

DARAY®



BSD 100

FOETAL DOPPLER


OPERATING MANUAL

DARAY®

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1. SAFETY GUIDANCE

This unit is internally powered equipment, and the degree of shock protection is type B. 

Type B protection means that patient connections comply with IEC 60601-1.

1.1 Safety precautions

To avoid the possibility of injury, observe the following precautions when using the device.

- **WARNING:** Do not use in the presence of flammable anaesthetic gases.
- **WARNING:** Do not throw batteries into fires as this may cause them to explode.
- **WARNING:** Do not touch the signal input or output connector and the patient simultaneously.
- **WARNING:** Do not monitor patient whilst the battery is charging.
- **CAUTION:** Refer servicing to qualified personnel.
- **CAUTION:** Do not immerse in any liquid i.e. the unit is not drip or splash-proof.
- **CAUTION:** Keep the device clean.
- **CAUTION:** Avoid vibration.
- **CAUTION:** Do not submit to high-temperature, electron beam or gamma radiation sterilization.
- **CAUTION:** 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. Keep them far away.
- **CAUTION:** The user must check that the equipment does not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.
- **CAUTION:** The following safety checks should be performed once every two years or as specified in the institution's test and inspection protocol by a qualified person to perform these tests.
 - Inspect the equipment for mechanical and functional damage.
 - Inspect the relevant safety labels for legibility.
 - Verify that the device functions properly as described in this manual.
- **CAUTION:** The battery must be properly disposed of according to local regulations.
- **CAUTION:** The DARAY BSD100 Foetal Doppler is a tool to aid the healthcare professional and should not replace normal foetal monitoring.
- **CAUTION:** We recommend that exposure to ultrasound should be kept to a minimum.
- **CAUTION:** Battery replacement should be done outside the patient environment (1.5m away from the patient).
- **CAUTION:** The device is only to be used with the battery cover closed.

2. INTRODUCTION

2.1 Overview

The DARAY BSD100 foetal doppler is a portable device used for foetal heart rate detection. It is suitable for gynaecology and obstetrics departments or clinics and for daily foetal heart rate detection.

The DARAY BSD100 foetal doppler consists of an emitter and receiver of an ultrasound signal, an analogue signal processor a FHR calculator and an LCD display.

2.1a Environmental conditions

Working environment

Temperature	+5°C ~ +40°C
Humidity	<85%
Atmospheric Pressure	86kPa ~ 106kPa

Transport and storage

Temperature	-10°C ~ +55°C
Humidity	<93%
Atmospheric Pressure	86kPa ~ 106kPa

2.2 Feature

- LCD display with backlight - can be used in all lighting conditions
- DSP technology ensures accuracy and reliability of foetal heart-rate detection
- High sensitivity 2 MHz continuous wave probe
- Ergonomic design, portable and convenient
- Built-in speaker
- Audio output socket
- Automatic power off
- Multi-display; FHR pulse, FHR value, probe type, battery status and volume
- Three working modes: real-time FHR display, mean FHR display and manual count display

