MultiLab Operator's Manual

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CHAPTER 1: CARE OF EQUIPMENT

Copyright

Technical Support

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Or contact your local Unetixs Vascular Field Representative

Contact Unetixs, Inc. for:

- Any questions regarding the operation of the system
- Service and repair information
- To purchase consumable items (paper, gel, replacement accessories) or options.

Do not return the system or accessories to the factory without prior authorization from the Customer Service Manager. Unauthorized returns will be returned to the sender at the sender's expense. To obtain authorization, write or call:

Customer Service hours are between 8:30 am and 5:00 p.m. Eastern Time. Please have your model and serial numbers ready prior to calling.

NOTES

Our Responsibility

As the manufacturer, Unetixs Vascular, Inc. is responsible for the effects on safety and performance only when:

1. Installation procedures, training, programming, modifications, or repair are performed by individuals authorized by Unetixs Vascular, Inc.
2. The MultiLab is used in accordance with instructions for use.

The Customers Responsibility

The user of the MultiLab is responsible for using the system according to instructions. The user is further responsible for the establishment of a general cleaning and maintenance schedule, the lack of which could lead to failure and premature retirement of the device.

Note: This system can be affected by radio frequency energy from other medical and non-medical devices. If other devices are causing interference:

1. Relocate either the MultiLab or other device.
2. Increase the distance between the MultiLab and the other device.
3. Power the MultiLab from a different source than the other device.
4. Consult Unetixs Service for other suggestions.

Note: Do not use other devices which intentionally transmit RF Signals such as cell phones, radio transceivers, or radio controlled products near the MultiLab while in operation.

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 technical support above.

Note for **2CP**: 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.

Intended Use and Misuse

Intended Use

The MultiLab 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.

Limited Warranty

Your system is warranted to be free from defects in both workmanship and in materials for:

24 months of parts
24 months of labor
6 months on cuffs
12 months on probes

This warranty period commences from the original date of purchase. The Acknowledgement of Acceptance must be returned within 10 days of the date of purchase.

All material found 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 Incorporated will not be liable for any special, indirect, incidental or consequential damages or loss, whether in contract, tort or otherwise.

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

The following incoming inspection is required whether it is a first time arrival or a return from service. Prior to clinical use, the instrument should be inspected for the following:

- Fill out and return your Acknowledgement of Acceptance immediately.
- Carefully inspect the cartons for damage that may have occurred during shipping. Open the carton carefully.
- Remove the system and its accessories (see packing list and shipping documents) from the shipping carton. Inspect the system for damage that might have been incurred during shipping.
- If you find any damage, notify the carrier and Unetixs Inc. (the manufacturer) Customer Service Department immediately. See the CUSTOMER SERVICE AND WARRANTY section of this manual for further information.
- Please also go through the packing documents and inspect your accessories for completeness and possible damage.

IMPORTANT: Save the entire original packing materials until you have confirmed the system operates properly. We STRONGLY recommend you save them for future service or moving.

Specified Environmental Conditions for use of MultiLab

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

SYMBOLS

Symbol	Definition
	Refer to Operator's Manual for Information
	Shock Hazard
	Do not dispose of in municipal waste. Wheeled bin symbol indicates separate collection for electrical and electronic equipment (WEEE Directive 2002/96/EEC)
IPX0	Identifies the degree of protection against Fluid & Dust.
	Alternating Current (AC)
	Type BF Equipment
	Class I
	Technical Support Phone Number

Safety

Definition of Warning and Caution symbols:

⚠ **WARNING** ⚠ Designates a possible dangerous situation. Non-observance may lead to death or the most severe injuries.

⚠ **CAUTION** ⚠ Designates a possible dangerous situation. Non-observance may lead to minor injuries or damage to the product.

Warning

⚠ Before operating instrument, please go through the Operator's Manual which contain theory of operation, setup, and application of device to minimize the risk of improper usage

⚠ 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.

⚠ Make frequent electrical and visual checks on Power cables, Doppler & PPG cables and Pneumatic hoses.

⚠ When the unit or its accessories have been dropped or severely abused, it should be checked by the qualified service personnel from Unetixs Inc. to verify proper operation.

⚠ Possible explosion hazard! Do not use the MultiLab Series II in the presence of anesthetics.

⚠ Possible explosion hazard! Do not use the MultiLab Series II in the presence of gas mixtures which may be flammable.

⚠ The device should not be used in MRI environment.

⚠ The device is to be operated by trained medical personnel only.

⚠ All the cables and tubing should be carefully routed to avoid the possibility of patient entanglement and strangulation. Patient should not be left unattended

⚠ Operators are not to leave the patient unattended during testing.

⚠ If the patient should feel severe discomfort during cuff inflation, the cuff can be deflated by pressing the deflate button on the MultiLab Series II screen or cuff pressure can be rapidly exhausted by pressing the capture button. The same result can be obtained by physically removing the air hose from the blood pressure cuff.

⚠ All power cords must have hospital grade plugs and be plugged into hospital grade outlets. (The electrical installation of the relevant room must comply with NFPA 70: National Electric Code of NFPA 99: Standard for Health Care Facilities. Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government.)

⚠ Use proper power cord with the correct attachment plug style. If the power source is 120 VAC, use a power cord which is a Hospital Grade Power Cord with NEMA 5-15 style plug, labeled for 125 volts AC with UL and C-UL approvals. If the power source is a 240 VAC supply, use the tandem (T blade) type attachment plug with ground conductor power cord that meets the respective European country's safety regulations.

⚠ Device should be located, such that user should have easy access for the removal of power card.

⚠ Changes or modifications not expressly approved by UNETIXS, Inc., may cause unexpected results (Shock Hazards to the patient or the operator), and may also void the warranty.

⚠ Risk of electrical shock! Do not remove cover. There are no user serviceable parts.

⚠ Do not re-use accessories labeled as single use.

⚠ U.S. Federal law restricts this device to sale by or on the order of a physician.

⚠ When transporting equipment always use the transport position (if applicable).

⚠ People who are suffering from Deep Vein Thrombosis (DVT, i.e., blood clot in the veins of the legs) should not undergo for 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.

Caution

⚠ The system is not intended for continuous or unattended monitoring.

⚠ The MultiLab Series II is non–invasive vascular diagnostic equipment and thus is neither for monitoring the patient's vital signs nor for use in ICU or in operating theater, administering or advice 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 and instrument.

⚠ 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 ºC) could damage the system and accessories.

⚠ 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.

⚠ Do not use the Ethernet ports for internet access, as computer viruses may occur. Ethernet connection is intended for communication with EMR and other patient healthcare software. If Ethernet port must be used, use of firewalls and/or virus protection scanning software is recommended.

⚠ Do not use devices like USB memory stick which is used with the system without scanning for virus or malware bytes. UNETIXS, Inc. assumes no responsibility if the user chooses to leave the system unprotected.

⚠ Unit to be operated in an un-interrupted power supply environment.

⚠ 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.

⚠ Do not hang anything from the monitor arm (LHS ERGO IDC option only).

⚠ Refer to the sections below for proper use of the monitor arm (LHS ERGO IDC option only) when the system is being transported, is at rest, or is in use.

⚠ Do not remove the cover of your MultiLab Series II or attempt to service the system. Any service on the MultiLab Series II must be performed by the factory or by a factory-authorized technician. Unauthorized service or part substitution may impair operation and will void the manufacturer warranty.

⚠ Unit to be serviced by UNETIXS, Inc. trained service personnel.

⚠ 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.

⚠ Use only in specified environmental conditions.

⚠ Avoid placing the device near diagnostic or therapeutic equipment like X-ray machines, ultrasound machines, electrically operated beds, etc.

⚠ Avoid use of mobile phones in the vicinity of the device.

⚠ If the PPG probe is applied using Velcro™, avoid excessive pressure during wrapping as this can obliterate arteriolar flow causing an abnormal waveform.

Preventive Maintenance & Cleaning

Preventive Maintenance - General

The MultiLab Series II has been designed in such a way as to minimize the amount of preventive maintenance required; however there are some things that should be monitored on a regular basis.

1. Check the connectors on the cable assemblies to insure that the connections are secure.
2. Check that the all 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 and air leakage, replace as needed.
5. Check monitor base to insure clamps are secure and that the monitor base is undamaged.
6. Check nuts and bolts used to secure the wheels to the cart to insure tightness.
7. Check all exposed hardware for tightness and correct functionality.

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

Preventive Maintenance - Technical

Please refer to LHS Assembly document, 11949-0003-01(see Technical Manual) to perform the following:

⚠ In addition to the user Preventive Maintenance above, the following should be performed by qualified service personnel once per year. Perform this maintenance more often if equipment is used in dusty or damp locations.

1. Remove all covers from MultiLab (if applicable)
2. Turn unit on.
3. Verify that the fan in the back of the module is working.
4. Verify that the fan in the computer assembly is working.
5. Turn unit off and unplug from power mains.
6. Remove computer assembly (11945-0000-01) from cart. (Except Roodra. The All-in-One Computer is not user serviceable)

7. Remove Module Assembly (11903-0000-01) from cart.
8. Vacuum the interior of the cart.
9. Check all interior cables for wear, replace as needed.
10. Check that all interior hardware is securely fastened.
11. Remove cover from Module assembly.
12. Vacuum interior of module.
13. Check that the module fan is clean and rotates freely.
14. Replace module cover.
15. Remove left side of cover from CPU assembly. (Except Roodra)
16. Vacuum interior of computer.
17. Check that CPU fan is clean and rotates freely.
18. Replace Cover on computer assembly.
19. Reinstall computer assembly into cart.
20. Reinstall module assembly into cart.
21. Replace all covers onto MultiLab Cart.

Cleaning

⚠ Shock Hazard! Turn the power off and disconnect the power cable before cleaning the Power supply parts, sensor, or probes.

⚠ Do not use abrasive cleaners on the MultiLab series or on any sensors or probes. Abrasive cleaners can damage the MultiLab series, sensors, display, and probes.

⚠ The exterior surface of the MultiLab series, 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 MultiLab series. 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.

The following products are approved for exterior surfaces except the touch screen surface:

- 70% isopropyl alcohol (IPA)
- Oxivir Tb (accelerated hydrogen peroxide based0)
- Protex spray or wipes
- Sani-Cloth HB (QUAT based)
- Sani-Cloth Plus (QUAT/IPA based)
- DISPATCH® Hospital Cleaner/Disinfectant with Bleach

Caution: Do Not Use T-Spray on Unetixs Products

The following products are approved for Doppler Probes, PPG Probes/Clips, and Lead Wires:

Do not immerse any UNETIXS PPG sensor, and probe connector in any liquid. Doing so may damage the connector. PPG sensor and probe can be wiped clean with alcohol or you may use:

- SONO Wipes™
- Sani Professional® No-Rinse Sanitizing Multi-Surface Wipes
- Sani-Cloth® Bleach Germicidal Disposable Wipe – Safe - However will cause discoloration to the probe casing)
- DISPATCH® Hospital Cleaner/Disinfectant with Bleach - (Safe - However cause discoloration to the probe casing)

The following products are approved for the Touch Screen and Roodra All-In-One:

- PDI Easy Clean cleaning wipes

Unetixs Infectious Control Keyboard Cleaning Instructions:

Lock keyboard: Hold down the lock key (1B) or both Ctrl keys (1) for 3 seconds to lock. The lock indicator signals that the keyboard is locked (1 and/or 2). Clean keyboard with approved cleaning method and approved disinfectant or soap and water. To unlock keyboard, repeat procedure.

Unetixs Infectious Control Keyboard Approved cleaning methods:

The use of the Following Cleaners are Approved to Clean the Unetixs Infectious Control Keyboard:

- SONO Wipes™
- Sani-Cloth – No Bleach

The following products are approved for cleaning keyboards:

1. To clean while the keyboard is plugged in, lock the keyboard by pressing the Locking Key for three seconds – Ergo and Roodra only.
2. Clean the surface of the product by wiping, brushing, spraying or dipping it. Use only rags, sponges or soft bristle brushes. DO NOT place the USB connector into the fluid.
3. Either wipe with dry cloth or allow to air dry.
4. Unlock the keyboard by pressing the Locking key for three seconds.

Disinfectants recommended

- Chlorine based (max 10% solution) – Chlorox, Novalsan, etc.
- Formaldehyde based - Formaldehyde Solution 37%, Vinco Formaldegen…
- Glutaraldehyde based – Aldacide 200, Lysofume, Wavicide, etc.
- Phenol based – Lysol I.C., Beaucoup, Magna Clean, Tek-Trol, etc.
- Alcohol based – Cavicide, Isopropyl Alcohol, Medicide, etc.
- Oxidizing – Hydrogen Peroxide 3% Solution, Lifegard Series, etc.
- Quaternary Ammonium – Roccal-D, Bacto-Sep, Parvosol, etc.
- Soap and water.
- DO NOT USE: Petroleum based cleaning fluids, such as Gasoline, Acetone, over 10% bleach solutions, temperature or pressure sterilization, buffing pads or scrubbing pads.

Cleaning Procedure for Unetixs MultiLab and Accessories:

Manufacturer's instructions for Proper Care of Straight and Contoured Cuffs: Web: www.hokanson.cc
Cleaning Cuffs: Removable covers on straight and contoured cuffs make cleaning easy. The cuff covers are made of Nylon and Velcro.

1. Remove the bladder then wash the cuff cover in warm water using mild soap in a washing machine on gentle cycle or by hand.
2. Open the top of the cuff cover 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.

Disinfecting Cuffs:

1. Spray or wipe entire surfaces of cuff with disinfectant until wet.
2. Allow the cuff to remain visibly wet for a minimum of 10 minutes to insure complete disinfection.
3. Wipe dry with clean cloth.

The following disinfectants have been tested for compatibility with our cuffs:

Please Note: The manufacturers do not claim effective disinfection on porous surfaces; we have been unable to find any disinfectants that claim disinfection on porous surfaces.

1. Hydrogen peroxide
2. Hydrogen peroxide with silver (Sanosil®)

3. Hydrogen peroxide
4. Peroxyacetic acid, silver (Steriplex™)
5. Silver with citric acid (PureGreen24™ & SpectraSan™ 24)
6. Octyl decyl dimethyl ammonium chloride with dioctyl dimethyl ammonium chloride with didecyl dimethyl ammonium chloride with dimethyl benzyl ammonium chloride (Protex™)
7. 99% isopropyl alcohol.

Note: Some disinfectants may cause the cuff blue color to bleed into cuff labeling. This does not affect the cuff's performance.

Do not sterilize cuffs: The design of the Cuffs is such that they are not sterilizable.

Pneumatic 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.
3. Dry thoroughly.
4. Do not use alcohol or solvents to clean the hose.
5. Do not allow the connectors to come in contact with liquids.
6. Do not fully immerse the hose in liquids.
7. Do not Autoclave, nor EtO sterilize, the hose.

Operation of the LHS Cart

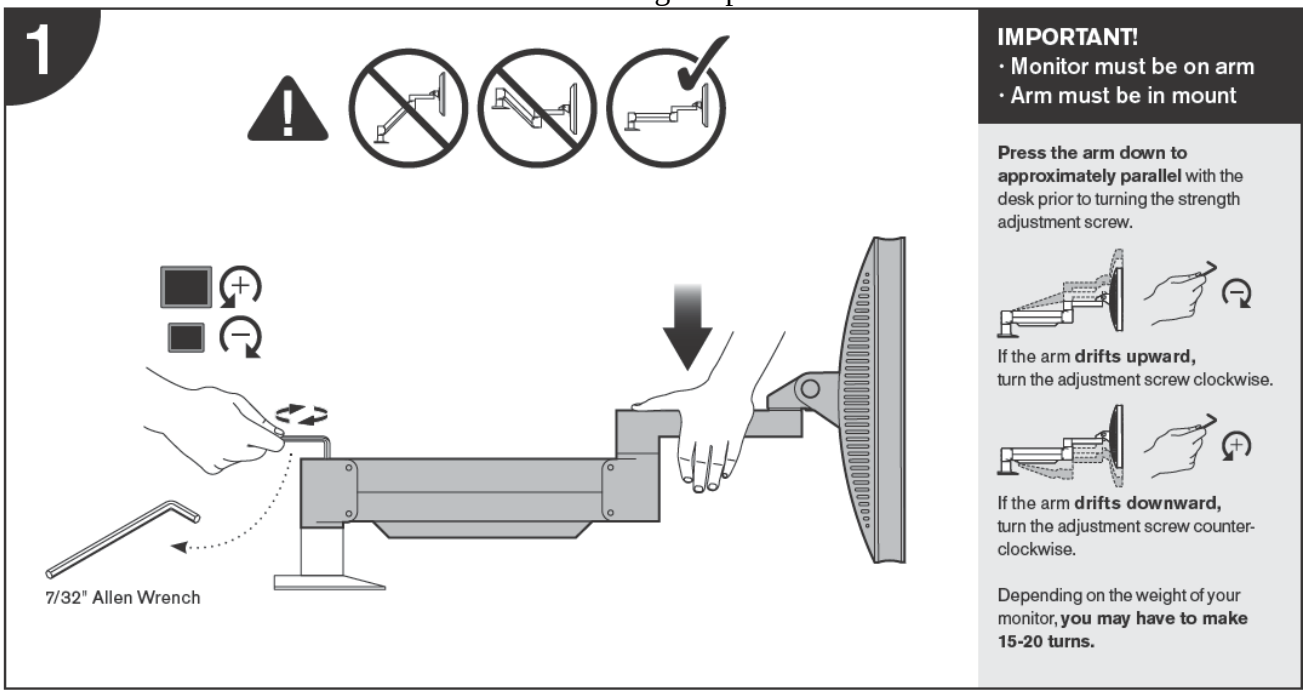
- **Storage Drawer**
  Accessory storage is conveniently located on the front of the cart, under the printer. Simply push down on the latch and pull. The latch will automatically re-engage when the drawer is closed.
- **Power Switch**
  The main power switch is located on the front of the cart, under the drawer. Make sure the computer has been properly shut down before turning off main power.
- **Cable Storage**
  An opening at the rear of the cart, at the bottom, is provided for power and network cables.
- **Casters**
  The cart has 4 locking casters. When the switch is up on each caster, the cart will move in any direction. The front casters lock completely (wheel brakes and directional lock) when the switch is down; use this position when performing studies (for ERGO IDC option, lock all four casters). The rear casters only lock directionally; they do not have wheel brakes. When transporting the cart, the front wheel switches should be up and the rear wheel switches should be down.
- **Rear Access Panel**
  This panel is found on the rear of the cart, near the top. Its main use is for service and maintenance functions. There are two latches holding the panel; both have to be disengaged simultaneously for the panel to be opened. Take care when removing as the whole panel comes off the cart. When replacing the panel, insert the bottom tabs first; the latches will re-engage automatically when the panel is closed.
- **Computer Access Panels**
  These panels are found on the Left (front of Computer Tower) and Right (rear of Computer Tower). Their main use is for service and maintenance functions. Take care during removal as the whole panel comes off of the cart. When replacing the panel, insert the bottom tabs first; the latch will re-engage automatically when the panel is closed.

Operation of the Monitor Arm (ERGO IDC option)

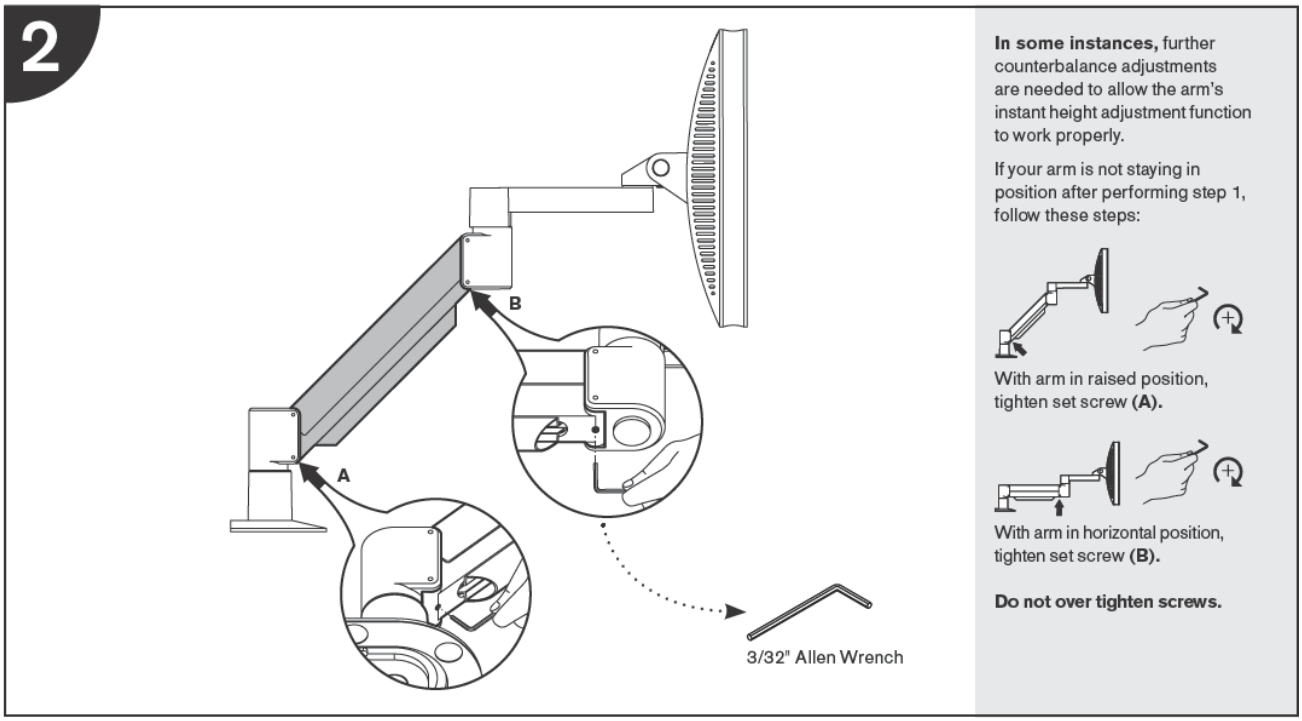
The MultiLab Series II LHS provides mobility of the monitor with its arm option. Benefiting from the fully ergonomic design, the arm has 31" of horizontal range and 18" of vertical range. It allows the monitor to tilt over 200 degrees. The arm rotates 360 degrees in three joints and can be easily folded in just 3"W x 10"H x 14"L of space for transportation or rest position. The operator can raise or lower the monitor, adjust the viewing angle or rotate the monitor. The state-of-art mechanical design also makes it durable, cleanable and recyclable.

Arm Alignment (if necessary)

Follow instructions below to counterbalance the arm using the provided 7/32" or 3/32" Allen Wrenches.

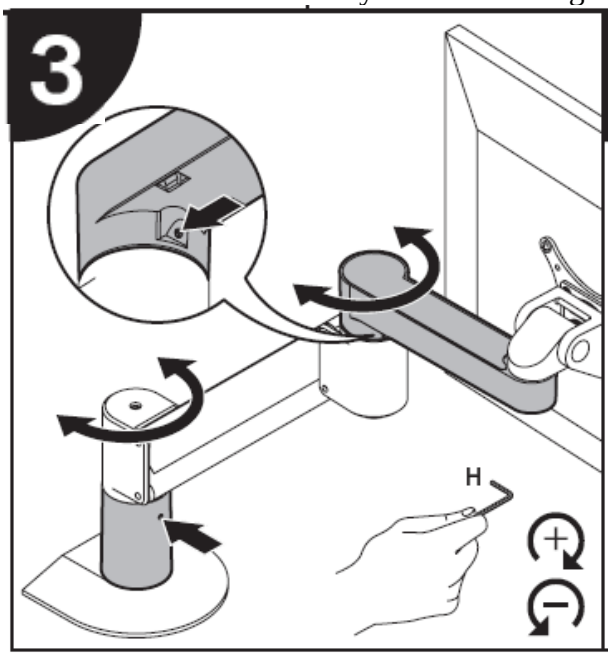


Counterbalance the Arm



Counterbalance the Arm

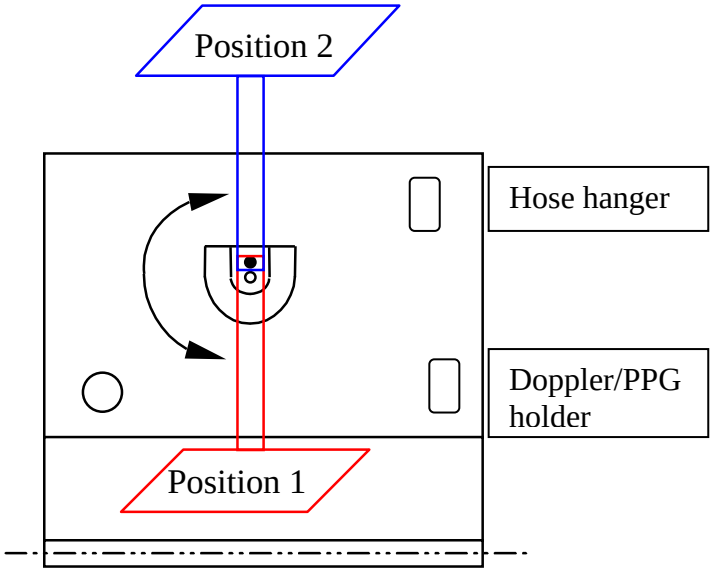
To align the arm rotation stability, adjust the arm as shown below using the provided 7/32" or 3/32" Allen Wrenches, so that the each section on the arm can move freely without drifting.



Arm rotation adjustment

Using the Arm

Your MultiLab Series II LHS will be set up so that the hose hanger and Doppler/PPG holder are located on the right side of the cart. The monitor arm is then free to move on the left half of the cart as shown. It can travel from Position 1 to Position 2 freely and stop at any position that you want in between (see below). The arm suspends the monitor weightlessly above the cart. It helps you to move the touch screen close and avoid glare on the monitor.



Top View

Since the MultiLab Series II LHS cart has four casters for its mobility, before you start your test you should lock all four casters (see previous section on LHS Cart Operation) to prevent the cart from moving while you are working with the arm. Move the caster switches down for the lock position.

The monitor arm operation is very straight forward. There are two handles on each side of the monitor for your convenience. To adjust the height, you can easily grab the handle and position the monitor up and down (see below).

Positions of the monitor

To adjust the viewing angle, you can tilt the monitor to the desired angle by holding the monitor with both handles. You can also rotate the monitor by moving the two handles and rotating the tilter.

Viewing angles

Cautions

For your safety and your patient's safety, the following instructions have to be followed during the study.

DO NOT tip the cart more than 5 degrees in any direction at any time.

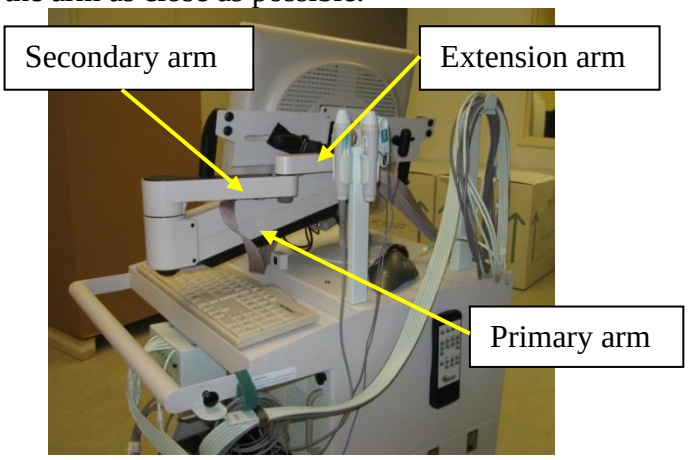
DO NOT hang foreign articles on the monitor arm. It might tip the cart.

Transportation position

Follow the steps listed below to move the MultiLab Series II LHS unit from one location to another:

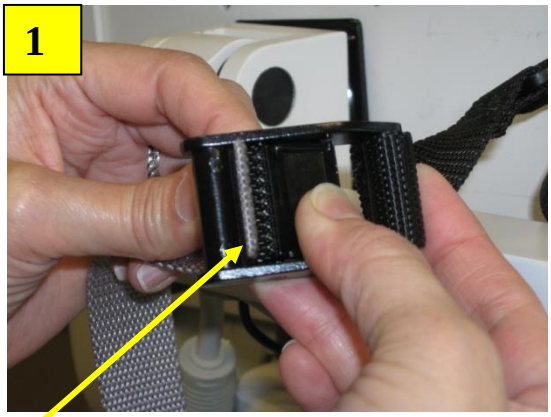
- Rotate the primary monitor arm counter-clockwise so that the primary arm is right in the middle of the cart front as shown below
- Adjust the position of the monitor so that the secondary arm and the extension arm rest right above the primary arm, aligning to it as shown.
- Rotate the monitor so that it stays to the left of the arm as close as possible.

Transportation position (left view)

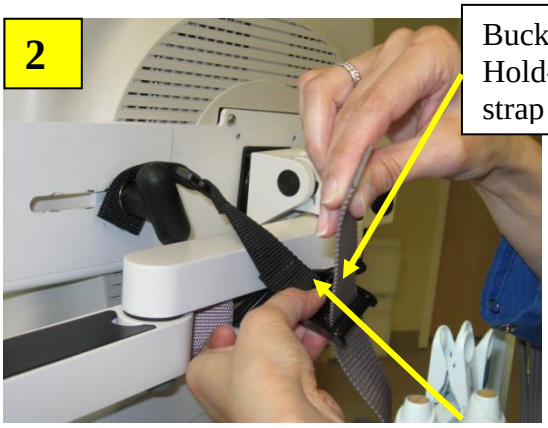


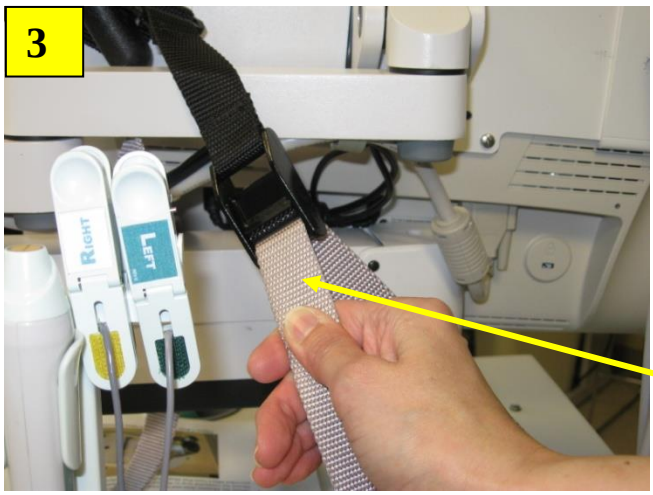
Transportation position (right view)

- Buckle the hold down strap and pull the free end tight by following the steps as shown below. This will secure the arm and prevent the monitor from moving.



Push the latch open with one hand and lead the strap through the gap using another hand.





Make sure the buckle is installed so that this latch can only be pushed inward.

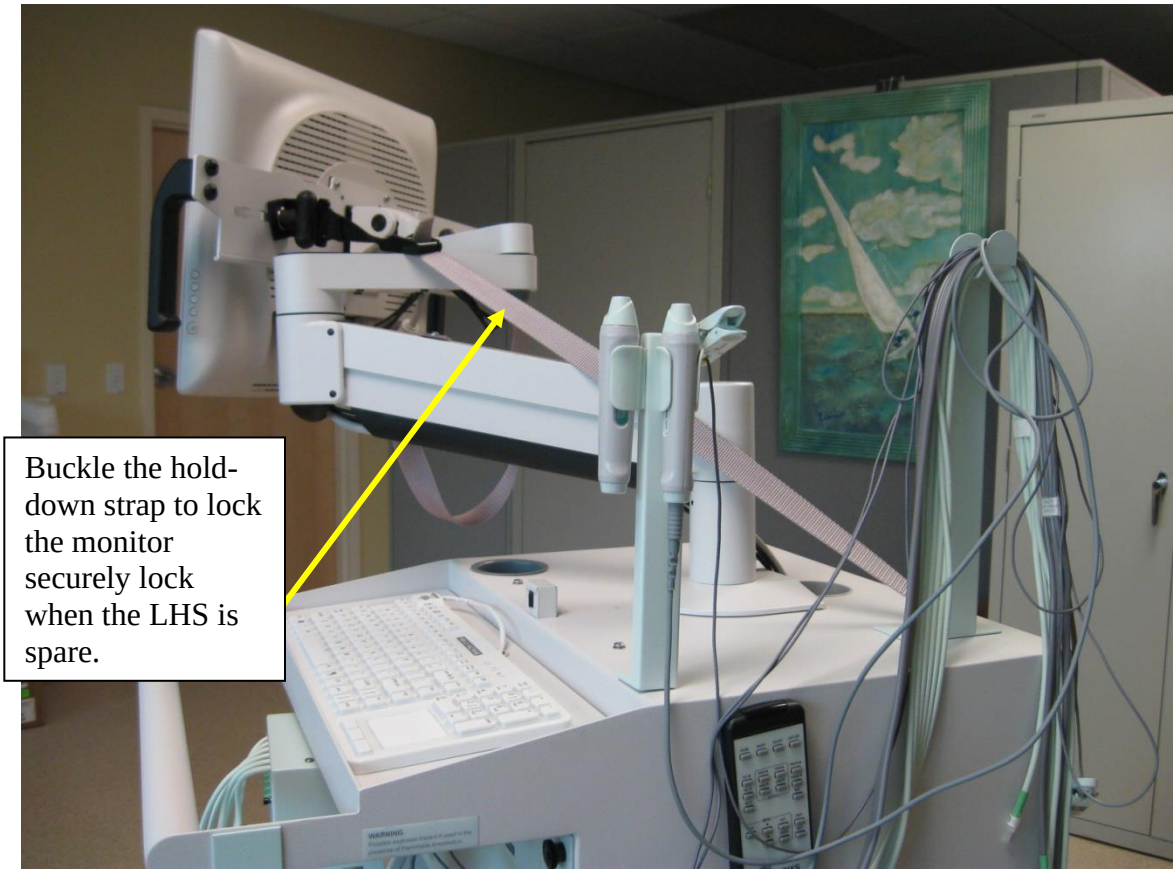
Pull the free end of the strap until the monitor is securely locked in place.

Transportation position: side view

- Unlock all four wheels.
- Push the handle to move the cart around. Watch out for bumps and obstacles.
- Cart should not be tipped more than 5 degree during transportation.
- At your destination, unbuckle the hold-down strap and lock all four wheels.

Rest/Safety position

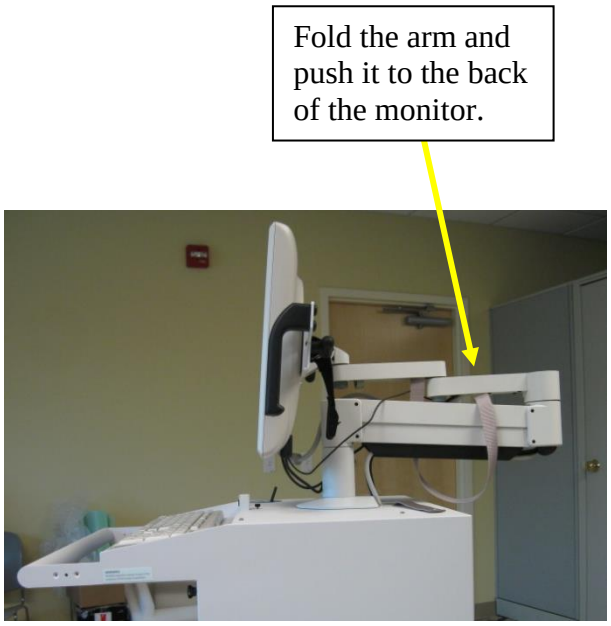
Another usage of the buckle and hold-down strap is to keep the monitor in a secured position when the unit is not in use. The hold-down strap can be easily tied with the buckle so that the monitor is locked securely to prevent any unexpected abrupt movement.



Keyboard position

While adding mobility to the monitor, the arm can still provide a center position for working on the collected data by pushing and folding the arm to the back of the monitor as shown below.

