

Troubleshooting (cont.)

Unstable heart rate display.	<ul style="list-style-type: none">a. Fetus is too young. Wait a few weeks before trying the test again, or try a manual method for determining heart rate.b. Fetus is moving. Wait a few minutes to see if the fetus settles down.c. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations.d. Probe is detecting blood flow sounds. Reposition the probe.e. Heart rates will vary. Use the average heart rate display.
Inaccurate heart rate display.	<ul style="list-style-type: none">a. The detected signal is maternal or maternal mixed with fetal sounds. A maternal sound, usually one half of the fetal sound, may produce harmonics which are in the fetal range. Reposition the probe to detect only fetal sounds.b. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations.c. Fetal heart rate is out of the display range. Harmonics may cause doubling of the displayed fetal heart rate.

Congratulations on your choice of the Pocket-Dop 3™

The Pocket-Dop 3 provides the features which have made Nicolet a world leader in Doppler technology: reliability, quality, sensitivity and value.

The purpose of this manual is to guide the user in the operation and care of the Pocket-Dop 3. Every reasonable effort has been made to present accurate information. Nicolet 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 Pocket-Dop 3 for the equipment warranty.

Note: The Pocket-Dop 3 is not to be used as an asymptomatic screening tool.

Caution: Federal law restricts this device to sale to or on the order of a physician.

Problem	Solution
<p>Weak or no Doppler signals detected (display shows constant "1--").</p>	<ul style="list-style-type: none"> a. Probe is not positioned correctly. Verify that the probe is positioned over the fetal heart and that the probe face is flat against the abdomen. b. Fetus is too young. Wait a few weeks before trying the test again, or try the other probe. c. Patient is excessively large. Try using the 2 MHz probe since its signal penetrates deeper. d. Ensure the use of ample coupling gel.
<p>No heart rate is displayed with audible tones.</p>	<ul style="list-style-type: none"> a. Signal is not strong enough to generate a display. Refer to the preceding section. b. Fetal heart rate is outside of the display range. c. Probe is positioned over a blood vessel and is detecting blood flow signals. Reposition the probe. d. The detected signal is placental flow. The characteristics of placental flow sounds produce a smooth Doppler envelope. A very smooth signal will not correlate, so no heart rate is displayed. Reposition the probe. e. Fetus is too young. Wait a few weeks before trying the test again, or try a manual method for determining heart rate.

Troubleshooting Pocket-Dop 3 Problems

Problem	Solution
Unit will not turn on.	<ul style="list-style-type: none"> a. Battery is dead. Recharge for 10 hours. b. Incorrect type of battery is installed.
Flashing display.	<ul style="list-style-type: none"> a. Battery is low and should be recharged. (Remember to never recharge the Pocket-Dop 3 when an alkaline battery is installed in the unit.)
Green Charging Indicator light doesn't illuminate.	<ul style="list-style-type: none"> a. Verify that the unit is properly seated in recharging stand. b. Verify that the recharger is plugged in and that the wall outlet has power. c. Verify that the cable from the wall transformer is plugged into the recharger base.
No sound detected, LCD shows the single dash.	<ul style="list-style-type: none"> a. Activate the unit by pressing top volume button.
Unit enters power down mode as soon as transducer is used.	<ul style="list-style-type: none"> a. Battery is low and should be recharged.
Battery does not hold charge.	<ul style="list-style-type: none"> a. Battery is not being charged. Is the green Charging Indicator light on? b. Battery needs to be replaced. Contact your dealer or Nicolet.
Static.	<ul style="list-style-type: none"> a. Use an ample supply of coupling gel to reduce excessive static. Also, hold the probe steady once a fetal heart beat is detected. b. Reduce the volume level.

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Product Description

The Pocket-Dop 3 is a hand-held obstetrical Doppler with interchangeable probes and a digital display of the fetal heart rate. The Pocket-Dop 3 has the following special features which will enhance your use of the product:

Heart Rate Display Using Autocorrelation.

