

Newman  Medical

*Employee Owned & Operated*

# simple ABI

## Vascular Diagnostic System User Manual



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## COMMON TERMINOLOGY

**ABI – Ankle Brachial Index** – the ratio of the ankle systolic blood pressure divided by the brachial (arm) systolic blood pressure.

**Distal** - situated away from the center of the body – i.e. “downstream”. An example - the ankle is distal to the calf.

**Distal Pressure** – A pressure taken distal to the method of occlusion. I.e. taking the brachial pressure below (distal to) the cuff.

**DP – (or DPA) -- Dorsalis Pedis 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 – Peripheral Artery Disease** – Typically atherosclerosis (also known as hardening of the arteries) in the leg.

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

**Proximal** – Points situated nearer to the center of the body – i.e. “upstream”. An example – the calf is proximal to the ankle.

**PT – (or PTA) – Posterior Tibial Artery** – artery on the inside of the ankle used in the ABI exam.

**PVD – Peripheral Vascular Disease** – Includes venous as well as arterial disease.

**PVR – Pulse Volume Recording** – 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.

**Reactive Hyperemia** - the transient increase in organ blood flow that occurs following a brief period of restriction of blood flow. In lower arterial this is typically done by placing a cuff on the thigh and occluding blood flow for 3-5 minutes, then quickly releasing. An extremely painful exam.

**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 – Toe Brachial 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 System from Newman Medical.

The simpleABI 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 is included with simpleABI PVR Systems

- Handheld Doppler with 8MHz probe
- PVR Hardware
- OPTIONAL - PPG Probe (ABI-300 only)
- Vascular Cuffs
- USB Cable
- OPTIONAL - Laptop PC - simpleABI is designed to work with a computer certified to IEC 60601-1, IEC-62368-1 or IEC 60950-1 and running Windows 10 (32 or 64 bit) or Windows 11 (64 bit) in the Operator environment.
- simpleABI User Manual

## Chapter 2 – Safety

### *Safety of Equipment*

simpleABI Systems are medical equipment. Although designed to withstand everyday use, care must be taken to ensure safe and continued operation. Do not abuse equipment. simpleABI Systems were designed according to domestic 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 reducing risk AFAP (**As Far As Possible**).

### *Intended Use*

This product is intended for use by health care providers for detection of blood flow in the veins and arteries and as an aid in the diagnosis of peripheral arterial disease.

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

### *Indications*

#### Indications for noninvasive physiologic testing

Common indications for lower extremity arterial physiologic evaluation include, but are not limited to:

- Peripheral arterial disease (PAD)
- Exercise-related limb pain (claudication symptoms)
- Limb pain at rest
- Extremity ulcer/gangrene
- Assessment of healing potential
- Absent peripheral pulses
- Digital cyanosis
- Cold sensitivity
- Arterial trauma and aneurysms
- Suspected arterial embolization

- Pre-procedure assessment (e.g., angioplasty, stent, bypass graft)
- Follow-up endovascular procedure (e.g., angioplasty, stent)
- Follow-up bypass graft
- Prognosis for healing (e.g., ulcerations, amputations)

## **Contraindications**

### **Contraindications for noninvasive physiologic testing**

Contraindications for lower extremity arterial physiologic evaluation include, but are not limited to:

- Morbidly obese patients in whom a high-thigh pressure may be not obtainable
- Casts, dressings, staples and/or open wounds
- Suspected or known acute deep venous thrombosis (DVT)
- Incompressible vessels with arterial calcification (TBI may be obtained)
- Post-interventional procedure (e.g., stenting, bypass graft)
- Recent surgery, trauma, ulcers, casts or dressings that should not be compressed by a blood pressure cuff
- Involuntary movement/tremors may render waveform collection suboptimal or unreliable

### **Contraindications of blood pressure measurements**

Contraindications of blood pressure measurements include, but are not limited to:

- Do not take an arm pressure in an arm with a shunt or dialysis graft.
- Patients with a side affected by stroke, mastectomy or renal fistula should avoid having blood pressure readings taken on this side.
- If a patient has an IV catheter in one arm, use the other arm to take the reading to prevent potential damage to the catheter and interruption of administration of medication.
- Lymphedema
- Paresis or paralysis
- Arterial or venous lines

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

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

**WARNING:** Do not leave a cuff inflated at high pressures for an extended period of time when on a patient.

**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 Chapter 8 – Maintenance, Cleaning.

**WARNING:** Any open lesion with the potential for contamination should be covered with an impermeable dressing.

**WARNING:** Connect only to a computer certified to IEC/AAMI 60601-1, IEC/UL 62368-1 or IEC/UL 60950-1. Computer is not intended for patient contact.