Front view



Side view

Keyboard position

Using the Medical Grade Keyboard (ERGO IDC, Roodra, 2CP)

The medical grade keyboard that is installed in Ergo, Roodra, and 2CP is a waterproof and contaminant resistant keyboard with an integrated three-button touchpad mouse. The touchpad is positioned on the right side of the keyboard under the same silicon rubber housing. The sealed rigid surface is durable and moisture resistant for easy cleaning. It is also quieter than most other keyboards and mice.

There are some specially designed keys on this keyboard for the user's convenience:

Locking key: Press and hold this key for three seconds to lock the keyboard and the touchpad. Press and hold the key for three seconds to unlock the keyboard and the touchpad.

Touchpad Locking key: Press and hold this key for three seconds to lock the touchpad. Press and hold the key for three seconds to unlock the touchpad.

Cleaning Reminder Key: To set cleaning reminder, press and hold the Left Ctrl key and press Cleaning Reminder key

- 1 time for every hour reminder,
- 2 times for every 2 hours reminder,
- 3 times for every 4 hours reminder,
- 4 times for every 8 hours reminder,
- 5 times for every 12 hours reminder,
- 6 times for every 24 hours reminder,
- 7 times for every 48 hours reminder, or
- 8 times for every 1 week reminder.

The C LED light (the LED to the left of the Num Lock LED) will blink when it is time to clean the keyboard. After the keyboard is cleaned, press the Cleaning Reminder key once to stop the blinking C LED and reset the timer to the last setting.

Backlight Key: Press this key
- 1 time for 30% brightness.
- 2 times for 60% brightness.
- 3 times for full brightness.
- 4 times to turn the backlight off.

Operation of the Roodra Cart (Standard Option)

- **Adjust Cart Height**
  A foot switch is located between the front wheels. Depress the foot switch to raise or lower the All-in-One Monitor, Keyboard Shelf, and Storage Drawer. At the lowest setting, the technologist can reach the touch screen from a seated position. When transporting or at rest, the Roodra should be in the lowest possible position.

- **Storage Drawer**
  Accessory storage is conveniently located on the front of the cart below vascular module shelf. Simply pull to open. There is no latch.
- **Electric Cord Management**
  The top of the keyboard shelf lifts up. Underneath one can visualize the power supply and power cords for the various electrical components of the Roodra. The lid of the electrical storage area can be locked with the supplied key.
  CAUTION – If the lock is utilized, do not misplace the key!
- **Pneumatic Hose Hanger**
  Drape the pneumatic hoses over the hangers found at the top of the Roodra tower.

- **Casters**
  The cart has 4 brake locking casters that rotate 360 degrees. The brake is engaged by depressing the textured edge of the caster as demonstrated in the figure below:

- **Roodra Module Power Switch**
  The power switch for the Roodra module is located on its back panel, next to the power cord. To turn on, simply move the switch to the "I" position. To turn off, move the switch to the "O" position.
  CAUTION – If relocating the Roodra to another room, be sure to turn off the Roodra module prior to unplugging the system.

- **All-in-One Computer and Monitor Power Switch**
  The power switch for the all-in-one computer and monitor can be found on the lower right corner of the front of the monitor. Touch momentarily to turn on. Press the Shutdown button from the software or use Windows™ Commands (Press Alt+F4 to open the Shut down Windows Dialog Box. Click the down arrow to choose Shut Down, touch OK)

- **All-in-One Computer and Monitor Batteries**
  If the supplied batteries are utilized in the all-in-one computer and monitor, the unit will stay on should Roodra lose power or be unplugged for relocation.
  CAUTION – Turn off the Roodra module prior to unplugging the system.

- **Network Cable Connection**
  Find the network connection port on the bottom of keyboard tray, facing downward.

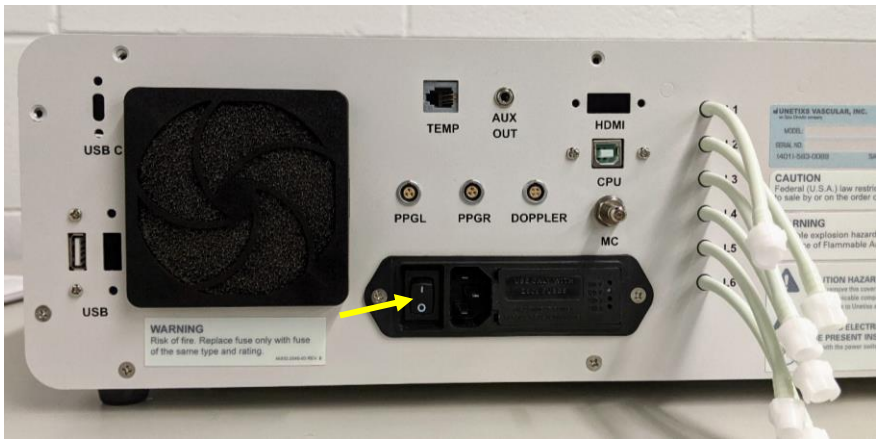
Operation of the Roodra Cart (ESA Option)

- **Transportation Position**
  Wrap AC power cord around rear handle.

Ensure all hoses and cables are off the floor to avoid damage and/or trip hazard.

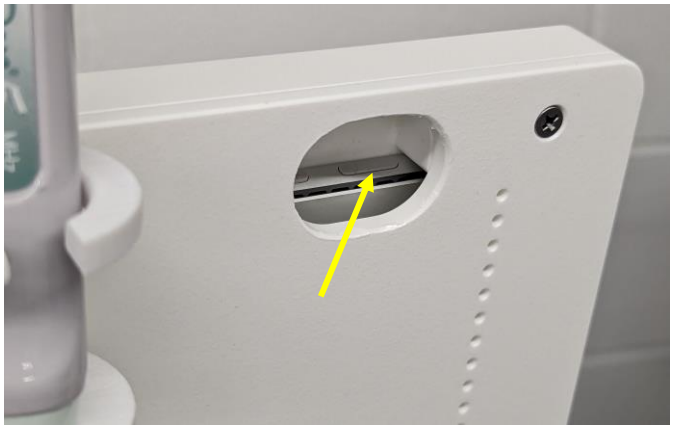
- **Casters**
  The cart has 4 brake locking casters that rotate 360 degrees. The brake is engaged by depressing the textured edge of the caster as demonstrated in the figure below:

- **Roodra Module Power Switch**
  The power switch for the Roodra module is located on its back panel, next to the power cord. To turn on, simply move the switch to the "I" position. To turn off, move the switch to the "O" position.
  CAUTION – If relocating the Roodra to another room, be sure to turn off the Roodra module prior to unplugging the system.

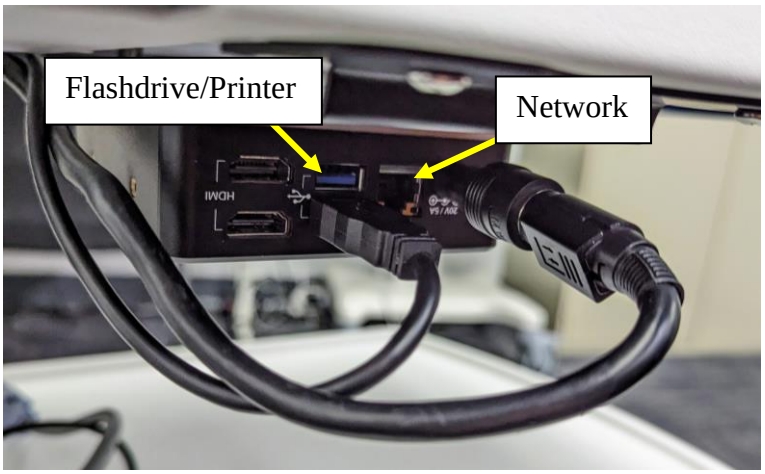


- **All-in-One Computer Power Switch**
  The power switch for the all-in-one computer can be found on the top right corner of the back of the monitor. Press to turn on. Press the Shutdown button from the software or use Windows™ Commands

(Press Alt+F4 to open the Shutdown Windows Dialog Box. Click the down arrow to choose Shut Down, touch OK)



- **Network & USB Connection**
  Find the network connection port and the USB port for flash drive or printer connection on the USB hub located under the storage drawer.

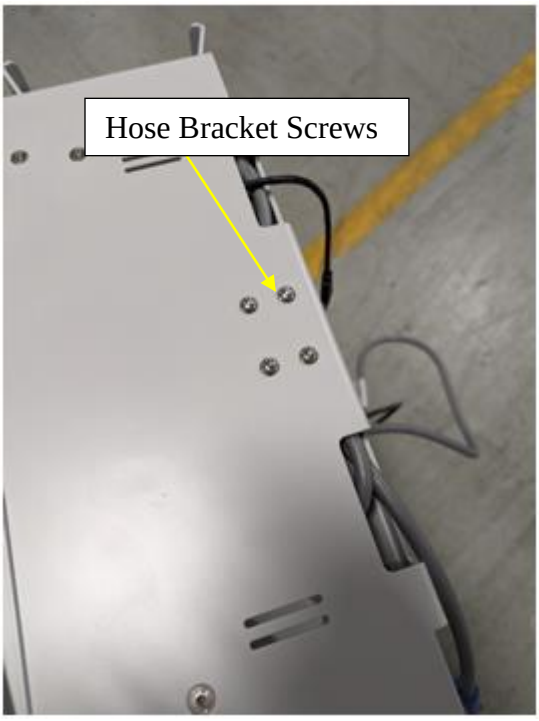


- **Storage Drawer**
  Accessory storage is conveniently located on the front of the cart below the keyboard shelf. Simply pull to open. There is no latch. The storage drawer can be locked with the supplied key.
  CAUTION – If the lock is utilized, do not misplace the key!

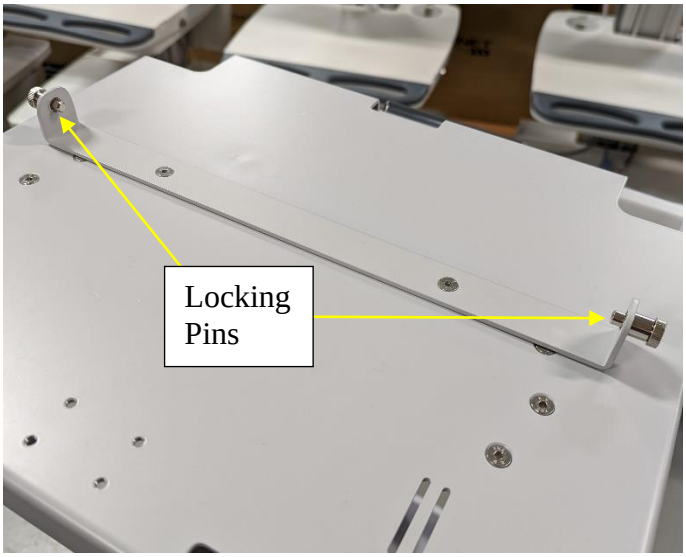
- **Printing**
  The cart must be plugged into AC Mains for printing to function. It is preferable if the cart and the printer are plugged into the same outlet. Remember to connect the USB cable from the printer into the port under the storage drawer (see USB Connection above).

Operation of the 2CP Cart

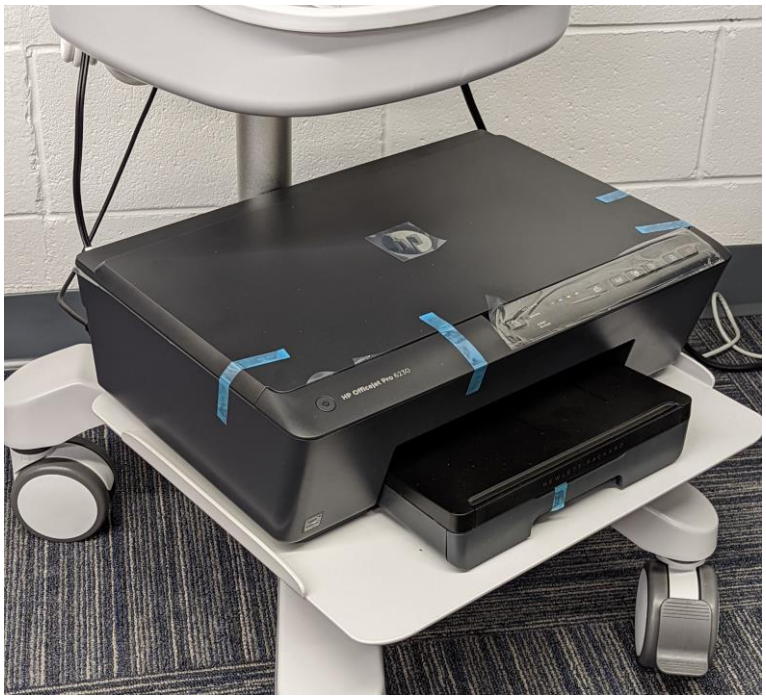
- **Assembly**
  1. Attach the hose bracket to the tabletop using the four M5 x 8 pan head screws that are attached to the tabletop already along with the Allen wrenches provided.



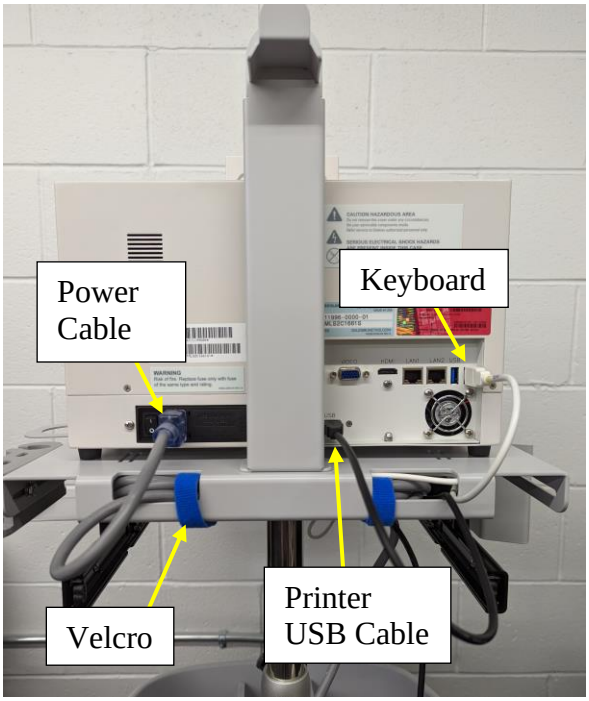
  2. On the 2CP mount located on the tabletop of the cart, there are two spring loaded locking pins. Pull the pins out and place the 2CP chassis into the bracket, letting the pins slide into the mounting holes on either side of the chassis to secure it in place.



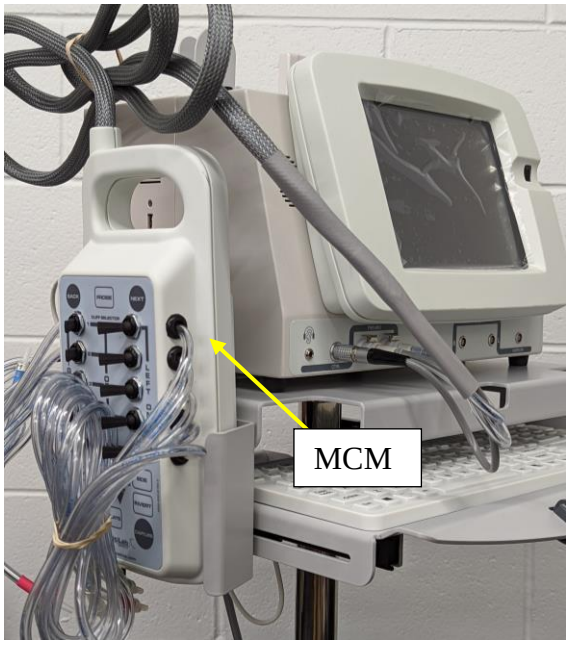
3. Place the printer on the printer shelf. Connect the printer power cable and USB printer cable to the printer. Connect the other end of the printer power cable to the power strip.

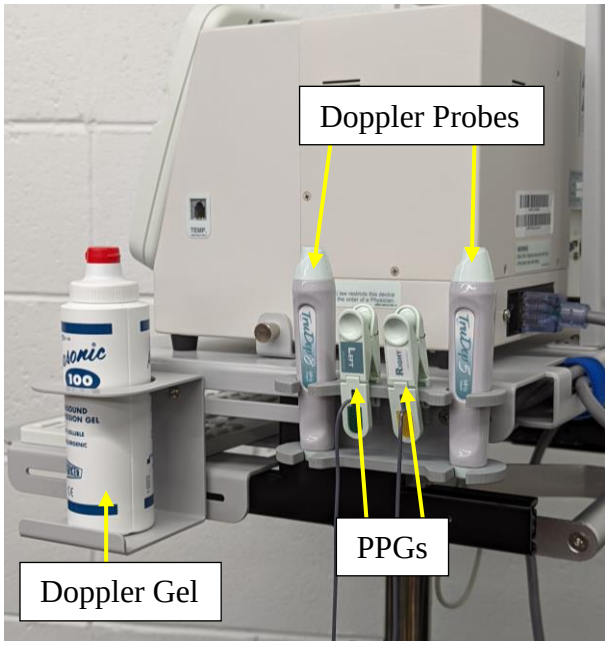


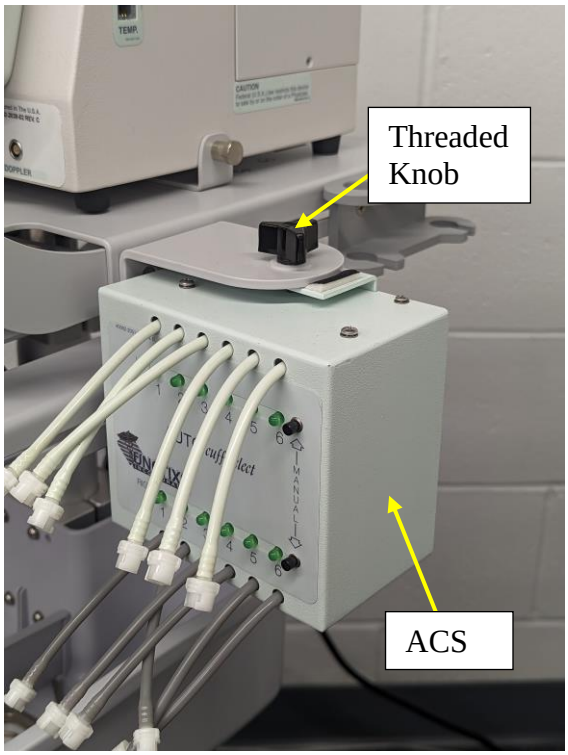
4. Pull out the keyboard tray as far as it will go. Place the keyboard on the keyboard tray and run its USB cable underneath the tabletop, through the back of the tabletop and connect to the back of the chassis. Bundle the excess keyboard USB cable within the Velcro straps underneath the tabletop and return keyboard tray to its closed position. Connect the power cable and USB printer cable to the 2CP chassis. Connect the other end of the power cable to the power strip.



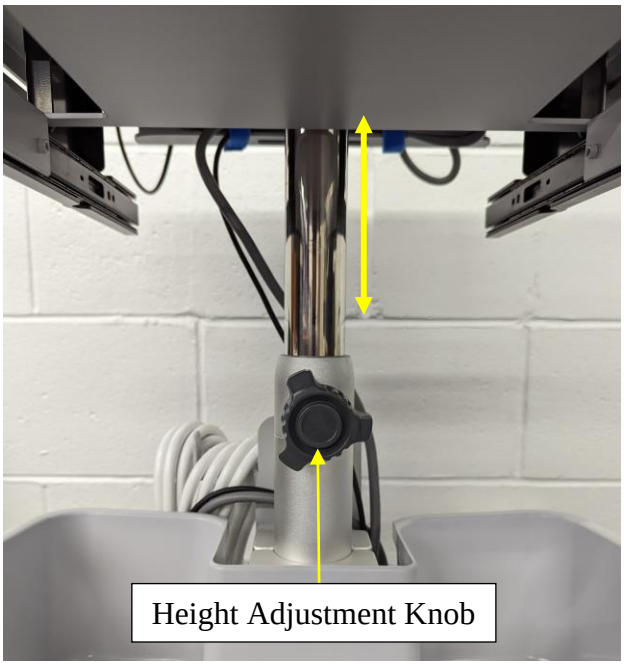
5. Attach the ACS, MCM, PPGs, Doppler probes, and doppler gel accessories to the cart as shown below. For the ACS, mount to the cart using the threaded knob of the ACS module and connect the ACS power cable to the rear DIN connector on the ACS.
   Note: Actual accessories will vary depending on your system.







- **Usage**
  - **Adjust Cart Height**
    To adjust the height of the cart, loosen the height adjustment knob on the pole. The gas assisted cylinder will allow you to raise or lower the tabletop. Once you have reached the desired height, tighten the knob to hold it in place.



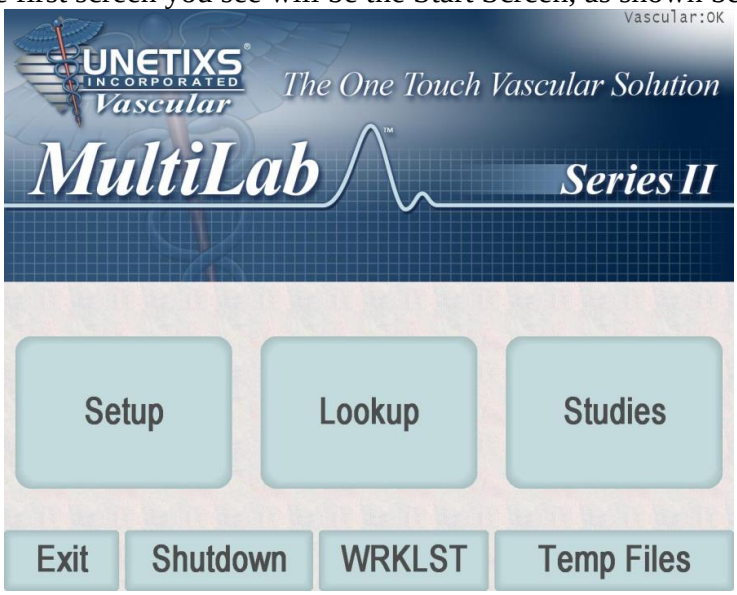
- **Casters**
  The cart has 4 casters that can rotate 360 degrees. The front two casters can be locked by depressing the brake.

- **Keyboard Tray**
  The keyboard tray can be pulled out for more convenient access to the keyboard. When the tray is pulled out all the way in an extended position, it will lock in place. To return to a closed position, pushing with a small amount of force will allow the tray to move again. It will lock in place again in the retracted position.

- **Transportation/Resting Position**
  When the cart is at rest or in transportation the height should be set to the lowest possible position, the keyboard tray should be locked in the closed position, the chassis should be secured in its mount, and there are no loose cables dangling. Also, when at rest the front casters should be in the locked position.

CHAPTER 2: START SCREEN FUNCTIONS

The MultiLab Series II is shipped ready to be used. Now that the system has been unpacked, assembled and plugged in, turn it on. On the MultiLab Series II-LHS, the power switch is located beneath the storage drawer in the bottom of the system cart. This switch will activate ALL electrical aspects of the MultiLab, including the printer. On the MultiLab Series II-P models, the power switch is located on the rear panel next to the power cord input. Once powered up, the first screen you see will be the Start Screen, as shown below:



Please note that the system can be controlled via the touch-sensitive video screen, the keyboard, or the remote control unit. The Start screen displays the following options:

SETUP Allows the user to go into the system to change factory presets, perform diagnosis and calibration of the system, configure custom exam protocols, etc.

LOOKUP Allows the user to access any patient studies archived on the Hard Disk Drive. **Note**: the name of this button is defined in the System Setup

STUDIES Allows the user access to the various vascular tests to be performed.

TEMP. FILES Allows user to access patient studies that have been performed, but not yet been archived to the Hard Disk Drive. (NOTE: if you suffer a power outage or interruption during patient testing, press this button after power resumes to access and resume the study in progress.)

WRKLST Activates DICOM worklist query. This requires our optional DICOM software. **Note**: the name of this button is defined in the System Setup.

SHUTDOWN Exits the MultiLab software and signals the Operating System to shut down.

EXIT Allows user to exit MultiLab Software.

The following are optional replacements to the exit button (see System Setup)

EXIT TO WINDOWS (For Windows™ Operating System) Allows user to exit MultiLab Software.

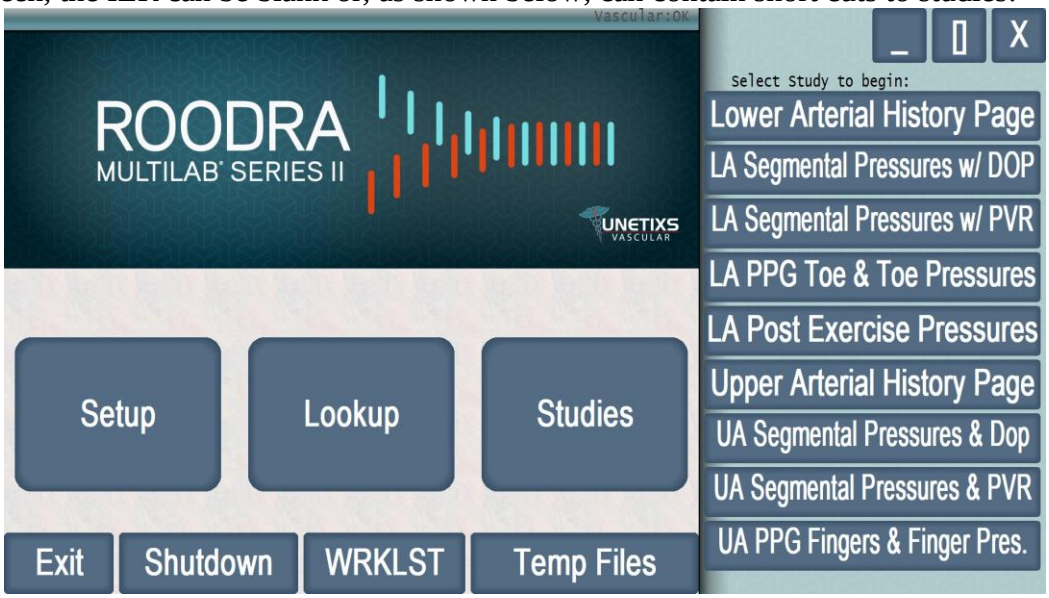
CONTRAST UP & DOWN (NOT functional on color screen models) Allows user to adjust visibility of the monochrome LCD screen to compensate for room lighting conditions.

Roodra Interactive Live Reporter (ILR)

Some MultiLab systems utilize a wide screen format, allowing more information and functionality on screen. Throughout the software on Roodra the left hand portion (⅔) of the screen will contain all MultiLab functions.

The right hand portion (⅓) of the screen contains the Interactive Live Reporter or ILR. Here we will discuss the start screen and the most common ILR buttons, other buttons will be discussed later in the manual.

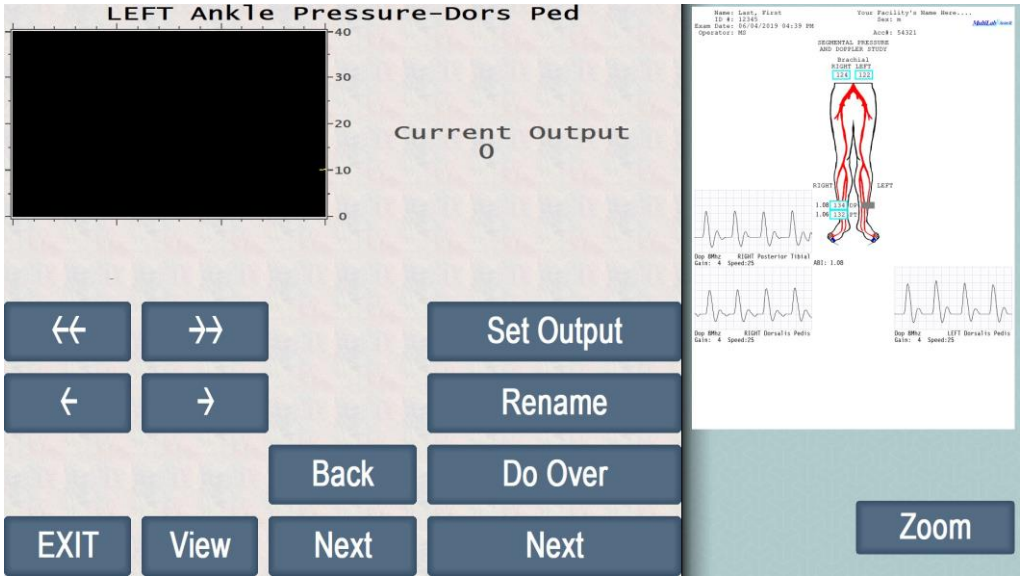
On the Start Screen, the ILR can be blank or, as shown below, can contain short cuts to studies:



The user may access all of the functions detailed above or go straight into a study. The buttons in the upper right corner will minimize the application (-), Restore the application (□), or Close the application (X).

ILR View

During an exam, the ILR can display the report as it is generated (see below); if the report is not shown, simply press the View button:



ILR Zoom

The ILR's Zoom button doubles the size of the report. The default zoom is to show the upper center of the report, where the pressures are shown, but simple press Zoom again to return to a full page view. When in the zoomed mode, you may change the focus by dragging, with the mouse or touch screen, on the report image itself; note that the focus will be remembered even if you change screens.

ILR Copy

When not performing an exam, the report can still be viewed. In these instances a Copy button will be provided instead of Zoom. The Copy button places a copy of the report onto the Windows™ clipboard (24-bit color, 2400x3150 pixels).

ILR Controls

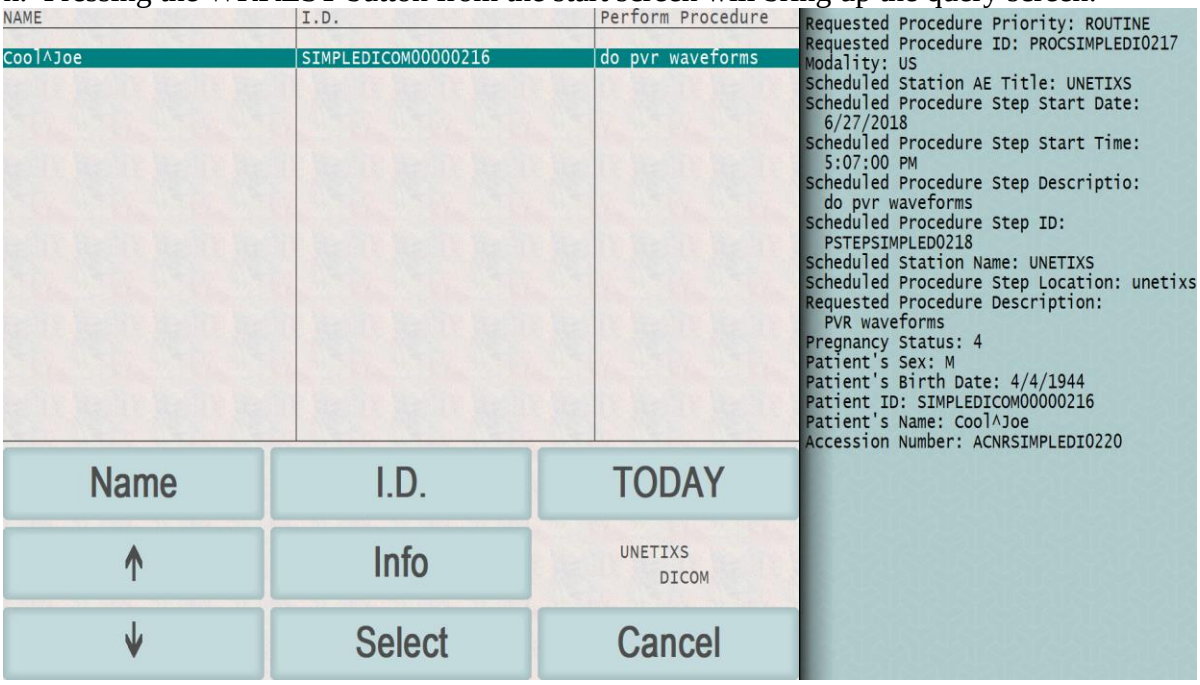
During an exam, for some modalities, the Controls button will allow for following parameters to be modified:

Speed: Adjusts the waveform sweep speed up ↑ or down ↓.
Inflate to: Adjusts the target inflation, for automatic inflation, up ↑ or down ↓.
Defl. rate: Adjusts the deflation rate, for automatic deflation, up ↑ (faster) or down ↓ (slower).

Note: Not that the parameters provided are dependent on the active modality for the exam.

Importing Patient Information (DICOM Worklist)

If you have the DICOM option on your system, you can use DICOM modality worklist to import patient information. Pressing the WRKLST button from the start screen will bring up the query screen:



The query buttons shown, for Name, ID, and TODAY, are configurable. To query for patient data, press one of the query buttons. **Note**: as shown above, one of the query buttons may be configured to happen automatically. Highlight the desired patient using the Up and Down Arrow buttons. Use the Info button if you need to see more information about the highlighted patient. Press Cancel to exit the query with no patient selected. Use the Select button to choose the highlighted patient.

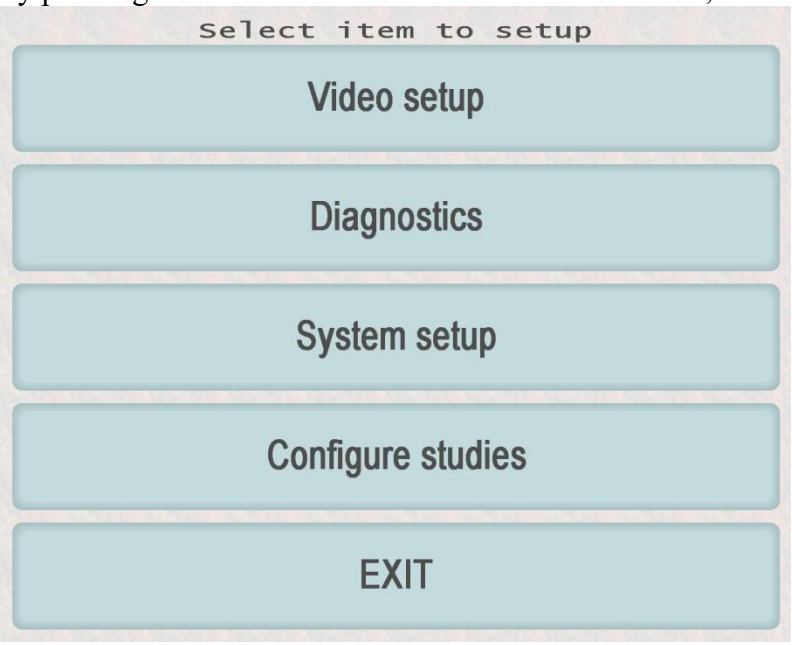
The selected patient will be shown on the start screen above the Lookup and Studies buttons. If you press Lookup, the selected patient will be searched for. If you press Studies, a study will be created using the information for the selected patient. To remove the selected patient, simply press the Temp. Files button followed by the Exit button.

Worklist ILR

The ILR will display the information for the highlighted patient, the same as the Info button. If the information does not fit on a single screen, a More button will be provided. Press the More button again to return to the initial information.

CHAPTER 3: SETUP FUNCTIONS

By pressing the "**SETUP**" button from the Start Screen, the following options become available:



CAUTION – There are areas within the SETUP menu which if accessed improperly, can decrease the performance of the instrument or cause it to stop working entirely. Only proceed in this portion of the program with factory assistance, or after thoroughly reading the operation of the functions listed below:

Note: There is no ILR function within Setup.

VIDEO SETUP	Allows user to calibrate the touch sensitive screen (will not normally need to be accessed).
DIAGNOSTICS	Allows user to access the Diagnostic and Calibration section of the instrument (do NOT access without consulting with Unetixs Service Technician)
SYSTEM SETUP	Allows user to access common system functions, such as changing date and time, data backup and printer utilities.
CONFIGURE STUDIES	Allows user to access the MultiLab custom study configuration editor to modify factory default studies or to create new unique studies.
EXIT	Returns user to the MultiLab Start Menu.

