

IMEXDOP_{CT+} Manual



Nicolet
V A S C U L A R
a division of VIASYS Healthcare

CONGRATULATIONS, you've made a smart choice.

The innovative IMEXDOP CT+ carries forward the acclaimed features which have made Nicolet Vascular a world leader in Doppler technology: reliability, quality and sensitivity. No other product can match the value provided by a Nicolet Doppler.

The IMEXDOP CT+ uses the leading ultrasound crystal and microchip technologies along with the unique probe design used in the Pocket-Dop II™. These are incorporated into a counter top-size unit for high quality sound and ease-of-use.

CAUTION:

Federal law (USA) restricts this device to use by or on the order of a physician.



The CE₀₃₄₄ Mark identifies compliance with the Medical Device Directive 93/42/EEC.

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SERVICE

Note: If the system is not functioning properly, do not operate until all necessary repairs are made and the unit is tested for proper functioning in accordance with Nicolet Vascular published specifications. It is recommended that all repairs be performed by a qualified service representative only. All non-medical equipment connected to this device, such as the tape recorder, must be battery powered or meet Class B leakage current requirements.

Service information and assistance is available on Nicolet Vascular Dopplers by phoning Nicolet at 1-800-525-2519 or (608) 441-2266.

If you need to send the unit in for repair contact Nicolet Vascular Technical Service first to obtain a Repair Authorization# (RMA). Package the product carefully (in its original container if possible) and return it to:

Attn: Service Department
Nicolet Vascular
2920 Commerce Park Drive
Fitchburg, WI 53719

Ship the product, insured, via U.S. Mail or United Parcel Service. **Include a note indicating the problem, the name of a contact person and their phone number.**

For service outside the United States, please contact the local distributor from whom you purchased the unit.

Warranty: It is important that you return the warranty card supplied with your IMEXDOP CT+ as soon as possible. The specific warranty conditions and limitations were sent with your system. Your IMEXDOP CT+ is protected by a limited warranty.

INDICATIONS/CONTRAINDICATIONS

The IMEXDOP CT+ is indicated for the following conditions: claudication, leg cramps, swollen or painful lower extremities, fetal viability, venous and arterial insufficiency.

⚠ Do not use on eyes. Addition of sterile sheath allows use within sterile field but not in an invasive manner.

INTENDED USES

The IMEXDOP CT+ uses include: the early detection of fetal life, the detection of blood flow in peripheral vessels, continuous wave Doppler screening of superficial and deep vessels for occlusive conditions, use in conjunction with conventional cuff for blood pressure monitoring, and to monitor blood flow during and after surgery.

SPECIFICATIONS

Ultrasound Frequency:	8.0 MHz \pm 10% 5.0 MHz \pm 10% 3.0 MHz \pm 10% 2.0 MHz \pm 10%
Dimensions:	4.3 x 6.2 x 8.8 in. 10.9 x 15.7 x 22.4 cm
Weight:	2 lbs. 11 oz. with one probe 1.22 Kilograms
Ultrasound Intensity (I_{SATA}):	
2 MHz =	0.9mw/cm ²
3 MHz =	4.3 mw/cm ²
5 MHz =	9.8 mw/cm ²
8 MHz =	14.8 mw/cm ²
Cord Length:	12 feet 3.66 meters
Battery Type:	12 V NiMH, User Replaceable
Battery Life:	75 minutes typical (Away from Charger)
Battery Recharge Time:	14 hours
Speakers:	Two 8 Ohm
Audio Output:	Approximately 1 watt
Available Chargers:	120 vac or 230 vac, 50/60 Hz
Power Input:	8 watts, max.
Display Accuracy:	\pm 2% of reading

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The purpose of this manual is to guide the user in the operation and care of the IMEXDOP CT+. Every reasonable effort has been made to present accurate information. Nicolet Vascular hereby disclaims and makes no warranty with respect to any diagnosis, clinical condition or interpretation made based on the information presented herein. Refer to the Limited Warranty sent with your IMEXDOP CT+ for the equipment warranty.