**WARNING:** To avoid safety or compliance issues, no modification of this equipment is allowed.

**WARNING:** Components of simpleABI Systems are not user serviceable. To maintain patient safety, do not maintain or clean equipment while in use.

**WARNING:** Not intended for use in conjunction with HF Surgical equipment.

**WARNING:** Doppler probe is not intended for immersion in liquids.

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

**CAUTION:** Do not inflate a cuff when it is not on a patient.

## **AIUM Statements**

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

*Approved May 19, 2020*

The potential benefits and risks of each examination should be considered. The as low as reasonably achievable (ALARA) principle should be observed when adjusting controls that affect the acoustic output and by considering both the transducer dwell time and overall scanning time. Practicing ALARA requires that users do all of the following:

1. Apply correct examination presets if built into the diagnostic ultrasound device. The review of manufacturer default presets for appropriateness is encouraged.
2. Adjust the power to the lowest available setting that provides diagnostic-quality images. If appropriate, reduce power at the end of each examination so the next user will start with the lowest acoustic output setting.
3. Monitor the mechanical index (MI) and thermal index (TI). Know the recommended upper limit of the MI, TI, and related duration limitations for the type of examination being performed.
4. Move/lift the transducer when stationary imaging is not necessary to reduce the dwell time on a particular anatomic structure. When possible, avoid fields of view that include sensitive tissues such as the eye, gas-filled tissues (lung and intestines), and fetal calcified structures (skull and spine)
5. Minimize the overall scanning time to that needed to obtain the required diagnostic information.

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

*Approved May 20, 2019*

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 experimental mammalian systems at diagnostically relevant exposures, but the clinical relevance of such effects is either not significant or is not yet known. Increased outputs and time of exposure can increase the likelihood of bioeffects. Ultrasound should be used only by qualified health professionals to provide medical benefit to the patient. Ultrasound exposures during examinations should be as low as reasonably achievable (ALARA)

#### **Safety in Research Using Diagnostic Ultrasound**

*Approved May 20, 2019*

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this use. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in research, experience from normal diagnostic practice may not be relevant to potential extended exposure times and altered exposure conditions in research. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study. In addition, informed consent, using a form approved by an Institutional Review board, should be obtained from the patient. Informed consent forms should include information about the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single patient should be justified and consistent with prudent and conservative use.

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

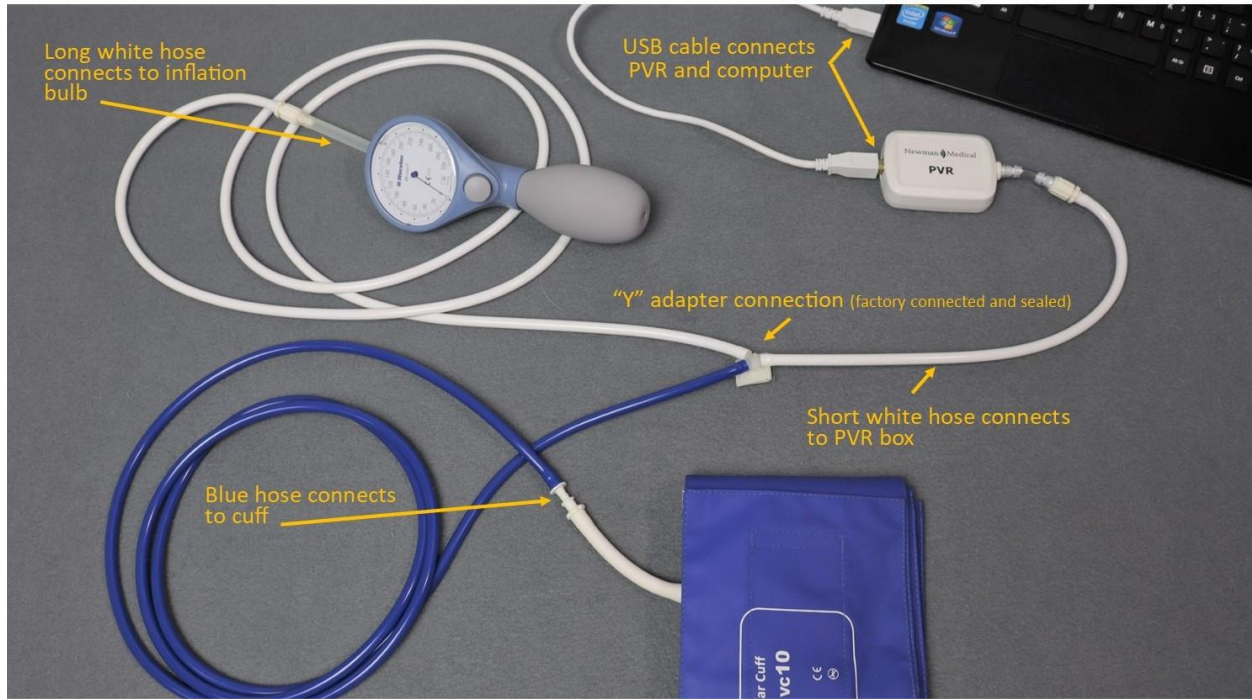
Installation of your simpleABI is straightforward but may require a few common tools. This installation is typically handled by a trained Newman Medical salesperson.

