

Newman  Medical

*Employee Owned & Operated*

# simple ABI ™

with CUFF:LINK™

## Vascular Diagnostic System User Manual



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## COMMON TERMINOLOGY

**ABI** – **A**nkle **B**rachial **I**ndex – the ratio of the ankle systolic blood pressure divided by the brachial (arm) systolic blood pressure.

**DP** – (or **DPA**) -- **D**orsalis **P**edis Artery --- the artery on top of the foot. Used in the ABI exam.

**MHz** – Megahertz – Millions of cycles per second --the frequency of the sound transmitted by a vascular probe is measured in megahertz - 8 million cycles per second, for example.

**PAD** – **P**eripheral **A**rtery **D**isease – Typically atherosclerosis (also known as hardening of the arteries) in the leg.

**PPG** – **P**hotoplethysmography –detects the pulse using reflected light from a small emitter/detector combination.

**PT** – (or **PTA**) – **P**osterior **T**ibial Artery – artery on the inside of the ankle used in the ABI exam.

**PVD** – **P**eripheral **V**ascular **D**isease – Includes venous as well as arterial disease.

**PVR** – **P**ulse **V**olume **R**ecording – a means of evaluating the condition of the arteries by looking at a waveform of small changes in cuff pressure caused by pulses in the arteries under the cuff.

**Segmentals** – Pressures and PVRs just like the ABI but done in more cuffs on the leg to assist in localizing the site of any occlusion. The Doppler probe can remain at the ankle for the pressures.

**TBI** – **T**oe **B**rachial Index – the ratio of the pressure in the toe divided by the brachial pressure. It is generally measured with a small toe cuff and a PPG probe

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# Chapter 1 – About simpleABI

Congratulations on your purchase of a simpleABI Cuff-Link™ System from Newman Medical.

The simpleABI Cuff-Link™ was designed to be the easiest and most intuitive system on the market for initial vascular assessment. We hope you find that to be the case. If not, please do not hesitate to call us and let us know how we can improve the product for you.

## What's new in the simpleABI System

- Simple and intuitive PC based interface
- Direct to Computer reporting software for ease of reimbursement

# Chapter 2 – Safety

## Intended Use

The simpleABI System was designed to aid in the diagnosis of peripheral arterial disease (PAD) through diagnostic exams including Ankle Brachial Index (ABI).

Caution: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

## Contraindications

**Contraindications:** Do not perform the ABI exam on someone suspected of having acute deep venous thrombosis, and do not take an arm pressure in an arm with a shunt or dialysis graft.

**Warning:** The device is not to be used on or near the eyes.

**Warning:** The device is for use only on intact skin.

**Warning:** The device is not to be plugged into a telephone or modem system.

## Safety of the Blood pressure cuffs

Inspect the cuffs for damage periodically. Do not leave a cuff inflated at high pressures for an extended period of time when on a patient. Do not inflate a cuff when it is not on a patient. Cuff covers may be washed by removing the bladders. Any open lesion with the potential for contamination should be covered with an impermeable dressing.

## Safety of Dopplers

The simpleABI was designed according to National and International consensus safety standards. Throughout design of this product, safety was the paramount concern. In view of that, this product was designed according to the principle of ALARA (**As Low As Reasonably Achievable**).

## AIUM Statements

### As Low As Reasonably Achievable (ALARA) Principle

*Approved March 16, 2008*

The potential benefits and risks of each examination should be considered. The ALARA (As Low As Reasonably Achievable) Principle should be observed when adjusting controls that

affect the acoustical output and by considering transducer dwell times. Further details on ALARA may be found in the AIUM publication "Medical Ultrasound Safety."

### **Prudent Use and Clinical Safety**

*Approved March 19, 2007*

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:

No independently confirmed adverse effects caused by exposure from present diagnostic ultrasound instruments have been reported in human patients in the absence of contrast agents. Biological effects (such as localized pulmonary bleeding) have been reported in mammalian systems at diagnostically relevant exposures but the clinical significance of such effects is not yet known. Ultrasound should be used by qualified health professionals to provide medical benefit to the patient.

### **Safety in Training and Research** *Approved March 19, 2007*

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:

When examinations are carried out for purposes of training or research, the subject should be informed of the anticipated exposure conditions and how these compare with normal diagnostic practice.

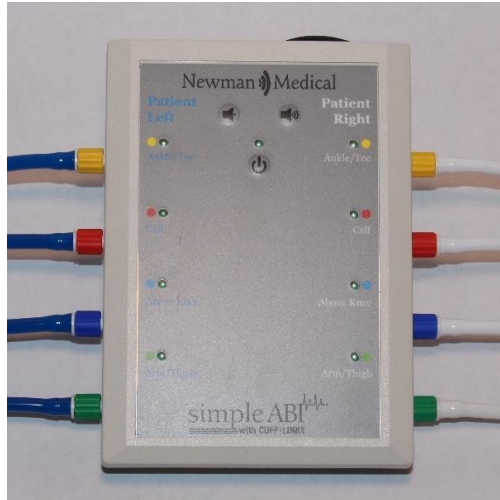
## **Chapter 3 – Setting up your simpleABI**

Installation of your simpleABI is straightforward but may require a few common tools. This installation is typically handled by a trained Newman Medical salesperson.

### **Stand Assembly**

If a stand was included with the order, please see the assembly instructions supplied with the stand.

