

ELECTRICAL SAFETY

MODEL 641-A



CAUTION!

FOLLOW THE MANUAL INSTRUCTIONS ON THE USE OF THIS EQUIPMENT.

Misuse of this equipment and inappropriate electrical connections will create a shock hazard. What appears to be simple connections to other equipment can put the patient and/or the operator at risk of electrical shock. Avoid use involving electrical contact with other equipment.

We assume no responsibility for misuse of our equipment.

WARNING!

THIS DOPPLER IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY.

This Doppler may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Doppler, or shielding the location.

The following is a guide to avoiding common potential hazards, this is NOT comprehensive, always seek the advice of a qualified Bio-engineer BEFORE making any electrical connections.

1. CONNECTING THE DOPPLER TO OTHER EQUIPMENT:

Connecting the Doppler to a computer, amplifier or intercom system can be extremely hazardous. There is a shock hazard unless a medical grade isolation transformer is used. The combined equipment must comply with Medical Systems Standard 60601-1-1 for the safety of the patient and the operator. Have a qualified technician or Bio-Engineer review and approve any proposed connections.

2. DO NOT OPERATE THIS INSTRUMENT FROM OTHER THAN ITS OWN SELF CONTAINED BATTERY. DO NOT USE ANY OTHER POWER SOURCE TO OPERATE THIS INSTRUMENT.

3. DO NOT OPERATE IN THE PRESENCE OF FLAMMABLE GAS OR HIGH OXYGEN CONCENTRATIONS.

4. WARNING!

THIS EQUIPMENT SHOULD NOT BE USED WITH A DEFIBRILLATOR.

SAFETY IS YOUR RESPONSIBILITY. IF IN DOUBT, SEEK EXPERT ADVICE

OPERATING INSTRUCTIONS

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This device is intended for obstetrical use only, NOT intended for vascular diagnosis.

This instrument is NOT meant for continuous monitoring during delivery. It is for intermittent use only.



All our obstetrical Dopplers use a probe which has two semicircular crystals, diameter being about 3/4". One crystal is used for sending the ultrasonic beam and the other half is used to receive the reflected signal. Since the beam is fairly small, the probe must be aimed rather precisely. We have chosen the 3/4" diameter size because in our experiments a larger probe caused a loss of sensitivity and a smaller size made it too difficult to find the fetus. This instrument is not meant for continuous monitoring during delivery. It is for intermittent use only.

To use the instrument, place some gel on the patient's abdomen over the area where you suspect the fetal heart to be. Place the probe in the gel BEFORE you turn on the Doppler to minimize noise and battery drain. Search for the fetus by tilting the probe rather than moving it over the surface. If you find that even with tilting you cannot find the fetal heart rhythm, then move the probe over the abdomen to another spot, moving the gel with it as much as possible. Raising the probe and replacing it on the abdomen will create a lot of noise and draw a lot of current from the battery. Make sure there is always a full coverage of gel on the surface of the probe and the skin underneath it as ultrasound does not readily go through air.

When you find what you believe to be the fetal rhythm, count its rate or compare it with the patient's wrist pulse. The fetal rate will normally be close to 150 beats per minute.

For our other Dopplers, earphones may be used. They are available from us or can be obtained locally. All pocket Dopplers must use a single ended (non-stereo) plug to take off the audio signal. When the earphones are plugged in, the speaker is disconnected so the sound is heard only through the earphones. The speaker in the instrument will not reproduce low-frequency sounds as well as the earphones. Also, earphones more effectively shut out room noise. Turn down the volume or turn the instrument off when you are going to move the probe position or lift it.

OPERATING INSTRUCTIONS

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THE COUPLING GEL

YOU MUST USE GEL IN FRONT OF THE PROBE.

We recommend you use a coupling gel made especially for ultrasound. Don't use a gel that is too thin. You can use sterile jellies internally.

Ultrasound coupling gels are available from us, or will usually be available from one of your surgical supply dealers. These gels are available in bulk, sterile packets and bottles. Gel in a semi-rigid tube with a small extended tip is easier to use than that which is in collapsible tubes. Refilling from bulk is much less expensive than buying more bottles or packets. Some tubes can be autoclaved.

PLEASE DO NOT USE ECG PASTE OR CREAM.

THE RED PROTECTIVE COVER MUST BE REMOVED FROM THE PROBE BEFORE USE.

