FM-2 (M2922A) Antepartum Fetal Monitor

SERVICE GUIDE

PHILIPS

Notice

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Conventions Used in This Guide

Warning
A warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution
A caution alerts you where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

Note— **A note calls your attention to an important point in the text.**

On your monitor, this sign indicates that there is detailed information in this book which you must read before proceeding with your task

Caution
US law restricts this device to sale by, or on the order of, a physician.

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1
General Information

Introduction

This guide tells you how to service and repair the monitor (M2922A). It describes the system hardware and software, tells you how to diagnose operating and servicing problems, and how to test the system.

As this monitor is intended to be installed by the customer, refer to the *Instructions for Use* for details of how to install the monitor.

The FM-2 *Antepartum Fetal Monitor Service Guide* supplements the maintenance and troubleshooting procedures carried out by the operator that are described in the *Instructions for Use*. Refer to the *Instructions for Use* for maintenance and troubleshooting procedures that may be performed during normal operation.

Any other maintenance and repair procedures beyond the level covered in the *Instructions for Use* are limited to replacement of:

- the battery
- three board assemblies inside the case (but excluding the main PCB)
- the speaker
- components of the LCD display installed in the front case assembly

The features available on the monitor you are servicing depend on which accessories were purchased. As this manual covers all accessories, consult your configuration listing to see which apply to your monitor.

As the only support strategy for the **Recorder** is unit exchange, in the event of a malfunction or failure, no repair or servicing information for it is included in this manual. For routine care and maintenance, refer to the *Instructions for Use*.

Only qualified service personnel should attempt to disassemble the monitor, or to remove or replace any internal assemblies.

Who Should Read This Guide

This guide is for any technical personnel servicing and repairing the FM-2 monitor (M2922A).

You must:

- understand English
- be familiar with standard medical equipment installation procedures
- be familiar with current conventional technical terms as used throughout this guide

What to Do Next

Familiarize yourself with the contents of this guide before attempting to service or repair the monitor.

Repair Strategy

Reading operating error messages and the error log helps to determine whether a fault is a hardware or software problem. Fault rectification is accomplished by replacement of the defective part at the assembly level. For example, faults may be repaired by replacement of a complete board where the fault is identified, or by exchanging the monitor.

Repair or replacement of individual components on the boards is not supported, and should never be attempted.

There are no servicing instructions in this manual for the Recorder (M2925A) as a repair is effected by exchanging the unit only.

After any repairs you must carry out the following tests:

- Power-On Self-Test (see "FM-2 Power-On Self-Test" on page 20)
- Performance tests (see "Testing Transducers" on page 90)
- Safety tests after repair (see "Safety Testing" on page 84)

Warnings, Cautions, and Notes

This guide uses three terms that are important for proper servicing of the monitor: Warning, Caution, and Note.

Warning
A warning calls your attention to an action or a possible situation that may result in injury or death to you or the patient.

Caution
A caution precedes an action that may result in damage to, or malfunction of the monitor. It indicates that special care is necessary for the safe and effective servicing of the monitor.

Note—**A note calls your attention to an important point in the text.**

On your monitor, this sign indicates that there is detailed information in this book and the *Instructions for Use* which you must read before proceeding with your task.

Symbols and Definitions

Symbol	Definition	Symbol	Definition
	Remote marker input connector symbol on monitor		Class II equipment symbol (double insulation)
IPX1	Drip-proof equipment classification on monitor		Type BF applied part symbol on monitor
220-240V~ 50-60 Hz, 0.08A	Power input symbol on power supply		Refer to accompanying documents
15V ~ 1A	Power supply connector symbol on monitor	RS-232	RS-232 connector (symbol on monitor housing)
15V ~ 1A	Power supply output connector on power supply		RS-232 connector (symbol on monitor label)
	Functional earth symbol on power supply		Printer connection symbol on monitor
	Indoor use only symbol on power supply		

Packing for Shipment

General Instructions

To ship the monitor for any reason, follow the instructions in this section.

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by the warranty. If the original shipping carton is not available, use another suitable carton.