1. Place computer onto mounting plate, ensuring all loop tabs on PC line up with respective hook tabs on mounting plate.
  - a. It is helpful to first check how the computer aligns on the mounting plate prior to placing hook and loop tabs.
2. Place all cuffs into basket.
3. Connect the Cuff-Link Control Unit to the computer with the included USB cable. Insert the remote-control cable firmly into the control box. Attach the hoses to the Cuff-Link Control Unit as shown below. Hoses are color coded to aid attachment. Depending on model chosen, systems will have 4 or 8 tubes. Both units are shown below.



4. Attach Doppler probe to Cuff-Link Control Unit.

### **FIELD INSTALLATION OF SIMPLEABI SOFTWARE**

This section applies only to systems where the software is installed in the field – computers shipped from Newman Medical already have the software loaded and this section does not apply.

**WARNING:** simpleABI is only supported on the following Windows Operating Systems:

- Windows 7 (32 or 64 bit)
- Windows 10 (32 or 64 bit)

Do not install on any other operating systems prior to contacting Newman Medical Technical Support for information.

**WARNING:** Use of other applications (word processing, games, internet) is not an appropriate use of a medical device and must be avoided to ensure proper operation of the simpleABI system.

#### **Software Installation Directions**

1. Plug in included USB Flash Drive into PC
2. Copy \*.msi to C:\ (.msi file will have different names depending on simpleABI system purchased)
3. Double Click \*.msi file to begin installation

#### **PVR Driver Installation-Windows 7 or Windows 10**

1. Plug in Cuff-Link Control Unit and make sure it is powered on.
2. Click the Windows Start Button (Windows Logo) and type 'Device Manager'
3. Select Device Manager (may be associated with control panel)
4. The simpleABI system will appear under 'Other Devices', make sure to expand that category to see 'Newman Medical simpleABI Device'
5. Right click Newman Medical simpleABI Device and select 'Update Driver'

6. Choose 'Browse my computer for driver software'
7. In the highlighted field ensure you are browsing the install folder C:\Newman Medical by typing "C:\Newman Medical" from the field.
8. Make sure 'Include subfolders' checkbox is selected
9. If a Windows Security window appears, select 'Install'
10. Driver should be properly installed and can be checked by opening simpleABI Reporting Software. If installed properly, top of simpleABI window will display 'Connected' in green highlight
  - a. If not installed properly, simpleABI software window will display 'Not Connected' in red highlight

## Chapter 4 – simpleABI Reporting Software

### Start-up

#### Add/Delete/Edit Doctor/Examiner/Practice Information/Logos

Under the *Edit* menu there are multiple options for editing the configuration of your software. You may add, delete, and edit practice information, examiner information, doctor information, output formats, impressions, and ICD codes. You can also upload practice logos to customize reports.

To close any editing form, select *File* → *Close Form*

#### Beginning an Exam

Find the simpleABI Reports icon on the computer desktop and select it. The simpleABI start-up screen with menus on the top will appear. Select *File* → *New* and the exam to be performed. Depending on the system chosen, you will have different choices of exams. Choose an exam and it will open on the screen.

#### Loading an Exam

From the simpleABI start-up screen, Select *File* → *Load* and the exam to be performed. You may select any previously report to populate the loading exam with data relevant to the exam. I.e. you can load an ABI exam into a segmental exam; all patient information and arm/ankle pressures and waveforms from previous exam will be loaded. You would need only to perform upper leg pressure/waveform measurements. Depending on the system chosen, you will have different choices of exams. Choose an exam to load and select a previous exam and it will open on the screen.

#### Saving an Exam

You can save your finished report as a PDF file using CTRL+S or select *File* → *Save*. Files are appended with Patient ID and a timestamp to differentiate exams. This command automatically saves 2 exam types by default: PDF and a XML data file.

#### Printing an Exam

You can print your exams using CTRL+P or by selecting *File* → *Print*

#### Help

Help is found by selecting *Help* menu. With an internet connection, you will be directed to Newman Medical's website where you can browse to our support pages with helpful hints and videos on using your simpleABI.

## **Chapter 5 – Performing Exams**

### ***Contraindications***

Do not perform vascular exams on someone suspected of having acute deep vein thrombosis, and do not take an arm pressure in an arm with a shunt or dialysis graft. The cuff should not be applied over a distal bypass or over ulcers. Any open lesion posing suspected contamination should be covered with an impermeable dressing or disposable vascular cuffs should be utilized.

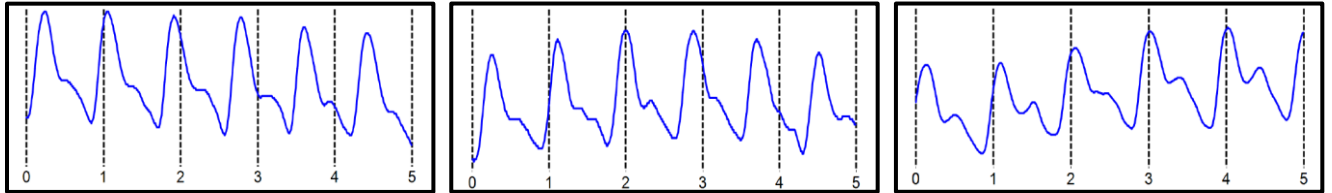


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## ***Interpretation of waveforms***

