

**CARE AND USE
OF THE
GREAT LAKES ORTHODONTICS
DIAGNOSTIC DOPPLER**

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Great Lakes Orthodontics, Ltd.

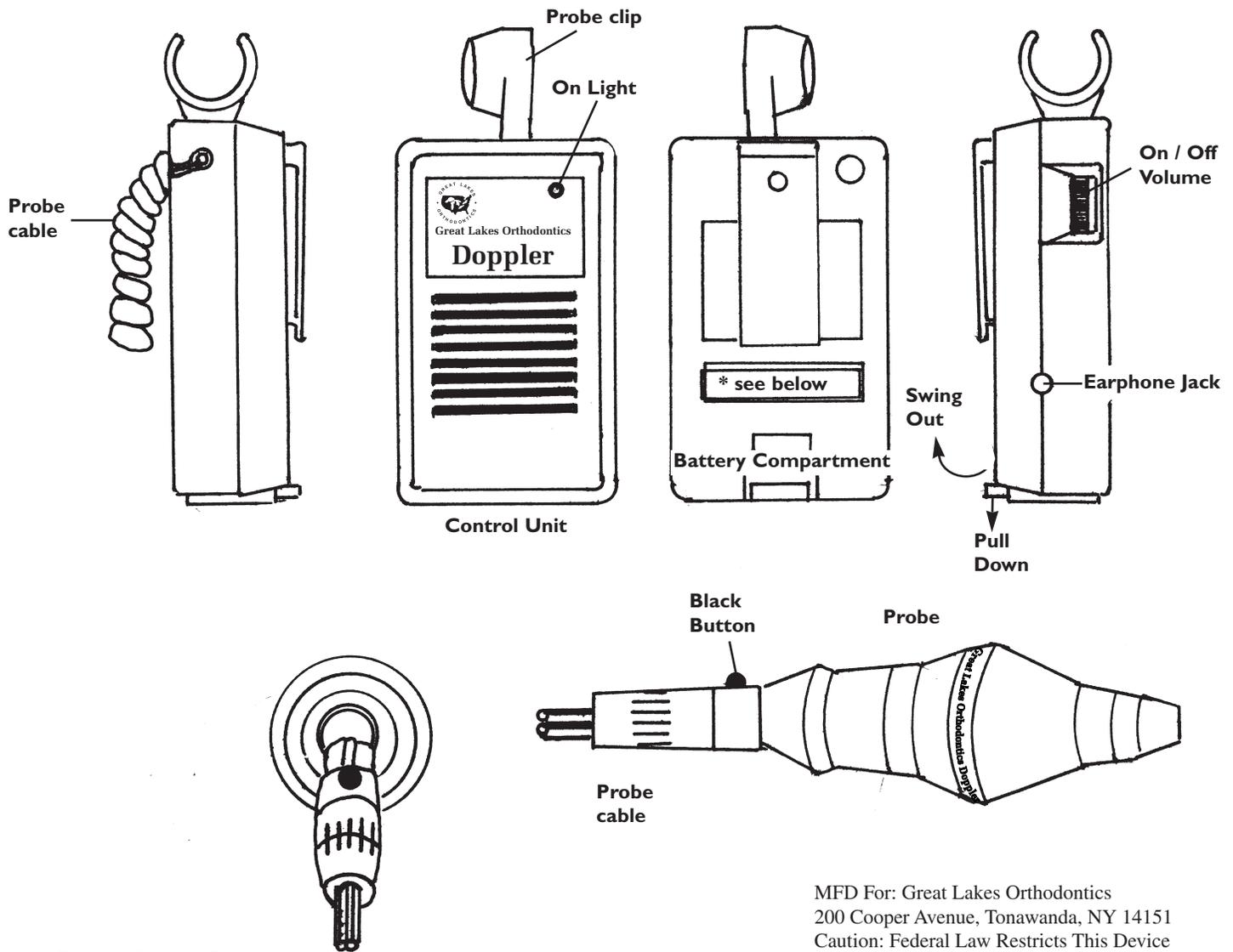
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Section I Parts

The probe contains the sensitive transducer head. The transducer includes a device that sends out or transmits the ultrasound waves, and a receiver that captures the altered ultrasound waves. Sophisticated electronics in the control unit converts the altered sound waves to an audible sound.

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

The control unit includes the battery compartment, micro-controller, the audio system and controls.

In the control unit the signals from the probe are processed, amplified and outputted through a loud-speaker. This method is somewhat subjective and requires that the examiner be experienced in understanding normal and abnormal characteristics.

Two standard AA alkaline cell batteries are required to operate this device. Ni-Cad rechargeable batteries may also be used.

The Doppler comes with a 5 MHz probe.

MFD For: Great Lakes Orthodontics
200 Cooper Avenue, Tonawanda, NY 14151
Caution: Federal Law Restricts This Device
To Use By Or On The Order Of A Doctor.

Section II

Controls

On/Off Volume-

The on/off switch and volume control are on the thumbwheel on the side of the unit.

