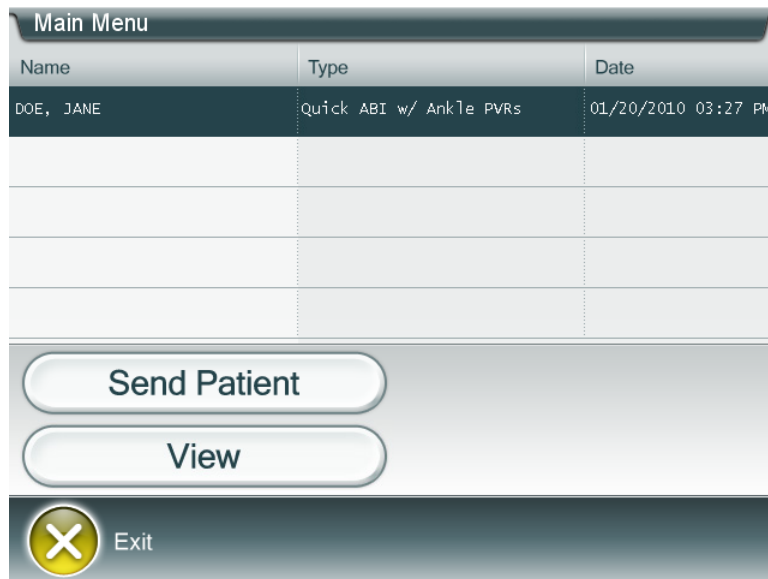
If Vasculink™ is enabled, the Vasculink™ button will be disabled as show below:



To disable Vasculink™ and return to 'Save' buttons, just press the 'Exit' button from the Main Menu and then press the 'Start' button from the Start Screen (see [chapter 2: Start Screen](#)).

Sending Studies

Pressing the 'Send' button from either the Edit Study (see [chapter 12: Editing Patient Studies](#)) or the Temp. Files (see [chapter 2: Temp. Files](#)) screen will bring up the following screen:



Select a patient to send by touching one of the 5 slots at the top of the screen. Press the 'view' button to review the image to be sent; you will be returned to this screen afterwards. Pressing 'Send Patient' will cause the Patient Information Review screen to be shown as follows:

Patient Information Review	
Family Name:	DOE
Given Name:	JANE
Middle Name:	
Name Prefix:	
Name Suffix:	
ID#	1234G5H
D.O.B.:	December 22, 1947

Cancel Accept

The operator must ensure that all fields are correct before pressing 'accept'. Incorrect data in these fields may cause problems later on when the study is received by another electronic system. If any data is incorrect, the operator can press the 'Cancel' button and correct the information using the 'Pat. Info' button (see **chapter 12: Editing Patient Studies**). If the information is correct press the 'Accept' button to have Vasculink™ initiate a transmission over the network.

Successful Transmission

If the network transmission succeeds you will see the following screen:

Patient Information Review	
Family Name:	WILLIAMS
Given Name:	MARK
Middle Name:	

VascuLink Successful

**VascuLink send completed successfully.
Press OK to continue.**

OK INFO

Cancel Accept

Failed Transmission

If a network transmission fails, you will see the following screen:



Most of the time networking is simple and easy to use. Problems that do occur can easily be solved provided that support staff is given sufficient information as to the nature of the problem.

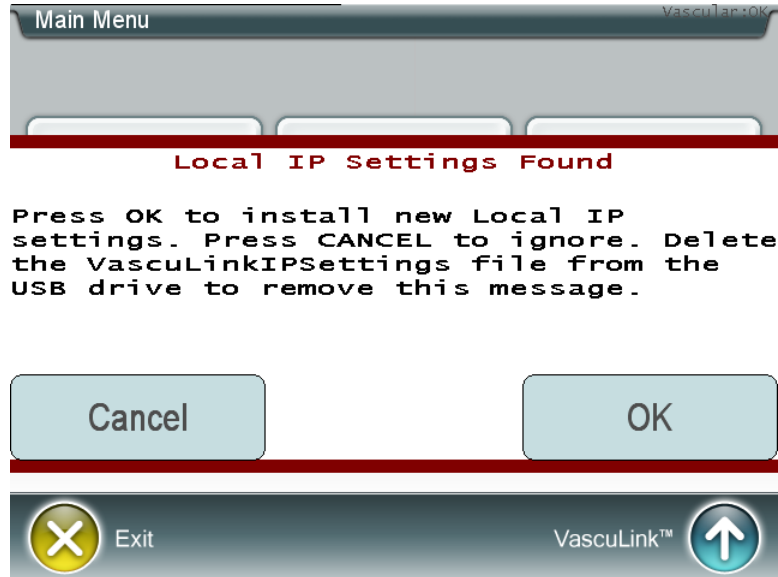
If you do see this screen, go to the back of the Revo® and verify that the network port is connected and has a green 'link' light. If it does not, try reconnecting the cable and then press the 'Retry' button to re-initiate the transmission.

