DigiDop

User Manual

Thank you for your purchase of a DigiDop Doppler. The DigiDop was designed to reproduce the sounds of the fetal heartbeats or vascular blood flow. We hope you find the DigiDop to be simple and easy to use.

Introduction

Description of Product

The DigiDop was designed for use in obstetrical examinations or for the aid in diagnosis of vascular conditions.

Safety of Equipment

DigiDop Systems are medical equipment. Although designed to withstand everyday use, care must be taken to ensure safe and continued operation. Do not abuse equipment. The DigiDop was designed according to domestic and international design and risk standards. Throughout design of this product, safety and elimination or reduction of risk was of paramount concern. In view of that, this product was designed according to the principle of reducing risk AFAP (**A**s **F**ar **A**s **Possible**).

Intended Use

2MHz and 3MHz probes were designed to detect fetal heartbeats during pregnancy.

5MHz, 8MHz, and PPG probes were designed to detect vascular blood flow.

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

Contraindications

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 perform vascular exams (using a blood pressure cuff) on someone suspected of having acute deep venous thrombosis

WARNING: Do not take an arm pressure in an arm with a shunt or dialysis graft.

WARNING: Probes are not intended to be used on open skin.

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.

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.

Digital Signal Clarity (DSC™)

The DigiDop is has advanced processing that digitizes the audio signal, which allows for the reduction of unwanted background noise. In addition, unlike most other Dopplers, the DigiDop recognizes probe in use and optimizes the sound quality for that probe.

Models

DigiDop
300 – Non-heart rate, non-rechargeable
301 – Non-heart rate, rechargeable
700 – Heart-rate display, non-rechargeable
701 – Heart-rate display, rechargeable
DD-II
330 – Non-heart rate, non-rechargeable
330A- Non-heart-rate, non-rechargeable, audio recording
330R – Non-heart-rate, rechargeable
330AR – Non-heart-rate, rechargeable, audio recording
770 – Heart-rate display, non-rechargeable
770A – Heart-rate display, non-rechargeable, audio recording
770R – Heart-rate display, rechargeable
770AR – Heart-rate display, rechargeable, audio recording
Tabletop
901 – Countertop size, Heart-rate display, rechargeable

Probes:

D2 – Obstetrical. The 2MHz probe is designed for use with larger patients or during late term pregnancy. Rated IP51.

D2W – Obstetrical. The 2MHz **waterproof** probe is designed for use with larger patients or during late term pregnancy **in water applications.** Rated IP68 – protection against water immersion at 1 meter for up to 12 hours.

D3 – Obstetrical. The 3MHz probe is designed for general purpose use during pregnancy. This probe is the most widely used probe for all stages of pregnancy. Rated IP51

D3W – Obstetrical. The 3MHz **waterproof** probe is designed for general purpose use during pregnancy. This probe is the most widely used probe for all stages of pregnancy **in water applications**. Rated IP68 – protection against water immersion at 1 meter for up to 12 hours.

D5 – Vascular. The 5MHz probe is designed for locating deeper lying vessels. The pen-tip sensor face aids in the location of specific vessels. Rated IP51

D8 – Vascular. The 8MHz probe is designed for locating shallow lying vessels. The pen-tip sensor face aids in the location of specific vessels. Rated IP51

DPPG – Vascular. The PPG probe is a unique photo-plethysmography probe using infrared light sensing to detect blood flow. Varying levels of flow produce an audio signal that corresponds to blood flow. It is particularly useful for detecting flow in the digits. Rated IP51.