PHYSIOLOGICAL EFFECTS OF ULTRASOUND

IMPLANTED DEVICES

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Also some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections and as a precaution, avoid using ultrasound close to these.

STUDIES NEAR SENSITIVE TISSUES

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina. Similarly, extreme care should be taken near other sensitive nervous tissue.

Based on experimental and epidemiological data, there is presently no identified risk associated with diagnostic ultrasound. However, a prudent and conservative approach is recommended in which diagnostic ultrasound should be used only for medical benefit and with minimal exposure.

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STRANGE NOISES FROM THE DOPPLER

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On occasion there are noises you might not expect from the Doppler when in fact the Doppler is working fine. The following are some common concerns and their causes.

Concern:	Cause:	Remedy:
Popping scratchy noises sounds when the probe is first placed on the skin.	Air bubbles in the gel are moving and/or popping. Hair movement can also cause these noises.	Use a new dab of gel that looks clear, push the probe down enough so hair is immobilized, and wait a few seconds for everything to settle. If the noise is not there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably working fine.
Static when the dry probe is moved through the air.	Loose connectors where the probe connects to the instrument, broken shield wire in the cable either at the connector or as it comes out of the probe.	There is normally some static generated when the cable is flexed, but it isn't severe. Replace probe or get connectors fixed. If the problem persists contact the factory.
High pitched tone and flow indicators (if so equipped) go to the extreme.	Radio interference from a mobile service, police station nearby, even another Doppler working close by. Usually occurs near large open windows, rarely in the center of the building.	Move the Doppler to another location away from windows and toward the center of the building. If the problem persists contact the factory.
Buzzing noise that almost obliterates the Doppler signal.	Electrocautery or other sparking device, bad fluorescent light fixture or neon signs nearby.	Move the Doppler to another location away from the interference. If the problem persists contact the factory.
Howling noise when probe is held or laid on a table with gel on it.	Probe is acting as a microphone and you are getting acoustic feedback.	Wipe gel from probe, If the noise does not occur without gel on the probe, it is probably working fine.

ADDITIONAL TESTS:

1. Try using earphones if you have a howling noise. If there is no howl using earphones but there is with a speaker, it is acoustic feedback.
2. Try a different probe, even if it is the wrong frequency it will let you know if the problem is noisy connectors in the instrument or frayed shielding near the probe body.

SUMMARY: The problem may simply be a probe or it may be peculiar to the environment in which it is used. If you have tried the tests and remedies mentioned and you still suspect a problem contact the factory toll-free at 1-800-547-6427.

CARE OF THE PROBE AND STERILIZATION

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The Doppler probes are easily ruined through misunderstanding and neglect. Over 90% of the failures of the Doppler are due to failure of the probe in some way. It will pay you to read what follows and transmit this information to any person using the Doppler.

ABOUT THE PROBE: The active part of the probe consists of two crystals. One transmits the ultrasonic waves and the other receives them. Each crystal can serve either function so it makes no difference how you plug in the probe to the panel jacks. The crystals are held in place by a material that protects the crystals and the tiny wires soldered to them. This material is vulnerable to attack by excessive heat, alcohol and ECG paste. We recommend an ultrasonic gel but in an emergency, use any surgical jelly. **DO NOT** use ECG paste or cream as a contact medium between the skin and probe.

After use, the probe should be gently wiped clean of the acoustical coupling gel with a soft tissue. If the gel has dried on the probe, place it under warm tap water to soften the gel and permit you to wipe it off. Should someone use a sharp instrument to scrape off dried gel, they may also succeed in scraping off the material covering the tiny wires and crystals as well. We speak from long experience. Damage such as this will make your probe inoperable. You must order a replacement, specifying the frequency marked on the connector or the label attached to the cable (e.g. 2.2, 2.1, etc.).

BE SURE THE PROBE FREQUENCY MATCHES THE TUNING OF THE INSTRUMENT. The frequency of the probe is marked on the connector end of the cable or is specified on a label attached to the cable. **DO NOT remove the label attached to the cable**, it contains important reordering and warranty information. The tuning of the instrument is marked with a stick-on label near the probe jacks on the front panel.

DISCONNECTING THE PROBES from the instrument should be minimized. Don't do it unless you need to, for two reasons. First the connectors wear and make erratic contact after many disconnects. Second, people have a tendency to pull on the cable instead of the connectors themselves and they break the soldered connection inside the cable connector.