#### **Assembly Directions**

1. Remove all materials from packaging.

2. Check that inventory matches packing list.
3. Plug PVR hardware into computer using included USB cable.
4. Use tubing assembly, as shown below, to attach inflation bulb, PVR box hardware, and cuff tubing.

**NOTE:** Care should be taken when attaching hoses. Do not overtighten connectors or damage may occur.



### **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.

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

- Windows 10 (32 or 64 bit)
- Windows 11 (64 bit)

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

**CAUTION:** 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

**NOTE: \*\*\*DO NOT INSTALL OFF REMOVABLE MEDIA\*\*\***

### **PVR Driver Installation**

1. Plug in PVR box. PVR uses Windows default drivers and is 'plug and play'.

2. Driver should be properly installed and can be checked by opening simpleABI Reporting Software, opening an exam, and clicking any PVR button.
  - a. If installed properly, top of pop-up waveform window will display 'Connected' and the following icon.
    - i. 
  - b. If not installed properly, pop-up waveform window will display 'Not Connected' and the following icon.
    - i. 

## Chapter 4 – simpleABI Reporting Software

### File Menu

#### Beginning a new exam

From the computer Desktop, select the simpleABI icon. The simpleABI start-up screen with menu items 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 previous 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, select a previous exam and it will open on the screen.

#### Saving an Exam

You can save your finished report using CTRL+S or selecting *File* → *Save*. Files are appended with Patient ID and a timestamp to differentiate exams. You may also overwrite this default file name. By default, the save command automatically saves the exam in PDF and XML data files. You may select additional file types under *Edit* → *Output Formats* (TIFF, BMP, JPG, CSV)

#### Printing an Exam

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

#### Closing an exam

You can close any open exam or editing form by selecting *File* → *Close Form* or CTRL+W

**Exiting the software** to exit software, select *File* → *Close Form* or ALT+F4.

### Edit Menu

**REPORT INFORMATION** You can edit referring doctor, examiner, interpreting doctor, and practice information and logo under this menu item. Logos and signatures must be of BMP format to be loaded into the system. There are some samples pre-filled, and you can add, edit, or delete these as you deem necessary.

#### 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*

**OUTPUT FORMATS** You can select from different formats to fit your needs. Options available are PDF, JPG, BMP, TIF, CSV (XML is our data format and cannot be deselected). By default, PDF is selected.

**IMPRESSIONS** exam impressions can be pre-filled using this menu item. Use only numbers for impression numbers.

**ICD CODES** ICD codes can be edited, added or deleted using this menu item. There are many pre-populated ICD codes; however, only some relevant codes have been selected to 'Show in List' on exams. You may choose to edit these as you deem necessary.

**CHART OPTIONS** chart options allow different scaling or auto-scale for PVR waveforms. By default, a scaling factor of 1.00 is selected.

**DICOM SETUP (OPTIONAL)** An optional license key must be purchased to access DICOM setup options. simpleABI DICOM provides the ability to connect to a PACS server, query worklist, and send image or Standard reporting DICOM formats.