PRODUCT DESCRIPTION

The IMEXDOP CT+ has some special features which will enhance your use of the product:

* **Standby Mode.** When the OFF/STDBY button is pressed, the unit turns off by entering the standby mode. While in this mode, there is still a small amount of energy running through the unit.

* **Automatic Power-down.** If the OFF/STDBY button is not pressed, the unit will automatically power-down by entering the standby mode after 3 minutes of not sensing a Doppler signal.

* **Smart Recharger.** This system uses a "smart" recharger for maximum convenience and long battery life. The unit is automatically charged when it is on its recharging stand. To use the Recharger, simply plug it into a 3 wire hospital grade outlet. A full charge takes approximately 14 hours. The Recharger also functions as a wall mounted stand when desired.

* **Safety Features.** Built-in safety features include very low ultrasound power. The IMEXDOP CT+ is safe to use while it is on the Recharger.

* **Heart Rate Display Using Autocorrelation.** The IMEXDOP CT+ uses a large liquid crystal display (LCD) for convenient viewing of the fetal heart rate and vascular pulse rate. Rates in the range of 60 to 199 beats per minute are displayed during obstetrical exams and 60 to 119 beats per minute during vascular exams. The LCD will show "1- -" if no heart rate is detected or if the heart rate is out of the display range. Advanced software algorithms provide heart rate tracking and accuracy.

* **Average Mode.** After obtaining a rate, you can view an average of these rates by pressing the ON/AVG button. The AVG symbol (see page 4) and the average rate will be displayed on the LCD for 10 seconds. Average Display = moving average of previous 10 calculations.

* **Interchangeable Probes.** Nicolet Vascular was the first manufacturer to offer interchangeable probes. Four frequencies are available to provide optimum performance - 2 MHz, 3 MHz, 5 MHz and 8 MHz. A digital fetal heart rate will be displayed when using the 2 MHz and 3 MHz obstetrical probes; the LCD will display a pulse rate when the 5 MHz and 8 MHz vascular probes are used.

Battery Care

The IMEXDOP CT+ uses a 12 volt rechargeable NiMH battery pack. Recommended operating temperatures for the unit and its batteries are 0 to 35 degrees C (32-95 degrees F). Recharging the batteries is easy. Simply turn the IMEXDOP CT+ "off" by pressing the OFF/STDBY button and place the unit on the recharging stand. When the battery charging indicator is on, the unit will automatically recharge. The unit should be left on the charging base when not in use. It is not possible to overcharge the battery.

Note: The IMEXDOP CT+ can be operated while it is on the charging stand, but the batteries will not charge while the unit is operating.

Battery Replacement

Typically the IMEXDOP CT+ batteries last two years or more. If battery replacement is necessary, they can be obtained from your dealer or from Nicolet Vascular. To replace the battery remove the two screws on the bottom of the unit. Next, remove the battery door. Remove and unplug the old battery and replace with a new one. Install the battery door and the door screws. Replacement batteries may need recharging before use.

Note: The battery manufacturer recommends the batteries be replaced every three years for reliable operation.

Transport and Storage

-10°C to 60°C
15% to 90% humidity (non-condensing)

Pressure

Main Unit and Probes 0.01 ATM to 1.2 ATM

CARE OF THE INSTRUMENT

Main Unit

Keep the main unit clean by wiping it periodically with a damp cloth. DO NOT IMMERSE in fluids. DO NOT AUTOCLAVE!

Doppler Probes

! WARNING: No part of the IMEXDOP CT+ is to be connected to a telephone line.

Caution: Do not use organic cleaning agents or alcohols. Do not allow detergent solutions to seep into the electronic portions of the system (controls, connectors). Do not completely immerse the probe in liquids.

Note: The following steps are recommended for the cleaning and disinfection of Imex probes before each use. The procedure renders clean probes which are neither sterile nor pyrogen free. When carried out according to standard clinical practice, it should help prevent the transfer of infectious agents, through the elimination of significant microbiological contamination between uses.

