...with people in mind
The Sonicaid™ FM800 Encore is in conformity with the Medical Devices Directive (93/42/EEC) and has been subject to the conformity assurance procedures laid down in the Council Directive.
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Standards compliance

**Sonicaid** FM800 Encore complies with:

- EN60601-1, 2006 Medical Electrical Equipment Part 1 General Requirements for Safety
- EN60601-1-1, 2001 Safety Requirements for Medical Electrical Systems [collateral standard]
- EN60601-1-2, 2007 General requirements for safety: Electromagnetic compatibility [collateral standard]
- EN60601-1-4, 1997 General requirements for safety: Programmable electrical medical systems [collateral standard]
- EN60601-2-30, 2000 Particular requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment [collateral standard]
- ISO9919, 2005 Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

**Patient safety**

**WARNING:** DO NOT TOUCH LIVE PARTS OF ANY EQUIPMENT (eg COM PORT CONNECTOR PINS ON A PC) AND THE PATIENT AT THE SAME TIME.

**CE Mark**


**Classification**

- **Shock Protection - Class** Class 1 mains powered equipment
- **Shock Protection – Degree** Type CF Applied Parts
- **Water Ingress Protection** Ordinary equipment
- **Safety in presence of Flammable Gases** Not suitable for use in presence of flammable gases
- **Operation Mode** Continuous
Indications for use

Huntleigh Healthcare Ltd Sonicaid FM800 Encore series fetal monitors (henceforth referred to as FM800E series) are indicated for use in monitoring fetal and maternal vital signs during the intrapartum and antepartum periods.

Sonicaid FM820E provides comprehensive fetal monitoring facilities, offering twin ultrasound fetal heart rate, separate fetal and maternal ECG channel, external and internal uterine activity monitoring and maternally/automatically sensed fetal movements.

Sonicaid FM830E provides additional maternal monitoring with the facility for simultaneous monitoring of maternal pulse oximetry and non-invasive blood pressure without the need for additional stand-alone devices.

Notes

Sonicaid Care analysis and Sonicaid Trend analysis are not approved for sale in the USA and Canada.

Do not use the maternal oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could cause burns. The oximeter may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

Limitations for use

Fetal monitors provide just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before taking appropriate action.

FM800E series monitors are intended to show trends in fetal and maternal life signs to give a "first line" indication. On-screen displays and printouts should not be used as a basis for clinical diagnosis; always confirm vital sign parameters by other means before making treatment decisions.

Ultrasound monitoring should be performed in accordance with current guidelines. The ALARA guideline (AIUM) recommends that ultrasound exposure should be kept As Low As Reasonably Achievable.

FM800E series monitors are not intended to be used in conjunction with defibrillator equipment. All transducers should be removed from the patient prior to using a defibrillator to avoid possible equipment damage and/or injury.
System Installation

These requirements must be met when an FM800E fetal monitor is connected to any of the following pieces of equipment:

- a central review and archiving system
- a PC

1. Non-medical equipment must comply with the relevant IEC or ISO safety standard. For Information Technology equipment, this standard is IEC950/EN60950.

2. Medical equipment must comply with IEC601-1/EN60601-1, or equivalent.

3. The configured system must comply with the system standard IEC601-1-1/EN60601-1-1.

4. If non-medical equipment (e.g. the PC or printer) with enclosure leakage currents greater than those allowed by IEC601-1/EN60601-1 is to be used in the patient environment (within 1.5m of the patient), the enclosure leakage currents must be brought within the limits laid down by IEC601-1/EN60601-1. This may be done by using an isolating transformer. Suitable types are available via Huntleigh Healthcare sales agents.

5. Anybody who connects additional equipment to signal input or signal output parts of the system is configuring a medical system, and is therefore responsible for ensuring that the system complies with IEC601-1-1/EN60601-1-1. If there is any doubt as to whether your system does comply, consult the technical service department of your local Huntleigh Healthcare Ltd representative.

The connection of extra equipment to the patient or FM800E could lead to the summation of leakage currents. In such circumstances the user must ensure that safe leakage currents are not exceeded.

Calibration

The NBP module should be calibrated every 12 months. See Section 15.5. Apart from this, there is no special procedure for calibrating FM800E.
Multiple Portable Socket Outlets
(including isolation transformers)

**Note**: an isolation transformer is a particular kind of multiple socket outlet. It is not recommended to power a medical system from a multiple portable socket outlet which is not supplied from an isolation transformer (IEC601-1-1/EN60601-1-1 Amendment 1).

If such an outlet is in use, it should comply with the requirements of Annex EEE.2 of IEC601-1-1/EN60601-1-1 Amendment 1.

- **Do not exceed the power rating for the multiple portable socket outlet.**
- **Do not place multiple portable socket-outlets on the floor.** This is to protect against mechanical damage and the ingress of liquids.
- **Multiple portable socket-outlets supplied with the system must not be used for powering equipment which does not form part of the system.** This is to prevent increased leakage currents, and overload of the multiple portable socket outlet.
- **If the system has been specified for use with an isolation transformer, do not connect any non-medical electrical equipment which forms part of the system directly to the wall outlet.** This is to prevent excessive leakage currents

**Non-medical electrical equipment situated in the patient environment (within 1.5 metres of the patient) must be powered via an isolation transformer, to limit leakage current.**

For more information on the connection and use of isolation transformers, consult the user manual for the medical system you have purchased.
Electromagnetic compatibility

Make sure the environment in which FM800E is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, it has been found to comply with IEC601-1-2/EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

Adding accessories or components to a system, or modifying a medical device or system, may degrade the immunity performance. Consult qualified personnel before making changes to the system configuration.

Service & Warranty

Huntleigh Healthcare’s standard terms and conditions apply to all sales. These contain full details of warranty terms and do not limit the statutory rights of the consumer. A copy is available on request.

If there is any reason to return the FM800E unit, please:

1. Clean the product, as described in the cleaning section.
2. Pack it in suitable packing.
3. Attach the decontamination certificate (or other written statement declaring that the product has been cleaned) to the outside of the package.
4. Mark the package "Service Department – FM800E" and return to the address below.

UK only - For further details refer to the NHS document HSG(93) 26.
Trademarks

Sonicaid™ is a registered trademark of Huntleigh Healthcare Ltd.
TraceVue™ is a registered trademark of Philips.
Safelinc™ is a registered trademark of Tyco.

Sensors

Care and disposal
Re-usable probes and sensors: store and maintain in accordance with the instructions supplied by the manufacturer. Probes and sensors which do not work, or which are no longer required, should be disposed of in accordance with local regulations.

Single-use probes and sensors: dispose of these after use in accordance with local regulations.

Oximeter sensors
Sensor types
BCI (Smiths Industries) 3444 Finger Sensor
NELCOR DS100A

Addresses

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1 Introduction

1.1 The FM800E series

FM800E series monitors are designed for antepartum and intrapartum monitoring. There are two monitors in the series:

**FM820E**  
Standard monitor  
Comprehensive monitoring using twin ultrasound and separate ECG channels. Gives great flexibility in monitoring multiple pregnancies.  
For example:  
- Twin ultrasound and maternal ECG  
- Ultrasound, fetal ECG and maternal ECG  
- Twin ultrasound plus fetal ECG  
FM820E also provides external and internal monitoring of uterine activity, and maternally/automatically sensed fetal movements

**FM830E**  
Standard monitor **plus**  
- Maternal pulse oximetry  
- Maternal non-invasive blood pressure

This reference manual covers the whole FM800E range and may describe some facilities not available in the FM800E you have purchased. Note that FM820E can be upgraded to FM830E.
**FM820E: standard features**

The following features are available on all monitors in the FM800E range:

- Alarms
- Annotation
- Audio
- Display autodim
- Direct FECG via scalp electrode
- Fetal event marker
- Ethernet connection to Central Review System
- Interface to Rimkus telemetry
- Interface to Sonicaid Fetalcare
- Interface to Sonicaid Centrale and other CMS Packages
- IUP: internal uterine activity
- Maternal Heart Rate via ECG (MECG lead supplied as option)
- Toco: external uterine activity
- Ultrasound 1: 1.0MHz
- Ultrasound 2: 1.0MHz
- Thermal printer
- SonicaidCare (antepartum) analysis *
- SonicaidTrend (intrapartum) analysis *
- Printing of Mean Arterial Blood Pressure *
- Actogram

* Not approved for sale in USA and Canada

**FM830E: standard features**

In addition to the above, the following features are available on FM830E monitors:

- Maternal pulse oximetry (MSpO₂)
- Maternal non-invasive blood pressure (NBP)
1.2 **Main unit: front panel**

1. Software control buttons
2. Display: see chapter 2
3. Connector module for oximetry and blood pressure (FM830E only)
4. Connection sockets for transducers
5. Printer drawer
6. Controls and on/off indicators: see chapter 2.
1.3 Connection sockets for transducers

ULT1  1.0 MHz Ultrasound transducer, green
ULT2  1.0 MHz Ultrasound transducer, green
MECG/FECG  Maternal ECG transducer, white
OR  Fetal ECG electrode, white (connected via leg plate)
TOCO/IUP  Toco contractions transducer, pink
OR  IUP catheter-transducer, pink

Classification symbol

This symbol indicates Type CF applied part.

Safety and performance are only assured when used in conjunction with the correct types of transducer. Do not attempt to connect any devices via these sockets other than those supplied or recommended by your Sonicaid dealer.
1.4 Main unit: rear connectors

1. Input socket for the AC mains supply
2. RS232 connector for Sonicaid Centrale, FetalCare, Philips TraceVue™, GMT Argus** Central Review Systems. 9-way D-type socket*
3. RS232 EXT 1 connector for external NBP, 9-way D-type socket (reserved for future use)*
4. LAN connector for connection to CRS via 10/100Mbps local area network. RJ45 socket
5. This symbol denotes Date of Manufacture
6. Connector for Rimkus Telemetry** 15-way D-type socket

* For pin connections, see Appendix 1.
** Not approved for use with Sonicaid FM800E in the USA or Canada.
**Connector module**

The FM830E incorporates additional connectors for maternal blood pressure and maternal oximetry on a connector module.

- **NBP** Maternal blood pressure
- **MSpO²** Maternal pulse oximetry

**Event marker connection**

Event marker connectors
1.5 The FM800E display

The FM800E's high-performance colour display combines superior visual performance with environmental ruggedness, making it suitable for a wide range of environments.

The principal benefits of the FM800E display are:
- High brightness and contrast
- Range of colours helps distinguish between displayed items
- Wide viewing angle: >160°
- Display auto-dims when FM800E is used in subdued lighting
- Extremely rugged and durable
- Reliable, long operating life

Note: as with other light-emitting displays, displaying fixed patterns on the screen can cause a limited degree of burn-in. Some slight variation in luminance, as a result of this, is perfectly normal.
1.6 Transducers and cables

Supplied with all units

Ultrasound transducers  Green, 1.0MHz (2-off)
Toco transducer  Pink
Transducer belts  3 pairs
Fetal ECG lead (5 different types available)  White
FECG lead leg belts/electrode pads  2
Fetal movement event marker  1
Mains lead  1

Supplied with FM830E

NBP air line  1
NBP adult cuff  1
Maternal SpO2 patient lead  1
Maternal SpO2 re-useable probe  1

Accessories supplied with all monitors in the FM800E range

Ultrasound gel  8oz
Printer paper  2 packs
Reference Manual (CD)  1
Getting Started card  1

Supplied as options (with any monitor in the FM800E range)

IUP lead  Pink
IUP single-use transducers
Maternal ECG lead  White
NBP small adult cuff
NBP large adult cuff
Trolley
Wall-mounting kit
Rimkus wireless transducer system
1.7 FM800E trolley or wall mounting

FM800E can be mounted on a trolley or wall mounted. A purpose-designed trolley is available. If FM800E is used with a trolley or wall mounting, then it must be attached to the trolley or wall mounting with the securing screws. Otherwise there is a danger of it falling off the trolley, or wall mounting, accidentally.

To assemble the trolley or wall mounting, and install the unit thereon, follow the instructions supplied by the manufacturer.

- **If the FM800E is being used on a trolley, make sure the trolley brakes are applied at all times, except when the trolley is being moved.**

- **Take care to ensure that trailing transducer cables and other connecting leads do not present trip hazards that could lead to the equipment falling and causing damage or injury. Always park unused transducers in the slots provided on the enclosure.**
2 FM800E Controls and Display

2.1 Controls and on/off indicator

Printer on/off switch and indicator.
Shows amber light when printer is switched on.

Audio volume down.

Audio volume up.

Printer fast forward.

Audio channel select. See Sections 5.2 and 6.3.

EasiNotes annotation. See Section 7.6.

Toco zero.

Power on/off switch and indicator.
Shows green light when FM800E is switched on.

Power on/off symbol.

Switching on
To switch on, press the Power on/off switch.

If FM800E beeps rapidly and continuously, it has failed its power-up self-test routine.
Contact your local Huntleigh Healthcare Ltd representative.
2.2 FM800E main screen

When FM800E is monitoring, fetal parameters are displayed down the left-hand side of the display, maternal parameters down the right-hand side. Each parameter is always displayed in the same position on the display. The diagram below shows the zones on the screen where the different parameters are displayed.

Buttons are not active until a transducer is connected. A triangular pointer indicates that a button is active.

For example:

Pressing a button brings up a setup screen for that parameter. This setup screen allows alarms and thresholds to be set.

The setup button in the main screen is for general setup procedures (setting the time and date, altering the default thresholds, and so on).