Video Setup

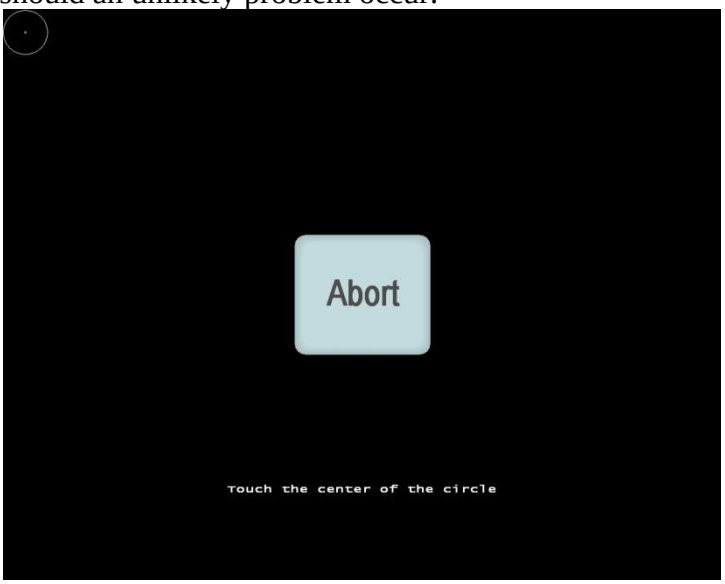
By pressing the "**VIDEO SETUP**" (or "V" key on the system keyboard) button on the touch-screen, the following options become available:

- Calibrate TOUCH
- EXIT

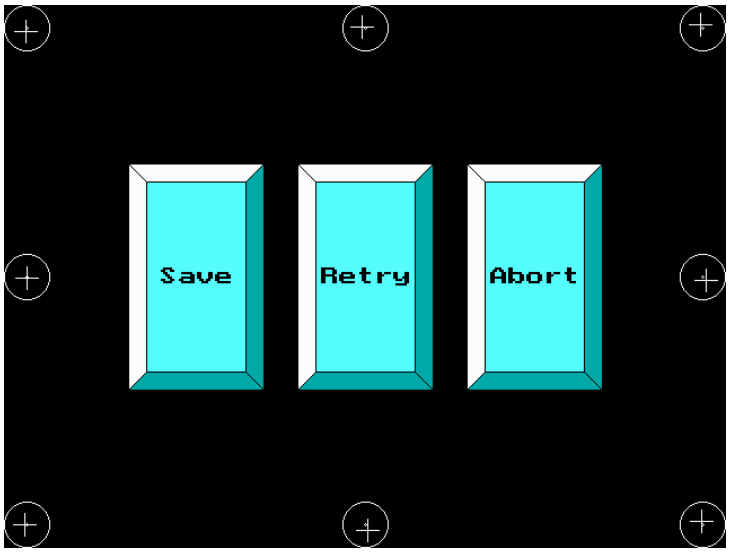
NOTE: If your system is functioning properly, do not re-calibrate the touch screen.

NOTE: Newer systems use a Windows™ touch driver to communicate with the touch screen. To calibrate these systems, exit the program from the start screen, and go to the control panel in Windows™. From there, select Touch screen and then press the Align button.

By pressing the "**Calibrate TOUCH**" button (or by pressing the "T" key on the system keyboard) the user can re-calibrate the touch screen should an unlikely problem occur:



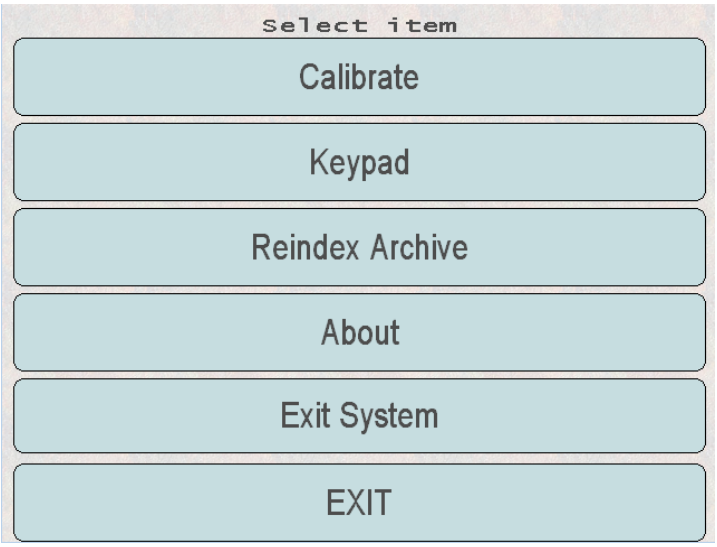
After pressing the Calibrate button you will see the above screen. Notice the circle in the upper left-hand corner. Touch it and another will appear. Keep touching the circles as they appear so the calibration of the touch capability will be complete. The following screen is a representation of all of the locations you will touch during this process.



If during this process you make a mistake you can select the retry button to retouch that location. You can also save your calibration when finished by pressing the save button (or "S" key on the system keyboard). If at any time you wish to quit this process press the Abort button. Once you press the save button you will return to the setup menu screen and then can continue with the setup of additional items in the system.

Diagnostics

If the **Diagnostics** option is selected from the **Setup** menu you will see the following screen.

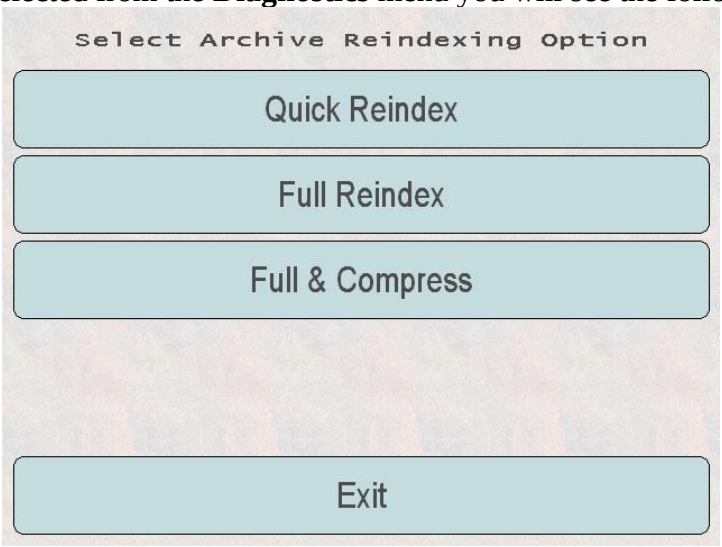


CAUTION: The "Calibrate" features on this screen should be used only while on the phone with a factory customer service representative. If for any reason you feel the unit is not functioning properly, first call the Unetixs Customer Service department before you enter this portion of the software program, as potential for misalignment of instrument is possible without proper supervision.

KEYPAD	Allows the user to test the remote control keypad (see chapter 7).
REINDEX ARCHIVE	Allows the user to check, rebuild, or compress the Archive database.
ABOUT	Shows the software version, company name, address, and phone number. Remote Help can be accessed here. Reply "Yes" when asked for permission. A password is not required; just touch Connect (only if asked by Unetixs service).
EXIT SYSTEM	Exits the MultiLab software (completely) and returns to the operating system.
EXIT	Returns to the setup functions screen.

Reindex Archive

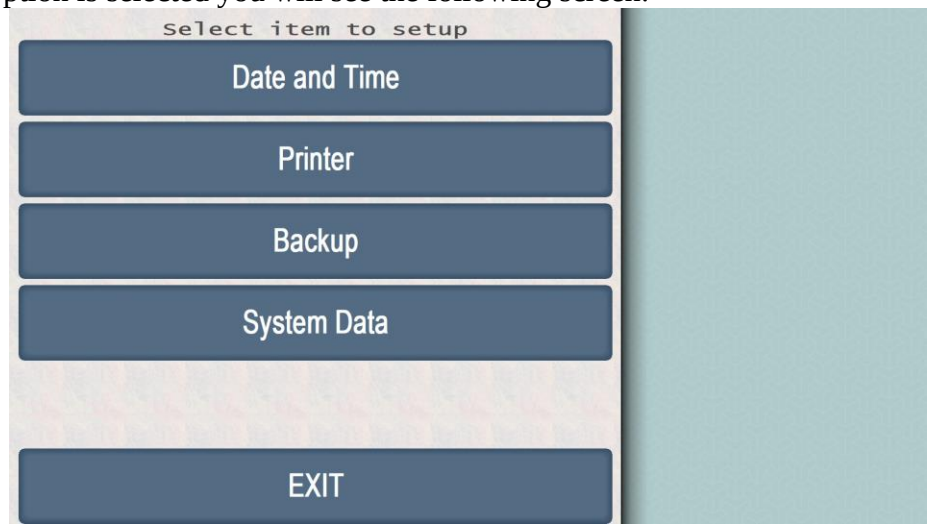
The archive is a collection of report pages where each page is a separate file in ascending order. A database is used to greatly increase the speed of all archive functions. A Maximum of 50000 pages can be stored. If the **Reindex Archive** option is selected from the **Diagnostics** menu you will see the following screen:



QUICK REINDEX	Checks all entries in the database and repairs only those that have a problem.
FULL REINDEX	Completely rebuild the database.
FULL & COMPRESS	Renumber the ascending files in the archive so that there are no gaps, and then completely rebuild the database.
EXIT	Returns to the Diagnostics Menu.

System Setup

If the system setup option is selected you will see the following screen:



DATE and TIME Allows the user to adjust the system for different time zones or to allow compensation for Daylight Savings Time changes.

PRINTER Allows user to access the printer troubleshooting utility.

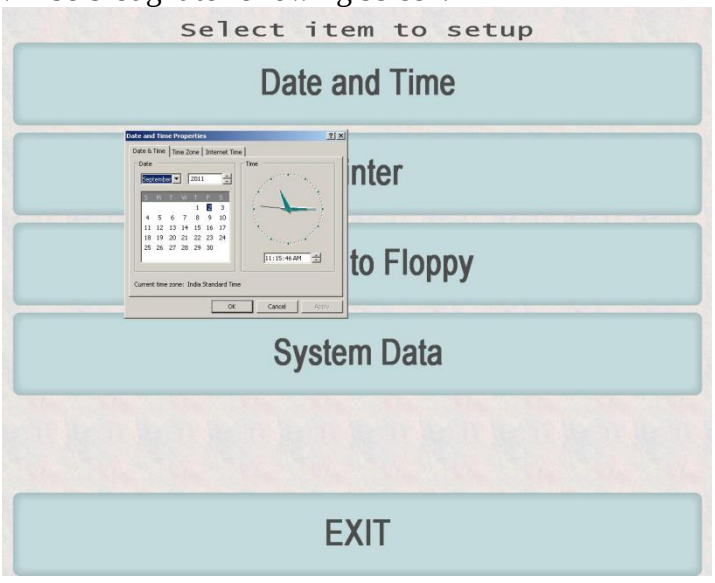
BACKUP Allows user to access the back-up utility to save patient files or custom studies to 3 ½″ floppy disks or USB Memory sticks.

SYSTEM DATA Allows user to access various internal hardware and software settings for the instrument.

EXIT Returns user to basic SETUP menu.

Changing Date and Time

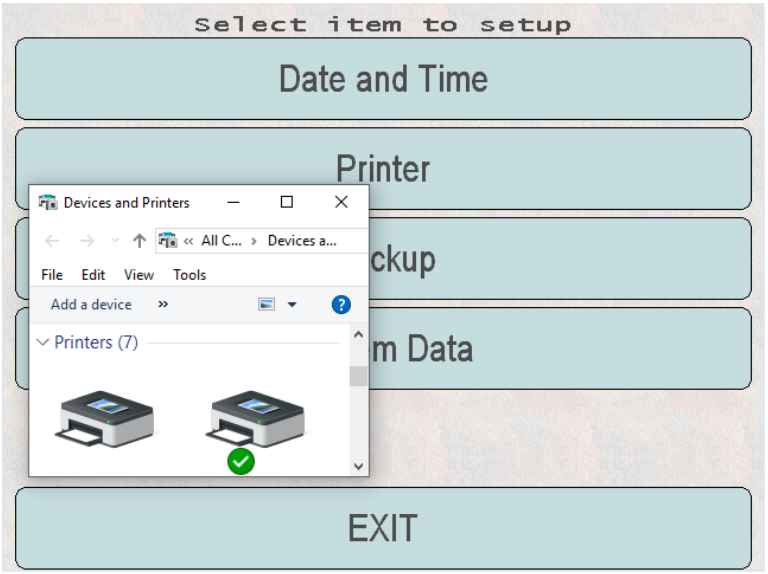
If you chose this option you will be brought to following screen:



Enter the date and time into the control panel, and then press 'OK'.

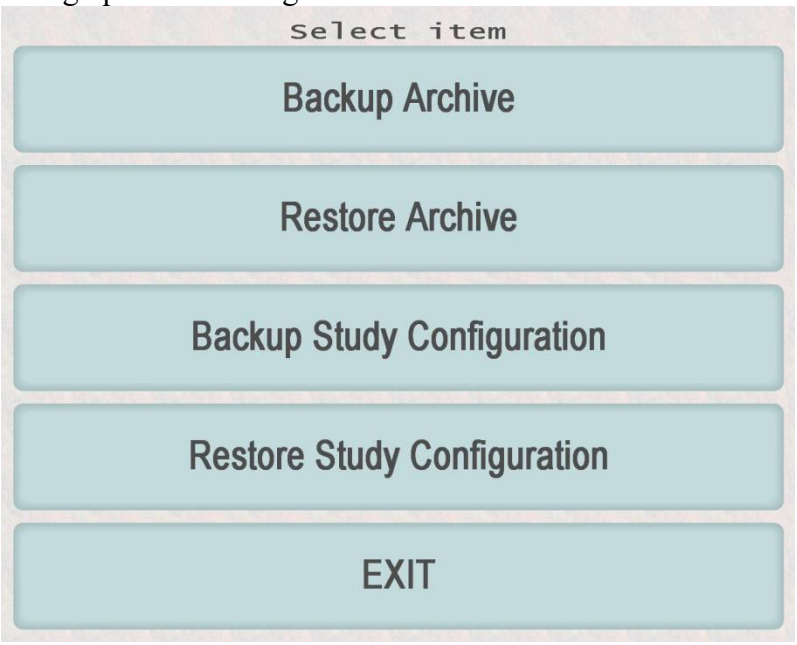
Printer Utility

NOTE: As Hewlett Packard™ frequently changes printer models and characteristics, the printer utilities are different as well. If your printer does not seem to be working properly, contact Unetixs Customer Service and identify the model of printer that came with your instrument.



Backing Up

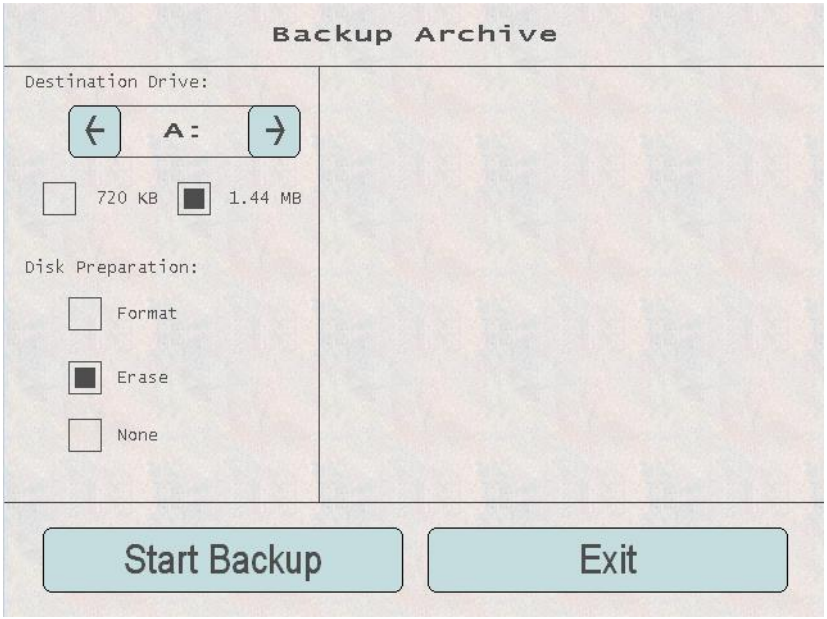
Touching "**Back UP**" will bring up the following screen:



BACKUP ARCHIVE	Backs up the archive of all your patient studies
RESTORE ARCHIVE	Restores previously backed up patient studies.
BACKUP STUDY CONFIGURATION	Backs up the studies you have custom configured.
RESTORE STUDY CONFIGURATION	Restores your backed up configurations.
EXIT	Exits this screen to the previous one.

Backing up Patient Studies

Touching 'Backup Archive', then 'Yes', will bring up the following screen:



To back up to floppy, set the destination drive to A or B, the size of the floppy, and then specify the disk preparation. If you have attached an external drive, such as a USB thumb drive, you may specify that drive's letter; no disk preparation is allowed for external drives. Press Start Backup to begin and follow any on-screen instructions.

When backing up to floppy, the filename on the floppy will be S2ARCBK.ZIP. When backing up to an external drive, the filename will start with UTX_0001.ZIP and count upwards from there.

Restoring Patient Studies

Touching 'Restore Archive', then 'Yes', will bring up the following screen:

Select the source drive and press Start Restore. Insert a disk into the source drive and press Continue. Press 'OK' on the reminder to reindex the archive when the restore is complete.

Overwrite Existing files are replaced by the files from the restore source.

Append Add the files from the restore source to the end of the Archive (files will be renamed).

Skip Existing archive file is kept and the restore source file is ignored.

Continue to follow the onscreen instructions until all source files are complete. For files on an external drive, each UTX_*xxxx*.ZIP file is considered to be a separate disk. Press Cancel and then Exit when all disks are complete.

Backup Study Configuration

Touch "Backup Study Configuration" on screen. Insert a blank Floppy Disk or USB memory device into the drive bay; the system will erase the floppy if it is not blank. Press the "Y" key on the keyboard when prompted if you wish to continue. NOTE: it is a very good idea to make a backup Study Configuration Disk after the instrument has been customized to your specifications. If you have 2 or more MultiLab instruments, you only need to custom configure your studies on one system, and using the Backup and Restore Study Configuration utility, enable all systems to run the exact same programs.

Newer windows systems can also back up to external drives. If no floppy disk is found, then the system will switch to backing up to the first compatible external drive found.

The software creates a file call S2STYBK.ZIP on the root of the destination drive.

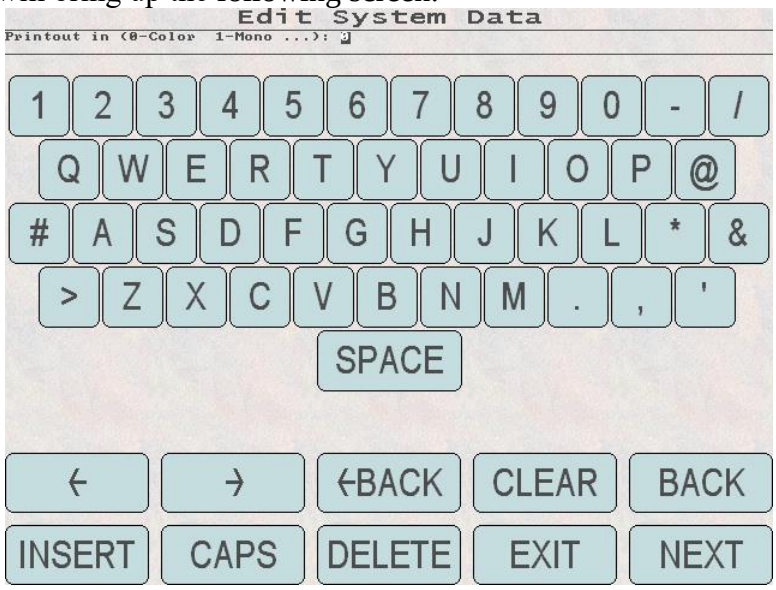
Restore Study Configuration

Press the "Restore Study Configuration" button on touch screen. Insert the desired Backup Study Configuration disk into the Floppy Disk Drive. Press the "Y" key on the keyboard when prompted to complete study restoration. Note: You may get a "file exists, do you want to overwrite it?" warning. Press "Yes" or "All" as a response.

Newer windows systems can also restore from removable USB drives. The floppy drive must be empty before the software will try to use an external drive. The software will use the first USB drive it finds.

System Data

Touching "**System Data**" will bring up the following screen:



Use the NEXT and BACK buttons to select an item. Use the EXIT button to return to the setup menu. The other buttons affect the currently selected item. The first item shown above affects the default output to the printer.

Pressing the NEXT button brings up the following item, which affects the output to the display when viewing reports:

Adding a value of two (+2) will change the default zoom when viewing reports.

CAUTION: Changing data from this point onward may result in decreased performance of the instrument, or failure to operate at all. Do not continue unless advised by Unetixs service personnel.

Pressing the NEXT button brings up the following item, which controls the printer:

This is the name of the printer to print to (**Note**: for network printers use the network URL instead). The software will print directly to older compatible DeskJet™ and LaserJet™ printers; to print to all other printers, place a '+' symbol as the first character as shown above. If no printer name is specified, as shown above, then the Windows™ default printer is used. A '-' character disables printing.

Pressing the NEXT button brings up the following item, which affects the screen when entering text data:

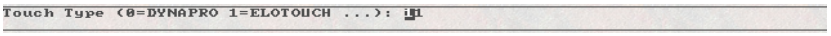
Pressing the NEXT button brings up the following item, which affects the CAPS LOCK keyboard option. This action is taken right before patient information is entered (name, id, etc…).

Pressing the NEXT button brings up the following item, which affects exit options on the Start Screen. The 'P' option shows contrast buttons for monochrome LCD displays, the 'CP' option shows nothing, the 'Exit' option shows just an exit button, the 'Windows' option shows an exit to windows button and the 'Shutdown' option shows both exit & shutdown.

Pressing the NEXT button brings up the following item, which inputs the hardware address of the RS232 touch.

Pressing the NEXT button brings up the following item, which inputs the interrupt address of the RS232 touch.

Pressing the NEXT button brings up the following item, which inputs the type of touch screen.



A value of 2 will open to a window instead of full screen, but the RS232 touch will be disabled. A value of 3 will start full screen but disable the R232 touch; this option will be used if a windows driver handles the touch screen. Adding four (+4) to the value will attempt to double the screen resolution, used by the software, to 1280 by 960 pixels (if the hardware is capable). Adding eight (+8) to the value will double the resolution but use as much vertical resolution as possible (usually up to 1280 by 1024 pixels). Adding twelve (+12) to the value will double the resolution, but use as much vertical resolution as possible while allowing the taskbar to remain visible (the taskbar must be arranged to be at the bottom of the desktop). Note: only one of the additive (+) options can be used.

Pressing the NEXT button brings up the following item, which inputs the type of digital I/O.

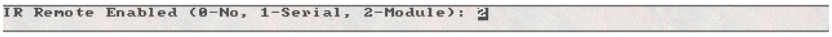
Pressing the NEXT button brings up the following item, which inputs the hardware address of digital output.

Pressing the NEXT button brings up the following item, which inputs the hardware address of digital input.

Pressing the NEXT button brings up the following item, which inputs the hardware address of the vascular.

Pressing the NEXT button brings up the following item, which inputs the interrupt address of the vascular.

Pressing the NEXT button brings up the following item, which enables the IR remote.



Pressing the NEXT button brings up the following item, which inputs the hardware address of the IR remote.

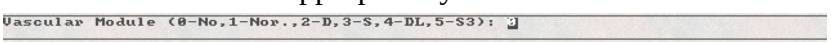
Pressing the NEXT button brings up the following item, which inputs the interrupt address of the IR remote.

Pressing the NEXT button brings up the following item, which enables the Automatic Cuff Selector (disabling the remote control cuff selector (see chapter 7). A value of 2 may be used if DIO is not needed.

Pressing the NEXT button brings up the following item, which sets the initial operating system command.

Pressing the NEXT button brings up the following item, which sets the operating system shutdown command.

Pressing the NEXT button brings up the following item, which sets the type of vascular. Check your module's serial number, if it ends in a letter then set this appropriately. **Note**: use 3 for Roodra.



Pressing the NEXT button brings up the following item, which sets the vascular supports for spectral Doppler.

Pressing the NEXT button brings up the following item, which activates the spectral probe's mute switch.

Pressing the NEXT button brings up the following item, which sets the button color (0-normal, 1-Blue).

Pressing the NEXT button brings up the following item, which sets the main archive location. If you wish to disable the archive, just make the first character a '\' (as in \C:\ARCHIVE\).

Pressing the NEXT button brings up the following item, which sets the file extension of the main archive.

Pressing the NEXT button brings up the following item, which sets the secondary archive location.

Pressing the NEXT button brings up the following item, which sets the file extension of the secondary archive.

Pressing the NEXT button brings up the following item, which sets the text of the export button (6 char. max).

Pressing the NEXT button brings up the following item, which sets the first export control program.

Pressing the NEXT button brings up the following item, which sets the first path to export to.

Pressing the NEXT button brings up the following item, which sets options for the first export.

Pressing the NEXT button brings up the following item, which sets the name for the first export.

Pressing the NEXT button brings up the following item, which sets the second export control program.

Pressing the NEXT button brings up the following item, which sets the second path to export to.

Pressing the NEXT button brings up the following item, which sets options for the second export.

Pressing the NEXT button brings up the following item, which sets the name for the second export.

Pressing the NEXT button brings up the following item, which sets the import control program.

Pressing the NEXT button brings up the following item, which sets the import destination path.

Pressing the NEXT button brings up the following item, which sets options for the import.

Pressing the NEXT button brings up the following item, which sets the text of the import button (6 char. max).

Pressing the NEXT button brings up the following item, which sets the title of the third import field (after name and I.D.).

Pressing the NEXT button brings up the following item, which sets the type of waveform scroll.

Pressing the NEXT button brings up the following item, which sets the new study button's text (10 char. max).

Pressing the NEXT button brings up the following item, which sets the lookup button's text (10 char. max)

Pressing the NEXT button brings up the following item, which sets the delay before manual inflation.

Pressing the NEXT button brings up the following item, which sets the delay before manual deflation.

Pressing the NEXT button brings up the following item, which inputs the right blood pressure offset.

Pressing the NEXT button brings up the following item, which inputs the right blood pressure span.

Pressing the NEXT button brings up the following item, which inputs the left blood pressure offset.

Pressing the NEXT button brings up the following item, which inputs the left blood pressure span.

Configure Studies

Due to the highly technical nature of study configuration, newer versions of the software have password protected this option. Contact Unetixs customer support if you feel you need to access this feature. This should only be performed by trained personnel.

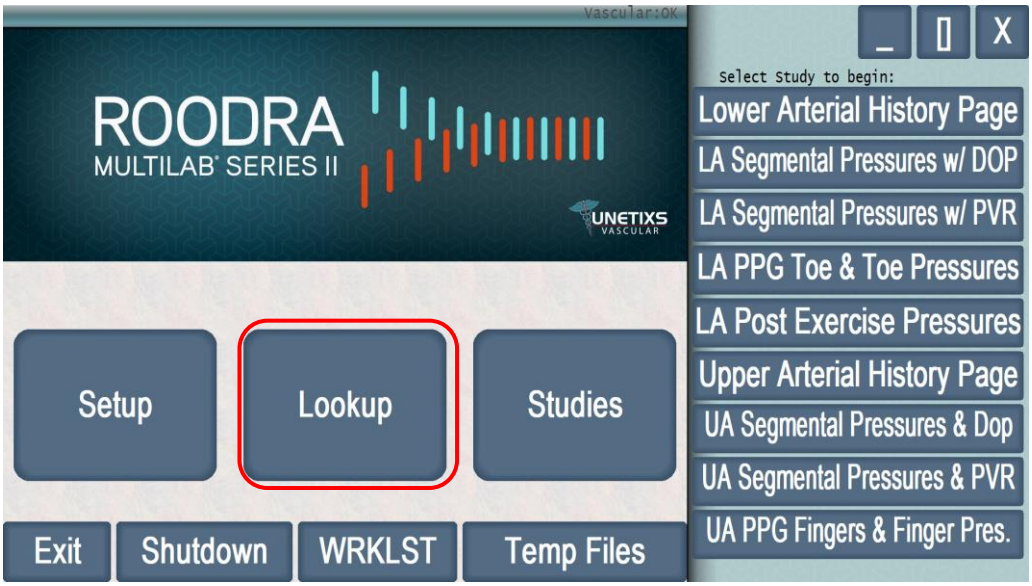
Since there are so many variables in the types of vascular studies that are performed, the order in which they are performed, and a multitude of personal preferences in the field of Physiologic Vascular Testing, the MultiLab Series II instruments have been designed to give unparalleled flexibility in customizing the MultiLab to each facility or even to each individual within the facility. See CHAPTER 11: CONFIGURING STUDIES.

Some of the more popular items that can be customized are: Inflation targets, which can be preset for each site (e.g. the Ankle site can be preset to inflate to 150 mmHg, while the calf can be set for 160 mmHg, Thigh – 175 etc. Deflation Rate – there are 40 different bleed rates for the pressure cuffs, adjustable in 1/8th mm per second intervals. Sequencing order, some prefer to do waveforms first, and then finish with Segmental Pressures. Others prefer the opposite. Some like to start at the thigh and work down the leg, others like to start at the ankle and move up. Wherever you like to start, and whatever order you like to proceed, the MultiLab can be configured exactly to your liking, even down to how you like your finished printed report to look.

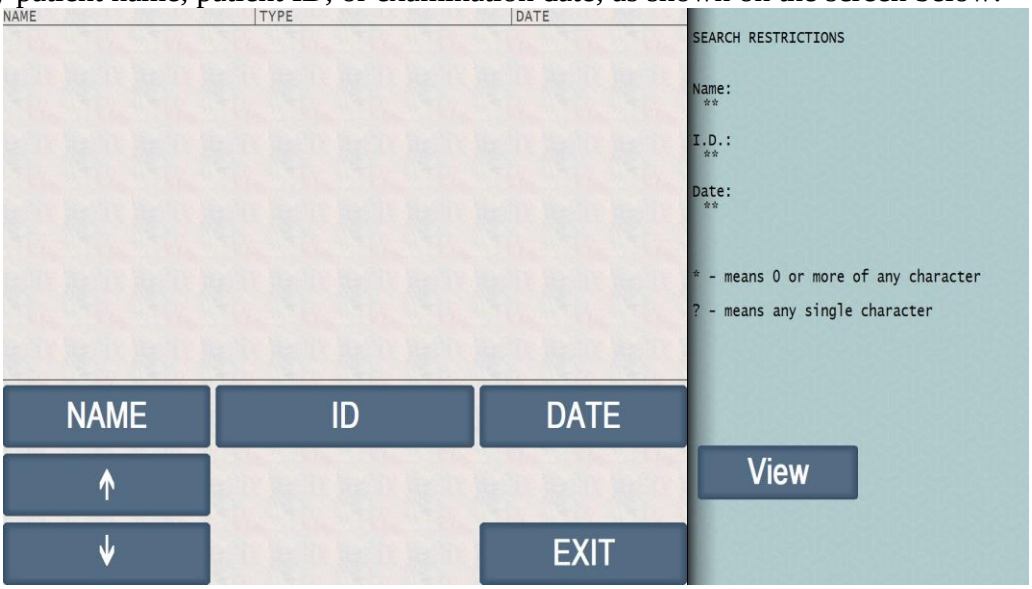
Since there are so many variables that can be modified, Configuring Studies merits a separate chapter of its own. Don't let the number of choices worry you, however, the MultiLab instruments come pre-loaded with a number of commonly performed standard vascular procedures.

The configuration utility does work with a touchscreen or mouse. On some screens an on-screen keyboard will be automatically displayed, but on others you must activate the onscreen keyboard by clicking the '▒' in the upper right hand corner. If keyboard help exists, at the bottom of a screen, those fields can be clicked on directly to perform those functions. Text fields can be directly clicked into. Number fields can be changed by dragging left (-1), right (+1), up (+10), or down (-10). Selection fields can be changed by dragging left or right.

CHAPTER 4: LOOKUP FUNCTIONS



The Lookup Function allows you to access patient reports that have been archived to the MultiLab hard disk drive. These files can be accessed at any time by pressing the "**Lookup**" button from the Start screen. You may get the error message "database missing: reindex for speed"; either continue as normal, or from the Start screen press setup, then diagnostics, then reindex archive, then finally full & compress. You can then look up archived patient reports by patient name, patient ID, or examination date; as shown on the screen below:



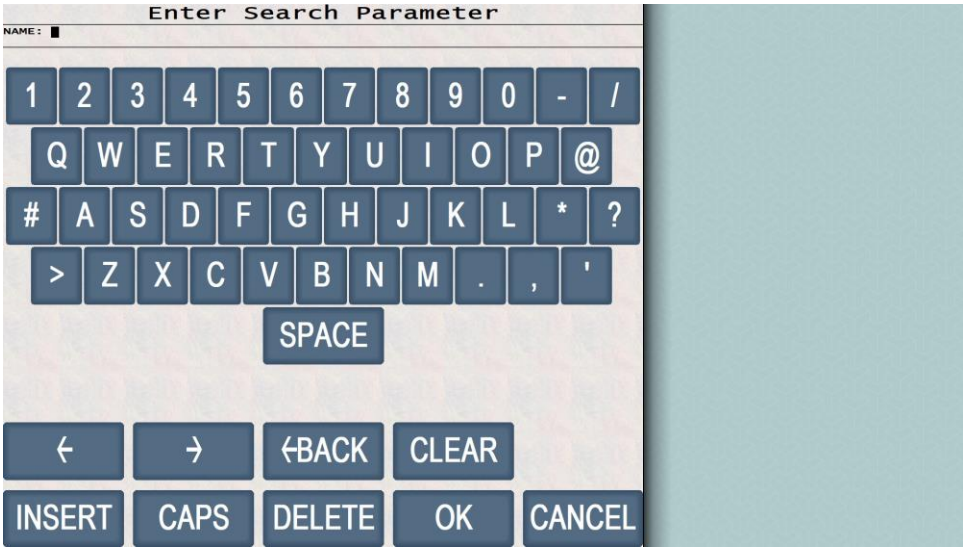
Lookup ILR

For the Lookup screen, the ILR can show the search restrictions entered. This is important since each search uses all three parameters, name, ID, and date, as restrictions to the patients found in the lookup. To view a highlighted patient report, simply press the View button and the ILR will display the report instead. To return from the report view, simply press the Clear button.

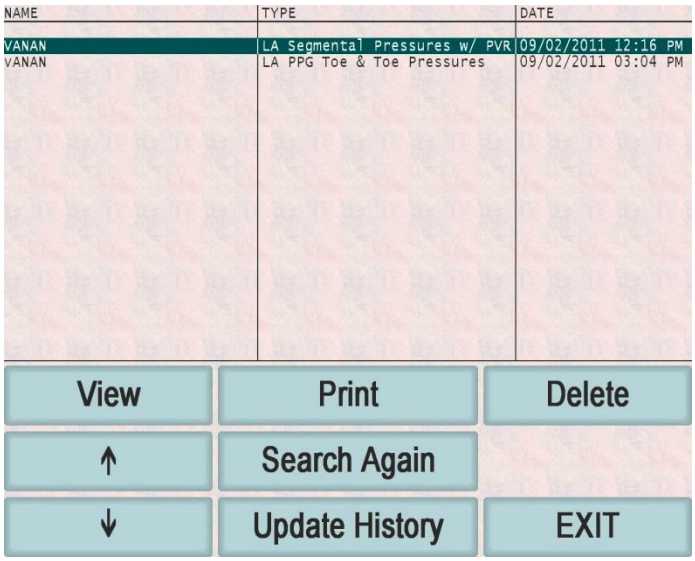
Lookup Example

For example, pressing the "**NAME**" button from the previous screen will prompt you to type in the patient name, as shown below. You can use the keyboard or the onscreen touch keyboard to enter this information. If you press the ENTER key on your keyboard or the "OK" button on the touch screen without entering in any name information, the MultiLab will display the first 100 archived patient reports.

