Grafco®

A Graham-Field Brand

14423-2 / 14423-4 / 14423-8 ULTRASOUND POCKET DOPPLER USER MANUAL

Important: Do not use the Pocket Doppler without first reading and understanding this manual! Save this manual for future use.

⚠ **Federal Law (USA) restricts this device to sale by or on the order of a physician. This product should not be used unless the operator has been instructed by a qualified healthcare professional.**

14423-INS-LAB-RevE13

CONTENTS

1 INTRODUCTION

This user manual contains important information and safety precautions for the Grafco Ultrasound Pocket Doppler. Before using the Pocket Doppler, please read and understand this entire user manual. Take special note of all safety precautions that begin “WARNING” and “CAUTION”. Save this user manual for future reference.

Info: The most current version of this manual can be found at www.grahamfield.com

INTENDED USE OF THIS DEVICE

The Grafco Ultrasound Pocket Doppler is intended for clinical use as an obstetrical evaluation tool. The Grafco Ultrasound Pocket Doppler may also be used for optional vascular monitoring. The Pocket Doppler is not intended to be used for treatment or diagnosis. Use the Pocket Doppler only as prescribed by a physician.

⚠ **WARNING: This device is not intended to be used for treatment or diagnosis. If Pocket Doppler results are ambiguous, please use other methods, such as a stethoscope, to verify immediately.**

⚠ **WARNING: To ensure patient safety, use this device only with accessories recommended by GF Health Products, Inc., your GF Health Products, Inc. authorized distributor, or your physician.**

INCLUDED FEATURES

Mini USB Probe Socket
Probe Detector
Built-in Speaker
Adjustable Volume
Alkaline Battery: LR6, AA, 1.5V
Low Battery Detector / Indicator
Obstetrical or Vascular Monitoring

OPTIONAL ACCESSORIES

The following accessories for use with the Grafco Ultrasonic Pocket Doppler are available from your GF Health Products, Inc. authorized distributor or www.grahamfield.com.

Item No.	Product Description
4001GF	Coupling Gel, case of 12 0.25 liter bottles
4002GF	Coupling Gel, 5 liter bottle
14423-2P	2.0 MHz Waterproof Probe
14423-4P	4.0 MHz Waterproof Vascular Probe
14423-8P	8.0 MHz Waterproof Vascular Probe

2 SAFETY INFORMATION

Safety Guidance

	**This unit has internally powered equipment, and the degree of shock protection is type B.**	**Type B protection means that this product is in accordance with permitted leakage currents and dielectric strengths of IEC 60601-1.**

SAFETY PRECAUTIONS

The safety statements presented in this chapter refer to the basic safety information that the operator of the Pocket Doppler shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to the operations. WARNING and CAUTION statements must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

Please note the following special statements, used throughout this manual, and their significance:

⚠ **WARNING: Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious personal injury.**

⚠ **CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in moderate or minor personal injury.**

▲ **NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product or property damage.**

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

WARNINGS

⚠ **WARNING: Federal Law (USA) restricts this device to sale by or on the order of a physician. This product should not be used unless the operator has been instructed by a qualified healthcare professional.**

⚠ **WARNING: Do not use the Grafco Pocket Doppler in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.**

⚠ **WARNING: Do not expose batteries to heat.**

⚠ **WARNING: Do not attempt to charge alkaline batteries; they may leak or catch on fire.**

⚠ **WARNING: DO NOT simultaneously touch signal input or output connector and the patient.**

⚠ **WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input connector, or signal output connector, configures a medical system, and is therefore responsible for verifying the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult your GF Health Products, Inc. authorized distributor.**

⚠ **WARNING: The Grafco Pocket Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.**

⚠ **WARNING: Exposure to ultrasound should be kept as low as reasonably achievable. This is considered to be good practice and should be observed at all times.**

⚠ **WARNING: Replace the battery at least 6 feet (1.5 meters) from the patient.**

⚠ **WARNING: Use only probes provided by GF Health Products, Inc. intended to be used with the Grafco Pocket Doppler.**

⚠ **WARNING: Do not stretch the probe cable further than 6.5 feet (2 meters).**

⚠ **WARNING: Electromagnetic Interference: Before operation, ensure that the environment in which the device is operated is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.**

⚠ **WARNING: The following safety checks/tests must be performed at least once every two years or as specified in your facility's test and inspection protocol, by a qualified person with adequate training, knowledge, and practical experience:**

- **Inspect the equipment for mechanical and functional damage.**
- **Ensure the safety labels are legible.**
- **Verify that the device functions properly as described in this manual.**
- **Test according to the pregnant woman's leakage current (IEC 60601-1/1988: Limit: 100 uA (B)).**

The leakage current should never exceed the specified limit. Record the data and store with the Grafco Pocket Doppler. If the device is not functioning properly or fails any of the above tests, contact GF Health Products, Inc. Technical Support at the phone number on the back cover, or your GF Health Products, Inc. authorized distributor.