3. INTRODUCTION OF FRONT AND REAR PANEL

3.1 Layout

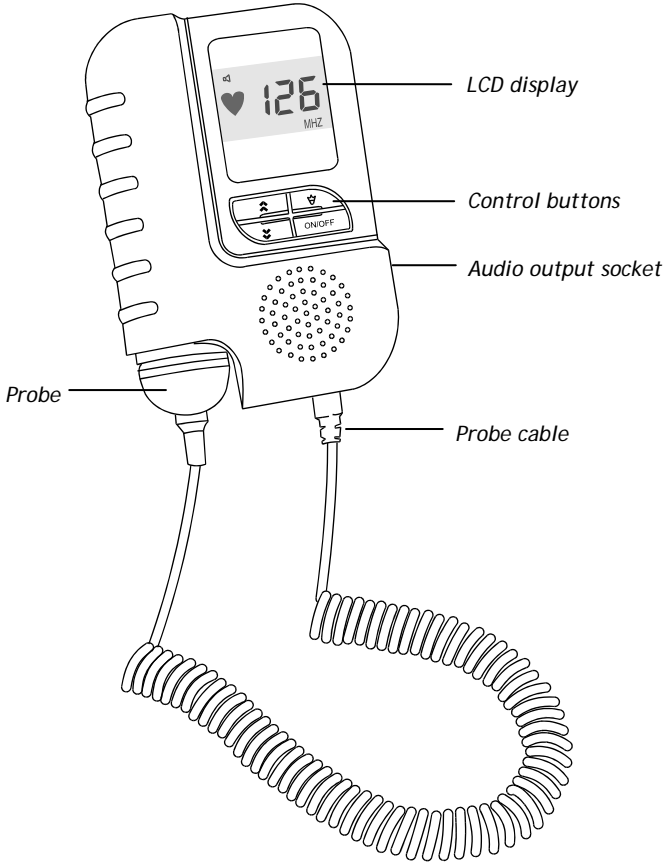


Fig 1

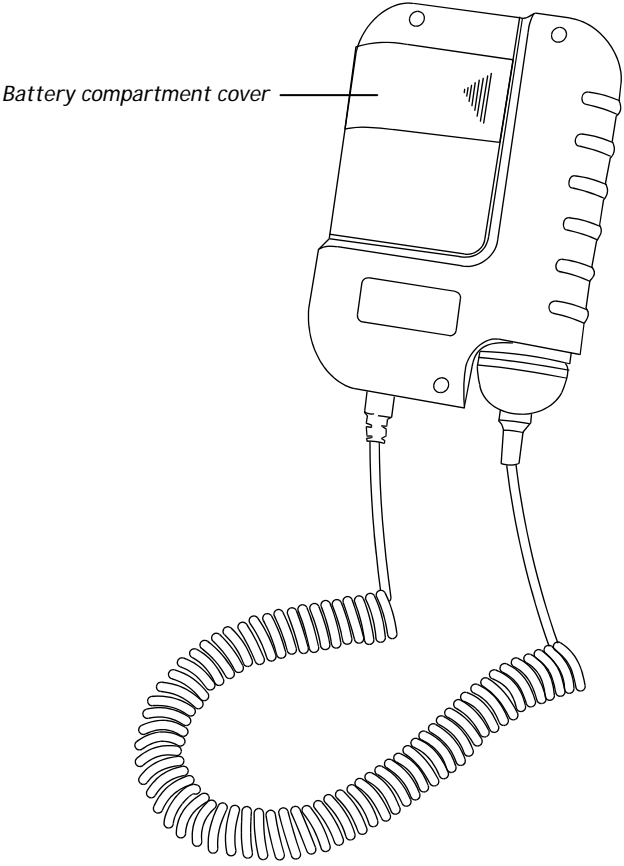


Fig 2

3.2 Display

Normal working displays

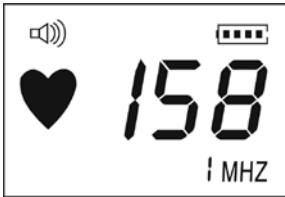


Figure 3-1

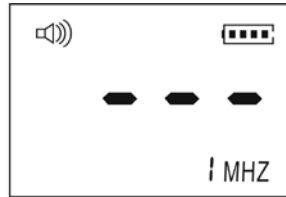


Figure 3-2

The number 158 is the foetal heart-rate (FHR) value detected in beats per minute (BPM).

When no FHR value is detected, dashes are displayed (see figure 3-2).

Speaker Volume

There are 4 levels. The volume can be increased or decreased by pressing 'up' or 'down'.

At the lowest level, sound is muted.

Battery charge indicator

There are 4 indicated levels. When the display shows no bars and the symbol starts flashing, it means the battery needs to be charged or replaced, otherwise the quality of foetal heart sound will be poor or inaudible, and the equipment will eventually automatically shut down.

3.3 Control buttons

There are four control buttons on the unit:

'ON/OFF' power button

To power the unit on, press and hold the power button for 2 seconds. To power the unit off, press and hold the power button again for 2 seconds.

Up button

Under normal operation, press this button once, the sound volume will be increased.

Down button

Under normal operation, press this button once, the sound volume will be decreased.

Backlight button

Press this button, the back light turns on, press again, it turns off. After 10 seconds of inactivity, the backlight will switch off automatically.

3.4 Rear panel

Audio output socket

For connection of headphones or audio recording equipment.

4. GENERAL OPERATION

4.1 Probe connection

Connect the probe to the main unit as indicated in figure 4-1. The connector is shaped and will only fit one way round. If you are having difficulty connecting the probe, look closely at the connector and the socket and try again.

