Product Information

Acute Fetal/Maternal Intrapartum Monitoring

The sonicaid FM800 Encore range is designed to provide flexible solutions for your fetal monitoring needs today and in the future. A choice of models allows you to select the facilities you require, from standard fetal monitoring capabilities to high-risk fetal and maternal care.

Advanced research and computer modelling techniques have enabled us to produce a fetal monitor with the world’s most accurate acquisition of fetal heart rate.

The sonicaid FM820 Encore offers twin ultrasound and separate ECG channels, allowing fully flexible monitoring of mother and fetus. In addition it also provides external and internal uterine activity monitoring. Automated sonicaid Actogram* and maternally sensed fetal movements also come as standard.

For close monitoring of the mother as well as the fetus, the sonicaid FM830 Encore is a fully integrated system which allows the simultaneous monitoring of maternal ECG, pulse oximetry and blood pressure without the need for additional standalone devices.

Fetal Heart Rate

Ultrasound

Pulsed directional Doppler system operates at 1.0MHz. The multi-crystal design has been optimised for wide angle even coverage. Accurate heart beat detection and rate calculation is provided by advanced ‘locate and track’ algorithms.

Manufactured in high-impact plastics, the transducers are robust and watertight. The ‘Widebeam’ technology allows the transducers to be easily positioned for optimal pick-up.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>30 - 240 bpm</td>
</tr>
<tr>
<td>Accuracy</td>
<td>&lt; ±1 bpm</td>
</tr>
<tr>
<td>Alarms</td>
<td>Tachycardia, Bradycardia, Signal Loss, Tachycardia, Bradycardia, Signal Loss, Tachycardia, Bradycardia, Signal Loss, Tachycardia, Bradycardia, Signal Loss, Tachycardia, Bradycardia, Signal Loss</td>
</tr>
<tr>
<td>Repetition rate</td>
<td>2.994 kHz</td>
</tr>
<tr>
<td>Frequency</td>
<td>1.0MHz</td>
</tr>
<tr>
<td>P-</td>
<td>&lt; 30KPa</td>
</tr>
<tr>
<td>I0b</td>
<td>&lt; 1mW/cm²</td>
</tr>
<tr>
<td>Ispta</td>
<td>&lt; 3mW/cm²</td>
</tr>
<tr>
<td>Resolution</td>
<td>16 bits</td>
</tr>
<tr>
<td>Safety</td>
<td>Type CF protection</td>
</tr>
<tr>
<td>Watertight</td>
<td>IPX7 rating</td>
</tr>
</tbody>
</table>

*Actogram is a registered trademark of CardioMetrics Ltd.
**Direct Fetal ECG**

True beat-to-beat peak detection and rate calculation with a resolution of one millisecond. An impedance check of the electrodes and electrode leads is performed automatically, a warning is given when the integrity of the scalp connection is questionable.

- **Range**: 30 - 240 bpm
- **Accuracy**: < +/- 2bpm
- **Alarms**: Tachycardia, Bradycardia, Poor connection (High/Low impedance), Dual rate detection
- **Display**: FHR values, Line graph, waveform complex
- **Trace**: Line graph, waveform complex
- **Notch filter**: 50 or 60Hz
- **Common mode**: Better than 80db within the signal bandwidth
- **Input impedance**: 10M Ohm
- **Input range**: 30μV - 500μV peak to peak
- **DC offset**: +/- 2V common mode, +/- 300mV differential
- **Common mode range**: +/- 20V @ mains frequency
- **Noise**: < 10μV peak to peak referred to input
- **Safety**: Type CF protection

**Signal Loss**

Automatic measurement of fetal heart rate signal loss on all fetal heart rate channels. Users prompted to reposition transducers when required.

- **CTG Trace**: % loss printed every:
  - 10 minutes @ 1cm/min paper speed
  - 5 minutes @ 2 and 3cm/min paper speed
- **Alarm**: % loss over last 5 minutes

**Fetal Alarms**

Audible and visual notification is provided for all fetal alarms. Power-on default values can be defined for all alarms by the hospital. Alarm limits are user adjustable.

The audible fetal alarm tone used is distinct from other categories of alarm in the monitor, and has an independent volume control.