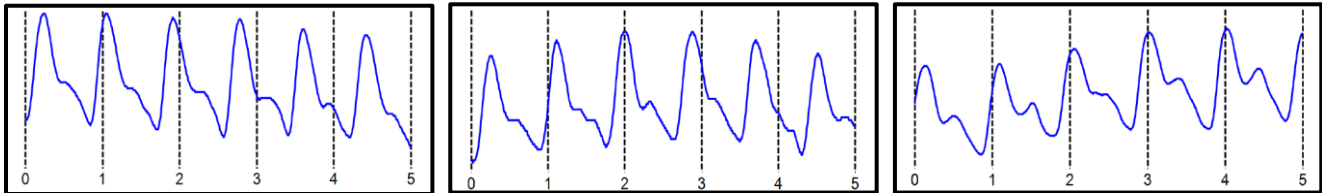
## Help

Help is found by selecting the Help Menu. You may view system information as well as, with an internet connection, be directed to Newman Medical's home page where you can browse our support pages with helpful hints and videos on using your simpleABI System.

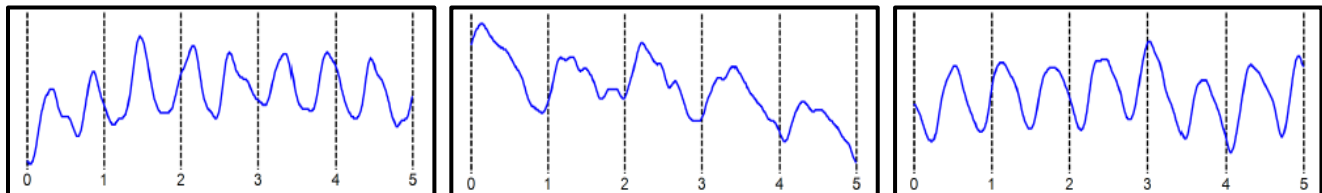
## Chapter 5 – Performing Exams

### *Interpretation of waveforms*

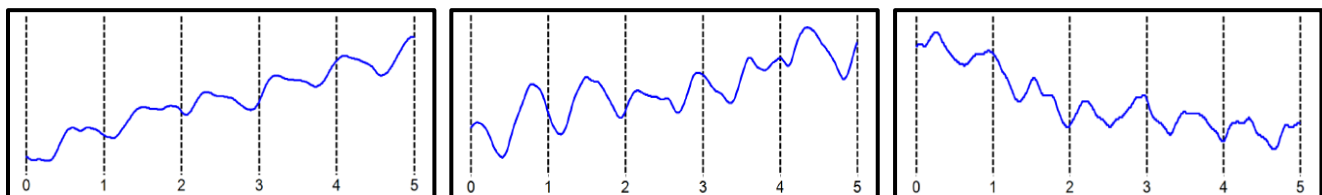
Pulse Volume Recording (PVR) is used to measure the change in pressure in the cuff caused by the small changes in volume that occur with each pulse. The analysis of the waveform is based on the shape of the waveform rather than the amplitude. PVRs are not affected by calcified arterial walls and are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



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



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



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 not likely any occlusive disease proximal to 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)

## ***ABI Examination***

Overview: 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.

Have the patient lie down in a supine position relaxed, head and heels supported in a comfortably warm room. Wrap appropriately sized cuffs (usually 12 cm on the arms and 10 cm on the ankles). On the arms apply the cuffs as you would for a standard blood pressure. On the legs, have the patient place their feet flat on the table with knees bent as you apply the cuff above their ankle. Cuffs should fit snugly so that fingers should slide between the cuff and limb with difficulty. The lower edge of the ankle cuff should be about an inch above the top of the medial malleolus (ankle bone).

Although the system will allow you to take the pressures and waveforms in any order, try to be consistent. The standard software workflow is to perform the right arm, right ankle, left arm, and finally left ankle.

### **Arm Pressure**

1. Connect the hose from the PVR to the first arm cuff. Place the Doppler probe over either the radial (preferred) or the brachial artery. **\*HINT\*** Hold the probe close to the end. It also helps to rest your hand on the patient to keep the probe in place. One of the keys to a successful exam is being able to keep the probe in place as you inflate and deflate. If it moves, you will not be able to hear the Doppler sounds return and you will have to repeat the inflation. Move the probe slowly back and forth laterally until the strongest arterial signal is heard.
2. Now inflate the cuff until the Doppler signal disappears and continue to inflate for another 10-20mmHg.
3. Slowly (about 2mmHg/second) deflate the cuff.
4. Note the pressure from the aneroid at the moment that you hear the first Doppler arterial sound return and enter that pressure into the brachial pressure box. This is the systolic pressure.