NOTICES

- ▲ **NOTICE: The main unit of the Grafco Pocket Doppler is designed for continuous normal operation. Do not immerse or submerge in any liquid.**
- ▲ **NOTICE: Keep the Pocket Doppler and its environment clean and dust-free. Protect the device from vibration, corrosive medicine, and high temperatures.**
- ▲ **NOTICE: Do not use high-temperature sterilizing process, low temperature steam, E-beam, or gamma radiation sterilization on this device or its accessories.**
- ▲ **NOTICE: If the Pocket Doppler will not be used for a prolonged period of time, remove the battery from the device.**
- ▲ **NOTICE: Keep the battery away from objects or materials with static electric charges.**
- ▲ **NOTICE: If the battery terminals become dirty, wipe them with a clean, dry cloth before using the battery.**
- ▲ **NOTICE: Batteries have life cycles. If the battery use time shortens noticeably, the battery's life cycle is over. Replace the old battery with a new one of the same size and type. Use only batteries recommended by GF Health Products, Inc.**
- ▲ **NOTICE: Remove a battery whose useful life cycle is over from the monitor immediately.**
- ▲ **NOTICE: For information on installing and removing the battery from the monitor, see Section 5, SETUP.**
- ▲ **NOTICE: Dispose of the battery in accordance with local regulations.**
- ▲ **NOTICE: Do not dispose of this device with household waste. Dispose of this device in accordance with your local laws and regulations.**

SYMBOLS

	Attention: Refer to accompanying documents (this manual).
CE 0123	**This item is compliant with Medical Device Directive 93/42/ EEC of June 14, 1993, a directive of the European Economic Community.**
	**This symbol consisting of two parts, see below.**
	**Indicates that the equipment should be disposed of according to local regulation for separate collection after its useful life. Do not dispose of this device with household waste.**
	Indicates that the equipment is put on the market after 13 August 2005.

3 HANDLING

GF HEALTH PRODUCTS, INC. FREIGHT POLICY

For your protection, read carefully

The carrier accepted this merchandise “in good condition” and is responsible for safe delivery. Before signing the freight bill, inspect the shipment carefully for damage or missing pieces.

Apparent loss or damage

Should visual inspection show loss or damage, this MUST be noted on the freight bill and signed by the carrier's agent. Failure to do so may result in the carrier failing to honor the claim. Please contact the carrier to obtain the paperwork necessary to file a claim or contact GF Health Products, Inc. Customer Service at the number on the back cover of this manual.

Concealed loss or damage

If damage is discovered after delivery is made, a concealed damage claim must be entered with the freight carrier. When this occurs, make a written request to the carrier for inspection. This request for inspection must be made within 15 days of delivery. The carrier will provide all paperwork necessary to file a concealed damage or loss claim, since such damage or loss is the carrier's responsibility.

UNPACKING

Info: Unless the Pocket Doppler is to be used immediately, retain containers and packing materials for storage until Pocket Doppler use is required.

1. Check for obvious damage to the carton or its contents. If damage is evident, please notify the carrier and your GF Health Products, Inc. authorized distributor.
2. Remove all loose packing from the carton.
3. Carefully remove all the components from the carton.

Inspection

Check the Pocket Doppler for nicks, dents, scratches, mechanical or other damage. Check all the cables and accessories.

STORAGE

Store the repackaged Pocket Doppler in a dry area.

▲ **NOTICE: Ensure that the temperature at the Pocket Doppler's location during storage does not fall below -4°F (-20°C) or exceed 131°F (55°C).**

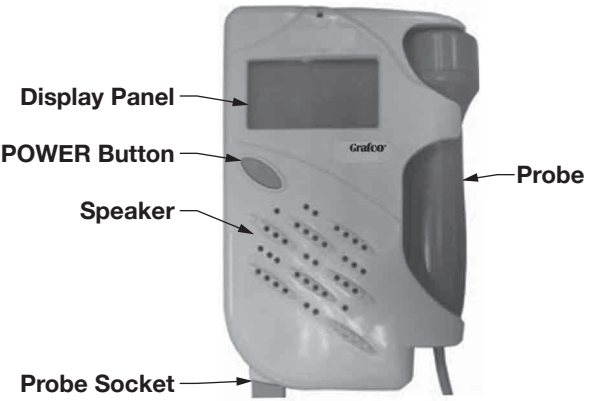
▲ **NOTICE: Ensure that relative humidity at the Pocket Doppler's location during storage does not exceed 93%.**

4 ULTRASOUND POCKET DOPPLER AND ACCESSORIES

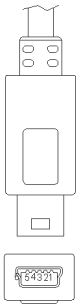
APPEARANCE AND FEATURES

The following figures illustrate the Pocket Doppler with the 2.0 MHz waterproof probe, and accompanying tables describe labeled features.