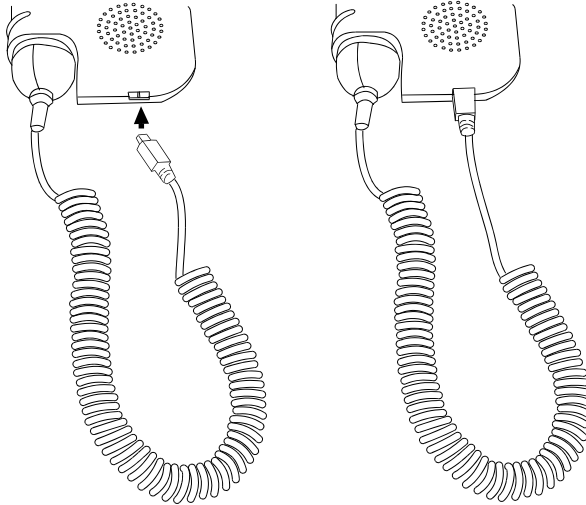


Fig 4.1

4.2 Probe operation

1. Hold the main unit with one hand, remove the probe carefully.
2. To replace the probe, hold the main unit with one hand, and holding the probe with other hand, place the probe into the probe holder and push it home. Do not force the probe. It should slip in and out of the holder easily. (See Figure 4-2)

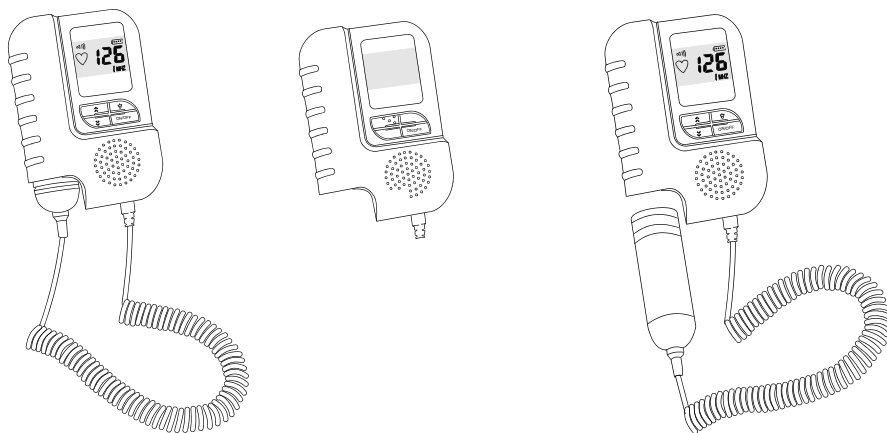


Fig 4.2

4.3 Replacing the battery

Battery removal

The battery compartment is on the underside of the unit (Figure 4-3). Open the battery compartment by sliding it in the direction of the arrow. Remove the battery from the battery compartment.

Battery replacement

Clip the new battery onto the battery connector. Fit it into the battery compartment and replace the battery compartment.

Battery compartment cover

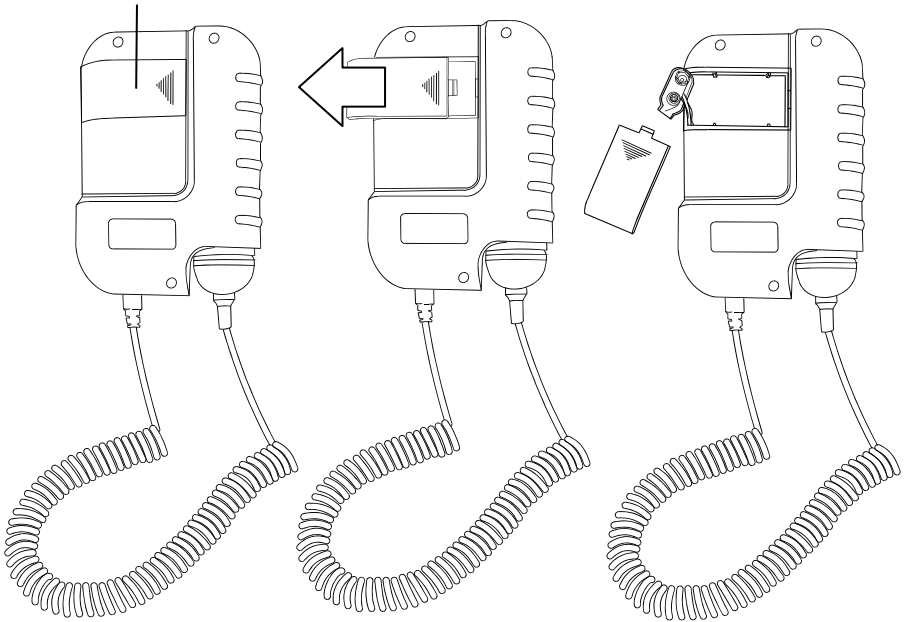


Fig 4.3

CAUTION Remove the battery if the device will not be used for an extended period.