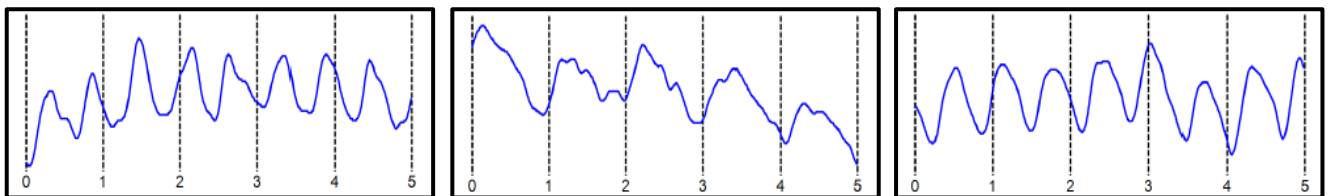
Pulse Volume Recording (PVR) is used to measure the change in pressure in the cuff caused by the small changes in volume that occur with each pulse. The analysis of the waveform is based on the shape of the waveform rather than the amplitude. PVRs are not affected by calcified arterial walls and are relatively easy to perform.

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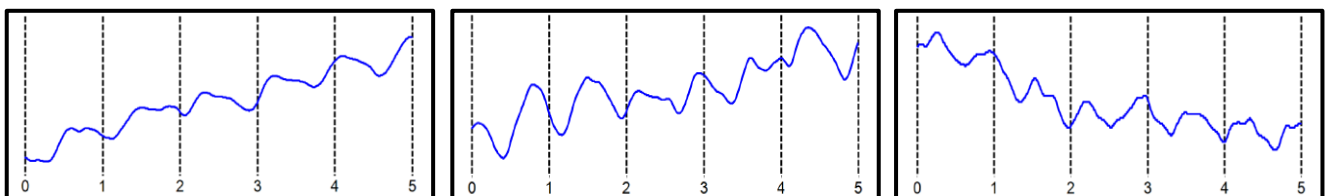
Normal: Waveforms with a rapid rise and a prominent reflected wave (dicrotic notch)

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Moderately Abnormal: Waveform starts to broaden and no reflected wave.

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Abnormal: No reflected wave, slow rise. Potential 'flatline'

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**Determining site of occlusion with PVR waveforms:**<sup>1</sup> A normal waveform at a site indicates that there is likely not occlusive disease proximal to that that cuff.

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<sup>1</sup> Daigle, Robert J., Techniques in Noninvasive Vascular Diagnosis, Summer Publishing, [www.summerpublishing.com](http://www.summerpublishing.com)

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## ***simplePVR Examination***

### **Purpose & Background**

The simplePVR™ procedure is a 1-2 minute exam to quickly and effectively assess the lower extremity arteries for peripheral artery disease. It utilizes PVR waveforms at both ankles.

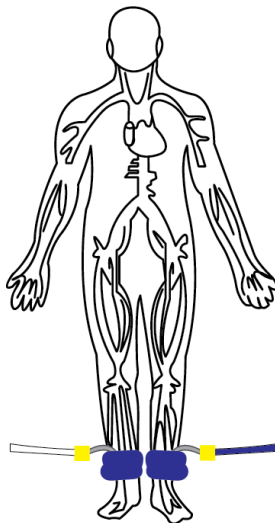
The simplePVR™ exam is a diagnostic test that examines arterial waveforms to determine the need for further vascular evaluation. The exam can be done in either a sitting or supine position and does not require the removal of shoes or socks.

### **Opening the exam**

On the computer desktop, double click the simpleABI icon. When the program opens select *File* → *New* → *New simplePVR Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### **Attaching cuffs**

Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link control unit to cuffs as shown below. The yellow connectors go to the ankles. White hoses go to the patient's right side, blue to the left. \*NOTE\* the image is reversed as if you are looking at the patient lying down



### **Obtaining Waveforms**

1. To obtain a **PVR waveform** click on the right box for taking a waveform in the middle of the screen. Press the button with the **waveform** image on it on the top right of the remote. The cuff will inflate to about 80 mmHg pressure, slowly deflate to about 65 mm and then hold that while the waveform is obtained. The patient should remain still during the measurement; the waveform will start to appear after the cuff reaches 65 mm.
2. If you are not satisfied with the waveform, just push the **waveform** button again
3. Press either **Next** after the waveform is obtained to move to the other side.

### **Left Side**

1. Repeat steps above for the left side.

### **Saving/Printing**

Save the report by selecting *File* → *Save* or pressing CTRL+S. Print the report by selecting *File* → *Print* or pressing CTRL+P.

### **Exam Helpful Hints**

#### How Pulse Volume Recording (PVR) Works

- Blood volume in the legs increases with each pulse and this increases the pressure in the cuff. These small changes are recorded and saved as the PVR waveform

#### Advantages of PVR

- PVRs provide a measure of the total blood flow through the limb unlike Doppler waveforms which show only the flow in the artery directly in front of the probe.
- PVRs are not affected by calcified arteries (if the ABI is greater than 1.4 it is likely due to calcified arteries)
- PVRs are easier to perform than Doppler waveform analysis
- The only skill required to acquire PVRs is the ability to wrap vascular cuffs snugly
- PVRs require patient cooperation; limb motion affects the waveform. Patients should be instructed not to move or talk during this test

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## ***ABI Examination***

### **Purpose & Background**

The ABI has become the best known and standardized test for PAD. Fundamentally it is the systolic blood pressure taken with the cuff at the ankle divided by the systolic pressure with the cuff on the upper arm. Recent reviews<sup>2</sup> and reimbursement criteria require that the measurements be done with a Doppler using both the DP and PT arteries at the foot.