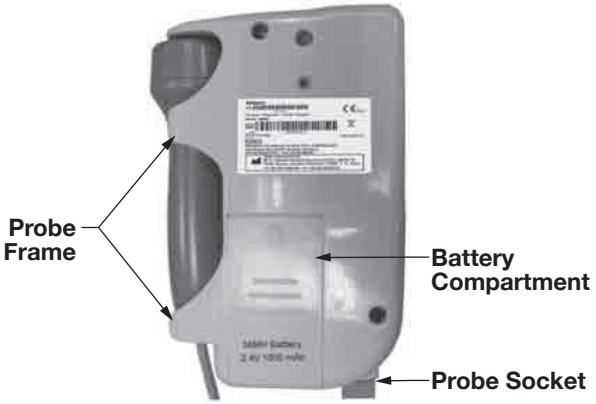
Front Panel



Feature	Function		
Display Panel	Displays system info		
	System status LED	The system status LED is at the left bottom corner of the display panel. Please see the following table for significance of LED indicators.	
	LED Illumination Color	LED Illumination Condition	Significance
	Green	Constant	Power on
		Flashing	Probe disconnected or not properly connected
	Orange	Flashing	Battery too low for operation; replace battery immediately
Brand	Grafco®		
Probe	The Probe is used to perform ultrasound monitoring		

<table>
<tr><td>Speaker</td><td colspan="3">The built-in speaker makes the fetal sounds audible</td></tr>
<tr><td>Power Button</td><td></td><td colspan="2">Turns the Ultrasound Pocket Doppler ON or OFF</td></tr>
<tr><td rowspan="8">Probe Socket</td><td colspan="3">The probe connects here to the Ultrasound Pocket Doppler</td></tr>
<tr><td rowspan="7">  </td><td>Jack</td><td>Definition</td></tr>
<tr><td>1</td><td>Power Supply</td></tr>
<tr><td>2</td><td>Signal</td></tr>
<tr><td>3</td><td>Probe Coding 1</td></tr>
<tr><td>4</td><td>Probe Coding 2</td></tr>
<tr><td>5</td><td>Probe Coding 3</td></tr>
<tr><td>6</td><td>(Shell) GND</td></tr>
</table>

Rear Panel



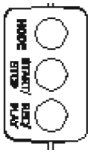
Feature	Function
Battery Compartment	Opens to install/replace battery
Probe Frame	Stores probe when not in use

Top Panel

Feature	Function				
Socket	Name	Picture	Function		
	Charge Socket		Not used		
	Earphone Socket		Connect earphone		
			Signal Interface	1	GND
				2	Signal
				3	Signal
				4	Signal
				5	Signal
Warning	⚠	Refer to accompanying documents (this user manual)			

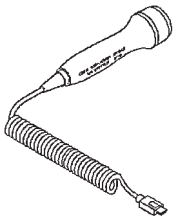
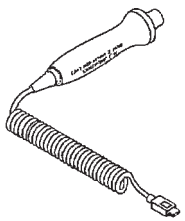
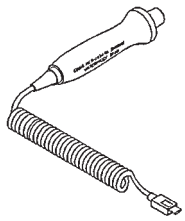
⚠ **WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult your GF Health Products, Inc. authorized distributor.**

Left Panel

Feature	Function		
Volume Control		Adjust volume	Increase volume: Rotate volume knob clockwise
			Decrease volume: Rotate volume knob counter-clockwise
MODE Button		Not used	
START/STOP Button			
REC/PLAY Button			

POCKET DOPPLER WATERPROOF PROBES

The 2.0 MHz, 4.0 MHz and 8.0 MHz waterproof probes connect to the main unit of the Grafco Pocket Doppler via the probe socket. The following table lists and describes the main information on each probe's label in order of appearance:

Pocket Doppler Waterproof Probe Label Table			
Picture of Probe			
Probe Label Text	**2.0 MHz Waterproof Probe**	**4.0 MHz Waterproof Vascular Probe ***	**8.0 MHz Waterproof Vascular Probe ***
CD	Continuous Wave Doppler		
X.0 (Central Frequency)	Central frequency = 2.0 MHz	Central frequency = 4.0 MHz	Central frequency = 8.0 MHz
A	Probe Version Number		
SNxxxxx:	Probe Serial Number		
Waterproof	The Probe is Waterproof		
IPX8 (Waterproof)	Water Ingress Protection Code, which indicates this probe can work continuously for 5 hours when immersed in water up to one meter deep.		

*** Vascular probes are used to monitor arteries and veins**

BATTERY

See Section 5, **SETUP**, for battery installation and replacement instructions.