**Fetal Movements**

Recorded with either the maternally sensed event marker, or automatically using Actogram™. This records the fetal limb and trunk movements by detecting low frequency Doppler signals through the ultrasound transducer.

**Uterine Activity**

**External**

Lightweight, watertight, flat-faced guard ring type tocodynamometer for accuracy and increased patient comfort.

- **Range**: 0-100 relative units
- **Sensitivity**: 100% FSD equivalent to 128g
- **Offset range**: +/- 100g
- **Baseline**: Manual and auto zero facility
- **Safety**: Type CF protection
- **Watertight**: IPX7 rating

**Internal**

An optional lead and single-use transducers are available for the direct measurement of intra-uterine pressure.

- **Transducers**: Intran Plus (or equivalent pre-calibrated transducer)
- **Pressure range**: 0-100 mmHg/0-15 kPa (user selectable)
- **Sensitivity**: 1mmHg
- **Accuracy**: +/- 2%
- **Safety Type**: CF protection
Maternal Heart Rate and ECG

Continuous measurement of maternal heart rate can be made using optional ECG leads.

If ECG is not being monitored the maternal heart rate is determined by the pulse oximeter. If neither ECG nor pulse oximetry is being used, an average pulse rate is determined by the non-invasive blood pressure system.

- **Range**: 30 - 240 bpm
- **Accuracy**: < +/- 1bpm
- **Alarms**: Tachycardia, Bradycardia, Poor connection (High/Low impedance)
- **Display**: FHR values, Line graph, waveform complex
- **Trace**: Line graph, waveform complex

Maternal Non-invasive Blood Pressure

Available on Sonicaid FM8 Encore only

The integrated non-invasive blood pressure system uses the oscillometric method to measure maternal systolic, diastolic and mean arterial pressures. The system can be operated in either manual or automatic modes.

The average maternal pulse rate is determined when maternal ECG or pulse oximetry are not being measured.

- **Method**: Oscillometric
- **Modes**: Manual or automatic
- **Measurement ranges**: Systolic 40 - 260mmHg, Diastolic 40 - 200mmHg, Pulse 30 - 220bpm
- **Accuracy**: +/- 2% or 3mmHg, whichever is greater
- **Auto Mode**: User-selectable interval of 3, 5, 10, 15, 20, 30, 45, 60, 90 and 120 minutes
- **Record/Display**: On screen display and printed record
- **Alarms**: Systolic high and low, Diastolic high and low
- **Safety**: Air leaks, movement, overpressure, Independent hardware and software safety controls to limit maximum inflation (300mmHg) and maximum measurement time (160s)
- **Standards**: ANSI/AAMI SP10-1992

Maternal Oxygen Saturation

Available on Sonicaid FM8 Encore only

The integrated adult pulse oximetry system using BCI™ technology enables measurement of maternal oxygen saturation.

The system can be used with a range of reusable and single patient use BCI™ sensors.

The maternal heart rate is determined when maternal ECG is not being directly measured.

- **Sensor type**: BCI™ 3444 Reusable Comfort-Clip® Oximetry Finger Sensor
- **Saturation range**: 0-99% SpO₂
- **Saturation accuracy**: +/- 1SD of normal distribution, within ranges:
  - 70 – 99% +/- 2
  - 0 – 69% unspecified
- **Pulse rate range**: 30 – 254 bpm
- **Accuracy**: +/- 2 bpm or +/-2% whichever is greater
- **Display**: Maternal %SpO₂ and heart rate
- **Trace**: Maternal %SpO₂ and heart rate printed every five minutes
- **Alerts**: High and low saturation, Pulse signal loss, sensor unplugged
Maternal Alarms

Audible and visual notification is provided for all maternal alarms. Power-on default values can be defined for all alarms by the hospital. Alarm limits are user adjustable.

The audible maternal alarm tone used is distinct from other categories of alarm in the monitor, and has independent volume control.

An alarm off icon is displayed if a maternal alarm is turned off.

Display

The high brightness full colour quarter VGA display provides superior visual performance in a wide range of ambient lighting conditions.

An auto-dimming facility reduces the display brightness in lower lighting conditions.