If you still see this screen, the 'INFO' button will bring up a screen of network information that may be used by either your own network support staff or Vasculink™ support staff to diagnose and repair your problem. Most problems occur at initial setup and are caused by incorrect settings.

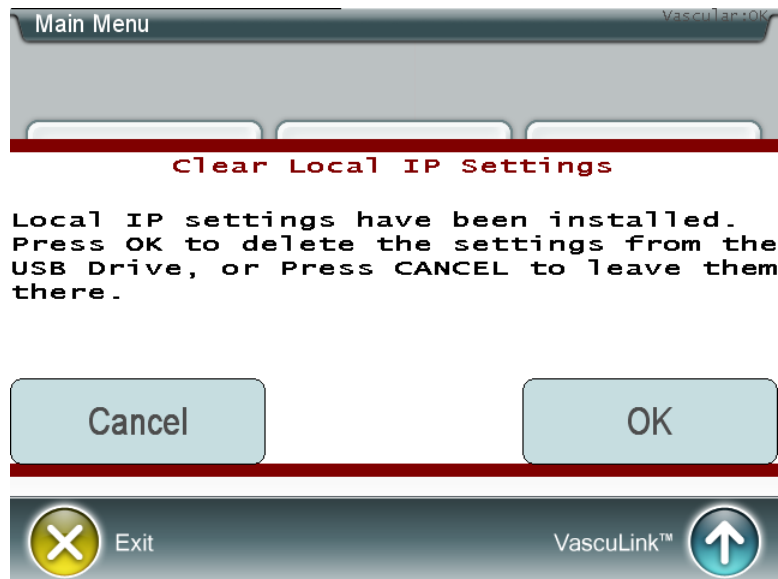
Setting up Vasculink™ (technical)

There are two main settings in a network environment, the local network settings of the Revo® (so it can connect to the network) and the network settings of the destination (the electronic device that receives information from the Revo®).

NOTE: The local settings can be changed by creating a VasculinkIPSettings.txt file on the root of the USB Flash Drive. A sample file may already be provided on your USB Flash Drive, but one can be downloaded from the Unetix Vascular support site at <ftp.Unetix.com/pub/multilab/Revo/Vasculink>. Usually the default factory (DHCP) settings in the Revo® are sufficient for most networks. The file may be edited with a text editor, such as Notepad. If you do need to affect these settings, make sure that the USB Flash Drive is engaged before enabling Vasculink™. Then, when you enable Vasculink™, you will see the following screen:

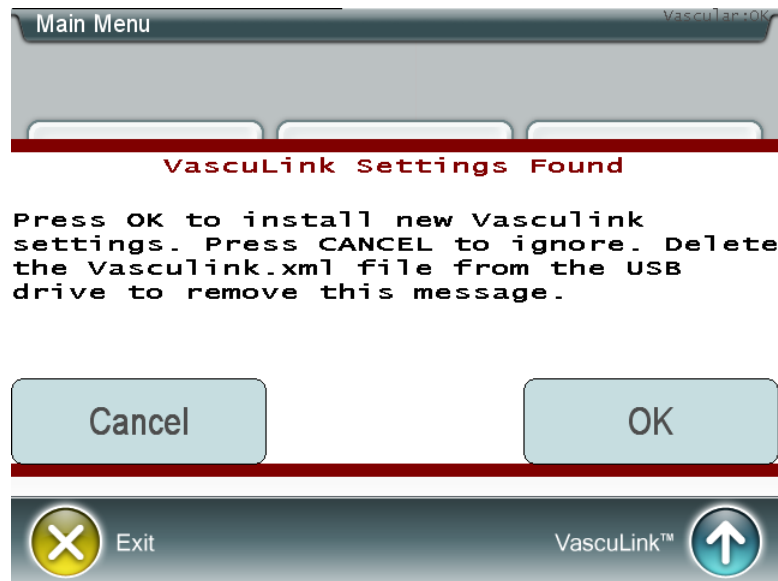


Pressing OK will install your settings and bring up the following screen:

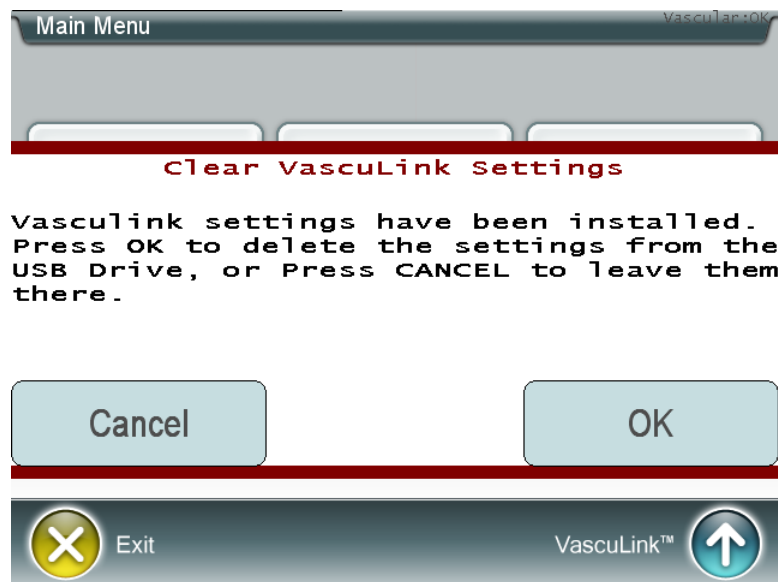


Press 'OK' to delete the VasculinkIPSettings file from the USB Flash Drive and continue with enabling Vasculink™.

The destination settings can be changed by creating a VasculinkSettings.xml file on the root of the USB Flash Drive. A sample file may already be provided on your USB Flash Drive, but one can be downloaded from the Unetixs Vascular support site at <ftp.Unetixs.com/pub/multilab/Revo/Vasculink>. There are no 'default' settings for this file as your destination on the network should be unique to your needs. The file may be edited with a text editor, such as Notepad, or an XML editor. To get the settings into the Revo®, make sure that the USB Flash Drive is engaged before enabling Vasculink™. Then, when Vasculink™ is enabled, you will see the following screen:



Pressing OK will install the destination settings and bring up the following screen:

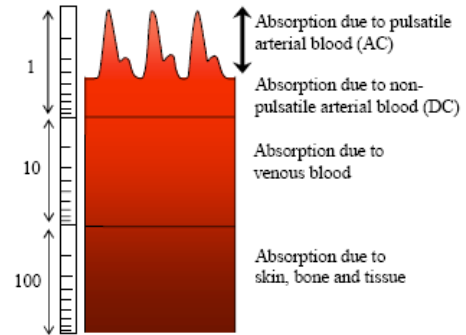
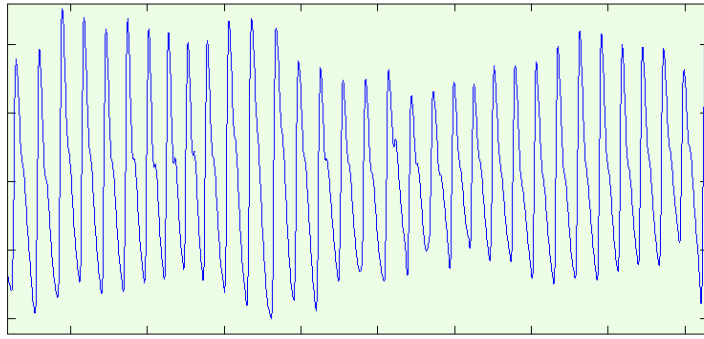


Press 'OK' to delete the VasculinkSettings file from the USB Flash Drive and continue with enabling Vasculink™.