⚠ **WARNING: Use only 1.5V alkaline battery (AA, LR6) or Ni-MH 1.2V rechargeable battery in this device.**

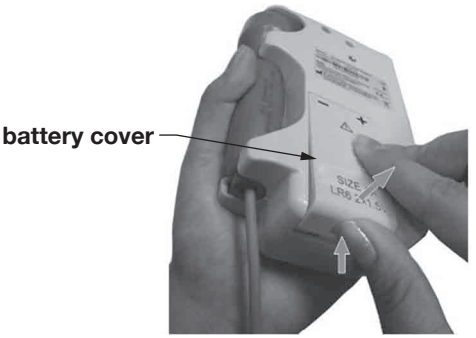
5 SETUP

INSTALLING OR REPLACING THE BATTERY

⚠ **WARNING: Ensure that Pocket Doppler power is off before replacing the battery.**

⚠ **WARNING: Install/replace the battery at least 6 feet (1.5 meters) from the patient.**

⚠ **WARNING: Use only 1.5V alkaline battery (AA, LR6) or Ni-MH 1.2V rechargeable battery in this device.**



battery installation

1. Open the battery compartment. Turn the Pocket Doppler upside down. Hold the main unit with one hand; press with thumb of other hand on the cover notch and push it upward and forward. The battery compartment will be open.
2. If replacing the battery, remove the old battery.
3. Install the battery, using 1.5V alkaline battery or Ni-MH 1.2V battery.

▲ **NOTICE: Ensure battery direction matches cover symbols.**

4. Close the battery compartment.

▲ **NOTICE: If the Pocket Doppler will not be used for a prolonged period of time, remove the battery from the device.**

▲ **NOTICE: Keep the battery away from objects or materials with static electric charges.**

▲ **NOTICE: If the battery terminals become dirty, wipe them with a clean, dry cloth before using the Pocket Doppler.**

▲ **NOTICE: Batteries have life cycles. If the battery use time shortens noticeably, the battery's life cycle is over. Replace the old battery with a new one of the same size and type. Use only batteries recommended by GF Health Products, Inc.**

▲ **NOTICE: Remove a battery whose life cycle is over from the Pocket Doppler immediately.**

▲ **NOTICE: Dispose of the old battery in accordance with local regulations.**

6 OPERATION

PROBE OPERATION

Removing the Probe from the Pocket Doppler

▲ NOTICE: Do not drag or drop the probe. Do not disconnect the probe from the Pocket Doppler.

1. The probe is stored in the Pocket Doppler probe frame. Hold the Pocket Doppler main unit with one hand and hold the top of the probe with the other hand.
2. Gently remove the top of the probe from the Pocket Doppler probe frame.
3. Remove the entire probe from the Pocket Doppler probe frame.

Placing the Probe in the Pocket Doppler

▲ NOTICE: Do not drag or drop the probe. Do not disconnect the probe from the Pocket Doppler.

1. Hold the Pocket Doppler main unit with one hand and hold the probe with the other hand.
2. Gently guide the middle of the probe into the Pocket Doppler's probe frame.
3. Gently replace the top of the probe entirely into the Pocket Doppler's probe frame.

Swapping Probes

▲ **NOTICE: Do not drag or drop the probe or the probe connector.**

The Pocket Doppler is shipped with one probe connected. To replace the connected probe with another Pocket Doppler probe:

1. Follow steps 1-3 in previous section, **Removing the Probe from the Pocket Doppler**.
2. Grasp probe connector body and gently pull out from Pocket Doppler probe socket.
3. Connect the new probe's connector: Grasp probe connector body and gently insert into Pocket Doppler's probe socket.

▲ **NOTICE: Place the unused probe in a secure location. When the Pocket Doppler is not used for a long time, store Doppler and probe in original packaging (see Maintenance/Storage section for proper storage conditions).**

TURNING ON THE POCKET DOPPLER

Press the front panel POWER button to turn on the Pocket Doppler.

FETAL HEART (FH) MONITORING

FH Monitoring with 2.0 MHz Waterproof Probe

Refer to picture at right. The audio fetal heart beat is sent out via the built-in speaker or attached earphone.

1. Palpate for the fetus position to find the best location to place the probe and hear the fetal heart rate.
2. Apply a liberal amount of gel to the probe head.
3. Place the probe head on the desired location. Assure that good coupling of the gel to the skin is achieved; the Fetal Heart rate will not be heard if adequate gel is not used and air is between the probe head and skin.
4. Slowly move the probe until a clear heart rate is heard.
5. Adjust the volume to the desired level.