The Pocket-Dop 3 uses a large liquid crystal display (LCD) for convenient viewing of the fetal heart rate. Heart rates in the range of 90 to 199 beats per minute are displayed. 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 excellent fetal heart rate tracking and accuracy.

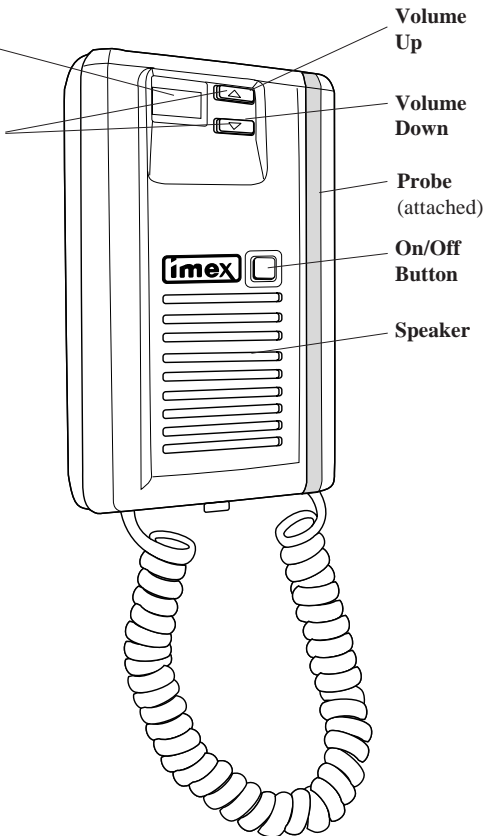
Mute/Average Heart Rate Display.

Mute: Press both volume buttons simultaneously to instantly reduce the speaker volume to the lowest possible setting. **Once the speaker is muted, the user can quietly wipe the gel off the probe without any loud static interference and without turning off the unit.** Press either volume button to restore the audio volume to the previous level. If neither button is pressed within 10 seconds, the volume will automatically return to the previous level.

Average Heart Rate Display: Press both volume buttons simultaneously to display the average fetal heart rate. The average heart rate will be displayed for 10 seconds before returning to the normal operation mode. This average is stored in the memory until the unit powers down and can be redisplayed by pressing both volume buttons. The average will be erased from the unit memory once the unit is turned off, and also after a new valid heart rate is detected.

Easy On/Off.

The Pocket-Dop 3 is turned on by pressing the On/Off button on the front panel of the unit. The Pocket-Dop 3 is turned off by again pressing the On/Off button.



Heart Rate Display Type:	LCD, 0.25-inch characters
Heart Rate Algorithm:	Autocorrelation from audio envelope
Speaker:	2-inch, 8 Ohms
Audio Output:	Approximately 0.5 watt
Headphones:	Use mono connected headphones with impedance of 8 Ohms or greater. Stereo headphones may be used with an adapter.
Maximum Ultrasound Intensities (I_{max})*:	2 MHz = 86 mw/cm ² (at 2.15 cm) 3 MHz = 54 mw/cm ² (at 1.52 cm)

This unit complies with criteria set forth in EN60601-1-2 tested to 3 Volts/Meter.

* The measures of intensity are as measured in water. In order to estimate the in-situ intensity, these are adjusted as follows:

$$\text{Intensity (in-situ)} = \text{Intensity (in water)} \times 10^{-[(3 \times d \times f)/10]}$$