The probe or sensor tip should be wiped clean, with a soft non-abrasive cloth or disposable wipe soaked in a aqueous disinfectant. Avoid aerosol preparations of disinfecting agents, since they may contain alcohol or organic solvents.

Clean, dry probes should be packaged in clean bags, covered trays, or other suitable systems for storage and transport.

Probe Sterilization: ETO and Sterad processes permitted.

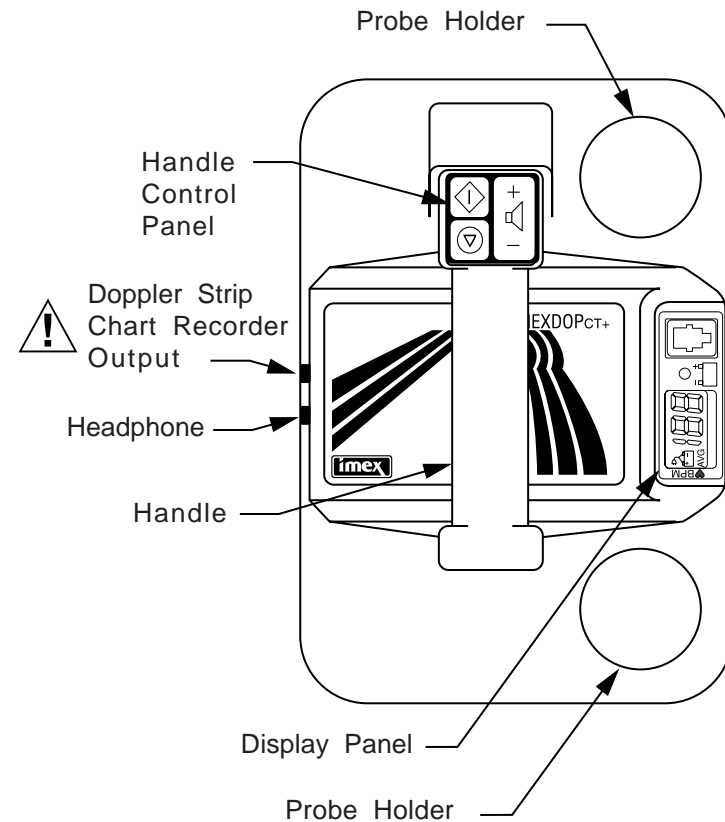


Figure 1 IMEXDOP CT+
(Top Down View)

! Recorder, if used, must conform to Class B requirements.

* **High Fidelity Sound.** This system has dual speakers for excellent sound quality.

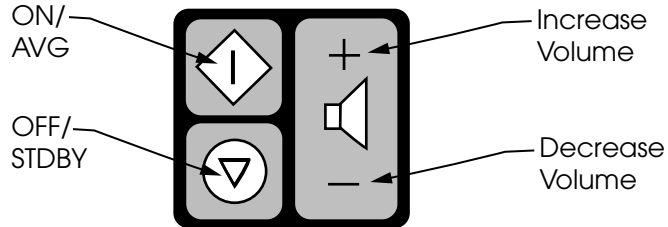
* **Low Battery Indicator.** A battery symbol will be displayed on the LCD when the batteries are low and need to be recharged. (see page 4)

* **Squelch Circuit.** The IMEXDOP CT+ eliminates the loud pops and crackles caused from moving the probe rapidly across the skin.

* **Squelch Switch.** Located under the battery in the battery compartment, the squelch switch can be changed from off to on. With the squelch switch in the "on" position, the squelch circuit is enabled, thus eliminating the pops and crackles encountered when repositioning the probe. With the squelch switch in the "off" position, the squelch circuit is disabled and, therefore, the probe movement sounds are audible. While somewhat noisier, having the squelch circuit disabled eliminates the time lapse between repositioning the probe and detecting a heart beat. This often allows for quicker detection, thus confirming that the probe is correctly positioned.

