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. If at any point you have questions, suggestions, or concerns, please do not hesitate to contact us.

Newman Medical
1-800-267-5549
info@newman-medical.com
www.newman-medical.com

Introduction

Intended Use

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

5MHz, 8MHz, and PPG probes were designed to aid in the diagnosis of peripheral vascular disease.

NOTE: 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, and do not take an arm pressure in an arm with a shunt or dialysis graft.

Safety of Dopplers

The DigiDop was designed according to FDA 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 to reduce risk **AFAP** (**A**s **F**ar **A**s **P**ossible).

AIUM Statements

As Low As Reasonably Achievable (ALARA) Principle

Approved April 2, 2014
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 April 1, 2012
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 April 1, 2012
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.

Description of Product

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

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 unit
701 – Heart-rate display, rechargeable unit
DD-II
330 – Non-heart rate, non-rechargeable
330R – Non-heart-rate, rechargeable
330AR – Non-heart-rate, rechargeable, audio recording
770 – Heart-rate display, non-rechargeable

770R – Heart-rate display, rechargeable
770AR – Heart-rate display, rechargeable, audio recording
Tabletop
990R – Countertop size, Heart-rate display, rechargeable

Probes:

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

D2W – Obstetrical. The 2MHz **waterproof** probe is designed for use with larger patients or during late term pregnancy **in water applications.**

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.

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**.

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

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

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.

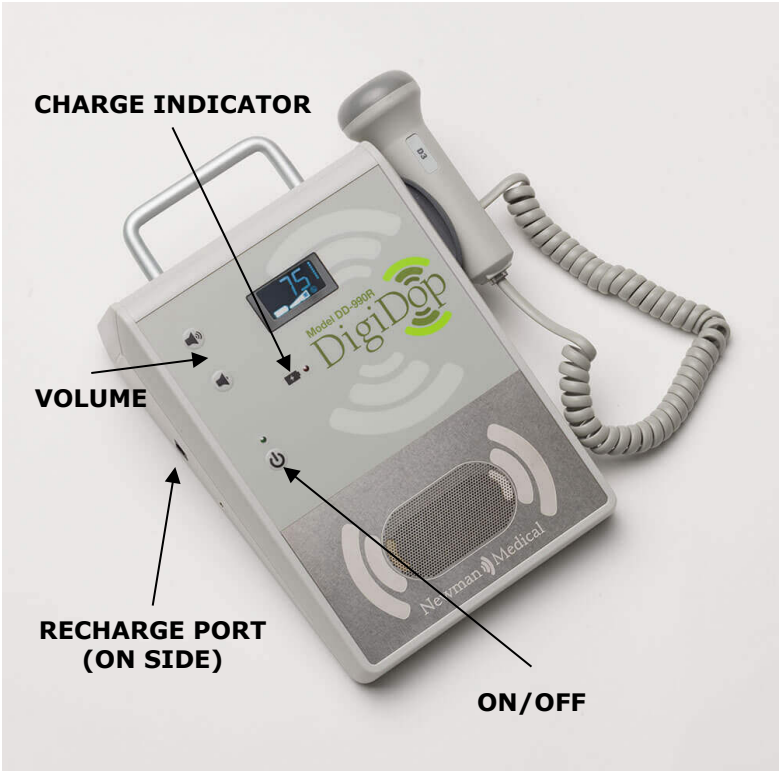
Operation and Use

DigiDop

(Models 300, 301, 700, 701)