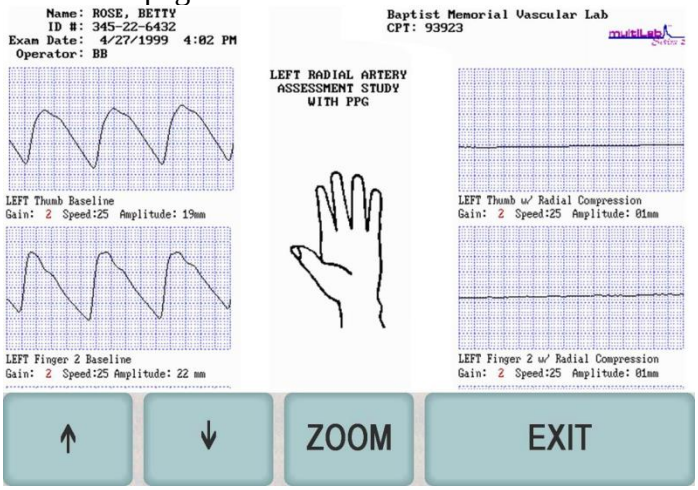
It is not necessary to enter the full patient name. For example, to search for "Washington" simply type "wash" or "ingt" and the MultiLab will display any patient records that have those four letters in that order.



Once the patient's names are displayed (as shown below) you can select a patient by using the up or down arrow keys to highlight the desired patient report. You can then view, print, or delete the patient's report by pressing the appropriate button.

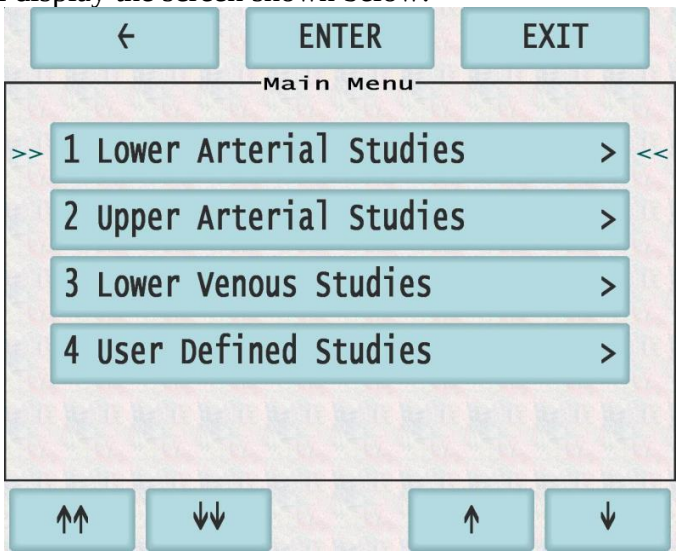


Below is an example of what will appear when you press the view button on the MultiLab screen. You can use the up or down arrows to view the entire page.



CHAPTER 5: STUDIES FUNCTION

The Patient Studies that can be performed by the MultiLab can be accessed by pressing the "**Studies**" button from the Start screen. This will display the screen shown below:



Note: the above screen is an example of the Factory Default main menu and can be modified in any desired fashion using the Study Configurator. The "Main Menu" shown above contains four sub-menus which in turn contain various studies. It is sometimes desirable to put your most common studies onto the "Main Menu" to reduce screen touches to access your patient exams.

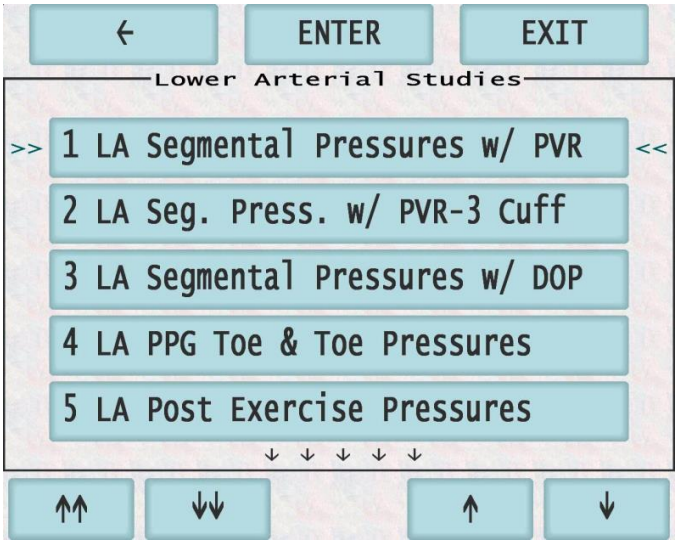
←	This will take you to the previous screen.
ENTER	This will take you into the study or sub-menu bracketed by the ">> <<" symbols.
EXIT	This will take you back to the Start screen.
↓↓	This will display studies or sub-menus 6 and higher (if any).
↑↑	This will display studies or sub-menus one page up (if applicable).
↓	This will move the selector brackets (>> <<) down.
↑	This will move the selector brackets (>> <<) up.
1, 2, 3, 4 or 5	These will take you into the study or sub-menu according to the number touched.

Studies ILR

For Studies function, the ILR will show the list of measurements for the selected study. There are no buttons.

Studies Example

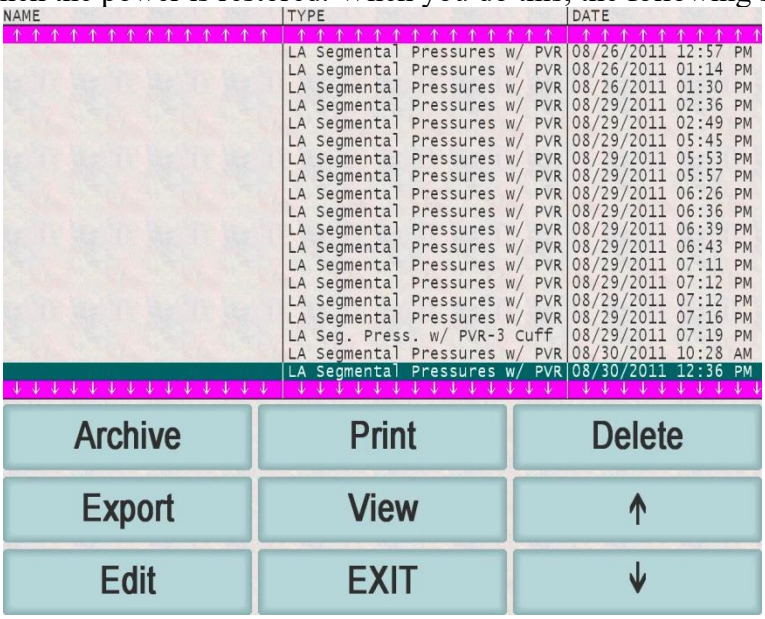
Pressing the "**Enter**" or "**1 Lower Arterial Studies**" from the above screen will bring up the Factory Default Lower Arterial Studies menu shown below:



Note: Any unwanted studies can be deleted and will not be displayed (see Configure Studies).

CHAPTER 6: TEMP. FILE'S FUNCTIONS

Pressing the "**Temp Files**" button from the Start screen will allow you to access patient reports that have not been archived to the MultiLab hard disk drive. For example, if the power should go out in the middle of a study press the "**Temp Files**" button when the power is restored. When you do this, the following screen will appear:



The most recent patient will be at the top. The following functions are available from the Temp. Files menu:

Archive Will save the patient report to the MultiLab hard disk drive. (See Archive Patient Reports in Chapter 10)

Print Will print the patient report. (See Printing Patient Reports in Chapter 10)

Delete Will delete the highlighted patient report. You will be given the opportunity to change your mind by touching "**No**" when prompted by the MultiLab "are you sure?" question.

Export Will export the patient report. (See Exporting Patient Reports in Chapter 10)

View Will allow you to view the patient report on the MultiLab screen.

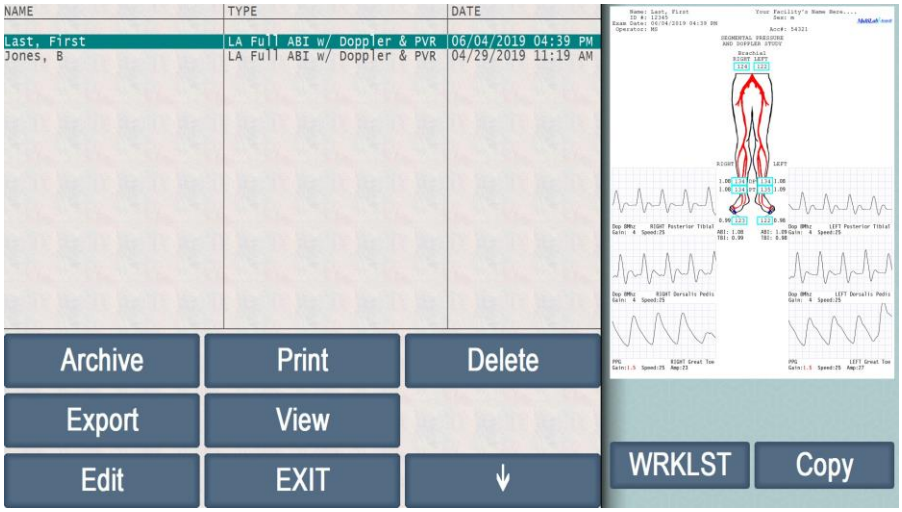
Edit Will allow you to go into, resume, or make changes to the highlighted patient report. (See Chapter 10: Editing Patient Reports)

Exit Will exit to the Start screen.

↑ This will allow you to move the highlight cursor up.

↓ This will allow you to move the highlight cursor down.

ILR Temp File Functions



When Temp File is opened the ILR will display the first study in Temp Files; which is the most recent study performed. As other studies are highlighted, the displayed report will change.

WRKLST Will allow user to see the worklist information for the selected study, if it exists. **Note**: the name of this button is defined in the System Setup.

More Will display more of the worklist. Keep pressing the button to return to the beginning of the worklist information.

View This is the default function. Will show the patient report for the select study

Copy Will copy a picture of the report to the Windows™ clipboard.

View ILR

If the View button is pressed, the ILR changes to show the patient's name and their file information on the system. The file information can be useful if you are viewing from the lookup and want to extract a particular patient's file. Also, a View button is available on the ILR. This View button will show the report for the patient which is the same report already being viewed, but the ILR may also have left and right arrow keys which can change the ILR's report view to other pages of the patient's study. From the report view, press the Info button to return to the file information.

CHAPTER 7: MULTILAB REMOTE CONTROLS

The MultiLab instruments will ship with either one or both of two devices for controlling the instrument remotely. They are the Remote Control Cuff Selector and the Wireless Remote Control.

The Remote Control Cuff Selector

The remote-control cuff selector manifold is used to hook up all the pressure cuffs at one time, and also allows remote control of the MultiLab Instrument. The cuff selector is best positioned between the patient's feet for most examinations. Upon inspection, you will notice 5 hoses exiting the cuff selector on each side. The #1 hose is longer than the remaining 4. Typically in a Lower Arterial study using the 4-cuff method, the #1 hose is attached to the arm cuff, the #5 hose to the ankle cuff, the # 4 hose to the calf cuff, etc…

If you desire to obtain toe pressures, or transmetatarsal PVR waveforms, feel free to attach the #1 hose to those cuffs after the Arm pressures have been obtained. The 10 toggle switches on the selector direct the flow of air to the desired cuff. When the switches are in the center position, all air valves will be closed, and no air will be directed to the cuffs. Make sure that only one switch is open at a time, unless performing certain bilateral studies (such as PVR) that record left and right channels at the same time.

The remote controls are self-descriptive in most cases with a few exceptions. When a waveform or pressure reading is "Captured" the "Baseline" and the "Gain" keys become scrolling keys. To scroll a captured waveform or pressure, "Gain" is for fast scrolling, "Baseline" will scroll slowly.

Other Remote Control Functions (with exception of above paragraph) are:

BACK	This will take the user to previous screen or backward 1 site.
NEXT	This will take user to next screen or forward 1 site.
PROBE	Allows user to activate and change probes during Pressure studies.
VOLUME	One touch will adjust volume by 1 step; pressing and holding will be continuous.
GAIN	One touch will increase or decrease Gain by next increment.
BASELINE	One touch will move baseline up or down by 1 increment, and holding will provide continuous movement.
SIDE	Used while scrolling "Captured" 2 Channel Waveforms (PVR or PPG). If Left side waveform is acceptable, but right is not, press the "SIDE" key to enable of scrolling 1 waveform (Left or Right) at a time.
INVERT	Inverts the Doppler Waveform. This button is active only in Doppler Waveform mode.
DEFLATE	One touch will begin Auto-deflation at preset rate (see Note*).
INFLATE	One touch will begin inflating to preset target pressure (see Note*).
CAPTURE	One touch will "Freeze" waveform or pressure. 2nd touch will move user to next site.

***Note**: If the Inflate or Deflate button is depressed slowly or held down for more than a moment, both buttons will revert to "Manual" mode allowing user to control inflation and deflation by continuing to hold

buttons down as long as Inflation or Deflation is desired. One Quick touch of either button will return controls to "Automatic" mode.

The Infrared Wireless Remote Control

The buttons on the remote control (Shown Below) function as follows:

PROBE Allow user to change the active probe. The active probe will be displayed on the MultiLab Screen

INVERT Invert the Doppler Signal (in Waveform Mode only)

D/OVER "Do Over" an Exam Segment

CAPTURE "Capture" a Waveform or Pressure

VOL ↑↓ Increase or decrease the volume of the Doppler probe

BASE ↑↓ Move the baseline (or waveform) up or down.

GAIN ↑↓ Increase or decrease the sensitivity of the active probe

PRESS ↑ Begins pump inflation. (See NOTE below)

PRESS ↓ Begins Cuff deflation. (See NOTE below)

MUTE One touch will reduce the Doppler volume to zero. A second touch will restore the previous volume setting

SIDE When performing bilateral studies, will activate Left, Right, or both sides for capturing waveforms or pressures, and when scrolling. The active side will be displayed on the Touch-Screen Color Monitor

BACK Move one site back each time button is depressed.

NEXT Advance one site forward each time button is depressed.

NOTE: The **PRESS ↑** and **PRESS ↓** buttons have TWO functions each: One brief touch of either button will begin automatic inflation or deflation. Depressing either button for more than one moment, will engage "Manual Mode", where button must be held down to continue inflation or deflation. When the instrument is operating in "Manual Mode" one quick touch of either button will resume automatic inflation or deflation.

Remote Control MENU Commands

This group of buttons is for use while navigating the MultiLab Video Menu screens. They are not used while performing studies on patients.

NEW Will allow user to select another exam to perform on a patient.

↑ And ↓ Buttons Will allow user to navigate up or down while Menu items are displayed on the monitor.

ENTER and EXIT Will allow user to select study or menu item displayed on the video monitor, or to exit from the current selection.

Scrolling Button Functions

The BASELINE (BASE) and GAIN keys also function as "Scrolling" keys when you have captured or "Frozen" a waveform or pressure. (On any "active" screen they will increase or decrease the position of the waveform or baseline and increase or decrease the sensitivity of the active probe.

The **BASE ↑** and **↓** are for SLOW scrolling (forwards and backwards)
The **GAIN ↑** and **↓** buttons are for FAST scrolling (forwards and backwards)

Battery Installation

The Infrared Wireless Remote Control requires 2 "AAA" batteries for operation. Unetixs recommends the use of alkaline batteries for maximum remote performance. Slide lower back portion of remote downward to reveal battery compartment as shown.

Insert 2 "AAA" batteries, paying attention to positive (+) and negative (-) alignment and close battery cover by sliding upward until cover "snaps" into place.

CHAPTER 8: AUTOMATIC CUFF SELECTOR USAGE

The optional Automatic Cuff Selector allows the operator to perform pressure examinations without having to manually open and close valves at each desired site.

The valves will automatically open and close to correspond to the desired sites. The valves are automatically activated by the software commands within each selected study. For most applications, the #1, right and left, valves will control the arm cuffs, the #2 valves will control to the thigh cuffs, the #3 valves will control the Above Knee cuffs, the #4 valves will control the Calf cuffs, the #5 valve will control the Ankle cuffs, and the #6 valves will control the Great Toe/Metatarsal cuffs.

Note: the right side hoses are clear and the left side hoses are blue. For newer systems and the Roodra, the right side hoses are gray and the left side hoses are light green.

A study configurator screen is shown:

```
                                1 Pressure

Tag: "RIGHT Brachial Pressure"          Gain Units: Normal
Pressure Designation: PA                Gain Unlocked
Print-X: 900    Print-Y: 500            Gain is set from previous site
Hide Timer                              Initial Gain: 4
                                        Baseline Invisible
Outer Graphic Box Disabled              Baseline Unlocked
Justification: Right                    Baseline is set from previous site
Print if captured                       Initial Baseline: 10.00 mm
                                        Audio Unlocked
Probe Unlocked                          Audio is set from previous site
Probe is set from previous site         Initial Audio (0 = Off): 2
Initial Probe: Doppler 8 MHz            Manometer Side: Right
                                        Auto Cuff Selector: Right 1
Inflation Type: Automatic               Export Code: 128
Target Pressure: 160                    Spectral: No
Overflow Pressure: 300
Deflation Type: Automatic
Deflation Rate: 3.000 mmHg/s
Capture Record: 0
Speed: 10 mm/sec
Filter: 28 Hz + HP

<F1> for Help          <F10> to Save and Exit          <ESC> to exit
```

The bottom right column in the study configurator is where the valve assignments are made. We can see from the screen that the Right Valve 1 is active while taking a Right Brachial Pressure. The valve numbers can be changed as desired and/or reassigned easily from the "Configure Studies" portion of the software.

The Automatic Cuff Selector is quite simple in its operation. The software controls the valves for every study, and each valve has a green light on the Auto Manifold. If you are uncertain which valve is active when performing an examination, just look to see which light is illuminated. In cases of Bilateral PVRs or Pressures, both lights will be illuminated.

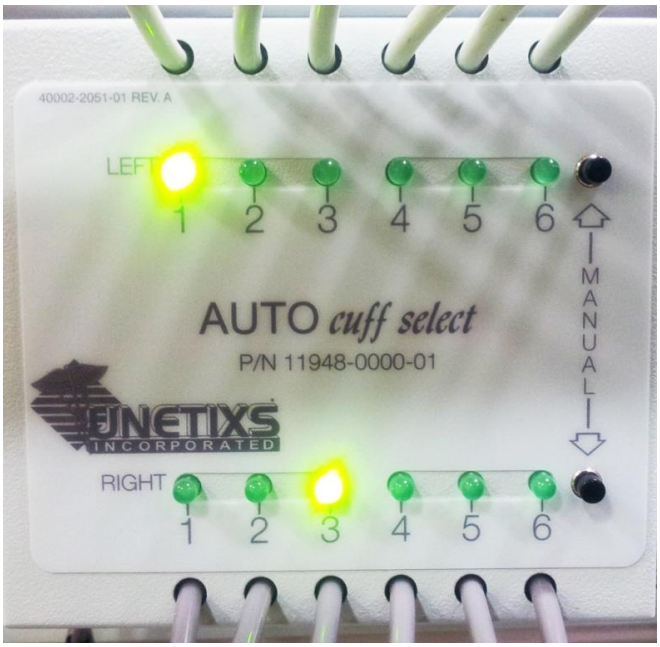
Auto Cuff Selector ILR

During an examination with a modality, the ILR report view will be highlighted with the current measurement. If the measurement involves the Auto Cuff Selector, that measurement will be highlighted with the color of the active hose:

Valve 1	Blue
Valve 2	Yellow
Valve 3	Green
Valve 4	Red
Valve 5	White
Valve 6	Black

Manual Operation on the Automatic Manifold

If for some reason, your Automatic Manifold is not switching properly, or if you simply wish to operate it manually, you will notice that there are two "Manual" switches on the front panel of the Automatic Manifold:



Repeatedly pressing the Left and Right "Manual" buttons will allow you to override the default setting in the software. Continue pressing the "Manual" button until the L.E.D. is illuminated over the desired valve number.

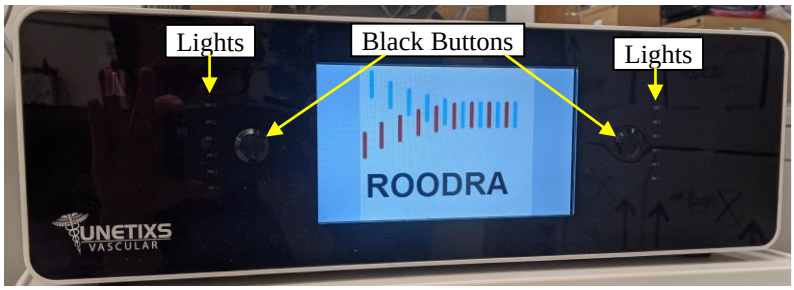
NOTE: If you are performing a field retrofit of these components, you must first alert the MultiLab so it will recognize this new component. Follow these steps to before you attempt to perform patient studies:

1. Press "Setup" from the Start-up Screen
2. Press: "System Setup".
3. Press: "System Data"
4. Observing the top line of the video monitor, continue pressing the "Next" button on the Touch-Screen until you see the following command: Auto Cuff Select.
5. Press "1" to activate the Automatic Cuff Selector and then press exit until you return to the Start screen. The Automatic Cuff Selector should now be functional.

Roodra Cuff Manifold

The cuff manifold is housed within the Roodra Module. Small, green lights will illuminate on the front panel of the Roodra Module corresponding to the cuff hose that is about to be utilized in the procedure. In a Doppler pressure modality, one light will be active, in PVR waveforms and PPG pressures two lights will be active.

The user may override the procedure and choose a different hose, or a different pair of hoses. Simply press one of the two black buttons (Right and Left) to advance the light(s) to the desired hose.



CHAPTER 9: PATIENT TESTING

In this chapter you will be introduced to the methods and concepts of patient testing that can be performed with MultiLab Series II instruments. All patient testing exams discussed herein follow clinically accepted methods and protocols. As there is always some variation from lab to lab and from individual to individual; we have created the Study Configuration utility (see CHAPTER 11: CONFIGURING STUDIES) so you can define the manner in which you wish to perform your exams if you decide not to use the factory preset studies.

Before we begin, it is important that we understand the various modalities that are incorporated into the instrument and the merits and shortcomings of each modality.

Modalities of Testing

Today's peripheral vascular labs use the following transducers to produce physiologic information about arterial and venous circulation in the arms, legs and digits of the hands and feet.

Doppler

Doppler is able to detect flow within a vessel through the use of the Doppler principle. CW (Continuous Wave) Doppler is used to evaluate the quality of flow within a vessel allowing the user to determine:

1. Presence or absence of flow
2. Direction of flow
3. Frequency changes relative to velocity changes
4. Frequency (velocity) waveform.

When CW Doppler is utilized during the segmental pressure exam, it is being used as a "stethoscope" to detect the presence or absence of flow.

CW Doppler is non-imaging and uses a probe housing both sending and receiving crystals. The MultiLab supports both 5 and 8 MHz Doppler transducers. The 8 MHz probe is best utilized for shallow lying (superficial) vessels, while the 5 MHz transducer, offering deeper penetration through tissue, is best used for vessels located further from the skin surface.

Strength: Can determine direction of blood flow, better suited to smaller vessels than a stethoscope for segmental pressure exams.

Weakness: Cannot "see" the vessel being examined, cannot determine optimum angle for velocity measurements, very operator dependent.

Photoplethysmography (PPG)

Photoplethysmography (PPG) is able to detect flow in the arterial bed located in the digits of the hands and feet. PPG is very sensitive to the minute pulse-volume changes that occur with each systolic pressure rise that occurs in the arterial tree. PPG uses a sending non-visible light transducer and a photo-voltaic infrared receiver transducer. PPG waveforms are very similar to PVR waveforms. PPG is also used in venous reflux testing to determine the time for venous refilling after emptying. PPG may be used to replace CW Doppler during the segmental pressure exam.

Strength: Very good at measuring micro-circulation in fingers and toes.

Weakness: Sensitivity can be reduced if digits are cold, or if sensor is applied too tightly or loosely.

Calibrated pulse volume recording (PVR)

Calibrated pulse volume recording (PVR) is able to detect the "total flow" in a limb segment by the use of a cuff wrapped around a limb segment and inflated to 65 mmHg pressure (the inflation pressure is used to eliminate venous flow artifact). As Arterial blood flows underneath the cuff, the limb segment expands causing a change in air pressure in the cuff. (Tissue volume swells with systole and rebounds during diastole.) This subtle change in cuff pressure results in a wave tracing (see interpretation manual) which is an indirect measurement of the flow of all the arteries beneath the cuff.

The Unetixs' MultiLab uses "Calibrated PVR" (which displays exact pressure AND air volume inside each cuff during recording) to insure the clinical validity and repeatability of PVR testing. The cuff Volume and Pressure measurements are printed on the final report for accuracy during interpretation.

Strength: Quick, simple to perform, detects collateral flow, reproducible, low operator error.

Weakness: Cannot identify individual vessels

Clinical Techniques for Peripheral Vascular Testing

Cuff Application

NOTE: For accurate systolic pressure measurements, the general recommendation is that a cuff width should be 20% larger than the diameter of the limb. An under-sized cuff causes falsely elevated pressures. Although an over-sized cuff will not affect segmental pressures they will dampen the amplitude during calibrated PVR testing.

Since we are diagnosing vascular disease instead of hypertension, most practitioners in the vascular field today utilize the "4-cuff method" (using 4 pressure cuffs on each leg) when performing Lower Limb Arterial Studies. While usually artificially elevating the above knee and thigh pressures, it is viewed as preferable by being able to differentiate between Superficial Femoral and Aortoiliac disease (see interpretation manual section on Segmental Pressures for more information).

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.

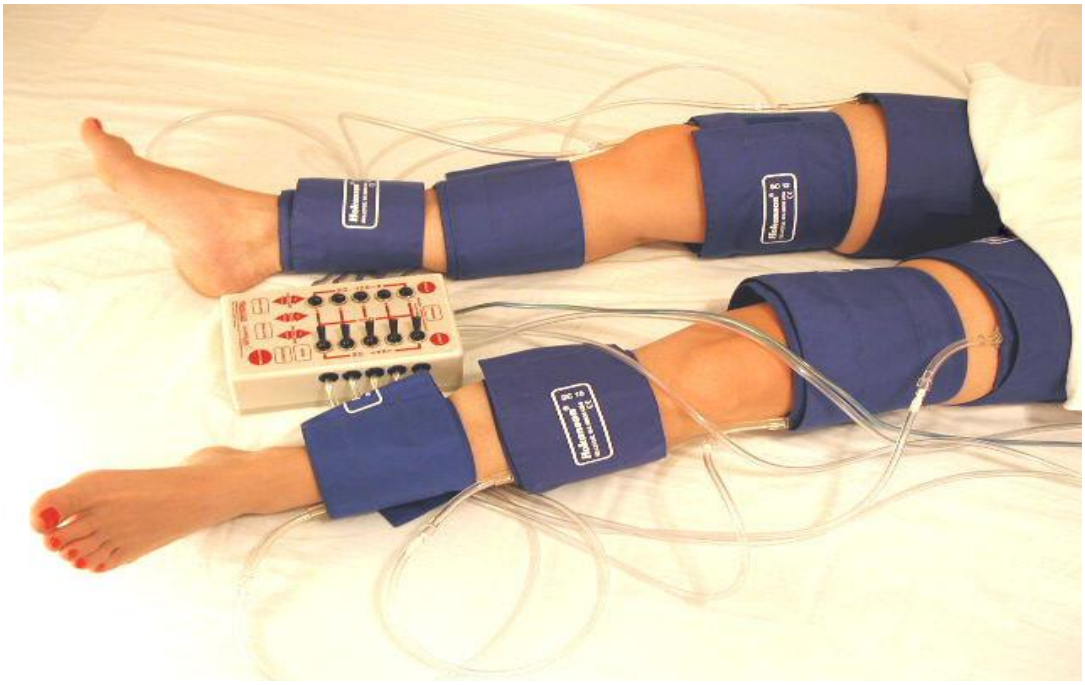
Cuff Sizes and Placement

The MultiLab instrument may ship with blood pressure cuffs designed for 3 or 4 cuff testing methods:

CC-17 (17 Centimeters wide) Contoured Thigh cuff for 3-cuff method.
SC-12 (12 Centimeters wide) for Above the Knee and High Thigh sites.
SC-10 (10 Centimeters wide) for Calf, Ankle and Arm sites.
TMC-7 (7 Centimeters wide) for Transmetatarsal or Hand use.
PC-2.5 (2 ½ Centimeters wide) for Fingers and Toes.

Optional cuffs (may be ordered directly from Unetixs) include:

CC-22	(22 Centimeters wide) Contoured Thigh cuffs for 3-cuff method.
SC-12L	(12 Centimeters wide) Extra-length cuffs for large Thighs.
DC-1.9	(1.9 Centimeters wide) for small Toes.



Proper cuff positioning for 4-cuff method

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.

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.

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 vessel is incompressible, "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".

Cuff Application as Related to C-PVR™

The Unetixs' MultiLab features true calibrated PVR (C-PVR™) that allows the technologist to ascertain immediately when there is a cuff miss-selection, wrapping error, or cuff leaks. The PVR waveform, when printed, appears with the "true-scaled" graph and notations on inflating pressure, cuff volume, units of measure, and gain setting.

Cuffs of equal width and in the same limb location (such as 2 thighs) should not have a volume difference greater than 15% (15 cc's per Hundred.) Observe the volume during inflation and at the monitoring pressure. If a discrepancy exists, check the following:

- Ensure cuffs are equally sized left and right.
- Ensure equal wrapping of cuffs in terms of tightness and location on limb.
- Ensure no unusual folding or wrinkling of the cuffs.
- Ensure cuff is not leaking (observable by a slow loss in pressure during acquisition of waveforms.)
- Repeat the test if necessary by pressing "Capture" and "Do Over"

If volume discrepancies are not avoidable, (can be due to limb atrophy, or edematous tissue) then be certain to call attention to the problem when reporting to the reading physician.

CW Doppler Application

The Unetixs' MultiLab comes with two CW Doppler probes – 5MHz and 8MHz. These are also known as the "low frequency" and "high frequency" probes. According to the physical principles of Doppler ultrasound a higher frequency has a greater the sensitivity to flow; and a lower frequency has a lower the sensitivity to flow. However, increasing the frequency of a probe will cause an increased attenuation (Attenuation is the loss of Doppler power as the beam travels through tissue). Thus lowering the frequency will lessen the attenuation. Use the low frequency for deep vessels such as in the groin and the higher frequency for all other applications.

NOTE: You can use the Doppler probes in 2 different ways – to obtain Segmental Pressure measurements, or to record Doppler Waveform tracings. When using the Doppler probe to take pressure measurements, use the 8 MHz probe on all but very heavy patients. When using the Doppler probe to record Waveform tracings, use the 8 MHz probe on the more superficial vessels and the 5 MHz probe on the deeper vessels (commonly Femoral and Subclavian, and sometimes Popliteal).

Illustration of cuff placement and proper Doppler Angle at Brachial artery

Doppler Technique

Doppler probes should always be used with Ultrasound Gel and be held like a pencil with the use of light pressure. Applying too much pressure on the Doppler probe can result in occluding the vessel you are attempting to examine.

The Doppler probe must be held at an angle of less than 60 degrees and pointed in the direction of flow. Ideally an angle of 45 degrees or less will provide the best Doppler detection signal. Since the angle to flow is

"assumed" (you cannot "see" the vessel with CW Doppler) the visual angle of the probe may not be the actual sampling angle. The best technique is to start with a "good" angle and listen for the "best" sound.

Unetixs' Doppler probes are bi-directional and the MultiLab has an Invert Button that allows the Doppler signal to be "flipped". Occasionally the best signal is derived with the probe pointing away from the direction of flow, resulting in a signal that is "upside down" or inverted. Always seek to create a graphic that is consistent with the signal that is heard. (This applies to all CW Doppler regardless of manufacturer.)

Use of filters when acquiring Doppler readings is usually not necessary and these should be set for the lowest setting in the System Configurations. Filters remove artifact but also decrease Doppler sensitivity.

If venous flow is causing artifact (visible or audible) in the arterial Doppler, apply a light pressure proximal or distal to the Doppler site. This will cause the venous flow to cease without affecting the arterial Doppler (in bi-directional CW Doppler, the venous flow can override, add to or subtract from the arterial signal).

PPG Application

The Unetixs PPG probes are light and thin and respond to the pulse volume of a digit very rapidly. The PPG probes can be applied using either the supplied Velcro™ straps, or the supplied PPG Clips. You can also remove the Velcro™ straps and use a short length of double-sided Scotch™ tape on the side of the probe containing the sensors. If Velcro™ is used, avoid excessive pressure during wrapping as this can obliterate arteriolar flow causing an abnormal waveform.

Both sensors should be in contact with the fleshy part of the digit and visually inspected to insure the absence of outside room-light interference.

Secure the PPG wires since wire motion and pulling can cause excessive motion artifact in the PPG graph with a prolongation of the testing time.

Illustration of PPG Sensor and digit cuff on Great Toe

Setting of Gain

The MultiLab has an automatic preset gain that can be altered during testing. Gain affects amplitude of the waveform, which is a diagnostic hallmark during interpretation.

Please note that Gain settings affect different studies in different ways. For example, when using the PPG sensor to obtain digit or segmental pressures, it is advantageous to reduce the gain as much as possible and still see distinct pulses on the MultiLab screen. Other studies may require you to increase the gain for an optimum examination. See the individual studies section to see how the Gain setting can be optimized for every exam. A reduction of Gain can reduce "overshoot" (when the waveform extends past the top and/or bottom of tracing).

Setting of Baseline

The MultiLab has an automatic preset baseline setting that can be altered during testing using the Baseline Up and Baseline Down controls on the touch-screen or the remote control.

The Baseline can be moved up or down without changing the size of the waveform on the display screen. It is advised when performing waveform studies using the Doppler, PVR or PPG sensors that the baseline be adjusted if necessary, so the entire waveform complex (peak to trough) is visible on the screen.

Setting the Volume (Audio)

Set the volume control for the Doppler probe for optimum listening. (NOTE: Remember that Doppler angle will also affect Doppler volume. If you are only hearing a faint Doppler sound, try adjusting the probe's position and angle before automatically reaching for the volume control.)

Optional Headphones can be plugged into the headphone jack on front of MultiLab. Plugging headphones in will disable system speakers, so others in the exam area will not hear the Doppler signals.

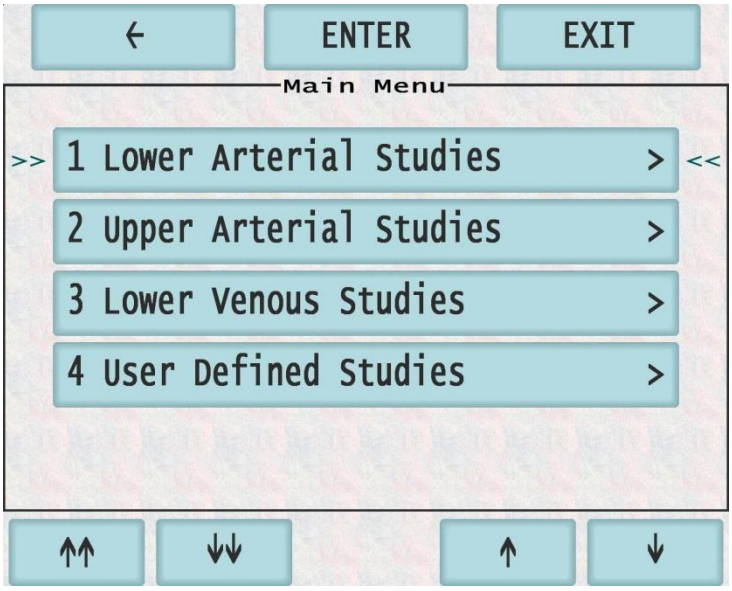
Lower Arterial Studies

NOTE: As the MultiLab instrument is almost infinitely configurable, the following section will pertain to individual types of exams. When any type of action is taken with the MultiLab, it will automatically sequence the user to the next site or even to a different type of study. It is possible to program the MultiLab to perform Segmental Pressures, Doppler Waveforms, PVR Waveforms, Digit Pressures, PPG waveforms and Post-Exercise Pressures all within the same custom program. For this reason we will treat each action separately.