### **Opening the Exam**

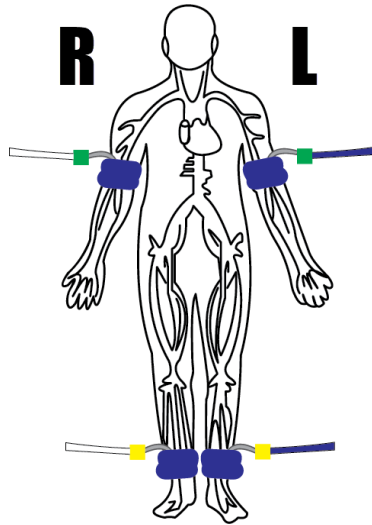
On the computer desktop, double click the simpleABI icon. When the program opens select *File* → *New* → *New ABI Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### **Attaching cuffs**

Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link Control Unit to cuffs as shown below. The green connectors go to the arm cuffs and yellow to the ankles. White hoses go to the patient's right side, blue to the left. \*NOTE\* the image is reversed as if you are looking at the patient lying down.

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<sup>2</sup> Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. *Circulation*. 2012;126



### **Arm Pressure**

1. Begin with the right brachial. Place the Doppler probe at a 45-degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained.
2. Press and hold **Inflate** on the Cuff-Link Remote (shown above) and inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. Release **Inflate** and the cuff will automatically deflate at the suggested rate of 2mmHg/second.
4. When you hear the Doppler signal return, pressing **Pressure** will store the pressure value in the exam.



### **Ankle Pressures**

1. Press **Next** on the remote and the system will move to the Dorsalis Pedis (DP) site. Find the arterial signal using the Doppler probe on the dorsalis pedis artery on top of the foot. Obtain the arterial pressure in the same manner you did on the arm. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)



2. Press **Next** and the system will move to the posterior tibial (PT) site. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return).



### **Waveform**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Left Side**

2. Repeat steps above for the left side.

The interpretation of the ABI values is based on recent guidelines.<sup>3</sup>

### **Saving/Printing**

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<sup>3</sup> A REPORT OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION TASK FORCE ON PRACTICE GUIDELINES. CIR.000000000000470, originally published November 13, 2016

Save the report by selecting *File*→*Save* or pressing CTRL+S. Print the report by selecting *File*→*Print* or pressing CTRL+P.

### **Exam Helpful Hints**

If the ankle pressure is high, above 200 mmHg, or the cuff cannot obliterate the Doppler sounds, this indicates that the artery may be incompressible due to calcification.

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## **The ABI with Toe (TBI) Examination**

### **Purpose & Background**

The ABI with Toe exam is typically performed after an ABI has been done, especially if the larger ankle arteries appear to be incompressible (pressure over 200mmHg) or anytime more information is needed about small vessel disease. The TBI is done using the PPG probe. The patient is supine and rested in a warm room.

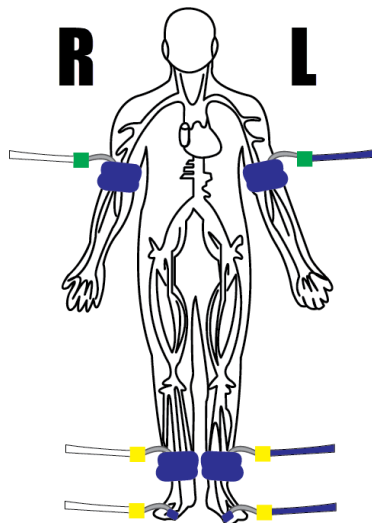
### **Opening the exam**

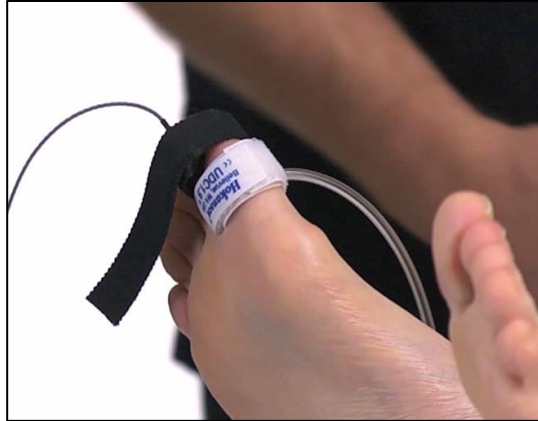
On the computer desktop, double click the simpleABI icon. When the program opens select *File*→*New*→*New ABI with Toe Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### **Attaching cuffs**

Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link control unit to cuffs as shown below. The green connectors go to the arm cuffs and yellow to the ankles or toes. White hoses go to the patient's right side, blue to the left.

If you have performed a previous ABI Exam, you may load the results into this exam by selecting *File*→***Load***→*ABI with Toe Report* and selecting the ABI Exam you previously performed.





### **Brachial Pressure**

1. Begin with the right brachial. Place the Doppler probe at a 45 degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained. (You may also use the PPG sensor to listen for the pulse. If using the PPG, place the sensor on the fleshy part of the finger opposite the fingernail. Wait for consistent beeps from the system.)
2. Press and hold **Inflate** on the Cuff-Link Remote (shown above) and inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. Release **Inflate** and the cuff will automatically deflate at the suggested rate of 2mmHg/second.
4. When you hear the Doppler signal return, pressing **Pressure** will store the pressure value in the exam.

