Freeplay FHRM

operating instructions

Contents

Introduction

The fetal heart rate monitor is a portable hand-held, robust device with a probe that uses Doppler ultrasound waves to detect the fetal heart.

It does not use disposable batteries and this enables the health professional to count the fetal heart rate in conditions where a reliable source of battery power or mains electricity may not be available.

There are a number of options to recharge or power the device, with the wind-up/self-powered being the most obvious.

The fetal heart can be “heard” on the loudspeaker while the fetal heart rate is shown on the display screen. The fetal monitor is most useful in assessing the condition of the fetus during labour.

The instrument is supplied complete with the following:

Freeplay FHRM doppler with 2MHz fetal detection probe
Mains connected Recharger unit
Operating instructions
Coupling Gel

The following symbols have been used on the instrument and are defined according to BS EN60601-1:2006

Type B equipment

Consult accompanying documents

Before using your Freeplay FHRM for the first time, please read these operating instructions carefully.

The FHRM

Components of the fetal monitor:

- The button to switch the monitor on or off.
- The display screen that shows the fetal heart rate.
- Heart icon flashes with each heartbeat.
- Battery icon that indicates when the battery is low.
- The loudspeaker.
- The wind-up handle to generate power.
- The green power light that shows when power is being generated.
- The connecting lead between the monitor housing and the probe.
- The ultrasound probe.
- The mains adaptor, power cable and DC input socket.

Display Screen

On/Off button

Ultrasound Probe
Use only with non-mineral oil based ultrasound gel or water

Loudspeaker

Power Sources

This fetal heart rate monitor runs off rechargeable batteries that are inside the device. The batteries may be recharged from three different power sources.

1. Mains electricity

The batteries can be charged from a mains electric power supply using a power adaptor:

- Plug the adaptor into a standard wall electricity plug and insert the cable into the power socket of the fetal monitor. Switch on the wall plug. Check that the green light on the fetal monitor is flashing. This means that the batteries are now charging from the electric power supply.
- It takes approximately 2 hours to fully charge the batteries. When they are fully charged the green light on the fetal monitor will flash on and off slowly.
- Now the fetal monitor will operate for approximately 7 hours continuously before the batteries need recharging again.

2. Wind-up power

The batteries can also be recharged with power created by turning the wind-up handle on the back of the fetal monitor:

- Turn the wind-up handle fast in any direction. The green light next to the power socket will come on brightly if you are winding the handle fast enough to create power. If the light does not come on, you are winding the handle too slowly and are not storing power in the batteries.
- If you wind the device for 60 seconds, it will function and show a reading for approximately 8 to 10 minutes, depending on the speed of winding.
- The longer and faster you wind the longer the fetal monitor will function without the need for further winding.
- You can store wind-up power by winding for any length of time.
- All power created by winding is stored in the batteries.

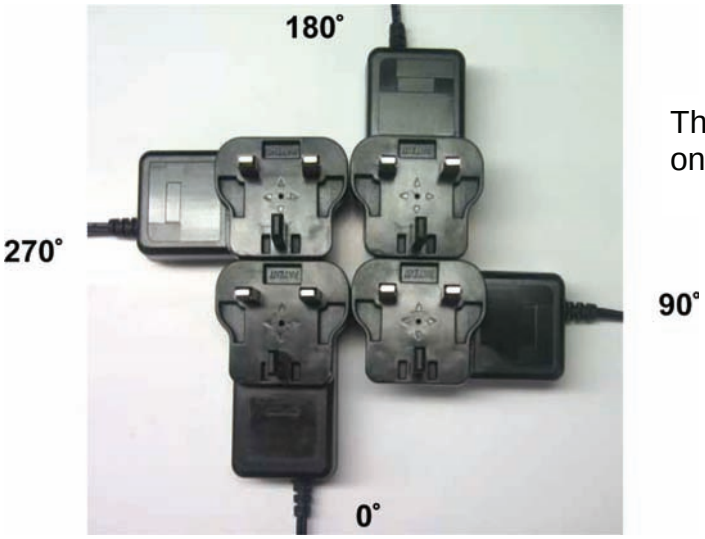
3. Solar energy

The batteries may also be recharged with solar power by connecting the fetal monitor to a solar panel.