Repacking in Original Carton

If available, use the original carton and packing materials. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.
2. Place in shipping carton and seal carton with packaging tape.
3. Label carton with shipping address and return address.

Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the monitor.

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.
3. Fill the bottom of the carton with at least 2 inches of packing material.
4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5. Seal the carton with packing tape.
6. Label the carton with the shipping address and return address.

Overview Of The Device

General Description

The device description included in this chapter focuses on the functional performance of the replaceable assemblies that may be identified as the probable cause of an apparent malfunction.

Refer to the *Instructions for Use* for information about the operation of the monitor and of the Recorder. That manual includes descriptions of the installation and setup of the monitor, modes of operation, recording of real-time patient data, and transmission of patient data to local or remote PCs.

Block Diagram of Operation

Figure 1 illustrates the functional operation of the monitor, including the accessories and options. It incorporates features of the mechanical design, indicating the physical relationship of the assemblies and components.
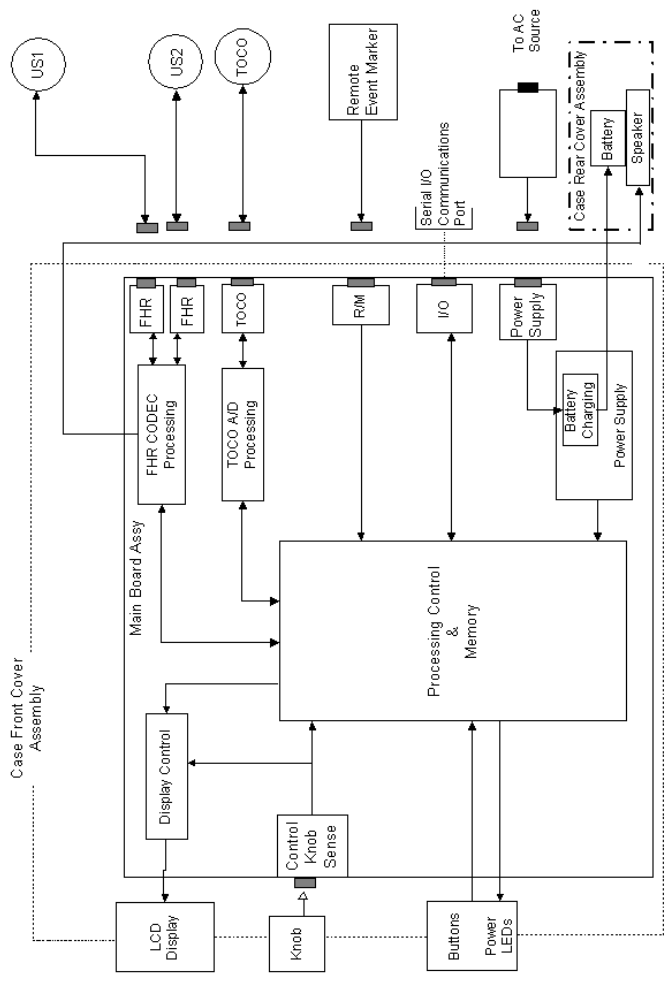
Figure 1   FM-2 Block Diagram of Operation

Mechanical Description

As indicated in Figure 1, except for the battery, speaker, interface board, and rear connector board, all functioning components of the monitor are installed as sub-assemblies of the case front-cover assembly. There are four sockets (event marker, Toco and two US) accessible on the left side panel. These are mounted on a side connector PCB, which is itself mounted on the main PCB.

The case rear-cover assembly includes the replaceable battery and the speaker assembly. The rear cover provides openings through which the three rear connector board-mounted connectors (serial, parallel and power input) are accessible. Additional mechanical features are included in Chapter 6, "Disassembly/Reassembly Guide".

LCD and Backlight

The LCD panel is a monochrome LCD display. It is a single-panel display with a resolution of 320 X 240 pixels. Data to be displayed are stored in the main board. Direct connection to the LCD panel is made through on-board header assembly J7.

