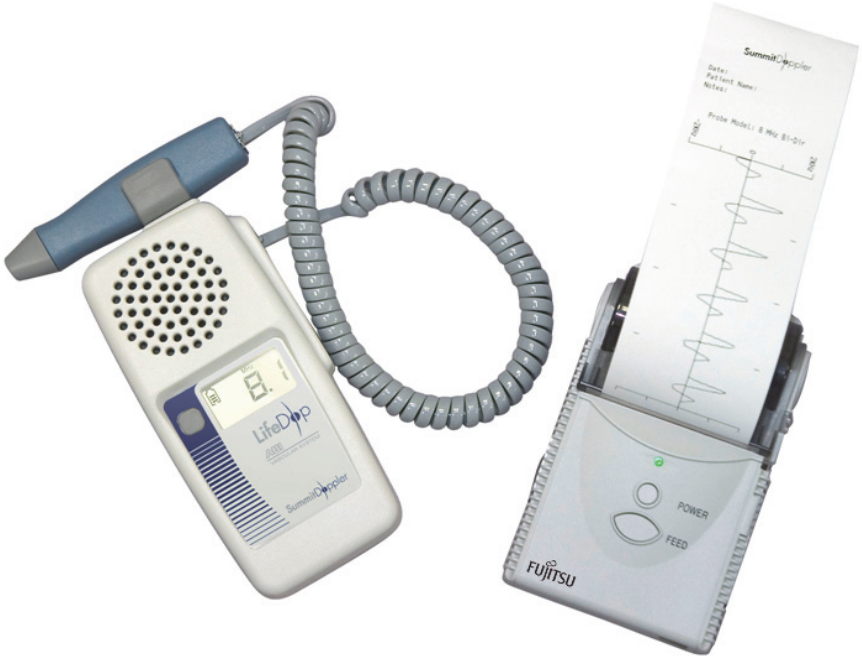
SummitDoppler™
a WALLACH SURGICAL brand

User Manual for the LifeDop® ABI Handheld Vascular System



REF **L250 ABI Series, PS1153**

WALLACH®
SURGICAL DEVICES

CE 0086

Thank you for choosing Summit Doppler products. We believe you have purchased the finest handheld Doppler and portable printer on the market. Your total satisfaction is our highest priority as we strive to continually improve our products and services. Please contact us with any suggestions. We look forward to enjoying a long-term relationship with you!

Wallach Surgical Devices
95 Corporate Drive
Trumbull, CT 06611 USA

Year of manufacture located on the device.

Here's how you can reach us
Phone: 1-800-243-2463
(203) 799-2000
Fax: (203) 799-2002
e-mail us at: customerservice@wallachsurgical.com
visit our website at: www.wallachsurgical.com

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Please read the manual carefully and become familiar with the operation, features and maintenance of your Doppler prior to using the device or accessories.

CE 0086

(This mark excludes the PSS® Model: 1153)

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

Wallach Surgical Devices provides general reimbursement information related to the diagnosis of peripheral arterial disease as an overview for our customers. It is important to understand that reimbursement is a complex process and requirements are subject to change without notice. It is the responsibility of the healthcare provider to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Prior to filing any claims, customers are advised to contact their third-party payers for specific coverage, coding and payment information. **Wallach Surgical Devices makes no promise or guarantee of reimbursement by Medicare or any other third-party payer.**

Intended Use

This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Caution

- U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.

Contraindications

Warnings

- The vascular probes are not for fetal use.
- The ultrasound probes are not to be used on or near the eyes.
- The device is for use only on intact skin.
- Do not plug any part of this device into a telephone or modem.
- This device is not intended for use with HF surgical equipment.

If there are questions or concerns regarding these warnings or contraindications, please do not hesitate to contact Wallach Surgical Devices for further clarification.

In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally – do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.

Safety of Ultrasound

The Doppler unit was designed with physician and patient safety in mind. In early design phases all potential hazards were eliminated or reduced to As Low As Reasonably Achievable (ALARA) by adhering to good design practices and industry wide safety standards. Ultrasound procedures should be performed with the ALARA principle in mind when delivering ultrasound energy into the body.

The following official statements from the American Institute of Ultrasound Medicine (AIUM) are provided for your general information regarding the safe use of ultrasound.

Clinical Safety

Approved March 1997, October 1982

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

Safety in Training and Research

Approved March 1997, March 1983

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation:

In those special situations in which examinations are to be carried out for purposes other than direct medical benefit to the individual being examined, the subject should be informed of the anticipated exposure conditions, and of how these compare with conditions for normal diagnostic practice.

Description of Product

The Summit LifeDop® ABI System is factory configured to include many features and product enhancements. Along with interchangeable ultrasound transducers, the Summit Doppler device is well suited to meet your specific needs.

Main Unit

The main handheld unit is ergonomically designed to fit the palm of your hand with comfort and allow easy access to each control feature. Each unit is individually tested and inspected to ensure the highest quality standards.

Printer Download – The LifeDop buffers 4 seconds of waveform data and waits until the printer is ready to print out a record of the examination.

LCD Display – The LCD display allows you to view information in large easy to read digits including probe ID, battery life, signal strength indicators, and multiple diagnostic indicators that ensure your unit is functioning at peak performance levels.

SSQ – Superior Sound Quality. LifeDop ABI is designed with a state-of-the-art sound system that produces excellent sound quality and long-term reliability.

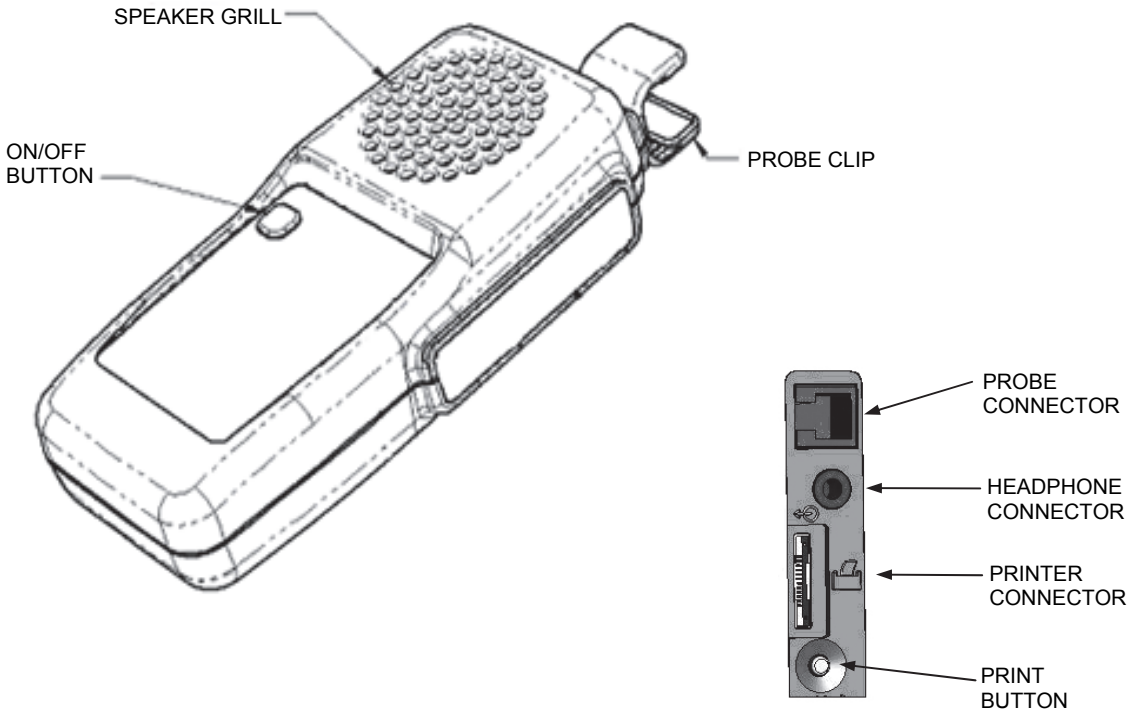
Probe

Summit Doppler ultrasound transducers were designed to meet your specific application need. Each probe has been ergonomically designed for comfort while providing excellent maneuverability for locating the vascular target. Every probe is carefully measured and tested to ensure it meets exacting performance standards.