Stop beep or make it quieter

FM800E beeps when a button or key is pressed. The loudness of the beep depends on the loudness of the fetal or maternal alarm, whichever is louder. To make FM800E beep more quietly or loudly, change the volume of the fetal and/or maternal alarms. See Section 8.2.

To stop FM800E beeping when a button or key is pressed:
> SETUP > SYSTEM SETTINGS > access code (2755) > AUDIO/GRAPHIC > KEY PRESS
2.3 Software control buttons

When the FM800E is switched on, the SETUP button is active. Other buttons are inactive. When any transducer is connected (apart from NBP), the button for that parameter becomes active, and the parameter name is displayed.

For example, when Ultrasound 1 is connected, the display shows:

When the FM800E detects the fetal heart rate, it displays the rate and a confidence indicator (the heart symbol). See Section 5.4.
2.4 Audio controls

FM800E can provide an audio signal for one channel at a time (Ultrasound, FECG, MECG or SpO₂). The default channel is ULT1. So, if FM800E is switched on with corresponding transducers connected for all the audio channels, and then audio is selected, an audio signal will be reproduced for ULT1. If there is any doubt, the FM800E display shows which channel is currently selected for audible monitoring.

For audio, see also Sections 5.2 and 6.3.

**Note:** If an audio-capable transducer is connected when audio is already turned on, the audio signal automatically switches to this most recently connected transducer.

The audio controls on FM800E allow the user to:

- change the audio volume
- change the audio channel

**Volume control**

To change the audio volume, press Audio Volume Up or Audio Volume Down.

![Audio Volume Down](image)

Audio Volume Down

![Audio Volume Up](image)

Audio Volume Up

**Changing the audio channel**

To change the audio channel, press the Audio Channel Select button on the front panel of FM800E until the required channel is selected.

![Audio Channel Select](image)
2.5 Printer controls

There are front panel controls for printer on/off, printer fast forward, and EasiNotes:

- Printer On/Off switch and indicator. Shows amber light when printer is switched on.
- Printer Fast Forward.
- EasiNotes annotation. See Section 7.6.

Printer setup

Printer setup is controlled by the software buttons ( > SETUP > SYSTEM SETTINGS > access code (2755) > PRINTER). The options are:

- Twin FHR*
- Print header
- Hospital name
- Paper speed
- FHR vertical scale
- FHR graticule
- Paper out buffer

See Section 4.3.

EasiNotes setup

- SETUP
- SYSTEM SETTINGS
- access code (2755)
- EasiNotes.

See Section 7.6.

- Note: twin FHR setting is not recommended for intrapartum monitoring
**Loading printer paper**

**Note**: the printer uses a thermal paper pack (part number 8400-8003), with no pre-printed graticule. If the paper pack shows a procedure for loading paper, this should be ignored, since it is not relevant to the FM800E.

1. Pull the FM800E paper drawer as far out as it will come (diagram A).
2. Remove the paper from its plastic wrapping. Make sure the words ‘THIS SIDE UP’ are visible, and that the arrow points to the back of the paper drawer.
3. Lift the first fold of paper towards you.
4. Place the paper pack centrally in the paper tray, with the first sheet centrally positioned over the roller (diagram B).
5. With a thumb on either side of the printer drawer, push the drawer in firmly until it clicks into place.

![Diagram A](image1.png)

![Diagram B](image2.png)
3 Setup

3.1 Overview

The Setup procedures are much simpler if the differences between Setup, Current Alarms, Default Alarms and System Settings are understood.

Setup User preferences available directly from the Setup screen.

Current Alarms Allows alarms to be set before connecting transducers. Settings remain in force until FM800E is switched off. When switched on again, the FM800E reverts to the default alarms. Alarms can be set for: FHR, MECG, NBP, MSpO2 Alarms can also be set from the main screen by pressing the key beside the parameter it is desired to change.

Default Alarms Default alarm settings protected by the access code (2755): Changes made using Default Alarms remain in force when FM800E is switched off and on again.

System Settings User preferences protected by the access code (2755): Changes made using System Settings remain in force when FM800E is switched off and on again.

3.2 Current alarms

This option allows the alarms to be altered for a monitoring session before connecting transducers. The changes made using this option do not remain in force when FM800E is switched off.

See Chapter 8.

3.3 Default alarms

This option allows the default alarms for the FM800E to be altered. The changes made using this option do remain in force when the FM800E is switched off.

See Chapter 8.

3.4 System settings

See Chapter 4.
3.5 Analysis

SETUP is also used to select SonicaidCare (antepartum) or SonicaidTrend (intrapartum) analysis:

SonicaidTrend analysis See Chapter 9.
SonicaidCare analysis See Chapter 11.

3.6 Time and date

To reset the date or time in FM800E:

1 > SETUP > TIME AND DATE.
2 > SETUP beside the time or date.
3 Use + and – to make the necessary changes.
4 > EXIT.

To change the date format, see Section 4.5, International Settings.

3.7 Patient details

Patient details are the patient name, patient ID and gestation period. They are printed on the header of the trace. They are not saved when FM800E is switched off.

Entering patient name and ID

To enter or edit the patient name and ID:

1 > SETUP > PATIENT DETAILS.
2 > ADD/EDIT beside Name or Number.
3 For each character of the name or ID:
   Press the key for the character group (e.g., ABCDEFGH).
   Then press the key for the character.
   To move the cursor: > LEFT or RIGHT.
   NB For non-standard characters: > NEXT PAGE.
4 When the name or ID is complete: > EXIT.

Gestation

To enter the gestational age of the fetus:

1 > SETUP > PATIENT DETAILS.
2 > ADD/EDIT beside Gestation.
3 > + or – as necessary.

To remove patient details

Switch FM800E off, then on.
3.8 Timer

A timer can be set to provide an alert when a given period of time (1–99 minutes) has elapsed. The timer starts when printing is started.

**Note** : the timer cannot be set when SonicaidCare analysis or SonicaidTrend analysis is in progress.

**To set the timer**

1. > SETUP > TIMER > ON.
2. Use + or – to set the length of time required.
3. > EXIT.

**Acknowledging the timer**

When the set time has elapsed, FM800E beeps repeatedly (providing that the beep is turned on). In the main screen, the Alarm Acknowledge key shows the message:

```
TIMER FINISHED
```

To stop the beep: > ALARM ACKNOWLEDGE.

**To turn the timer off**

> SETUP.
> TIMER.
> OFF.
3.9 Actogram settings

Actogram on/off (not available in the USA and Canada)
To turn the actogram features on or off:
> SETUP
> NEXT PAGE
> ACTOGRAM
Press ACTOGRAM IS OFF/ON to turn the actogram feature on or off.

To increase or decrease the sensitivity of Actogram
> SETUP
> NEXT PAGE
> ACTOGRAM
> SET ACTOGRAM GAIN ULT1*
> use + or – to set the gain required.

Changing the Actogram display setting
> SETUP
> NEXT PAGE
> ACTOGRAM
> ACTOGRAM OUTPUT [this cycles on each press between GRAPH, (check)MARKS and GRAPH + (check)MARKS]

Changing the Actogram threshold
> SETUP
> NEXT PAGE
> ACTOGRAM
> SET ACTOGRAM THRESHOLD
> use + or – to set the threshold as required.
> [the required threshold may depend on whether the trace is showing a high incidence of artefact. It is recommended to set the threshold between 40 and 60%.
]
Observe the Actogram trace for a short period to see if the setting is satisfactory.

* The settings will apply to ULT1 or ULT2, depending upon which transducer(s) are connected. To check/alter the settings for ULT2, unplug the ULT1 transducer, press > EXIT, connect transducer to ULT2, press < ACTOGRAM.
4 System Settings and Default Alarms

4.1 Overview

The System Settings and Default Alarms screens allow preferences to be set which are protected by an access code (2755). These preferences remain in force when you switch the FM800E off, and then on again.

System settings

The System Settings screen allows the operator to:

- Add or change EasiNote descriptions
- Display or not display the baby graphic
- Display or not display FECG or MECG waveforms
- Beep or not beep when a key is pressed
- Change the printer setup
- Change the international setup
- Beep or not beep when an Event Mark is recorded
- Select the host interface (e.g., Sonicaid FetalCare, Sonicaid Centrale, Philips TraceVue)

Service information can also be accessed via System Settings:

> SETUP.
> SYSTEM SETTINGS.
> access code (2755).

Default alarms

The Default Alarms screen allows the following default alarms to be changed:

- FHR
- MECG
- NBP
- MSPO2  \( \text{FM830E only} \)
4.2 Changing the default alarms
When the FM800E is switched on, the alarm settings for FHR, ME~CG, NBP and MSpO₂, and the mode setting for NBP, revert to the hospital defaults.

To change the hospital defaults:
1. > SETUP > DEFAULT ALARMS > access code (2755).
2. Press the key for the parameter, the default setting of which it is desired to change.
3. Change the alarm settings. See Section 8.1.

Resetting to factory defaults
To restore FM800E configuration, as originally delivered from the factory:
> SETUP.
> SYSTEM SETTINGS.
> enter access code (2755).
> SERVICE CENTRE.
> DIAGNOSTICS.
> RESET TO FACTORY DEFAULTS.

4.3 Printer setup

Hospital name
To enter (or edit) the hospital name printed on the trace:
> PRINTER.
> HOSPITAL NAME.

Enter the hospital name in the same way as for Patient Details. See Section 3.7.

Print header
The header comprises the hospital name, patient name and gestation. Options are to have the header printed either when the unit is first powered up, whenever the printer is started, or never.

To switch header printing on or off:
[> SETUP > SYSTEM SETTINGS > access code (2755)]
> PRINTER.
> PRINT HEADER once or twice, as required.

Paper-out buffer
If the paper runs out, FM800E can store data for up to 10 minutes, and then fast print when the paper is refilled until it catches up with the real-time incoming data. When this happens, the stored data is held in the paper-out buffer.
The default is for the paper-out buffer to be enabled (i.e. FM800E will store data if the paper runs out). To switch off the paper-out buffer, or switch it on again after it has been switched off:

> PRINTER.
> PAPER OUT BUFFER.

**Paper Speed**
To change the paper speed:

> PRINTER.
> PAPER SPEED once or twice, as required.

**FHR graticule**
The FHR graticule can be printed at intervals of 5 bpm or 10 bpm.

To alter the FHR graticule:

> PRINTER.
> FHR GRATICULE.

**FHR scale for twins**
If twins are being monitored, each FHR trace can be printed on its own scale, or both on the same scale.

To alter the vertical scale for twins:

> PRINTER.
> TWIN FHR.

**FHR vertical scale**
The FHR vertical scale can be 20 bpm/cm or 30 bpm/cm. At 20 bpm/cm the range is 50-210 bpm. At 30 bpm/cm it is 30–240 bpm.

To change the vertical scale:

> PRINTER.
> FHR SCALE.
4.4 Audio/graphic settings

Baby graphic
To display (or stop displaying) the picture of a baby on the main FM800E screen:
[ > SETUP > SYSTEM SETTINGS > access code (2755)]
> AUDIO/GRAPHIC.
> BABY GRAPHIC.

Audible key press
To switch on (or off) the beep which accompanies every key press:
> AUDIO/GRAPHIC.
> KEY PRESS.

Audible event mark
To switch on (or off) the beep which accompanies the marking of an event:
> AUDIO/GRAPHIC.
> EVENT MARK.

ECG waveform display
To display (or stop displaying) ECG waveforms when Maternal ECG or Fetal ECG is being recorded:
> AUDIO/GRAPHIC.
> ECG WAVEFORM.

Note: the waveforms appear only if an ECG signal is connected. But if the instrument is switched off, and then later switched on again, it remembers the request for ECG waveforms to be displayed.
4.5 International settings

Supply frequency (50Hz or 60Hz)
To alter the supply frequency:
[ > SETUP > SYSTEM SETTINGS > access code (2755)]
> INTERNATIONAL.
> SUPPLY FREQUENCY.

Language
To change the language appearing on the display:
> INTERNATIONAL.
> LANGUAGE.
Select the required language.

Date format
To change the date format:
1 > INTERNATIONAL.
2 Press the key opposite the current date format.
3 Repeat if necessary.

The opposing key allows the day, month and year separator to be set:
> ‘/’ or ‘.’

Contractions units of measurement
For Toco, the contractions scale is 0–100%, relative units.
For IUP, the units of measurement are mmHg (0–100) or kPa (0–15).

To select mmHg or kPa for the IUP transducer:
> INTERNATIONAL.
> IUP UNITS.
4.6 Serial interface

When connecting to a central review system, the FM800E needs to be told whether the central review system is a Sonicaid system or a non-Sonicaid system that recognises the Philips Series 50 fetal monitors digital interface protocol.

FM800E has been tested with Sonicaid Centrale and Philips TraceVue. For other central review systems, consult the description of the Serial Interface Protocol in the Sonicaid FM800E Service Manual, part number 751339.

To select the appropriate serial interface:

1 > HOST INTERFACE.

2 Use the labelled key to select the host interface type.

   For Sonicaid FetalCare make sure the setting is ‘RS232 Sonicaid’.

   For Philips TraceVue make sure the setting is ‘RS232 HP 50’.

   For Sonicaid Centrale, make sure the setting is either ‘RS232 HP 50’ when connecting via the serial port, or ‘Network HP 50’ when connecting via the LAN interface.

3 > EXIT.

4 Switch off FM800E. Wait for about 10 seconds.

5 Switch FM800E on again.

See also Chapter 12.