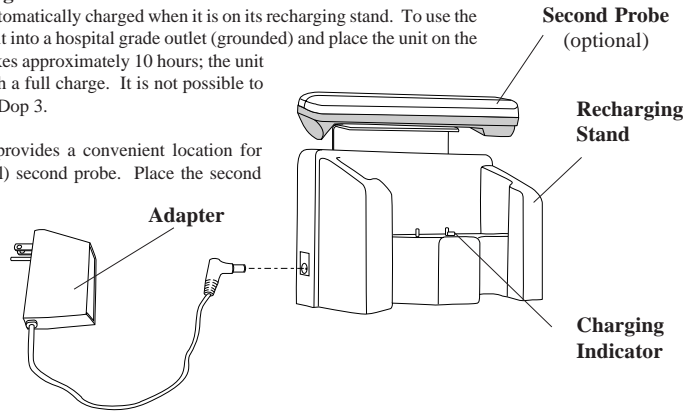
where f is the frequency in MHz, and d is the distance from the transducer to the hydrophone in centimeters.

Accessories provided with the Pocket-Dop 3

Convenient Recharger.

The Pocket-Dop 3 is automatically charged when it is on its recharging stand. To use the recharger, simply plug it into a hospital grade outlet (grounded) and place the unit on the stand. A full charge takes approximately 10 hours; the unit can be used all day with a full charge. It is not possible to overcharge the Pocket-Dop 3.

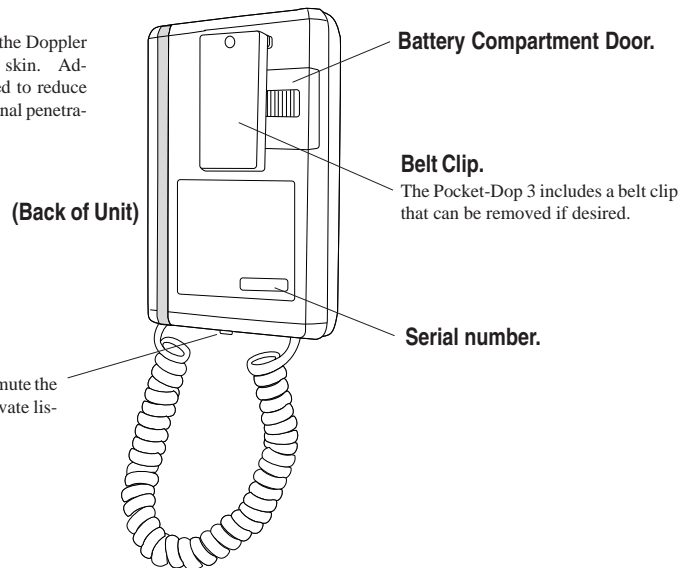
The recharging stand provides a convenient location for storage of the (optional) second probe. Place the second probe face down on the probe holder; the probe is held in place magnetically.



CAUTION: Use the recharger *only* when the specified NiCad battery is installed in the unit. Recharging with an alkaline battery installed will cause severe damage to the unit.

Coupling Gel.

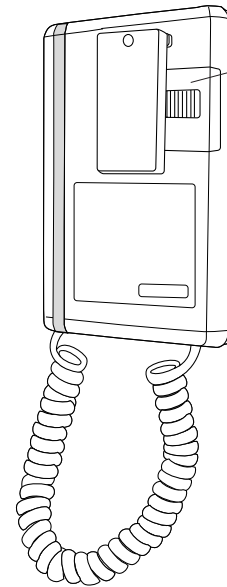
The coupling gel allows the Doppler signals to penetrate the skin. Adequate gel should be used to reduce static and enhance the signal penetration.



Care of the instrument

Keep the instrument clean by wiping it periodically with a damp cloth and mild disinfectant cleaner. **DO NOT** immerse in fluids or use solvent cleaners. **DO NOT AUTOCLAVE!** If sterilization of the Pocket-Dop 3 or probes is desired, it can be done with a cold gas sterilization (such as ethylene oxide at less than 140 degrees F) or the Sterrad System. The user is responsible for verification of sterility.

