

# Newman Medical

*Employee Owned & Operated*

# ABI-Q

## 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.

**Dicrotic Notch** - a secondary upstroke in the descending part of a pulse tracing corresponding to the transient increase in aortic pressure upon closure of the aortic valve. Also called dicrotic wave.

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

**PAD - Peripheral Artery Disease** – Typically atherosclerosis (also known as hardening of the arteries) in the leg.

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

**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.

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# Chapter 1 – About simpleABI-Q

Congratulations on your purchase of a simpleABI-Q System from Newman Medical.

The simpleABI-Q was designed to be an easy and intuitive system 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-Q Systems

- PVR Hardware
- Inflation Bulb
- 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:** 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:** Device 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.

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

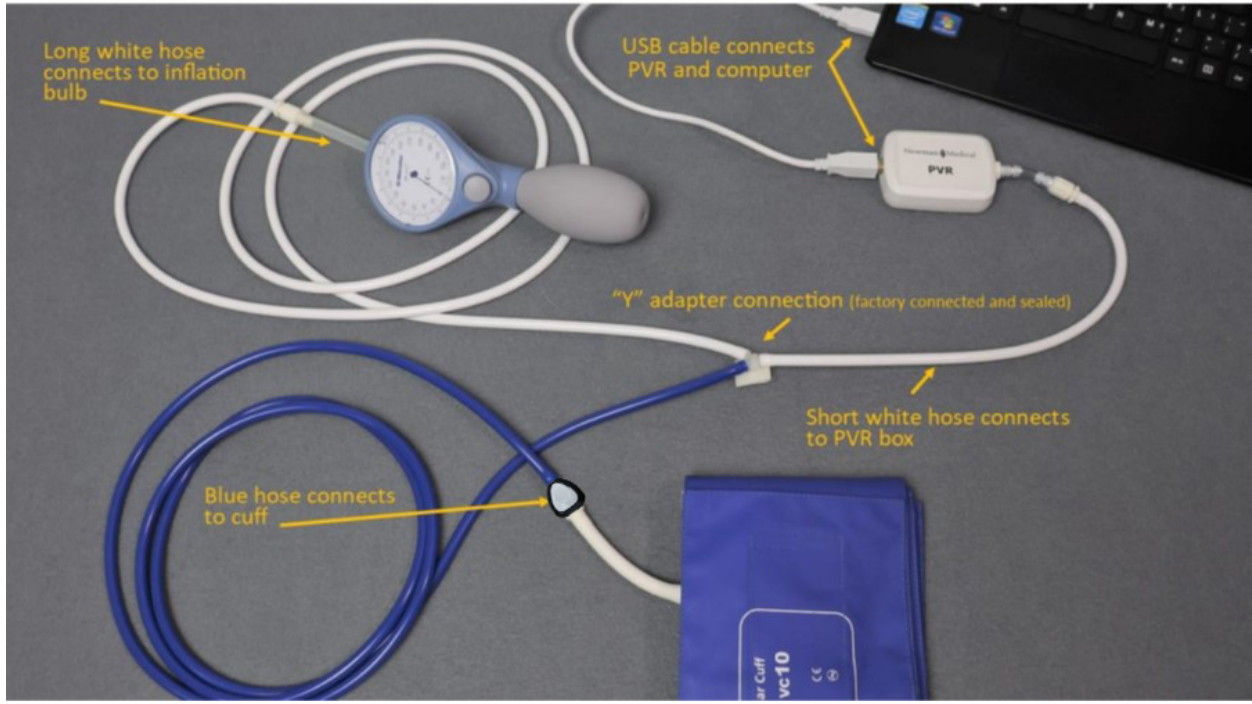
Installation of your simpleABI is straightforward but may require a few common tools. This installation is typically handled by a trained Newman Medical salesperson.

### **Assembly Directions**

1. Remove all materials from packaging.

2. Check that inventory matches packing list.
3. Plug PVR unit 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 will already have the software loaded and this section does not apply.

**CAUTION:** simpleABI is 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-Q 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 unit to computer. PVR utilizes standard Windows 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.



- b. If not installed properly, pop-up waveform window will display 'Not Connected' and the following icon.



# 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. 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

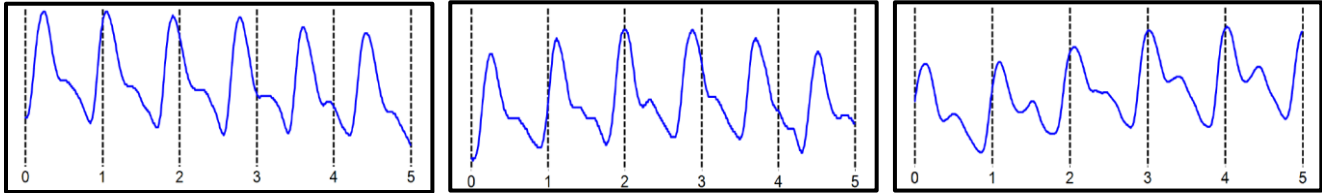


Help is found by selecting the Help Menu. You may view system information as well as, with an internet connection, be directed to Newman Medical's home page where you can browse to our support pages with helpful hints and videos on using your simpleABI System.