Note: Sonicaid Centrale can also support the ‘Sonicaid’ protocol option
5 Monitoring Fetal Parameters

5.1 Preliminary

1. Ensure that the transducers and transducer belts are clean and ready for use.
2. Switch on FM800E.
3. Check the printer:
   - Is there sufficient paper for the monitoring session?
   - Is the drawer fully pushed in?
4. Check the printer setup (graticule, scale, paper speed etc).
5. Enter patient details, if required.

5.2 Audio signal

An audio signal can be obtained for FHR and Fetal ECG:
- For FHR the FM800E gives an audible representation of the Ultrasound signal.
- For FECG the FM800E beeps each time it detects a fetal heartbeat.

The volume control and channel select buttons are on the front panel of FM800E. The channel select button selects the eligible channels in turn.

The eligible channels are those which:
- a) can produce an audio signal,
- and b) have a transducer connected.

To select Audio for a channel, press Channel Select until the Audio symbol appears by that channel. To turn Audio off, press Channel Select until the Audio symbol does not appear at all.
5.3 Ultrasound monitoring

1. Connect the green transducer to the green socket marked ULT1 on FM800E. In the FM800E main screen, the ULT 1 button becomes active.

2. Palpate the abdomen to determine fetal lie and position.

3. Make the patient comfortable in a semi-recumbent or sitting position. Place the belt around the abdomen, and secure over transducer button.

4. Apply Aquasonic coupling gel liberally to the face of the transducer. Position the transducer on the abdomen over the fetal site. Move it slowly until the characteristic hoof-beat sound of the fetal heart is heard.

5. When a good signal is being obtained, FM800E displays the FHR. Check that the fetal heart pulse lamp flashes with each fetal heartbeat, and that the FHR is distinct from the maternal pulse rate taken at the mother's wrist. Make a note of the maternal pulse on the chart paper.

7. Connect the fetal event marker to the socket on the side panel. Explain to the mother how and when to use it. Note that a timeout between presses prevents markers being generated at overly frequent intervals.

8. Adjust the sound level with the volume controls on the front panel of FM800E.

9. To start printing, press the printer on/off button.

Note: FM800E displays a schematic diagram of a fetus (or fetuses, if two transducers are connected). These diagrams do not show the actual position of the fetus. If desired, the display of this graphic can be suppressed - see Section 4.4.
Transducer positioning for Ultrasound monitoring

Hints on monitoring

- Make sure the transducer is placed in the optimum position. Avoid positions with strong placental sounds (swishing) or the fetal cord pulse at the same rate as the fetal heart.
- If the fetus is in the occipitoanterior presentation and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus.
- It is not possible to monitor the fetal heart rate unless an audible fetal heart signal is present. It is important to distinguish the fetal pulse from the maternal pulse. To do this, feel the mother’s pulse during the examination, or monitor Maternal HR with ECG or MSpO₂.
5.4 The FHR confidence indicator

The heart symbol which appears against the FHR display is a confidence indicator, not an indicator of signal strength.

If the heart symbol is displayed in outline only, and no FHR is displayed, the FM800E cannot detect the fetal heartbeat.

If the heart symbol is displayed in the form of a ‘beating’ heart alternate small and large filled heart, and the FHR is displayed, the FM800E can detect a fetal heartbeat. The colour gives a confidence indication, where –

- Yellow is low confidence
- Orange is moderate confidence
- Red is high confidence

5.5 False recording of low baseline FHR

When monitoring a low baseline FHR using Doppler ultrasound, the heart rate may be falsely reported. This effect is known as *double-counting*, and is characteristic of ultrasound fetal monitoring.

In normal circumstances the atrium and ventricle beat almost simultaneously. The ultrasound reflected from these two chambers is used by fetal monitors to calculate the FHR. When the FHR is low, at 70-80bpm, there is a longer time interval between the atrial and ventricular contractions. A fetal monitor may take the reflection from each chamber as a separate beat and therefore falsely calculate the FHR.

It can also happen, though very rarely, that the monitor double counts signals which are maternal in origin.

The Sonicaid FM800E’s heart rate detection system separates movements of the heart away from the transducer from those towards the transducer. This helps to correct some instances of double-counting, but does not entirely prevent it.
How to minimise the chances of double counting occurring

1 Always palpate the abdomen and listen to the fetal heart with a Pinard stethoscope or hand-held Doppler unit before applying the ultrasound transducers. This helps to verify the fetal heart and to locate the area where best signal quality can be expected.

2 Palpate the maternal pulse for one minute simultaneously and record it on the printed output.

3 Recording a signal for maternal ECG/MSpO₂ will help to identify any cross-correlation between maternal and fetal heart rates.

4 Listen to the fetal heart rate using the FM800E Audio signal. The sound should be like a galloping horse, not a swishing sound from maternal vessels.

5.6 Ultrasound for twins

1 Set FM800E to TWIN SCALES or SINGLE SCALE.

[ > SETUP > SYSTEM SETTINGS > access code (2755) > PRINTER > TWIN FHR]

2 Palpate the abdomen and ascertain the lie of each fetus.

3 Place both ultrasound transducers on the patient’s abdomen in the optimum position. Use the ULT1 transducer to monitor the first, presenting twin. Make the transducers secure with belts.

4 To hear the audio signal for each twin, press the Channel Select on the front of FM800E. The Audio symbol shows which is the active audio channel.

5 Check that the two heart rates are different. If the heart rates appear similar:

FM800E beeps

The display shows !CHECK TRACE FOR SAME HEART RATE

The printer prints this symbol on the trace

Make sure that the transducers are positioned correctly.

6 Connect the fetal event marker to the socket on the side panel. Explain to the mother how and when to use it.
5.7 Fetal ECG (using a scalp electrode)

Connection
The FECG transducer is connected via the white socket on the front panel labelled MECG/FECG. This is used to connect either Fetal or Maternal ECG transducers. It is possible to monitor FECG for a fetus independently of the ultrasound monitoring. Therefore it can be used with a single fetus, twins, or even triplets.

Note: Sonicaid Antepartum Care Analysis (see section 11) cannot be used in conjunction with Fetal ECG. If Care Analysis is required, ensure that a Fetal ECG probe is not connected to the FM800E.

Note: in the USA and Canada the use of FDA-compliant fetal scalp electrodes is required. The Safelinc fetal ECG electrode (part number 900X259) is recommended. In other countries, Sonicaid electrodes (part number 1400-0160) or Safelinc electrodes may be used.
Monitoring procedure using Sonicaid electrodes

Caution: read the instructions for use supplied with the fetal ECG scalp electrode

1. Apply ECG electrode gel to the base of the electrode leg plate, then strap the electrode leg plate to the front of the thigh. Secure with the belt.
2. Connect the electrode leg plate to the white socket on FM800E.
3. Attach the fetal scalp electrode to the fetal scalp or the presenting part as described in the electrode instructions.
4. Connect the electrode leads to the leg plate. The polarity of these connections is not important. Make sure a good signal is maintained.
5. Allow a few minutes for the signal to stabilize and a clear fetal heart rate to be displayed. The signal quality indicator should be a solid, filled heart. Check the signal visually by displaying the FECG waveform (see below).
6. The FM800E carries out its own internal impedance check. If the check fails, the message CHECK FECG CONNECTIONS will be displayed.
7. Adjust the volume control as necessary.

FECG socket:
- pin 1 M REF
- pin 2 FECG REF
- pin 3 FECG electrode

Key:
- 1 FECG socket on FM800E
- 2 Red
- 3 Green
- 4 M REF
- 5 Red
- 6 Black
- 7 FECG electrode
- 8 ECG REF
Monitoring procedure using Safelinc electrodes

Caution: follow the instructions for use supplied with the fetal ECG scalp electrode

1. Following the manufacturer’s instructions, attach the FECG lead to the mother’s leg, using the adhesive pad.
2. Following the manufacturer’s instructions, attach the FECG electrode to the fetal presenting part.
3. Connect the FECG electrode to the FECG lead.
4. Allow a few minutes for the signal to stabilise and a clear fetal heart rate to be displayed. The signal quality indicator should be a solid, filled heart. Check the signal visually by displaying the FECG waveform (see below).
5. The FM800E carries out its own internal impedance check. If the check fails, the message CHECK FECG CONNECTIONS will be displayed.
6. Adjust the volume control as necessary.

**Diagram**

FECG socket:
- pin 1 M REF
- pin 2 FECG REF
- pin 3 FECG electrode

Key:
- 1 FECG socket on FM800E
- 2 M REF
- 3 FECG REF
- 4 FECG electrode
Displaying the FECG waveform

When FECG is monitored using a scalp electrode, the FM800E monitor shows the fetal heart rate in the same way as it shows the ultrasound heart rate: as a numerical rate together with the confidence indicator (the flashing heart symbol). There is also an option to display the FECG waveform.

The factory default is to display the waveform. So a brand new FM800E will display FECG waveforms if there is an FECG transducer connected. From then on the FM800E remembers the on/off setting from the last time it was used.

To switch the display on:

> SETUP.
> SYSTEM SETTINGS.
> access code (2755).
> AUDIO/GRAPHIC.
> ECG WAVEFORM.
> EXIT > EXIT.

The FECG waveform now appears in place of the baby graphic:
Printing the FECG waveform
1  Make sure the FM800E is already printing the trace.
2  Make sure the FECG waveform is displayed.
3  > the EasiNotes annotation button.
4  > PRINT ECG.

FEHG trace printout:
5.8 Accidentally recording the wrong signal

As previously referred to (section 5.6), it is possible when monitoring twins, to pick up the signal for the ‘wrong’ twin. It is also possible, if the ultrasound transducer is incorrectly placed, for it to pick up the maternal heart instead of the fetal heart. Similarly, it is possible for the maternal ECG to be mistaken for the fetal ECG. To help guard against these possibilities, the FM800E routinely compares the heart rates obtained from different sources. If any two rates appear similar (within 3bpm), for more than three minutes, then:

FM800E beeps
The display shows !CHECK TRACE FOR SAME HEART RATE
The printer prints this symbol on the trace
The message and warning are the same no matter what two rates are similar.
If the rates continue to match, the warning is repeated every 2 minutes 30 seconds.

If the FM800E displays this warning, check the validity of the signals being recorded. The following pairs of rates are compared:

ULT1 with ULT2
ULT1 with FECG
ULT1 with MECG
ULT1 with MSpO2 (heart rate)
ULT2 with FECG
ULT2 with MECG
ULT2 with MSpO2 (heart rate)
FECG with MSpO2 (heart rate)
6 Monitoring Maternal Parameters

6.1 Contractions (using Toco transducer)

1. Ensure that the Toco transducer and belt are clean and ready for use.
2. Connect the Toco transducer to the pink socket on FM800E.
3. Place the belt round the abdomen, and secure it over the transducer button.
4. DO NOT USE COUPLING GEL. Wipe off any gel present on abdomen around this area.
5. Clip the Toco transducer through one of the three positioning holes on the buckle so that it is retained on the midline half-way between the mother’s fundus and the umbilicus.
6. Contractions activity is measured as a % of full scale deflection. The contractions measurement automatically zeroes to 10%. If it is suspected that the transducer is not zeroed correctly, press the pink Toco Zero button on the front of FM800E, at a moment when the mother is not experiencing a contraction.

6.2 Contractions (using IUP transducer)

FM800E is designed for use with an Intran disposable catheter transducer.

1. Connect the IUP connecting lead to the pink socket on FM800E.
   Caution: read the instructions for use supplied with the intrauterine catheter.
2. Set IUP units of measurement, if required.
   [SETUP > SYSTEM SETTINGS > access code (2755) > INTERNATIONAL > IUP UNITS]
3. Insert the catheter as described in the instructions.
4. Zero the transducer as described in the instructions supplied with it. Zero FM800E by pressing the pink Toco Zero control on the front panel.
   Or > IUP, then > ZERO.
5. To confirm placement and function of the transducer, ask the patient to cough. A spike should be observed in the contractions measurement.
6. Connect the fetal event marker to the socket on the side panel. Explain to the mother how and when to use it.
6.3 Maternal ECG

Monitoring MECG allows a check to be made that the fetal heart rate being recorded does in fact belong to the fetus and not the mother.

Audio signal

An audio signal is available for MECG. If Audio is selected for MECG, the FM800E beeps each time it detects a maternal heartbeat. The volume control and channel select buttons are on the front panel of the FM800E.

To select Audio for MECG, press Channel Select until the Audio symbol appears by the MECG display. To turn Audio off completely, press Channel Select until the Audio symbol does not appear at all.

MECG monitoring procedure

1 Use self-adhesive disposable electrodes. Placement of the electrodes is not critical, though it is a good idea to have the lower electrode placed clear of the diaphragm, as the muscles here are very active in contraction.

A recommended arrangement might be:

![MECG Arrangement Diagram]

2 Connect the MECG lead (white) to the MECG/FECG socket on FM800E.

3 Clip the three flying leads of the MECG lead to the electrodes. They are colour-coded white, black and red (W, B and R in the diagram above).

4 Allow a few minutes for the signal to stabilise and a clear maternal heart rate to be displayed. Check the signal visually by displaying the MECG waveform (see below).

5 The FM800E carries out its own internal impedance check. If the check fails, the message: CHECK MECG CONNECTIONS is displayed.

6 If audio is selected for the MECG channel, adjust the volume control as necessary.
If the maternal and fetal heart rates appear similar:

- FM800E beeps
- The display shows ![CHECK TRACE FOR SAME HEART RATE]

Confirm the source of the fetal heart being monitored.