Operation and Use

DigiDop

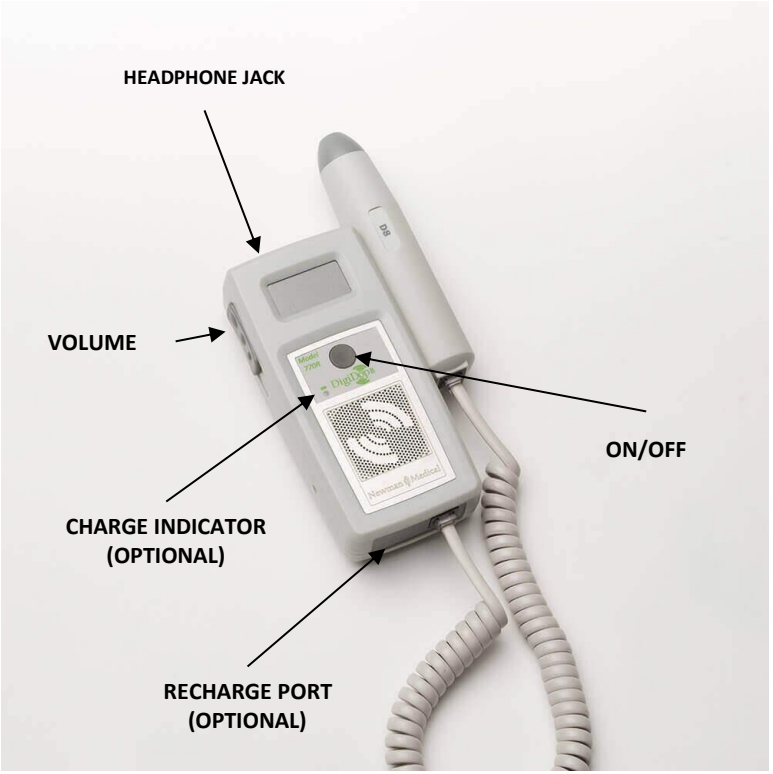
Models 300, 301, 700, 701

DigiDop Tabletop

Model 901

DD-II

Models 330, 330A, 330AR, 330R, 770, 770A, 770AR, 770R



Turning Unit On/Off

Turn the unit on by pressing the on/off button while the unit is off. The LCD illuminating (and sound from the speaker) indicates power is on.

Turn the unit off by pressing the on/off button again.

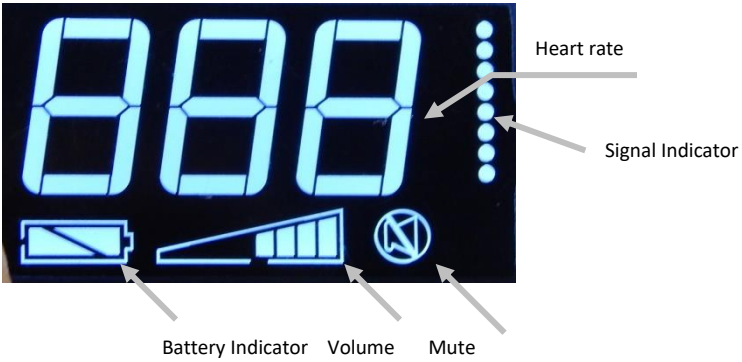
The DigiDop automatically turns itself off after 3 minutes of inactivity. This auto shut off feature preserves battery life and serves to eliminate complete battery drain in case of accidental failure to shut off the unit.

LCD Display (optional)

The LCD display was designed to be easy to read from many viewing angles and under variable lighting conditions. It has indications for battery voltage level, heart rate, volume, and signal indicator.

The audio only DigiDop units have a LCD display that does not include the heart rate, but includes the other indications.

Display View



Volume Control

Volume is controlled with the volume up and down buttons (990R) or with the volume slider. The unit will retain the volume setting while turned off. The DigiDop system will not automatically mute when a headphone is plugged into the unit. However, minimizing the volume will mute the speaker and only play sounds through the headphones.

Battery Monitoring

The DigiDop periodically checks the status of the batteries. As the battery voltage drops, half of the internal symbol disappears. After further battery discharge, all of the internal

battery symbol disappears. Finally, the outline of the battery symbol will begin to flash, indicating the batteries need to be recharged or replaced.

Smart Recharge System (optional)

The DigiDop can be ordered with an intelligent battery recharger that intelligently charges rechargeable batteries. Simply plug the AC adapter into the recharge port to begin charging unit. It is recommended that to achieve a full charge the DigiDop is left plugged into the AC adapter for 3-6 hours, however, quick charging for immediate use can be accomplished by plugging into the AC adapter for as little as 15 minutes. It will not hurt the batteries to leave them charging while not in use.

NOTE: By design, the unit may not be used while the batteries are being charged.

NOTE: Do not leave alkaline batteries in the unit if the unit is to be stored. Alkaline batteries may leak without cause if left unused for long periods of time.

CAUTION: Do not attempt to recharge alkaline batteries. Damage to electrical components may occur.

Audio recording

Audio recording is available on some models. These can record up to 30 seconds of the Doppler sounds. Record by pushing and holding the record button while recording. The recording indicator light will come on while recording and go out when the 30 second memory is full. Press and release the button to play back the recorded sounds.

Product Use

CAUTION: For any Doppler examination, 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.

CAUTION: If skin irritation occurs during product use, use of the unit should be discontinued.

Finding the Fetal Heartbeat (2 & 3 MHz)

For early term fetal detection, start the probe at the pubic bone and slowly move along the midline-rocking the probe slowly from side to side until a heartbeat is heard. For mid to late term fetal detection the best chance of finding the heart sounds are to start near the top of the uterus and move toward the navel and from one side of the abdomen to the other, slowly rocking the probe until the heartbeat is heard. The fetal heartbeat reminds many people of a galloping horse and can vary in tone from a distant swishing sound to a hard-clopping sound depending on the position of the baby and probe.

