# Philips FM-2 Portable Antepartum Fetal Monitor

## Features

- Lightweight and portable, with carrying handle.

- Easy to read display for viewing of FHR and Toco traces and numerics.

- On-screen scrolling for viewing stored fetal traces.

- 15 BPM separated grid lines for easy viewing of fetal heart rate accelerations for NST assessment.

- Twins ultrasound monitoring capability.

- Configurable audible and flashing fetal heart rate alarms.

- Uses watertight transducers compatible with entire Series 50 range of fetal monitors.

- Event marker for easy documentation of events and kick counts.

- 12-hours memory for fetal traces.

- Internal battery power or AC power from external power supply.

- 6-hours (approx.) battery back-up operation, rechargeable during normal monitoring.

- Download capability to transmit traces stored in its memory to a PC or a Philips OB **TraceVue** surveillance and alerting system.

- Online transmission to a monitoring system such as OB **TraceVue**.

- Easily connects to off-the-shelf printer for documentation.

## Description

FM-2 is a fetal monitor for non invasively measuring, and showing maternal uterine contractions and the fetal heart rate as a graphic display, and optionally on a strip chart recorder, printer or OB **TraceVue** system. The data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy non-stress test (NST).

This portable fetal monitor offers a solution for antepartum screening in the private doctor's office, outpatient clinics, and for remote applications such as traveling nurses visiting patient's homes, or for clinics in rural areas seeking remote consultation.

It is intended for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home or during transport under the direction of a licensed practitioner.

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## Alerting

The FHR alarming has configurable upper, lower and delay time alarm limits. Enabled alerts are both visible and audible. Alerting can be switched off.

## Transducers

It uses the same transducers originally designed for high acuity care settings. Reliable, durable, water tight, and easy to clean they interface to all Series 50 fetal monitors.

## Chart-Ready Documentation Using a Printer

Connects to an HP DeskJet printer, using standard printer paper. This gives an economical, chart-ready printout that can be stored in the patient record. It can be faxed easily for remote consultations. See the Printer Specifications for a list of supported printers.

## Interface to OB TraceVue Surveillance and Alerting System

The monitor can transmit patient data via a modem to an OB **TraceVue** system. It can also connect directly to an OB **TraceVue** system for realtime, online monitoring.

## Traditional Documentation Using the Recorder

You can share the optional external recorder between several FM-2 monitors, to document stored fetal traces as traditional paper documentation. Also, the recorder has a real-time fetal trace output when connected continuously to the FM-2 monitor.

## Monitor Connectors and Interfaces

- RS232 serial port (9pin male) for modem, PC, cellular phone.
- Standard parallel printer port for connecting printer or recorder.
- Connector for remote event marker cable.
- 3 transducer sockets (2 US, 1 Toco).
- Power inlet for power supply.

## Self Test

The monitor automatically performs a self test when the power is switched on.
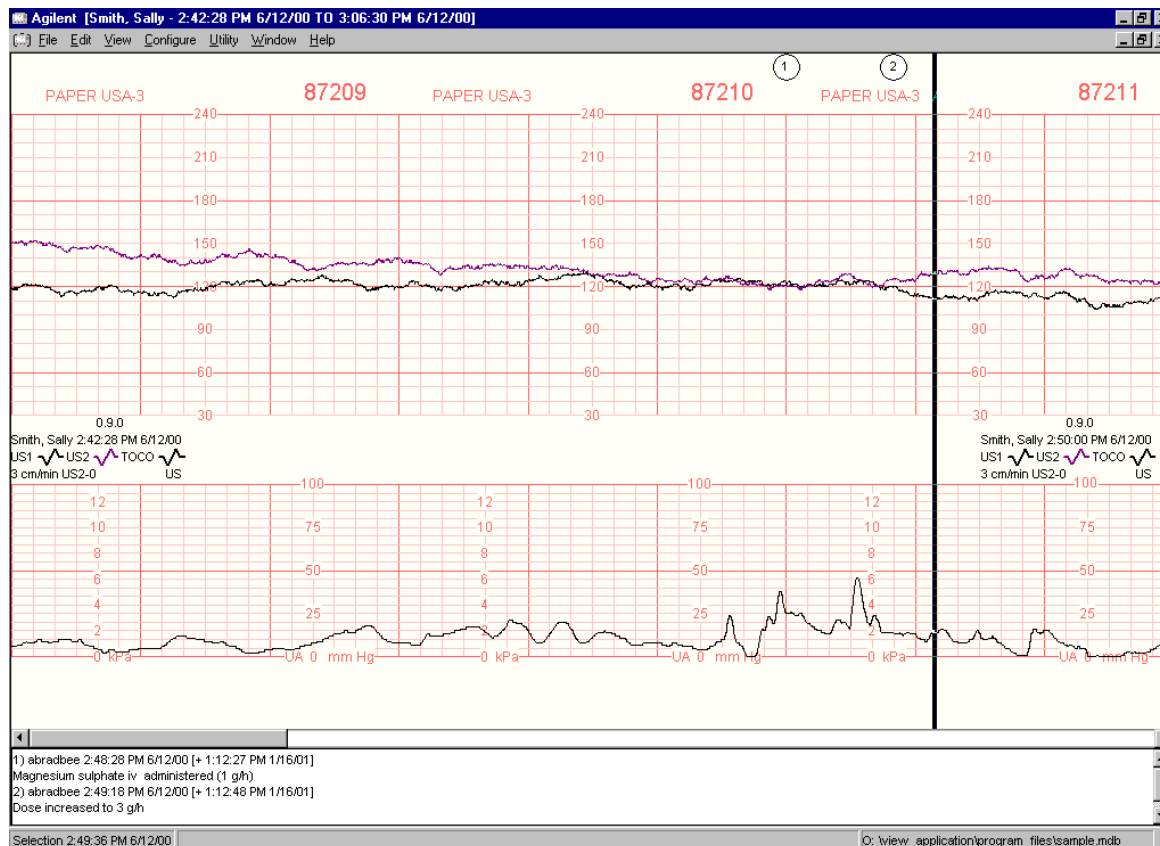
## Mounting

