

FETAL DOPPLERS

USER MANUAL
D920/FD1+

WARNING/CAUTIONS & SAFETY

Federal law restricts this device to sale by or on the order of a licensed practitioner.

Do not use in the sterile field unless additional barrier precautions are taken.

Do not use in or around the eye.

Do Not: Immerse in any liquid,
Use solvent cleaner,
Use high temperature sterilizing processes (such as autoclaving),
Use E-beam or gamma radiation sterilization.

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Sterisol or Hibiscrub **should never be used** on any part of the system.



This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker. We recommend that the source of interference is identified and eliminated.

To prevent electrical shock, under no circumstances should the **D920/FD1+** headphone output be connected to a device connected directly to electric power - for example, a tape recorder using an AC adaptor - unless both devices comply with the shock protection requirements of safety standards UL2601-1, EN60601-1, EN60950, EN60065, UL544 or EN60335

Dopplex® Dopplers are screening tools to aid the healthcare professional and should not be used in place of normal fetal monitoring. If there is doubt as to fetal well-being after using the unit, further investigations should be undertaken immediately using alternative techniques.

We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable - (ALARA guidelines). This is considered to be good practice and should be observed at all times.



Before using your D920/FD1+, please study this manual carefully and familiarize yourself with the features and operation.

WARNING/CAUTIONS & SAFETY

Acoustic Safety

Continuous wave Doppler ultrasound instruments such as the **D920/FD1+** have been used extensively for medical diagnosis in the United States for over 25 years. Throughout this period, there have been no reports of adverse effects to patients or instrument operators at the acoustic intensities recommended for diagnostic use. Despite this highly favorable safety experience, available data are not conclusive and the possibility remains that unwanted biological effects might be identified in the future.

Authorities therefore recommend that ultrasound procedures be performed in accordance with the "ALARA" principle, which states that the energy delivered to the patient should always be kept **As Low As Reasonably Achievable**. With the **D920/FD1+**, the transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

Acoustic intensity data ($I_{SPTA,3}$) for the probe available for use with the **D920/FD1+** is summarized in the following table. The values cited are based on measurements in water using a calibrated hydrophone and are stated as the estimated derated intensities. The derated intensity constitutes the most biologically relevant parameter available since true determinations of the actual absorbed dose in tissue would require invasive measurement techniques. The derated intensity is, therefore, calculated mathematically using a derating factor consisting of a constant (the assumed attenuation coefficient) and allowing for the frequency of the probe and the distance from the probe face to the hydrophone.

The calculated derated intensity values for the **D920/FD1+** compare very favorably with previously reported acoustic safety data for Doppler ultrasound instruments and are appropriate for all clinical applications recommended in this manual.

WARNING/CAUTIONS & SAFETY

Acoustic Safety (contd..)

As the operating mode of the **D920/FD1+** probes are continuous wave, ISPPA figures are not applicable.

**Acoustic Output Table, Track 1,
Non-Auto-Scanning Mode**

Model	Max. Value ISPTA.3	W _o	f _c	Z _{sp}	A ₋₆ , (Z _{sp})	EBD
OP2	45	41	2.0	2.5	1.1	1.2
						2.5

Notes

- Measurement uncertainty: varies with probe and measurement
Random
 - typically $\pm 20\%$ (max. $\pm 32\%$)
Systematic
 - typically $\pm 6.5\%$ (max. $\pm 8\%$)

Definition of Terms

ISPTA.3	is the derated spatial-peak, temporal-average intensity (milliwatts per square centimeter)
W_o	is the ultrasonic power (milliwatts)
f_c	is the center frequency (MegaHertz)
Z_{sp}	is the axial distance used to calculate the derated intensity (centimeters)
A₋₆, (Z_{sp})	is (/4) x (X ₋₆ , Y ₋₆) are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6dB dimensions in the X-Y plane where Z_{sp} is found (centimeters)
EBD	are the entrance beam dimensions for the azimuthal and elevational planes (centimeters)

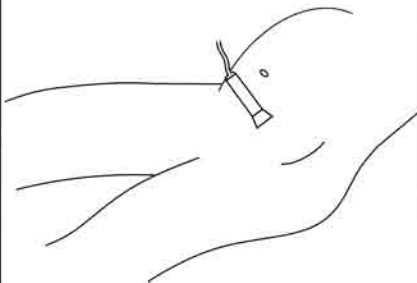
OPERATION INSTRUCTIONS & MAINTENANCE

During Use

The product will automatically switch off after 5 minutes of no signal for **D920** and after 1 minute for **FD1+**. When the battery symbol appears on LCD display, the battery needs replacing.