Chapter 14: Theory of Operation

PPG

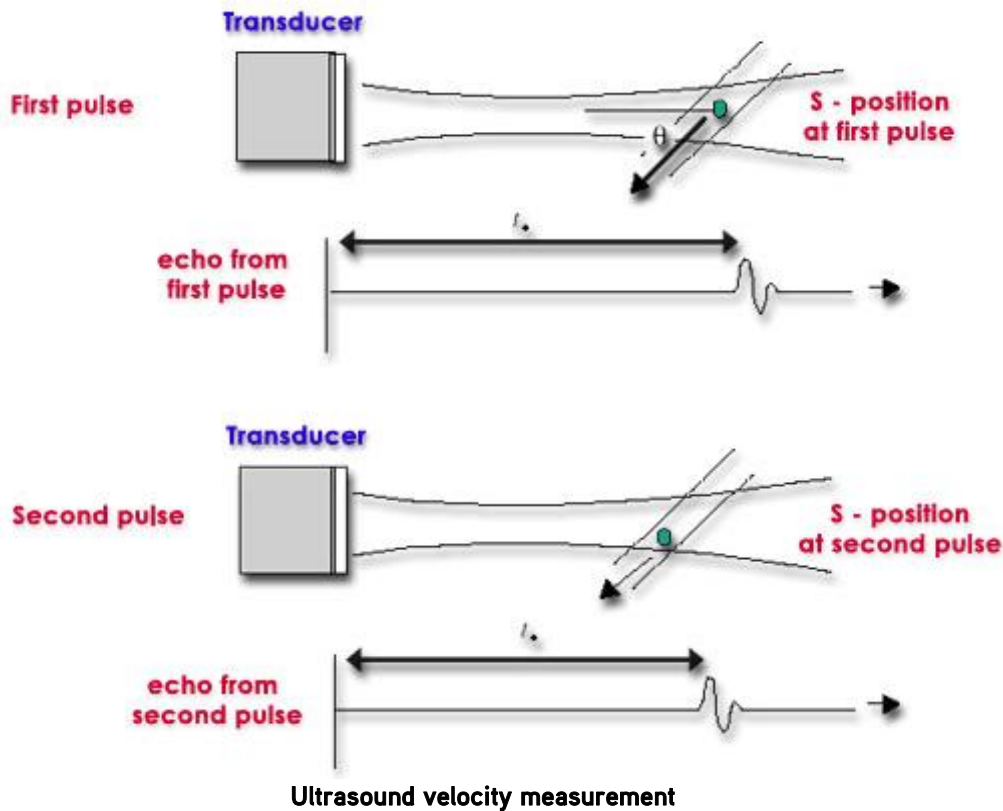
A photoplethysmographic (PPG) signal is optically obtained by using IR LED, which monitors the perfusion of blood to the dermis and subcutaneous tissue of the skin. The change in volume caused by the pressure pulse is detected by Beaming the IR light through the skin using IR LED and then measuring the amount of light either transmitted or reflected to a photodiode. Each cardiac cycle appears as a peak in the waveform of the photodiode's light-generated current, as seen in Figure As shown:



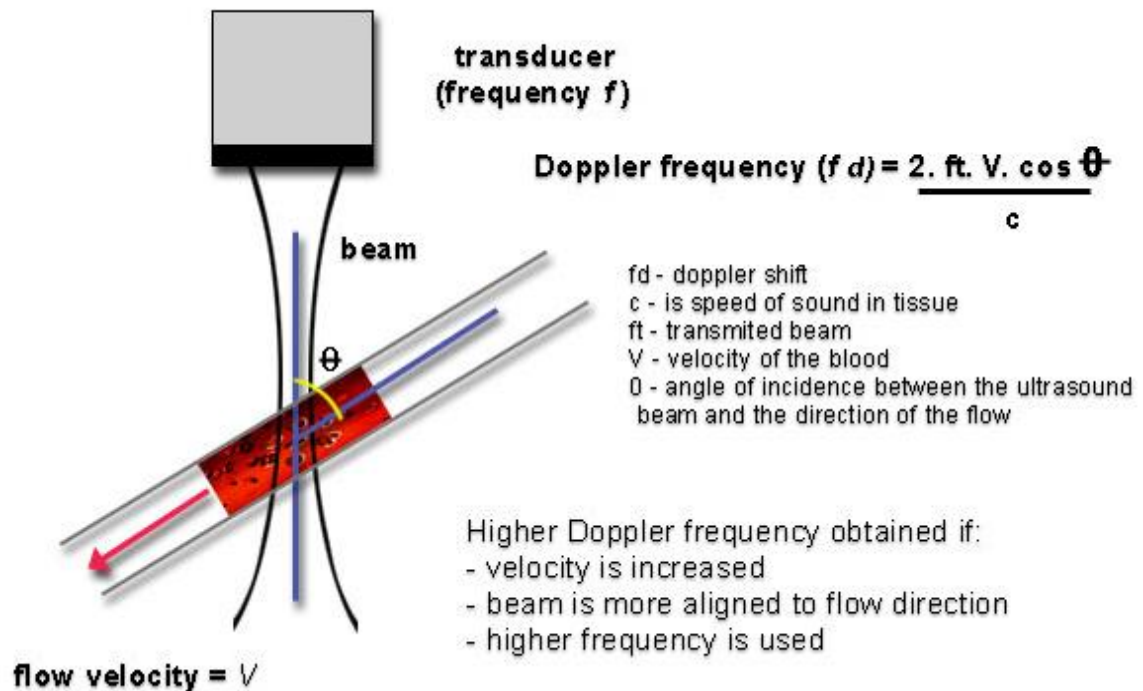
Example of Pulsed IR LED waveform received by the sensor