The monitor can be mounted on a wallstand or a rollstand.

## Interface to PC

FM-2 viewer is an optional, customer installable, PC software utility running on an IBM-compatible PC. See the FM-2 Viewer Specifications for system requirements.

It acts as a receiver and electronic storage medium. It accepts fetal traces downloaded from the monitor, either directly, or via a modem. It also offers the possibility to browse, annotate and print complete, or partial patient records. Data can be stored electronically on the PC or other storage media.



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## Monitoring Accessories

### Standard Accessories and Supplies

These are included with the monitor

- 1 x Doppler Ultrasound FHR Transducer-M1356A[1]

- 1 x External TOCO Transducer - M1355A

- 1 x Remote Event Marker - 15249A

- 2 x Reusable Abdominal Belts - M1562A

- 1 pack of three transducer knob adapters - M1356-43203

- 1x 250ml ultrasound gel

- User's Guide

- Pocket Guide to Fetal Monitoring and Assessment by Susan Martin Tucker (English language shipments only). ISBN 0-323-00884-4, 4th edition

- Service Guide

### Additional Supplies and Accessories

These are not included with the monitor, but can be purchased separately.

- M1356A - Second Doppler Ultrasound FHR Transducer for twins monitoring.

- M3919A - Canvas Tote Bag
  with room for monitor plus accessories.

- M1569A - Belt Fastening Button
  Pack of 10.

- M2208A - 100 Disposable Abdominal Belts
  1.3m long, 50mm wide (52" long, 2" wide). 1 box of 50 blue and 50 pink.

- 40483A - Ultrasound Transmission Gel
  12 x 250 ml bottles, shelf life 24 months maximum, 6 months minimum.

- 40483A - 5 Liter Refill Container
  shelf life 24 months maximum, 6 months minimum.

- M1910A - Paper
  Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, 30-240 FHR scale, 1 min (3cm) highlights. Orange (USA).

- M1911A - Paper
  Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, plus 0-13 kPa scale, 50-210 FHR scale, no highlighted 3 cm lines. Green (International).

- M1913A - Paper
  Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, 50-210 FHR scale, 1 min (3cm) highlighted lines. Green. Not available in Europe.

## Associated Products

### External Recorder (M2925A)

The recorder is an external device for printing stored fetal traces, or realtime fetal trace output. It connects to the FM-2 via a standard (IEEE 1284 compliant)) printer cable.

### FM-2 Viewer Utility Software (M2926A)

The monitor can send data to an IBM-compatible PC running Microsoft NT4 or 98.

See the specifications section of this data sheet for system requirements.

### Mounting (M3904A and M3909A)

- M3904A - GCX Wallmounting.

- M3909A - GCX Rollstand

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1.The monitor has twins capability built in. To monitor twins you require an additional ultrasound transducer. Purchase additional M1356A.