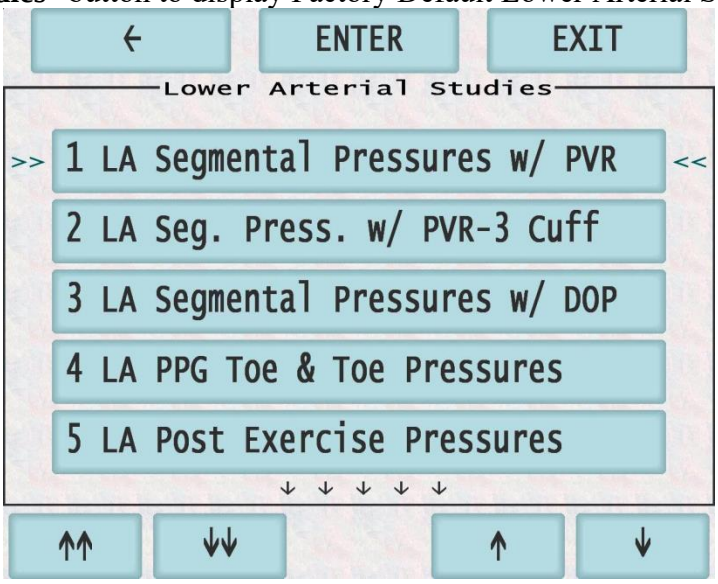
NOTE: Depending on how the instrument has been set-up, the video screen may look different from those displayed below.

History Page

From MultiLab Start screen, press the "**Studies**" button on touch screen to bring up Main Menu Screen as seen below:

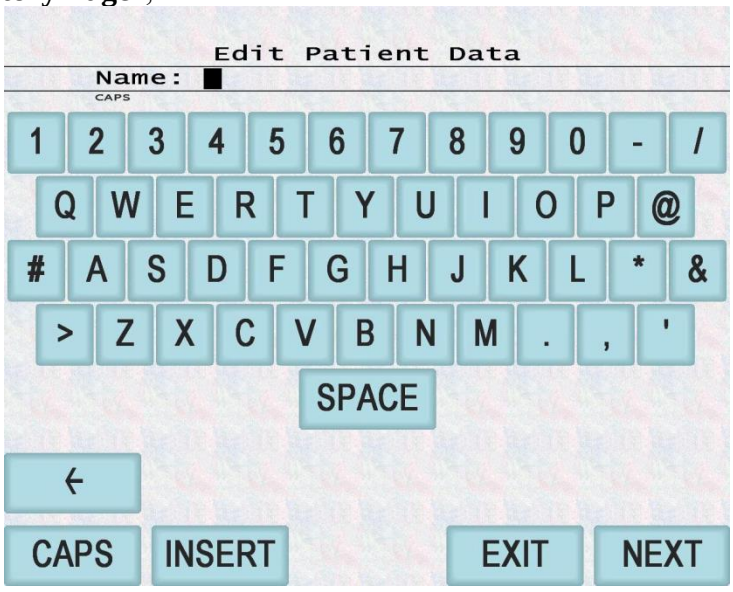


Touch "**Lower Arterial Studies**" button to display Factory Default Lower Arterial Studies Screen as shown:



Touch the "↓↓" button to display the rest of the Lower Arterial Studies as shown:

Touch "**Lower Arterial History Page**", the Edit Patient Data screen will be shown as follows:



Using the Keyboard or Touch-Screen, type in the Patient's name, (typically last name first) and press the "Enter" key or touch the "NEXT" button on the touch-screen. Enter the Patient ID (usually a Social Security or Medical Records number) and press "Enter." Continue to enter data as prompted by the Video Screen.

Patient Data ILR

The ILR for this screen will show all of the Patient Data, not just the line being edited. You may touch the ILR to change the focus for editing to a particular field. The View button is available to see the report view. Press the Info button to return to showing all of the Patient Data.

Patient History

When you get to the Patient History section, you will see a number of questions presented on the screen. A simple "Yes" or "No" can answer most questions, or more data can be entered to provide more detail. You have 1 line of type in which to enter data about a particular question.

Press the "Escape" key on the keyboard to exit the Patient History Page. NOTE: this page is completely user definable, and the factory-preset page is just an example of some of the information commonly gathered before a vascular examination is performed. Please consult the section on Study Configuration or contact Unetixs, for assistance on modifying the report page.

Press the "New Study" button on touch-screen to retain current patient information and to select the examination to be performed, without have to re-enter patient data (name, ID, etc…).

Foreign Language Data

The software will allow the following foreign language characters to be entered as patient data: Ç, ç, Æ, æ, Ä, Å, â, ä, à, å, á, É, é, ê, ë, è, ï, î, ì, í, Ñ, ñ, Ö, ô, ö, ò, ó, Ü, ü, û, ù, ú, and ÿ. If you are using a keyboard for a different language, make sure the default input language is set in Windows™. **NOTE**: Unetixs does not provide keyboards for alternate languages.

History ILR

Only the report view is shown for the history page. The Zoom button is available to expand the report.

Arm Pressures

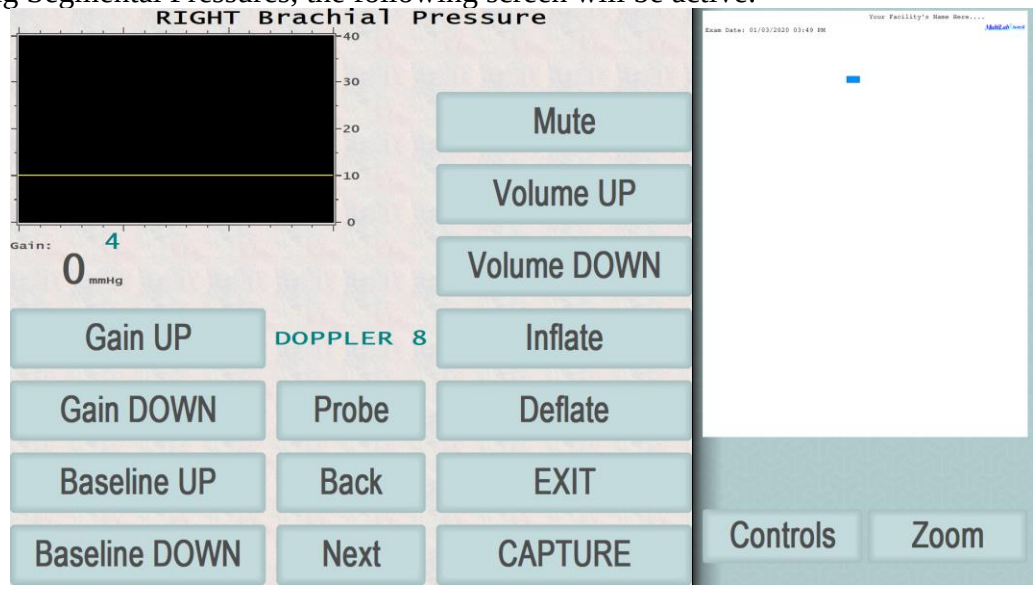
Patient Preparation

Patient should be supine on padded exam table. Have patient remove shoes, socks or stockings and clothing from legs (patient CAN leave undergarments on). It is advisable to have either a gown or some other covering over patient to ensure patient stays warm during exam. A cold examination room can cause vasoconstriction in certain patients, which can negatively affect the examination.

Apply 1 SC-10 blood pressure cuff to each arm (see page 52) and apply SC-10 cuffs at the ankle and calf sites, and SC-12 cuffs above the knee and at the high thigh sites (see page 51).

NOTE: Many technologists prefer to start the segmental pressure examination at the brachial sites to establish a "baseline" pressure then proceed to the ankle to see if ankle pressure equals or exceeds the brachial reference pressure (the higher of both arm pressures).

When performing Segmental Pressures, the following screen will be active:



The functions available on this screen are as follows:

WAVEFORM SCREEN Displays information from the active probe (see PROBE)

GAIN UP Increases the size of the waveform from the selected probe.

GAIN DOWN Reduces the size of the waveform from the selected probe.

BASELINE UP Will move the waveform UP without changing its size.

BASELINE DOWN Will move the waveform DOWN without changing its size.

PROBE Allows user to change active probe.

BACK Takes user back to previous site.

NEXT This advances user to next site.

VOLUME / MUTE This adjusts the volume.

INFLATE Begins cuff inflation to preset target. **NOTE**: a brief touch of this button will begin automatic inflation. If button is depressed for more than a moment, the unit will switch to manual inflation mode, where pump will continue to operate as long as button is depressed (or until maximum allowed pressure is obtained). Auto-inflation can be resumed by quickly touching the "Inflate" button again. This button can be configured, in the study configuration, for manual inflation only.

DEFLATE Begins automatic cuff deflation at preset bleed rate. Unit will emit a soft "ticking" sound to indicate deflation is in process. **NOTE**: a brief touch of this button will begin automatic deflation. If the button is depressed for more than a moment, the unit will switch to manual deflation mode, where the cuff is deflated at the maximum rate. Auto deflation can be resumed by touching the "Deflate" button again. This button can be configured, in the study configuration, for manual deflation only.

CAPTURE Will capture the pressure displayed on the screen to the right of the Waveform Box.

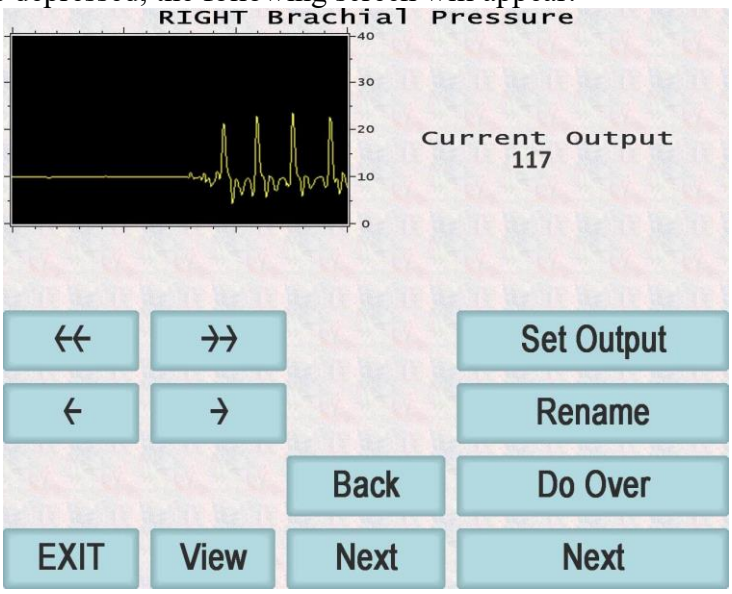
EXIT Takes operator to the "Edit" screen where user can View, Print or Edit the examination (see EDIT screen section below). **NOTE:** No patient data is saved when 'EXIT' is pressed from this screen.

To begin Segmental Pressure study at Right Brachial site, ensure the Right Brachial cuff is attached to the proper hose on the Cuff Selector and that the proper valve is active. Apply ultrasound gel to the brachial artery, and locate vessel using the Doppler probe at an approximate 45° angle to the surface of the arm (see page 52 for General Doppler positioning).

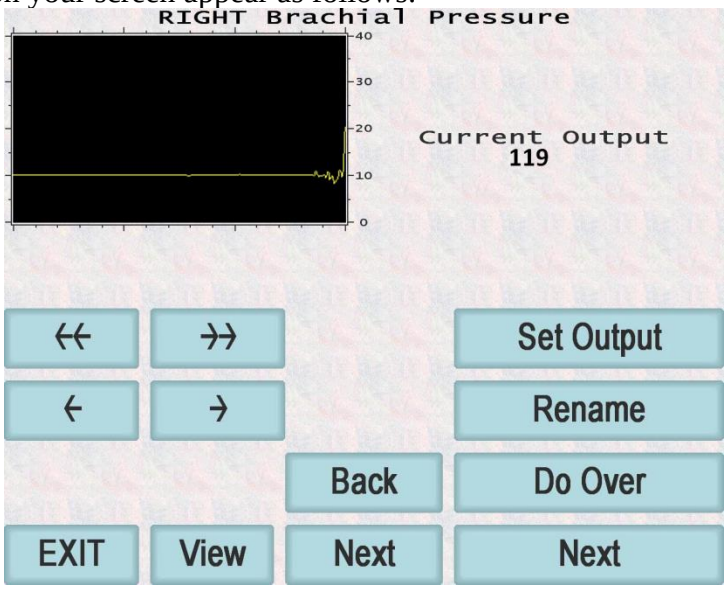
Move probe as necessary to maximize the level of the Doppler sounds. Press "Inflate" button once to begin inflating arm cuff. Inflate the cuff until the Doppler sound ceases (waveform on video screen will "flat-line" at

this point) and then press the "Deflate" button once. Press the "Capture" button when Doppler sound reappears. (NOTE: it is NOT necessary to capture the very first sound you hear – a small movement from the patient may emit a Doppler sound, so better to wait for several "beats" before "Capturing" the pressure.)

Once the "Capture" button is depressed, the following screen will appear:



The pressure displayed under "Current Output" (in this picture, 117 mmHg) represents the pressure in the cuff when the "Capture" button was depressed. To ensure accurate systolic pressures, scroll the pulses back to the first pulse to display the Peak Systolic Pressure. Use the "←←" button to scroll quickly and the "←" key to scroll slowly, so the results on your screen appear as follows:



You can now press the "Next" button to record this pressure and advance to the next site. You may press "Capture" on your remote to advance. The other buttons on this screen function as follows:

SET OUTPUT Use this button to manually enter information – Typically you will use this feature to denote a calcified or incompressible vessel, e.g. you have inflated the cuff to 250 mmHg pressure and you can still hear (and see) a pulse. Press the "Capture" button at this point and then the "Set Output" button. You would then type in "CNO", ">250" or "250+" and then press "OK" or the "Enter" key to denote that the vessel was still pulsatile at this pressure. You could also type "AMP" if limb segment displayed at top of screen had been amputated.

RENAME If for some reason, you have taken a good pressure reading, but realized it did not match up with the site displayed on the MultiLab monitor, you do not need to re-do the

pressure. Instead, press this button and then the up and down arrow keys to display the proper pressure site.

DO OVER If you feel you have made an error after capturing a pressure, press this button to "unfreeze" the screen and repeat pressure reading at that site.

If satisfied with captured pressure, proceed to the next site by pressing "Next" (or "Capture" on remote control). Repeat procedure at Left Arm site.

NOTE: You can view captured pressures at any time by pressing "View"; return by pressing "Exit".

Pressure ILR

The ILR for pressures allows for extra controls for sweep speed, inflation target, and deflation rate. You can also view the report. Use the Zoom button to see the pressures more easily while performing the exam.

Ankle and Leg Pressures

Ensure the Ankle cuff is attached to the proper hose on the Cuff Selector and that the proper valve is active. Locate Posterior Tibial (PT), or Dorsalis Pedis (DP), artery with the 8 MHz Doppler probe. Inflate to occlusion, deflate and capture pressure as in previous section.

NOTE: You can obtain Ankle pressures at both Posterior Tibial AND Dorsalis Pedis Arteries if desired – please refer to Study Configuration section.

NOTE: If artery is still pulsatile when pump reaches target setting, press and HOLD "**Inflate**" button down to continue inflating cuff to occlusion pressure. Do NOT exceed a pressure of 250 mmHg in the cuff unless instructed by your Medical Director.

Use ankle artery with strongest signal (PT or DP) and proceed in taking pressures up the leg. If no Doppler signal can be detected at the PT or DP artery, press the "**Probe**" button to activate the Right or Left PPG sensor and affix to Great Toe of foot being examined (see page 53). If a pulse is observable on-screen, inflate cuff until pulse "flat-lines." Sometimes the flat line will disappear off-screen at point of occlusion. If this occurs, wait several seconds for the flat-line to reappear, press the "**Deflate**" button and "**Capture**" pressure when pulse reappears. Continue taking pressures up the leg using the PPG sensor.

Toe Pressures

Toe pressures can be obtained by applying the DC-2.5 Digit cuff to base of the Great Toe and affixing the Left or Right PPG sensor to the end of the digit. If a pulse is observable on-screen, inflate cuff until the pulse "flat-lines." Sometimes the flat line will disappear off-screen at point of occlusion. If this occurs, wait several seconds for the flat-line to reappear, press the "Deflate" button and "capture" pressure when pulse reappears.

When taking 2 pressures simultaneously, it is possible to capture one side before the other; simply touch the waveform box or the side with the returned pulse. **NOTE**: it is also possible to switch to the Doppler probe after touching the waveform box; but only one size can be activated for Doppler (both boxes must be touched).

NOTE: There is an option to equip the MultiLab with Toe Bleed Valves that are attached to the cuff selector. The Toe Bleed Valve will automatically deflate the cuff; the "**Deflate**" button will not be used.

NOTE: It is desirable to adjust the Gain as low as possible (½" - ¾" tall pulses) when obtaining Toe pressures, as this will result in a "flatter" flat-line and will also be less susceptible to "wander" off the video screen during inflation and deflation.

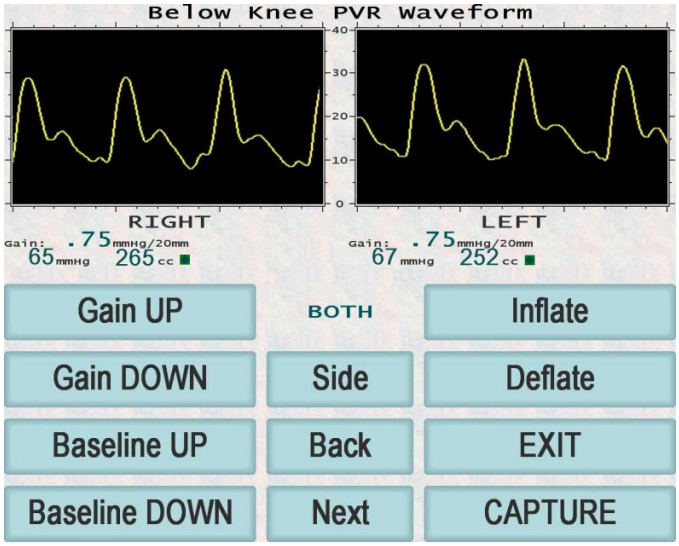
NOTE: If the PPG sensor or Velcro™ strip is touching the toe cuff during cuff deflation, artifact may be observed, resembling small pulses that coincide with the system "ticking." Separate the sensor from the cuff to eliminate this communicating artifact.

PVR Waveforms

Before performing PVR waveforms, please read preceding chapter on "Calibrated PVR" to gain an understanding of how to obtain an optimum result using this modality. NOTE: For proper interpretation of PVR waveforms, ALL gain settings must be the same at all cuff sites. You may adjust the Gain downward to eliminate "overshooting" (tops and bottoms of waveforms out of the waveform box), but any waveforms captured before downward adjustment, must be redone at the new Gain setting.

Position pressure cuffs on Patient legs as shown on page 51. As the MultiLab performs PVR tracings bilaterally, ensure the proper cuffs are attached to the proper hoses on the Cuff Selector and that the proper valves are active. Push "**Inflate**" to begin cuff inflation. The pumps will automatically inflate the cuffs to between 62 and 68 mmHg on both sides.

NOTE: If the pressure in one or both cuffs drops below 62 mmHg, the letters "**UND**" will appear below the pressure reading indicating lower than optimum pressure. (This is not uncommon on patients with leg swelling or large limbs) Press the "**Inflate**" button again, and the MultiLab will automatically add pressure to one or both cuffs as needed.



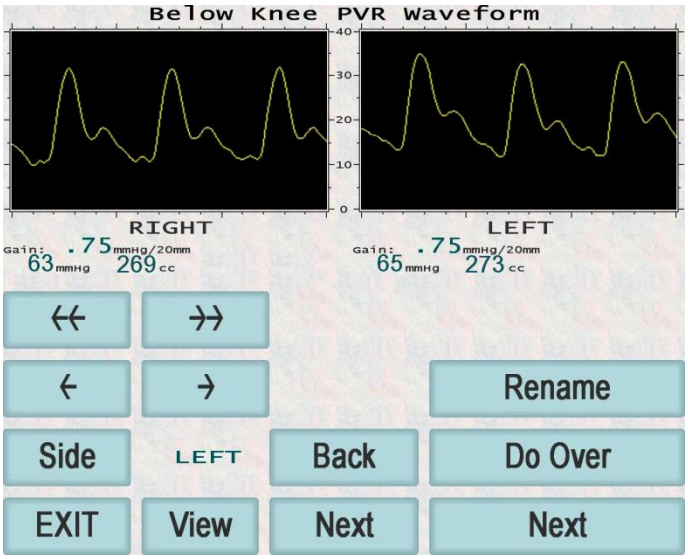
Before capturing the PVR waveforms, ensure cuff volumes are within 15% of each other by observing onscreen lights beneath waveforms. If cuff volumes are within 15%, both lights will glow green as on the screen above. If they are not, re-do the PVR waveforms (see below).

Also ensure that waveform Gain is properly set. The "peaks" and "troughs" of the waveform complex must be visible on the screen. On typical patients, the waveform amplitude will be lower at the ankle and high-thigh sites than at the calf and above-knee sites. If your ankle waveforms are taking up most of the video screen, your calf waveforms will almost certainly have the top and bottom "chopped off" at that gain setting. Use the "**Gain Down**" button to reduce the size of the waveform.

Use the "**Baseline**" buttons to center the Waveforms if needed, without changing the size of the waveform.

NOTE: It is very important for proper interpretation that all PVR waveforms are obtained at the same Gain setting. If you have to lower the Gain so that the calf PVR waveform will fit on the screen, press the "**Back**" button and then the "**Do-Over**" button to re-do the ankle tracing, making sure you lower the Gain to the same setting you used at the calf. It is also NOT advisable to make a PVR waveform "look bigger" by using the "**Gain Up**" button.

Once you observe consistent wave tracings on the screen, press **"Capture"** to freeze the waveforms and bring up the following screen:



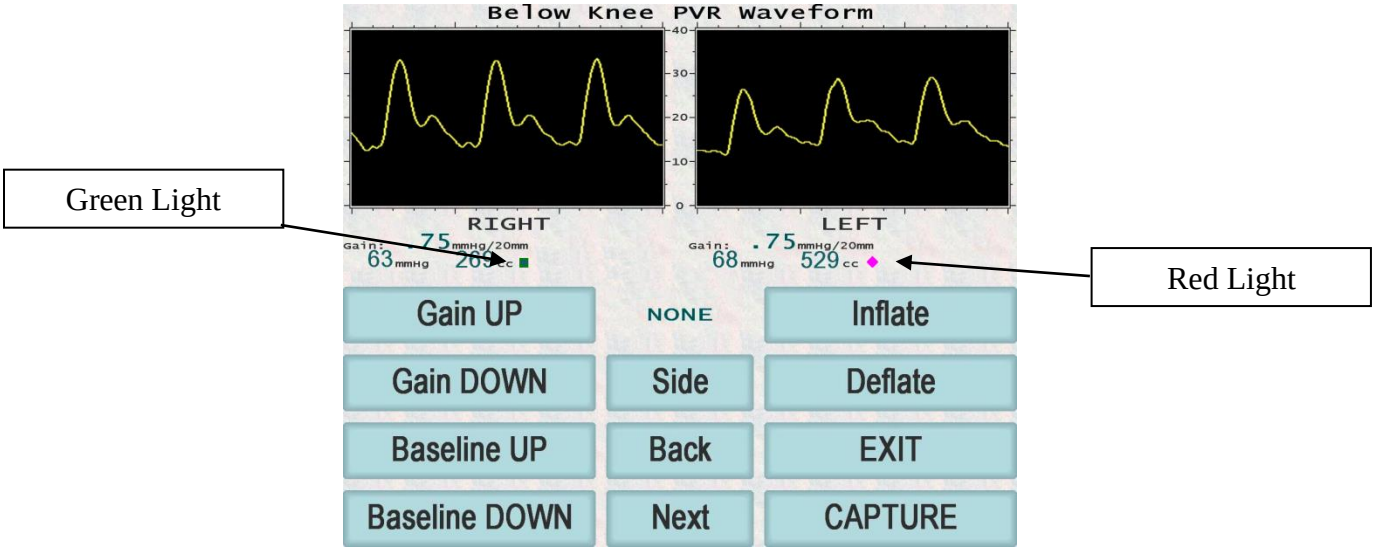
Once you have captured the waveforms, it is possible to "scroll" back up to 30 seconds on both sides or individually. You will notice the button labeled "**Side**" on this screen. The default setting is "Both" meaning both waveforms will be scrolled back together.

If you wish to scroll the waveforms individually press the "**Side**" button once to activate one side. Pressing the "**Side**" button again will activate the opposite side.

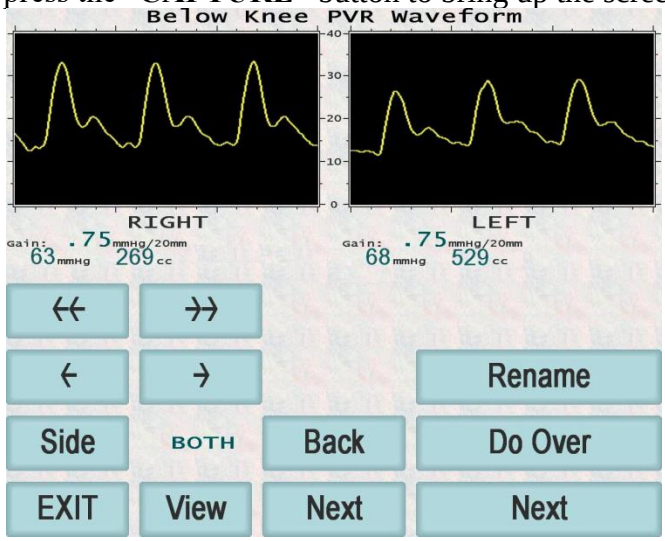
NOTE: you can view captured waveforms at any time by pressing "Exit" and "View". Return to the examination by pressing "Exit" and "Back".

Re-doing PVR Waveforms

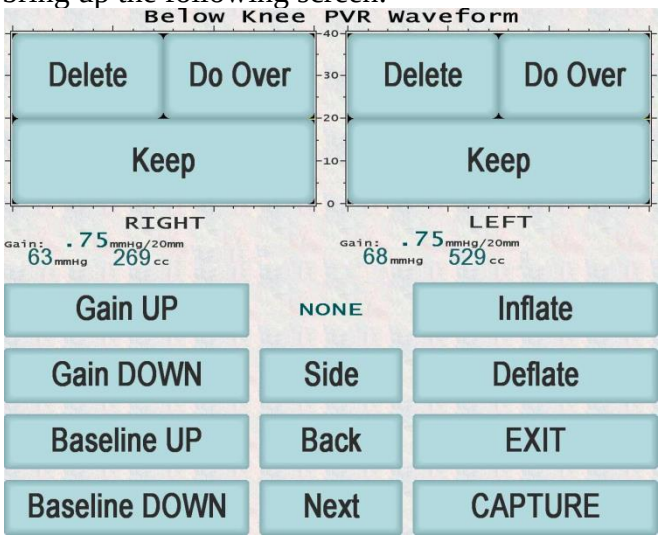
If PVR volumes are not within 15% of each other, a red light will appear underneath the waveform with too much volume. As is shown in the illustration below, an excess of air volume in a cuff can artificially dampen a PVR wave tracing and make it appear abnormal.



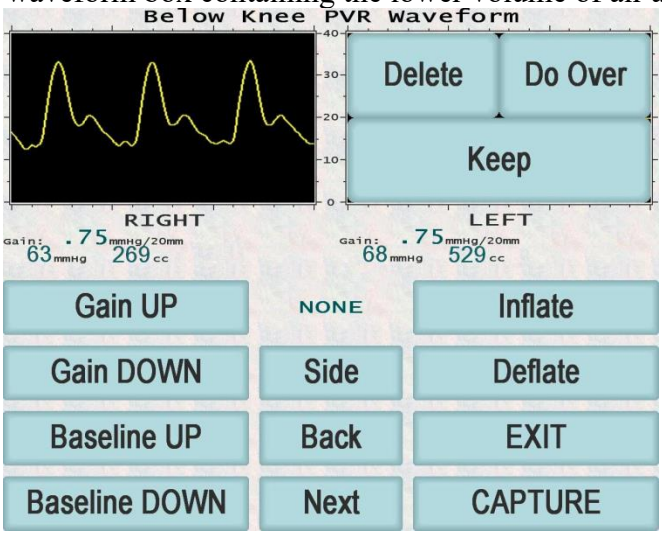
To correct such an occurrence, press the "**CAPTURE"** button to bring up the screen below:



Press the "**Do-Over"** button to bring up the following screen:



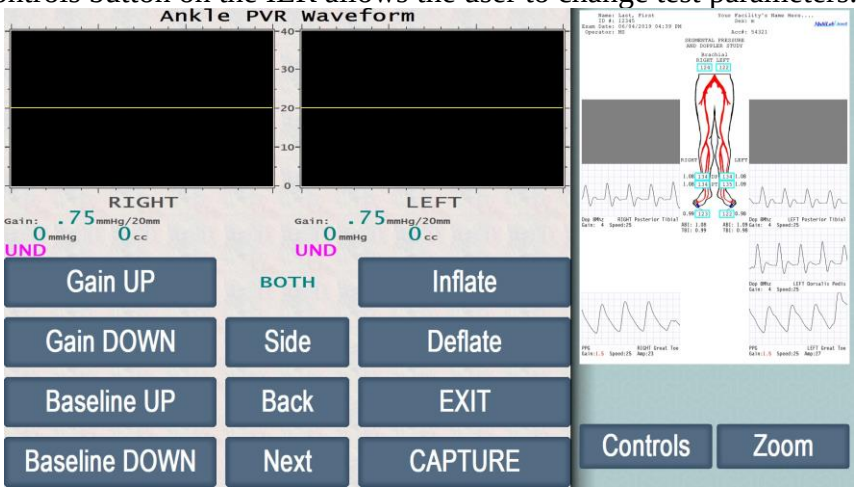
Press the "**Keep**" button on the waveform box containing the lower volume of air as shown below:



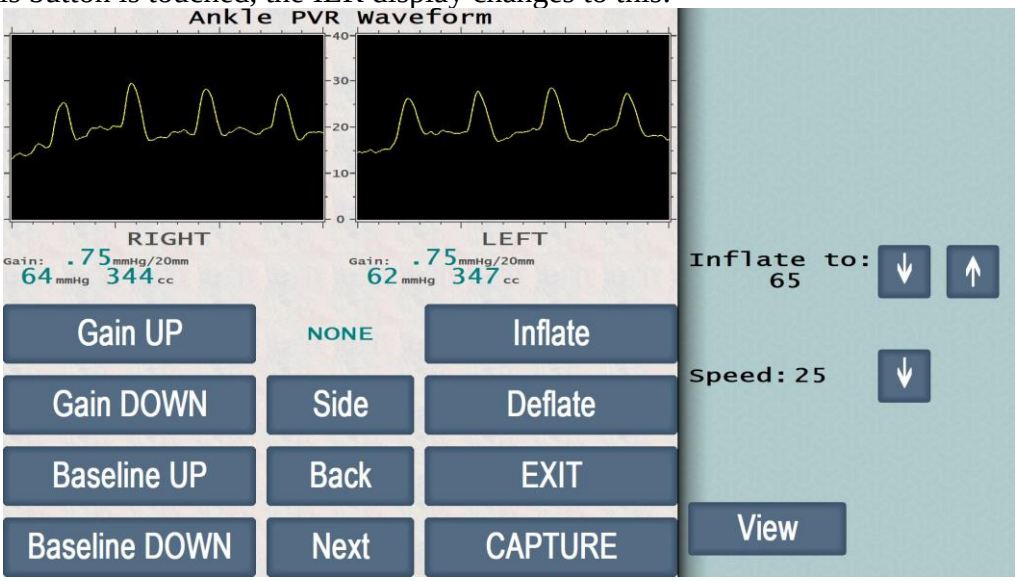
Press the **"Do Over"** button on the box containing the larger volume of air (the one with 529cc above). Disconnect the cuff with the greater volume from the hose, and re-wrap the cuff more snugly. Re-connect the hose, and press **"Inflate"** to continue. Note that it is not necessary to deactivate the frozen cuff when re-doing one waveform as the MultiLab will not port air to the cuff with the "kept" waveform.

ILR PVR Functions

In all modalities, the Controls button on the ILR allows the user to change test parameters.



When the Controls button is touched, the ILR display changes to this:

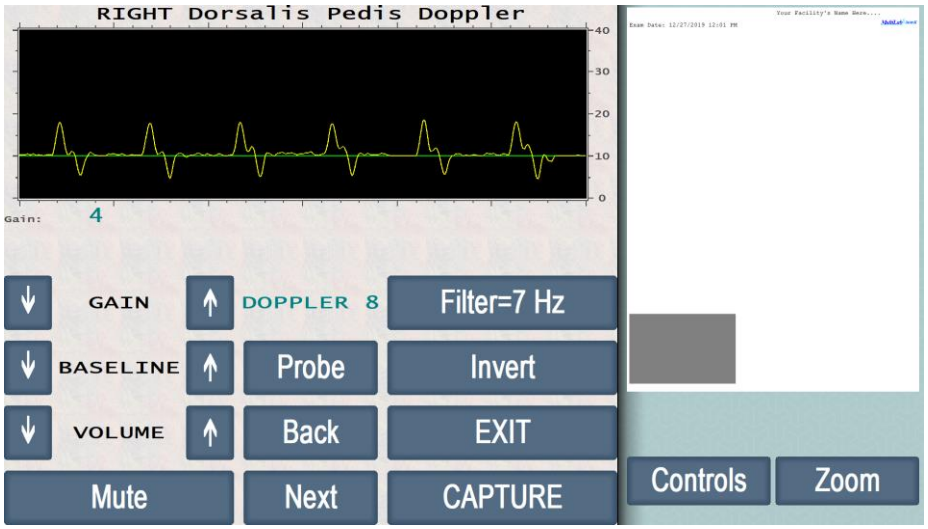


Here, the user can change the target inflation pressure (55 – 75 mmHg). The sweep speed can be slowed to 10 cm/sec.

Doppler Waveforms

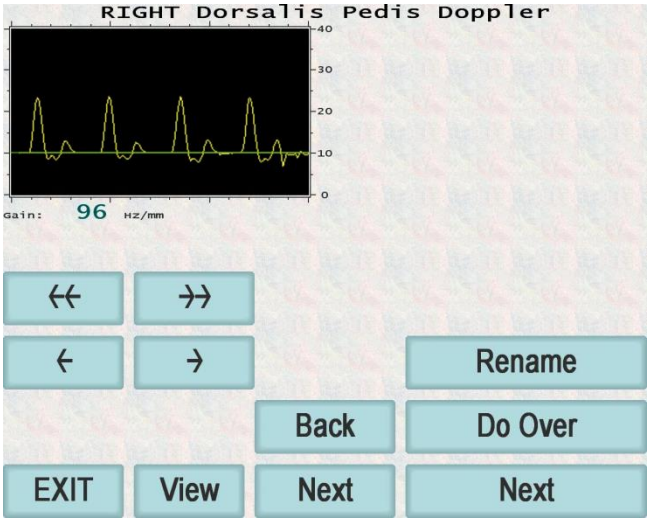
Before performing the Doppler Waveform exam on a patient, please read the information about CW Doppler in the "Modalities" section of the Manual. The Doppler Screen is shown below and contains many of the same buttons as previously discussed studies, with the exception of the "**Invert**" and the "**Mute**" buttons. Occasionally, you may obtain a better Doppler waveform by pointing the Doppler probe AWAY from the heart. Doing so will display flow information "upside down" on the MultiLab screen. Press the "**Invert**" button and the Systolic Flow will appear above the baseline.