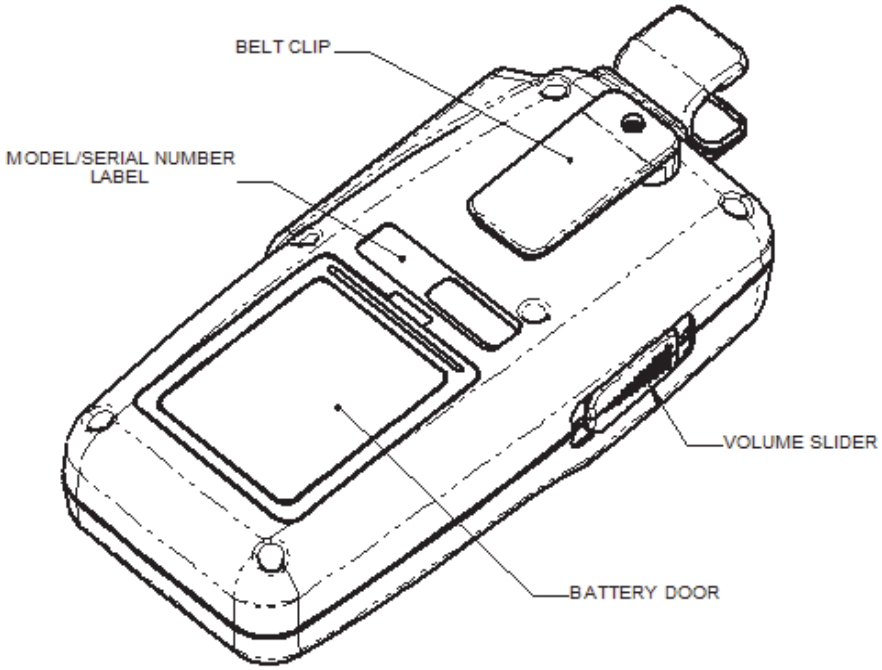
8 MHz Bi-Directional Probe – This standard "pencil" style probe is an excellent vascular tool for locating specific shallow vessels in the peripheral vascular system. The narrow grip and small face of the probe make it ideal for maneuvering for maximizing the signal in both flow directions.

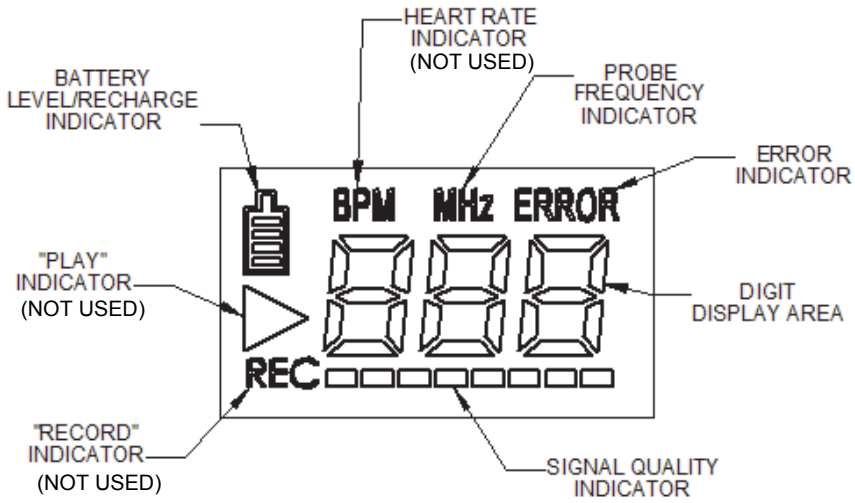
5 MHz Bi-Directional Probe (optional) – This "pencil" style probe, with wide beam and deep penetration, is designed for locating deep vessels in the peripheral vascular system. The narrow grip is easy to maneuver.

Operation and Installation

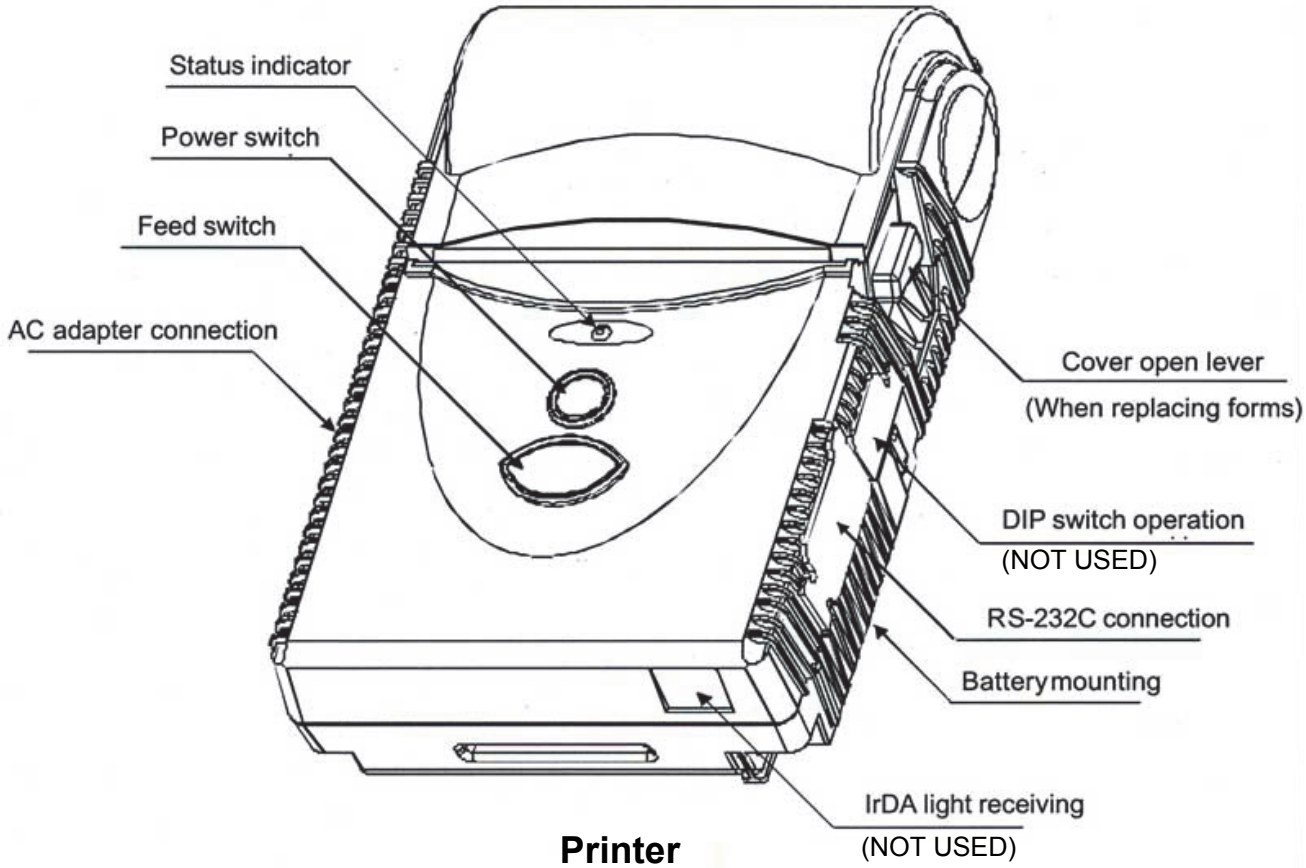


Side Panel Controls





LCD Display



Printer

A comprehensive In-Service Training Video (disk) is provided with your handheld doppler.

Turning Unit On/Off

Turn the LifeDop on by pressing the On/Off button. LCD indicators show power status. The LifeDop automatically shuts itself off after 5 minutes if it is not being used.

Turn the Printer on by pressing and holding the On/Off button until the green LED comes on (approximately 3 seconds). Printer automatically shuts itself off after 30 minutes.

Volume Slider

The audio level can be adjusted using the Volume Slider. Moving the slider up will increase the volume, while moving it down will decrease it. The volume slider does not affect the headphone output.

ABI Diagnostic Examination Procedure

Setup

1. In a warm room, have the patient take off shoes and socks and rest in a supine position for approximately 5 minutes prior to taking pressures. Patient should wear thin, loose fitting clothing. Avoid rolling up sleeves or pant cuffs in such a manner that it obstructs blood flow [1]. Bulky items such as sweaters should be removed.

2. Wrap the cuffs snuggly around the arms and ankles as shown below (Figures 1 and 2). The edge of the cuff should be placed approximately 1 to 2 inches above the site of examination. Select the proper cuff width, equivalent to 40% of the patient's limb circumference. In general, average sized adults use 10 cm cuffs, while larger adults use 12 cm cuffs [1].

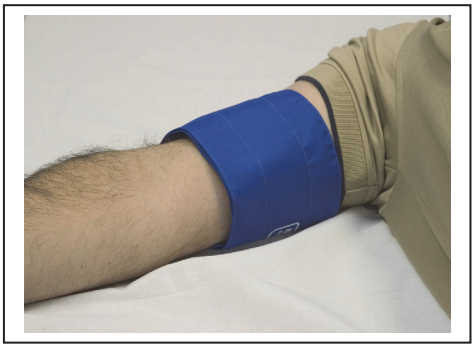


Figure 1

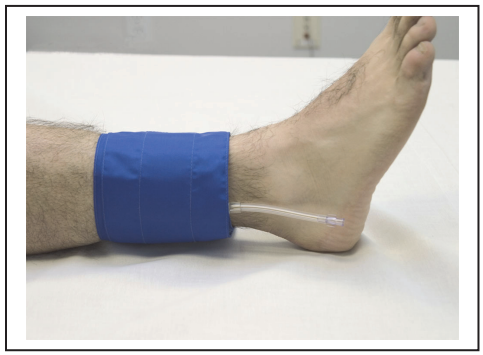


Figure 2

While applying the cuffs, it may be a good time to explain the examination to the patient and answer any questions they may have during this period.

Brachial Pressures

3. Apply a small amount of gel to the brachial artery site and place the Doppler probe at approximately 45 degrees, pointing in the direction toward the shoulder as shown in Figure 3. Slide the probe laterally across the right arm to find the brachial artery and obtain the best signal possible.

4. Find a stable and comfortable position to brace the probe hand while quickly inflating the cuff 20 mmHg above the occlusion pressure; at this point Doppler sounds are no longer heard. Be sure that the Doppler probe stays on the artery during inflation [2].