Light-

The green light will go on when the unit is on. As the batteries run down the light will go out.

Section III

General Hints and Limitations

This Doppler is designed and constructed to be reliable under normal use. As a medical instrument, it should be treated with care. When being used, personnel trained in its use should be present. The use of this device is not a substitute for medical training and knowledge. This Doppler is intended to augment the user's medical skills.

This Doppler is not explosion proof. Do not use in the presence of flammable or explosive gas.

These general hints should help in a Doppler exam:

- use plenty of ultrasound transmission gel. Apply the gel to the patient's face. Ultrasound is almost completely stopped by any air or bubbles between the skin and the probe. The gel also provides for lubrication. Without the gel, movement of the probe, along the hair and skin will provide false sounds.
- move the probe slowly. A slow rocking and rotating motion will minimize noise and help eventual location of the superficial temporal artery to start the exam. Most recommend resting your little finger gently on the patient to stabilize the probe and avoid unwanted motion.
- don't press too hard. This may be uncomfortable to the patient, will squeeze out the transmission gel and may distort the tissues in the joint to provide unnatural motion and/or sounds.

This unit complies with criteria set forth in EN60601-1-2 (Collateral Standard: Electromagnetic Compatibility) tested to 3 Volts/Meter.

Section IV

Doppler Troubleshooting Guide

PROBLEM	POSSIBLE SOLUTION
No sound	<p>Is light on? No? - Check batteries - Open case by pulling down on small tab on back of case at the bottom while pulling the lower part of the back away from the front. Are the batteries installed correctly with + as shown? If not, replace them correctly. Sometimes the ends of the batteries or the connections inside become corroded and this can be fixed by rubbing or scraping the connections and battery tips.</p> <p>Still no? - Try replacing the batteries with standard AA alkaline cells. These type batteries are commonly available at most stores. If replacing the batteries does not fix the problem, it is best to call and then return the complete system to Great Lakes for repair, since the problem could be in the main unit.</p> <p>Yes? - This means the batteries are probably OK. Check to see if the volume control is turned all the way up and that the probe is connected properly and firmly to the cord from the main unit. To be sure that the probe is connected properly, try removing the probe and reconnecting it, making sure that it is lined up correctly with the key on the connector going into the slot on the probe. Tap on the end of the probe with a finger moistened with gel or water. If you have another probe available, try connecting it to the main unit. If that probe works, the problem is probably in the probe and you may have to send the probe back in for service. If no sound is heard, call Great Lakes and arrange for service.</p>
Weak sound or distorted sound	<p>Are you using enough gel? The gel should be applied to the patients face not the probe. Gel dries out after awhile and can also be inadvertently wiped off when moving the probe. Water as a gel does not fill gaps as well. Try using more gel. Also, if the sound is distorted, try turning the volume down - don't use more than necessary.</p>
Static	<p>See above comment on gel. Also, try not to move the probe over the surface of the skin as you are listening to the joint. Some background "hiss" is normal.</p>

FOR REPAIR SERVICE, call Great Lakes at 1-800-828-7626

After receiving a returning goods authorization (RGA) number, return the unit for service:

1) include a note on the problem, 2) the RGA number, and 3) send it insured to:

Attention: Repair Department
Great Lakes Orthodontics, Ltd.
200 Cooper Avenue
Tonawanda, N.Y. 14150

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Section V

Care Of The Instrument

Keep the instrument clean by wiping it periodically with a damp cloth.

DO NOT IMMERSE in any fluid. DO NOT USE solvent cleaners.

DO NO AUTOCLAVE or use high temperature sterilization processes, or use where E-beam or gamma radiation sterilization is used. Where sterilization is required, use cold gas sterilization (such as ethylene oxide at less than 140 degrees F.). The user is responsible for verification of sterility.

The transducer, especially the head - the area touching the skin, is very sensitive. Protect the unit, especially the transducer from being dropped, from hitting other hard surfaces or objects, in transit. Wipe gel off the transducer head with a dry towel. Wipe immediately after use. DO NOT IMMERSE the transducer in any fluid.

Section VI

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 in March 1993:

“Diagnostic ultrasound has been in use since the late 1950’s. Given the 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 efforts may be identified in the future, current data indicates that the benefits to patients of the prudent use of diagnostic ultrasound outweighs the risks, if any, that may be present.”

The device uses as low an ultrasound power as practical. Prudent use on the operator’s part would include minimizing the length of time that the patient is undergoing the ultrasound exposure. (Once an operator is well trained and routinely uses the doppler, the TMJ exam will take only minutes. At the start of using the doppler, it could take up to 10 minutes for a complete exam. These time frames can be considered within safe operating standards.)

Section VIII

Warranties

The Doppler system (central unit and transducer) carries a 5 year parts and one year labor warranty under normal use.

The Doppler is to be used only for the intended and labeled indications presented in this manual. This warranty does not apply to any Doppler repaired or altered by anyone not authorized in writing by Great Lakes. This warranty does not apply to batteries, shipping case, or other accessories or to damage from shipping, tampering, misuse or negligence.