The backlight of the LCD is a Cold Cathode Fluorescent Lamp (CCFL) mounted as part of the LCD panel. The AC high-voltage is turned on and off by a digital control bit from the main-board-mounted drive.

Serial I/O Communications Port

The RS-232 interface is totally isolated from the interface board through the use of high-speed optical isolators and isolated 5-volt power supply.

See Chapter 2, "System Interfaces" for serial connections, pinouts, cables and supported modems.

Parallel I/O Communications Port

The parallel communications port is used to connect the monitor to the Recorder or to a standard PCL Level 3 printer. At the time of printing, not all PCL Level 3 printers are supported. For printers that have been validated for use

with the monitor, please see "Parallel I/O Communications Interface" on page 18.

For further details of the pinouts and the cable specifications, see Chapter 2, "System Interfaces".

Keypad and Navigation Wheel

There are seven front-panel switches, two LEDs, and one wheel push-button switch. All of these buttons go to the main-board except for the ON/OFF push button, which goes directly to the power supply. The software monitors these signals to determine which buttons were pushed. The two LEDs are located on the control panel and inform the user of mains or battery operation.

The wheel consists of a mechanical rotary encoder wheel with a momentary push button switch. As the knob is rotated, quadrature-coded outputs are generated. The phase relationship between the two signals, in quadrature, reflect the clockwise or counter clockwise rotation of the wheel. This relationship is translated to move the cursor on the LCD display forward or backward, depending on which way the wheel is rotated.

Power Supplies

The unit is operated from a 6-volt 4 AH sealed lead acid battery. The power supply provides enough power to charge the battery even when the unit is operating.

The monitor power is controlled by alternate button closures of the front panel membrane switch. Unit operation *starts* only via a push of the front panel button, but operation will *stop* after a delay of a few seconds when pushing the front-panel membrane switch. This delay permits the main-board processor to shut down in an orderly fashion, after storing the parameters and data, if any.

Measurements Channels

Ultrasound Channel

The monitor has two ultrasound sockets, US 1 and US 2, located on the side panel of the monitor. Either one or two M1356A ultrasound transducers can be connected. The latter case allows twins monitoring. (Refer to the *Instructions for Use* for transducer specifications).

The transmitter pulsing the ultrasound transducer is gated by control circuitry, and return signals are processed in the CODEC circuitry on the main board.

Toco Channel

The Toco circuit uses a Wheatstone bridge, with two strain gauge elements mounted on a load beam. The differential output voltage is proportional to the force applied to the load beam through the plunger. The Toco circuit is powered from a single regulated 5V-supply excitation.

The amplified and filtered TOCO signal is converted by a 12-bit analog to digital converter, providing an output scale of 2.56LSBs/gram.

Mountings

The monitor can be mounted in two ways using the following optional items:

- GCX roll stand (M3909A)
- GCX wall-mount (M3904A)

Refer to the fitting instructions that come with the relevant option.

Routine Maintenance and Cleaning

For detailed instructions on how to clean the monitor and the monitoring accessories, see the *Instructions for Use*.

For instructions on cleaning the Recorder, refer to the *Instructions for Use*.

Routine Maintenance and Cleaning

2
System Interfaces

Overview

The monitor has the following system interfaces:

- Serial I/O interface
- Parallel I/O interface

Note—**The serial and parallel interfaces are not electrically isolated against each other.**

Serial I/O Communications Interface

The RS-232 interface is totally isolated from the interface board through the use of high-speed optical isolators and isolated 5-volt power supply.

The RS-232 communications interface port is for communicating with:

- a desktop modem (see "Supported Modems" on page 14)
- a GSM cell phone modem (see "Supported Modems" on page 14)
- a PC/AT computer

The RS-232 communications protocol supports connections to OB **TraceVue**. These connections are:

- direct (cable) connection to the OB **TraceVue** system, to supply real-time patient data (System Online).
- via modem to supply complete patient records (System Batch).

It will also be used for software upgrades in the future.

The pinouts for the DB9 connector are shown in the following table.