### **Ankle DP Pressure**

1. Move the tubing to the ankle cuff.
2. Obtain the ankle pressure at the Dorsalis Pedis (DP). Place the Doppler over the DP artery on the top of the foot. Use light pressure and move the probe laterally to obtain the best signal. The DP is often harder to find; be sure not to press too hard as it is over bony structures and relatively easy to occlude.
3. Now inflate the cuff until the Doppler signal disappears and continue to inflate for another 10-20mmHg.
4. Slowly (about 2mmHg/second) deflate the cuff.

5. Note the pressure from the aneroid at the moment that you hear the first Doppler arterial sound return and enter that pressure into the DP pressure box.



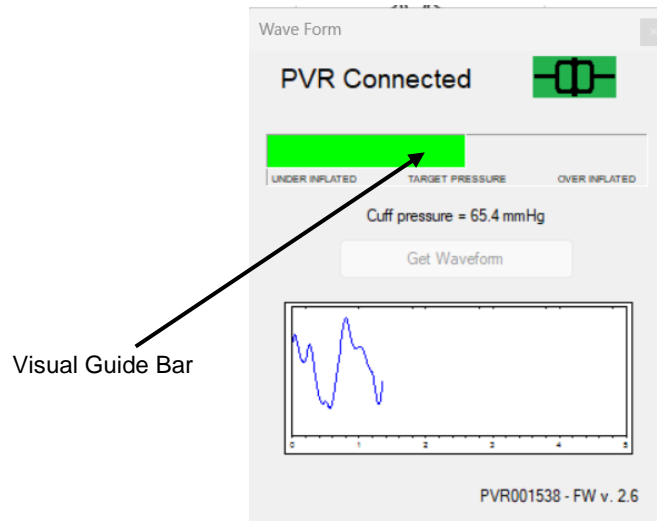
### Ankle PT Pressure

1. Obtain the ankle pressure at the Posterior Tibial (PT). Place the Doppler over the PT artery near the ankle bone. Use light pressure and move the probe laterally to obtain the best signal, making sure to angle the probe proximally. The PT is often found at the midpoint between the ankle bone and the Achilles tendon.
2. Now inflate the cuff until the Doppler signal disappears and continue to inflate for another 10-20mmHg.
3. Slowly (about 2mmHg/second) deflate the cuff.
4. Note the pressure from the aneroid when you hear the first Doppler arterial sound return and enter that pressure into the PT pressure box.



### Obtain Waveforms

1. On the screen, click on the respective **Waveform Field** in the report associated with the patient's right side (the left side of the screen).
2. Using the aneroid, inflate the cuff to about 80 mmHg. Deflate the cuff down to about 65mm and stop. You will see a visual guide bar on the screen above the **Get Waveform** button. The center section of the target pressure guide will turn green (if the guide is red, then pressure is too low or too high). When a constant green, click the **Get Waveform** button. **PVRs require patient cooperation; limb motion affects the waveform. Patients should be instructed not to move or talk during this test.** The waveform will appear and when complete the pop-up will disappear and the waveform will be present in the **Waveform Field** in the exam.
3. If you are not satisfied with the waveform, leave the cuff inflated (in the green) and click on the **waveform field** and then **Get Waveform** buttons again to overwrite the previous waveform.
4. When complete, release the air in the cuff.



### **Left Side**

1. Repeat steps above for the left side.

The interpretation of the ABI values is based on recent guidelines.<sup>2</sup>

**\*HINT\*** 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.

### **SAVING/PRINTING REPORT**

You can save your finished report using CTRL+S or selecting *File* → *Save*. Files are appended with Patient ID and a timestamp to differentiate exams. You may also overwrite this default file name. By default, the save command automatically saves the exam in PDF and XML data files. You may select additional file types under *Edit* → *Output Formats* (TIFF, BMP, JPG, CSV)

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

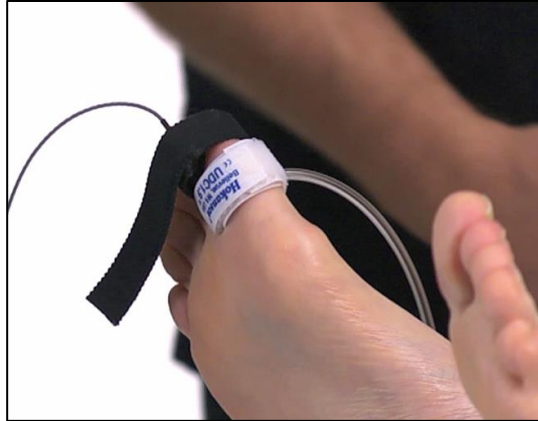
Background: The ABI with Toe exam is typically performed after an ABI has been done, especially if the larger ankle arteries appear to be incompressible (pressure over 200mmHg) or anytime more information is needed about small vessel disease. The TBI is done using the PPG probe. The patient is supine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