AC Mains Adaptor

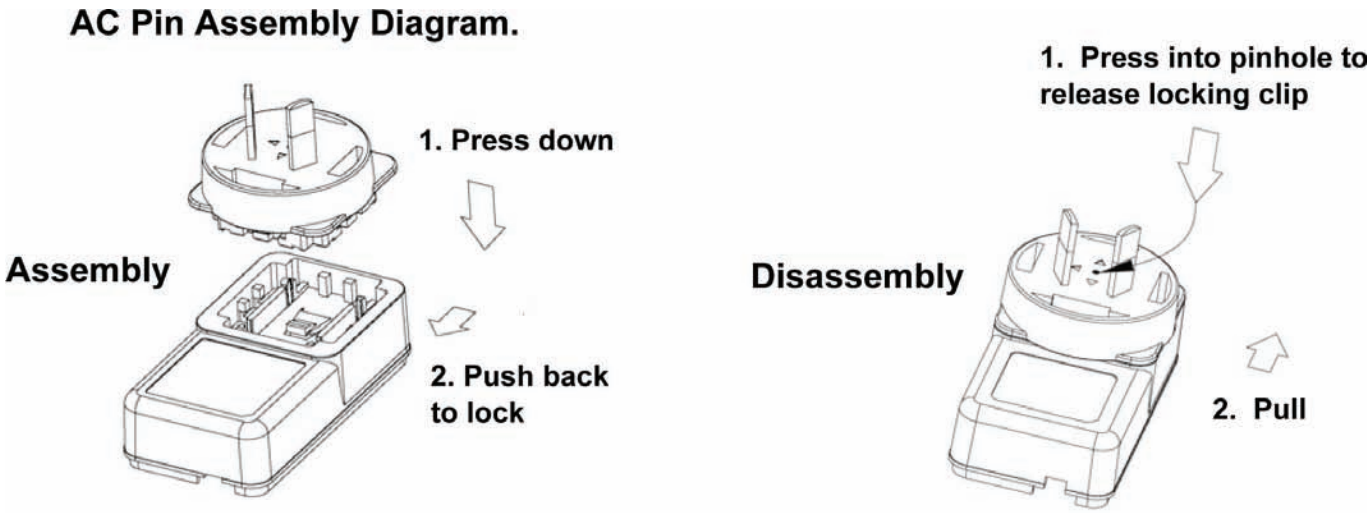
The Freeplay FHRM is supplied with a universal AC mains adaptor to allow the FHRM to be charged when AC Mains is available

The mains adaptor is supplied with 3 plug heads to suit the local AC mains connection



The plug heads can be fitted in one of 4 orientations.

Fitting and removing plug heads



How to use the FHRM

- First choose the power supply you will use to charge the batteries and make sure you have enough power stored in the batteries to complete your examination.

- Clean the ultrasound probe by wiping it with a cloth and disinfectant agent such as chlorhexidene or sodium hypochlorite, **NEVER** use alcohol on the FHRM.

- Switch the fetal monitor on by pressing the on/off button.

- Put a gel, **or water,** on the ultrasound probe/or mother's abdomen and place the probe on the mother's abdomen and move it around until the fetal heart is heard well.

- **It is important NOT to use a mineral oil based gel (eg: KY jelly) between the probe and the skin. An aqueous (water based) gel must be used. Or water alone is quite adequate. The reason is that the molecular structure of mineral oil is small in comparison with the molecular structure of ultrasound plastics. This means that over time oil will migrate through the transducer faceplate and debond the ultrasound crystals on the other side. To repeat, the Doppler head manufacturer maintains that water is adequate to create an air-free seal between the Doppler head and skin if an aqueous gel is unavailable.**

- Keep the probe in that position when a good signal is heard.

- The flashing heart symbol ♥ on the display screen indicates that a readable heart rate is detected and the fetal heart rate per minute is shown on the screen.

- The power source must be disconnected from the monitor before it can be used. You will not be able to switch the monitor on if it is still attached to the power source. This is a safety feature.

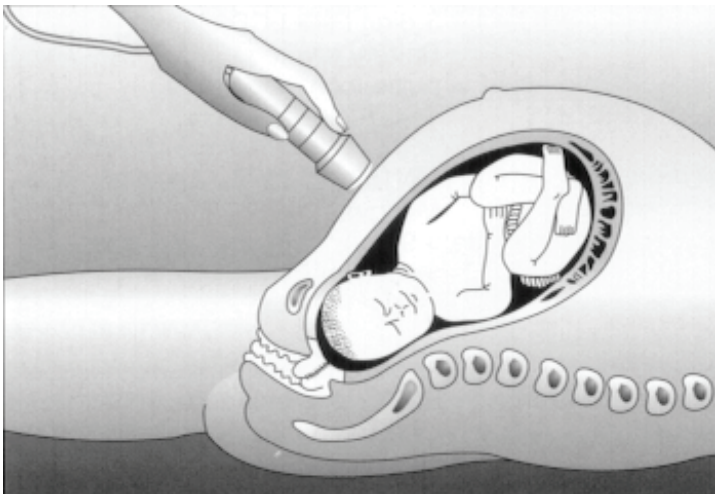
Fetal heart detection

The **FMRM** can be used to detect the beating fetal heart from approximately the 10th week of gestation, though this will vary between patients.

Apply a liberal amount of coupling gel to the area just above the symphysis pubis and position the transducer face flat against the abdomen. Tilt the transducer slowly until the fetal heart is heard in the loudspeaker.