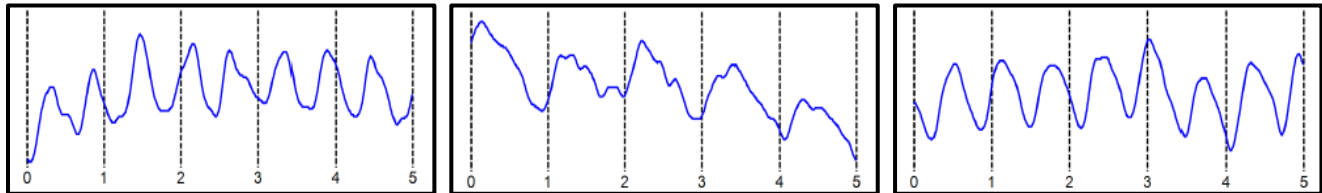
## Chapter 5 – Performing Exams

### *Interpretation of waveforms*

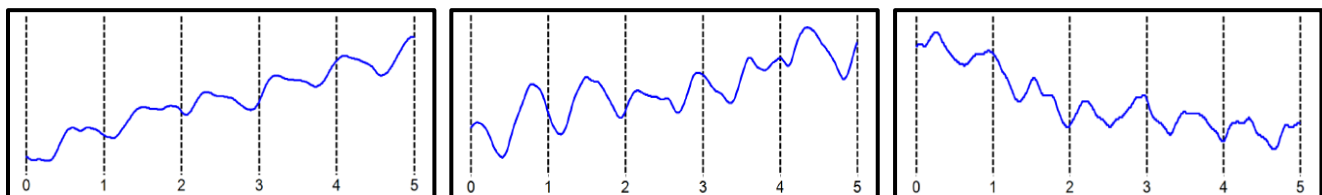
Pulse Volume Recording (PVR) is used to measure the change in pressure in the cuff caused by the small changes in volume that occur with each pulse. The analysis of the waveform is based on the shape of the waveform rather than the amplitude. PVRs are not affected by calcified arterial walls and are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

### Purpose & Background

The ABI-Q™ 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 ABI-Q™ exam is a diagnostic test that examines arterial waveforms to determine the need for further vascular evaluation.

### Opening the exam

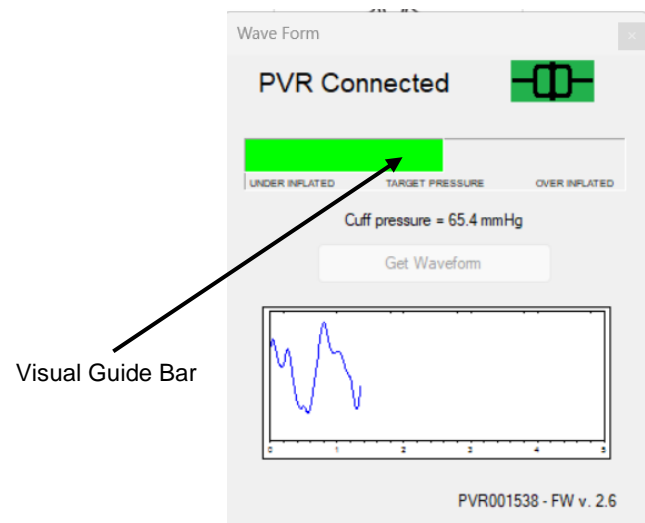
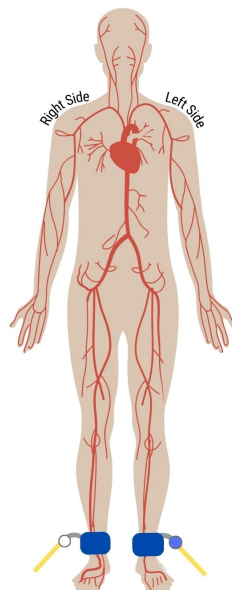
On the computer desktop, double click the simpleABI icon. When the program opens select *File* → *New* → *New ABI-Q Report*. The report will open and you can enter patient information, risk factors, symptoms, ICD codes, etc.

### Attaching the cuffs

Have the patient lie down in the supine position relaxed, head and heels supported in a comfortably warm room. Wrap appropriately sized cuffs (usually 10 cm on the ankles). 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).

### 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. Tighten the thumb valve and inflate the cuff to about 80 mmHg pressure and then slowly deflate to about 65 mmHg 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** button again to overwrite the previous waveform.

4. When complete, release the air in the cuff.

### **Left Side**

1. Move the hose to the leg ankle cuff and repeat the above steps.

### **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)

## **Chapter 6 - Detailed Description**

### **Operation and Use**

The PVR hardware is designed to aid in diagnosis of vascular conditions including aiding in obtaining systolic pressures during a vascular examination.

### **Turning unit ON/OFF**

Power is supplied to the unit by the USB cable. If the PVR hardware is plugged into the computer, the PVR is powered on.

## **Chapter 7 – Tips & Troubleshooting**

### **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.

## **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 equipment in liquid.

**CAUTION:** The equipment is 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, that the unit is cleaned and examined regularly as follows:

### **After every examination**

To disinfect unit, use an appropriate disinfectant spray or wipe and follow the manufacturer's instructions.

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

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

### **Periodically**

Inspect the unit and cuffs for signs or cracks or breaks. If any sign of leaking 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.

## 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

**simpleABI-Q System**

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

**PVR Unit**

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

## 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 Test Level	60601 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> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>
Radiated RF EN/IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m 80MHz to 2.5GHz	

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.

<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.

<sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

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 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 simpleABI Systems 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