The DC component of the signal reflects the bulk absorption of the skin tissue, while the AC component is directly attributable to variation in blood volume in the skin caused by the pressure pulse of the cardiac cycle.

DOPPLER PROBE



The diagram shows a scatterers S moving at velocity V with a beam/flow angle θ . The velocity can be calculated by the difference in transmit-to-receive time from the first pulse to the second (t_2), as the blood moves through the beam.



Doppler Ultrasound

Doppler ultrasound measures the movement of the scatterers (blood corpuscles) through the beam as a phase change in the received signal. The resulting Doppler frequency can be used to measure velocity if the beam/flow angle is known.

PVR Cuff

Pulse volume recording, or PVR, is a test that measures blood flow in the leg arteries. PVR can be used to diagnose PAD in the legs, determine how severe the disease is, and find the general location of the blockage. The PVR test is fast and painless, and does not require entering the body.

Blood does not flow through the body with continuous, uninterrupted flow. Instead, with each beat of the heart blood is pushed through the body in "pulses." The PVR test uses pressurized cuffs to monitor how these pulses travel through the legs, allowing doctors to find blood flow problems that may be caused by PAD. The pulsing of blood is measured at several different parts of the leg; PVR can also show roughly where the blockages are.

Chapter 15: Care, Maintenance, Warranty and Service

Care and Preventative Maintenance

The Revo™ has been design in such a way as to minimize the amount of preventative maintenance required. However, there are some things that should be monitored on a regular basis.

- 1) Check the connectors on the cable assemblies to ensure that the screw-on sections are secure.
- 2) Check that all the ventilation slots are clear of obstructions and dust. Vacuum if necessary.
- 3) Inspect all cable assemblies (including power cables) for damage or wear. Replace any suspect cables.
- 4) Inspect blood pressure cuff bladders for signs of wear. Replace as needed.
- 5) Check nuts and bolts use to secure the wheels to the pedestal to ensure tightness.
- 6) Check all exposed hardware for tightness and correct functionality.

The unit should be returned to the factory once every 24 months for calibration (this service is included in Unetixs service contracts).

Troubleshooting

Most problems can be fixed by simply restarting the system. Turn off the system with the power switch. Unplug the system from power for 10 seconds. Plug back in and turn back on. If this does not fix your problem then contact service.

By default the system power settings, in Windows, are set to disable sleeping and to disable turning off the display. If these are changed, you may notice a color inversion or a partial shifting of the display. To fix this, just restart the system. To turn these off again, connect a keyboard. Press the “windows” key and type “power”. Touch “Power and Sleep Settings”. Set Screen “Turn off after:” to “Never”. Set Sleep “PC goes to sleep after:” to “Never”. Close the Settings window and restart the system.

Cleaning

Shock Hazard! Turn the power off and disconnect the power cable before cleaning the adapter, Revo™, sensor, probes.

Do not use abrasive cleaners on the Revo™ or on any sensors or probes. Abrasive cleaners can damage the Revo™, sensors, display, and probes.

The exterior surface of the Revo™, except for the display screen, may be wiped clean with alcohol and dried with a soft, dry cloth. It is best to use a cotton cloth to clean the Revo™. Paper towels or tissues can scratch the surface of the display.

Do not use full strength alcohol on the display screen. Repeated use of strong cleaners can damage the screen. Clean the display window by wiping it with a clean, soft, lint-free cloth sprayed with common glass cleaner. Do not spray glass cleaner directly on the display.

1. Sensors & Doppler Probe

Do not immerse any UNETIXS PPG sensor, Doppler Probe or the probe’s connector in any liquid. Doing so may cause damage. PPG sensor and Doppler probe can be wiped clean with alcohol.