The IMEXDOP CT+ is shipped with the squelch circuit disabled (squelch switch in the "off" position). To enable the squelch circuit, remove the battery compartment door and push the squelch switch to the right ("on" position) as indicated on the label in the battery compartment.

Handle Control Panel



LIMITATIONS

The theory of Doppler ultrasound is beyond the scope of this manual, but is covered in many recent publications. The IMEXDOP CT+ is designed to be reliable, but as with all medical instruments, should be treated with care. The unit should be used only in the presence of trained personnel. While the IMEXDOP CT+ augments the user's medical skills, it is not a substitute for medical training and knowledge.

WARNING

The IMEXDOP CT+ is not explosion proof. Do not use the IMEXDOP CT+ or probes in the presence of flammable or explosive gases. Do not immerse the unit or probes in fluids and do not autoclave.

SAFETY OF ULTRASOUND

The American Institute of Ultrasound in Medicine (AIUM) has addressed the concerns relating to the safety of ultrasound and has issued the following statement as of March 1993:

"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 AIUM herein addresses the clinical safety of such use:


No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."

Nicolet Vascular has always strived to use as low an ultrasound power as practical. The level of ultrasound power emitted by the IMEXDOP CT+ is not adjustable. Prudent use on the operator's part would include minimizing the length of time that the patient is undergoing the ultrasound exposure.

PRODUCT SAFETY

 **CAUTION: Read and understand the User's Manual before use.**

CLASSIFICATION ACCORDING TO IEC-601-1:

 **Protection against electric shock:** Type B, Class II
Protection against spill: Ordinary Equipment
Internally Powered Equipment
Mode of Operation: Continuous Operation

WARNING: Equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

VASCULAR EXAMS

A Doppler is very valuable for locating vessels for injections or IVs, obtaining difficult blood pressures or listening to flow within a vessel.

Apply a liberal amount of gel to your vascular probe and gently place it over the vessel at a 45 degree angle (approximately). It is not necessary to press hard. If preferred, use headphones to eliminate the speaker sounds.

Move the probe *slowly* taking care not to scan too quickly thus missing the vessel.

Arterial sounds pulsate with every heart beat and venous sounds are spontaneous with respiration. The sound a vein produces is similar to that of a wind storm.

These characteristic sounds are easily heard and can be utilized to determine if a vessel is diseased.

GENERAL HINTS

Use plenty of couplant. Ultrasound is almost completely stopped by any air or bubbles between the skin and the probe. Liberally use the ultrasound gel for best results.

Move the probe slowly. When searching for the fetal heart a slow rocking and rotating motion will minimize noise and help avoid missing the heartbeat. Rest your hand on the patient to stabilize the probe and to avoid unwanted motion and noise.

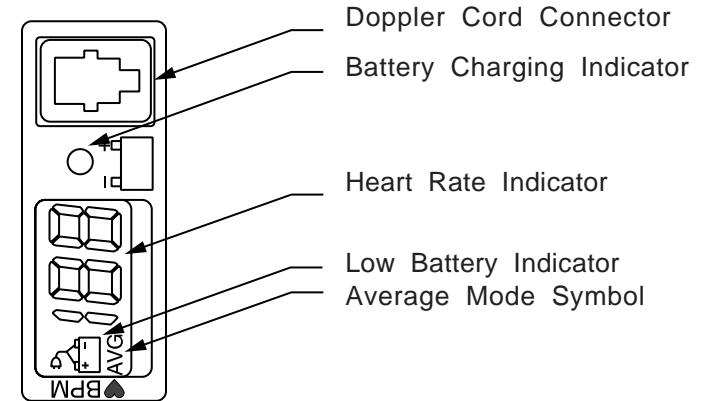
Maintain probe contact. It is important to keep the probe at approximately a 30-45 degree angle to the skin. Holding the probe in this manner allows you to obtain the best possible sounds.

Carrying the Unit. Be careful when carrying the IMEXDOP CT+ that you do not allow the probes to fall out of the holders. The 2 MHz and 3 MHz probes can be lodged securely, however, the 5 MHz and 8 MHz probes cannot be secured in the probe holders. Never presume the probes are lodged tightly. Always physically touch them to check their position.