⚠ **WARNING: It is not possible to monitor FHR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.**

⚠ **WARNING: For best quality audio, place the probe in the optimum position.**

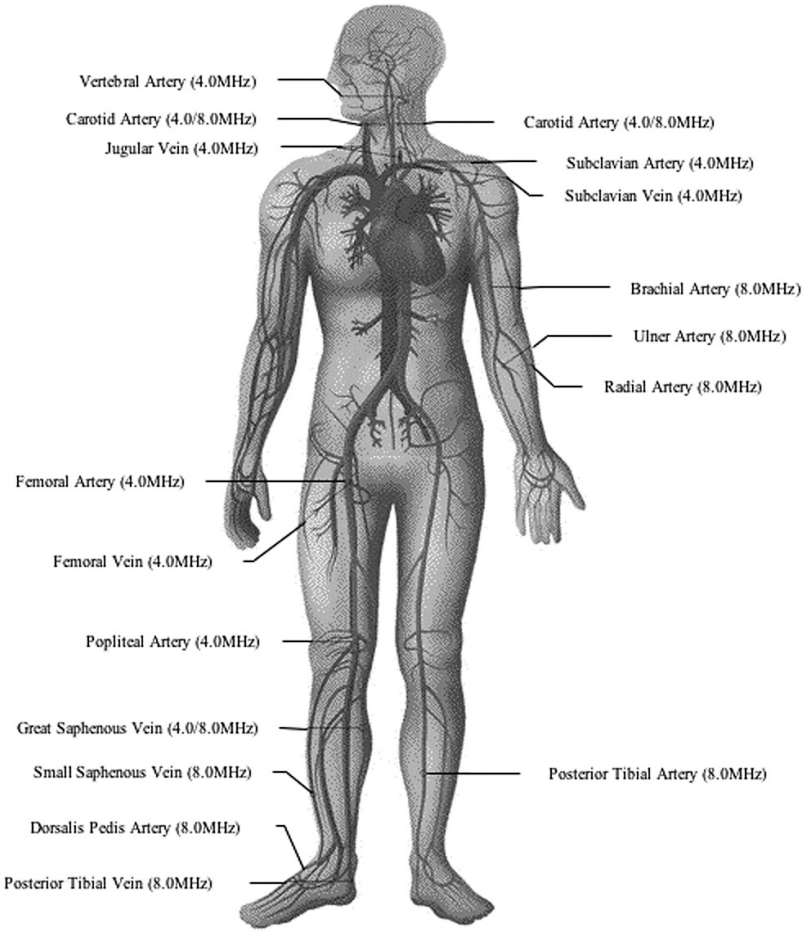
⚠ **WARNING: For best quality audio, avoid positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate).**

⚠ **WARNING: If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring, prolonged lying in the supine position should be avoided. Sitting up or lateral positions are preferable and may be more comfortable for the mother.**

VASCULAR MONITORING WITH 4.0 OR 8.0 MHZ PROBE (OPTIONAL)

The 4.0 MHz and 8.0 MHz probes can be used to perform vascular monitoring assessment of blood flow.

The 8.0 MHz probe is used for more superficial evaluation than the 4.0 MHz probe. Refer to the following probe site illustration to determine the best probe to utilize.



1. Apply a liberal amount of gel on the site to be examined.
2. Place the probe so that the head is at least at 45º to the vessel to be examined.
3. Adjust the position of the probe to obtain the loudest audio signal. For best results, keep the probe as still as possible once the optimum position is located.
4. Adjust the audio volume as necessary.

Info: Arteries emit high-pitched rhythmical pulsation sounds, while veins emit non-rhythmical pulsation sounds similar to rushing wind.

TURNING OFF THE POCKET DOPPLER

1. When the session is finished, press the front panel POWER button to turn off the Pocket Doppler.
2. Use a clean, dry, non-abrasive cloth to gently wipe off the remaining gel from the probe. After thoroughly cleaning the probe, replace it in the Pocket Doppler probe frame.

REPLACING THE BATTERY

When the Pocket Doppler battery power is low, turn the power off and replace the battery. See Section 5, **SETUP**, for instructions on battery replacement.

7 MAINTENANCE AND CLEANING

⚠ **WARNING: Failure on the part of the responsible facility employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.**

MAINTENANCE

⚠ **WARNING: Before use, inspect the Pocket Doppler and probe(s) to ensure there is no visible evidence of damage which may affect the functioning of the device or pregnant woman's safety, or create the potential for the device to operate in an unsafe manner. Thereafter, inspect the device for evidence of damage at least once each week. If damage is evident or suspected, contact GF Health Products, Inc. Technical Service at the number on the back cover or your GF Health Products, Inc. authorized distributor before use.**

⚠ **WARNING: The following safety checks/tests must be performed at least once every two years or as specified in your facility's test and inspection protocol, by a qualified person with adequate training, knowledge, and practical experience:**

- **Inspect the equipment for mechanical and functional damage.**
- **Ensure the safety labels are legible.**
- **Verify that the device functions properly as described in this manual.**
- **Test according to the pregnant woman's leakage current (IEC 60601-1/1988: Limit: 100 uA (B)).**

The leakage current should never exceed the specified limit. Record the data and store with the Grafco Pocket Doppler. If the device is not functioning properly or fails any of the above tests, contact GF Health Products, Inc. Technical Support at the phone number on the back cover, or your GF Health Products, Inc. authorized distributor.