**Displaying the MECG waveform**

When MECG is being monitored, the FM800E display shows the maternal heart rate in the same way as it shows the ultrasound heart rate: as a numerical rate together with the confidence indicator (the flashing heart symbol). There is also an option to display the MECG waveform.

The factory default is to display the waveform. So a brand new FM800E will display MECG waveforms if there is an MECG transducer connected. From then on the FM800E remembers the on/off setting from the last time it was used.

To switch the display on:

> SETUP.
> SYSTEM SETTINGS.
> access code (2755).
> AUDIO/GRAPHIC.
> ECG WAVEFORM.
> EXIT > EXIT.

The MECG waveform now appears in place of the baby graphic:
Printing the MECG waveform
1. Make sure the FM800E is already printing the trace.
2. Make sure the MECG waveform is displayed.
3. > EasiNotes annotation button.
4. > PRINT ECG.

MECG trace printout:
6.4 Maternal Blood Pressure

FM830E can measure the mother’s systolic and diastolic blood pressure, mean arterial pressure*, and the average pulse rate during the measurement. Measurements can be made manually or automatically (at an interval defined by the user).

An alarm is triggered if the mother’s blood pressure goes above or below certain limits, or if the measurement fails. The alarm can be switched off if preferred.

* This feature not available in the USA or Canada

Note: in countries where mean arterial pressure is not used, the value for mean arterial pressure is not shown on the FM800E printout. Any obstetric data management system connected to FM800E should be configured not to display the mean arterial pressure.

Attaching the cuff
1. Place the cuff around the mother’s arm, approximately 5cm above the elbow.
2. Connect the cuff hose to the FM800E air hose.
3. Connect the FM800E air hose to the NBP connector on the FM800E patient module.

Displaying results
FM800E displays systolic and diastolic pressure, in the format 135/75, beside the NBP button. This result is displayed for an hour, or until the next NBP measurement.

If maternal ECG or maternal oximetry is not being monitored, FM800E also displays the average pulse rate during the last NBP measurement. This value is displayed beside the MECG button for 10 minutes, or until the next NBP measurement.

Note: if taking NBP measurements every 3 minutes, set print speed to 2cm/min or 3cm/min; otherwise there will not be room on the paper for every result.

Taking measurements manually
1. Connect the cuff to the NBP socket on the connector module.
2. > NBP. The NBP SETUP screen advises whether in Manual or Auto Mode.
3. To change from Auto to Manual: > MANUAL.
4. The ALARMS symbol advises whether the alarm is on or off.

To turn the alarm on or off: > ALARMS > ON or OFF. If the alarm is set on, the alarm limits and volume can be reset, if required. See Chapter 8.

5. Attach the cuff to the mother. See above.
6. To take a measurement: > NBP > START MEASUREMENT.

To stop a measurement, after it has started: > STOP NBP.
**Taking measurements automatically**

1. Connect the cuff to the NBP socket on the connector module.

2. > NBP > AUTO.

3. Set the interval between measurements by pressing + or −.

4. The alarm symbol informs whether the NBP alarm is on or off.
   
   ![Alarm on](image1) ![Alarm off](image2)
    
   To turn the alarm on or off: > ALARMS > ON or OFF. If the alarm is set on, the alarm limits and volume can be reset, if required. See Chapter 8.

5. Attach the cuff to the mother. See above.

6. > START AUTO CYCLE to start taking measurements.

7. To take a non-automatic measurement, while remaining in Auto Mode:
   
   > NBP > MEASURE NOW.

8. To stop taking measurements: > NBP > STOP AUTO CYCLE.
   
   To stop a particular measurement: > STOP NBP. FM800E remains in Auto Mode, and displays 00/00 as the current measurement.

**Failed measurements (manual and automatic)**

When an NBP measurement fails:

- The NBP display shows 00/00.
- An error code or message explains why the measurement failed. See Section 14.4.
- An audible alert sounds, if NBP alarms are on.

If there is an error condition in Auto Mode, the Auto cycle is halted, but FM800E remains in Auto Mode. To restart automatic measurements: > NBP > START AUTO CYCLE.

**Note**: if the error is over-pressure (code 906), the alert always sounds.
6.5 Maternal Oximetry

FM830E can measure the mother’s blood oxygen saturation and pulse rate. An alarm sounds if the mother’s oxygen saturation drops below a certain level, or if her pulse rate goes above or below certain limits. If monitoring Maternal ECG, the MECG heart rate overrides the pulse rate from the oximeter.

Caution

1 Use only maternal oximetry sensors which have been manufactured and licensed by the manufacturer. Always follow the instructions for use supplied with the maternal oximetry sensor.
2 The maternal oximetry sensor will not give accurate results if the mother is wearing nail varnish.
3 Nail varnish remover contains acetone. Contact with acetone will damage the maternal oximetry sensor.

Do not use the maternal oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could cause burns. The oximeter may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
Procedure
1 Connect the maternal oximetry sensor to the maternal oximetry cable.

2 Connect the oximetry cable to the FM800E connector module. Ensure that the connector key on the oximeter lead is correctly aligned with the MSpO2 socket keyway on the FM800E connector module. Push the connector straight in until it locks. Do not twist.

3 Attach the sensor to the mother. See the instructions supplied with the sensor.

4 The ‘searching’ symbol appears while the sensor looks for an oximetry signal.

5 When it finds a signal, the ‘searching’ symbol disappears, and is replaced by the ‘pulse amplitude’ and ‘signal quality’ symbols.

6 Reset the alarm limits and alarm volume, if necessary. See Chapter 8.

7 To obtain an audible pulse tone, press Channel Select until the Audio symbol appears by the MSpO2 display.

8 Start monitoring. Check the pulse tone volume, if Audio is selected.

Note: if FM800E does not display the ‘Searching’ symbol in step 4, make sure the oximetry sensor is connected to the oximetry module.

Guide to MSpO2 symbols

- Searching
- Pulse Amplitude
- Signal Quality: good
- Signal Quality: poor
Start and stop monitoring
To start monitoring, in the MSpO₂ SETUP screen: > START. After about 5 seconds, the mother’s blood oxygen level appears in the MSpO₂ section of the display, with a pulse amplitude indicator. If not monitoring Maternal ECG, the mother’s pulse rate also appears.

If Audio has been selected for MSpO₂, the pulse beat is indicated by an audible ‘pulse tone’, which sounds with each beat of the mother’s pulse.

Disconnecting the oximetry sensor
To disconnect the oximetry sensor, grip the outer part of the connector and pull to release the locking catches.

Caution
Do not try to disconnect the oximetry module by pulling on the lead. This will be unsuccessful, and the connector module may be damaged.
7 Events and Alarms

7.1 What is meant by an alarm?
During most monitoring sessions things occur which are to some extent unexpected or outside normal routine. These are referred to collectively as alarms, even though many of them are not in the least alarming. They include:

- Signal going outside the normal range
- Loss of signal
- Elapsed time counter
- Failure of the FM800E unit

Of these, the first requires the attention of a midwife or doctor. The signal going outside the normal range is sometimes cause for concern, and sometimes not.

Other so-called alarms are unlikely to be cause for alarm at all.

7.2 What is seen and heard?

Audible indicators
FM800E has five different beep tones. These indicate:

- Fetal alarms (highest tone)
- Maternal alarms
- Key presses, general warnings, fetal event by marker button or Actogram
- Fetal pulse rate from FECG
- Maternal pulse rate from MECG or MSpO₂ (lowest tone)

Printed Indicators
- Fetal alarms
- Maternal alarms
**Visual indicators**

<table>
<thead>
<tr>
<th>Type of alarm</th>
<th>What is seen and heard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal outside range</td>
<td>The alarm beeps sound and the ALARM ACKNOWLEDGE key becomes active. The value which is out of range, and the arrow adjacent to the ALARM ACKNOWLEDGE message, flash alternately. Triggered alarm condition printed when printer running.</td>
</tr>
<tr>
<td>Signal loss, Ultrasound/FECG</td>
<td>The alarm beeps sound and the ALARM ACKNOWLEDGE key becomes active. The ‘lost parameter’, and the arrow adjacent to the ALARM ACKNOWLEDGE message, flash alternately.</td>
</tr>
<tr>
<td>Signal loss, contractions/MECG</td>
<td>The Heart symbol flashes. The sensor lifted signal may appear if this is the cause of the signal loss.</td>
</tr>
<tr>
<td>Signal loss, oximetry</td>
<td>No NBP value</td>
</tr>
<tr>
<td>Signal loss, blood pressure</td>
<td>An alarm beeps 5 times, and a message explains why (eg ‘movement’, ‘air leak’)</td>
</tr>
<tr>
<td>Coincidence alarms (see section 5.6)</td>
<td>A single warning beep and the message: ‘CHECK TRACE FOR SAME HEARTRATE’</td>
</tr>
<tr>
<td>Fetal events</td>
<td>Triangular marker at the top of the FHR trace</td>
</tr>
<tr>
<td>Clinical events</td>
<td>✴ printed on FHR trace, with space for manual annotation</td>
</tr>
<tr>
<td></td>
<td>OR Clinical event notes above the FHR trace</td>
</tr>
<tr>
<td>Timer</td>
<td>Message:</td>
</tr>
<tr>
<td></td>
<td>• Alarm Acknowledge</td>
</tr>
<tr>
<td></td>
<td>▲ TIMER FINISHED</td>
</tr>
<tr>
<td>FM800E failure</td>
<td>EITHER a blank screen</td>
</tr>
<tr>
<td></td>
<td>OR an error message</td>
</tr>
</tbody>
</table>
### 7.3 Responding to alarms

<table>
<thead>
<tr>
<th>Type of alarm</th>
<th>Recommended user response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal outside range</td>
<td>Acknowledge alarm</td>
</tr>
<tr>
<td></td>
<td>Doctor or midwife to decide what action to take</td>
</tr>
<tr>
<td>Loss of signal</td>
<td>Acknowledge alarm, if appropriate</td>
</tr>
<tr>
<td></td>
<td>For FHR: reposition the transducer</td>
</tr>
<tr>
<td></td>
<td>For other parameters: check transducer attachment and connections</td>
</tr>
<tr>
<td>Timer</td>
<td>Depends on why the timer was set in the first place</td>
</tr>
<tr>
<td>FM800E failure</td>
<td>1 Stop monitoring.</td>
</tr>
<tr>
<td></td>
<td>2 Remove transducers from mother.</td>
</tr>
<tr>
<td></td>
<td>3 If there is an error message, make an exact note of what it says.</td>
</tr>
<tr>
<td></td>
<td>4 Return FM800E to Huntleigh Healthcare Ltd or their local representative.</td>
</tr>
</tbody>
</table>

**Acknowledging alarms**

To acknowledge an alarm: > ALARM ACKNOWLEDGE in the main screen. This turns off the audible alarm and resets the counters on which the calculation of alarm states is based. The visual indication continues – i.e. the value which is out of range continues to flash. When printing, an ALARM ACKNOWLEDGE will be printed.

If more than one alarm has been triggered, ALARM ACKNOWLEDGE turns them all off.
7.4 Controlling alarms

There are four ways of controlling alarms:

- Acknowledge (i.e. silence) it when it occurs. See Section 7.3.
- Switch it off, so that it is never triggered.
- Alter thresholds so that it occurs more frequently or less frequently.
- Alter the volume of the audio alarm.

Switching alarms off
To switch an alarm off, press the parameter key, then OFF, then EXIT.

Altering alarm thresholds and volume
See Chapter 8.

7.5 Recording fetal movements

The mother can record fetal movements using the fetal event marker. A triangular event mark is printed at the top of the fetal heart rate trace, and FM800E beeps, if the audible beep is switched on.

1. Connect the event marker to the jack socket on the side of FM800E.
2. Give the event marker to the mother. Tell her to press the button every time she feels a fetal movement.

To turn the audible beep off or on
1. > SETUP > SYSTEM SETTINGS > access code (2755).
2. > AUDIO/GRAPHIC > EVENT MARK.
3. > EXIT.
7.6 Actogram

Note: the Actogram feature is not available in the USA and Canada.

Actogram uses the low-frequency content of the signal from the ULT1 ultrasound transducer to detect fetal movements, and give an activity profile of the fetus.

**ACTOGRAM IS NOT INTENDED FOR USE DURING LABOUR.**

Recorded activity represents fetal movements (breathing, limb and trunk movement) or non-fetal movements (transducer movement, maternal coughing or other movement).

The Actogram value can be printed as a line graph on the contractions trace, or as fetal event marks above the trace, or both. An event mark is printed every time the amplitude goes above a set threshold. The default threshold is 40% of full scale deflection, but it can be set to any value in the range 0–99%.

**Data storage (paper-out buffer)**
FM800E does not store the Actogram event marks, activity graph or threshold value.

**Twins**
Note: Actogram should not be used when monitoring twins, as it can confuse fetal movements from twins.
**Actogram graph and event marks**

The following illustration shows Actogram graph and event marks superimposed on the contractions trace.
7.7 Recording clinical events (EasiNotes)

EasiNotes allows clinical events to be recorded as clinical event notes above the fetal heart rate trace. If an attempt is made to record a clinical note when there is not enough room on the trace for one, the FM800E records a clinical event mark instead.

To enter a clinical event note or mark
1. Press the EasiNotes button on the front panel of FM800E.
2. Open a submenu (Drugs, Position, etc).
3. Choose an item from the submenu.
   OR To enter a mark: > MARK.
   [Add a handwritten note to the trace, if required]
4. > EXIT.