5. PRODUCT SPECIFICATIONS

Anti-electric shock type	Internally powered equipment
Anti-electric shock degree	Type B equipment
Degree of safety in presence of flammable gases	This equipment is not suitable for use in presence of flammable gases.
Working system	Continuous running equipment

Physical characteristics

Dimension	145(L)×100 (W) ×40 (H) mm
Net weight	0.3kg (including battery)
Display	LCD 39×27mm

FHR performance

FHR Measuring Range:	50BPM~210BPM
Resolution	1BPM
Accuracy:	±1% ±1BPM
Audio Output Power:	1W
Auto Shut-off:	After 1 min. no signal

Ultrasound

Working Frequency:	2.0MHz±5%
P-	<0.35MPa
Iob	<5mW/cm ²
Working Mode	In pulse
Power Supply	Built-in rechargeable battery
Working Voltage	9 V
Speaker power	1 W

6. MAINTENANCE AND ORDERING INFORMATION

6.1 Maintenance

To prolong the life of the unit

- The probe's acoustic surface is fragile and must be handled with care.
- Gel must be wiped off from the probe after each use.

The user must check that the equipment does not have any visible evidence of damage that may affect patient safety or the product's capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

The equipment should undergo periodic safety testing to ensure correct patient isolation from leakage currents; this should include leakage current measurement. The recommended testing interval is at least once every two years or as specified in the institution's test and inspection policy.

The accuracy of FHR is controlled by the equipment and can not be adjusted by user. If the FHR result is in doubt, please use another method, such as a stethoscope, to verify immediately or contact the manufacturer.

6.2 Cleaning

Before cleaning, switch off the power and take out the battery.

Keep the exterior surface of the device clean and free of dust and dirt. Clean the exterior (LCD display screen included) with a dry, soft cloth. If necessary, clean it with a small amount of soap and water solution and wipe dry with a clean cloth immediately. Wipe the probe with a soft cloth to remove any remaining gel. Clean with soap and water only.

- **CAUTION:** Do not use strong solvent, e.g. acetone.
- **CAUTION:** Never use an abrasive such as steel wool or metal polish.
- **CAUTION:** Do not allow any liquid to enter the product.
- **CAUTION:** Do not immerse any part of the device into any liquid.
- **CAUTION:** Avoid pouring liquids on the device while cleaning.
- **CAUTION:** Remove all cleaning solution from the device.

Wipe the surface of probe with 70% ethanol or isopropanol alcohol. Dry with a clean, dry cloth or allow to air-dry.

6.3 Disinfection

Clean the unit's surface and the probe as mentioned above. Wipe the surface of the probe with 70% ethanol or isopropanol alcohol. Clean the probe surface with a dry, soft cloth.

CAUTION: Do not submit to low-temperature steam sterilization.

CAUTION: Do not submit to high-temperature, electron beam or gamma radiation sterilization.

Returns Policy

IMPORTANT!
Before returning your item, you must call us on 0844 375 9000

We want you to be completely satisfied with your purchase. If you need to return goods purchased from DARAY Ltd, please read the following information carefully.

The DARAY Ltd returns policy provides guidance on when you can return goods we have supplied, and what you can expect from us once you do. To see our detailed returns policy and procedure visit www.daray.co.uk/returns

TYPE OF RETURN	REMEDY
DAMAGED GOODS OR DOA* Goods which are physically damaged on delivery, or which do not function.	We must be notified within 24 hours of receipt.
GOODS DEVELOPING A FAULT Goods which have developed a fault within the warranty period.	Within 14 days of delivery we will replace the item as DOA*. If the fault develops after 14 days, but within the warranty period, we will initiate the returns procedure.
NON WARRANTY Goods which have developed a fault outside the warranty period.	If a fault develops outside the warranty period, we will initiate the returns procedure.
OTHER Any situation which is not covered by the above.	We will try to help, but we cannot normally offer a refund.

*DOA - dead on arrival

For additional clarification, please refer to our terms and conditions at www.daray.co.uk/terms.

In a small number of cases, we may determine that a replacement would not work any better than the original product we supplied. In such cases we will only offer a refund rather than a replacement for qualifying returns.

Replacement bulbs are not eligible for returns, unless they are faulty or damaged.