2. PVR cuff

The reusable cuff may be cleaned by wiping it with a damp cloth or sponge. If necessary, the cuff may be disinfected by wiping with 70% alcohol, mild bleach solution, or other disinfectant. Disposable cuffs are for single patient use and are not intended to be disinfected.

Removable covers make cleaning easy. The cuff covers are made of Nylon and Velcro. Remove the bladder then wash the cuff cover in a washing machine on gentle cycle or by hand using mild soap. Open the top of the cuff and line dry only. When completely dry, reinsert the bladder. If bladder is contaminated, wash it in soapy water and rinse well without getting any liquid in the bladder or tubing.

Be sure to observe the following laundering precautions (disposable cuffs and neoprene bladders should not be laundered).

- Remove the inflatable bladder from the cuff before laundering the cuff.
- Strong bleach solutions will damage the cuff.
- Temperatures over 275° F (135° C) will damage the cuff.
- Close the Velcro® fastener before laundering the cuff.
- Soaking the cuff in dark-colored solutions may stain or discolor the cuff.

Hand laundering (as opposed to machine laundering) will prolong the life of the cuff. Wash the cuff in warm, soapy water. Rinse the cuff thoroughly. After cleaning the cuff, allow the cuff to air dry, and then insert the inflation bladder in the cuff.

Disinfect surfaces of the cuff by spraying or wiping the entire surface with disinfectant until wet. Allow the cuff to remain visibly wet for a minimum of 10 minutes to insure complete disinfection. Wipe dry with clean cloth. The following disinfectants have been tested for compatibility with the cuff (note that no manufacturer claims effective disinfection on porous surfaces): Hydrogen peroxide, hydrogen peroxide with silver (Sanosil®), hydrogen peroxide, peroxyacetic acid, silver (Steriplex™), silver with citric acid (PureGreen24™ & SpectraSan™ 24), Octyl decyl dimethyl ammonium chloride with dioctyl dimethyl ammonium chloride with didecyl dimethyl ammonium chloride with dimethyl benzyl ammonium chloride (Protex™), 99% isopropyl alcohol, or T-Spray™. Note: Some disinfectants may cause the cuff color to bleed into cuff labeling. This does not affect the cuff's performance.

3. Hose cleaning

Clean the hose according to hospital protocol for cleaning of reusable equipment cables. Typically this protocol consists of the following:

1. Disconnect the hose from the monitor and cuff.
2. Wipe the hose with a nonabrasive cloth moistened with a mild detergent and warm water or a disinfectant. Dry thoroughly.
3. Do not use alcohol or solvents to clean the hose.
4. Do not allow the connectors to come in contact with liquids.
5. Do not fully immerse the hose in liquids.
6. Do not autoclave or EtO sterilize the hose.

Limited Warranty

Your Revo™ system is warranted to be free from defects in both workmanship and in materials for 24 months. This warranty period commences from the original date of purchase. Exceptions are:

- PVR and BP cuffs – 6 Months
- Printer – 3 Months
- PPG Probes and Doppler Probes – 12 Months

All material found to be defective within the warranty period will be repaired or replaced at no extra charge by the manufacturer. Unetixs, Inc. assumes no liability for service representation. The warranty will be void if the instrument is determined to have been subjected to abnormal environmental conditions, mechanical or physical abuse.

This warranty is exclusive and is in lieu of all other warranties expressed or implied, including but not limited to any implied merchantability or fitness for a particular purpose or use. Unetixs, Inc. will not be liable for any special, indirect, incidental or consequential damages or loss, whether in contract, tort or otherwise.

Unetixs, Inc. reserves the right to make improvements in the design, construction and appearance of its products without notice.

Service

Acceptable accessories, such as cuffs, hoses, cables, sensors, probes, clips, etc... can be obtained through customer service.

10632-0010-01 BP Cuff, SC-10	12940-0000-01 Left Hose Assembly	11928-0000-01 Left PPG Clip
10633-0025-02 BP Cuff, PC-2.5	12941-0000-01 Right Hose Assembly	11938-0000-01 Left PPG Sensor
11963-0000-01 TruDop 8 Probe	10378-0001-01 Power Supply	11929-0000-01 Right PPG Clip
11930-0000-01 Doppler Cable	10629-0003-01 Line Cord	11939-0000-01 Right PPG Sensor

For customer service, please contact Unetixs at:

1-800-486-3849 or log on to Unetixs.com

Or Email at:

Service@unetixs.com

Glossary of Terms

A

ABI: Ankle Brachial Index; the Ankle pressure divided by the Brachial Pressure.