Later on in pregnancy the best signals are generally found higher up the abdomen.

Avoid sliding the transducer over the abdomen as this results in an increase in the background noise and makes it more difficult to detect the fetal heart sounds.



Frequently asked questions

Q: What if the fetal monitor turns off unexpectedly?

A: There is no power left. Choose your power option and charge the batteries again before you switch the fetal monitor on once more.

Q: Can you damage the fetal monitor by turning the handle too fast?

A: No. The faster you turn the handle the more power you will store in the batteries.

Q: What happens if you turn the handle in the wrong direction?

A: It does not matter in which direction you turn the handle. Either direction will generate power.

Q: Is it safe to use the fetal monitor near other electrical equipment?

A: Yes. The fetal monitor will not affect or be affected by other electrical equipment.

Q: Can the operator or patient receive an electric shock from the fetal monitor?

A: No. It is specially designed so that it cannot give an electric shock.

Q: Will the device be damaged if it is dropped?

A: It may be damaged, especially if the probe is dropped. However it has been designed to be robust and is not easily damaged.

Q: When do you know that the fetal heart rate reading on the display screen is accurate?

A: The reading is only reliable if there is a heart icon (♥) shown and if the heart rate does not change frequently on the display screen. If the icon is not shown or the heart rate changes all the time, reposition the probe on the mother's abdomen and make sure that she remains still, as movement can interfere with the reading. If the heart rate is less than 100, make sure you are not measuring the mother's pulse rate by comparing the reading on the display screen with the mothers' wrist pulse rate.

A self-learning programme for professionals on fetal heart rate monitoring during intrapartum care can be accessed free on www.pet.org.za

Specification

Ultrasound

Frequency	2MHz continuous wave
Transducer	2 crystal narrow beam
Output Power	<10mW/cm2
Audio Response	300Hz—1KHz
Fetal Heart Rate	Multipoint real time autocorrelator 50—210 bpm

Unit Controls

Keys	1 key for unit on / off
Indicators	LCD Display with icon for battery low and pulse. Charge indicator

Power Supply

Hand Crank	60 seconds for approximately 8 to 10 minutes of use
AC Mains Charger	2 hours for approximately 7 hours of use
AC Mains Rating	100—240 VAC, 50—60Hz , 0.6A
BS / IEC Class	2

Enclosure

Material	ABS
Dimensions	180 x 90 mm
Weight	590g

Safety

Classification	Type B—IEC 60601-1-1996

Care of your FHRM

After each use carefully wipe excess coupling gel from the transducer with a soft tissue. Never use alcohol or any other solvent to clean any part of the FHRM, as these may cause damage. If cleaning becomes necessary wipe the FHRM with a damp cloth moistened with a mild detergent or a disinfectant agent such as chlorhexidene or sodium Hypochlorite (Milton).
The transducer face is very delicate and may be damaged by dropping.

WARNINGS

FHRM is not to be used in the presence of flammable anaesthetics, flammable gases or in an oxygen rich environment.

If in any doubt of the Fetal Heart Rate from the FHRM always use another method to establish the well being of the Fetus.

Do not attempt to use on a patient when connected to a mains supply.

Service

A service manual for this equipment, which includes circuit diagrams, parts lists and test procedures, is available and may be purchased from your supplier or contact PET at info@pet.org.za.

Warranty

Your FHRM is warranted for a period of 1 year against defects in material and workmanship. Any instrument that proves to be defective within that period will be repaired or replaced free of charge, provided that:

i) the instrument has not been damaged accidentally or by misuse or mishandling.
ii) no unauthorised attempts at repair have been made.
iii) the goods are returned to PET or it's authorised representative, freight pre-paid (please email us on info@pet.org.za to make arrangements).

Under no circumstances whatsoever shall Freeplay Energy Ltd, PET or Ultrasound Technologies Ltd have any liability for loss or for any indirect or consequential damage.

Emissions

Care has been taken through the design and manufacturing processes to minimise the EM emissions that may be produced by this equipment. However, in the unlikely event that the unit causes an EM disturbance to adjacent equipment, we suggest that the procedure is carried out 'out of range' of the affected equipment.

Immunity

If the user has any doubt regarding the unit's EM immunity during routine operation, we suggest that the source of EM disturbance is identified and its emissions reduced.
If the user has any doubt regarding the identification and resolution of adverse EM conditions, please seek advise from Ultrasound Technologies Ltd.

Symbols used


Type B Equipment, Unit Classification


Unit On/Off control


Attention. Consult accompanying documents.


This symbol on the product or on its packaging indicates that this product must not be disposed of with your normal waste.
WEEE Directive (2002/96/EC)

Manufactured for Freeplay Energy and PET by:-

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This Equipment complies with the essential requirements of the European Council Directive 93/42/EEC + 2007/47/EC

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