▲ **NOTICE: Keep the Pocket Doppler and its environment clean and dust-free. Protect the device from vibration, corrosive medicine, and high temperatures.**

▲ **NOTICE: Do not use high-temperature sterilizing process, low temperature steam, E-beam, and/or gamma radiation sterilization on this device or its accessories.**

CLEANING

⚠ **WARNING: Before cleaning the Pocket Doppler or probes, turn the Pocket Doppler power off and remove the battery.**

▲ **NOTICE: Do not use strong solvent such as acetone to clean Pocket Doppler or probe.**

▲ **NOTICE: Do not use an abrasive such as steel wool or metal polish to clean Pocket Doppler or probe.**

▲ **NOTICE: Do not allow any liquid to enter the probe socket while cleaning the Pocket Doppler or probe.**

Cleaning the Pocket Doppler

▲ **NOTICE: Do not immerse Pocket Doppler. Do not allow liquid to enter the ultrasound system.**

▲ **NOTICE: Do not pour liquids on the Pocket Doppler while cleaning.**

1. Keep the exterior surface of the Pocket Doppler clean and free of dust and dirt.
2. Clean the exterior surface of the unit with a clean, dry, nonabrasive cloth.
3. If necessary, clean the unit with a clean cloth dampened with soap and water, then immediately wipe dry with a clean, dry, non-abrasive cloth.

▲ **NOTICE: Do not allow any cleaning solution to remain on the surface of the Pocket Doppler or the probe after cleaning.**

Cleaning the Pocket Doppler Probe

▲ **NOTICE: Do not allow liquid to enter the ultrasound system.**

▲ **NOTICE: Do not pour liquids on the ultrasound system or probe socket while cleaning.**

The Pocket Doppler probe's acoustic surface is fragile and must be handled with care.

1. To prolong the life of the probe, after each use, gently wipe off the remaining gel from the probe with a clean, dry, non-abrasive cloth.
2. After thoroughly cleaning the probe, replace it in the Pocket Doppler probe frame.
3. If necessary, wipe the external surface of probe with 70% ethanol or isopropranol alcohol.
4. Allow to air dry.

▲ **NOTICE: Do not allow any cleaning solution to remain on the surface of the Pocket Doppler or the probe after cleaning.**

DISINFECTION

Disinfecting the Pocket Doppler Probe

▲ **NOTICE: Do not allow any liquid to enter the probe socket while disinfecting or immersing the probe.**

1. Clean the exterior surface of the probe as recommended in the previous section.
2. To disinfect the probe, immerse the probe in a solution of Benzalkonium Bromide, 0.5% Chlorhexidine, 2% Glutaraldehyde, or 75% ethanol.
3. Wipe the probe with a clean, dry, non-abrasive cloth to remove any remaining moisture.

▲ **NOTICE: Do not allow any cleaning solution to remain on the surface of the Pocket Doppler or the probe after disinfecting.**

8 SPECIFICATIONS

<table>
<tr><td rowspan="3">Model Number and Name</td><td>14423-2</td><td colspan="2">Ultrasonic Pocket Doppler with 2.0 MHz probe</td></tr>
<tr><td>14423-4</td><td colspan="2">Ultrasonic Pocket Doppler with 4.0 MHz probe</td></tr>
<tr><td>14423-8</td><td colspan="2">Ultrasonic Pocket Doppler with 8.0 MHz probe</td></tr>
<tr><td>Safety</td><td colspan="3">Complies with: EN 60601-1/1990</td></tr>
<tr><td rowspan="6">Classification</td><td>Anti-electric Shock Type</td><td colspan="2">Internally powered equipment</td></tr>
<tr><td>Anti-electric Shock Degree</td><td colspan="2">Type B equipment</td></tr>
<tr><td rowspan="4">Degree of Protection against Harmful Ingress of Water</td><td>Main Unit</td><td>Non-protected</td></tr>
<tr><td>2.0 MHz Waterproof Probe</td><td rowspan="3">IPX8 Water Ingress Protection Code, which indicates this probe can work continuously for 5 hours when being immersed in water within 1 meter</td></tr>
<tr><td>4.0 MHz Waterproof Vascular Probe</td></tr>
<tr><td>8.0 MHz Waterproof Vascular Probe</td></tr>
<tr><td>Degree of Safety in Presence of Flammable Gases</td><td colspan="2">Equipment not suitable for use in presence of flammable gases</td></tr>
<tr><td>Working System</td><td colspan="2">Continuous running equipment</td></tr>
<tr><td>EMC</td><td colspan="2">Group I Class B</td></tr>
</table>