Operation

Apply a liberal amount of gel to the abdomen. Place the faceplate of the probe flat against the abdomen as shown:



Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Avoid sliding it over the skin.

In early pregnancy a full bladder may improve sound detection. In later pregnancy the best signals are generally located higher on the abdomen. The fetal heart sounds like a galloping horse at approximately twice the maternal rate. A wind-like sound is heard from the placenta.

FD1+ Only

In this mode the Fetal Heart Rate (FHR), averaged over 4-heart beats, is displayed on the 3-digit readout. This gives a FHR display found in conventional fetal monitors. The LCD displays an outline heart symbol.



Outputs

D920/FD1+ have a standard 3.5mm stereophonic socket for connection of stereo headset. The loudspeaker is muted when the headset is connected.



Note that the Doppler signal output is mono only. This output can be used for connection to a tape recorder for recording the Doppler audio signal.

OPERATION INSTRUCTIONS & MAINTENANCE

After Use

1. Press and release the On/Off button.
If you forget to switch the unit off, it will automatically shut-off.
2. Refer to the cleaning section before storing or using the unit on another patient.

The control unit and the body of the probes are robust and require no special handling. However, the probe tip is delicate and must be handled with care.

Cleaning

Remove excess gel before parking the probe. Clean with a damp cloth impregnated with mild detergent. Do not allow fluid to seep into either unit.

For disinfection, use a soft cloth dampened with Sodium Hypochlorite 1,000ppm (2oz bleach per each gallon of water) or alcohol.

Alcohol saturated swabs can be used on the probe tip.

Coupling Gel

Use water based ultrasound gel ONLY.

Changing the Battery

1. Press the cover of the battery compartment, slide it downwards and lift out old battery if replacing.



2. Insert the new battery, ensuring the polarity of the new battery corresponds with the + and - signs shown on the battery compartment label.
3. Slide the cover back into position

If a battery is inserted incorrectly, the **D920/FD1+** will not operate and **NO** damage to the unit will occur. Simply remove the battery and re-insert with correct polarity.

SERVICE RETURNS

Service Returns

If for any reason your **D920/FD1+** is being returned, please:

1. Clean the product following the instructions in the section "*Operation Instructions & Maintenance*".
2. Pack it in suitable packing.
3. Mark the package "Service Department - **D920/FD1+**".

For service, maintenance and any questions regarding this product, please contact:

TECHNICAL SPECIFICATION

Product Name:	Audio Dopplex®/Fetal Doppler® +	
Model No.:	D920/FD1+	
Height:	140 mm (5.5")	
Width:	74 mm (2.9")	
Depth:	27 mm (1.1") excluding pocket clip	
Weight:	295 gms (10oz) including probe & battery	
Audio Output:	500mW rms (max) typical	
Headset Output:	25 mW rms max. (32 headphones), (max. Applied voltage +9vdc)	
Auto Shut-Off:	D920 - After 5 minutes of no signal FD1+ - After 1 minute of no signal or 5 minutes continuous operation.	
Display:	Custom reflective liquid crystal	
Case Material:	ABS Polycarbonate alloy	
Battery type Recommended:	9 volt alkaline manganese - 6LR61/6LF22 or equivalent (eg. MN1604)	
Battery Voltage:	9V nominal	
Battery Life:	Typically	FD1+ 250 x 1 minute examinations D920 500 x 1 minute examinations (depending on use and battery type)
Probe Transmitter: Frequency:	2.0 MHz \pm 1%	
Effective Area of Active Transmitter Element:	233 mm \leq (\pm 15%)	
Complies With:	BS5724: Part 1 : 1989, EN60601-1 : 1988	
IEC601-1 Classification:	Type of shock protection Degree of shock protection Protection against water ingress Degree of safety in presence of flammable gases Mode of operation	Internally powered equipment Type B equipment Ordinary equipment Equipment not suitable for use in presence of flammable gases Continuous
Operating Temperature:	+10°C to +30°C (50°F to 86°F)	
Storage Temperature:	-10°C to +40°C(-50°F to 104°F)	



**Means, Attention consult this manual.
Refer to Safety Section**

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Supplied by Huntleigh Healthcare Inc. 40 Christopher Way, Eatontown, NJ 07724-3327