To edit EasiNotes
1. > SETUP > SYSTEM SETTINGS > access code (2755).
2. > EasiNotes.
3. Open a submenu (Drugs, Position, etc), then edit the notes using the same text editing procedure as for Patient Details (see Section 3.7).
4. When finished editing: > EXIT.

To restore the default EasiNotes
1. Set the screen display to a language other than the one currently displayed.
   [SETUP > SYSTEM SETTINGS > access code (2755) > INTERNATIONAL > LANGUAGE]
2. Then reset the screen display to the required language.
8 Setting Alarm Thresholds

8.1 Default alarm thresholds

FM800E comes with factory-set alarm thresholds for all parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>High</th>
<th>Low</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULT 1, ULT 2, FECG</td>
<td>160 bpm</td>
<td>110 bpm</td>
<td>Off</td>
</tr>
<tr>
<td>FHR Signal Loss</td>
<td>30 %</td>
<td>None</td>
<td>Off</td>
</tr>
<tr>
<td>MECG</td>
<td>120 bpm</td>
<td>50 bpm</td>
<td>On</td>
</tr>
<tr>
<td>Maternal Blood Pressure, Systolic</td>
<td>160 mmHg</td>
<td>90 mmHg</td>
<td>On</td>
</tr>
<tr>
<td>Maternal Blood Pressure, Diastolic</td>
<td>90 mmHg</td>
<td>50 mmHg</td>
<td>On</td>
</tr>
<tr>
<td>Maternal Oximetry</td>
<td>None</td>
<td>94 %</td>
<td>On</td>
</tr>
</tbody>
</table>

Changing thresholds

If the current thresholds are changed, the changes remain in force until FM800E is switched off. If the default thresholds are changed, the changes remain in force permanently. The screens for changing current and default thresholds are the same. The only difference is the option required to select to access the screen.

To access the current alarm thresholds screen:
   > SETUP
   > CURRENT ALARMS

To restore the default thresholds, switch FM800E off and on again.

To access the default alarm thresholds screen:
   > SETUP
   > DEFAULT ALARMS
   > access code (2755)

Changing FHR thresholds is explained in some detail. The procedure for changing other thresholds is so similar that it is explained much more briefly.
8.2 FHR thresholds (Ultrasound and FECG)

To change the thresholds for FHR (Ultrasound 1, Ultrasound 2 or FECG), press ULT 1, ULT 2 or FECG in the main screen. The FHR SETUP screen appears.

There are three conditions which can trigger an alarm:

High FHR  
FHR rises above a defined level for a defined period.  
Default: 160 bpm for 30 seconds or longer.

Low FHR  
FHR falls below a defined level for a defined period.  
Default: 110 bpm for 10 seconds or longer.

Signal Loss  
More than a given percentage signal loss in a defined period.  
Default: 30% in the last 5 minutes.

For High and Low FHR the defined level and duration can be changed. For Signal Loss the defined percentage can be changed.
High FHR or Low FHR
To change the limit or delay for High or Low FHR, press FHR:

To change the high limit:
> HIGH LIMIT + or HIGH LIMIT –

To change the high delay:
> HIGH DELAY + or HIGH DELAY –

To change the low limit:
> LOW LIMIT + or LOW LIMIT –

To change the low delay:
> LOW DELAY + or LOW DELAY –

When the new alarm levels have been set: > EXIT.

Alarm volume
To change the volume of the audio alarm, use the ALARM VOLUME controls in the FHR SETUP screen:

 Increase volume     Decrease volume

Switching off the High FHR and Low FHR alarm
In the FHR SETUP screen: > OFF.

Note: this does not turn off the Signal Loss alarm.
**Signal Loss alarm**
To change the defined percentage:
1 > SIGNAL LOSS in the FHR SETUP screen.

2 To increase the percentage: > +
   To decrease the percentage: > –

3 > EXIT.

The Signal Loss alarm state ends when a continuous minute of signal has been received since the last alarm, or when the percentage signal loss for the last five minutes has fallen below the alarm threshold.

**Switching off the Signal Loss alarm**
From the FHR SETUP screen: > SIGNAL LOSS > OFF.

**FHR alarms and Signal Loss**
It may happen that the FHR goes beyond the FHR threshold, and then into signal loss, and that the next rate received is again beyond the FHR threshold.

The episode of signal loss is treated as:
Beyond the threshold if signal loss < 50% of time period
Signal loss if signal loss > 50% of time period

In the first case an alarm is triggered. In the second case an alarm is not triggered.
8.3 Maternal blood pressure thresholds

To change the thresholds for maternal blood pressure:

1. From the main screen: > NBP > ALARMS.
2. To change the Systolic or Diastolic high limit:
   > SYSTOLIC or DIASTOLIC
   > HIGH LIMIT + or HIGH LIMIT —
   To change the Systolic or Diastolic low limit:
   > SYSTOLIC or DIASTOLIC
   > LOW LIMIT + or LOW LIMIT —
3. To change the alarm volume, use the ALARM VOLUME controls:
   
   Increase volume
   Decrease volume
4. To turn the alarm off, in the NBP ALARMS screen: > OFF.
5. To return to the NBP SETUP screen: > EXIT.

8.4 MECG thresholds

To change the thresholds for maternal ECG:

1. From the main screen: > MECG > ALARMS.
2. To change the Bradycardia threshold (low limit):
   > LOW LIMIT + or LOW LIMIT —
   To change the Tachycardia threshold (high limit):
   > HIGH LIMIT + or HIGH LIMIT —
3. To change the alarm volume, use the ALARM VOLUME controls:
   
   Increase volume
   Decrease volume
4. To turn the alarm off: > OFF.
5. To return to the main screen: > EXIT.
8.5 Maternal oximetry threshold

To change the threshold for maternal oximetry:

1. From the main screen: > MSpO₂ > ALARMS.

2. To change the threshold for O₂ SAT:
   > LOW LIMIT + or LOW LIMIT —

3. To change the alarm volume, use the ALARM VOLUME controls:
   ![Increase volume] ![Decrease volume]

4. To turn the alarm off: > OFF.

5. To return to the main screen: > EXIT.
9 CTG Chart View

9.1 Introduction

FM800E can provide an on-screen trace display, which mimics the paper printout as closely as possible. Switch to this display by pressing > GRAPH, whereupon the screen changes to the format shown below.

[Diagram of CTG chart view]

Actual traces are not shown on the above screen for clarity, but these are “written” at the far right, the screen scrolling from right to left.

9.2 Screen Layout

The current time and date are shown at the top of the screen.

The chart speed is shown in the bottom right hand corner of the screen. This is the same as that selected for the printer (see 4.3); i.e. either 1, 2 or 3 cm/min.

A graticule is displayed, the vertical lines corresponding to one minute of elapsed time. There are two vertical scales. One appears every 12, 6 or 4 minutes (at 1, 2 or 3 cm/min. respectively), and is marked from 60 to 200. This is the heartbeat scale. Each of these is time stamped (23:04 in this example).
The other vertical scale also appears every 12, 6 or 4 minutes, interleaved with the first. This uses just the bottom part of the screen and corresponds to TOCO/MSpO2 in the range 0-100%.

There is a position indicator at the bottom of the screen that gives a visual indication of whereabouts the scrolling “window” is in relation to the overall trace. The white marker reduces in width as the trace length increases, reflecting the proportion of the total trace shown on the screen.

### 9.3 Button Functions

The functions of the buttons are as follows:

<table>
<thead>
<tr>
<th>Button No.</th>
<th>Graphic</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image" alt="ULT1 UL2" /></td>
<td>Press repeatedly to select an input source (transducer). The current selection is shown reversed (ULT2 in this case).</td>
</tr>
<tr>
<td>2</td>
<td><img src="image" alt="square block" /></td>
<td>The square block adjacent to this button changes colour to match the source selected above. Press this button to toggle the source on/off. If a source is off, it is shown above with a line through it, the block changes to a box outline, and the trace is not displayed.</td>
</tr>
<tr>
<td>3</td>
<td><img src="image" alt="scroll forward" /></td>
<td>Use this button to scroll forward through the trace. This button does not appear until the trace has filled at least one full screen.</td>
</tr>
<tr>
<td>4</td>
<td><img src="image" alt="scroll backward" /></td>
<td>This button skips to the beginning of the trace – i.e. the start of recording.</td>
</tr>
<tr>
<td>6</td>
<td><img src="image" alt="exit" /></td>
<td>Returns to the main monitor screen.</td>
</tr>
<tr>
<td>7</td>
<td><img src="image" alt="clear trace" /></td>
<td>Clears the trace buffer. Recording starts anew.</td>
</tr>
<tr>
<td>8</td>
<td><img src="image" alt="play" /></td>
<td>Use this button to scroll backward through the trace. This button does not appear if the screen is already at the beginning of the trace.</td>
</tr>
<tr>
<td>9</td>
<td><img src="image" alt="home" /></td>
<td>This button skips to the end of the trace – i.e. where the latest trace information is written.</td>
</tr>
</tbody>
</table>

Note: Buttons 5 and 10 are not normally used, apart from when an alarm event occurs; button 5 is used to cancel it.
9.4 Trace Buffer

The trace buffer is the internal memory where the trace information is stored. The length of the buffer is such that it can store:

- 24 hours of data at 3cm/min.
- 36 hours at 2cm/min.
- 72 hours at 1cm/min.

Beyond this, the oldest data is discarded and the buffer then retains the previous 24, 36 or 72 hours of trace information.

**IMPORTANT**

The information stored in the trace buffer cannot be extracted or printed.

The trace buffer is cleared if the unit is turned off, or in the event of a power failure. Any trace information stored will be lost.
10 SonicaidTrend Intrapartum Analysis

10.1 Introduction

SonicaidTrend intrapartum analysis is a software option available with all FM800E series monitors. It measures fetal heart rate parameters at regular intervals, and describes the trace in a way that is quantitative and not qualitative. The analysis is not intended as a replacement for skilled visual interpretation of the trace, but it does help long-term changes in the fetal heart rate pattern to be assessed.

Caution: the analysis is valid only during the first stage of labour.

No guidelines on interpretation or limits of normality are provided, but the clinician can use the numeric values to identify and quantify the relative changes in fetal heart rate parameters over a period of time.

Numerical description of the trace allows direct comparison between traces. It also provides training support for trace interpretation, and readily available data for clinical research projects.

IMPORTANT

SonicaidTrend analysis describes the fetal heart rate on the CTG (CST) record. Interpretation and diagnosis of the record remain the responsibility of the appropriately qualified medical staff.

Note: Sonicaid Trend analysis is not approved for sale in the USA and Canada.
10.2 Sonicaid Trend analysis

Analysis is performed at 15 minutes, and every 15 minutes thereafter. The analysis fits a baseline using the last 60 minutes of fetal heart rate data collected, then calculates the following parameters:

- Baseline heart rate (bpm) for the last 60 minutes
- Baseline heart rate (bpm) for the last 15 minutes
- Short-term variation (msecs) for the last 60 minutes
- Deceleration size (beats) for the last 60 minutes
- Deceleration size (beats) for the last 15 minutes

**Note**: a choice is available as to whether results for the deceleration size parameter are shown or hidden.

**Confidence indicator**

The analysis provides a confidence indicator showing the reliability of the baseline fit, and hence the fetal heart rate parameters. Confidence is shown as High, Medium or Low (H, M or L).

If the confidence indicator is Medium or High, the analysis results reliably reflect the fetal heart rate pattern. If the confidence indicator is Low, interpret the results in relation to the appearance of the trace. Use them only if they are considered to be a sensible reflection of the visually assessed pattern.
10.3 Using SonicaidTrend analysis

Turning SonicaidTrend analysis on
By default, SonicaidTrend analysis is turned off.

To turn it on:
> SETUP
> INTRAPARTUM ANALYSIS
> ANALYSIS ON.

Starting SonicaidTrend analysis

1. Turn the analysis on.
2. Set up FM800E to record a normal CTG (NST).
3. Start printing.

Note: when SonicaidTrend analysis is running, the display shows an I in the lower right corner, together with a confidence indicator (see previous page) for each channel.

Stopping SonicaidTrend analysis

Press the printer on/off button to stop the printer.

Deceleration size parameter

To print and display deceleration size:
> SETUP
> INTRAPARTUM ANALYSIS
> DECELERATION PRINTING IS OFF
10.4 Sonicaid Trend analysis results

Printed results
The parameter values and confidence indicator are printed on the contractions section of the trace. A key to the parameters is printed on the trace header, and again three minutes before the end of each 60-minute period.

60-minute values are available after the first hour. Until then the results show ‘NA’.

Signal loss
If signal loss is > 50%, the results show ‘SL’.

Displayed results
To display results:
> SETUP
> INTRAPARTUM ANALYSIS
> RESULTS (for ULT1, ULT2 or FECG)

To return to the main screen:
> EXIT

10.5 Viewing trend data
To see a trend of the analysis results for up to the last four hours:
> SETUP
> INTRAPARTUM ANALYSIS
> ULT1 TREND (or ULT2 TREND or FECG TREND)

To return to the main screen:
> EXIT
11 SonicaidCare Antepartum Analysis

11.1 Intended use

The intended use of Sonicaid Care analysis is to analyse antepartum CTGs (NSTs) in pregnancies from 26 weeks gestation onwards. It can be used on women who are experiencing Braxton-Hicks contractions, but it is not intended for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, and epidural anaesthesia.