STERILIZATION:

A probe with cracks in the epoxy covering or damage to the cable will allow organic material to be trapped inside. These probes cannot be properly sterilized.

Ethylene Oxide gas, Sterrad and TSO₃ sterilization processes are tested and verified to cause minimal damage to Parks probes.

Exposure of the probes to Ethylene Oxide (Gas Type 10/90) will produce a 10⁻⁶ sterility assurance level (SAL).

Sterilant gas:	equivalent of 10%EO/90%HCFC
Temperature:	(125° - 135° F) 51.6° - 57.2° C
Gas concentration:	600 ± 30 mg/l
Exposure time:	minimum of 120 minutes (full cycle)

Follow the procedure provided by the manufacturer of your sterilization equipment for maximum probe life.

Excessive heat will ruin both the crystals in the probe and the cable. Possible consequences are softening of the material covering the crystals with subsequent peeling and/or excessive noise generated in the probe from deposition of chemicals inside. A sterile water rinse after chemical sterilization is recommended.

Sterilization by any method is going to shorten the life of the probe, but the cost per use is quite low.

A PROBE EXTENSION CABLE may be purchased which allows you to keep the Doppler out of the sterile field when the probe is to be used intraoperatively. This cable is about four feet long and costs very little.

**IF YOUR PROBE HAS AN IDENTIFICATION LABEL ATTACHED TO THE CABLE, DO NOT REMOVE IT!
IT CONTAINS IMPORTANT REORDERING AND WARRANTY INFORMATION.
WARRANTY VOID IF REMOVED.**

GENERAL MAINTENANCE OF THE DOPPLER

MODEL 641-A

NOTES FOR THE SERVICE TECHNICIAN

POSSIBLE PROBLEMS

1. The Doppler is tuned to a frequency which is different from that marked on the probe. This occurs in hospitals that have Dopplers and probes of more than one frequency. The probes and instruments get mixed up. We try to circumvent this by sending a particular hospital Dopplers and probes of the same frequency. The probe frequency is marked on its connector or indicated on a label attached to the cable. The Doppler frequency is indicated next to the probe connectors on the instrument. A variation of .1 MHz is not significant at around 5 or 10 MHz, but it is around 2 MHz.
2. The battery is either the wrong type or was shorted while being installed. The result is diminished battery life.
3. An attempt is made to feed the signal from the earphone jack on the Doppler to another device for either amplification or processing and it does not work. The most likely reason for this is that a tip-ring-sleeve-type (stereo) plug has been used. You must use a single ended plug to take off the audio signal.

True service problems can be broken down into the following general categories which are listed in the approximate order of their occurrence.

1. Failure of the probe. This accounts for about 90% of all the service problems. The user should keep a spare probe of the proper frequency on hand if they depend on the Doppler.
2. Probe connectors or panel jacks are making poor contact and there is "static". The center pin wiping on the panel jack is usually at fault. A sharp tool can be used to bend the wiping sleeve inward and stop the noise.
3. Failure of the battery or plastic case because the instrument was dropped. Battery connector is sprung so that a good contact is not made.
4. A leaking battery has corroded battery connector so that good contact is not made or corrosive fluid has penetrated end insulators causing electrical leakage to ground.
5. Component failure, un-soldered joint or poorly soldered joint, wire to battery or connector broken (perhaps only internally). Look for broken resistors around the edge of the circuit board. They may be broken inadvertently during the process of changing the batteries.

In general we suggest you return the unit to us for service that might be complicated or that may require transistors. The reason is that transistors are often selected for low noise or their dc operating characteristic. Customers in the U.S. can contact us toll-free by calling **1-800-547-6427**. Our regular business phone is **503-649-7007**. Office hours are Monday through Friday, 7:00 am to 3:30 pm, Pacific Time.

Manufactured in the U.S.A. by:

PARKS MEDICAL ELECTRONICS, INC.