Battery Replacement



Typically the Pocket-Dop 3 battery lasts two years or more. The battery included with your unit is a special 8.4-volt battery containing one extra cell. To achieve the best results, this type of battery must always be used. If battery replacement is necessary, batteries can be obtained from your dealer or from Imex. To replace a battery, remove the battery compartment door and remove the old battery. Install the new battery with the connector end toward the outside of the unit and with the wires between the battery and the battery compartment door. Replace the battery compartment door. The replacement battery may need recharging before use.

Product Compatibility

The Pocket-Dop 3 was not designed to be compatible with other products. Nicolet recommends using only Nicolet-brand accessories that have been approved for use with the Pocket-Dop 3.

SPECIFICATIONS

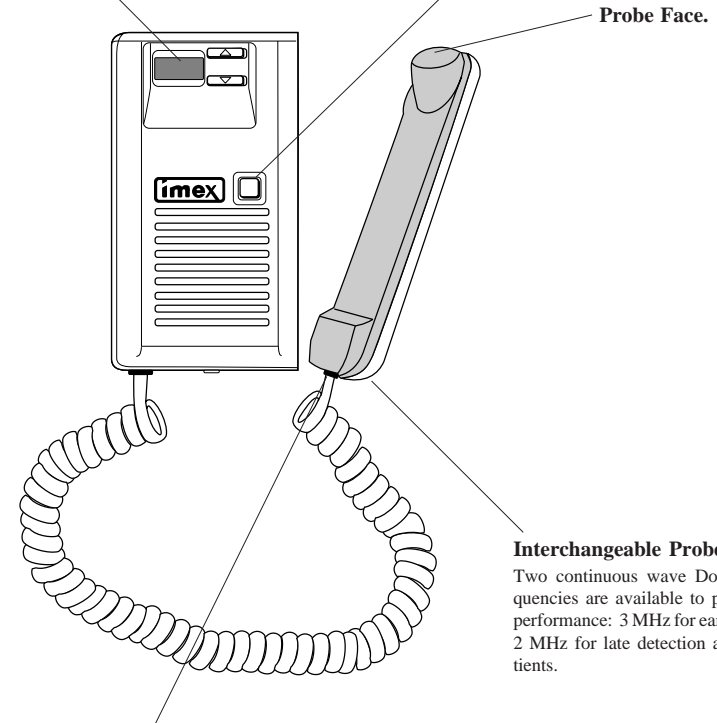
Ultrasound Frequency:	3.1 MHz \pm 5% 2.1 MHz \pm 5%
Dimensions:	5.0" x 3.27" x 1.0"
Weight:	10 oz. with one probe 62.5 grams
Cord Length:	6 feet 2.36 meters
Battery Type:	VARTA V7/8R, 8.4-volt NiCad, user replaceable. (May also be used with a 9-volt alkaline battery but must not be placed on the recharging stand while an alkaline or other non-rechargeable battery is in the unit.)
Battery Capacity:	More than 60 exams of one minute duration each
Battery Recharge Time:	10 hours (3.5 hours to restore 50% of capacity)
Storage Temperature:	Store the unit at a temperature between 0 to 35 degrees C (32 to 95 degrees F)
Display Range:	90-199
Display Resolution:	1 beat per minute
Display Accuracy:	\pm 1 beat per minute at low end of display range; \pm 5 beats per minute at high end of display range

Automatic Power Down.

This feature conserves the life of the battery. If the unit is not properly turned off, it will automatically power down after 3 minutes of not detecting a valid heart rate. While in the power down mode, a single dash (-) appears on the LCD. The unit can then be turned off by pressing the On/Off Button, or the top volume button can be pressed to resume testing. If left in the power down mode, the battery will become completely discharged within 3 days.

Low Battery Indication.

The LCD flashes to indicate that the battery is low and needs to be recharged soon. The heart rate continues to be displayed, but the digits flash on and off.



Probe Connector.

Exchanging probes is a simple matter of holding the probe in one hand, grasping the connector at the bottom of the probe in the other hand, firmly depressing the clear button on the key at the end of the connector, and pulling straight apart.