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## Specifications

## Monitor (M2922A)

Federal Law restricts this device to use by or on the order of a physician.[1]

### Standards Compliance

The FM-2 Portable Antepartum Fetal Monitor complies with the requirements of the Medical Device Directive 93/42/EEC and the following safety standards:

- EN60601-1/IEC60601-1, EN60601-1-1, EN60101-2-37
- IEC 1157
- IEC 60601-1
- UL2601-1
- CAN/CSA C22.2#601.1-M90

Class II equipment, double insulated
Continuous operation

| Parameter | Input Connector | Resulting Isolation |
|---|---|---|
| US | BF | BF |
| Toco | BF | BF |

### Electromagnetic Compatibility

Complies with EN60601-1-2

### Environmental

| | |
|---|---|
| Operating Temp: | -10$^o$C to 45$^o$C (50$^o$F to 110$^o$F) |
| Storage Temp: | -20$^o$C to 60$^o$C (-29$^o$F to 175$^o$F) |
| Relative Humidity: | 20% to 90% non condensing |
| Altitude: | 0-3048m (10,000 ft) |

### Dimensions

| | |
|---|---|
| Height: | 15.24 cm (6.0 inches) |
| Width: | 26.4 cm (10.4 inches) |
| Depth: | 13.7 cm (5.4 inches) |
| Weight: | 2.27 kg (5lb) |

### Power - Battery

| | |
|---|---|
| Type: | Lead acid, rechargeable. |
| Operation: | minimum 2-hours fully charged at 10$^o$C, longer at higher temperature. |
| Recharge during monitoring: | Maximum 14 hours full recharge during monitoring (typical 11 hours). |

| | |
|---|---|
| Recharge without monitoring: | Maximum 8 hours to full recharge when no monitoring occurs (typical 4.75 hours). |
| Low power warning: | Approximately 30 minutes at 25$^o$C. |

### Power - External Power Supply

| | |
|---|---|
| AC-powered | 110-120V~, 50-60Hz, 0.15A or 220-240V~, 50-60Hz, 0.08A |

### Display

| | |
|---|---|
| Backlight: | Cold cathode fluorescent |
| Active area: | 3.78" x 2.83" (320 x 240 dots) |
| Resolution: | 85 dots per inch |
| Contrast: | 10:1 |

### Ultrasound

| | |
|---|---|
| $I_{sata}$: | < 4mW |
| BPM range: Paper scale: | USA paper: 30-240 BPM, International Paper: 50-210 BPM. |
| Ultrasound processing range: | 50-240 BPM. |
| Accuracy: | ±1% ±1 BPM. |
| Leakage current: | ≤10 μA @ 264 VAC applied to transducer. |
| Isolation: | >4 kV RMS, Type BF applied part. |

### Toco

| | |
|---|---|
| Range: | 0-100 relative units |
| Resolution: | 1 count |
| Accuracy: | ±1% ±1 relative unit |
| Leakage: | ≤10 μA @ 264 VAC applied to transducer |
| Isolation: | >4 kV RMS, Type BF applied part |

## Transducers

### Doppler Ultrasound FHR (M1356A)

| | |
|---|---|
| Weight: | 185 g (6.5 oz) |
| Cable length: | 2.5m (8ft 2in) |
| Diameter: | 75mm (2.95in) |
| Latex free | |

### External Toco (M1355A)

Transducer Weight: 180 g (6.3 oz)
Cable length: 2.5m (8ft 2in)
Diameter: 75mm (2.95in)
Latex free

## Remote Event Marker (15249A)

Length: 2.8m (9ft 2in)

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1.USA only

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Weight 75g (2.65oz)
Latex free

## Reusable Abdominal Belt (M1562A)

Length: 1.3m (52in)
Width: 50mm (2in)

With button holes, and pre-attached buttons. Can be further cut. Contains latex.

## FM-2 Viewer Utility Software (M2926A)

Windows operating system-based utility software. Supplied on CD-ROM, together with operating instructions, license and 3m PC connection cable.

System requirements:

- IBM-compatible PC (200MHz Pentium or equivalent)

- Standard VGA graphics adapter with 8MB memory

- CD-ROM drive

- 60 MB (minimum) available space on hard drive

- Windows 98, or NT (with service pack 6a) operating system

Microsoft®, and Windows® are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

The FM-2 viewer utility software complies with the requirements of the Medical Device Directive 93/42/EEC.

Federal Law restricts this device to use by or on the order of a physician.

## Printers

Supported printers are:

- HP DeskJet 990Cxi

- HP DeskJet 980Cxi

- HP DeskJet 960c

- HP DeskJet 840c

- HP DeskJet 640c

- HP DeskJet 350

- HP Photosmart 1215

This list will be updated periodically. Contact Philips Medical sales for details about currently supported printers.