Spare parts ordered on our website or from supplied part codes are not be eligible for credit. We will accept returns and exchange for the correct item.

If you purchase an item incorrectly you can return it within 14 days and it can be exchanged for another product of equal or higher value, excluding transportation charges incurred.

If you send us goods that do not qualify for return, you will invalidate your claim to any refund, and you will be obliged to compensate DARAY Ltd for the cost of return postage and any other reasonable costs incurred processing the goods.

Your statutory rights are not affected

WARRANTY

TERMS AND CONDITIONS OF WARRANTY

1. To qualify for this warranty you must register on www.daray.co.uk or return to Daray Ltd (Daray) the duly completed warranty-registration form accompanying the product.
2. Daray warrants this product (excluding lamp) against faulty material and workmanship during the period of the warranty. The period of warranty is the period stated on your warranty card and commences on the date of purchase of the product. In the event that the product is not in good working order Daray will provide, during the warranty period, a free repair service within the United Kingdom. The warranty is subject to proof of purchase being provided; therefore, you should retain your original receipt.
 - 2.1 The repair service consists of the provision of spare parts and/or replacement products (at Daray's discretion) which will be provided on an exchange basis and will either be new, equivalent to new or reconditioned. All replaced spare parts and products shall become the property of Daray.
 - 2.2 Daray's only obligation under this warranty is the provision of the service as set out above.
 - 2.3 All products are returned to Daray at the customer's cost and risk. Products to be returned should be adequately packed. For the address to send returns to please visit www.daray.co.uk
3. Daray's arrangements for providing service provided under this warranty may include the use of sub-contractors.
4. This warranty does not cover damage or defects in the Product caused by or resulting from:
 - Wilful neglect or negligence by anyone other than Daray;
 - Improper use, storage or handling of the product;
 - Use of non-Daray approved parts (such as replacement lamps) not compatible with the Product;
 - Fire, accident or disaster;
 - Use of non-Daray modifications other than in accordance with Daray's instructions;Attachment of fittings and accessories not approved by Daray;
Repairs, modifications carried out by service personnel not approved by Daray;
 - Damage caused by chemical corrosion from cleaning agents not approved by Daray.
 - Failure to use or install the product in accordance with the manufacturer's instructions.
5. Nothing in this warranty shall have the effect of restricting or excluding the liability of Daray in respect of:
 - a) Death and personal injury caused by the negligence of Daray, or for fraud;
 - b) Under the *Consumer Protection Act 1987* to a person who has suffered damage caused by a defective product or to a dependant or relative of such a person;
 - c) Direct damage to your property caused by the proven negligence of Daray.
6. This agreement does not give any rights other than those expressly set out above and in particular, Daray will not be responsible for any loss of income, profits or contracts or any direct or indirect consequential loss, damage caused to or suffered by the purchaser as a direct result of this agreement.
7. This warranty is offered (subject to these terms and conditions) in addition to, and does not affect your statutory rights.
8. Daray may disclose your details and other personal information to companies within the Daray group including any subsidiary company or sub contractor of Daray for the purposes of performing our obligations hereunder.
9. You must not resell outside the UK any products supplied by Daray and covered by the *Export of Goods (Control) Order 1992* (or any law that replaces it) without obtaining all necessary licences. You also agree not to sell the product in the UK if you know or think that the person buying the product intends to export it without getting the necessary licences. You agree to impose similar conditions to these on anyone you sell the product to.
10. These conditions shall in all respect be governed and construed in accordance with English law and the exclusive jurisdiction of the English courts.

DARAY[®]

WARRANTY REGISTRATION
TO VALIDATE YOUR WARRANTY
PLEASE COMPLETE IN BLOCK CAPITALS
AND RETURN IN A WINDOWED DL ENVELOPE
TO OUR FREEPOST ADDRESS

ALTERNATIVELY REGISTER ONLINE AT WWW.DARAY.COM



3 YEAR AFTERCARE PLAN

NAME:
COMPANY:
EMAIL:
PHONE:
FAX:

ADDRESS:

PURCHASED FROM:

DATE OF PURCHASE:

Freepost Plus RRAS-YGXE-SLBC
Daray Ltd
Marquis Drive
SWADLINCOTE
DE12 6EJ

Occasionally DARAY would like to send you information about our special offers and promotions. If you do not wish to receive such information, please tick here:

Privacy statement: DARAY will not pass on your details to any third party.

PRODUCT:
SERIAL No:



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