The "**Mute**" button will automatically quiet the Doppler Probe, and is helpful when moving from one site to the next. Pressing the "**Mute**" button again will return the Doppler volume to the previous setting.



To obtain Doppler Waveform tracings, locate the vessel identified on the top of the MultiLab Screen with either the 8 MHz or 5MHz Doppler probe. As the vessels are sometimes in places you are not expecting, it is a good idea to apply a liberal amount of Ultrasonic Gel to the area of the vessel. This will allow you to move the probe to find the best signal without having to stop and apply more Gel.

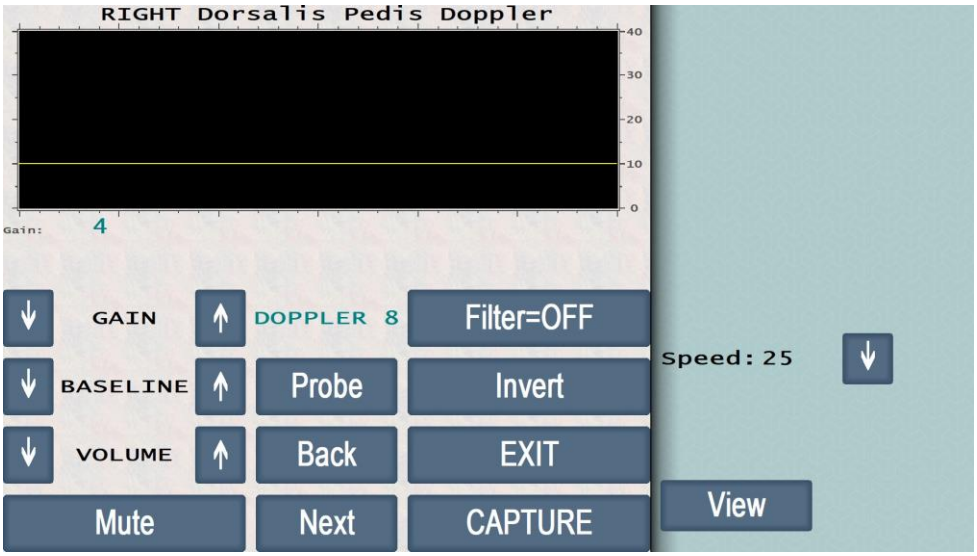
Keep in mind that the MultiLab will store 30 seconds of Doppler waveforms. If you are performing an exam on a patient with severe disease, it can sometimes be difficult to obtain several representative waveforms in a row. Once you have seen what you consider to be the best waveforms obtainable (always strive to display multiple phases on your waveforms) press the "Capture" button to store. As with the other studies, you can scroll the waveforms, rename them, or do them again by pressing the appropriate buttons. You can move to the next site by pressing "**Next**" from the following screen.



Do Over: In the event that scrolling does not provide the desired result of an artifact free waveform, touch Do Over. Obtain another waveform, touch capture. The just acquired waveform will be on the left, the previous waveform on the right. All 30 seconds of scroll time is available on the left side; use the swap button (not shown) to make the previous waveform the active one. Whichever waveform is on the left will be used for the report.

Doppler ILR Function

When the Controls button is touched in the Doppler modality ILR, the user can change the sweep speed of the Waveform from 25 cm/sec to 10 cm/sec.



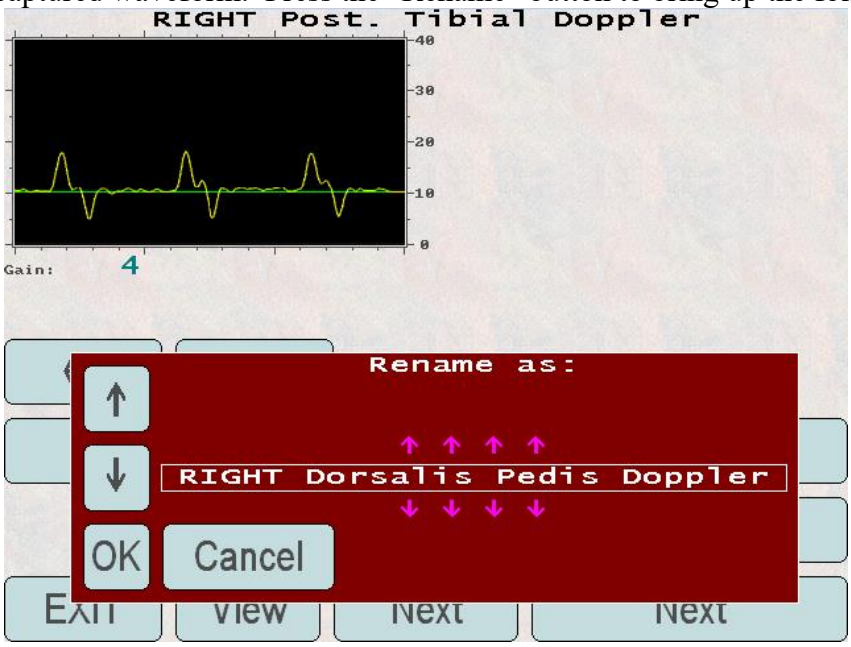
Helpful Hints for Doppler Waveforms

If you are hearing the Doppler sounds but not seeing waveforms on the screen, this usually means that your Doppler angle is 90° (perpendicular) to the vessel. Adjust the probe angle as needed to obtain a visible Doppler tracing.

If you can hear and see the Doppler but the waveform on the screen does not seem to represent what you are hearing; it is possible that the Doppler probe may be too high a frequency to get the sound wave into the center of the vessel (Where the flow is faster). Try switching to the 5 MHz probe, or pressing the probe into the limb (don't press too hard or you may cause your patient discomfort and/or compress the vessel you are attempting to examine.

You can capture and compare 2 waveforms at the same site by using Do-Over. For more than 2 waveforms, do the following (Using the Dorsalis Pedis artery as an example): Capture a waveform tracing at the Dorsalis Pedis artery. The next site that will typically appear will be the Posterior Tibial screen. Continue examining the Dorsalis Pedis artery, (possibly moving the probe to a different spot on the foot) and capture another waveform.

Press the "Exit" and "View" buttons to observe both waveforms on the MultiLab screen. If the second waveform (which in this case will be labeled "Posterior Tibial") looks "better" than the first tracing, press "Exit" and "Back" to return to the captured waveform. Press the "Rename" button to bring up the following screen:



Use the up and down arrow buttons to display the proper artery name on the video screen (in this case "Dorsalis Pedis"), and then press "O.K." The second waveform will automatically "overwrite" the first captured waveform. If upon examination the initial waveform looked "better" simply press the "Do Over" key to continue with the exam.

PPG Digit Waveforms

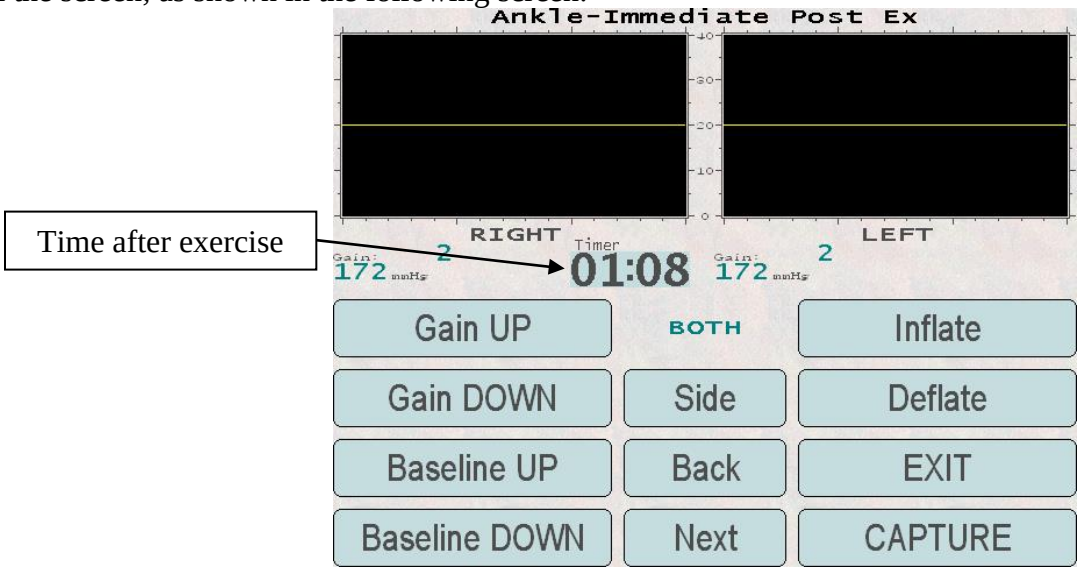
This exam can be performed on the fingers or toes. Apply Right PPG sensor to the Right digit and the Left PPG sensor to the Left digit (see page 53). Adjust the Gain so that waveform occupies a half to two-thirds of the Waveform Box on the MultiLab Screen. Capture waveforms and scroll if necessary to present several consistent waveforms. Repeat on remaining digits. Make sure Gain is set the same for all digits.

PPG Waveform ILR

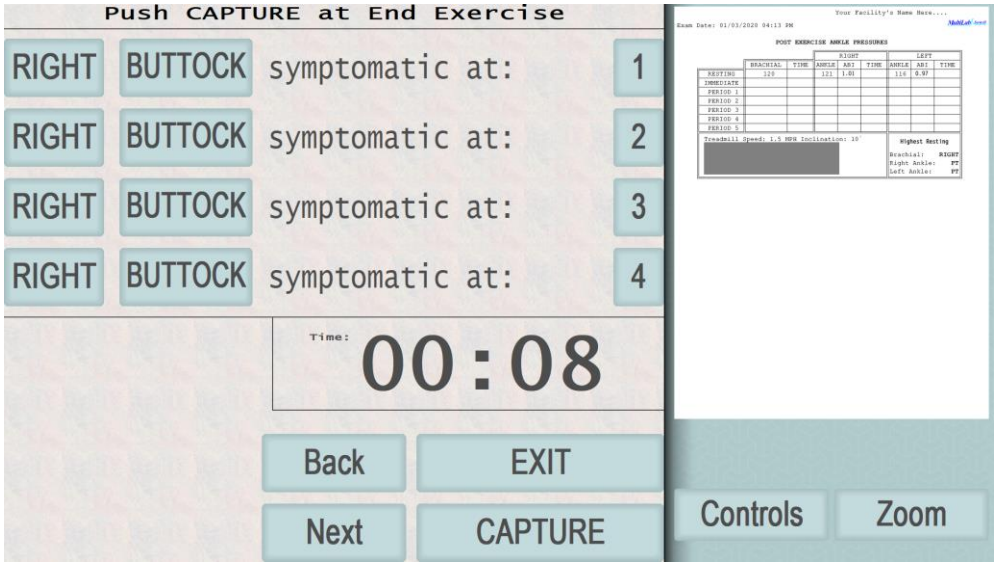
The ILR Controls button allows the user to adjust the sweep speed of the PPG waveform. View allows user to see the report.

Post Exercise Pressures

This exam compares pressures taken at rest (usually brachial and ankle) with pressures taken after exercise (or hyperemia). After the exercise it may take time for the pressures to return to normal, so pressures are usual taken at regular intervals after exercise. To help the technologist keep track of time, the MultiLab will include a timer on the screen; as shown in the following screen:



In addition to showing the time while operating the machine, the MultiLab has a special screen for showing the time during exercise:



1, 2, 3 or 4 If the patient shows symptomatic signs during exercise, press one of these buttons to capture the time that the symptom took place. This time will be placed next to the number pressed.

RIGHT Press this to indicate which side (or both) was symptomatic. Keep pressing this button until the desired side appears.

BUTTOCK Press this to indicate what location was symptomatic. Keep pressing this button until the desired location appears

BACK Takes user back to the previous site.

NEXT Advances user to the next site

EXIT Returns to the "Edit" screen. No symptoms or time is saved.

CAPTURE Will capture the time displayed. In the example above, this would be used to capture the amount of time the patient exercised.

Time Screen ILR

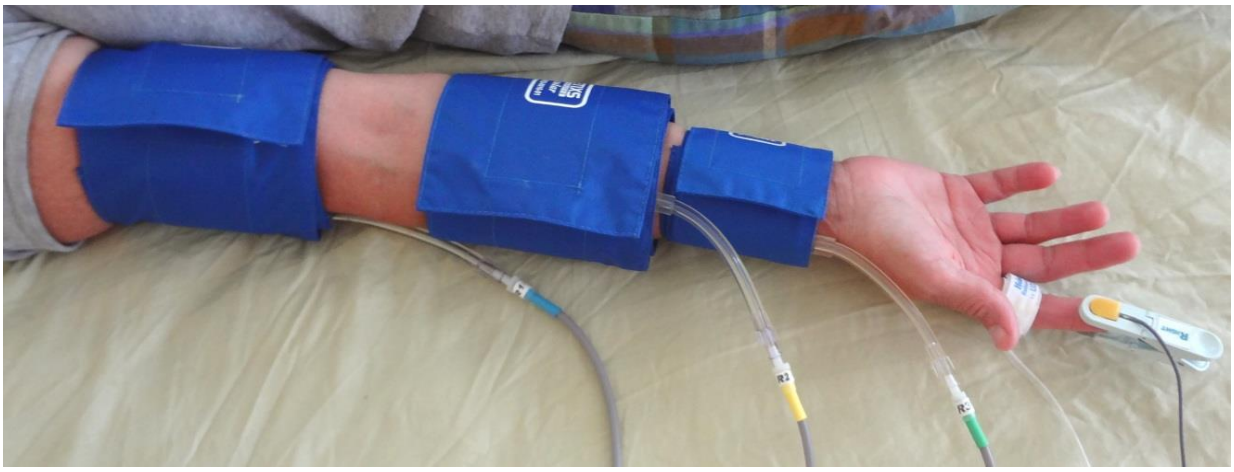
The Controls button offers nothing for the time screen. The report image does show the resting pressures and also indicates the higher pressure for the Brachial and Ankle sites. If you do not have the ILR, you can hit "Back" and "View" to see the report image; simply press "Exit" then "Back" to return to the study. **NOTE**: when taking the post-exercise Brachial pressure, the right hose will always be used.

Upper Arterial Studies

Upper extremity arterial studies are fundamentally similar to the lower arterial studies with the exception of the Thoracic Outlet Syndrome, Raynaud's disease, Allen's Test and Radial Artery Assessment studies, which will be described in detail below.

Segmental Pressures and Waveforms

This exam is indicated when the patient presents with *chronic* arm, hand or finger pain with no visible signs of trauma, swelling or redness. With patient lying supine on exam table, SC-10 cuffs are positioned at the biceps area, the forearm and the wrist, while a DC-2.5 digit cuff is attached to the base of the index finger with the corresponding Right and Left PPG sensors at the tips of both index fingers (see below).



Upper arterial cuff placement, left arm

To obtain pressure from the biceps cuff, use the 8 MHz Doppler transducer at the brachial artery. For the forearm and wrist cuffs, use the 8 MHz Doppler at the radial artery. When doing finger pressures, the MultiLab will automatically activate the Right and Left PPG sensors for this portion of the exam (refer to above section on Toe pressures for obtaining finger pressures).

For a complete upper arterial exam, you will need to obtain waveform tracings of the arms to accompany the pressure readings. You can use PVR or Doppler to obtain these tracings. (Refer to PVR and Doppler Waveform sections above for detailed information.)

Thoracic Outlet Study

This study is indicated when the patient presents with *intermittent* arm, hand or finger pain or numbness. These symptoms can be caused by a mechanical compression of the Subclavian artery and/or attending nerve bundle as they exit the chest cavity, during specific patient movements.

Patient should be seated on exam table for this exam with Right PPG sensor attached to right index or third finger, and Left PPG sensor attached to the corresponding left finger.

Although this exam can be performed with any number of patient maneuvers, the following 5 positions are commonly used for the Thoracic Outlet Examination. We begin the study by recording baseline PPG wave tracings. The Baseline Position is typically hands in lap resting, with palms up.

Adjust the Gain so that the on-screen waveform takes up from ½ to ⅔ of the waveform box. When the waveforms are stable, depress the capture button.

Adson's Maneuver – Have patient take a deep breath and turn head toward the extreme right (or left) side. Typically, the head is turned in the direction of the side being measured. As patient holds breath and has head turned capture wave tracings when stable.

Costoclavicular Maneuver – Have patient take a deep breath and try to touch chin to chest. At the same time ask patient to move both shoulders back as far as possible. Capture wave tracing when stable.

Hyperabduction "A" Maneuver – Have patient sit erect and move arm with active sensor out 90 degrees with the palm facing the floor. Capture waveforms when stable.

Hyperabduction "B" Maneuver – Have patient sit erect and move arm with active sensor straight over head with the palm facing forward. Capture waveforms when stable.

Note that while the above example shows only one active sensor, it is possible to perform this exam with both sensors at the same time. For example, in the case of the Hyperabduction "B" Maneuver show above, it would be done with both sensors and both arms over the head.

Raynaud's Examination (Cold Immersion)

There are various methods for performing the Raynaud's exam. One of the most efficient methods for this evaluation is the use of infrared thermometry (optional accessory for the MultiLab Series II instruments).

Baseline digital temperatures are taken by pointing the temperature sensor directly at the pads of the fingertips, **maintaining a distance of ¼ to ½ inch from digit.** Depress the trigger on the temperature instrument to activate the sensor. Releasing the trigger "captures" the temperature. Repeat this process on the remaining digits.

After all digit temperatures have been obtained, have patient immerse hands (or feet) in an ice-water bath for 30 seconds. After immersion take all digit temperatures quickly after patting the hands dry.

Repeat this procedure at 5, 10, 15, and 20 minute intervals after immersion. Digit temperatures in normal patients will return to or exceed baseline temperatures after 10 minutes. If the temperatures of all digits have returned to or exceeded baseline temperatures, the study can be terminated at that point. Continue temperature measurement until all digits have returned to or exceeded baseline temperatures or until the 20 minute interval has been reached.

Thermometry ILR

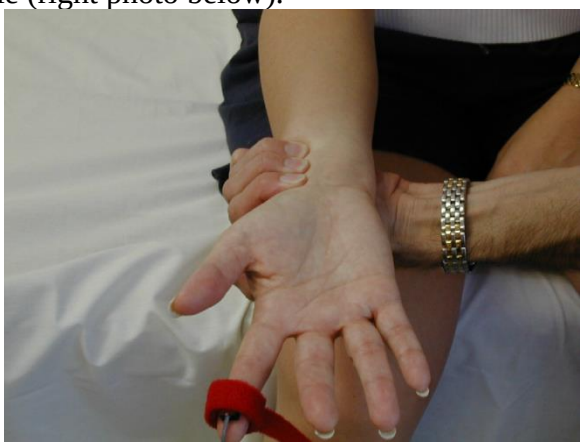
The Controls button offers nothing for the thermometry screen. The report can be viewed and zoomed.

Allen's Test

The Allen's test is useful in assessing arterial contribution to the fingers, and the patency of the Palmar Arch. With patient seated, attach the right PPG sensor to the right index or 3rd finger, and the left PPG sensor to the corresponding left digit.

- Record a "baseline" waveform with patient's hands in lap, palms up (left photo below).
- Compress the Radial artery, and capture on-screen waveform after stabilization. (right photo below)

- Release the Radial Artery; compress the Ulnar Artery. Capture waveform after it stabilizes (left photo below).
- Compress both of the Radial and Ulnar arteries simultaneously, and capture waveform, (or lack thereof) when stable (right photo below).



Radial Artery Assessment Study

This study is useful in ascertaining the suitability of the Radial artery for harvest in Coronary Bypass Graft

surgery. To perform the exam, patient should be seated with hands in lap. Place the PPG sensor on the thumb of the hand to be examined. Adjust Gain so that waveform takes up a half to two-thirds of the on-screen waveform box. Capture waveform when stable. Leaving the sensor in place, compress the radial artery with your index, third and ring fingers (see Allen's Test). The resulting on-screen waveform will reflect the blood flowing to the thumb from the Ulnar Artery through the Palmar Arch. Capture this waveform when stable.

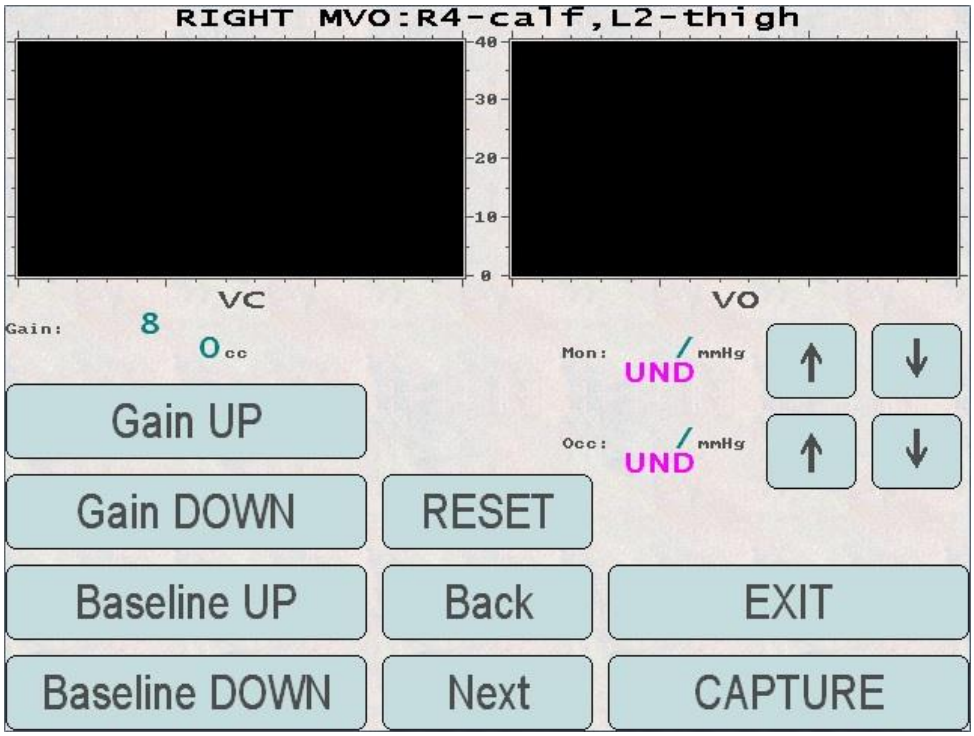
Next, place the PPG sensor on the index finger and capture waveforms with and without Radial artery compression. Repeat on remaining digits.

Lower Venous Studies

MVO/Maximum Venous Outflow Examination

This examination will test for obstruction to venous outflow from the lower leg regardless of the cause. It is a measure of the speed which blood can flow out of a maximally congested lower leg where an occluding thigh cuff is suddenly removed. The advantage of this study is that it is sensitive to obstruction due to any cause at almost any level. It is also capable of detecting obstructing thrombus in the calf veins, iliac veins, and vena cava where ultrasonography and venography are less effective. It also detects venous obstructions due to tumors, and other extrinsic disease processes. The disadvantage to this test is that it is only able to detect significant venous obstructions and will not rule out deep vein thrombosis.

First, raise patient's leg while in supine position, approximately 8" using a pillow or other cushioned material. The knee of the leg to be examined should be flexed and externally rotated. With the patient properly positioned, place a 10 CM cuff around the maximum circumference of the calf and attached the R4 hose. Place a thigh cuff to the high thigh area and attach the L2 hose.



On the screen we will see two waveform tracings: on the left venous capacitance (VC), and on the right venous outflow (VO). Inflate the 10 CM calf cuff pressure to 15 mmHg using the up arrow for "Mon:" on the software screen. Allow for the pressure to stabilize in the cuff and adjust the pressure as necessary to get to 15 mmHg (**NOTE**: do not adjust the "Mon:" cuff for the remainder of the exam). Now press the "Reset" button to calibrate the baseline. Next, inflate the thigh cuff to 60 mmHg using the up arrow for "Occ:" on the software screen. The thigh cuff will then inflate and cause the veins in the thigh area to occlude; the arterial flow into the calf will cause swelling and displace air in the 10 CM cuff (**NOTE**: continue to adjust the pressure in the "Occ:" cuff to

keep the pressure at 60 mmHg). The waveform tracing will rise above the baseline in the VC capture box (If after 30 seconds the tracing goes off the chart, abort the test by removing the hoses from the cuffs and reducing gain). The waveform tracing will rise until it reaches a plateau for a period of 10 seconds with no increase.

When the plateau is reached press "Capture" and then, a second later, release the air pressure in the occluding thigh cuff (**NOTE**: it is advisable to use a rapid deflator on the thigh cuff). This will activate the VO capture box and the waveform tracing will go down toward the baseline. You must press "Capture", again, within 5 to 25 seconds of the first capture. In the VO capture box scroll the point of the pressure release, of the occluding thigh cuff, to the left ⅓ of the box. Position the white vertical line at the point of deflating the cuff. The red line will represent the expected time (typically 1 second) for measurement of venous outflow (after 1 second); the desired result is a percentage of VC to VO1 (venous outflow after 1 second) (**NOTE**: the waveform's trace point at the right size of the VC capture box indicates the value for VC). If the flow returns to baseline within 1-2 seconds, no significant venous obstructions are indicated. If the flow takes longer to return, this will demonstrate that there is a significant venous obstruction.

MVO ILR

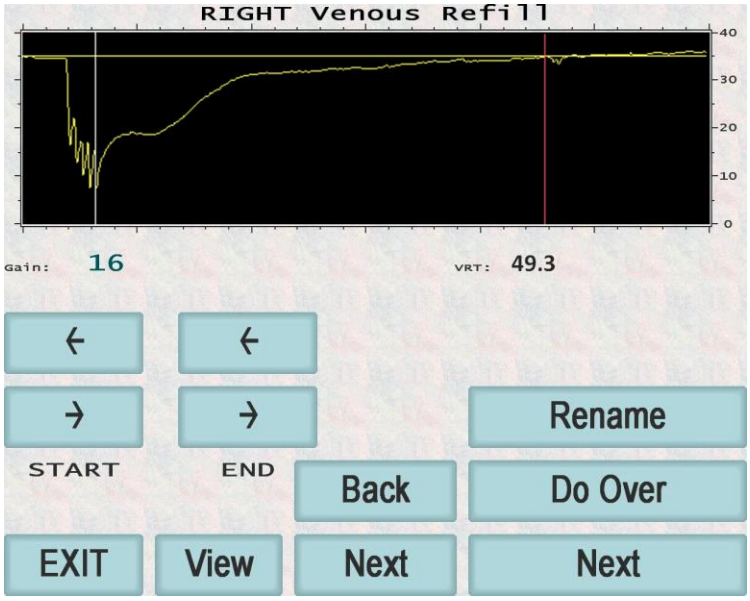
The Controls button offers a change to the sweep speed. The report can be viewed and zoomed.

Venous Refill Examination

This examination will test the competency of the valves in the leg veins. Patient should be seated on padded examination table with legs hanging unsupported (exam can also be performed with patient seated in chair with knee bent and foot slightly forward). It is important that the exam table have adequate padding so as not to compress the Saphenous (SP) Vein.

For right leg examination, place the right PPG sensor approximately 2" above the ankle on the Medial aspect of the leg. Press the "Reset" button on the MultiLab screen to display output from PPG sensor. It is important to have the leg at a stable venous capacitance state before beginning the examination. This is achieved by continuing to press the "Reset" button until the on-screen tracing from the PPG sensor shows no more upward movement.

When on-screen tracing is stabilized, press the "Reset" button once more and wait for 5 – 7 seconds. (This will allow the interpreting physician to see that indeed the patient had achieved a stable venous state before exercise.) After the 5 – 7 second period, have patient dorsiflex and plantar flex the foot 5 to 7 times to empty the calf veins. Have patient relax limb and wait for the screen to auto-capture. (**NOTE:** you can also capture the results by pressing the "Capture" button any time after the deflected tracing re-crosses the baseline.)



Each foot flexion should result in a downward deflection of the PPG tracing. Gain should be adjusted so that the downward deflections measure 15 or more millimeters (total) on the MultiLab screen. Occasionally you will encounter a patient who through arthritis or other motion limiting condition, will not be able to flex the foot deep enough or often enough to produce the vein emptying necessary for a clinically acceptable examination. In these instances, it may become necessary to augment the limb manually to achieve the vein emptying required.

To manually augment the limb, place both hands around the calf of the limb to be examined and squeeze the limb 5 – 7 times within 5 – 7 seconds. Augmentation should produce a downward deflection of the PPG signal like is shown in photo above. Remove hands from limb and wait for screen to auto-capture.

Venous Refill ILR

The Controls button can change the sweep speed and inflation target. The report can be viewed and zoomed.

Calculating the Results

When the capture screen is displayed, you must adjust the timing calipers to calculate an accurate Venous Refill Time (VRT). Using the END "→" key, move the end timing caliper (in Red) to the point at which the deflected PPG tracing crosses the baseline (see previous figure).

Use the START "← →" buttons to move the Start timing caliper (in white) to the end of the last downward deflection as shown above.

The time displayed, between the two timing calipers, is the Venous Refill Time for that limb (shown onscreen).

Use of Tourniquets

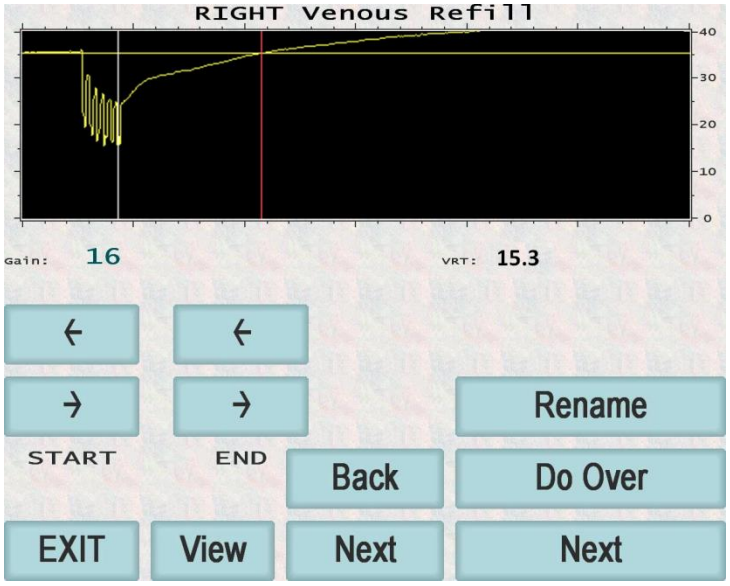
The MultiLab instruments can be configured to print up to five VRT graphs on a single page. Many practitioners like to measure VRT after isolating the superficial or perforating veins using tourniquets above the ankle and above or below the knee. There are two common methods of applying the tourniquets. The first method is to take a wide rubber strip or length of tubing and to tie it around the desired area. The second method involves the use of a tourniquet cuff (typically a 5cm width). This cuff is inflated to 60 mmHg pressure by attaching the appropriate pneumo hose from the MultiLab to the tourniquet cuff and pressing the "Inflate" button once.

Helpful Hints for Venous Refill Exams

As the veins are elastic, it is not uncommon for the veins to expand during the examination. The sign of this occurring is when the venous refilling trace bisects the baseline after the foot exercises, and continues up and off the screen (see photo below). This is an indication that the venous capacitance has increased. To reduce or

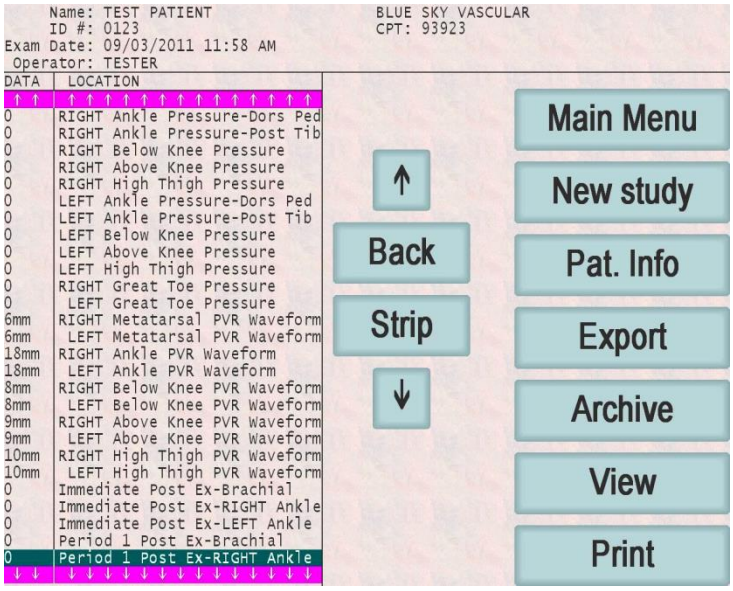
eliminate this artifact, you can "condition" the venous system prior to the examination, by asking the patient to perform 10 – 15 toe raises before applying the sensors and beginning the examination.

If you observe an abnormal tracing (VRT of <20 sec. with increased capacitance) like the one below, press "Do-Over" and repeat the exam.



CHAPTER 10: EDITING EXAM AND PRINTING REPORTS

If you are in the middle of an examination, and wish to jump to the middle or end of the program, press the "**EXIT**" button to bring up the EDIT screen as shown:



The cursor will automatically default to the location you exited from. Using the "↑" and "↓" buttons, you can scroll to any other location quickly by highlighting the desired location and touching the "Back" button. In the event of a power outage, simply move the highlighted cursor to the first blank data field, as shown above, and then press the "**Back**" button to resume the patient study.

The buttons shown on the Edit Screen function as follows:

BACK will return user to the site that is highlighted
STRIP will print (in black and white) JUST the information that the cursor is currently highlighting
UP ARROW will move the cursor bar up
DOWN ARROW will move the cursor bar down

MAIN MENU will exit user to the MultiLab Start Screen
NEW STUDY will allow user to perform another study on current patient without having to re-enter patient name or identification. Note: the name of this button is defined in the System Setup.
PAT. INFO will allow user to add or correct any patient information that is missing or incorrect
EXPORT will bring up the export control menu (see below)
ARCHIVE will bring up the archive control menu (see below)
VIEW will display any captured information, as it will appear on the printed page
PRINT will bring up the print control menu (see below)

Edit Exam ILR

The exam edit ILR defaults to the report view and allows you to touch the report to retake a patient measurement. The controls are the same as "ILR Temp File Functions" on page 44. The following buttons are also provided:

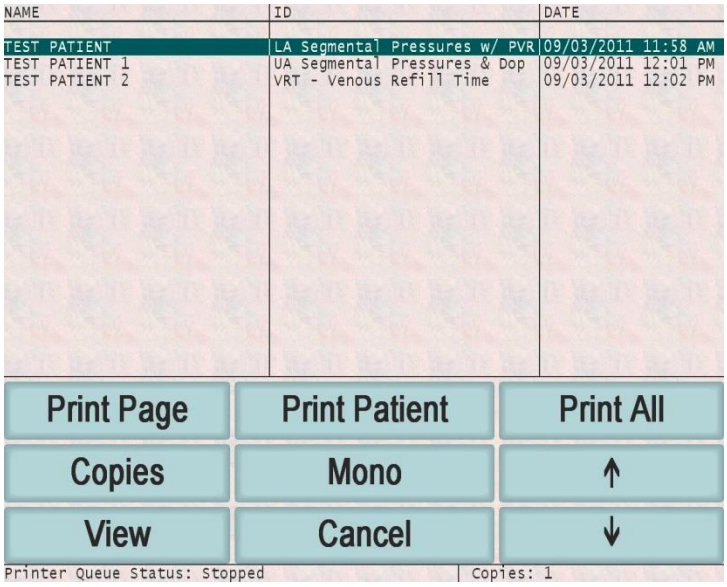
RIGHT ARROW will change the edit focus to the next page of the patient exam.
LEFT ARROW will change the edit focus the previous page of the patient exam.

Printing Patient Reports

The MultiLab software has a sophisticated printing system. It can queue and print multiple report pages while allowing the user to continue operation of the MultiLab. Report pages will print in the background while you operate other functions of the MultiLab. Depending on your usage of the MultiLab printing may temporarily be suspended, but will continue as system resources become available. For example, entering patient information requires fewer resources than inflating cuffs. Note that in the Windows version, the print queue is handled by the operating system.