The analysis provided by the Sonicaid Care is intended to assist, not to replace, the physician's visual assessment of a trace. As such, Sonicaid Care is not a diagnosis, but an aid to clinical management. Diagnosis remains the responsibility of an appropriately qualified physician. Indeed, both the physician's visual assessment of the trace and the analysis provided by Sonicaid Care should be considered within the context of a full clinical assessment before decisions are made regarding management. Such a clinical assessment may include further tests such as umbilical blood flow velocity waveforms or biophysical profiling.

Note: Sonicaid Care analysis is not approved for sale in the USA and Canada.

11.2 Overview

SonicaidCare antepartum analysis is a software option available with all FM800E series monitors. The software tests fetal heart rate parameters against the criteria which define a normal record. Abnormalities are highlighted.

IMPORTANT

The analysis describes fetal heart rate, toco and fetal movements. Interpretation and diagnosis of the CTG (NST) record remain the responsibility of the appropriately qualified medical staff.

The analysis is valid for admission testing, but is not valid during labour.
11.3 The Dawes/Redman criteria

- An episode of high variation, above the first centile for gestational age.
- No decelerations > 20 lost beats (> 100 lost beats on records longer than 30 minutes).
- Basal heart rate between 116 and 160 bpm, though a slightly lower or higher rate may be acceptable after 30 minutes, if all other parameters are normal. An asterisk on the analysis results shows that the fetal heart rate is low or high, but that in the context of the rest of the record, it is acceptable.
- At least one fetal movement or three accelerations.
- No evidence of a sinusoidal fetal heart rate rhythm.
- Short-term variation should be 3 ms or greater.
- Either an acceleration
  - Or variability in high episodes > the tenth centile and fetal movements > 20.
- No errors or decelerations at the end of the record.

11.4 Care analysis

Analysis is performed at 10 minutes, and every 2 minutes thereafter up to a maximum of 60 minutes. The analysis fits a baseline to the fetal heart rate data collected so far, and from this measures accelerations and decelerations. Short-term variation is calculated, and episodes of high and low variation looked for.

The system then compares the calculated results with the Dawes/Redman criteria. If the record appears normal, the message CRITERIA MET appears, and FM800E gives a single beep. Otherwise, CRITERIA NOT MET is shown.

The analysis can be stopped once the criteria have been met. FM800E produces a report of the analysis results at the end of the trace. Abnormalities are highlighted. If the analysis is not stopped, it is possible for the results to change to CRITERIA NOT MET. As more data is received, a subsequent analysis may re-fit the baseline so that, for example, an episode of high variation is no longer above the first centile.

If monitoring is not stopped before 10 minutes, the first analysis is not performed. After 60 minutes, the analysis stops, even if monitoring is continued. The results printed will be those from the final analysis at 60 minutes.
Event marks for twins
SonicaidCare analysis does not take account of fetal movements when analysing twins.

Alarms
During analysis the Signal Loss alarm is fixed at 30%. In addition, there is a fixed Toco alarm that alerts the user to a constant Toco value for 10 minutes. Once this alarm has been acknowledged, it will not re-alarm during the same analysis.

Fetal ECG
Since the analysis is not valid during labour, it does not run on the FECG channel.

Note: The analysis will not run, or will be abandoned, if an FECG probe is connected.

11.5 Using SonicaidCare analysis

Starting SonicaidCare analysis
1 Set up FM800E as for recording a normal CTG (NST).
2 Enter the gestational age
   [ > SETUP > ANTEPARTUM ANALYSIS > GESTATION ]
   Or enter the gestational age first:
   [ > SETUP > PATIENT DETAILS > GESTATION ]
3 Start printing.

Note: when SonicaidCare analysis is running, the display shows an A in the lower right corner, together with the status for each channel being analysed and an elapsed time indicator. Status indicators are:

✓ Criteria met
x Criteria not met
N Not applicable (i.e. no results yet)

Checking the progress of SonicaidCare analysis
To check the key results, after the first analysis:
> SETUP
> ANTEPARTUM ANALYSIS
> ULT 1 RESULTS (or ULT2 RESULTS)

FM800E shows the last calculated values for short term variation, number of minutes of high variation and basal heart rate. An asterisk beside a figure indicates an abnormal result. See Abnormalities, in Section 11.6.
Stopping SonicaidCare analysis
Stop printing. FM800E prints the analysis results.

Turning SonicaidCare analysis off
> SETUP
> ANTEPARTUM ANALYSIS
> ANALYSIS OFF

The analysis also defaults to OFF when FM800E is switched off, then on again.

11.6 SonicaidCare analysis report

When the analysis is stopped, the printer produces a report of the analysis results at the end of the trace. The report shows:

- Values for the calculated parameters
- When the Dawes/Redman criteria were first met
- Whether the Dawes/Redman criteria were met at the time the analysis was stopped
- Abnormalities

Reasons for not meeting the criteria
If the criteria were not met when the analysis was stopped, the reasons are given as coded numbers alongside the CRITERIA NOT MET message:

<table>
<thead>
<tr>
<th>Code</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Basal heart rate outside normal range</td>
</tr>
<tr>
<td>2</td>
<td>Large decelerations</td>
</tr>
<tr>
<td>3</td>
<td>No episodes of high variation</td>
</tr>
<tr>
<td>4</td>
<td>No movements and fewer than 3 accelerations</td>
</tr>
<tr>
<td>5</td>
<td>Baseline fitting is uncertain</td>
</tr>
<tr>
<td>6</td>
<td>Short-term variation is less than 3ms</td>
</tr>
<tr>
<td>7</td>
<td>Possible error at the end of the record</td>
</tr>
<tr>
<td>8</td>
<td>Deceleration at the end of the record</td>
</tr>
<tr>
<td>9</td>
<td>High-frequency sinusoidal rhythm</td>
</tr>
<tr>
<td>10</td>
<td>Suspected sinusoidal rhythm</td>
</tr>
<tr>
<td>11</td>
<td>Long-term variation in high episodes below acceptable level</td>
</tr>
<tr>
<td>12</td>
<td>No accelerations</td>
</tr>
</tbody>
</table>
Abnormalities

Double asterisks indicate one of the following conditions:
- Fetal heart rate < 116 bpm or > 160 bpm on a record of less than 30 minutes
- Decelerations > 100 lost beats (> 20 lost beats on record of less than 30 minutes)
- No moves and fewer than 3 accelerations
- No episodes of high variation
- Short-term variation < 3ms
- No accelerations and
  - either < 21 movements per hour
  - or long-term variation in episodes of high variation below the tenth centile
- Long-term variation in episodes of high variation below the first centile

A single asterisk indicates one of the following conditions:
- Short term variation < 4 ms, but ≥ 3ms
- Basal heart rate < 116 bpm or > 160 bpm on a record ≥ 30 minutes
- Decelerations present, but not meeting the criteria for size or record length

A single asterisk does not necessarily mean that the record cannot pass the criteria. If all other parameters are normal at the 30-minute point, the abnormality could be considered to be within acceptable limits to meet the analysis criteria.

Basal heart rate warnings

A basal heart rate of 115 bpm or lower triggers a printed warning:

WARNING: LOW BASAL FHR
CHECK THAT FHR DOES NOT CONTINUE TO FALL
FETAL MOVEMENTS PRESENT? SINUSOIDAL RHYTHM?
12 Using FM800E with a PC System

The FM800E can be connected to the following PC-based Central Monitoring Systems:
- Sonicaid FetalCare analysis and replay system
- Sonicaid Centrale
- Hewlett Packard/Agilent/Philips TraceVue central review

12.1 Using FM800E with FetalCare

Connecting FM800E to FetalCare

1. Connect the Sonicaid FetalCare connecting lead to the RS232 connector on the rear of FM800E. See Section 1.4.
2. Connect the lead to the COM1 port on the rear of the Sonicaid FetalCare.
3. Make sure the FM800E has the Sonicaid interface enabled. See Section 4.6.

Note: for full details of PC connections, and instructions for using the system, see the Sonicaid FetalCare User Guide Operating Handbook.

Setting up FM800E for use with FetalCare

1. > SETUP > SYSTEM SETTINGS > access code (2755).
2. > SERIAL INTERFACE.
3. Make sure the RS232 button says ‘Sonicaid’. If it says ‘HP’, then press it to change to ‘Sonicaid’.
4. > EXIT.
5. Switch off FM800E. Wait for about 10 seconds.
6. Switch FM800E on again.
12.2 Using FM800E with Sonicaid Centrale, Philips TraceVue™

Connecting FM800E to Sonicaid Centrale or Philips TraceVue™

There are a number of ways in which FM800E may be connected to Sonicaid Centrale or other CMS’s such as TraceVue. Some of the combinations are described below but the list is not exhaustive. For other ways of connecting consult the central monitoring system administrator.

1 Directly - using RS232

Connect an RS232 lead to the RS232 CRS connector on the rear of FM800E. See Section 1.4. Connect the other end of the lead to a spare RS232 input port of the central monitoring system.

2 Directly - using RS422

Connect an RS232 to RS422 conversion lead to the RS232 CRS connector on the rear of FM800E. See Section 1.4. Connect the other end of the lead to a spare RS422 input port of the central monitoring system. If the RS422 adaptor requires power, this should be provided by a medically approved power supply. If in doubt, consult the central review system administrator or electrical safety department.

3 Indirectly - using RS232 and a TraceVue computer with the FM800E

Connect an RS232 lead to the RS232 CRS connector on the rear of FM800E. See Section 1.4. Connect the other end of the lead to an RS232 input port on the TraceVue computer. Make sure the TraceVue computer is connected to the local area network. The computer, and all its peripherals, should be powered via a medical type mains isolating transformer. If in doubt, consult the central review system administrator or electrical safety department.

4 - Indirectly - using LAN

Using the LAN facility to connect to a CRS via a hospital network is covered in an appendix at the rear of this manual.

For full details of PC connections, and instructions for using the system, see the documentation supplied with the central review system.
Setting up FM800E for use with Sonicaid Centrale or Philips TraceVue™

1. > SETUP > SYSTEM SETTINGS > access code (2755).
2. > SERIAL INTERFACE.
3. Make sure the RS232 CRS button says ‘HP’. If ‘Sonicaid’ is displayed, then press the RS232 CRS button to change to ‘HP’.
4. > EXIT.
5. Switch off FM800E. Wait for about 10 seconds.
6. Switch FM800E on again.

If connected to a Philips TraceVue™ system, the FM800E trace can be annotated using the TraceVue™ system. See the documentation supplied with the TraceVue™ system.

Note: Sonicaid Centrale can also support the ‘Sonicaid’ protocol option.
13 Telemetry

Please refer to the manual supplied with the telemetry receiver and transducers before connecting and using the equipment.

For the availability of the operator’s manual for the telemetry unit in other languages, consult:
Rimkus Medizintechnik, Feldkirchenerstrasse 6, D-85599 Parsdorf, Germany

See also Appendix 3 of this manual - “Getting Started with the T800”

Note: Rimkus telemetry is not approved for use with Sonicaid FM800E in the USA or Canada.

13.1 Connecting the telemetry unit

1 Identify the connector of the FM800E-to-telemetry cable labelled “FM800” and plug into the Rimkus connector on FM800E. See Section 1.4.

2 Connect the other end of the FM800E-to-telemetry cable (labelled “T800E”) to the telemetry receiver.

3 Connect the telemetry receiver to the mains power supply.

13.2 Using the telemetry unit

1 Switch on the telemetry unit.

2 Check that the transmitter is fully charged.

3 Examine the mother, and establish the best position for the transducers.

4 Attach the transducers securely to the mother.
14 Troubleshooting

14.1 FHR

No FHR signal displayed

Is FM800E switched on?
Is the FHR transducer connected?

High % signal loss

Check transducer placement.
Is the transducer broken?
Consider switching from Ultrasound to FECG.

No FHR trace printed

Has the Print button been pressed?
Is there paper in the paper tray?
Is the paper tray fully pushed in?

Only one trace (twins) OR
Traces superimposed (twins)

Correct ‘FHR scale for twins’ in Printer setup. See Section 4.3.

No beep when button pressed.

Beep may be turned off. Section 2.2.

Alarm not working

Alarm may be turned off. Section 7.4.

14.2 Oximetry

No signal appears when the oximetry sensor is connected

Check connector jack is properly inserted.
Check connections between connecting cable and sensor.
Check finger properly inserted.
Nail varnish can interfere with readings – try own finger.

Signal disappears after some time of monitoring


14.3 Fetal event marker

No mark appears on the trace when the mother presses the event marker

Is the event marker connected?
Enough time elapsed since button last pressed?

FM800E does not beep when the mother presses the event marker

Is the event marker connected?
Is the beep turned off? See section 7.5.
14.4 Maternal blood pressure error codes

<table>
<thead>
<tr>
<th>Message</th>
<th>Description</th>
<th>User action</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARTEFACT</td>
<td>Irregular pulse or excessive motion.</td>
<td>Make sure patient keeps still during measurement.</td>
</tr>
<tr>
<td>AIR LEAK</td>
<td>Reading terminated because target pressure was not reached within 60 seconds.</td>
<td>The cuff is loose or not connected properly. OR The cuff bladder or hose has a leak. OR The hose is not properly connected to FM800E.</td>
</tr>
<tr>
<td>OVER PRESSURE</td>
<td>Cuff over-pressurised.</td>
<td>Make sure the patient does not press the cuff, or bend her arm too much.</td>
</tr>
<tr>
<td>MALFUNCTION</td>
<td>No reading reported.</td>
<td>Check cuff and hose, then try another measurement. If the problem persists, note the error message, and contact Huntleigh Healthcare Ltd or their representatives.</td>
</tr>
</tbody>
</table>

14.5 Printing

Poor print quality

1. Make sure the correct paper is loaded. FM800E uses Sonicaid paper (part number 8400-8003).
2. Make sure the paper tray is fully pushed in.
3. Try printing again.
4. If there is no improvement, clean the print head. See Section 15.4.