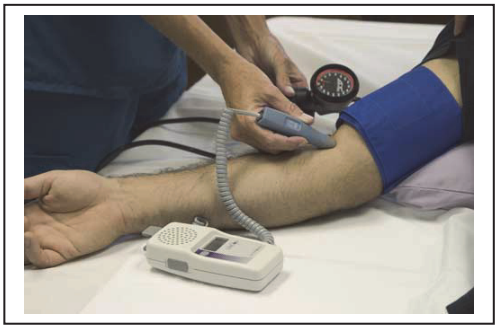


Figure 3

5. Deflate the cuff at approximately 2 mmHg per second by gently squeezing the pressure release trigger on the inflator. Listen for the blood flow sounds to return. When the flow sounds return, this is the systolic pressure. Once this pressure is obtained, rapidly deflate the remaining pressure in the cuff [2].

6. Repeat this process for the left arm and record the results on the ABI Assessment Chart as shown in Figure 4.

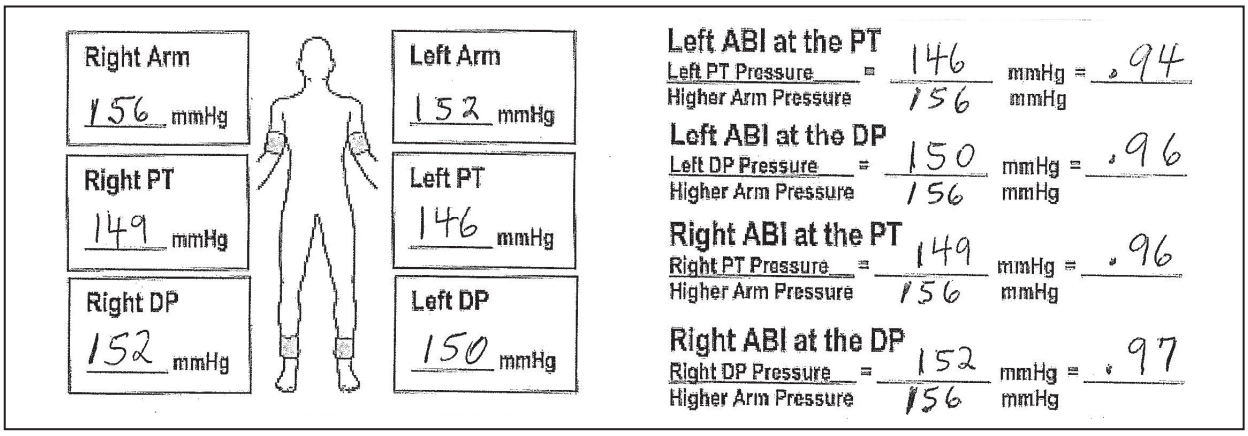


Figure 4

7. The greater of the two pressures will be used to calculate the ABI. A pressure difference of 20 mmHg or more between the two brachial sites is an indication of upper extremity stenosis. The pressures should be re-confirmed and further testing should be considered if repeatable [2].

Right Ankle PT Pressures and Printout

8. Before the right ankle systolic pressures are determined a waveform is required. Acquire the Doppler signal at the PT as shown in Figure 5. Apply a small amount of gel to the site and angle the Doppler probe at approximately 45 degrees, pointing the probe tip in the direction toward the calf and knee. Slide the probe slowly across the site until the best signal is obtained. Ideally, strong tri-phasic flow can be heard, however, in cases of restricted flow, the best signal may only be bi-phasic or mono-phasic. It is helpful to monitor the signal bars on the display to observe the directionality of the waveform prior to storing and printing. **(Cuff inflation is not used for obtaining waveforms.)**

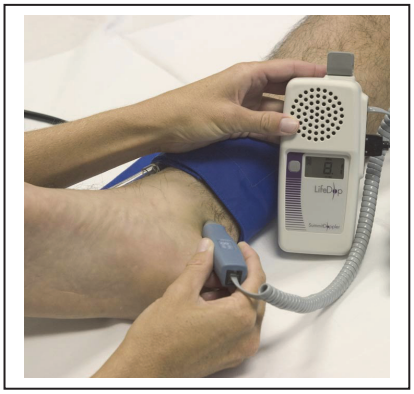


Figure 5

To print the waveform: Maintain the best signal possible for a minimum of 4 seconds and press the red button on the side of the LifeDop to buffer the waveform for printing. Turn on the printer and connect the cable. Once the printer communication with the LifeDop is established, the waveform will begin to print.

9. Apply the printed Doppler waveform to the ABI Assessment form by folding the printout in half lengthwise and peeling the protective paper from the label as shown in Figure 6. For more details, refer to the "Printing a Waveform" section. Then check the appropriate boxes on the form to indicate the vessel location and complete the form by filling in the patient risk factors and symptoms.

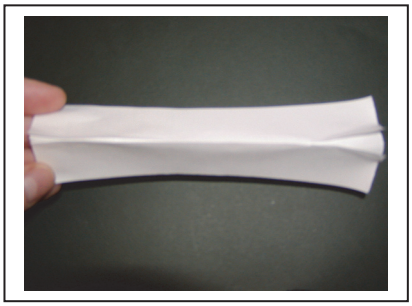
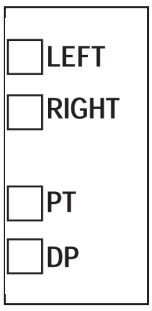


Figure 6



Check box portion of the form

10. For right ankle systolic pressures, use the Posterior Tibial (PT) artery. Refer to Figure 5. Find a stable and comfortable position to brace the probe hand while quickly inflating the cuff 20 mmHg above the occlusion pressure when Doppler sounds are no longer heard. Be sure that the Doppler probe stays on the artery during inflation [2].

11. Deflate the cuff at 2 mm Hg/sec by gently squeezing the pressure release trigger on the inflator. Listen for the blood flow sounds to return - this is the systolic pressure. Once blood flow returns, rapidly deflate the remaining pressure in the cuff [2].

    Note: If the ankle pressure is significantly greater than the higher of the two brachial pressures, the artery may be calcified and non-compressible. The pressures should be re-confirmed and further testing should be considered if repeatable[3].

Right Ankle DP Pressures

12. For right ankle systolic pressures, use the Dorsalis Pedis (DP) artery. Refer to Figure 7. Find a stable and comfortable position to brace the probe hand while quickly inflating the cuff 20 mmHg above the occlusion pressure when Doppler sounds are no longer heard. Be sure that the Doppler probe stays on the artery during inflation [2].

13. Deflate the cuff at 2 mm Hg/sec by gently squeezing the pressure release trigger on the inflator. Listen for the blood flow sounds to return - this is the systolic pressure. Once blood flow returns, rapidly deflate the remaining pressure in the cuff [2].

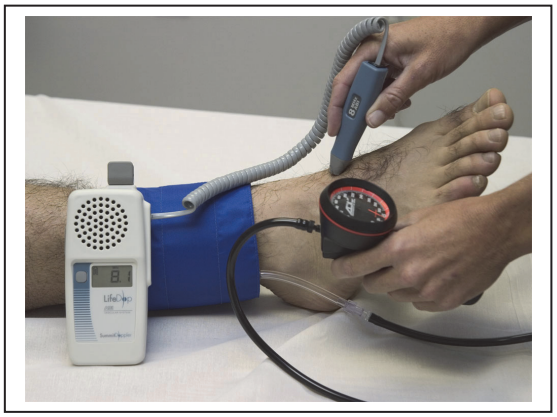


Figure 7

14. Repeat this process for the **left ankle** and record the systolic pressure results on the ABI Assessment Chart.

    Note: If the ankle pressure is significantly greater than the higher of the two brachial pressures, the artery may be calcified and non-compressible. The pressures should be re-confirmed and further testing should be considered if repeatable[3].

Calculate the ABI and Complete the Form

15. For the left side ABI, divide the left ankle pressure by the higher of the two brachial pressures and record the result. This can be done with a calculator or by using the provided ABI Calculator Chart.

    Repeat this step for calculating the right side ABI, again using the higher of the two brachial pressures [3].