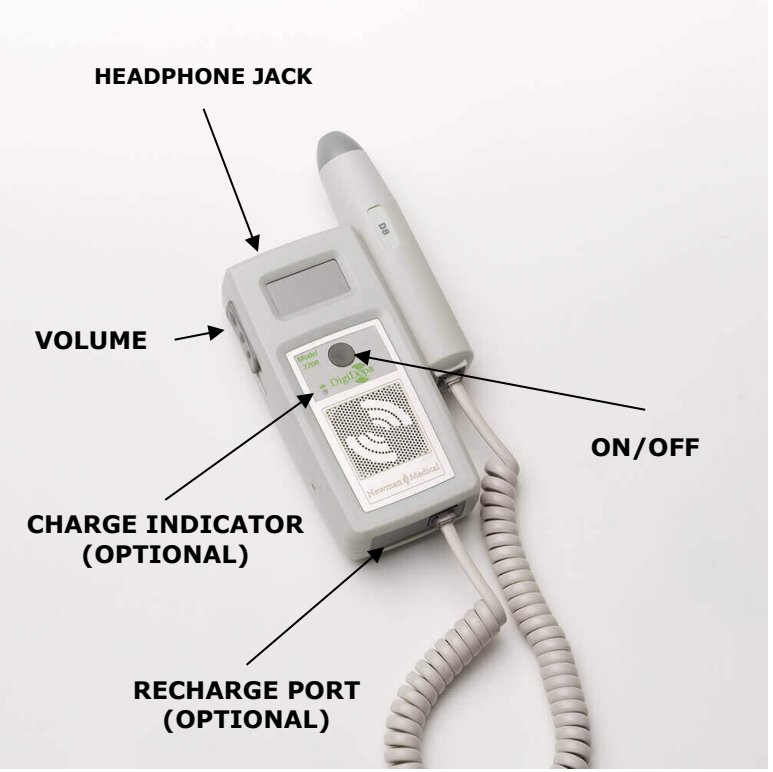
DigiDop Tabletop

Model 990R



DD-II

Models 330, 330AR, 330R, 770, 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.

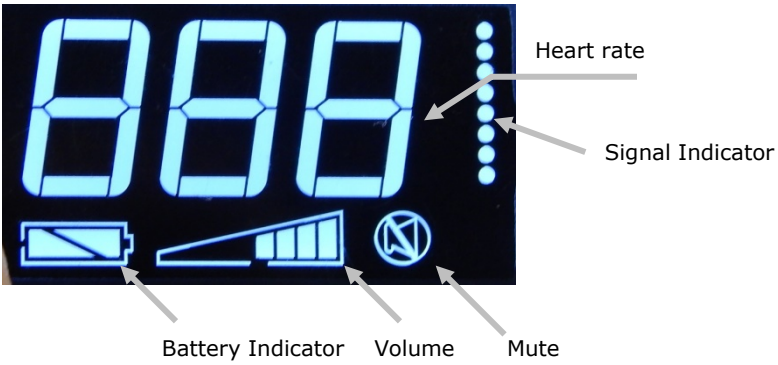
The DigiDop automatically turns itself off after 3 minutes of inactivity. This auto shut off feature preserves battery life and serves to eliminate complete battery drain in case of accidental failure to shut off the unit.

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, first half of the internal symbol goes away, then

the other. Next the outline of the battery will begin to flash. When this occurs, it is time to charge the battery. It will not hurt the batteries to leave them on charge when not in use.

Smart Recharge System (optional)

The DigiDop can be ordered with an intelligent battery recharger that prevents charging of non-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.

NOTE: The unit may not be used while the batteries are being charged.

NOTE: Do not attempt to recharge alkaline batteries. Non-rechargeable batteries will not charge. With the Smart Recharge System, DigiDop units will not cause battery leakage under normal recharging conditions.

NOTE: In model 990R the charge indicator is illuminated red while the unit is charging and turns off when the unit is fully charged. On other units the light is illuminated red while charging and turns green when charged.

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, and Cleaning

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

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

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

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

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. 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. Because we use a premium rechargeable battery, 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.

Troubleshooting

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

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, 330R, 330AR, 770, 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 990R
Dimensions: 230 x 155 x 90 mm (9 x 6 x 3.5 inches)
Weight: 540 grams (19 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	3.5mm stereo plug

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
Transducer Model: 5MHz
Operating Mode: Continuous Wave (CW)
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.

5-year Warranty and Service Policy

The DigiDop is guaranteed to be free from defects in materials and workmanship 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 a 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.

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