### **Ankle Pressures**

1. Press **Next** on the remote and the system will move to the Dorsalis Pedis (DP) site. Find the arterial signal using the Doppler probe on the dorsalis pedis artery on top of the foot. Obtain the arterial pressure in the same manner you did on the arm. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)
2. Press **Next** and the system will move to the posterior tibial (PT) site. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)

### **Ankle Waveform**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold

that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Toe Pressure**

1. Press **Next** on the remote and the system will move to the Toe site. Place the PPG sensor on the fleshy part of the toe opposite the fingernail. Wait for consistent beeps from the system. A warm towel aids blood flow in the toes. Obtain the toe pressure in the same manner you did on the arm and ankles. The toe cuff inflates rapidly – a light tap of the inflate is best. (**Inflate** until occlusion, release **Inflate**, press **Pressure** on signal return)

### **Toe Waveform**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Left Side**

1. Repeat the above pressures and waveform sequence for the left side of the patient.

### **Saving/Printing**

Save the report by selecting *File* → *Save* or pressing CTRL+S. Print the report by selecting *File* → *Print* or pressing CTRL+P.

### **Exam Helpful Hints**

A warm toe is a big help. Keep the toe covered if you can with a towel or warm towel, if available. Let the patient rest and relax before inflating the cuffs. Anchor the cord from the PPG sensor to the foot with some adhesive tape.

Toe pressures are difficult to obtain in patients with small vessel disease. Pressures can be obtained with the Doppler probe as well, but it is more difficult as the digit arterial signal is hard to locate.

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## ***Segmental Examinations***

### **Purpose & Background**

A segmental exam of the leg is an extension of the ABI exam. In this test, you can attempt to localize the site of an occlusion by taking the pressures and waveforms at more locations on the leg.

By observing the difference in pressure between adjacent sites on the leg you can tell if there is an occlusion between those sites.

A greater than 20mmHg difference between sites is considered positive for a significant stenosis in the artery between or under the cuff.



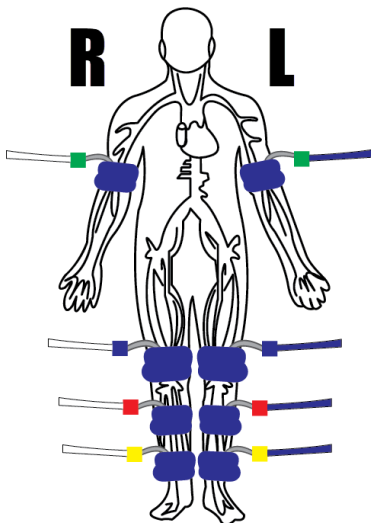


### **Opening the exam**

On the computer desktop, double click the simpleABI icon. When the program opens select *File*→*New*→*3 cuff Segmental Report (or 4 cuff)*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### **Attaching cuffs**

Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link control unit to cuffs as shown below. The green connectors go to the arm (or thigh) cuffs, red to the calves, blue to above the knee cuffs, and yellow to the ankles. White hoses go to the patient's right side, blue to the left. \*NOTE\* the image is reversed as if you are looking at the patient lying down



### **Brachial Pressure**

1. Begin with the right brachial. Place the Doppler probe at a 45 degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained.
2. Press and hold **Inflate** on the Cuff-Link Remote (shown above) and inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. Release **Inflate** and the cuff will automatically deflate at the suggested rate of 2mmHg/second.
4. When you hear the Doppler signal return, pressing **Pressure** will be store the pressure value in the exam.

### **Ankle Pressures**

1. Press **Next** on the remote and the system will move to the Dorsalis Pedis (DP) site. Find the arterial signal using the Doppler probe on the dorsalis pedis artery on top of the foot. Obtain the arterial pressure in the same manner you did on the arm. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)
2. Press **Next** and the system will move to the posterior tibial (PT) site. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)

### **Ankle Waveform**

Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Calf Pressure & Waveform**

1. Press **Next** on the remote and the system will move to the calf site. Obtain the arterial pressure and waveform in the same manner you did on the ankles.

### **Above Knee Pressure & Waveform**

1. Press **Next** on the remote and the system will move to the above knee site. Obtain the arterial pressure and waveform in the same manner you did on the ankles.

### **Thigh Pressure & Waveform (Certain segmental exams)**

1. Press **Next** on the remote and the system will move to the thigh site. Obtain the arterial pressure and waveform in the same manner you did on the ankles.

### **Left Side**

Repeat the above pressures and waveform sequence for the left side of the patient

### **Toe Pressure (Certain segmental exams)**

1. Press **Next** on the remote and the system will move to the toe site. Obtain the arterial pressure in the same manner you did on the arm and ankles or using the PPG sensor. \*NOTE\* digit cuffs inflate very quickly a light tap on the inflate button will often suffice (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)

### **Toe Waveform (Certain segmental exams)**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote.

### **Saving/Printing**

Save the report by selecting *File*→*Save* or pressing CTRL+S. Print the report by selecting *File*→*Print* or pressing CTRL+P.

### **Exam Helpful Hints**

#### Elevated Leg Pressures

If the ankle pressure is high, above 200 mmHg, or the cuff cannot obliterate the Doppler sounds, this indicates that the artery may be incompressible due to calcification.