Note: You should not exit or turn off the MultiLab program (see Exit on the Start Screen) until printing has finished. If this or other incidents, such as a paper jam or paper out, should occur your patient data will be cleared from the printing system, but can be re-printed at any time in the future. Simply select "Temp Files" from the Start screen and re-print any unprinted report pages after any problem is resolved. Also, after clearing problems with a printer (paper out, paper jam, etc…) it is a good idea to power cycle (turn off then turn on) the printer before reprinting any pages.

When you press the print button from a menu screen, the following screen will appear:



The following functions are available from the print control menu screen:

Print Page adds the page that is highlighted to the printing system and exits.
Print Patient adds all pages matching the highlighted patient name to the printing system and exits.
Print All adds all of the listed pages to the printing system and exits.

Copies will allow the user to print multiple copies of the same report. Number is in lower right of screen.

Mono/Color will allow the user to print reports in Color or Monochrome (Black & White), e.g. press Mono if you want a report in Black and White.

View will display the highlighted study, as it would appear on the printed page. Note: the report color in view is set in the System Setup.

Cancel will exit the print control menu. Also resets the number of copies.

Up Arrow will move the cursor bar up.

Down Arrow will move the cursor bar down.

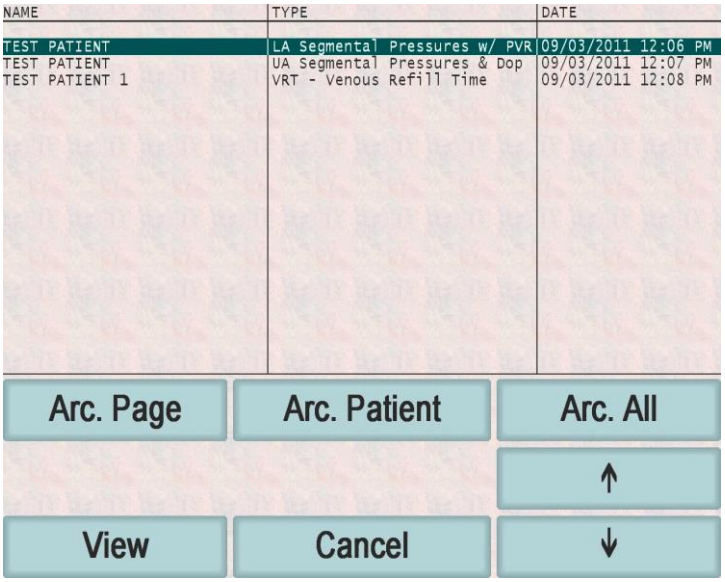
Printing ILR

The ILR will, by default, show the report page for the highlighted line. The INFO button changes the ILR to the name of the printer and its status. Press the Update button to refresh the printer's status as it changes over time.

Archiving Patient Reports

Your MultiLab is capable of storing fifty thousand report pages in its archive. **The limitation is that once a study is archived, it can no longer be changed.** Thus, you shouldn't archive a report page until you are sure that no further changes are needed (say, after a physician signature). Once a report page has been archived, it is permanently removed from the temporary file and then placed into the lookup (see Chapter 4, Lookup Functions).

When you press the archive button from a menu screen, the following screen will appear:



The following functions are available from the archive control menu screen:

Arc. Page archives the page that is highlighted, removes it from the temporary file, and exits.

Arc. Patient archives all pages matching the highlighted patient name, removes them from the temporary file, and exits.

Arc. All archives all of the pages, removes all pages from the temporary file, and exits.

View will display the highlighted study, as it would appear on the printed page.

Cancel will exit the archive control menu.

Up Arrow will move the cursor bar up.

Down Arrow will move the cursor bar down.

Archive ILR

The Archive ILR will show, by default, the destination file paths for the archive. The View button is available.

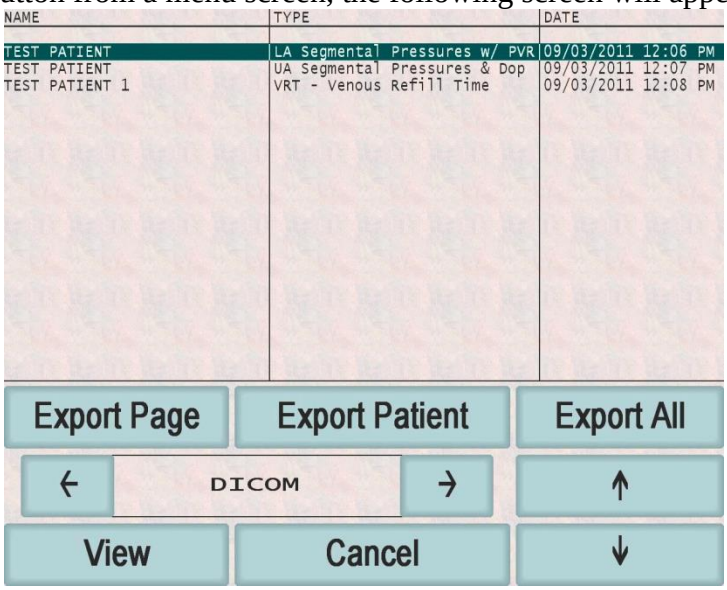
Exporting Patient Reports

The export feature of the MultiLab is designed to be a configurable way of connecting the MultiLab to an external device (not the printer, display, or internal storage of the MultiLab). Some examples of external devices are:

PACS (DICOM)	ZIP Drive	ICAVL Database	CD-R/W
Network Server	Floppy Disk	Facsimile	USB Drive

Note that connectivity is an option for the MultiLab and must be purchased separately. Specific connectivity options are outside the scope of this manual and are typically unique for each user. This section is included here because the export menu is standard, regardless of what device is being exported to.

When you press the export button from a menu screen, the following screen will appear:



The following functions are available from the export control menu screen:

Export Page	exports the page that is highlighted and exits.
Export Patient	exports all pages matching the highlighted patient name and exits.
Export All	exports all of the pages and exits.
View	will display the highlighted study, as it would appear on the printed page.
Cancel	will exit the export control menu.
Up Arrow	will move the cursor bar up.
Down Arrow	will move the cursor bar down.
Right Arrow	change the type of export
Left Arrow	change the type of export

Export ILR

The Export ILR will show, by default, what will be exported and where the export will go. The View button is available.

CHAPTER 11: CONFIGURING STUDIES

Since there are so many variables in the types of vascular studies that are performed, the order in which they are performed, and a multitude of personal preferences in the field of Physiologic Vascular Testing, the MultiLab Series II instruments have been designed to give the user unparalleled flexibility in customizing the MultiLab to each facility or even to each individual within the facility.

Some of the more common items that can be customized are:

Inflation targets which can be preset for each site (e.g. the Ankle site can be preset to inflate to 165 mmHg, while the calf can be set for 175 mmHg, Thigh – 180 etc…)

Deflation Rates there are 40 different bleed rates for the pressure cuffs, adjustable in 1/8th mm per second intervals.

Sequencing order some prefer to do waveforms first, and then finish with Segmental Pressures. Others prefer the opposite. Some like to start at the thigh and work down the leg, while others like to start at the ankle and move up.

Wherever you like to start, and whatever order you like to proceed, the MultiLab can be configured exactly to your liking, even down to how you like your finished printed report to look.

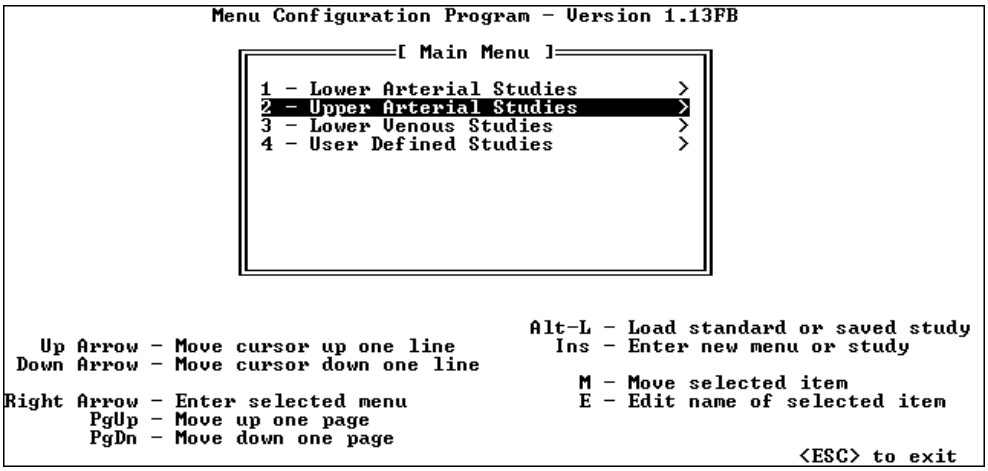
Before you begin, start to think about the protocol that you use for a specific type of study. Whether it is an upper or lower extremity exam, it may consist of any combination of Patient questions, Limb Pressure measurements, Doppler, PVR or PPG wave tracings, Post-exercise measurements, digit pressures, and possibly technologist notes or a physician interpretation. Unlike any instrument ever designed, the MultiLab is not "modality driven" but "protocol driven", meaning that a given study may combine any or all of the above listed components, and that unlike any other vascular instrument available, allows the user to determine what the final exam print-out will look like. For example, you can take a pressure measurement anywhere you desire, follow that with a digit PPG wave tracing, a PVR tracing at the Right and Left Ankles, and then finish with Doppler wave tracings at the Common Femoral sites. You can then press the "Print" button and combine all these various modalities on a 1 page printed report.

Although there are many variables that can be modified, the MultiLab instrument comes pre-loaded with a number of commonly performed standard vascular procedures that are ready to use. If you are an advanced Vascular Specialist, and want to set the instrument up to your exact specifications, this chapter will familiarize you with the basics to really personalize your instrument. Please bear in mind that your instruments' Patient studies can be modified at any time, and if you should require more assistance in customizing any portion of your studies, please do not hesitate to contact Unetixs Vascular. It is a simple matter to call us on the phone, describe the desired modifications, and let us configure custom protocols for you.

The easiest way to custom-configure a study is to choose a pre-loaded MultiLab Standard study which most closely matches your desired protocol. (Please don't be afraid to proceed, as if a mistake is made, the study can be deleted, and a new one loaded an infinite number of times from a directory within the MultiLab software program.)

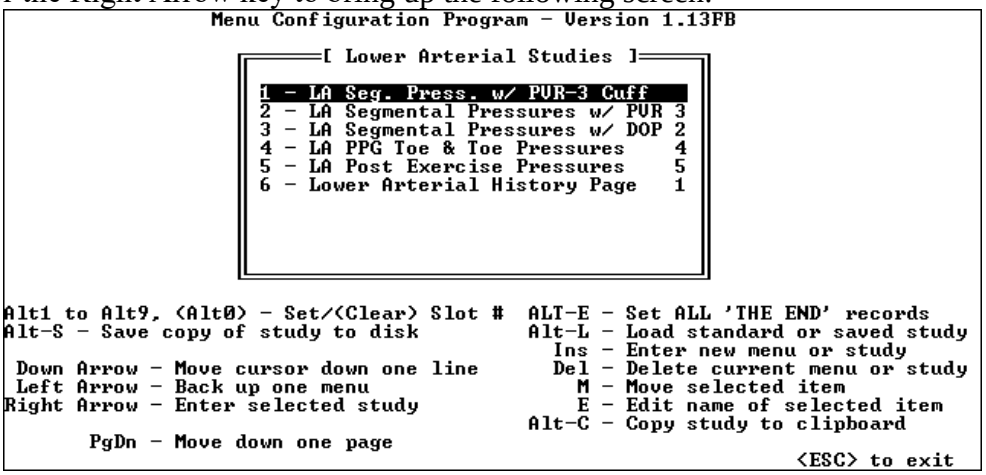
NOTE: Before custom configuring any Patient studies, press the "Temp Files" button on the Start screen and archive any files in the directory. Failure to do so may result in loss of data in an un-archived Patient study.

Press the "Setup" button, followed by the "Configure Studies" button. If there are no studies in the "Temp Files" directory, you will see the following screen, which is a representation of the Main Study Menu as it ships from the factory:

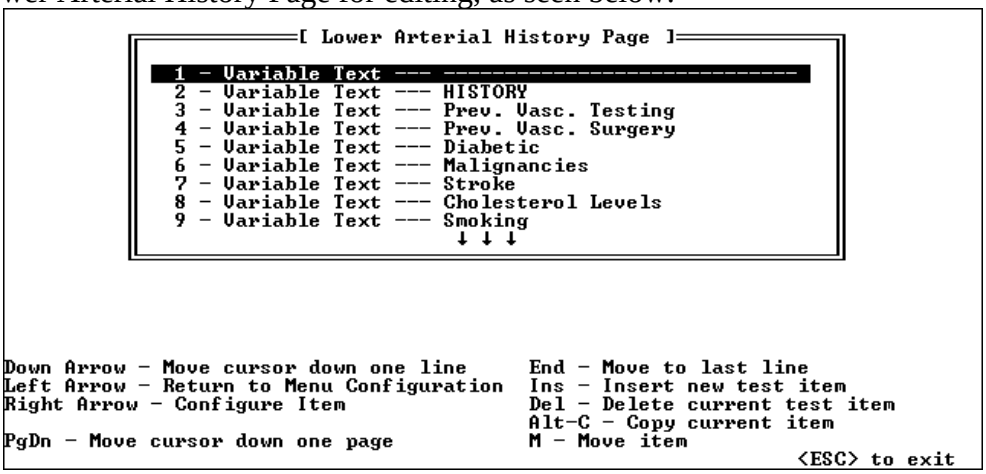


Customizing an Existing Study

The keyboard keys work as stated below the Main Menu box. If, for example, we wished to customize the existing Lower Arterial Patient History Page, you would highlight the "Lower Arterial Studies" entry (#1) and press the "Enter" or the Right Arrow key to bring up the following screen:

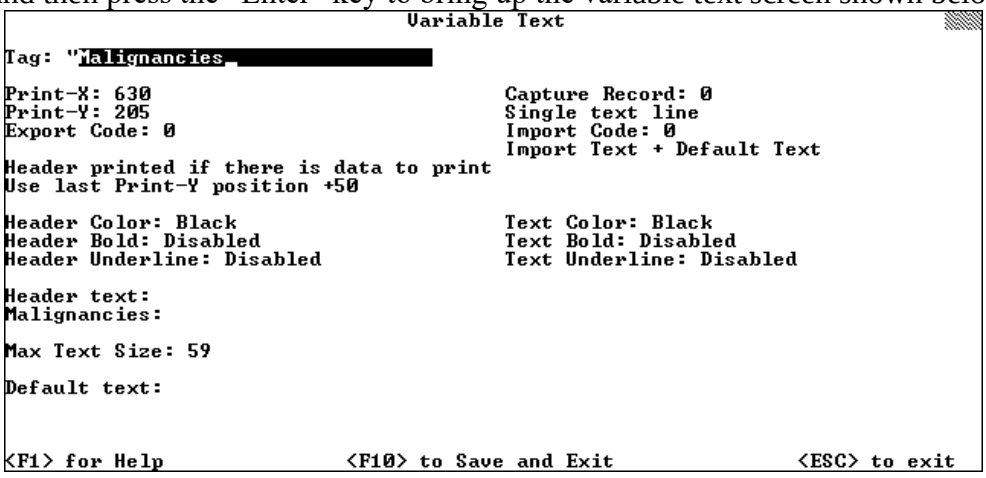


Highlight the "Lower Arterial History Page" entry by using the up and down arrow keys, and press the "Enter" key to open the Lower Arterial History Page for editing, as seen below:



Inside any MultiLab standard or custom studies, you will find a variety of components or "modules" that make up that study. Fixed Text and Variable Text modules are examples of these. These modules are for printing text entries on the report page. As you might imagine, a "Fixed Text" module will place a text entry on the report page that is "Fixed" or in other words, not able to be changed by the operator during the examination. The "Variable Text" module, on the other hand, would allow the user to input text data, such as a Patients name or ID, or whether the patient is diabetic, a smoker, or has a history of Heart Disease.

If for example, you wished to change a question on the Patient History page from "Malignancies" to "Hypertension" you would simply highlight the sixth Variable Text entry that reads "Malignancies" (using the down arrow key) and then press the "Enter" key to bring up the variable text screen shown below:

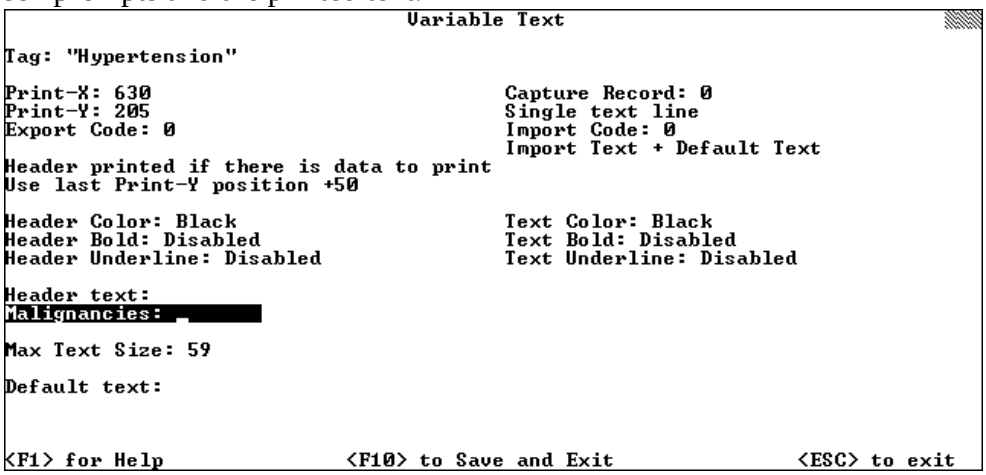


Note: Since this chapter is a basic primer on configuring studies, only some of the properties will be described.

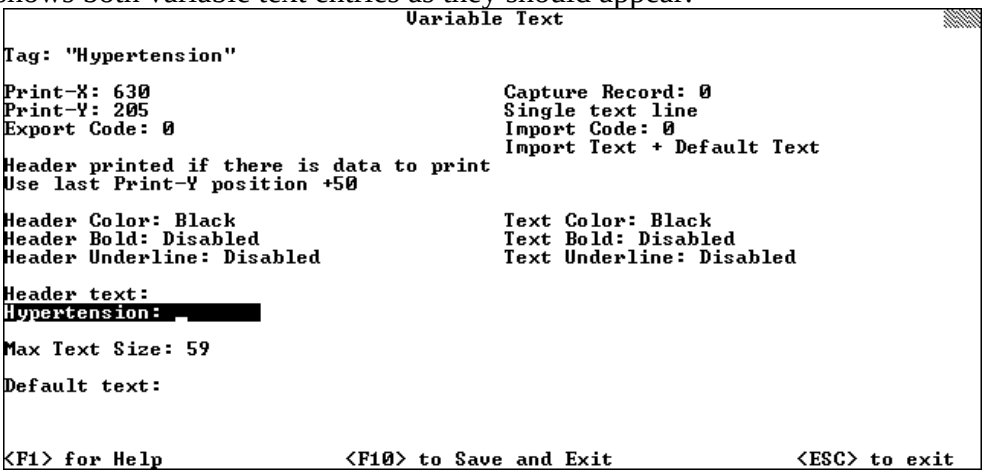
Some various fields and functions of the "Variable Text" entry are described below:

TAG	Will display the text printed in the highlighted text box inside the study configurator and on the MultiLab screen (but WILL NOT be displayed on the printed page.)
PRINT X	Defines where on the page the data will be printed on the horizontal plane (left to right)
PRINT Y	Defines where on the page the data will be printed on the vertical plane (top to bottom)
HEADER TEXT	Will print the text printed in the highlighted text box below on the MultiLab report

In the example below, we have substituted the word "Hypertension" for the previous entry (Malignancies) in "Tag" box but not in the "Header Text" box. Failure to change both field entries will result in a discrepancy between the on screen prompts and the printed text.

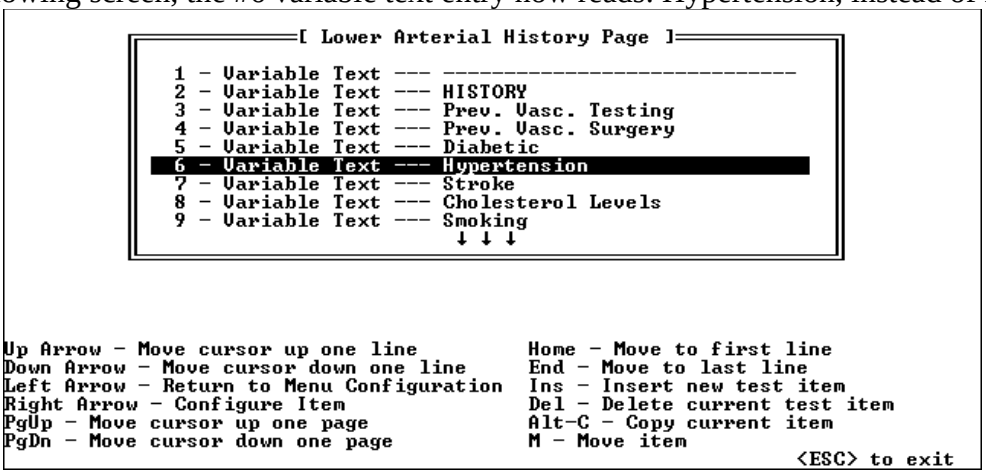


The screen below shows both variable text entries as they should appear:



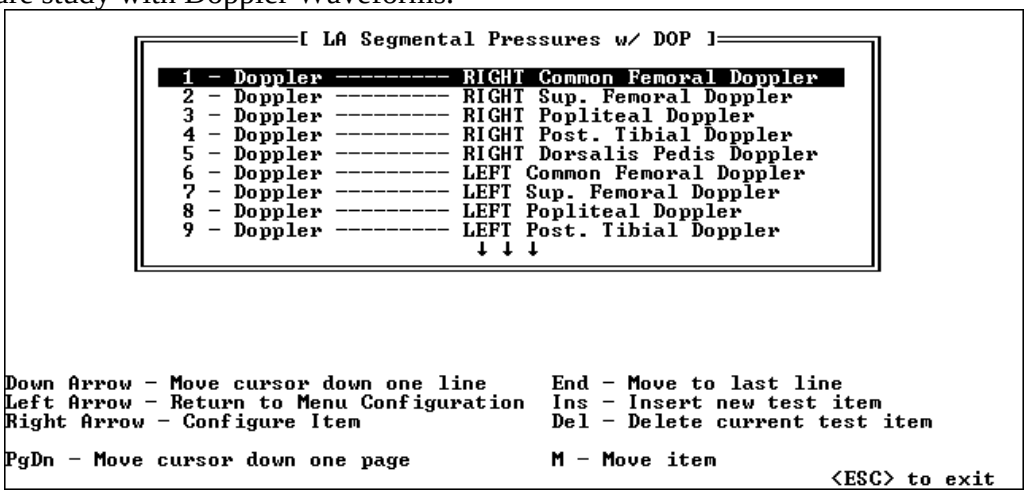
Note: it is necessary to add 1 space after the colon when changing "Header Text" entries, before pressing the "F10" key to save and exit. Failure to do so will result in a text misalignment on the printed report.

As seen by the following screen, the #6 variable text entry now reads: Hypertension, instead of Malignancies:



Changing the Sequence of an Examination

To give an example of how to change the sequence of an exam's components, we'll go into a Lower Arterial Segmental Pressure study with Doppler Waveforms.



You will notice that the first item that will come up is a Doppler waveform at the Right Common Femoral site. If you wanted to rearrange the sequence of the study, and take your Doppler tracings after your pressures, you can simply scroll down to the desired pressure site, and select it by pressing the "M" (for Move Item) key. Once

selected, you can now move the selected pressure site to the number one position, and "paste" it into place by pressing the "Enter" key when it is in its desired location.

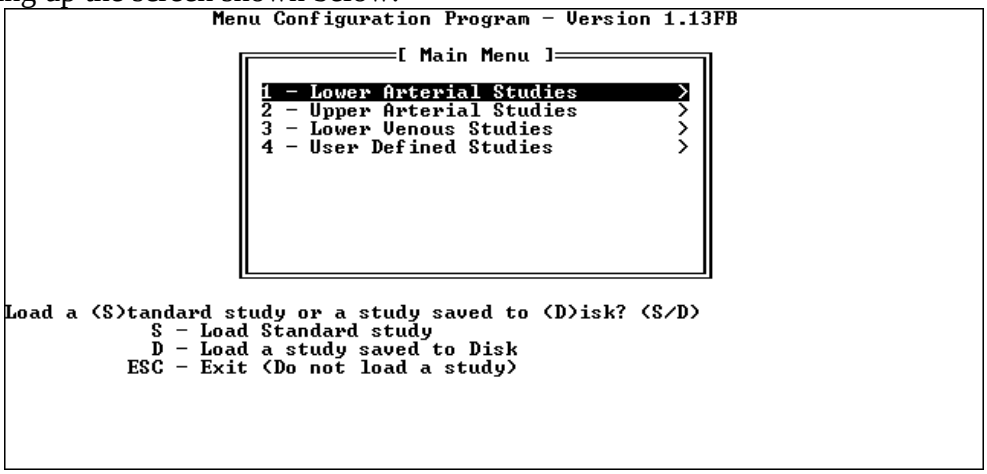
Loading and Customizing a New Standard Study

Again, you can customize an existing patient study as shown above or you can load a standard study. Unetixs' "Standard" studies include almost every aspect or "modality" that someone may wish to perform in a patient encounter. For example the "Segmental Pressures with PVR" standard study includes: Resting systolic pressures at the (Right and Left) Brachial, Ankle DP, Ankle PT, Calf, Above Knee, and High Thigh sites as well as PVR tracings at the Trans-Metatarsal, Ankle, Below Knee, Above Knee and High-Thigh sites.

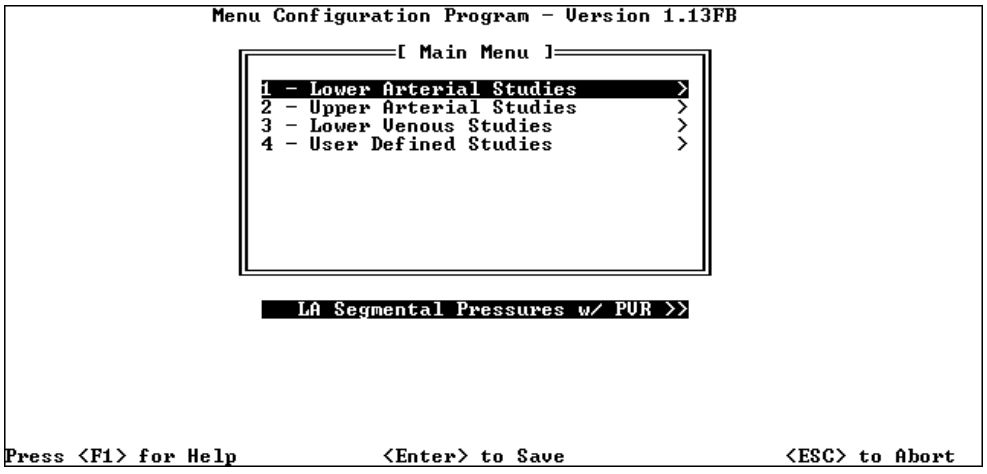
Also included in this "Standard" are Systolic Toe Pressures, immediate Post-Exercise pressures at the Brachial and Ankle sites, and 3 more intervals of Post Exercise pressures after that. As is pre-programmed into this Standard Study, the intervals will read: Period 1, 2, and 3 Post Exercise. If your exam protocol calls for pressures to be taken 3 minutes, 6 minutes and 9 minutes after exercise, the program can be easily modified to reflect these values both on-screen and on the printed report.

If you do not perform Toe Pressures or Post-Exercise Pressures as part of your Lower Arterial protocol, these items can simply be deleted, and will not show up on your on-screen prompts or your printed report. The "Segmental Pressures with Doppler" Standard is similar in configuration, but will prompt the user to obtain Doppler tracings at the Common Femoral, Superficial Femoral, Popliteal, Posterior Tibial, and Dorsalis Pedis arteries. Any one of these Waveform Tracing sites can be deleted or renamed as desired.

To load a new "Standard Study" to modify, simply press the "Alt L" key from anywhere in the study configurator, to bring up the screen shown below:



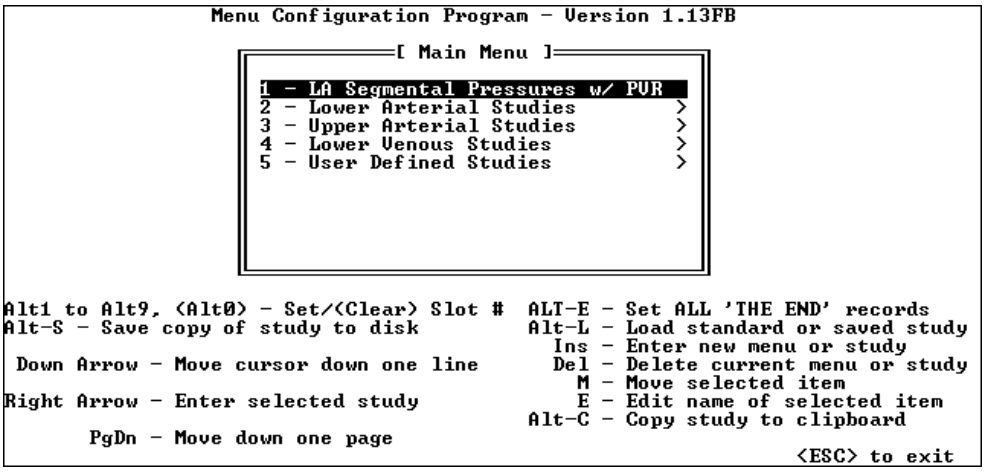
Pressing the "S" key to load one of the standards stored in permanent MultiLab memory will bring up the following screen:



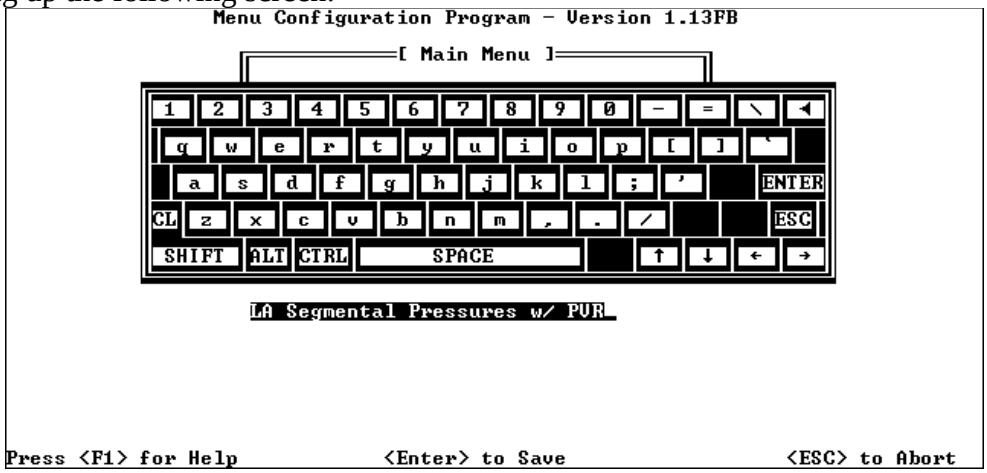
Pressing the "Right Arrow" (→) key will toggle through the following Standard Studies:

1) LA Segmental Pressures w/ PVR
2) LA Seg. Pressures w/ PVR-3 Cuff
3) LA Segmental Pressures w/ DOP
4) LA PPG Toe & Toe Pressures
5) LA Post Exercise Pressures
6) Lower Arterial History Page
7) VRT – Venous Refill Time
8) MVO - Maximum Venous Outflow
9) UA Segmental Pressures & PVR
10) UA Segmental Pressures & DOP
11) UA PPG Fingers & Finger Pres.
12) Upper Arterial History Page
13) Thoracic Outlet Study
14) Allen's Compression Test
15) LA Cold Tolerance Thermometry
16) UA Cold Tolerance Thermometry
17) Impotence Assessment
18) LA Quick Pressures w/ PVR
19) UA Quick Pressures w/ PVR
20) Right Radial Assessment w/PPG
21) Left Radial Assessment w/PPG
22) LA Post Exercise PPG Pressure

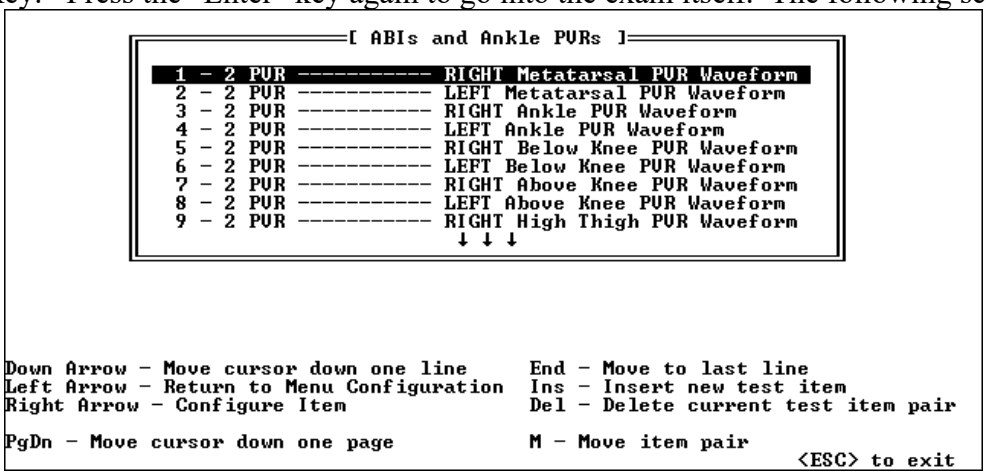
For example, let's make a new custom study that will be a follow-up exam for patients who have had bypass surgery. The new study will be a "limited" exam consisting only of ABIs and PVR tracings at the ankle. Since the standard "LA Segmental Pressures w/ PVR" includes those components, and many more, we will load that standard to begin our new study. Pressing the "Enter" key when that standard is displayed (as above) will load it onto the Main Menu screen as follows:



Let's begin by changing the name of the study. To do this, simply press the "E" key when the desired study is highlighted to bring up the following screen:



Using the "backspace" key, delete the contents of the cell, and then type in "ABIs and Ankle PVRs" and then press the "Enter" key. Press the "Enter" key again to go into the exam itself. The following screen will appear:

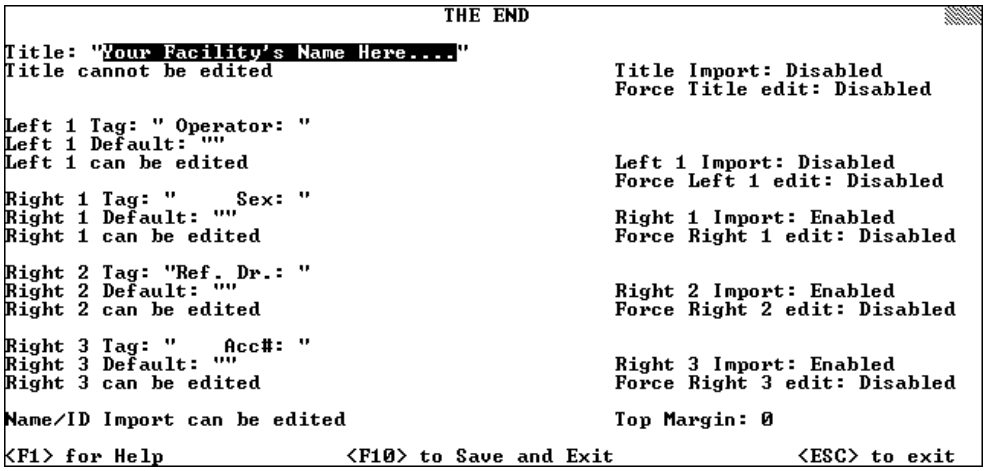


To remove the Metatarsal waveforms, press the "delete" key and then pressing the "Y" key when asked "Are you sure you wish to delete this item?". Note that both the left and right will be removed with a single deletion. Since we wish to keep the Ankle waveforms, we will skip those two sites and continue on by deleting the Below Knee, Above Knee, and High Thigh waveforms the same way.