16. Figure 8 shows a sample completed form. Other examples of completed forms are located in the rear of this document.

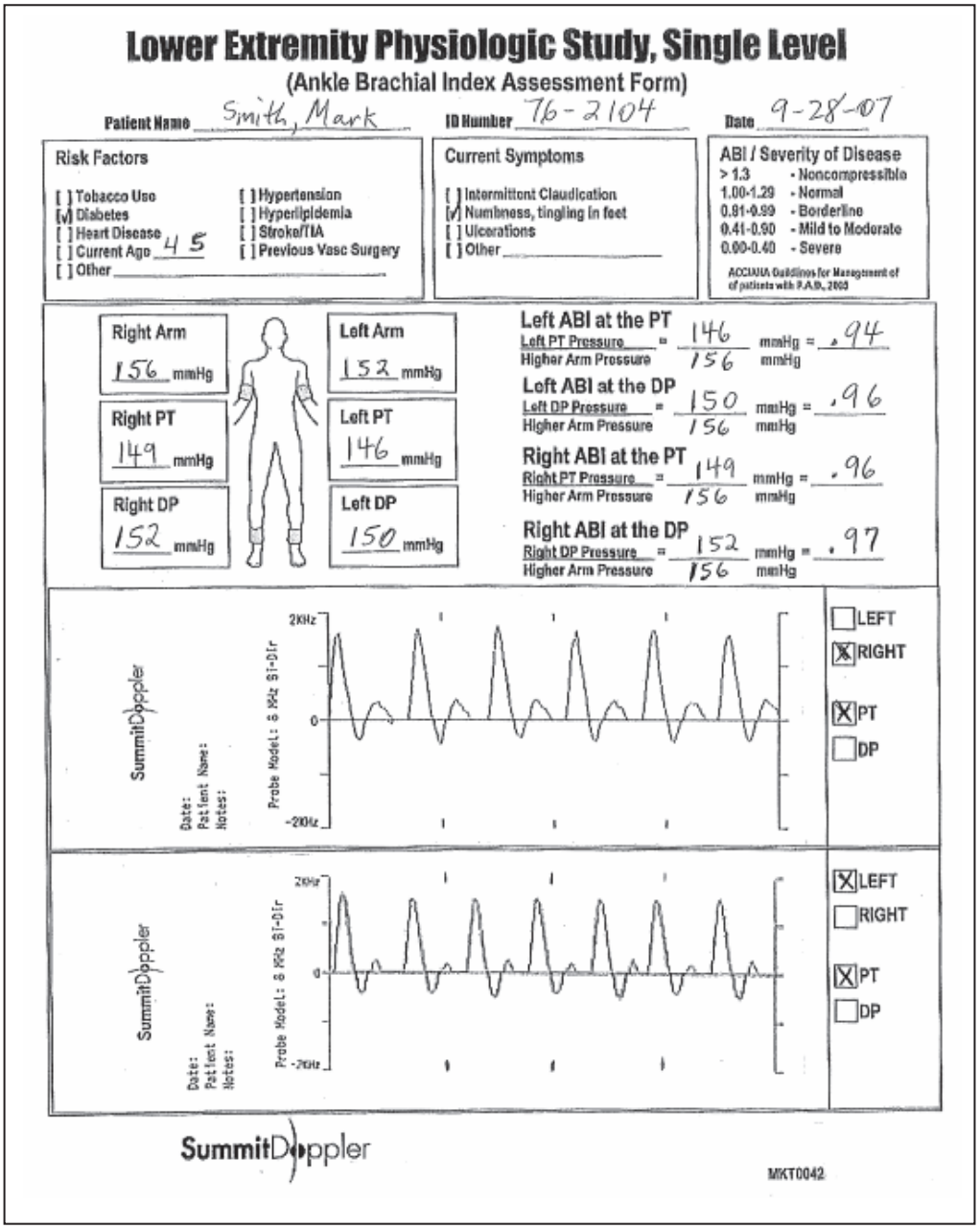


Figure 8

References:

[1] Human Blood Pressure Determination by Sphygmomanometery: American Heart Association (AHA), 2001

[2] Techniques in Noninvasive Vascular Diagnosis – an Encyclopedia of Vascular Testing; Daigle RJ, Summer Publishing, 2002: 137-148

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

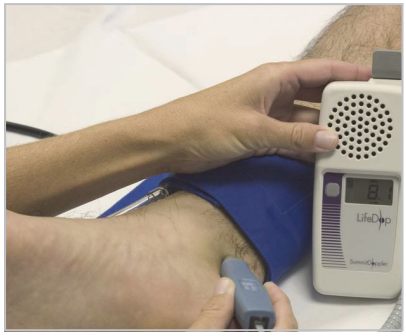
Obtaining Doppler Signals and Printer Operation

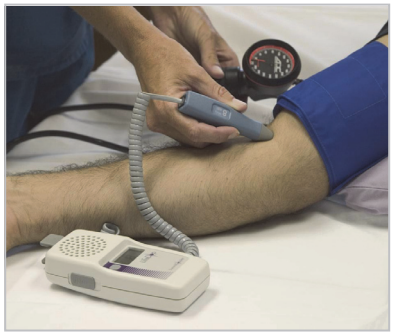
Caution

- Doppler examinations should be performed only by trained individuals.

For any Doppler examination, it is essential that an adequate supply of coupling gel be used to transmit the ultrasound energy from the probe to the surface of the skin. Re-apply more gel if it starts to dry out or spread so thinly that an air gap occurs between the probe and the skin. It is not necessary to cover the entire surface of the probe, only the probe face. Applying too much gel makes the unit difficult to clean and does not aid in the performance of the probe.

For the best results, angle the probe approximately 45 degrees from the skin surface over the general location of the vessel. Slowly move the probe side to side and vary the angle of the probe until the vascular sounds are heard. Changing the angle of the probe has an effect on the frequency of the sound. The steeper the probe angle, the higher the frequency of the sound.





Signal Quality Indicator

Once flow sounds are found, the signal strength indicators give the user a visual display of the flow direction and relative strength of the signal. Four bars of the left indicate flow toward the probe, while the four bars to the right indicate flow away from the probe. Vary the probe position and angle as described above while viewing the indicators to obtain the best results.

Buffering a Waveform

Once the desired flow is found, press the red "PRINT" button on the side of the unit to buffer the PREVIOUS four seconds of flow. When the waveform is buffered, as indicated by "STR" on the display, the probe is temporarily shut off and can be removed from the patient. The printer need not be connected to buffer the waveform - the LifeDop waits until the printer is ready.

Note: Only one waveform can be buffered at a time and the LifeDop must remain ON in order to retain the waveform.

Connecting the Printer

Ensure that the printer is loaded with paper and connect the cable to the printer and LifeDop as shown, with connector tabs down as labeled "THIS SIDE UP". Turn the printer on by **HOLDING the power button down** (approx. 3 seconds) until the LED comes on. If the printer is functioning properly and ready to print, the LED will flash green twice every second.

Warning

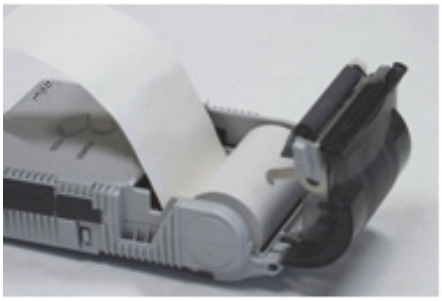
- Forcing the cable upside down will cause damage to the connector pins on the LifeDop, cable and printer. Note label "THIS SIDE UP".

Printer Connections

Note: When turning the printer on or off, it is important to remember to hold the button down, approximately 3 seconds, before the printer will respond.

Warnings

- Install the paper roll in the printer so the external side (heat sensitive side) of the rolled paper is against the print head (down).
- Do not use printer paper other than the type specified and supplied with the Summit Doppler. Other paper types could result in damage or degraded print quality and may void the warranty.



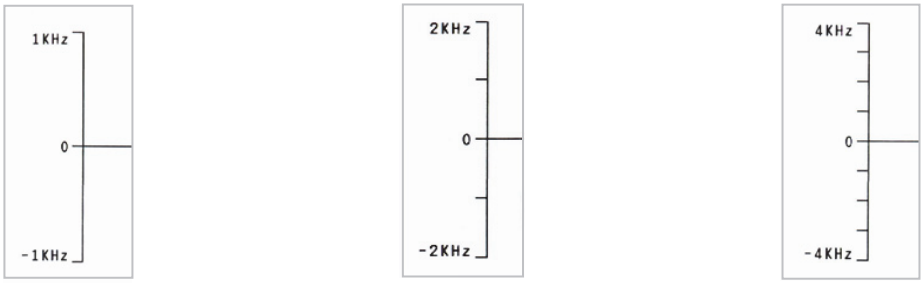
Loading Paper

Printing a Waveform

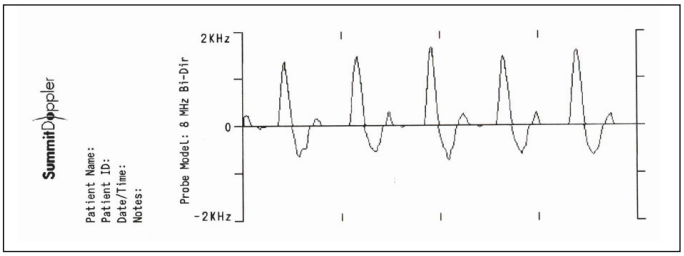
Warnings

- The print head becomes hot during printing. Do not touch the print head after printing.
- Turn off the printer and check that the head is fully cooled before attempting to fix a paper jam, replacing paper, or removing the print roller for any reason.

Once the printer is operational and the cables are in place, the LifeDop will automatically download the waveform and printing will begin. If the PRINT button is pressed while the printer is connected and ready, printing will start immediately. Waveforms are automatically scaled to a maximum frequency of 1 kHz, 2 kHz or 4 kHz for optimal waveform height. Markings on the vertical axis are provided every 1 kHz. Printer calibration is not required.