Interchangeable Probes.

Two continuous wave Doppler probe frequencies are available to provide optimum performance: 3 MHz for early detection, and 2 MHz for late detection and for large patients.

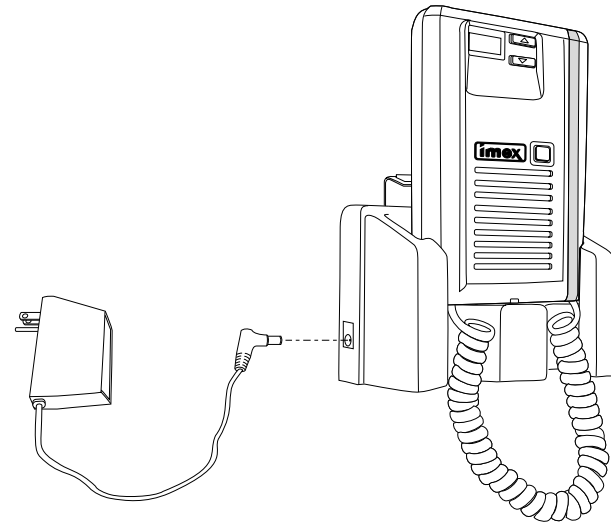
Operation (cont.)

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. The fetal heart beat 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.

When you have completed the exam, press both volume buttons simultaneously to display the average heart rate that was compiled by the microprocessor using the last few seconds of data. The average will remain displayed for 10 seconds. Press the On/Off button to turn off the Pocket-Dop 3 and then wipe the gel off the face of the probe. Return the probe to the side of the unit to protect the probe face from damage. If you forget to turn off the system, it will automatically power down after 3 minutes of not detecting a valid heart rate.

Installation

The Pocket-Dop 3 recharger can be stored on a table or desk top. Simply plug the recharger cord into the side of the recharging stand and plug the transformer into a hospital grade outlet. In health care facilities, the National Electrical Code, section 517-81, requires placement of the recharger outside of the patient vicinity. For wall mounting, follow the instructions provided in the wall attachment kit (optional).



Warning

THE POCKET-DOP 3 IS NOT EXPLOSION PROOF. DO NOT USE THE POCKET-DOP 3 OR PROBES IN THE PRESENCE OF FLAMMABLE OR EXPLOSIVE GASES. DO NOT IMMERSE THE UNIT OR PROBES IN FLUIDS AND DO NOT AUTOCLAVE.

Limitations

The theory of Doppler ultrasound is beyond the scope of this manual, but is covered in many recent publications. The Pocket-Dop 3 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 Pocket-Dop 3 augments the user's medical skills, it is not a substitute for medical training and knowledge.

NOTE: The Pocket-Dop 3 provides the listener with information about the fetus. However, under poor signal conditions, the fetal heart sounds and readings may not be accurate. (Refer to the Troubleshooting section at the end of this manual for a description of sensitivity problems and solutions.) If there is any doubt about the fetal condition after using the Doppler, further investigation should be initiated immediately.

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:

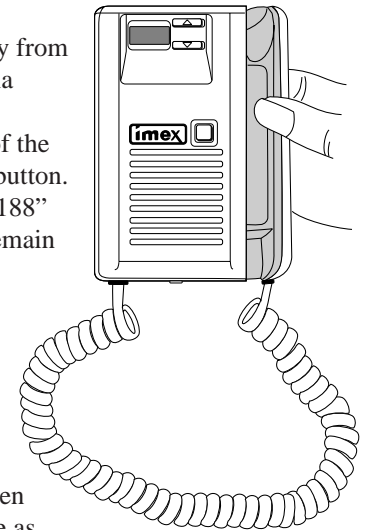
No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that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

Nicolet has always strived to use as low an ultrasound power as practical. The level of ultrasound power emitted by the Pocket-Dop 3 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.