Many times, when attempting to detect the fetal heart, the maternal vascular sounds are heard instead of (or in some cases, in addition to) the fetal sounds. These maternal sounds can come from one of the major arteries, the placenta, or the umbilical cord. The maternal vascular sounds are typically higher in frequency at a lower rate. The heart calculation will display either the maternal rate (if greater than 50 bpm) or the fetal rate, whichever portion of the signal is stronger.

If the fetal heart sounds cannot be detected using the DigiDop procedure as described above, a second exam should be performed using another commercially available fetal monitor as a repeated test.

Vascular (5 & 8 MHz)

Slowly move the probes in the area of examination until vascular sounds are heard. Given the small area of the vascular probes, the strength of the Doppler signal is highly location specific. Do not press too hard to avoid occluding the flow.

General Care, Maintenance, Cleaning, & Disposal

CAUTION: Transmit and receive elements in probes are crystalline in structure and are susceptible to breakage if abused or dropped.

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

CAUTION: No part of the unit is designed for sterilization processes such as autoclaving or gamma radiation.

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.

The DigiDop requires very little maintenance. It is important, however, for the continued functionality of the unit and the health of the patients to that the unit is cleaned and examined regularly as follows:

After every examination

Excess gel should be wiped off after each examination. Unit should be cleaned with a damp water or alcohol-based wipe. Mild soap or detergent may 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.

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

CAUTION: The DigiDop is not intended to be used on open skin. If there is evidence of open wound contamination, ensure to disinfect the unit before using again.

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 customer service.

Battery Replacement

CAUTION: The DigiDop uses AA batteries (300, 301, 700, 701 & 990R) or AAA batteries (330, 330AR, 330R, 770, 770AR, & 770R). Do not attempt to use any other size batteries in the unit. The DigiDop non-rechargeable batteries should be alkaline cells for longest life. Newman Medical provides premium rechargeable batteries, replace rechargeable batteries only with approved batteries. Please call customer service or visit our website for further information.

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

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

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.

Troubleshooting

Please call customer service with questions if unit malfunctions and a solution may not be found below.

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 heart sounds as described in “Operation and Use”
- Damaged Probe

- A probe that is suspected to have been dropped may have damaged transmit/receive elements. If the elements are damaged the unit will produce low or no output.

Heart Rate Inaccurate

- Locate the probe for a stronger signal.
- Avoid mixing maternal and fetal sounds.

Battery Level Flashing

- The voltage of the batteries is low.
- Change or charge the batteries as soon as possible.

Specifications

Models 300, 301, 700, 701
Dimensions: 150 x 65 x 35 mm (6 x 2.5 x 1.25 inches)
Weight: 340 grams (12 ounces)
Battery Type: 3 x 1.5 nominal volts (AA/R6)

Models 330, 330A, 330AR, 330R, 770, 770A, 770AR, 770R
Dimensions: 120 x 60 x 35 mm (4.7 x 2.3 x 1.4 inches)
Weight: 260 grams (9 ounces)
Battery Type: 3 x 1.5 nominal volts (AAA/R03)

Models 901
Dimensions: 210 x 155 x 115 mm (8.25 x 6 x 4.5 inches)
Weight: 850 grams (30 ounces)
Battery Type: 3 x 1.5 nominal volts (AA/R6)

All Models:
Level of Protection against electrical shock:
Type B Applied Part
Class II Equipment

Comply with the following standards:
IEC60101-1, IEC60601-2, IEC60601-2-37

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 Life – AA/R6	600 minutes (NiMH) 800 minutes (Alkaline)
Battery Life – AAA/R03	250 minutes (NiMH) 300 minutes (Alkaline)

Heart Rate Range	50 ~ 220 BPM
Heart Rate Calculation accuracy	±3 BPM
Sensitivity	9 weeks gestation (3MHz)
Audio Cable Interface (excludes 901)	3.5mm stereo plug
Audio Output Power	1.1W

Acoustic Properties

Acoustic Output	Model	
	2.0 MHz	**3.0 MHz**
$I_{SATA(max)}$ (mW/cm^2)	9.6	12.6
W_0 (mW)	20.0	14.2
EBD (radiating element) (cm^2)	1.57	1.125
f_c (MHz)	2.20	2.96
PD (second)	CW	CW

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).

$I_{SPPA.3}$ **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:

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

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

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

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.

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 DigiDop 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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical

EN/IEC 61000-4-8			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	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. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.

[a] 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.

[b] 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.

5-year Warranty and Service Policy

The DigiDop is guaranteed to be free from defects in materials and workmanship, including breakage, for 5 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 DigiDop assume neither responsibility nor liability for incidental or consequential damages arising from the purchase of this product.

The manufacturer and distributor of DigiDop 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.