ABI chart: A chart showing accepted normal to abnormal values of an ABI.

Amplitude: The height of a waveform. This can be affected by changing scale. For a Doppler waveform this can be affected by the angle of approach.

Angle of approach: The angle of the Doppler probe to the vessel being insonated. The amplitude is directly proportional to the cosine of this angle. At 90° to the vessel, the amplitude will approach 0 (cosine of 90° = 0).

Artifact: Waveform output that is not generated by the patient. For Doppler signals, this can be reduced by lowering the filter to a value closer to 3.5Hz.

B

Baseline: A center point for a waveform. For Doppler waveforms, the baseline is the point of zero flow. This point can be moved up or down by using the Baseline control.

Bayonet fitting: Used to connect the pneumatic hose to the cuff. The cuff has a male Bayonet fitting and the pneumatic hose has a male Bayonet fitting.

Brachial artery: A continuation of the axillary artery beyond the lower margin of the teres major muscle.

C

C-PVR™: See Calibrated pulse volume recording.

Calibrated pulse volume recording: A technique for ensuring the accuracy of PVR waveforms by alerting the operator in cuff wrapping issues.

Capture: Operator control to end obtaining patient information and to move on to editing that information.

CNO: Shorthand for "Could Not Occlude". The operator may enter this in lieu of a pressure when said pressure is above safe levels (typically 200 to 250 mmHg).

Control panel: Part of the operating system software that controls facets of its operation. These parts are not created by Unetixs Vascular Inc.

Cuff: Thin sealed air bladder encased in an elongated cloth covering. The cloth covering contains Velcro to hold the cuff in place when wrapped around a limb segment. The air bladder is connected to a Revo™ hose for taking pressures and PVR waveforms.

D

Default printer: The printer that is selected in the operating system.

Deflation cycle: When taking a pressure measurement, the deflation cycle is initiated after the completion of the inflation cycle (See Inflation cycle). The deflation cycle starts after the press and release of the deflate button which causes the pressure in the cuff to be released in a controlled fashion.

Doppler cable: Wire from the TruDop® probe to the Revo™ system.

Doppler cable port: Port on the Revo™ to connect the TruDop® Doppler cable.

Doppler probe: Ultrasonic device which connects to the Revo™ to display arterial waveforms.

Doppler waveforms: Waveforms created using a Doppler probe.

Dorsalis Pedis artery (DP): Dorsal artery of the foot. It arises at the anterior aspect of the ankle joint and is a continuation of the anterior Tibial artery.

Dual channel: The ability to perform two measurements at the same time, usually in a bilateral fashion.

DVT: Deep Vein Thrombosis; the formation of a blood clot in a deep vein.

E

Exam: A collection of measurements performed upon a patient for diagnostic purposes.

F

Facility name: A title line at the top of every Revo™ report; usually the name of the facility where exams are performed.

Flat (or Flat-line): When taking a pressure measurement, a complete and correct inflation cycle (See Inflation cycle) is when the waveform tracing has become flat. This means that the waveform tracing is a horizontal line. It is usually a good idea to see a couple of seconds of flat-line, after the inflation cycle, before starting the deflation cycle (See Deflation cycle).

H

Hypertensive: Refers to a patient with high blood pressure.

I

Incompressible: A vessel is considered incompressible when its systolic blood pressure exceeds safe levels (typically 200 to 250 mmHg).

Inflation cycle: When beginning to take a pressure measurement, a press and release of the inflate button

starts the "inflation cycle" where the Revo™ will inflate the cuff to a predetermined pressure. The object is to inflate the cuff beyond the systolic pressure.

Invert: A Doppler waveform control to reverse the displayed directions. Normally, forward flow (towards the probe) is above baseline. If invert is active then reverse flow (away from the probe) is above baseline.

L

Luer fitting: Previously used to connect the pneumatic hose to the cuff. The cuff has a female Luer fitting and the hose has a male Luer fitting.

M

Main menu screen: Main navigation screen for the Revo™.

Medial Malleolus: Protruding bone on the inner side of the ankle

Medially: A position in the middle of a body part.

P

PAD: Peripheral Arterial Disease

Patient data/information/study: Exam results for a patient.

PDF (file): Adobe Portable Document Format. A computer file that is readable across most computer platforms.

PICC line: Peripherally Inserted Central Catheter line for delivery of treatments such as antibiotics or chemotherapy.

Pneumatic hoses: Hoses to connect the Revo™ to a cuff.