#### Efficient, less painful protocols

Current CPT guidelines for CPT code 93923 state that is PVR waveforms are being utilized, only pressures at the ankles must be obtained. **Pressures** do not need to be obtained at the calf, above knee, or thigh.

This has many advantages – most notable

1. This protocol significantly reduces the time necessary for this exam.
2. This protocol will be significantly less painful for your patients

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## ***ABI with Exercise Examination***

### **Purpose & Background**

The ABI with Exercise test is useful for differentiating true vascular claudication from other non-vascular pains. The stress can be produced by treadmill walking exercise (CPT 93924) or by toe/heel raises (CPT 93923).

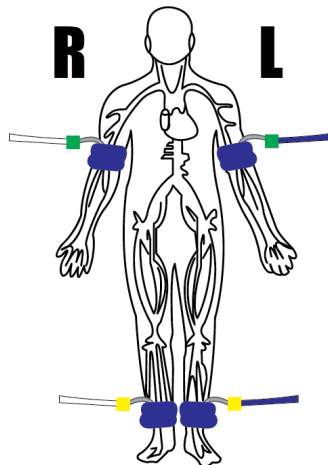
### **Contraindications**

- Questionable cardiac status
- Severe pulmonary disease
- Ischemic rest pain, ulceration, or ankle pressures <40mm Hg
- Non-compressible tibial arteries
- Do not perform the ABI exam on someone suspected of having acute deep venous thrombosis, and do not take an arm pressure in an arm with a shunt or dialysis graft.

Explain to the patient that they will be exercising, either walking or doing toe raises, or until pain stops them. Ask them to tell you when and where pain occurs. Remind them to report any chest pain, shortness of breath, or severe fatigue.

**Opening the exam** On the computer desktop, double click the simpleABI icon. When the program opens select *File* → *New* → *New ABI with Exercise Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

**Attaching cuffs** Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link control unit to cuffs as shown below. The green connectors go to the arm cuffs and yellow to the ankles. White hoses go to the patient's right side, blue to the left. \*NOTE\* the image is reversed as if you are looking at the patient lying down



## **Resting Portion**

### **Brachial Pressure**

1. Begin with the right brachial. Place the Doppler probe at a 45 degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained.
2. Press and hold **Inflate** on the Cuff-Link Remote (shown above) and inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. Release **Inflate** and the cuff will automatically deflate at the suggested rate of 2mmHg/second.
4. When you hear the Doppler signal return, pressing **Pressure** will be store the pressure value in the exam.

### **Ankle Pressures**

1. Press **Next** on the remote and the system will move to the Dorsalis Pedis (DP) site. Find the arterial signal using the Doppler probe on the dorsalis pedis artery on top of the foot. Obtain the arterial pressure in the same manner you did on the arm. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)
2. Press **Next** and the system will move to the posterior tibial (PT) site. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)

### **Waveform**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Left Side**

1. Repeat the above pressures and waveform sequence for the left side of the patient.

### **Exercise**

1. Have the patient perform 50 toe raises or until pain is prevalent OR hall walking for 5 minutes or until pain is prevalent,
2. Repeat resting ABI protocol described above.

### **Saving/Printing**

Save the report by selecting *File*→*Save* or pressing CTRL+S. Print the report by selecting *File*→*Print* or pressing CTRL+P.

### **Exam Helpful Hints**

#### **Cuffs**

Leave cuffs on for hall walking or toe raises, but disconnect tubing.

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## **The ABI Stress Examination**

### **Purpose & Background**

The ABI Stress-Treadmill test is useful for differentiating true vascular claudication from other non-vascular pains. The stress can be produced by treadmill walking exercise (CPT 93924) or by toe/heel raises (CPT 93923).

### **Contraindications**

- Questionable cardiac status
- Severe pulmonary disease
- Ischemic rest pain, ulceration, or ankle pressures <40mm Hg
- Non-compressible tibial arteries
- Do not perform the ABI exam on someone suspected of having acute deep venous thrombosis, and do not take an arm pressure in an arm with a shunt or dialysis graft.

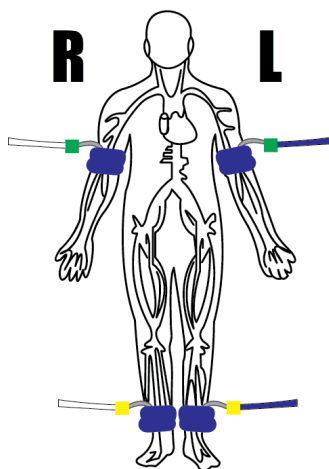
Explain to the patient that they will be exercising, either walking or doing toe raises, or until pain stops them. Ask them to tell you when and where pain occurs. Remind them to report any chest pain, shortness of breath, or severe fatigue.

### **Opening the exam**

On the computer desktop, double click the simpleABI icon. When the program opens select *File* → *New* → *New ABI Stress - Treadmill Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### **Attaching cuffs**

Wrap appropriate cuffs at each site. Attach the hoses from the Cuff-Link control unit to cuffs as shown below. The green connectors go to the arm cuffs and yellow to the ankles. White hoses go to the patient's right side, blue to the left. \*NOTE\* the image is reversed as if you are looking at the patient lying down



### **Brachial Pressure**

1. Begin with the right brachial. Place the Doppler probe at a 45 degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained.
2. Press and hold **Inflate** on the Cuff-Link Remote (shown above) and inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. Release **Inflate** and the cuff will automatically deflate at the suggested rate of 2mmHg/second.
4. When you hear the Doppler signal return, pressing **Pressure** will be store the pressure value in the exam.