## Recorder (M2925A)

### Dimensions

| | |
|---|---|
| Height: | 12.5 cm (4.9 inches) |
| Width: | 23.4cm (9.2 inches) |
| Depth: | 26.2 cm (10.3 inches) |
| Weight: | 3.54 kg (7lb 13oz) |

## Standards Compliance

### Safety

- Complies with EN60601-1, EN60601-1-1
- Class I equipment, requires 3-prong outlet with protective earth
- Continuous operation

### Electromagnetic Compatibility

Complies with EN60601-1-2

### Power

| | |
|---|---|
| AC-powered | 110-120V~, 50-60Hz, 0.15A<br>or<br>220-240V~, 50-60Hz, 0.08A |
| Consumption: | 20 watts maximum at normal supply voltage |

### Environmental

| | |
|---|---|
| Operating Temp: | -10°C to 45°C<br>(50°F to 110°F) |
| Storage Temp: | -20°C to 60°C<br>(-29°F to 175°F) |
| Relative Humidity: | 20 to 90% non condensing |
| Altitude: | 0-3048m (10,000ft) |

## Recorder Paper (Thermal)

| | |
|---|---|
| Style: | Z-fold |
| Pack size: | 150 pages |
| End-of-pack: | Mark along paper edge, stop sign on last page |
| Loading: | Front door, drop-in, self aligning |
| Paper detectors: | Paper out, and recorder loading door open |
| Paper speeds: | Normal (1, 2, and 3 cm/min ±1%) and batch print (average 25 cm/min) |
| Paper tracking accuracy: | ±1% (exclusive of paper accuracy) |
| M1910A: (Canada and USA) | 30-240 FHR range, orange grid, no kPa scale, 3cm highlighted lines. |
| M1911A: (International) | 50-210 FHR range, green grid, kPa scale, no highlighted lines. |
| M1913A/J: (Japan) | 50-210 FHR range, green grid, no kPa scale, 3 cm highlighted lines. |

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Philips offers a wide range of fetal monitors for different environments and applications. Review the capabilities of all fetal monitors to help you choose the monitor that is right for your needs.

| Feature<br><br>Table legend:<br>● Standard<br>O Optional<br>— Unavailable | | FM-2 (M2922A) | Series 50A (M1351A) | Series 50 IP-2 (M1353A) | Series 50 XM (M1350B) | Series 50 XMO[a] (M1350C) |
|---|---|---|---|---|---|---|
| Designed for portability/transport | | ● | – | – | – | – |
| Integrated fetal trace display | | ● | – | – | – | – |
| On screen NST assessment aid | | ● | – | – | – | – |
| Battery operation and AC operation from power supply | | ● | – | – | – | – |
| Off the shelf printer interface | | ● | – | – | – | – |
| PC utility software | | ● | – | – | – | – |
| External recorder | | ● | – | – | – | – |
| Integrated recorder | | – | ● | ● | ● | ● |
| Fetal trace data storage (12 hours) | | ● | – | – | – | – |
| Transmission to obstetrical surveillance system (for example OB TraceVue) via phone line | | ● | o | – | – | – |
| Twins heart rate separation | | ● | ● | ● | ● | ● |
| Direct system interface to obstetrical overview system such as OB TraceVue | | ● | ● | ● | ● | ● |
| Watertight, easy to clean transducers | | ● | ● | ● | ● | ● |
| Indication when two channels record the same heart rate (Cross Channel Verification - CCV) | | – | ● | ● | ● | ● |
| Indication when you accidentally record maternal $SpO_2$ (Cross Channel Verification plus - CCV+) | | – | – | – | – | ● |
| Performance PLUS! technology to ensure continuous, accurate and high-quality ultrasound traces | | – | ● | ● | ● | ● |
| Precision signal track and hold to reduce artifacts and increase sensitivity | | – | ● | ● | ● | ● |
| Interface to external fetal pulse oximeter ($FSpO_2$) | | – | o | o | o | – |
| Gross fetal body movement recording (fetal movement profile - FMP) | | – | o | o | ● | ● |
| External fetal measurements | Single US FHR | ● | ● | ● | ● | ● |
| | Twin US FHR | ● | o | ● | ● | ● |
| | Toco | ● | ● | ● | ● | ● |
| Internal fetal measurements | DECG | – | – | ● | ● | ● |
| | IUP/TTUIP | – | – | ● | ● | ● |
| | Fetal $SpO_2$ ($FSpO_2$) | – | – | – | – | ● |
| Integrated maternal measurements | NIBP and $SpO_2$ | – | – | – | ● | ● |
| | MECG | – | – | ● | ● | ● |
| Interface to external maternal monitor | | – | o | o | o | o[b] |

a. Series 50 XMO not available in USA or Japan

b. When maternal parameters are not already integrated in the Series 50 XM/XMO monitor (that is, you have not ordered option A03)

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