<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>134° typical</td>
</tr>
</tbody>
</table>

Monitored Data Display

The following data is displayed for each monitoring mode:

- **ULT1/ULT2**
  - Fetal heart rate, 30 - 240 bpm
  - Pulse/Confidence indicator
  - Line graph

- **FECG/MECG**
  - Fetal/maternal heart rate, 30 - 240 bpm
  - Pulse indicator
  - Waveform complex
  - Line graph

- **TOCO**
  - UA, -5 - 100 relative units
  - Line graph

- **IUP**
  - Uterine pressure, 0 - 100mmHg/1 - 15 kPa
  - Line graph

- **MSpO₂**
  - Maternal oxygen saturation %
  - Maternal pulse amplitude
  - Maternal heart rate
  - Line graph

- **MNBP**
  - Maternal systolic and diastolic pressures
  - Measurement mode
  - Time to next measurement
  - Current cuff pressure

Interactive Messages

As well as displaying monitored data and the current date and time, the display is also used to provide interactive text messages to the user regarding clinical alarms and system alerts.
Controls

The basic functions of the monitor are operated by the following dedicated control keys on the front panel:

- Power on/off
- Volume up/down
- Audio channel select
- Toco/IUP zero
- Printer on/off
- Printer fast forward
- EasiNotes clinical annotation

All control keys have a tactile operation for positive feedback and are water resistant for easy cleaning.

Graphical User Interface

Clear separation of fetal and maternal parameters; clearly communicate all important information to clinical staff at a glance.

As well as displaying monitored data, the display is used in conjunction with 10 ‘soft keys’ to set and control monitor functions.

Rapid one-press access is provided to the control settings and alarms for each parameter. Intuitive and easy to learn setup menus allow the monitor to be customised to local requirements.

EasiNotes

The EasiNotes facility provides a quick and accurate method of annotating the CTG. A clinical note is printed on the CTG by simply selecting the required note from lists on the display.

The lists are easily customised by the user to keep them up to date with local protocols and procedures.

Printer

A high resolution thermal array print head is used for high quality accurate printing of monitored data. Paper is quickly and easily loaded into the printer drawer.

The use of plain paper ensures perfect registration of the trace to the graticules, and allows printing of separate FHR scales for twin monitoring.

Appropriate scales, annotation and graticules are printed automatically on plain thermal paper for the mode of use selected.

| Print head | 128mm thick film |
| Resolution | 8 dots per mm |
| Printer speeds | 1, 2, or 3cm/minute (user selectable) |
| Paper | 10 cm/minute fast forward |
| Printer speeds | Plain thermal paper, z-fold |
| FHR scales | 45m length (75 hours @ 1cm/minute) |
| Standard and 25 year ArchiTrace paper available |
| Toco scale height | 30 – 240 bpm or 50 – 210 bpm (user selectable) |
| Automatic annotation | 40mm with 30 - 240 bpm and 33.5mm with 50 - 210 bpm scale |
| Paper speed | Time and date |
| Monitoring modes | Paper speed |
| Fetal heart rate signal loss |
| User annotation | Monitoring modes |
| Hospital name |
| Mother’s name, ID number and gestational age |

Auto Paper-out Store

All monitored data is automatically stored when the printer paper runs out to ensure that valuable data is not lost, and a continuous record is maintained.

When new paper is fitted, the last 10 minutes of stored data can be rapidly printed at 10cm/min. Real time printing is then resumed.
Connections

Front Panel

ULT1 1.0MHz ultrasound transducer
ULT2 1.0MHz ultrasound transducer
FECG/MECG Fetal or Maternal ECG lead
TOCO/IUP Toco transducer or IUP lead

In addition, on the appropriate models:

MSpO2 Maternal pulse oximetry
MNBP Maternal non-invasive blood pressure

Side/Rear Panel

Event marker x 1
RS232 x 2, isolated, for connection to external systems
RJ45 x 1, isolated LAN connection
Auxiliary x 1, for radio telemetry/wireless transducers

Interfaces

Telemetry Rimkus T800 Wireless Transducer System
RS232 sonicaid Centrale central review & archiving system
Obstetrics Management systems from other leading suppliers
sonicaid FetalCare - CTG analysis system
LAN sonicaid Centrale central review & archiving system
Obstetrics Management systems from other leading suppliers

Fetal Heart Rate Analysis*

This objective assessment provides a unique fetal heart rate analysis system, reducing the problems associated with visual interpretation of the CTG, providing consistent decision support and reassurance to clinical staff.

sonicaidCare Antepartum CTG Analysis*

For use in the Antepartum period, and for an admission test, the analysis system measures fetal heart rate parameters and performs a test against criteria for a normal record. The criteria have been developed based upon the analysis of over 48,000 records.