### **Setting up**

On the computer desktop, select the simpleABI icon. To open the ABI with Toe Report, select *File* → *New* → *New ABI with Toe Report*. The ABI with Toe report form will open on the screen. Wrap cuffs on the arms (typically 12cm). Wrap cuffs on the ankles (typically 10cm) and wrap digit cuffs on the great toes as far down towards the base as possible. Attach the PPG probe and sensor to the DigiDop, replacing the Doppler probe.

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.

<sup>2</sup> 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease, J Am Coll Cardiol. 2017 Mar, 69 (11) e71-e126.



### **Brachial Pressure**

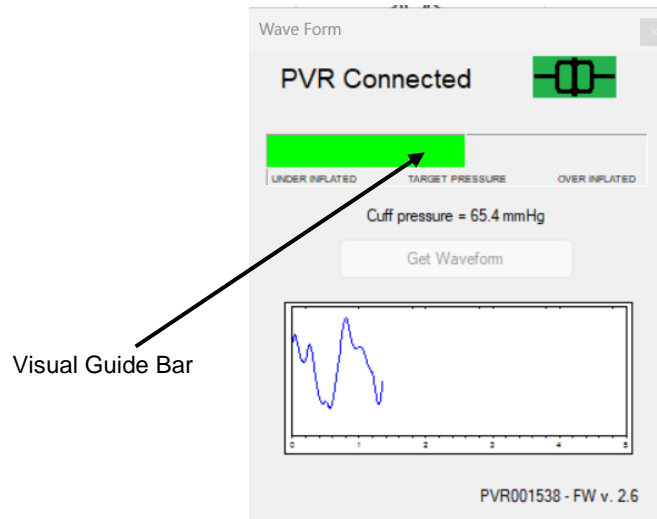
1. Begin with the right brachial. Place the Doppler probe at a 45-degree angle to the skin over the radial or brachial artery. Use plenty of gel and slowly move the probe laterally until the best signal is obtained. (You may also use the PPG sensor to listen for the pulse. If using the PPG, place the sensor on the fleshy part of the finger opposite the fingernail. Wait for consistent beeps from the system.)
2. Using the handheld aneroid, inflate the cuff until you no longer hear the signal - continue for an additional 10-20 mmHg.
3. The thumb button on the aneroid is a variable release mechanism – i.e., the more you depress the button the faster the deflation rate. Using the thumb release, deflate at the suggested rate of 2mmHg/second (10mmHg for every 5 seconds may be slightly easier to monitor)
4. When you hear the Doppler signal return, note the pressure from the aneroid. Enter that pressure into the right brachial field on the exam.

### **Ankle Pressures**

1. Press tab or use the cursor to move to the Dorsalis Pedis (DP) field. 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. (Using the aneroid, inflate until occlusion + 10-20mmHg, release at 2mmHg/second, note pressure when Doppler signal returns)
2. Press tab or use the cursor to move to the Posterior Tibial (PT) field. Find the Doppler signal on the posterior tibial artery. Obtain the arterial pressure in the same manner as other sites.

### **Ankle Waveform**

1. On the screen, click on the respective **Waveform Field** in the report associated with the patient's right side (the left side of the screen).
2. Using the aneroid, inflate the cuff to about 80 mmHg. Deflate the cuff down to about 65mm and stop. You will see a visual guide bar on the screen above the **Get Waveform** button. The center section of the target pressure guide will turn green (if the guide is red, then pressure is too low or too high). When a constant green, click the **Get Waveform** button. **PVRs require patient cooperation; limb motion affects the waveform. Patients should be instructed not to move or talk during this test.** The waveform will appear and when complete the pop-up will disappear and the waveform will be present in the **Waveform Field** in the exam.
3. If you are not satisfied with the waveform, leave the cuff inflated (in the green) and click on the **waveform field** and then **Get Waveform** buttons again to overwrite the previous waveform.
4. When complete, release the air in the cuff.