Physical Characteristics	**Size (W x D x H)**	**3.50 x 1.34 x 5.55 inches (89 x 34 x 141 mm)**	
	Weight (including battery)	**.66 lb (<300 g)**	
Environment	**Working**	**Temperature**	**41°F ~ 104°F (5°C ~ 40°C)**
		Humidity	**25% - 80% (non-condensing)**
		Atmospheric Pressure	**12.47 psi ~ 15.37 psi (860hPa ~ 1060 hPa)**
	Transport and Storage	**Temperature**	**-4°F ~ 131°F (-20°C ~ 55°C)**
		Humidity	**25% - 93% (non-condensing)**
		Atmospheric Pressure	**10.15 psi ~ 15.37 psi (700hPa ~ 1060 hPa)**
FHR Performance	**FHR Measuring Range**	**50 bpm ~ 210 bpm**	
	Resolution	**1 bpm**	
	Accuracy	**±3 bpm**	
Audio Output Power	**0.5W**		
Battery	**Battery Type Recommended**	**1.5V alkaline battery (IEC 60086, LR6/AA) or Ni-MH 1.2V rechargeable battery**	
	Battery Stand-by Time	**> 9 hours**	

Ultrasound	**Nominal Frequency**	**2.0 MHz Waterproof Probe**	**2.0 MHz**
		4.0 MHz Waterproof Vascular Probe	**4.0 MHz**
		8.0 MHz Waterproof Vascular Probe	**8.0 MHz**
	Working Frequency	**2.0 MHz Waterproof Probe**	**2.0 MHz ±10%**
		4.0 MHz Waterproof Vascular Probe	**4.0 MHz ±10%**
		8.0 MHz Waterproof Vascular Probe	**8.0 MHz ±10%**
	P-	**< 1MPa**	
	I_{ob}	**< 10 mW/cm^2**	
	I_{spta}	**< 100mW/cm^2**	
	Working Mode	**Continuous Wave Doppler**	
	Effective Radiating Area of Transducer	**2.0 MHz Waterproof Probe**	**245mm^2 ±15%**
		4.0 MHz Waterproof Vascular Probe	**32mm^2 ±15%**
		8.0 MHz Waterproof Vascular Probe	**14mm^2 ±15%**

9 LIMITED WARRANTY

GF Health Products Inc. warrants the Grafco Pocket Doppler and its components to be free from manufacturing defects for a period of one year. This warranty is extended only to the original purchaser/consumer or dealer/non-consumer of this new product and to no other purchaser or transferee.

The Warranty period for the consumer commences on the first date a product is delivered to consumer by seller/dealer. If the product is rented or leased, the warranty period commences on the invoice date from *GF Health Products, Inc.* A copy of the invoice showing date of purchase must be provided when submitting warranty claims. When proof of purchase date is not provided, warranty coverage shall commence upon *GF Health Products, Inc.'s* invoice date to the dealer/purchaser.

If within the warranty period, the product or component part is proven to *GF Health Products, Inc.'s* satisfaction to be defective, *GF Health Products, Inc.* shall provide, at its option, one of the following: (1) repair or replacement of any defective or nonconforming part or product or (2) a credit and/or refund of the original selling price. GF HEALTH PRODUCTS, INC.'S SOLE OBLIGATION AND YOUR EXCLUSIVE REMEDY UNDER THIS WARRANTY SHALL BE LIMITED TO SUCH REPAIR, REPLACEMENT, CREDIT AND/OR REFUND. This warranty does not include any labor charges incurred in replacement part(s) installation or any associated freight or shipping charges to the manufacturer.

For warranty service, please contact the authorized dealer from whom you acquired your *GF Health Products, Inc.* product. Upon receiving notice of an alleged defect in a product, *GF Health Products, Inc.* will issue a return authorization. The defective product or part(s) must then be returned, at the purchaser's cost, for warranty inspection using the serial number as identification (or, if the product is not serialized, lot number and date code) within thirty (30) days of return authorization issue date. In the event you do not receive

satisfactory warranty service, please contact *GF Health Products, Inc.* at the address below. DO NOT return products to our factory without prior authorization.

LIMITATIONS AND EXCLUSIONS: The foregoing warranty shall not apply to serial numbered products if the serial number has been removed or defaced. Products subjected to negligence, abuse, misuse, improper operation, improper maintenance, improper cleaning, improper storage, or damages beyond *GF Health Products, Inc.'s* control are not covered by this warranty, and that evaluation shall be solely determined by *GF Health Products, Inc.* This warranty shall not apply to problems arising from normal wear and tear or failure to follow instructions. The warranty shall also not apply to products modified without *GF Health Products, Inc.'s* express written consent; nor shall it apply if parts not manufactured by *GF Health Products, Inc.*, or if parts not complying with original equipment specifications are added to *GF Health Products, Inc.* products, or if the product or part is serviced by an entity not authorized by *GF Health Products, Inc.*

The foregoing warranty is exclusive and in lieu of all other express warranties and implied warranties, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, and shall not extend beyond the duration of the express warranty provided herein, and the remedy for violations of any implied warranty shall be limited to the repair, replacement, credit and/or refund of the defective product or part pursuant to the terms contained herein. *GF Health Products, Inc.* shall not be liable for any consequential or incidental damages whatsoever.

This warranty gives you specific legal rights and you may also have other legal rights which vary from state to state (province to province). Some states (provinces) do not allow the exclusion or limitation of incidental or consequential damage, or limitation on how long an implied warranty lasts, so the above exclusion and limitations may not apply to you.