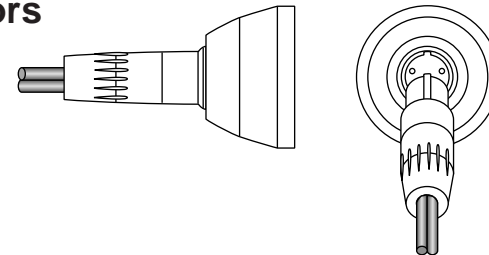
Headphone Connector

A headphone jack, located on the back of the unit, is provided for monaural headphones. (See Figure 1 on page 2.) When the headphone plug is inserted, the speaker is muted for private listening. An external mono to stereo adapter can be used to enable the use of stereo headphones. The impedance of any headphone or ear piece used must be 8 Ohms or greater.

Display Panel



Connectors



Exchanging probes is a simple matter of holding the probe in one hand, grasping the connector in the other hand, depressing the black button firmly and pulling straight apart. Do not twist the connector, just pull.

Reconnect a probe by aligning the key on the connector with the slot on the probe and pushing together until a click is heard.

ACCESSORIES

<u>P/N</u>	<u>Description</u>
A100	Gel
SP-0004	Single, Earphone
V100	IV Pole Mount
T200	2MHz Obstetrics Probe
T300	3MHz Obstetrics Probe
T500	5MHz Vascular Probe
T800	8MHz Vascular Probe
S100	25 Non-Sterile Sheaths (3.5" x 12")
S300	25 Sterile Sheaths (3.5" x 12") with gel

OPERATION

1. Depress the ON/AVG Switch located in the handle control panel. The heart rate indicator, low battery indicator and average mode symbol on the display panel will become active. (See Page 4)
2. Make sure that the Doppler probe cord is connected to the display panel.
3. Apply gel to the face of the probe and begin the Doppler examination.
4. Adjust the volume on the handle control panel as needed by pressing on the top, or + end of the volume button, to increase the volume and on the bottom, or – end of the volume button, to decrease the volume. The IMEXDOP CT+ will be preset at mid-range volume level when turned on.
5. When you have completed the exam, depress the OFF/STDBY switch on the handle control panel. If you forget, the unit will automatically power-down after 3 minutes of not sensing a Doppler signal.
6. Refer to the cleaning instructions to clean the probes.
7. Return the IMEXDOP CT+ to the recharging stand and check that the green battery charging indicator on the display panel is lit. (See Page 4)

OBSTETRICAL EXAMS

Doppler ultrasound in an obstetrical application is primarily used to reassure the mother of the presence of fetal life. In some patients the fetal heart can be heard as early as 8 to 12 weeks. It should be audible 95% of the time in 12 week pregnancies, and nearly 100% after 14 weeks.

The exam is most easily done with the patient supine, although it may also be accomplished in a sitting or standing position.

Expose the abdomen and apply a generous amount of coupling gel to the face of the probe. It is important to maintain good coupling at all times with no air bubbles between the probe and the abdomen.

The key to the examination is to intercept the fetal heart with the beam from the probe. The beam travels in a relatively straight direction much like a flashlight beam.

In the first trimester, the best technique is to start with the probe on the midline of the abdomen and aimed downward behind the pubic bone. The probe should be rocked very slowly to search the most likely areas. Because the fetal heart sounds are faint at this time, be careful not to scan too quickly or the sounds may be missed.

It is often difficult to find the fetal heartbeat during the first trimester and this by itself is not a cause for alarm. A full bladder may make finding the heartbeat a little easier.

The fetal heartbeat sounds like a galloping horse and is about twice the speed of the mother's heart rate. The placental blood flow sounds more like a whirlwind.

Note: The IMEXDOP CT+ provides the listener with information about the fetus; however, if there is any doubt about the fetal condition after using the Doppler, further investigation must be initiated immediately.