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 $I_{SPTA.3,}$ is the derated spatial-peak temporal-average intensity, fC, 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 – Resources, 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
   42 Sherwood Terrace, Suite 2
   Lake Bluff, IL 60044
   800-267-5549

simpleABI 300

User Manual

Newman Medical

42 Sherwood Terrace, Suite 2

Lake Bluff, IL 60044, USA

1-800-267-5549

info@newman-medical.com

www.newman-medical.com

Contents

$I_{SPPA.3}$ **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/cm2 .

$p_{r.3}$ **derated peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

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

f_c **center frequency** (MHz). For MI and ISPPA.3, fc 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, fc 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 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, W0, 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:

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

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

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

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

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum Value			0.0223	86.4	86.4
Associated Acoustic Parameters	$p_{r.3}$	(Mpa)	0.041		
	W_o	(mW)		9.26	9.26
	f_c	(MHz)	5.61	5.61	5.61
	z_{sp}	(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	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum Value			0.0495	555	555
Associated Acoustic Parameters	$p_{r.3}$	(Mpa)	0.0923		
	W_o	(mW)		9.02	9.02
	f_c	(MHz)	7.84	7.84	7.84
	z_{sp}	(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_{SPTA}:	28.2%
Total uncertainty for f_c:	2.0%
Total uncertainty for MI:	14.1%

$I_{SPTA.3}$ **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).

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's new in the simpleABI System

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

Chapter 2 – Clinical Information

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 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 (**A**s **L**ow **A**s **R**easonably **A**chievable).

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 does require a few common tools. This installation is typically handled by a trained Newman Medical salesperson.

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

DigiDop

Dimensions-imperial (h x w x d)	6” x 2.5” x 1.25”
Weight (with 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 1.2 volts, AA NiMH
Battery Life	500, 1-minute exams

PVR Boxes

Dimensions-imperial (h x w x d)	2.75” x 2.0” x 0.8”
Weight	200 grams (8 ounces)
Interface	USB, Type B

Acoustic Properties (DigiDop)

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 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.

If storing the unit for a prolonged period of 90 days or longer without use, please 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.

Battery Replacement

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

WARNING: The DigiDop uses AA batteries. Do not attempt to use any other size batteries in the unit.

Open the battery compartment by sliding the battery compartment door to the side. 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.

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

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

- Windows XP, Service Pack 3
- Windows 7, Starter Edition (32 or 64 bit)
- Windows 7, Professional Edition (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.

Tools needed:

- Phillips head screwdriver, #2 preferred

Assembly Directions

1. Remove all materials from packaging.
2. Check that inventory matches packing list.
3. Place caster base on the floor.
4. Locate mounting pole and remove screw and washers from the bottom of the pole.
5. Insert pole into caster base and screw the two together until locking washer is flat.
6. Place PC onto mounting plate, ensuring all 4 loop tabs on PC line up with respective hook tabs on mounting plate.
    a. The system 300 has a PC designed specifically for the mounting plate and the battery will guide the alignment of the PC and mounting plate.
    b. It is helpful when using your own PC to first check how the PC aligns on the mounting plate prior to placing hook and loop tabs.
7. Place all 4 cuffs into basket.
8. Attach Doppler probe to Doppler main unit with coiled cord. Slide Doppler into Doppler cradle on simpleABI pole.

Software Installation Directions (system 100)

1. Plug in included USB Flash Drive into PC
2. Copy NewmanMedicalSetup.msi to C:\
3. Double Click NewmanMedicalSetup.msi to begin installation

PVR Driver Installation-Windows XP

1. Plug in either PVR box.
2. At prompt, select 'Install from a list or specific location (Advanced) and click the 'Next>' button
3. Check the box that says 'Include this location in the search:' and browse to C:\PROGRAM FILES\NEWMAN MEDICAL\SIMPLEABI REPORTING\PVRDRIVER
4. Click OK and then Click the 'Next>' button. This will begin the install for the driver for the PVR boxes.
5. Driver should be properly installed and can be checked by opening simpleABI Reporting Software and clicking on the respective PVR button on an opened ABI Report. If installed properly, pop-up window will display 'Left/Right PVR Device Connected'
    a. If not installed properly, pop-up will read 'Left/Right PVR Box Not Detected'

PVR Driver Installation-Windows 7

6. Plug in either PVR box.
7. Double Click on icon in taskbar that says 'Installing device driver software'
8. On pop-up window click link that says 'Skip obtaining driver software from Windows Update'. Click Yes on pop-up confirming skipping finding driver using Windows Update.
9. Click the 'Start' Button (Windows Logo) and click 'Devices and Printers'
10. Scroll to 'Unspecified' Devices and double click the Newman Medical PVR Device.
11. Click the 'Hardware' Tab
12. Click the 'Properties' button
13. Click the 'Change Settings' button
14. Click the 'Properties' button
15. Click the 'Driver' Tab
16. Click the 'Update Driver' button
17. Click 'Browse my computer for driver software'

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.

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**

Power Button LED flashing

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

Chapter 8 – Maintenance and Cleaning

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

WARNING: The DigiDop is not designed for sterilization processes such as autoclaving or gamma radiation.