Auto-Scaling – 1 kHz, 2 kHz and 4 kHz

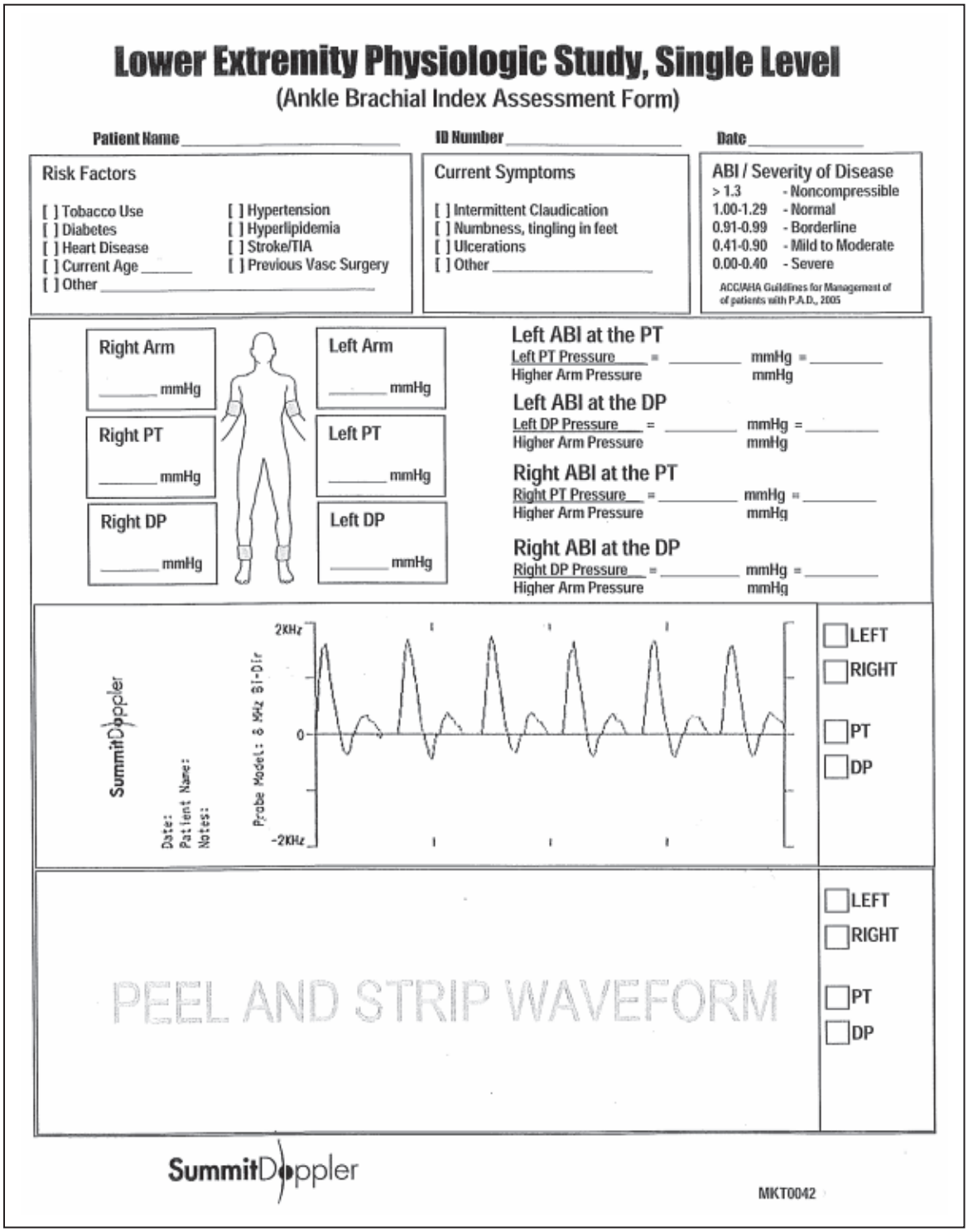


Sample Printout

Blood flow in the direction toward the probe is shown above the baseline. Flow away from the probe is shown below the baseline. These two traces are provided so that flow in both directions can be displayed simultaneously.

Report Generation

Report generation is made very simple with adhesive-backed printer paper provided by Wallach Surgical Devices - eliminating the need to cut and tape the strip of paper. The label paper backing is precut down the center – fold the paper down the middle and peel from the center. Attach the waveform to the pre-printed ABI Assessment Form.



ABI Assessment Form with one waveform strip in place

Diagnostic Monitoring

All LifeDop Doppler units perform continuous diagnostic monitoring and give a visual indication of battery level. The LifeDop uses a multiple level battery shaped icon that indicates the voltage level of the battery. The battery outline will flash when the battery level is very low, indicating that the user should change the batteries soon after the current examination is complete.

Once the unit is on, the LifeDop performs a series of diagnostic checks. The unit first checks and displays the frequency of the probe that is being used. This display will not change unless the probe is changed or the power is cycled, in which case the display will again temporarily confirm the frequency of probe that is connected.

The unit then checks for proper internal operating temperature, battery voltage, reference voltage and power supply voltage levels. If any of these characteristics are out of range, the display will show the ERROR indicator and a failure code associated with the diagnostic error. Diagnostic functions are periodically checked while the unit is on to ensure the Doppler is operating at peak performance. Refer to the table below for failure codes.

Diagnostic Codes – Contact Wallach Surgical Devices Service Department

1 – Temperature too low	6 – 5 Volt Supply too high
2 – Temperature too high	7 – Battery Voltage too low
3 – Reference Voltage too low	8 – Battery Voltage too high
4 – Reference Voltage too high	9 – Printer miscommunication
5 – 5 Volt Supply too low	

The printer will perform a self-test print by turning the printer on while the feed button is being held down. A checkered test pattern will print in addition to the printer configuration and loaded fonts.

Accessories

To order accessories [gel, batteries, rechargers, printer paper (labels), cables], contact Wallach Service at 1-800-243-2463 or (203) 799-2000 to order by phone, or order on-line on our website www.wallachsurgical.com

Maintenance and Cleaning

Warnings

- The LifeDop is not designed for liquid immersion. Do not soak the Doppler main unit or probes in liquids. Use only spray or wipe cleaners and disinfectants. Do not use products containing bleach.

- The LifeDop is not designed for sterilization processes such as autoclaving, gamma radiation, or hydrogen gas.

- The LifeDop is not intended to be used on open skin. If there is evidence of open wound contamination, disinfect the probe before using again as described below.

The LifeDop Doppler requires very little maintenance. However, it is important to continuing function of the unit and the health of the patients that the unit is cleaned and examined regularly per the following guideline:

After every examination:

Excess gel should be wiped off prior to docking the probe. Probes and main unit should be cleaned with a damp cloth using warm water or presaturated isopropyl alcohol wipes. In particular, pay close attention to clean the seams along the plastic lines at the probe face but **do not allow water or spray to enter through the connectors or speaker grill**.

To disinfect unit, use commercially available spray or wipe disinfectants registered with the EPA. Clorox® Broad Spectrum Quaternary Disinfectant is the only disinfectant that is Wallach Surgical Devices approved for use with the L250 ABI product. Follow the manufacturer's instructions and wipe unit until it is dry of solutions. Examiners should wash hands and change gloves after every exam. Refer to local and hospital policies for cleaning and disinfection policies.

Store the unit in a clean area free from dust and debris. Follow temperature and humidity guidelines as specified at the end of this manual.

Warning
- If the unit is to be stored for longer than 90 days without use, remove the batteries prior to storage.

Periodically (at least annually):

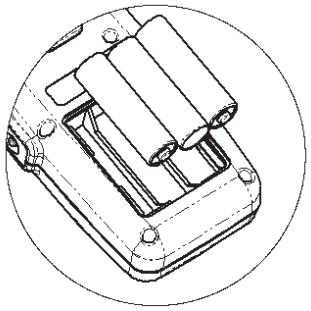
Inspect the main unit and probes for signs of cracks or breaks in the mechanical housing. Inspect cables and connectors for signs of wear or failure. The user should discontinue use of the unit with any sign of loss of housing integrity. Contact Wallach Surgical Devices for service.

It is recommended that rechargeable batteries be replaced annually.

Replacing LifeDop Batteries

Warning
- Replace batteries only with batteries supplied by Wallach Surgical Devices. The battery compartment only accepts AA size batteries. See the Accessories section for reordering of parts information.

Open the battery compartment by depressing the tab and pulling outward on the battery door. Remove the existing drained batteries by pushing on the end of the battery that compresses the battery contact spring and lift upwards. It is acceptable to use a small tool or pen to assist in this step.



Replace the batteries by paying close attention to the polarity indicators on the battery and the polarity indicators on the battery holder in the compartment. Positive (+) aligns with positive (button) and negative (-) aligns with negative (spring). Insert the battery such that the spring contacts are loaded first and then press the battery firmly into place.

Warning
- If the batteries have been inserted incorrectly, the unit will not function but the LifeDop will not be damaged.

Recharging Printer Batteries

Warnings

- Use only the battery and AC adapter supplied with the printer. Use of any other battery and/or AC adapter is hazardous and may cause damage to the equipment.

- Do not connect the printer to the Doppler while the printer is charging.

Printer Recharger

It is recommended that the printer be recharged prior to first use. Turn the printer off. Lift the rubber flap on the left side of the printer and plug in the connector of the recharge adaptor. Make sure recharger is plugged into a standard 120VAC outlet. When properly connected, the LED will be red. Upon completion of charging the LED will turn off. Remove the recharger and replace the rubber flap.