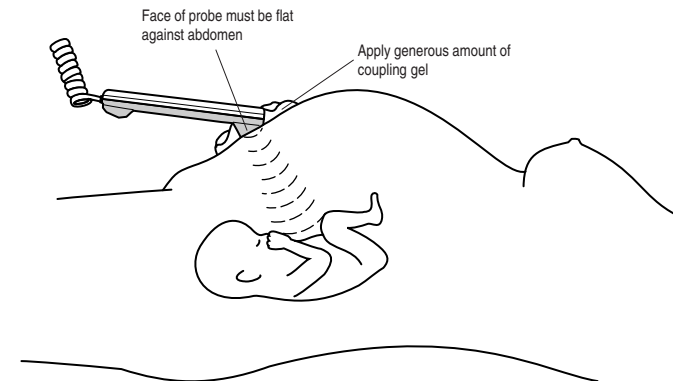
Operation During Obstetrical Exams

Doppler ultrasound is primarily used to detect a fetal heart beat, and to determine fetal position and viability. 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.

Remove the probe from the side of the unit by grasping the probe and rolling it back and away from the unit. Since the probe attaches to the unit via magnets, this method of removal is easier than pulling the probe directly away from the side of the unit. Turn on the unit by pressing the On/Off button. The LCD will light and momentarily display “188” before changing to display “1—” which will remain until a valid heart rate signal is detected.

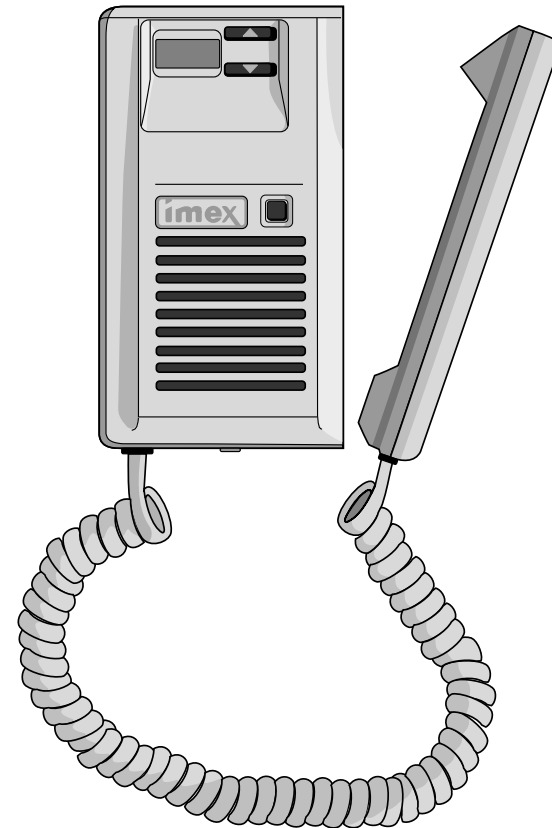


Expose the mother's abdomen and apply a generous amount of coupling gel to the abdomen. Holding the probe somewhat like a pencil, place the probe face **flat** against the abdomen. It is important to maintain good coupling at all times with no air bubbles between the probe and the abdomen. Adjust the volume as needed by pressing the top volume button to increase the volume and the lower button to decrease the volume. Press and hold down each volume button individually to increase/decrease the volume more quickly. The Pocket-Dop 3 automatically starts with the volume at about 2/3 of the maximum level. If preferred, start the examination using headphones for privacy.



POCKET-DOP 3

User's Manual



M7-0214 - Rev G

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

Service

Service information and assistance is available on the Pocket-Dop 3 by phoning Nicolet at 1-800-525-2519 or 608-441-2266.

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

Att: 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 and the name of a contact person and their phone number.**

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

Warranty: It is important that you return the warranty card supplied with your Pocket-Dop 3 as soon as possible. The specific warranty conditions and limitations were sent with your system. Your Pocket-Dop 3 is protected by a limited warranty.

European Authorized Representative

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