The warranties contained herein contain all the representations and warranties with respect to the subject matter of this document, and supersede all prior negotiations, agreements and understandings with respect thereto. The recipient of this document hereby acknowledges and represents that it has not relied on any representation, assertion, guarantee, warranty, collateral contract or other assurance, except those set out in this document.

GF Health Products, Inc. ("Graham-Field")
2935 Northeast Parkway
Atlanta, GA 30360
Tel 770-368-4700

10 APPENDIX A, EC DECLARATION OF CONFORMITY

EC Declaration of Conformity	
Manufactured for	GF Health Products, Inc., 2935 Northeast Parkway, Atlanta, GA 30360
Product	Ultrasound Pocket Doppler
Classification	(MDD, Annex IX): IIa
We herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - as amended by Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.	
Directives	General Applicable Directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Standards applied	EN ISO 9001, ISO13485, EN ISO14971, EN ISO10993-1, IEC 601-1, EN 60601-1-1, BS EN 60601-1-4, IEC 60601-1-2, EN 61157, EN 1041, EN 60417-2-2000, IEC/TR 60878-2003, EN 980, EN 55011, ISO 1000, YY 0111-93, EN 61266, EN ISO 780 , GB/T 14740, GB/T 15464
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr 65, D-80339 München, Germany.
Identification number	CE 0123

11 APPENDIX B, EMC INFORMATION

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic Emissions—for all Equipment and Systems

Guidance and manufacturer's declaration—electromagnetic emission		
The Grafco Ultrasound Pocket Doppler is intended for use in the electromagnetic environment specified below. Do not use the system in environments which do not comply with the specifications listed below.		
Emission test	**Compliance**	**Electromagnetic environment–guidance**
RF emission CISPR 11	Group 1	The Grafco Ultrasound Pocket Doppler uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Grafco Ultrasound Pocket Doppler is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity—for all Equipment and Systems

Guidance and manufacture's declaration—electromagnetic immunity			
The Grafco Ultrasound Pocket Doppler is intended for use in the electromagnetic environment specified below. Do not use the system in environments which do not comply with the specifications listed below.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30% RH.

Electromagnetic Immunity—for all Equipment and Systems that are not Life-Supporting

Guidance and manufacturer's declaration—electromagnetic immunity			
The Grafco Ultrasound Pocket Doppler System is intended for use in the electromagnetic environment specified below. Do not use the system in environments which do not comply with the specifications listed below.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Grafco Ultrasound Pocket Doppler, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Info 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Info 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Grafco Ultrasound Pocket Doppler is used exceeds the applicable RF compliance level above, the Grafco Ultrasound Pocket Doppler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Grafco Ultrasound Pocket Doppler.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Grafco Ultrasound Pocket Doppler

The Grafco Ultrasound Pocket Doppler is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Grafco Ultrasound Pocket Doppler as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed previously, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Info 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Info 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 APPENDIX C, OVERALL SENSITIVITY

Overall Sensitivity (2 MHz Probe)										
Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A (d)	Two-way Attenuation $B=\sum B_a+B_w$							
			$\sum B_a$ (T:mm B_a:dB)					B_w (dB)	B (dB)	
1.58 A=45.7dB @2 MHz	50	45.7	T	20	4.8	4.0	-	0	57.6	
			Ba	40	9.6	8.0	-			
	75	45.7	T	20	4.8	3.4	-	0	56.4	
			Ba	40	9.6	6.8	-			
	100	45.7	T	20	4.8	3.4	-	0	56.4	
			Ba	40	9.6	6.8	-			
	200	45.7	T	20	4.8	-	-	0	49.6	
			Ba	40	9.6	-	-			
2.38 A=43.2dB @2 MHz	50	43.2	T	20	4.8	3.4	2.2	0	60.8	
			Ba	40	9.6	6.8	4.4			
	75	43.2	T	20	4.8	3.4	1	0	58.4	
			Ba	40	9.6	6.8	2			
	100	43.2	T	20	4.8	3.4	-	0	56.4	
			Ba	40	9.6	6.8	-			
	200	43.2	T	20	4.8	1	-	0	51.6	
			Ba	40	9.6	2	-			
Doppler Frequency (Hz)	333									

Overall Sensitivity (2 MHz Probe)				
Diameter of Target Reflector (mm)	V_n (r.m.s.) mV	V_n (r.m.s.) mV	$C = 20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
1.58 A=45.7dB @2 MHz	186	94	5.93	109.2
	175	90	5.78	107.8
	174	89	5.82	107.9
	173	90	5.68	100.9
2.38 A=43.2dB @2 MHz	178	89	6.02	110.0
	170	90	5.52	107.1
	165	85	5.76	105.3
	160	85	5.49	100.2
Doppler Frequency (Hz)	Velocity of Target (cm/s)		12.5	

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