Troubleshooting

Warnings

- Use alternate equipment in case of unit failure. Call the Wallach Surgical Devices Service Department if the probe or main unit malfunctions.

- Do not drop or mishandle the LifeDop, probes or accessories. Damage to sensitive electrical components, speakers, cables, transducers or plastic is likely to occur.

<u>Poor sound quality</u>

Inadequate gel use
Try to relocate the probe for a better signal
Improper choice of probe Frequency
Interference from other equipment
Probe coiled cable or battery contacts may be intermittent
Debris in the speaker may cause poor sound
Device damage from dropping the LifeDop, probes or accessories

<u>Battery indicator flashing – Error 5 or Error 7</u>

Consult the Diagnostic Monitoring Section; replace batteries as described in Replacing Batteries.

<u>Probe frequency does not match the connected probe</u>

Check probe that is attached to ensure it is the correct one, or no probe attached. If the correct probe is being used, contact Wallach Surgical Devices' Service Department.

<u>Radio Frequency Interference</u>

The LifeDop was tested for immunity to electromagnetic interference at a level of 3 V/meter. Interference during normal operation may occur in the presence of fields stronger than 3 V/meter. If this occurs, try to increase the distance between the LifeDop and the source of interference. Contact Wallach Surgical Devices for more information.

Printer LED Red or Orange

Green LED	Orange LED	Red LED	Error	Solution
Flash 2x			No Error	Normal
		Flash	Low Battery	Recharge
	Flash 1x		Out of Paper	Reload Paper
	Flash 2x		Open Cover	Close Cover
	Flash 3x		Thermal Failure	Call Wallach
	Flash 4x		Voltage Failure	Call Wallach

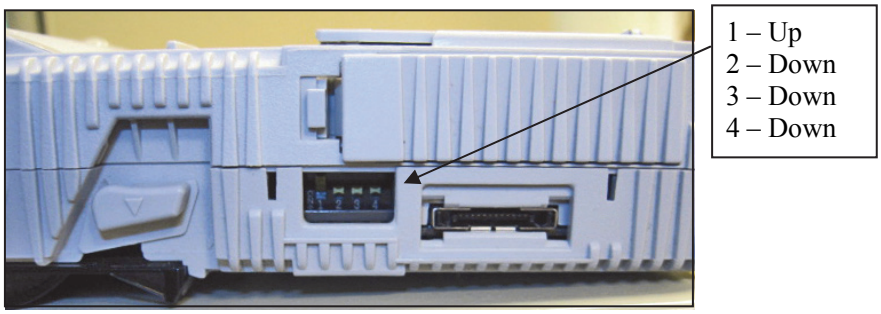
Printer DIP switches are preset at the factory. The printer will not function properly if they are moved from these set positions.

Printer Not Printing (Error 9)
The LifeDop and printer have lost communication. This may be due to a printer jam, paper empty, low printer battery or any of the above printer error codes. To clear the error, lift the paper cover lever, reseat the paper roll and close the cover. If printer communication is re-established, the LifeDop will automatically print the buffered waveform. If Error 9 persists, turn off both printer and LifeDop and re-start waveform buffer.

Waveform appears to be the same above and below the base line
This anomaly normally occurs when the probe is close to perpendicular to the vessel. Reacquire the Doppler signal with the probe angle at 45 degrees as described in Obtaining Doppler Signals.

Faint signal is audible, but waveform is not obtained on printout
The LifeDop main unit is designed to reject noise and certain artifacts. Even a valid signal must reach a threshold before it can be printed; therefore it is normal for some very weak signals to be rejected.

Printer Switches not set in proper location
The printer switches have been preset at the factory to the proper location; however if they have been changed the printer will not function. Orient the printer and set the DIP switches to match the following:



Reference materials for Peripheral Vascular testing:
Noninvasive Diag of Peripheral Vascular Disease; W. Robert Felix, Jr., 1988
Current Noninvasive Vascular Diagnosis; Ali F. Aburahma, Edward B. Diethrich, 1988
Vascular Disease Foundation; www.vdf.org
American Heart Association; www.americanheart.org
American Diabetes Association; www.diabetes.org

Specifications

Degree of protection against electric shock:

Type B Applied part

Class II Equipment

Degree of protection against ingress of water:
IPX4 – extending 2.5 cm from tip
IPX1 – entire probe 2.5 cm from tip, excluding connector

Designed and tested to meet:
IEC601-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-37, EN5011-A
Connect the LifeDop only to equipment that meets the appropriate standards.

	LifeDop	**Printer**
Dimensions (h x w x l):	140 x 70 x 35 mm	136 x 84 x 43 mm
Weight:	320 grams	280 grams
Operating temperature:	10 to 40 °C	0 to 40 °C
Operating humidity:	30 to 75 %	20 to 85 %
Transport/Storage temp:	–20 to 50 °C	–20 to 60 °C
Transport/Storage humidity:	5 to 90%, non-condensing for both units	
(beyond 30 days, battery to be stored between –20 and 30 °C)		

	LifeDop	**Printer**
Battery life:	100, 4-minute exams	500 prints
Battery type and voltage:	AA Alkaline 1.5V x3	Lithium-ion 3.7V

Audio bandwidth and power:	245 Hz – 4 kHz, 0.33 W
Audio cable pin out:	3.5 mm stereo plug Tip - toward, Ring - away, Shaft – common **Note: Common is not a ground connection**
Printer Paper Type/Size (max):	Thermal, 58 mm wide, 33 mm diameter
Printer Speed:	35 mm/sec, 8 seconds for standard printout
Printer Resolution:	48 mm wide, 8 dots/mm, 384 dots/line
Printer Impact Resistance:	1.5 meter on linoleum floor
Printer Communication:	RS232, 8 data bits, 1 stop bit, no parity, 115.2 Kbaud
Printer Recharger:	Input – 100-120 VAC, 29 VA, 50/60 Hz Output – 5 VDC, 2.3 A, center positive
Waveform Frequency Scale:	Auto scaled to max 4 kHz, 2 kHz and 1 kHz
Waveform Time Scale:	25 mm/sec, 100 mm length w/ 4 sec of data
Printout Length:	175 mm total with header

⚠ Attention: Consult Accompanying Documents

Transducer Model: LifeDop 5 MHz Bi-Dir **Operating Mode:** Continuous-Wave (cw)
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			**0.05**	**500**	**0.5**
Associated Acoustic Parameter	$P_{r.3}$	(Mpa)	0.12		
	w_o	(mW)		32.7	0.32.7
	f_C	(MHz)	5.50	5.50	5.50
	z_{sp}	(cm)	0.85	0.85	0.85
	Beam Dimensions	x_{-6} (cm)		0.4	0.4
		y_{-6} (cm)		0.6	0.6
	EBD	Az (cm)		0.4	
		Ele. (cm)		0.8	

Transducer Model: LifeDop 8 MHz Bi-Dir **Operating Mode:** Continuous-Wave (cw)
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			**0.04**	**365**	**0.37**
Associated Acoustic Parameter	$P_{r.3}$	(Mpa)	0.116		
	w_o	(mW)		15.7	15.7
	f_c	(MHz)	8.43	8.43	8.43
	z_{sp}	(cm)	0.63	0.63	0.63
	Beam Dimensions	x_{-6} (cm)		0.42	0.42
		y_{-6} (cm)		0.14	0.14
	EBD	Az (cm)		0.6	
		Ele. (cm)		0.3	

$I_{SPTA.3}$ the **derated spatial-peak temporal-average intensity** (mwatts per cm^2).
$I_{SPPA.3}$ the **derated spatial-peak pulse-average intens**ity (watts per cm^2).
MI the **Mechanical Index**.
$P_{r.3}$ the **peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported for MI.
W_o the total time-average **ultrasonic power** (mwatts).
f_c the probe **center frequency** (MHz).
z_{sp} the axial distance at which the reported parameter is measured (cm).
x_{-6}, y_{-6} are the –6dB beam dim. in the x-y plane where z_{sp} is found (cm).
EBD the **entrance beam dimensions** (cm). These dimensions are the same as the dimensions of the transmit crystal.

Measurement Uncertainties:

Power:	+34, -42%
Pressure:	+11, -16%
Intensity (Ispta):	+23, -26%
Frequency:	± 5%

Acoustic Output Parameters are measured in water. Derated values, denoted by the subscript ".3", take into account a conservative level of attenuation that would be encountered in the human body. The derated intensity values ($I_{.3}$) are obtained from water values of intensity (I_w) at a depth of z calculated by:

$$I_{.3} = \exp(-0.23*0.3*f*z)*I_w$$

(where f is the probe frequency in MHz and z is the depth in centimeters)

The derated peak rarefactional pressure is calculated from the value of measure water (pr) by:

$$P_{r.3} = \exp(-0.115*0.3*f*z)*p_r$$

(where pressure is given in megapascals)

Additional Output Reporting Information for IEC 61157

8 MHz: $I_{ob} < 112$ mW/cm^2

Note that parameter Z_{sp} in the probe reporting tables is the same parameter as I_p in IEC 61157.

Operating Conditions: There are no user controls which affect the ultrasound output.

ABI Glossary Guide

ABI Index – (Ankle-Brachial Index) A vascular test used to assess lower extremity circulation. It is the ratio of ankle pressure to the highest of bilateral brachial pressures providing a guide to severity of PAD.