### **Ankle Pressures**

1. Press **Next** on the remote and the system will move to the Dorsalis Pedis (DP) site. Find the arterial signal using the Doppler probe on the dorsalis pedis artery on top of the foot. Obtain the arterial pressure in the same manner you did on the arm. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)
2. Press **Next** and the system will move to the posterior tibial (PT) site. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure. (Hold **Inflate** until occlusion, release **Inflate**, press **Pressure** on Doppler signal return)

### **Waveform**

1. Press **Next** and the system will move to the waveform site. Press and release the button with the **Waveform** image on the top right of the remote. The cuff will inflate to roughly 85mmHg and deflate to the proper pressure (65mmHg) and hold that while the waveform is obtained. The waveform will start to appear when the cuff has reached 65mmHg. The patient should remain as still as possible during the measurement.

### **Left Side**

1. Repeat the above pressures and waveform sequence for the left side of the patient.

### **Exercise**

1. Have the patient walk on treadmill at 1-2MPH, 10% grade, for 5 minutes or until pain precludes the patient from walking further.
2. Repeat resting ABI protocol described above immediately following exercise and monitor for up to 5 more periods.

### **Saving/Printing**

Save the report by selecting *File*→*Save* or pressing CTRL+S. Print the report by selecting *File*→*Print* or pressing CTRL+P.

### **Exam Helpful Hints**

#### **Cuffs**

Leave cuffs on for treadmill protocol, but disconnect tubing.

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## Chapter 6 - Doppler Description

### Doppler – Operation and Use

The Doppler probe is designed to aid in diagnosis of vascular conditions including aiding in obtaining systolic pressures during an ABI examination.

#### Turning the unit ON/OFF

Power to the unit is controlled by the **ON/OFF** button located in the center of the Cuff-Link Control Unit. Pressing and releasing the button will cycle the unit through the power sequence. The LED in the power button will remain illuminated during operation.

#### Volume

The Doppler has multiple volume levels. These are controlled with the volume up and down buttons.

#### Probes:

8 MHz – Vascular. simpleABI Systems come standard with an 8MHz probe designed for locating shallow lying vessels. The pen-tip sensor face aids in the location of specific vessels during examination.

5 MHz – Vascular. An optional 5MHz probe is available for simpleABI Systems and designed for locating deeper lying vessels. The wider sensors may aid in maintaining the probe location on the vessel during examination.

PPG – The Photoplethysmograph probe uses the absorption of infrared light by blood cells in the blood to produce an audible beep each time it detects a vascular pulse in the near surface vessels.

#### Obtaining Doppler Signals

**Caution:** For any examination utilizing a Doppler, it is essential that an adequate supply of gel is 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. Given the small area of the vascular probes, the strength of the Doppler signal is highly location specific.

## Chapter 7 – Tips & Troubleshooting

### Poor Sound Quality

Inadequate gel use-apply more gel

Probe location-search for vascular sounds as described in **Chapter 5 – Performing Exams**

## Chapter 8 – Maintenance and Cleaning

**WARNING:** simpleABI components are not designed for liquid immersion. Do not soak or drop the Doppler probes in liquid.

**WARNING:** Probes are not designed for sterilization processes such as autoclaving or gamma radiation.

**WARNING:** Probes are 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 Doppler probes require very little maintenance. It is important, however, for the continued functionality of the unit and the health of the patients to that the unit is cleaned and examined regularly as follows:

**After every examination**

Excess gel should be wiped off after each examination. Probe should be cleaned with a damp water or alcohol based wipe. Mild soap or detergent can be used. In particular, pay attention to any surface openings on the unit including, but not limited to, the speaker grill.

Practitioners should wash hands and change gloves after every exam. Please follow local and hospital guidelines for cleaning and disinfection policies.

To disinfect unit, use an isopropyl alcohol wipe or spray, such as Parkers Labs Protex® and follow the manufacturer’s instructions.

Store unit in a clean area free from dust and debris in an indoor environment.

**Periodically**

Inspect the unit for signs or cracks or breaks in the surface housing. If any sign of cracking or damage is evident, use of the unit should be discontinued. Please contact Newman Medical for service.

## **Chapter 9 – Specifications**

Level of Protection against electrical shock

Type B Applied Part; Class II Equipment

Designed to meet the following standards:

IEC60601-1, IEC60601-2, IEC60601-2-37

**simpleABI System**

Height (inclusive)	107 cm (42 inches)
Weight (inclusive)	5.5 kgs (12 pounds)
Transport/Storage Temperature	-20° ~ 50°C (-4° ~ 122°F)
Transport/Storage Humidity	5% ~ 90%, non-condensing
Battery Life	10 hours



## Acoustic Properties

System: DigiDop Operating Mode: Continuous Wave (CW)  
 Transducer Model: 5MHz Application(s): Peripheral Vascular

Acoustic Output			MI	I <sub>SPTA.3</sub> (mW/cm <sup>2</sup> )	I <sub>SPPA.3</sub> (mW/cm <sup>2</sup> )
Global Maximum Value			0.0223	86.4	86.4
Associated Acoustic Parameters	p <sub>r.3</sub>	(Mpa)	0.041		
	W <sub>o</sub>	(mW)		9.26	9.26
	f <sub>c</sub>	(MHz)	5.61	5.61	5.61
	Z <sub>sp</sub>	(cm)	1.10	1.10	1.10
	Beam Dimensions	x-6 (cm)		0.154	0.154
		y-6 (cm)		0.540	0.540
	PD	(usec)	CW		CW
	PRF	(Hz)	n/a		n/a
	EBD	Az. (cm)		1.052	
Ele. (cm)			0.526		