19460 S.W. Shaw, Aloha, OR 97007

1-800-547-6427 or 503-649-7007

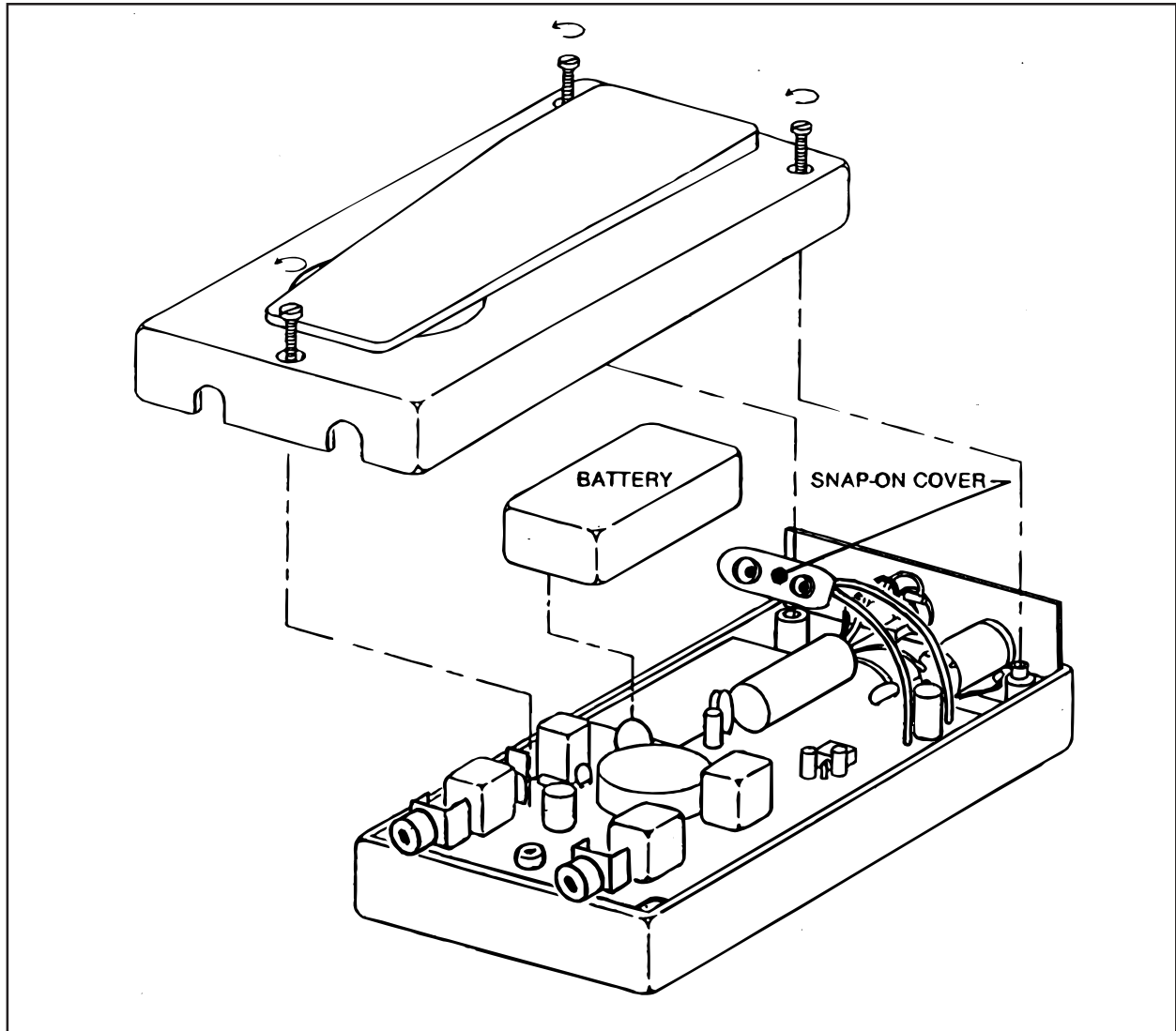
Fax - 503-591-9753

CE Units Available for European Market
Visit our Web Site at - www.parksmed.com

BATTERY REPLACEMENT

MODEL 641-A

THIS DEVICE USES A 9 VOLT BATTERY FOR ITS POWER SOURCE.



⚠ FOR BETTER PERFORMANCE ALWAYS USE A 9 VOLT ALKALINE BATTERY.

When the sound gets weak or distorted, the battery should be replaced.

CAUTION: Never use mercury batteries!

TO REMOVE BATTERY

Remove three screws on the back of instrument, lift off back and unsnap the battery by pulling off the snap-on cover.

When replacing the battery, be sure the snap-on-cover is properly mated to the battery terminals before applying pressure to snap it into place.



Battery must be recycled or disposed of properly.