0.90 – 1.30	Normal
0.70 – 0.89	Mild
0.40 – 0.69	Moderate
< 0.40	Severe [1]

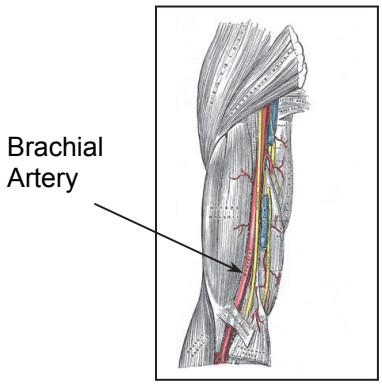
Aneroid – An actuating pressure device, used for inflating cuffs for obtaining blood pressures in vascular studies.

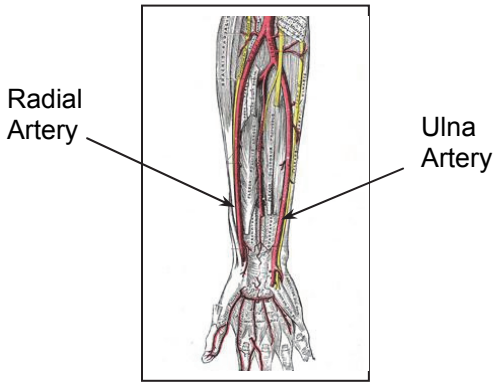
Arterial – Pertaining to arteries, or vessels that carry blood from the heart to tissues throughout the body.

Atherosclerosis – A thickening, hardening, and loss of elasticity of the walls of blood vessels, especially arteries due to accumulation of lipid materials.

Bi-Directional – Directional, pertaining to the ability to sense or move in two directions. In the case of Doppler probes, it is the ability to distinguish blood flow both toward and away from the transducer.

Brachial Artery – Main artery of the arm, continuation of the axillary artery on the inside of the arm [2]. The brachial branches into two primary arteries of the forearm, namely the radial and ulna arteries.





Calcification – Deposits of lime salts in the walls of arteries.

Claudication – A severe pain in calf muscles occurring during walking but which subsides with rest, resulting from inadequate blood supply due to atherosclerosis or occlusion.

Diastolic – Pertaining to diastole, the part of the heart cycle in which the heart is in a period of relaxation. Corresponding to minimum blood pressure.

Hypertension – A condition in which the patient has a higher blood pressure than that judged to be normal.

Hyperlipidemia – An elevation of lipids, or fats, in the bloodstream including cholesterol, phospholipids and triglycerides.

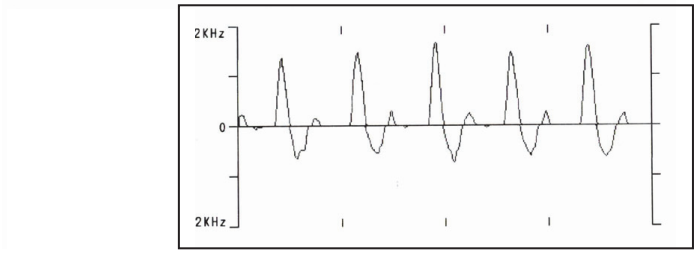
Noncompressible Artery – Condition in which the cuff pressure cannot occlude an arterial vessel, typically due to calcification, resulting in abnormally high ABI measurement [3].

Occlusion – The closure, or state of being closed, of a vessel.

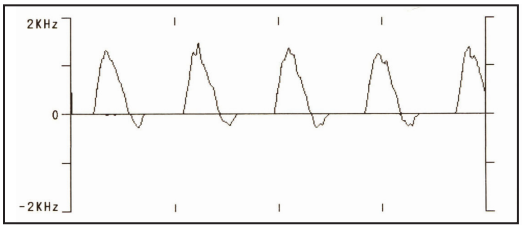
P.A.D. – (Peripheral Arterial Disease) A disease of atherosclerosis of the abdominal aorta and arteries of the lower extremities [1].

Phasic – Pertinent to phased behavior, appearance of states of regularly occurring cycle of changes.

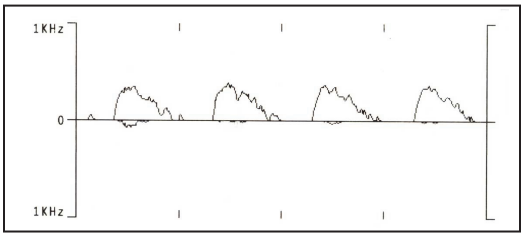
Tri-Phasic Audio – Blood flow sounds with three major components – typically associated with normal blood flow, corresponding visually to the following [2]:



Bi-Phasic Audio – Blood flow sounds with two major components – typically associated with diminished blood flow, corresponding visually to the following [2]:



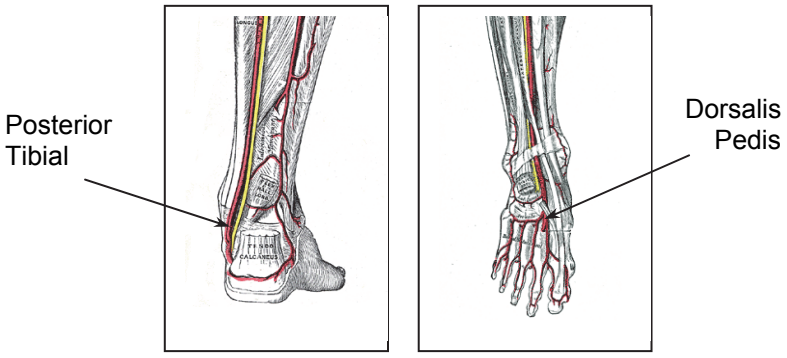
Mono-Phasic Audio – Blood flow sounds with one major component – typically associated with PAD, corresponding visually to the following [2]:



Pedal Artery – Arteries associated with the foot.

Posterior Tibial – Main artery leading into the foot, located behind the tibia bone. Can be accessed for ABI assessment behind the ankle notch [3].

Dorsalis Pedis – Main artery leading to the toes, located on top of the foot. Can be accessed for ABI assessment on a line extending from between the first two toes to the midline of the foot [2].



Sphygmomanometer – Instrument for determining arterial blood pressure.

Stenosis – The constriction or narrowing of a vessel.

Supine – A position of lying on the back - face, palm and feet facing upward.

Systolic – Pertaining to systole, the part of the heart cycle in which the heart is in a period of contraction. Corresponding to maximum blood pressure.

Venous – Pertains to the veins, or vessels that carry blood from tissues throughout the body back to the heart.

References:

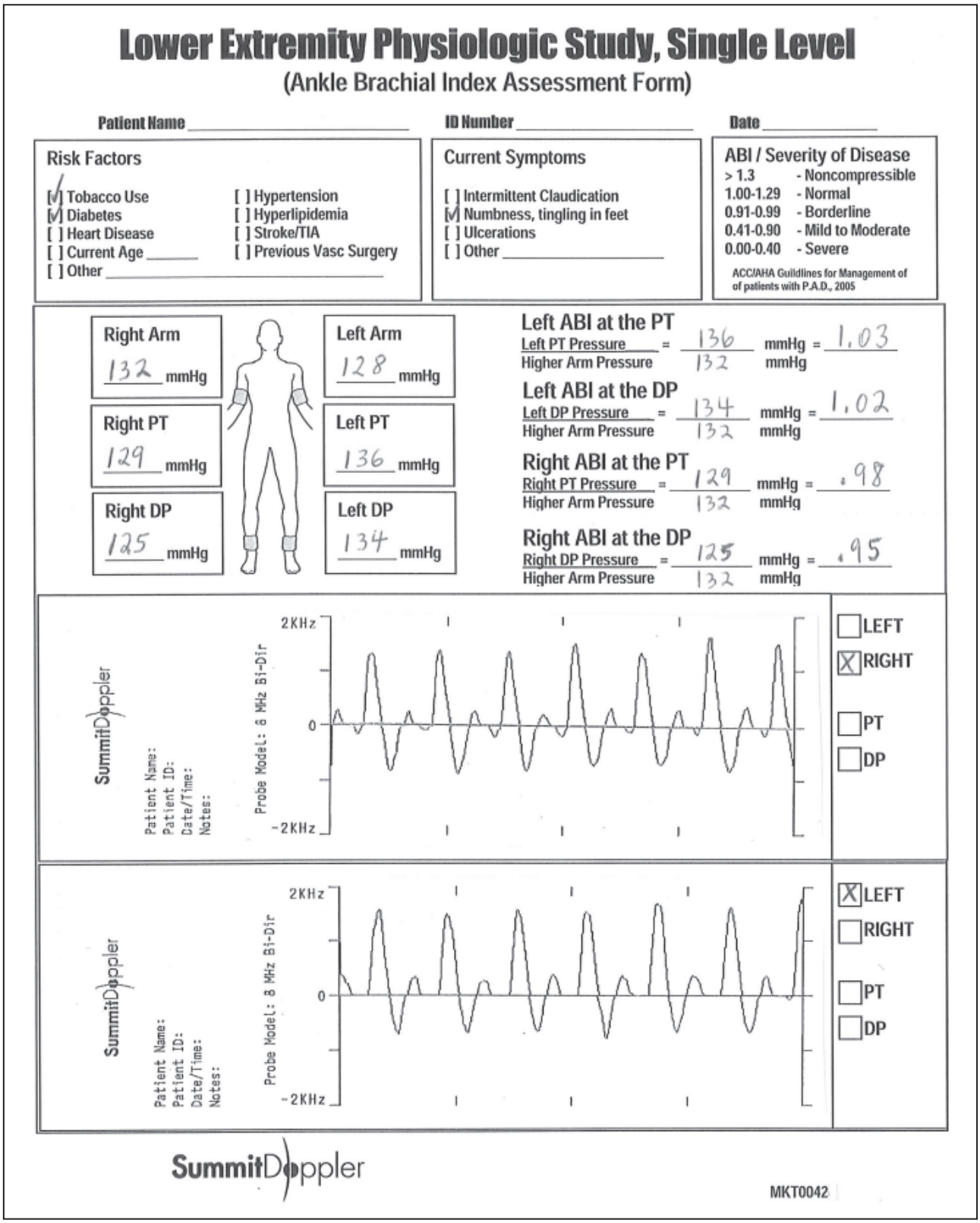
Unless otherwise noted: Taber's Clyclopedic Medical Dictionary 13th Edition; Thomas CL (Ed), F.A. Davis Company Publishing