System: DigiDop Operating Mode: Continuous Wave (CW)  
 Transducer Model: 8MHz, narrow Application(s): Peripheral Vascular

Acoustic Output			MI	I <sub>SPTA.3</sub> (mW/cm <sup>2</sup> )	I <sub>SPPA.3</sub> (mW/cm <sup>2</sup> )
Global Maximum Value			0.0495	555	555
Associated Acoustic Parameters	p <sub>r.3</sub>	(Mpa)	0.0923		
	W <sub>o</sub>	(mW)		9.02	9.02
	f <sub>c</sub>	(MHz)	7.84	7.84	7.84
	Z <sub>sp</sub>	(cm)	0.50	0.50	0.50
	Beam Dimensions	x-6 (cm)		0.231	0.231
		y-6 (cm)		0.121	0.121
	PD	(usec)	CW		CW
	PRF	(Hz)	n/a		n/a
	EBD	Az. (cm)		0.203	
Ele. (cm)			0.457		

### Measurement Uncertainties:

Total uncertainty for power:	28.2%
Total uncertainty for I <sub>SPTA</sub> :	28.2%
Total uncertainty for f <sub>c</sub> :	2.0%
Total uncertainty for MI:	14.1%

I<sub>SPTA.3</sub> **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).

I<sub>SPPA.3</sub> **derated spatial-peak pulse-average intensity** (watts per square centimeter). The value of IPA.3 at the position of global maximum MI (IPA.3@MI) may be reported instead of ISPPA.3 if the global maximum MI is reported.

MI **Mechanical Index**. The value of MI at the position of ISPPA.3, (MI@ISPPA.3) may be reported instead of MI (global maximum value) if ISPPA.3 is ≤ 190W/cm<sup>2</sup>.

p<sub>r.3</sub> **derated peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

W<sub>o</sub> **ultrasonic power** (milliwatts). For the operating condition giving rise to ISPTA.3, W<sub>o</sub> is the total time-average power; for the operating condition subject to reporting under ISPPA.3, W<sub>o</sub> is the ultrasonic power associated with the transmit pattern giving rise to the value reported under ISPPA.3.

f<sub>c</sub> **center frequency** (MHz). For MI and ISPPA.3, f<sub>c</sub> is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter. For ISPTA.3, for combined

modes involving beam types of unequal center frequency,  $f_c$  is defined as the overall range of center frequencies of the respective transmit patterns.

$z_{sp}$  the axial distance at which the reported parameter is measured (centimeters).

$x_{-6}$ ,  $y_{-6}$  are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where  $z_{sp}$  is found (centimeters).

PD **pulse duration** (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.

PRF the **pulse repetition frequency** (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.

EBD the **entrance beam dimensions** for the azimuthal and elevational planes (centimeters).

EDS the **entrance dimensions of the scan** for the azimuthal and elevational planes (centimeters).

The reporting values for ultrasonic power,  $W_0$ , and non-derated spatial average temporal average ISATA required by paragraph 2.1.2 of the FDA Guidance [3] as well as the derated spatial-peak temporal-average intensity,  $ISPTA.3$ , provided for reference only, are calculated for all probes as illustrated in the sample calculations below.

For Non-Auto scanning modes reporting parameters are calculated as:

$$W_0 = I_{SPTA.0} * PF$$

$$I_{SATA.0} = W_0 / (\text{entrance beam area})$$

$$ISPTA.3 = I_{SPTA.0} * e^{-0.069 f_c z}$$

Where  $I_{SPTA.0}$ , is the non-derated spatial-peak temporal-average intensity,  $ISATA.0$  is the nonderated spatial-average temporal-average intensity at the transducer face and  $ISPTA.3$ , is the derated spatial-peak temporal-average intensity,  $f_c$ , the waveform center frequency,  $z$ , the axial distance between the probe and hydrophone,  $PF$ , the power factor which is calculated by integrating the normalized cross axis and raster scan data selecting the largest  $PF$  value, which is an "effective area" used to calculate  $W_0$ , the ultrasonic power.

## **Chapter 10 – Warranty, Service, & Support**

The simpleABI System and components are guaranteed to be free from defects in material and workmanship for 2 years from the original sale of the device. This guarantee includes all parts and labor required to repair or replace the unit, including shipping the unit back to the customer. Customer is responsible for the adequate packaging and return of the unit for servicing. Products will be repaired or replaced in a reasonable amount of time, to be determined by service personnel.

The manufacturer and distributor of a simpleABI System assume neither responsibility nor liability for incidental or consequential damages arising from the purchase of this product.

The manufacturer and distributor of simpleABI Systems are not responsible for damages occurring from misuse or neglectful handling of the device. Any abuse, neglect, or alteration of the equipment, including dismantling of the unit (other than by trained service personnel), from its original specifications nullify all stated and implied warranties.

To return a unit for servicing:

1. Call customer service for a return authorization.
2. Clean the product prior to packing and shipping.
3. Adequately package and return the unit to:

Newman Medical  
Attn: Service  
5350 Vivian Street, Unit C  
Arvada, CO 80002  
800-267-5549