Some NBP measurements are not being printed on the trace

When NBP measurements are taken every 3 minutes, and print speed is set to 1cm/min, there is not room on the paper for every result. Either take measurements every 5 minutes, or increase the print speed.
14.6 What to do next?

If a problem cannot be resolved using this Troubleshooting guide, please contact your Huntleigh Healthcare Ltd representative. You may be asked what software version your FM800E is running.

To find this out:
> SETUP.
> SYSTEM SETTINGS.
> access code (2755).
> SERVICE CENTRE.
> PRODUCT INFORMATION.

<table>
<thead>
<tr>
<th>PRODUCT INFORMATION</th>
<th>EXIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODEL</td>
<td>SONICAID FM830E</td>
</tr>
<tr>
<td>SERIAL NUMBER</td>
<td>751AX0100011-08</td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td>16/05/2008</td>
</tr>
<tr>
<td>VERSION</td>
<td></td>
</tr>
<tr>
<td>SH2-1(D)</td>
<td>2.1.48</td>
</tr>
<tr>
<td>MSP430-E</td>
<td>2.3.14</td>
</tr>
<tr>
<td>Au1100</td>
<td>1.3.11</td>
</tr>
<tr>
<td>EPLD</td>
<td>0.4</td>
</tr>
<tr>
<td>SPB FS</td>
<td>1.2</td>
</tr>
<tr>
<td>SH2-2 (P)</td>
<td>2.1.48</td>
</tr>
<tr>
<td>MSP430-T</td>
<td>2.3.14</td>
</tr>
<tr>
<td>FPGA</td>
<td>rev 15</td>
</tr>
<tr>
<td>SPB</td>
<td>Issue 2</td>
</tr>
</tbody>
</table>

Make a note of the numbers listed for SH2-1, SH2-2, MSP430-E, MSP430-T, AU1100 and EPLD.
15 Cleaning and Maintenance

Always switch off FM800E and disconnect the AC supply cable and transducers before attempting to carry out any cleaning or maintenance.

15.1 The FM800E main unit

Cleaning after use

Wipe the instrument case with a cloth dampened in soap or detergent solution to remove aquasonic gel, blood, saline etc. Wipe dry with a clean cloth.

Do not allow any fluid to enter the unit.
Do not use isopropyl alcohol to clean the FM800E main unit.
Do not expose metal components (e.g. snap connectors) to chemicals.

Sterilising the case

Sterilisation is not normally required.

15.2 Transducers: NBP cuff, maternal oximetry sensor

For cleaning, disinfection, sterilization and maintenance of these items, read the instructions supplied by the transducer manufacturer.
15.3 Transducers and leads: Ultrasound, FECG, MECG, external Toco

Cleaning (Ultrasound, FECG, MECG, and external Toco transducers)

After use, wipe the ultrasound transducers, event marker, fetal ECG electrode leg plate and IUP extension cable with a cloth dampened in soap or detergent solution to remove aquasonic gel, blood, saline etc. Wipe dry with a clean cloth.

Caution: do not expose metal components (eg snap connectors) to chemicals.

Disinfection (Ultrasound, FECG, external Toco transducers, all re-usable leads apart from maternal ECG)

After use, clean the transducers as described above. Then wipe the transducers and leads with an alcohol solution (70% ethanol or isopropanol) in accordance with instructions provided by the disinfectant manufacturer.

Disinfection (maternal ECG lead)

After use, clean the maternal ECG lead as follows:

1. Wipe with a cloth soaked in a solution of chlorine bleach in water (no stronger than 1:10 mixture) or in a 2% Glutaraldehyde solution, such as Cidex.

2. Wipe the lead with a clean damp cloth, then a clean dry cloth.

Care of ultrasound transducers

Ultrasound transducers should be kept dry and preferably below 45°C. Gel must be wiped from the ultrasound transducers after use, and before placing on the storage rack on the side panel.

The following should never be used to clean the transducers: Phenolic, detergent-based disinfectants containing cationic surfactants, ammonia-based compounds, or antiseptic solutions such as Steriscol or Hibiscrub
15.4 User maintenance

The checks below can be performed by any user of the equipment.

Mechanical inspection

Every three months:

1. Inspect the AC supply cable, transducers, and all other assemblies and connectors for loose or broken parts, or any other damage.
2. Pay particular attention to the AC supply socket.
3. Look carefully for cracks which may allow the ingress of liquids or gels.
4. Replace any broken or damaged transducers or cables.
5. If there is damage to the main FM800E unit, contact your local Huntleigh Healthcare Ltd representative.

Cleaning the print head on the printer

1. Pull the paper tray out as far as it will go.
2. Remove the paper pack.
3. Using a lint-free cloth and pure alcohol, wipe along the full width of the print head, which is beneath the plastic edge of the paper compartment.
4. Replace the paper tray and paper pack.

Check NBP cuffs and hose

Once a month:

1. Check the NBP hose. Straighten out any kinks and distortions.
2. Check the cuff(s) for wear and damage.

Check oximetry sensor

Once a month:

Check the oximetry sensor for any signs of wear or damage.
15.5 Technical maintenance

The checks below should be performed by a qualified maintenance engineer in the hospital.

Fuse check and replacement

Every six months:

1. Remove the fuse module using a small screwdriver.
2. Raise the small latch and remove the fuse board for access to the fuses.
3. Check the AC supply fuses are of the correct value:
   
   2.5A(T) for all supply voltages

Note that to maintain compliance with the required standards, fuses must only be replaced with the correct Huntleigh part as described in section 15.8.

Functional check

Every six months:

1. Connect the AC supply, the transducers and the accessories.
2. Switch ON.
3. Check that FM800E can perform the functions described in this Reference Manual.

Check oximetry sensor

Check the sensors every three months:

> SYSTEM SETTINGS.
> SERVICE CENTRE.
> DIAGNOSTICS.

Follow the instructions on screen.
Check NBP pressure

Every twelve months, check NBP pressure:
 > SYSTEM SETTINGS.
 > SERVICE CENTRE.
 > DIAGNOSTICS.
 > NBP CALIBRATION.
 Follow the instructions on screen

15.6 Corrective maintenance

All corrective maintenance must be performed by qualified engineers approved by Huntleigh Healthcare Ltd, Sonicaid Products.

The Sonicaid FM800E Service Manual (order part number 751339) is designed as an aid to engineers in maintenance and service of repairable parts.

15.7 Servicing

Servicing

Servicing should be performed only by Huntleigh Healthcare Ltd or their appointed service agent. If you have difficulty obtaining service for FM800E, contact Huntleigh Healthcare Ltd.
15.8 Accessories, consumables and spares

Please refer to the Accessories & Consumables catalogue included with the monitor for further details of products available for use with the FM800E. The latest issue of this catalogue is available on request from local Huntleigh representatives. Available accessories, consumables and spares include:

Accessories

- Trolley
- Wall Mounting Bracket
- FEGC Connecting Leads
- MECD Connecting Leads
- IUP Catheter Connecting Lead
- Service Manual

Consumables

- Aquasonic Gel (various sizes)
- Sonicaid Printer Paper
- Transducer belts
- Fetal Scalp Electrodes & Leg Plates
- Adult ECG Electrodes
- Disposable IUP Catheter Transducer

Spares

- Ultrasound, Toco and SpO2 Transducers
- NBP Cuff (Various Sizes)
- Patient Event Marker
- ECG Connecting Leads (Various)
- Mains Fuses
16 Specifications

16.1 Physical and environmental

Physical
- Height (all models) 186mm (7.3in)
- Length (all models) 358mm (14.1in)
- Width (FM820E) 363mm (14.3in)
- Width (FM830E) 392mm (15.5in)
- Weight (FM820E) Gross weight 18kg (includes transducers etc) Net weight 15kg
- Weight (FM830E) Gross weight 19kg (includes transducers etc) Net weight 16kg

Recommended operating, storage and transport conditions
- Operating temperature +10°C to +35°C
- Storage/transport temperature –20°C to +50°C
- Operating pressure 68 to 106 kPa (680 to 1060 mB)
- Storage/transport pressure 68 to 106 kPa (680 to 1060 mB)
- Operating humidity 10% to 75% RH, non-condensing
- Storage/transport humidity 10% to 90% RH, non-condensing

16.2 AC supply voltage and fuse values

- Rated AC supply voltage 100–120V, 220–240V, 50–60Hz
- Fuse values T2.5A HBC for all input voltages
- Power rating 100VA
## 16.3 Transducers

### Ultrasound

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>30 to 240 bpm</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 1 bpm over the range 100–180 bpm</td>
</tr>
<tr>
<td>Alarms</td>
<td>High and Low FHR: 30 to 240 bpm</td>
</tr>
<tr>
<td></td>
<td>Signal Loss: % loss in last 5 minutes</td>
</tr>
<tr>
<td>Mode</td>
<td>Directional pulsed Doppler</td>
</tr>
<tr>
<td></td>
<td>Repetition rate 3.0kHz</td>
</tr>
<tr>
<td>Frequency</td>
<td>1.0MHz (green)</td>
</tr>
<tr>
<td>P–</td>
<td>&lt;1MPa</td>
</tr>
<tr>
<td>lob</td>
<td>&lt;20mW/cm²</td>
</tr>
<tr>
<td>Ispta</td>
<td>&lt;100mW/cm²</td>
</tr>
<tr>
<td>Resolution</td>
<td>12 bits</td>
</tr>
<tr>
<td>Safety</td>
<td>Type CF protection</td>
</tr>
</tbody>
</table>

### FECG

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>30 to 240 bpm</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 1 bpm over the range 100–180 bpm</td>
</tr>
<tr>
<td>Alarms</td>
<td>As Ultrasound</td>
</tr>
<tr>
<td>Common mode rejection</td>
<td>Better than 66dB within the signal bandwidth</td>
</tr>
<tr>
<td>Input impedance</td>
<td>10M Ohm</td>
</tr>
<tr>
<td>Input range</td>
<td>30µV to 500µV peak to peak</td>
</tr>
<tr>
<td>DC offset</td>
<td>±2V common mode</td>
</tr>
<tr>
<td></td>
<td>±300mV differential</td>
</tr>
<tr>
<td>Common mode range</td>
<td>±20V @ mains frequency</td>
</tr>
<tr>
<td>Noise</td>
<td>&lt;10µV peak-to-peak referred to input</td>
</tr>
<tr>
<td>Safety</td>
<td>Type CF protection</td>
</tr>
</tbody>
</table>
### Uterine activity (external Toco)
- **Range**: 0–100 relative units
- **Sensitivity**: 100% FSD equivalent to 120g
- **Offset range**: ±100g
- **Auto zero**: Manual and auto zero facility
- **Safety**: Type CF protection

### Uterine activity (internal IUP)
- **Transducers**: Intran Plus (or any pre-calibrated transducer)
- **Pressure range**: 0–100 mmHg/1–15 kPa (user selectable)
- **Sensitivity**: 5µV/V/mmHg
- **Accuracy**: ±5%
- **Safety**: Type CF protection

### Maternal heart rate and ECG
- **Range**: 30–240 bpm
- **Accuracy**: ±1 bpm
- **Alarms**:
  - High and Low Rate: 30–240 bpm
  - Signal Loss
- **Safety**: Type CF protection
**Maternal blood pressure**

Method: Oscillometric

Measurement ranges:
- Systolic: 50–280 mmHg
- Diastolic: 10–260 mmHg
- Pulse: 40–240 bpm

Accuracy: ±2% or 3mmHg, whichever is greater

Modes: Manual or automatic

User-selectable interval in Auto Mode:
- 3, 5, 10, 15, 20, 30, 45, 60, 90 or 120 minutes

Record/display:
- On-screen display and printed record of:
  - Systolic blood pressure
  - Diastolic blood pressure
  - Pulse rate
- Printed record of:
  - Mean arterial pressure

[Note: Mean arterial pressure not shown in the USA or Canada]

Alarms:
- Systolic High: 55–255 mmHg
- Systolic Low: 50–250 mmHg
- Diastolic High: 35–220 mmHg
- Diastolic Low: 30–215 mmHg
- System: air leaks, movement, overpressure etc

Safety:
- Type CF protection
- Hardware and software controls to limit:
  - Inflation (max. 300 mmHg)
  - Measurement time (max. 160 secs)