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

The DigiDop requires very little maintenance. It is important, however, for the continued functionality of the unit and the health of

Don't be discouraged if measuring the ABI seems slow or clumsy at first. Like any procedure, the ABI becomes easier to do with practice.

Chapter 6 - Detailed Description

DigiDop Doppler – Operation and Use

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

Power On/Off

Power to the unit is controlled by the **POWER** button located in the center of the 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.

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 power button LED flashes, the battery level is low and batteries should be charged 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.

Recharge

The simpleABI comes with a rechargeable DigiDop. Simply plug the AC adapter into the charging jack at the bottom of the DigiDop to begin charging unit. The unit may not be used while the batteries are being charged. It is recommended that to achieve a full charge the DigiDop is left plugged into the AC adapter overnight, however, quick charging for immediate use can be accomplished by plugging into the AC adapter for 15 minutes.

Probes:

18. Browse to 'C:\Program Files\Newman Medical\SimpleABI Reporting\pvrDriver and click the next button
19. Click 'Install this driver software anyway' on the Windows security window. This will begin the install for the driver for the PVR boxes.
20. Driver should be properly installed and can be checked by opening simpleABI Reporting Software and clicking on the respective PVR button on an opened ABI Report. If installed properly, pop-up window will display 'Left/Right PVR Device Connected'
    a. If not installed properly, pop-up will read 'Left/Right PVR Box Not Detected'

Chapter 4 – simpleABI Reporting Software

Entering Doctor/Examiner/Practice Information

Before using your system, you should enter some information into your simpleABI Reporting Software. Under the **EDIT** menu, you can fill in doctor, examiner, and practice information as you want it to appear on reports. There are some examples pre-filled and you can add, edit, or delete these as you see necessary.

To close the data maintenance (EDIT) form, select *File\Close Form*

Starting a New Exam

You start a new exam by pressing CTRL+A or select *File\New\ABI Report.*

Saving Your Exam as a PDF

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.

Saving Your Exam as a TIFF

You can save your finished report as a TIFF file using CTRL+T or select *File\Save.* Files are appended with Patient ID and a timestamp to differentiate exams.

Printing Your Exam

You can print your exams directly to the computer's default printer using CTRL+P or select *File\Print*

Help

Help is found by selecting *Help/www.newman-medical.com.* With an internet connection, you will be directed to Newman Medical's home page where you can browse to our support pages with helpful hints on using your simpleABI.

Chapter 5 – Performing Exams

Initial Steps

Step 1. Have the patient lie in a supine position with shoes and stockings removed for 5- 10 minutes prior to obtaining blood pressure measurements.

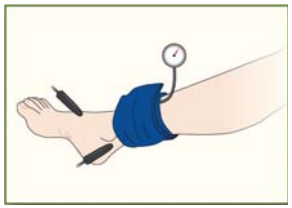
Step 2. Apply the blood pressure cuffs snugly on each arm and leg. On the arms apply the cuffs as you would for a normal blood pressure. On the legs, have the patient place their feet flat on the table with knees bent as you apply the cuff above their ankle. Cuffs should fit snugly so that fingers should slide between the cuff and limb with difficulty. PVR boxes are color coded and marked for left and right and should be connected to cuffs placed on the ankles.

Arm Pressures

Step 1. On the arm, locate the artery by palpitation, if possible. Place the Doppler probe at an angle to the skin over either the radial or brachial artery. Use plenty of ultrasonic gel.

HINT Hold the probe close to the end and support the probe on the skin so that the probe does not move as the cuff is inflated and deflated. 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.

Step 2. Inflate the cuff until you no longer hear the signal, and continue for an additional 15-20 mmHg. Slowly bleed pressure until the signal returns and note that return pressure. This is the systolic pressure. Then rapidly deflate the cuff. Enter the systolic pressure into the respective brachial box on the report.



Ankle Pressures

Step 1. Now take the pressures at the ankle, using the Doppler probe on the posterior tibial (PT) artery, which is usually found just behind (roughly half an inch- about the diameter of a dime) the ankle bone.

Step 2. Inflate the cuff until you no longer hear the signal, and continue for an additional 15 or 20 mmHg. Slowly bleed pressure down until the signal returns and note that pressure. This is the systolic pressure. Rapidly deflate the cuff. Enter the systolic pressure into the respective tibial field on the report.

Step 3. Now take the pressure at the foot using the Doppler probe on the dorsalis pedis (DP) artery, which is usually right on top of the foot. To avoid occluding the arteries by pressing too hard with the probe, be gentle. Inflate and bleed the cuff as you did with the PT artery. Enter the systolic pressure into the respective DP field on the report.

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 and the ABI is not calculated.

Waveforms

Step 1. Inflate cuff to ~90mmHg and bleed pressure to 65mmHg. Set aneroid on exam table when finished bleeding pressure to 65mmHg to avoid affecting waveforms with your movement.

Step 2. Press 'Right PVR' or 'Left PVR' button (side under test). simpleABI Reporting software will display a waveform in the chart below the button and query the user if the waveform is present. Press 'yes' or 'no'.

*****Repeat above steps on other side of the body*****

Helpful Hints

- Be sure to use enough gel.
- Use a cuff size that is right for both the arms and ankles of the patient.
- In a small percentage of patients, one of the ankle pressures will be non-detectable; use the detectable pressure for calculating the ABI.