### Toe Pressure

1. Press tab or use the cursor to move to the toe pressure field. Find the arterial signal using the Doppler or PPG probe on the toe. Obtain the arterial pressure in the same manner you did on the arm. \*NOTE\* digit cuffs inflate rapidly. (Using the aneroid, inflate until occlusion +10-20mmHg, release at 2mmHg/second, note pressure when Doppler/PPG signal returns)

### Toe Waveform

1. On the screen, click on the respective **Waveform Field** in the report associated with the patient's toe.
2. Using the aneroid, inflate the cuff to about 80 mmHg. Deflate the cuff down to about 65mm and stop. You will see a visual guide bar on the screen above the **Get Waveform** button. The center section of the target pressure guide will turn green (if the guide is red, then pressure is too low or too high). When a constant green, click the **Get Waveform** button. **PVRs require patient cooperation; limb motion affects the waveform. Patients should be instructed not to move or talk during this test.** The waveform will appear and when complete the pop-up will disappear and the waveform will be present in the **Waveform Field** in the exam.
3. If you are not satisfied with the waveform, leave the cuff inflated (in the green) and click on the **waveform field** and then **Get Waveform** buttons again to overwrite the previous waveform.
4. When complete, release the air in the cuff.

### 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.



## Chapter 6 - Detailed Description

### Operation and Use

The Doppler, probes, and pressure sensors are designed to aid in diagnosis of vascular conditions including aiding in obtaining systolic pressures during a vascular examination.

### Main Unit

The body of the unit is a one-piece enclosure. The unit was designed for comfort and ease-of-use during examinations. Each unit is tested to ensure the highest quality possible.

### Turning unit ON/OFF

Power to the unit is controlled by the **ON/OFF** button located in the center of the unit. Pressing and releasing the button will cycle the unit through the power sequence.

The DigiDop automatically turns itself off after 3 minutes of inactivity. This auto shut off feature preserves battery life and serves to eliminate complete battery drain in case of accidental failure to shut off the unit.

### Battery Monitoring

The DigiDop periodically checks the status of the batteries. When the battery symbol on the LCD is half full the batteries are getting low and replacement batteries should be available. When the battery symbol on the LCD flashes, the battery level is low and batteries should be replaced immediately.

### Volume

The DigiDop has multiple volume levels. These are adjusted by sliding the volume slider on the left-hand side of the main unit.

### 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.

## Chapter 7 – Tips & Troubleshooting

### 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.

### Poor Sound Quality

Inadequate gel use-apply more gel

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

### Obtaining Waveforms

- Wrap the cuff snugly.

- While wrapping cuffs, do not let the patient try to help by lifting their leg - as soon as they relax their muscles the cuff will become loose.
- Placing a pillow under the patient's heels may aid the examination.
- Have the patient remain as still and quiet as possible while taking the waveforms.
- If the patient has tremors that interfere with the waveform, having them do a few dorsiflexions with their toes before taking the waveform can sometimes help.

### **Battery Symbol on LCD flashing**

The voltage of the batteries is low. Charge the batteries as soon as possible.

## **Chapter 8 – Maintenance, Cleaning & Disposal**

**CAUTION:** Newman Medical recommends leaving your computer on overnight once a week to allow for system updates to occur while system is not in use.

**CAUTION:** simpleABI components are not designed for liquid immersion. Do not soak or drop the main unit or probes in liquid.

**CAUTION:** The equipment not designed for sterilization processes such as autoclaving or gamma radiation.

The equipment requires very little maintenance. It is important, however, for the continued functionality of the unit and the safety 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. Unit 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, the battery compartment, the audio output, and the parting line between the front and back shell.

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 appropriate disinfectant spray or wipe and follow the manufacturer's instructions.

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

If storing the unit for a prolonged period of 90 days or longer without use, remove the batteries prior to storage.

### **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.

Inspect the cuffs for damage. Cuff covers may be washed by removing the bladders.

### **Disposal**

This device and accessories must be disposed of according to local regulations after their useful lives. Alternatively, they may be returned to Newman Medical for recycling and proper disposal.

### **Battery Replacement**

**CAUTION:** Replace rechargeable batteries only with approved batteries. Please call customer service or visit our website for further information.

**CAUTION:** The Doppler unit uses AA batteries. Do not attempt to use any other size batteries in the unit.

Open the battery compartment by pressing the tab on the battery door and opening the battery compartment. Remove the drained batteries by pulling one of batteries out of the unit from the positive (button) end of the battery.

Replace the batteries by paying close attention to the polarity indicators on the battery and the polarity indicators on the battery door. Align the batteries according to the symbols located in the battery compartment.