Posterior Tibial artery (PT): Artery located on the inside of the ankle behind the medial malleolus.

PPG: Photoplethysmography, or a device to measure arterial flow using a light emitter and sensor.

PPG (toe) waveforms: Arterial waveforms of the toe obtained using a PPG sensor.

PPG clips: Special clip to increase the efficiency of applying a PPG sensor to a toe.

PPG connector: Port on the Revo™ (both right and left) to connect the PPG sensor to the Revo™.

PPG sensor: See PPG.

Pressure indicator: Onscreen manometer displaying the pressure in the cuff.

Protocol: Sequence of measurements in a patient exam.

Protocol steps: See Protocol.

Proximal: Nearest to the center of the body.

Pulsatile: Having a pulse.

Pulse: Arterial vibration caused by a pulsation of blood pumped by the heart.

Pulse volume recording: See PVR.

PVR: Pneumoplethysmography, or a device to measure arterial volume through the ankle using a cuff.

PVR (waveform) tracing: Waveform obtained using a Pulse Volume Recorder

R

Radial artery: A main artery on the lateral side (side with the thumb) of the forearm.

Report: Either a PDF file or a printout of a completed exam.

Return of flow: When taking a pressure, a PPG sensor or a Doppler Probe is used to sense "return of flow." This is the exact point when the cuff pressure is low enough for arterial flow to resume.

S

Scale: The amount of gain applied to the waveform. This directly affects the amplitude of the waveform by using the Scale control. Lower scale numbers mean lower amplitude.

Scroll: Movement of the waveform in either a left to right or right to left direction. After a waveform or pressure has been captured, the Scroll control allows the user to exactly set the waveform position or select the correct pressure measurement point.

Set output: User control to manually set a pressure output. This is especially useful for incompressible vessels (see CNO).

Shutdown: User control to initiate an operating system shutdown. It is strongly recommended to use this control before turning off the system.

Signal: True waveform output from the patient (as opposed to artifact; See Artifact).

Single channel: Unilateral measurement system on either the right or left side of the body.

Start: User control to start using the Revo™ after the storage mode has been selected.

Storage mode: Method the Revo™ will use to store temporary files. In USB storage mode, the files are stored on the USB flash drive. In Temporary Storage mode, the files are stored in RAM and will be cleared every time the Revo™ is restarted.

Study: See Exam.

Supine: Lying on back with face upwards.

Systolic pressure: The high number of a patient's blood pressure, typically 120mmHg at the arm. This is the type of pressure that the Revo™ measures at the Arm (brachial), Ankle, and Toe.

T

TBI: Toe Brachial Index; the Toe pressure divided by the Brachial Pressure.

Temp. files: The place where the Revo™ stores patient studies that have not been saved or printed (see Storage mode).

Thumb drive: See USB flash (storage) drive.

Touch screen: A user input device which overlays the main output screen. The input device allows the Revo™ to register the exact position that the operator is touching on the screen.

TruDop®: The trademark name of Unetixs Vascular Inc.'s Doppler probe used on the Revo™.

U

Ulnar artery: A main artery of the medial aspect (side away from the thumb) of the forearm.

Ultrasound gel: A hypoallergenic water based gel used to couple the Ultrasonic transducer of the TruDop® Doppler probe with the arterial vessel of a patient.

USB flash (storage) drive: A file storage device that connects to the Revo™ via its USB port.

V

Vascular studies: Patient exams pertaining to their vascular system. These are the types of studies that the Revo™ performs.

Vasoconstriction: The narrowing of a blood vessel resulting from the contracting of the vessel's muscular wall.

Venous access port: A tube inserted into a vein (typically the Subclavian or Jugular) for the delivery of medicine and the taking of blood samples. The plastic or metal port can be found near the surface of the skin.

W

Waveform box: When taking a pressure or waveform measurement, this is the area at the top of the Revo™ screen with the waveform in it.

Waveform tracing: The patient signal or artifact (See waveform box).

(This page is intentionally blank)

Revo[®]

Operator's Manual



For Additional Help Contact:

Unetixs Vascular, Inc.

333 Strawberry Field Road, Suite 11, Warwick, RI 02886

401-294-7559 Tel / 401-294-3893 Fax

800-486-3849

www.unetixs.com



Do not dispose of in municipal waste. Wheeled bin symbol indicates separate collection for electrical and electronic equipment (WEEE Directive 2002/96/EEC)

Dispose of any contaminated/biohazard materials through the proper channels.