We will then skip over the Brachial and Right Ankle pressures, now items3, 4, 5, and 6, and delete the Below Knee, Above Knee, and High Thigh pressures leaving the Left Ankle pressures as items 7 and 8. Then delete the Below Knee, Above Knee and High Thigh pressures for the Left side along with the Great Toe pressures (only one delete for the pair!). It will appear at this point that our goal has been accomplished, but there is one more step to perform: removing the Post-Exercise pressures and setting the Facility Name that will print on the top of the report page.

There are two ways to remove the Post Exercise pressures; you can scroll down and manually delete them or put them below the "The End" entry. Since we need to make a modification in "The End" entry any way, we will choose to put them below it. To get to the "The End" entry, simply press the "End" key and your cursor will automatically be moved to that location (#108). We will then proceed by moving the "The End" entry up to position #44 and pressing the "Enter" key to "lock" it in that location. Any item that appears below the "The End" entry will not be a part of the examination.

To finish our custom exam, we will press the "Enter" key on the highlighted "The End" entry to bring up the following screen:

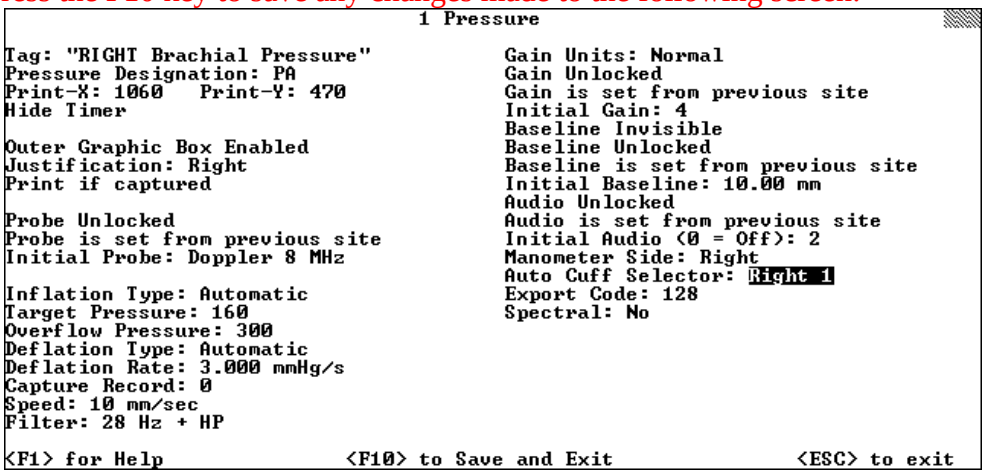


Use the backspace key and keyboard to correct the facility name. Press F10 key to save the change. The new exam is finished. Press the "escape" key several times to return to the MultiLab Start screen to perform the exam.

Customizing Pressure Studies

As mentioned earlier, there are a number of parameters that can be configured within a pressure examination. Below is an example of a single pressure screen. Rather than explain all the parameters in detail, we will instead focus on the most common modified elements.

Note: You must press the F10 key to save any changes made to the following screen:



Changing the Target Pressure

The target pressure is the pressure the MultiLab will inflate the pressure cuff to with one touch of the screen, or remote control. To change the target pressure, simply toggle down to the "Target Pressure" line; then, using the right and left arrow keys, the default value can be increased or decreased. Some users prefer to set the target pressure to 200mmHg, and simply stop the inflation process by pressing the "deflate" button once the vessel is compressed.

Changing the Deflation Rate

By moving your cursor down to the "Deflation Rate" line the deflation rate can be changed by using your left and right arrow keys. The factory preset deflation setting is 3 mmHg deflation per second, but that rate may be increased or decreased by 1/8th mmHg increments. The maximum bleed rate available is 5 mmHg of deflation per second.

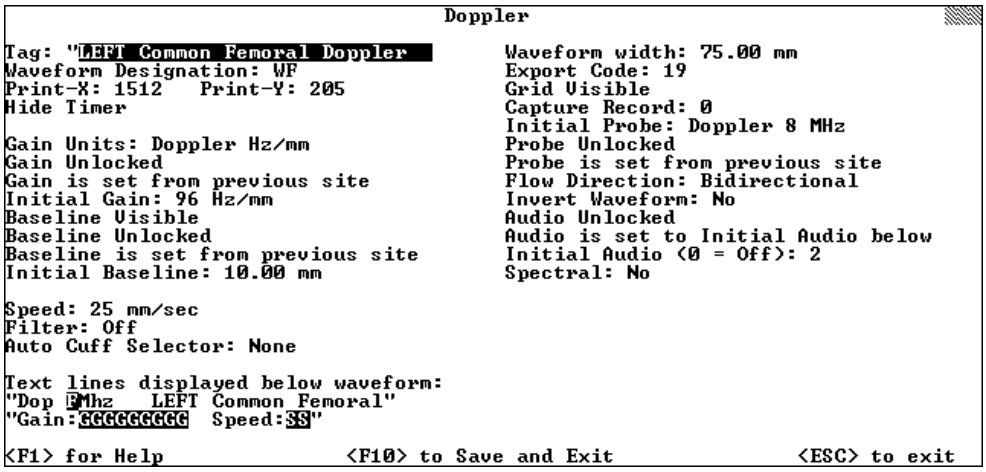
Changing Active Inflation Hoses

You can assign any inflation hose, on a MultiLab with an auto cuff selector, to any cuff site. Move the cursor to the "Auto Cuff Selector" line and using the right and left arrow keys to select Right or Left hoses 1 – 6 to be assigned to the site listed at the top of the screen.

Modifying Doppler Studies

If you are performing a Doppler Waveform study, there are a number of parameters that you can adjust to further customize your instrument.

Some of the more common parameters to modify in a Doppler Waveform Study would be Site to examine, where the waveform is to be printed on the finished report, Gain units, Baseline, and Sweep Speed.



Doppler Gain Units

Doppler gain units can be expressed in "Hz/mm" (Hertz per millimeter) or "Normal" values. The former is a value that describes the frequency shift of the Doppler probe, and the latter would be more a "laymen's" version of this. The factory default setting is "96 Hz/mm". What this means is that a Doppler shift of 96 Hz from the Doppler probe will cause an upstroke of 1 mm (one millimeter) in the on-screen waveform box and on the printed report.

Even though scientifically correct, this display of gain may be counter-intuitive to some, as the smaller the gain units expressed in this fashion, the HIGHER the gain. For example, a gain setting of 48 Hz/mm would require half the amount of Doppler shift to generate the same 1 mm upstroke, effectively increasing the gain by a factor of two.

For those with a more linear mindset, we have the ability to display the Gain units in the "Normal" mode, in which a Gain setting of "4" correlates to the 96 Hz/mm setting described above. With "Normal" Gain units, a doubling of the Doppler gain would be "8" (correlating to 48 Hz/mm), a value that is twice that of 4. Changing these values (by using the Left and Right arrow keys in the configurator) will change how they are displayed on the MultiLab Video Screen and on the printed report.

Doppler Filter

The operator also has the ability to "preset" a Doppler Filter to remove waveform artifact in subjects with very low blood flow at high gain settings. The factory preset for this feature is "Off" as the Unetixs Doppler, while being quite sensitive, is relatively free of artifact. There are four levels of filtering available from 28 Hz (least amount of filtering) to 3.5 Hz (highest level of filtering). As filtering can affect important diagnostic waveform criteria, Unetixs recommends not using Doppler Filters from the preset, but to use only filtering when necessary during patient examinations.

Doppler Baseline

The factory baseline preset for Doppler Waveforms is 10 mm, meaning that of the 40 mm vertical space in the waveform box, the top 30 mm will display flow above the baseline (typically forward flow), while the bottom 10 mm will display flow below the baseline (typically reverse flow). You can change the default baseline settings for each site by using the Left and Right arrow keys. Please note that the baseline can be adjusted "on-the-fly" at any time during a patient examination, so keep that in mind when considering changing this factory preset.

Doppler Sweep Speed

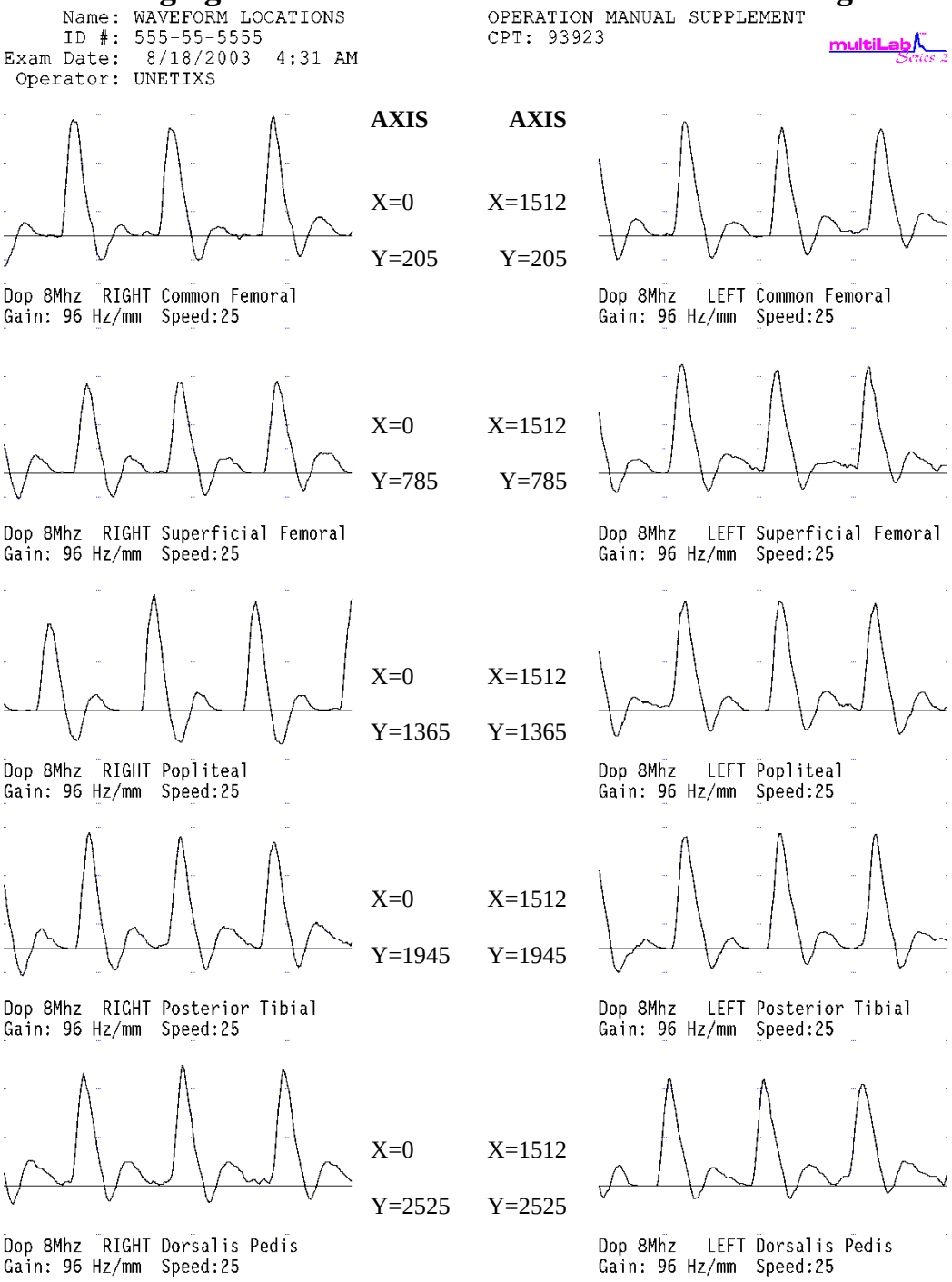
For Doppler Waveform Studies, the default sweep speed is 25 millimeters per second. As the waveform box on the report page is 75 millimeters wide, this will allow you to capture 3 seconds worth of waveform information. If for some reason you wished to "slow" down the sweep speed, you could display more waveforms by reducing the sweep speed using your Left arrow key. A sweep speed of 10 mm/second would allow for the capture of 7.5

seconds of waveforms. Please note, however, that sweep speeds of less than 25 mm/second (which is typically considered "real-time") will result in waveform compression, making waveform analysis more difficult.

Changing Location to Examine

The default settings for Lower Arterial Doppler Wave tracings are the Common Femoral, Superficial Femoral, Popliteal, Posterior Tibial, and Dorsalis Pedis Arteries. Some facilities may not wish to exam the Superficial Femoral Artery, for example. In this instance, the Left and Right Superficial Doppler Waveform entries could simply be deleted. If you wished to substitute one location for another, (like changing the Dorsalis Pedis site to the Peroneal Artery, for instance) this can be accomplished by changing both the "Tag" line and the "Text Line to be displayed below waveform". Change them so that they read, or mean, the same (see the previous example in changing a "Variable Text" item).

Changing the Waveform Location on the Printed Page



You will notice that each Doppler Waveform has a different "X" and "Y" coordinate that determine where it will be printed on the finished report. The MultiLab software will allow for the printing of ten 75mm wide waveform boxes on each report page.

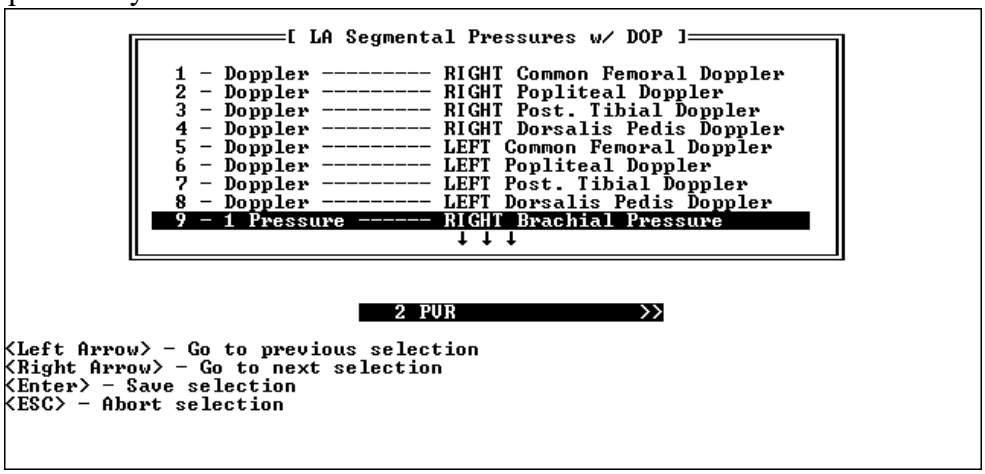
In the example above where we simply deleted the Superficial Femoral Doppler Waveforms, the printed report would have a "hole" where the Superficial Femoral waveforms would normally be printed. To make for a more visually pleasing report page, you could move the Popliteal, Posterior Tibial, and Dorsalis Pedis up, thus leaving the blank space at the bottom of the page. Since there is room on each printed page for ten 75 mm waveform boxes, you could even make use of that space by inserting some Toe Waveforms, for example.

The above page gives the coordinates for the locations of the waveform boxes. Simply change the Print "X" and "Y" coordinates for any waveform you wish to print in other than its default position.

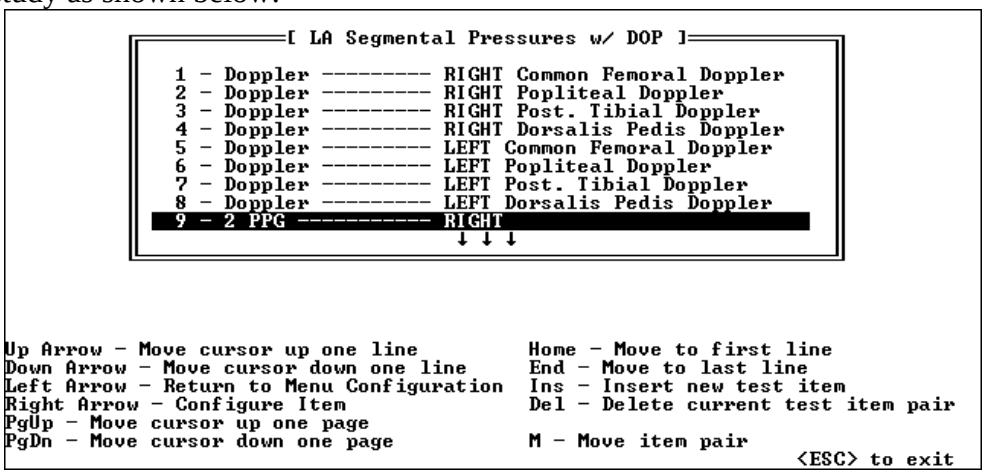
Inserting Waveforms

As was mentioned earlier, it is possible to "mix and match" various waveforms on a single page. In order to do this however, you must have available space on the page you wish to put the waveforms. Looking at the previous page you will notice that there are ten Doppler waveforms already on that page. You would not be able to insert any more waveforms into that study. However as in the previous example of "Changing the Waveform Location on the Printed Page" where we deleted the Superficial Femoral Doppler and moved the remaining sites up, there would be 2 spaces at the bottom of the page (X=0, Y=2525, and X=1512, Y=2525).

If we desired, we might put some Toe PPG waveforms in that space by pressing the "Insert" key after the "Left Dorsalis Pedis Doppler" entry as shown below:



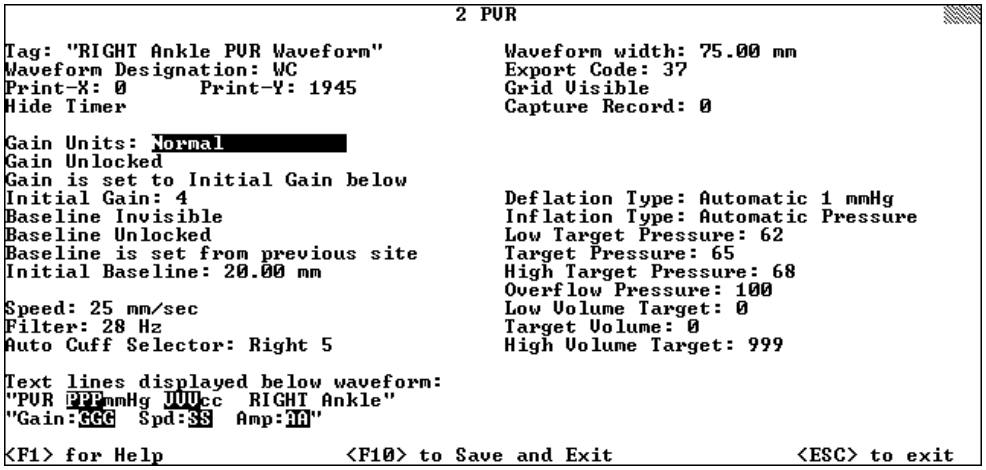
You will then be presented with a number of "modules" that you could insert into the exam you are creating. Press the Right Arrow key to bring up "2 PPG" and press the "Enter Key. This will load the "2 PPG waveform" module into your study as shown below:



Now to complete the exam, highlight the "Right PPG" entry and press the "Enter" key. Then type "Great Toe PPG Waveform" in the Tag line. Using your Down Arrow key move the cursor to the "Print Y" parameter (since the location we wish to insert this new waveform is going to be X=0 and Y=2525, we skipped directly to "Y") and change the value to "2525". To change a number, you may use the Right and Left arrow keys to raise or lower the desired values; add in the "Ctrl" key to go even faster or press "End" to go to the maximum value (In the "Y" axis, one touch of the "End" key will change the value to "2571" and on the "X" axis will take you to "1512".)

Once the print parameters have been properly set, use the "Down arrow" key to move the cursor to the entry that reads: "Text lines displayed below waveform" and type "Waveform Right Great Toe" after the "PPG" entry. Press "F-10" to Save and Exit. Repeat steps for the Left Toe Waveform, but make the Print "X" value "1512" and the "Y" value "2525".

Modifying a PVR Study



If you are performing a PVR Waveform study, there are a number of parameters that you can adjust to further customize your instrument. Most commonly, you may wish to adjust Gain Units, Default Gain settings, and Target Pressures.

Gain Units

PVR Gain units can be expressed in "Pneumo mmHg/20mm" or "Normal" values. The former is an engineering value that describes the sensitivity setting of the PVR sensors, and the latter would be more a "laymen's" version of this. The factory default setting for the Ankle, Calf, Above Knee, and High Thigh sites is ".75 mmHg/20mm". What this means is that a pressure increase of .75 mmHg (three quarters of one millimeter of Mercury) at the internal PVR sensor will cause an upstroke of 20mm (twenty millimeters) in the on-screen waveform box and on the printed report.

Even though scientifically correct, this display of sensitivity may be counter-intuitive to some, as the smaller the gain units expressed in this fashion, the HIGHER the sensitivity. For example, a gain setting of .375 mmHg/20mm would require half the amount of pressure increase to generate the same 20 mm upstroke, effectively increasing the sensitivity of the gain by a factor of two.

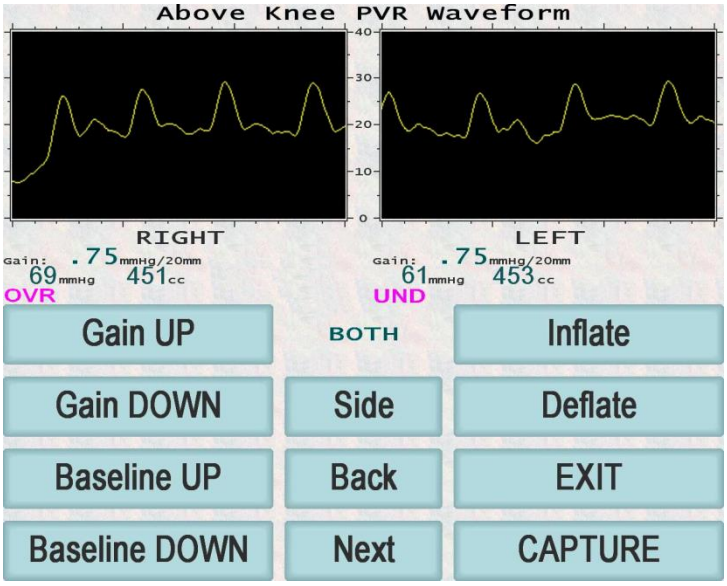
For those with a more linear mindset, we have the ability to display the Gain units in the "Normal" mode, in which a Gain setting of "4" correlates to the .75 mmHg/20mm setting described above. With "Normal" Gain units, a doubling of the PVR sensitivity would be "8" (correlating to .375 mmHg/20mm), a value that is twice that of 4. Changing these values (by using the Left and Right arrow keys in the configurator) will change how they are displayed on the screen and on the printed report.

Default Gain Settings

Default Gain settings can be adjusted individually site by site, either in the "XX mmHg/20" or "Normal" modes by using the Left and Right arrow keys.

NOTE: Be sure to check with your Medical Director and Interpreting physician before altering the factory-preset values.

Target Pressures



The "Target Pressure" is the amount of air pressure (in mm's of Hg) that the blood pressure cuff will automatically be inflated to, with one touch of the on-screen or remote controls. The default factory setting is 65 mmHg, as that is the value most commonly used by the U.S. medical community. This "Target Pressure" can be raised or lowered by using the Left and Right arrow keys. We also allow the user to define "High" and "Low" target pressures as well. These High and Low settings serve two purposes. First, they will alert the MultiLab operator if the desired air pressure in the PVR cuffs should go above or below these values by displaying the letters "OVR" and "UND" in red below the on-screen pressure value as shown below. The second use of these upper and lower targets is for the benefit of the interpreting physician, whereas the cuff pressure will print out in red on a color report page if it does not fall into the range between the "High" and "Low" Target pressures.

Saving Custom Study Configurations

After you have customized your MultiLab protocols to your satisfaction, remember to save a copy of these customized protocols in the event you have a computer problem or a hard disk drive failure. To save your unique studies, get a blank 3 ½" floppy disk (or a USB thumb drive). Label it "MultiLab Custom Studies", and insert it into the "A" drive bay (or USB port). From the MultiLab Start screen, press "Setup", System Setup", "Backup" and then "Backup Study Configuration". Save this disk (or USB drive) in a safe place.

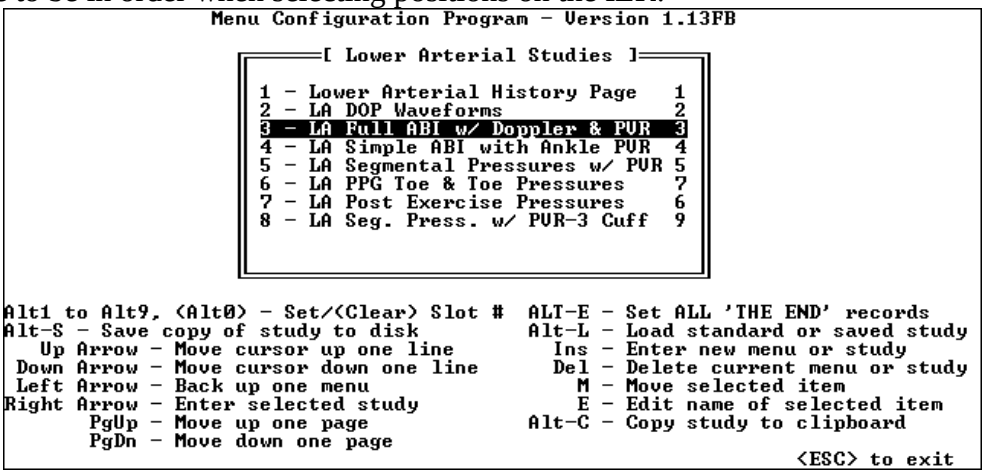
Restoring Custom Study Configurations

Obviously it is a good idea to backup your custom study configuration in the event of a computer problem. This is also an ideal way to "synchronize" one or more MultiLab instruments at either the same or remote locations, thus ensuring standardization of exams from instrument to instrument or location to location. To "restore" or duplicate a custom set of studies, simply place the backup disk (or USB drive) created in the paragraph above into the desired MultiLab system and press "Setup", System Setup", Backup" and "Restore Study Configuration". You may get a request to insert the last disk of the backup set; just answer OK to continue. After this, you may get an overwrite warning; answer "yes to all" to this warning. Remove the floppy disk (or USB Drive) when finished.

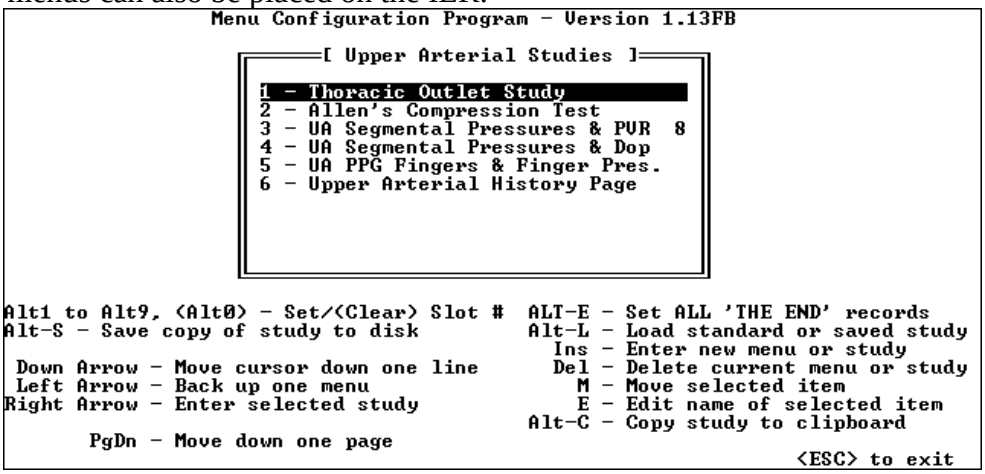
***WARNING** – To prevent data loss in the Temp. Files area, all data should be printed and deleted before restoring a study configuration. You may also Archive the data instead. In either case the Temp. Files must be empty before restoring a study configuration.

Configuring the ILR

Up to 9 study shortcuts can be placed on the ILR Start Screen. To place a study shortcut on the ILR, choose a menu in the study configurator. Highlight the study. Use the Alt key and numbers 1 – 9 (Alt1, Alt2….) to choose a location on the ILR. To remove a study from the ILR, highlight and touch Alt0. As can be seen below, the studies do not have to be in order when selecting positions on the ILR:



Studies from other menus can also be placed on the ILR:



CHAPTER 12: THEORY OF OPERATION

PVR Cuff

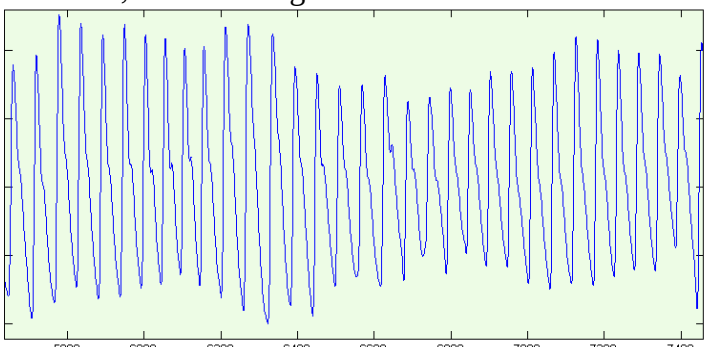
Pulse volume recording or PVR is a test that measures blood flow in the leg arteries. PVR can be used to diagnose PAD in the legs, determine how severe the disease is, and find the general location of the blockage. The PVR test is fast and painless, and does not require entering the body.

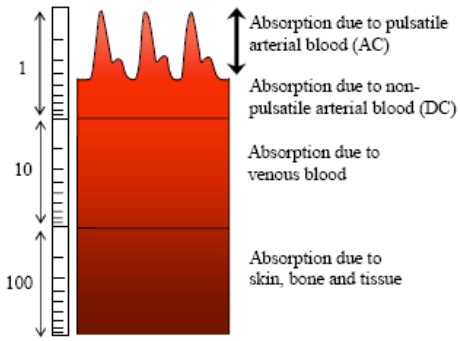
Blood does not flow through the body with continuous, uninterrupted flow. Instead, with each beat of the heart blood is pushed through the body in "pulses." The PVR test uses pressurized cuffs to monitor how these pulses travel through the legs, allowing doctors to find blood flow problems that may be 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.

PPG

Photoplethysmography (PPG) is optically performed 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 below:



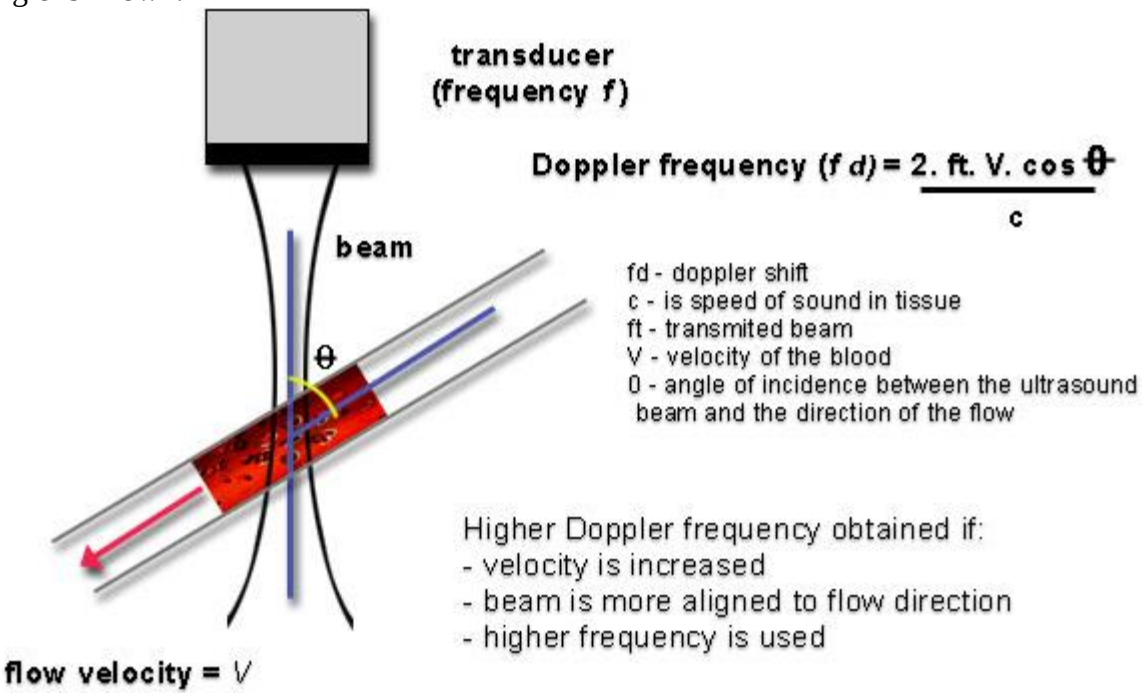


Example of Pulsed IR LED waveform received by the sensor

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 Ultrasound

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



5MHz probe (TD5) typical values

Acoustic Output			MI	$I_{SPTA.3}$ mW/cm^2	$I_{SPPA.3}$ W/cm^2
Global Maximum Value			0.032	173.13	.18
Associated Acoustic Parameter	P_r. (MPa):		.086		
	W_0 (mW)			25.8	25.8
	f_0 (MHz)		5.09	5.09	5.09
	Z_{sp}		.70	.70	.70
	Beam Dimensions	X_{-6} (mm)		5.30	5.30
		Y_{-6} (mm)		3.21	3.21

8MHz probe (TD8) typical values

Acoustic Output			MI	$I_{SPTA.3}$ mW/cm^2	$I_{SPPA.3}$ W/cm^2
Global Maximum Value			0.02	56.44	0.06
Associated Acoustic Parameter	P_r. (MPa):		.05		
	W_0 (mW)			18.9	18.9
	f_0 (MHz)		7.90	7.90	7.90
	Z_{sp}		1.1	1.1	1.1
	Beam Dimensions	X_{-6} (mm)		6.26	6.26
		Y_{-6} (mm)		1.64	1.64

$I_{SPTA.3}$ Derated Spatial-peak temporal-average intensity
$I_{SPPA.3}$ Derated Spatial-peak pulse-average intensity
MI Mechanical Index
P_r Peak-rarefactional acoustic pressure
W_0 Output power
f_0 Acoustic Center frequency
Z_{sp} Depth at which the reported parameter is measured
Operating Conditions: There are no user controls which affect the ultrasound output.
Measurement Uncertainties: ±19.4 percent for all intensity values reported
±9.7 percent for all the pressure values
±9.7 percent for the Mechanical Index

CHAPTER 13: GLOSSARY OF TERMS

A

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

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 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 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 MultiLab 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 probe: Ultrasonic device which connects to the MultiLab to display arterial waveforms.

Doppler waveform: Waveform made by 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.

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 MultiLab 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).

G

Gain: The amount of amplification applied to the waveform. This directly affects the amplitude of the waveform by using the Gain control. Lower Gain mean lower amplitude.

I

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

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

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

Medial: 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 MultiLab 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 MultiLab (both right and left) to connect the PPG sensor to the MultiLab.

PPG sensor: See PPG.

Protocol: Sequence of measurements in a patient exam.

Proximal: Nearest to the center of the body.

Pulsatile: Having a pulse.

Pulse: Arterial vibration cause by a bulbous 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.

S

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).

Start screen: Main navigation screen for the MultiLab.

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 MultiLab 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 MultiLab 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 MultiLab 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 MultiLab.

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 memory stick: (also USB thumb drive, USB memory device, or USB drive) A file storage device that connects to the MultiLab via its USB port.

V

Vascular studies: Patient exams pertaining to their vascular system. These are the types of studies that the MultiLab 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 MultiLab screen with the waveform in it.

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

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For Additional Help Contact:

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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.