Standards:
- ANSI/AAMI SP10-1992
Maternal oximetry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor types</td>
<td>BCI (Smiths Industries) 3444 Finger Sensor</td>
</tr>
<tr>
<td></td>
<td>NELLCOR DS100A</td>
</tr>
<tr>
<td>Do not use the oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could cause burns. The oximeter may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.</td>
<td></td>
</tr>
<tr>
<td>Saturation range</td>
<td>0-99% SpO₂</td>
</tr>
<tr>
<td>Saturation accuracy</td>
<td>±1SD of normal distribution, within ranges:</td>
</tr>
<tr>
<td></td>
<td>70–99% ±2 digits</td>
</tr>
<tr>
<td></td>
<td>0–69% unspecified</td>
</tr>
<tr>
<td>Pulse rate range</td>
<td>30-240 bpm</td>
</tr>
<tr>
<td>Pulse rate accuracy</td>
<td>±2 bpm or ±2%, whichever is greater</td>
</tr>
<tr>
<td>Record/display</td>
<td>On-screen display and printed record of:</td>
</tr>
<tr>
<td></td>
<td>Maternal % SpO₂</td>
</tr>
<tr>
<td></td>
<td>Heart rate</td>
</tr>
<tr>
<td>Alarms</td>
<td>High and low saturation: 85-99% SpO₂</td>
</tr>
<tr>
<td></td>
<td>Signal loss: Pulse or ECG</td>
</tr>
</tbody>
</table>
16.4 Controls

Simple functions
Control keys on front panel:
- Power on/off
- Volume up/down
- Audio channel select
- Toco/IUP zero
- Printer on/off
- Printer fast forward
- Clinical event mark

Higher-level functions
10 ‘soft keys’ on the display

16.5 Printer

Print head 128mm thick film
Resolution 8 dots per mm
Printer speeds 1, 2, or 3cm per minute (user selectable)
10 cm per minute fast forward
Paper Plain thermal paper, z-fold, 45m length
FHR scales 30–240 bpm or 50–210 bpm (user selectable)
Annotation
- Hospital name, time, date, paper speed, monitoring modes, signal loss
- Mothers name and ID number (optional)
16.6 Connections

Front panel
ULT1 (all models) 1.0MHz ultrasound transducer
ULT2 (all models) 1.0MHz ultrasound transducer
MECG/FECG (all models) Maternal/fetal ECG lead
TOCO/IUP (all models) Toco transducer/IUP lead
MSpO2 (FM830E) Maternal pulse oximetry
NBP (FM830E) Maternal non-invasive blood pressure

Rear panel, all models
RS232 2, isolated
LAN 1, isolated for CRS
Auxiliary 1, for telemetry system

Interfaces
Telemetry Rinkus Telemetry
System Sonicaid Centrale
Sonicaid Fetalcare
Philips TraceVue™ central review system
External maternal monitors Not available
### 16.7 Display

<table>
<thead>
<tr>
<th>Technology</th>
<th>Full Colour TFT Liquid Crystal Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>11.5cm x 8.6cm (4.5in x 3.4in)</td>
</tr>
<tr>
<td>Resolution</td>
<td>¼ VGA, 320 x 240</td>
</tr>
<tr>
<td>Viewing Angle</td>
<td>&gt;160°</td>
</tr>
</tbody>
</table>

#### Data display

<table>
<thead>
<tr>
<th>Data</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULT1 and ULT2</td>
<td>Fetal heart rate (30–240 bpm)</td>
</tr>
<tr>
<td></td>
<td>Pulse rate lamp and confidence indicator</td>
</tr>
<tr>
<td>FECG</td>
<td>Fetal heart rate (30–240 bpm)</td>
</tr>
<tr>
<td></td>
<td>Pulse rate lamp</td>
</tr>
<tr>
<td>MECG</td>
<td>Maternal heart rate (30–240 bpm)</td>
</tr>
<tr>
<td></td>
<td>Pulse rate lamp</td>
</tr>
<tr>
<td>TOCO</td>
<td>0–100 (relative units)</td>
</tr>
<tr>
<td>IUP</td>
<td>0–100mmHg or 1–15 kPa</td>
</tr>
<tr>
<td>MSpO₂</td>
<td>Oxygen saturation</td>
</tr>
<tr>
<td></td>
<td>Pulse amplitude</td>
</tr>
<tr>
<td></td>
<td>Pulse rate</td>
</tr>
<tr>
<td>NBP</td>
<td>Systolic and diastolic pressures</td>
</tr>
<tr>
<td></td>
<td>Pulse rate</td>
</tr>
<tr>
<td></td>
<td>MAP</td>
</tr>
</tbody>
</table>
16.8 Safety

i) FM800E is designed to comply with:
   EN60601-1 (2005)

ii) FM800E is Class 1 equipment, with protective earth via the AC mains input. FM800E
    must be connected to an earth supply complying with local safety standards. The
    installation engineer must check that the supply voltage falls within the permitted
    range as specified on the supply voltage label.

iii) This equipment is not explosion-proof and must not be used in the presence of
     flammable anaesthetics. It is ordinary equipment (not drip-proof or splash-proof),
     designed for continuous operation.

iv) The equipment must be serviced only by authorised and qualified personnel.
    Huntleigh Healthcare Ltd cannot accept responsibility for safety compliance,
    reliability and performance if modifications or repairs are carried out by unauthorised
    personnel. Identical replacement parts must be used.

v) If there is doubt whether FM800E is operating correctly, when being used on a
    patient, fetal condition must be checked by an alternative diagnostic method without
    delay.

vi) The protective category against electric shock of all patient-applied parts is
    Type CF.

vii) Installation is the responsibility of the vendor via a competent person, approved by
    Huntleigh Healthcare Ltd.

viii) This equipment is not protected against:
     a) the effects of defibrillator shocks or discharge.
     b) the effects of high-frequency currents.
     c) the effects of ‘bistoury’ - either TENS (Transcutaneous Electrical Nerve Stimulation), or
        electro-surgery.
The nature of the parts in direct or indirect contact with the patient is:

- Ultrasound transducers: ABS plastic
- External Toco transducer: ABS plastic with Thermoplastic Elastomer Overmoulding
- Sonicaid FECG electrode: Stainless steel
- Sonicaid FECG electrode lead: Stainless steel, rubber
- Safelinc FECG electrode: Stainless steel
- Intran IUP catheter: Polyurethane plastic
- MSpO2 probe: Biocompatible plastics
- Transducer belts: Latex-free fabric
- ECG leg plate belt: Fabric

All patient contact parts are biocompatible and comply with EN30993-1.

### 16.9 Ultrasound safety considerations

**General**

Diagnostic ultrasound has been in use for over 35 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. However, available data are not wholly conclusive, and the possibility remains that biological effects may be identified in the future.

It is therefore deemed desirable by medical and scientific authorities that exposure to ultrasound be limited to the duration and intensity appropriate for the clinical objective. Because fetal tissue could be more sensitive to biological effects by reason of rapid cell division, it is particularly desirable that ultrasound exposure of pregnant subjects be kept to a minimum.

At present, there is a clear consensus that the benefits to patients of prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present. See:

**Fetal use**
FM800E is designed for continuous fetal heart rate monitoring during pregnancy and labour. Interpretation of fetal heart rate patterns can diagnose fetal and maternal problems and complications.

**Minimising patient exposure**
The acoustic output of FM800E is internally controlled and cannot be varied by the operator. The duration of exposure, however, is fully under the operator's control. The examination techniques we have recommended will help the user to get the maximum amount of diagnostic information with the minimum amount of exposure.

**Acoustic output**
Sonicaid FM800E is exempt from the declaration of acoustic output information in accordance with clause 4 of IEC 1157 (EN 61157). This is because the Maximum Probable Levels (MPL) of the following three parameters are below the limits specified in clause 6, namely:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit</th>
<th>MPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>peak negative pressure</td>
<td>1MPa</td>
<td>25kPa</td>
</tr>
<tr>
<td>output beam intensity (I_{ob})</td>
<td>20mW/cm²</td>
<td>0.5mW/cm²</td>
</tr>
<tr>
<td>spatial-peak temporal-average intensity (I_{spta})</td>
<td>100mW/cm²</td>
<td>3mW/cm²</td>
</tr>
</tbody>
</table>

Power measurements were made by the National Physical Laboratory, Teddington, Middlesex, UK in accordance with NEMA UD-2 (2004).
Appendix 1: External Connections

RS232 interfaces:
9-way D-type sockets, individually isolated to 500V DC.

The FM800E has two RS232 Serial ports for use with external devices as follows:

<table>
<thead>
<tr>
<th>Port</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRS</td>
<td>Interface to Central Review System – e.g. Sonicaid Centrale, FetalCare etc.</td>
</tr>
<tr>
<td>EXT 1</td>
<td>Reserved (Interface to external FSpO2)</td>
</tr>
</tbody>
</table>

Pin Connections:

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal</th>
<th>Input/output</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rx</td>
<td>Input</td>
</tr>
<tr>
<td>2</td>
<td>Tx</td>
<td>Output</td>
</tr>
<tr>
<td>4</td>
<td>Isolated 0V</td>
<td>Reference</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fetal event marker connector
1/4" jack socket.

Pin Connections:

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tip</td>
</tr>
<tr>
<td>2</td>
<td>Ring</td>
</tr>
<tr>
<td>3</td>
<td>Sleeve</td>
</tr>
<tr>
<td></td>
<td>Switch</td>
</tr>
<tr>
<td></td>
<td>Signal ground (via switch)</td>
</tr>
<tr>
<td></td>
<td>Chassis ground, via anti-static network</td>
</tr>
</tbody>
</table>
LAN interface:
The LAN interface is an optional feature. It enables the FM800E to be connected to a Central Reviewing System via standard structured Ethernet cabling over a 10/100Mbits/s link. It thereby allows the distance between the two systems to be greatly increased, and the link can be made via an existing in-house network if required using standard routers and switches.

Before the FM800E can be connected to a network, it must be assigned an IP address which is compatible with the hospital network. Setting up and configuring the network connections is a task requiring some familiarity with network configuration, and knowledge of the installed network. It is recommended that the task is carried out by Huntleigh Service staff.

For those users wishing to carry out the work themselves, documentation is available from the Huntleigh Healthcare Service Department.

To enable the network interface on the FM800E:

> SETUP
> SYSTEM SETTINGS
> access code (2755)
> HOST CRS INTERFACE
> NETWORK HP 50
> EXIT (3 times to return to the main screen)

Switch the power off, wait 30 seconds and switch the unit back on again. The settings only become effective at power up.

Note: With an RS232 link, each bed is associated with a unique port number on the CRS. This means that it is possible to move monitors from bed to bed and the CRS will still correctly link data received with the applicable bed. Using an Ethernet link however, every connection point on the LAN is identical; the CRS cannot associate an individual bed to an individual connection point at the bedside. This means that monitors cannot be moved from bed to bed without reconfiguring the port assignments on the CRS.
Appendix 2: Transducer Problems

The following tests will show whether there is a problem with an Ultrasound transducer. If there is a problem, contact the Service Department of Huntleigh Healthcare Ltd, or their appointed service agent.

**Preliminary**
1. Connect the ultrasound transducer to FM800E.
2. Turn on FM800E.
3. Select the required audio channel.
4. Adjust the volume to the required level.

**System test**
1. Hold the ultrasound transducer in one hand, with the transducer face against the palm.
2. Stroke the back of the hand repeatedly with one finger. See diagrams below. If necessary, use water or gel to obtain good contact between the palm and transducer.
3. Check that the audio output, pulse lamp, heart rate display and printer trace on FM800E are synchronised with the finger movement.
Ultrasound transducer test
The crystal elements in a transducer can be damaged if the transducer is dropped. If one or more crystals have been damaged, this can leave non-receptive areas on the transducer face, reducing the beam coverage.

The positions of the crystals behind the transducer face are shown below:

To check that the individual crystals are working:
1. Squeeze a small amount of Aquasonic gel on to the transducer face over each crystal.
2. Move the gel tube rapidly up and down over each crystal, keeping the tip of the gel tube in contact with the transducer. Check that an audio signal synchronised with the tube movement is obtained.
Appendix 3: Getting Started with T800

Connecting the T800 Wireless Transducer System

1. Ensure the receiver aerial is fitted and securely fastened to the connector on the rear panel.
2. Connect the power cable from a suitable wall socket to the mains connector on the rear panel.
3. Plug the end of the data cable labelled T800E into the 15-way ‘D’ socket on the rear panel.
4. Plug the other end of the cable labelled FM800 into the 15-way ‘D’ socket on the rear panel of the FM800E.
5. Before operating, ensure the transducers are plugged in and fully charged (takes 3 to 4 hours).

Battery Charging (Amber)

Battery Fully Charged (Green)
Monitoring FHR and Uterine Activity

1. Unplug the T800 transducers. The antenna symbol appears on the FM800E display to indicate 'Wireless Transducers in use'.

2. To monitor the FHR, determine fetal lie and position. Apply gel to the transducer face. Position on the abdomen so as to get optimal fetal heart sounds. Secure in position with belt.

3. Make sure FHR is clear, and distinct from the maternal pulse taken from the patient's wrist. FHR signal quality is shown by the flashing heart symbol (see 5.4).

4. Adjust the volume of the fetal heart sounds to the desired level.

5. To monitor uterine activity, position the Toco transducer halfway between the fundus and the umbilicus, and secure with belt.

6. Zero the Toco. Make sure the uterus is relaxed, then press the pink Toco zero button.
During use, the T800 displays the transducer battery life and RF signal quality as indicated below.

- **Transmitter off or out of range (Black)**
- **Ultrasound and Toco transducer battery state – GOOD (Green)**
- **Ultrasound and Toco transducer battery state – LOW (Amber)**
- **Ultrasound and Toco transducer battery state – EMPTY (Red)**
- **Transducer battery low or out of range (Red)**
- **Transducers in range (Green)**
- **Weak RF signal (Amber)**

**On completion of monitoring session**

1. Clean the transducers and return them to the T800 by plugging them into the front panel for charging.
2. Return the FM800 to normal ‘wired’ transducer monitoring by pressing the button adjacent to the X?