The analysis is initiated after ten minutes monitoring, and every two minutes thereafter. At each analysis the user is advised whether the CTG meets the criteria for a normal record. At the end of the monitoring session, an analysis report is printed and any abnormalities are highlighted.

sonicaidTrend Intrapartum FHR Analysis*

Designed for assessment of the first stage of labour, the FHR analysis system provides on-line measurement of fetal heart rate variability, baseline, and decelerations at regular intervals to assist in identifying and quantifying relative changes over time. The analysis results can be viewed on the display or printed on request.

Telemetry/Wireless Transducer (Option)*

The sonicaid FM800 Encore range is compatible with the Rimkus T600 series radio telemetry and Rimkus T800 wireless transducers systems. This provides the labouring patient the freedom and convenience of mobility, whilst also allowing continuous monitoring of ultrasound and Toco.

The Rimkus T800 is also an appropriate solution for continuous safe low voltage monitoring in water using its watertight transducers.
Performance and Safety Standards

The sonicaid FM800 Encore range conforms to the European Council Directive 93/42/EEC concerning medical devices and the following:
- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-4
- IEC 60601-2-25
- IEC 60601-2-27
- IEC 60601-2-30
- IEC 60601-2-37
- IEC 60601-2-49
- UL 60601-1
- ISO 9919
- Nema UD2
- ANSI/AAMI SP10 (FM830 only)

Power

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply voltage</td>
<td>90 – 264V auto-sensing</td>
</tr>
<tr>
<td>Supply frequency</td>
<td>50 – 60Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>100VA</td>
</tr>
</tbody>
</table>

Environmental

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating temp.</td>
<td>+10°C - +35°C</td>
</tr>
<tr>
<td>Storage temp.</td>
<td>-20°C - +50°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10 - 90%, non-condensing</td>
</tr>
</tbody>
</table>

Physical

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>18.6 cm (7.3 in)</td>
</tr>
<tr>
<td>Width</td>
<td>35.3 cm (13.9 in) FM820</td>
</tr>
<tr>
<td></td>
<td>38.2 cm (15.1 in) FM830</td>
</tr>
<tr>
<td>Length</td>
<td>35.8 cm (14.1 in)</td>
</tr>
<tr>
<td>Weight</td>
<td>9.5 kg (21 lbs) max</td>
</tr>
</tbody>
</table>

Service and Warranty

The sonicaid FM800 Encore monitor, excluding transducers and sensors is covered by a comprehensive 2 years parts and labour warranty. A worldwide network of field engineers and support organisations provide first class service, to ensure total support for the lifetime of our equipment leaving you to the real business of patient care.

Accessories

The following accessories are included with all monitors in the sonicaid FM800 Encore range:
- 2 x 1.0MHz ultrasound transducers
- Fetal ECG lead (Non touch-proof*, Safelinc, Eziplug*, Philips and Qwik Connect available)
- Toco transducer
- Fetal movement event marker
- 6 x transducer belts
- 2 x FECG attachment belts/pads
- 250ml (8oz) ultrasound gel
- 2 x printer paper
- User handbook
- Getting started card
- Mains lead
Maternal Monitoring Accessories

**sonicaid FM830 Encore** only
- NBP air line
- NBP cuff, adult
- Adult SpO\textsubscript{2} patient lead
- BCI™ 3444 Reusable Comfort-Clip\textsuperscript{®} Oximetry Finger Sensor

**Options**

The following optional items are available for the **sonicaid FM800 Encore** range:
- IUP connection lead
- IUP single patient use transducer
- IUP kit (connection lead and 10 x IUP transducers)
- Maternal ECG lead
- Maternal ECG skin electrodes
- NBP cuff, small adult
- NBP cuff, large adult
- Trolley/Cart
- Wall-mounting kit
- Un-interruptible Power Supply
- Rimkus Telemetry
- Rimkus Wireless Transducers

* Not available for sale in USA and Canada