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

[2] Gray, Henry. Anatomy of the Human Body. Philadelphia: Lea and Febiger, 1918: 20th edition edited by Warren H. Lewis, 2000

[3] Techniques in Noninvasive Vascular Diagnosis – an Encyclopedia of Vascular Testing; Daigle RJ, Summer Publishing, 2002: 137-148

Sample Completed Forms



Lower Extremity Physiologic Study, Single Level

(Ankle Brachial Index Assessment Form)

Patient Name _____ ID Number _____ Date _____

Risk Factors

[✓] Tobacco Use
[✓] Diabetes
[ ] Heart Disease
[ ] Current Age _____
[ ] Other _____
[ ] Hypertension
[ ] Hyperlipidemia
[ ] Stroke/TIA
[ ] Previous Vasc Surgery

Current Symptoms

[ ] Intermittent Claudication
[✓] Numbness, tingling in feet
[ ] Ulcerations
[ ] Other _____

ABI / Severity of Disease

> 1.3	- Noncompressible
1.00-1.29	- Normal
0.91-0.99	- Borderline
0.41-0.90	- Mild to Moderate
0.00-0.40	- Severe

ACC/AHA Guidlines for Management of of patients with P.A.D., 2005

Right Arm	132 mmHg
Left Arm	128 mmHg
Right PT	129 mmHg
Left PT	136 mmHg
Right DP	125 mmHg
Left DP	134 mmHg

Left ABI at the PT
Left PT Pressure 136 mmHg / Higher Arm Pressure 132 mmHg = 1.03

Left ABI at the DP
Left DP Pressure 134 mmHg / Higher Arm Pressure 132 mmHg = 1.02

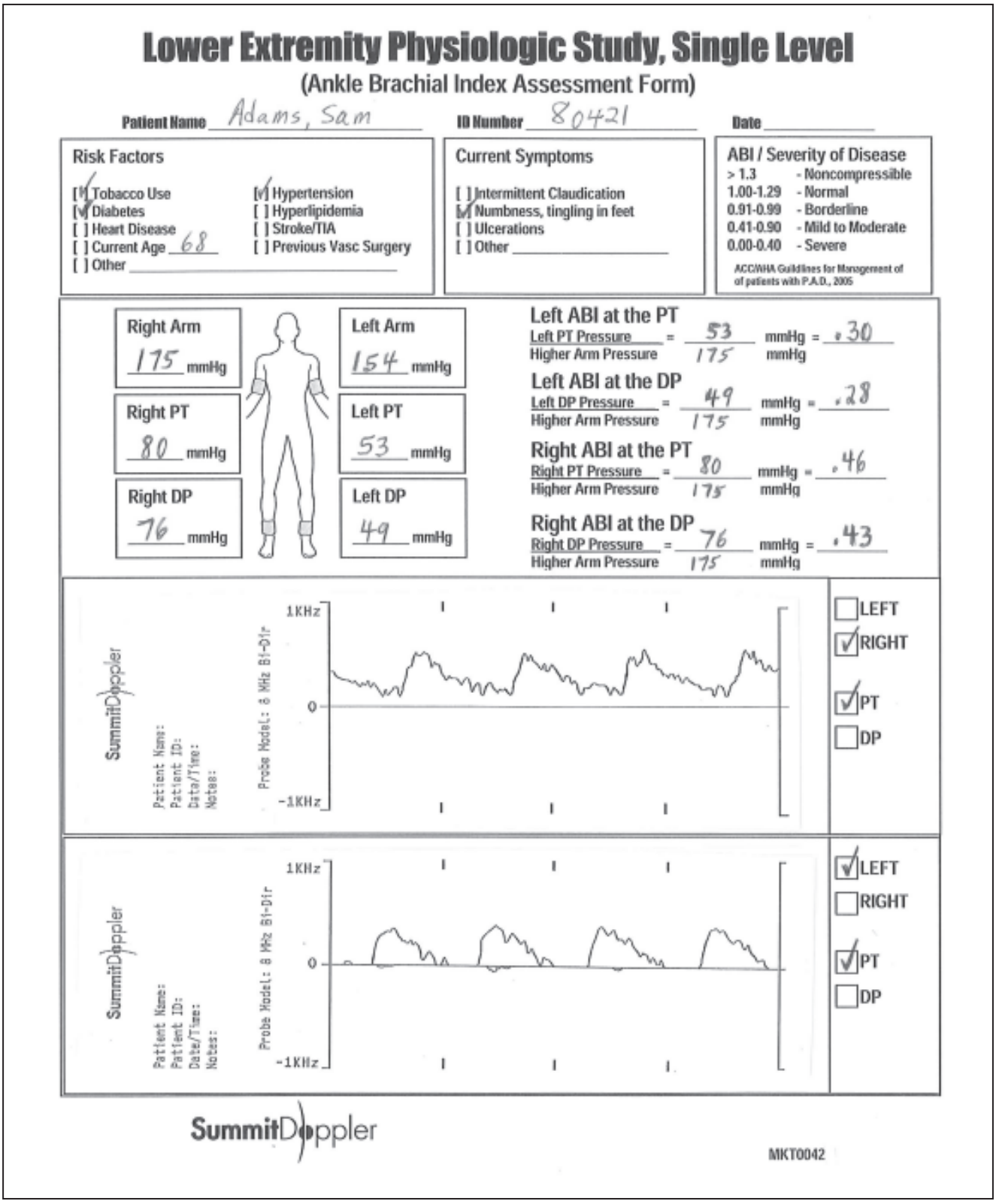
Right ABI at the PT
Right PT Pressure 129 mmHg / Higher Arm Pressure 132 mmHg = .98

Right ABI at the DP
Right DP Pressure 125 mmHg / Higher Arm Pressure 132 mmHg = .95

SummitDoppler

MKT0042

Normal ABI Values and Tri-Phasic Blood Flow No PAD



Severe ABI Values and Mono-Phasic Blood Flow
Moderate to Severe PAD

Warranty and Servicing Policy

The warranty on this product is that it will be free from defects in material and workmanship for 12 months from the original sale of the device. Product life is specified to be 5 years from manufacture, though the device may be repairable beyond this timeframe. This includes all parts and labor required to repair or replace the unit to original specifications and shipping costs associated with sending the product back to the customer. Customer is responsible for providing adequate packaging materials and shipping costs to Wallach Surgical Devices. Products shall be repaired or replaced in a reasonable amount of time.

Wallach Surgical Devices' liability for any claim is limited to materials and labor associated with repair or replacement. In no event shall Wallach Surgical Devices be liable for incidental or consequential losses or damages in connection with the purchase of this product.

Wallach Surgical Devices disclaims all express or implied warranties, agreements or arrangements other than issued in this warranty.

Wallach Surgical Devices is not responsible for damages to the device that occur as a result of the inadequate packaging on return shipments to Wallach Surgical Devices, improper maintenance or cleaning as described in the user manual, misuse, abuse, alteration of the equipment from it's original specifications, or dismantling the unit (other than by Wallach Surgical Devices approved service technicians).

Service Returns: To return products to Wallach Surgical –

1. Call Wallach Surgical Devices to obtain a Return Authorization and to receive any final instructions prior to shipping
2. Clean the product prior to shipping
3. Ensure the device is well-packaged and suitable for shipment

Send the product to:

Repair Department
Wallach Surgical Devices
95 Corporate Drive
Trumbull, CT 06611 USA

For customer service, technical service, cleaning, maintenance or shipping questions please call (203) 799-2000 or 1-800-243-2463.

Explanation of Symbols

REF	Reorder Number
SN	Serial Number
LATEX	Latex Free
	ATTENTION: See instructions for use.
	Manufacturer
	Date of Manufacture
	Symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
CE 0086	Product conforms to the Medical Device Directive 93/42/EEC
EC REP	Authorized Representative in the European Community.
	Keep Dry
	Type B Applied Part
	Class II Equipment

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WALLACH®
SURGICAL DEVICES

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: 800-243-2463
(203) 799-2000
Fax: (203) 799-2002

customerservice@wallachsurgical.com
www.wallachsurgical.com

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