**NOTE:** If the batteries have been incorrectly inserted, the unit will not work, but will not be damaged. Please re-insert the batteries correctly.

## 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

Weight (inclusive)	3.6 kgs (8 pounds)
Transport/Storage Temperature	-20° ~ 50°C (-4° ~ 122°F)
Transport/Storage Humidity	5% ~ 90%, non-condensing

### Doppler Unit

Dimensions-(h x w x d)	150x65x35 mm (6x2.5x1.25 in)
Weight (with probe & batteries)	370 grams (13 ounces)
Operating Temperature	10° ~ 40°C (50° ~ 104°F)
Operating Humidity	30% ~ 75%
Transport/Storage Temperature	-20° ~ 50°C (-4° ~ 122°F)
Transport/Storage Humidity	5% ~ 90%, non-condensing
Battery Voltage, type	3 x 1.5 volts, AA
Battery Life	800, 1-minute exams

### PVR Unit

Dimensions-imperial (h x w x d)	2.75x2.0x0.8
Weight	200 grams (8 ounces)
Interface	USB, Type B

### Acoustic Properties (DigiDop)

System:	<u>DigiDop</u>	Operating Mode:	<u>Continuous Wave (CW)</u>
Transducer Model:	<u>5MHZ</u>	Application(s):	<u>Peripheral Vascular</u>

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	D <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>0</sub>	(mW)		9.02	
	f <sub>c</sub>	(MHz)	7.84	7.84	
	Z <sub>sp</sub>	(cm)	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>0</sub> **ultrasonic power** (milliwatts). For the operating condition giving rise to ISPTA.3, W<sub>0</sub> is the total time-average power; for the operating condition subject to reporting under ISPPA.3, W<sub>0</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<sub>c</sub> is defined as the overall range of center frequencies of the respective transmit patterns.

Z<sub>sp</sub> 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 zsp 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<sub>0</sub>, 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:

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

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

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

Where  $I_{SPTA,0}$ , is the non-derated spatial-peak temporal-average intensity,  $I_{SATA,0}$  is the nonderated spatial-average temporal-average intensity at the transducer face and  $I_{SPTA,3}$ , 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 – Electromagnetic Compatibility

All medical equipment may produce electromagnetic interference or be susceptible to electromagnetic interference. The following are guidance and manufacturer’s declarations regarding EMC for SimpleABI.

- simpleABI Systems need special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following pages.
- **Warning:** This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the SimpleABI system or shielding the location.
- Portable and Mobile RF communications equipment can affect the performance of SimpleABI. Please use the guidelines and recommendations specified in Tables 15.3.1 and 15.3.2.
- Other Medical Equipment or Systems can produce electromagnetic emissions and therefore can interfere with the functionality of SimpleABI. Care should be used when operating SimpleABI adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, SimpleABI should initially be observed to verify normal operation in the configuration in which it will be used.
- The electrical cables, external power supplies and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and electrical accessories with SimpleABI. If a third-party supplier offers cables, external power supplies and electrical accessories for use with SimpleABI and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from SimpleABI or decreased electromagnetic immunity of SimpleABI.

**Table for Electromagnetic Emissions**

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
The simpleABI System is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions - CISPR 11 (Radiated & Conducted)	Group 1	The simpleABI System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions - CISPR 11 (Radiated & Conducted)	Class A	The simpleABI System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

**Table for Electromagnetic Immunity**


Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The simpleABI System is intended for use in the electromagnetic environment specified below. The customer or the end user should assure it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Electromagnetic Discharge (ESD) EN/IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Conducted RF EN/IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of SimpleABI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2\sqrt{P}</math> 80MHz to 800 MHz</p> <p><math>d = 2.3\sqrt{P}</math> 800MHz to 2.5GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended minimum separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p>
Radiated RF EN/IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m 80MHz to 2.5GHz	

			Interference may occur in the vicinity of equipment marked with the following symbol:  
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SimpleABI is used exceeds the applicable RF compliance level above, the SimpleABI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SimpleABI.</p> <p><sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p>			
Recommended separation distances between portable and mobile RF communications equipment and the SimpleABI.			
SimpleABI unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SimpleABI can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and SimpleABI as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
0.1	.38	.38	.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## Chapter 11 – Warranty, Service, & Support

The simpleABI System and components are guaranteed to be free from defects in material and workmanship for 2 years (5 years for the DigiDop and its probes) 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