Table 1   Fully wired DB9 RS-232 Null-modem pinouts

Pin	Connects to pin	Signal	Details
1 and 6	4	DTR	Data Terminal Ready
2	3	TxD	Transmit data to external devices
3	2	RxD	Receive data to external devices
4	1 and 6	DCD, DSR	Data Carrier Detect, Data Set Ready
5	5	Gnd	RS-232 Ground
7	8	CTS	Clear To Send
8	7	RTS	Request To Send
9	9	-	Ring indicator, not connected

The cable (M1380-61624) is a 3 meter long, fully wired RS-232 Null-modem cable supplied with the viewer software. It is also available as an OB **TraceVue** option.

Supported Modems

Note—**As modems are not designed to fulfil the electrical requirements of a medical device in terms of leakage current and isolation, a modem must be located outside of the patient vicinity.**

The following modems are the only modems that are currently validated and supported:

- a MultiTech Systems MT-5600ZDX desktop modem
- a Nokia 6210GSM cellular phone modem (GSM type)

MultiTech Systems MT-5600ZDX

Modem Default Initialization String

The monitor sends the following default modem initialization string:

'ATE0X4&K0\r'

This is the first string sent by the monitor, and it is not customizable, nor is it obvious to the user.

The monitor expects to see an "OK" come back from the modem after the initialization string has been sent.

If an "OK" is returned to the monitor (that is, confirmation that a modem is connected), the monitor then sends the user-customizable initialization string, preceded by "AT" and followed by "\r".

The Attention characters, 'AT', at the beginning of the initialization string start the command mode. The '\r' at the end represents a Return, when the characters entered in the command line and stored in the modem's command buffer are executed. The monitor always automatically enters the Attention (AT) and Return (\r) characters.

Therefore, the user never needs to enter "AT" or "\r".

The dialing also works in the same manner. The user never needs to enter the return "\r" after the phone number. First, the monitor sends "ATD", then the user-entered phone number, then "\r". "ATD" is simply the command to dial with whichever dialing method is set as the default. (The default setting as shipped is Tone dialing.)

If it is necessary to change the dialing method from Tone to Pulse, or vice versa, then this is specified in the user-entered initialization string.

For example, to change to the Pulse dialing method, simply enter a **P** in the modem initialization string.
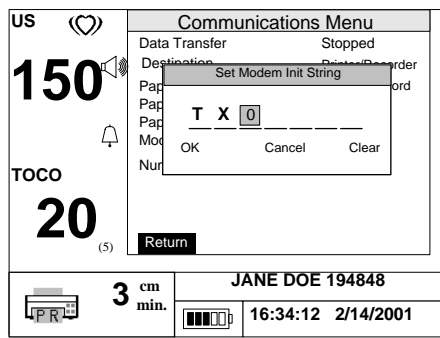
The components of the default initialization string are explained in the following table.

Table 2   MultiTech MT-5600ZDX initialization string commands

Command	Explanation
E0	Switches to verbose mode. To establish whether a modem connection is effective, the modem replies to the signal sent by the monitor with an 'OK' signal, or an error signal, rather than just a result code (e.g. 0, 1, etc.). If an 'OK' is received, then it is positive confirmation that the modem is connected and functional.
X4	Switches to extended result codes, along with smart dialling. The modem checks for a dial tone, dials, then checks for a ring back or a busy signal after dialling. This is not appropriate in local exchange branches.
X0	Selects basic result codes and blind dialling (dials even if there is no line), as an alternative to use in local exchange branches.
&K0	No modem initiated flow control (disables the flow control).

For detailed information about the MultiTech Systems MT-5600ZDX and how to set it, please refer to the modem's *Owner's Manual*.

The commands above are only applicable to Rockwell/Conexant-based MultiTech Systems modems. At the time of printing, the MultiTech MT-5600ZDX is the only desktop modem that has been validated for use with the monitor.

The monitor may also work with other modems, but this has not been tested, and consequently no other modems are officially supported.

Customers may use any other modem after successful verification of several trace transmissions.

Nokia 6210GSM

Instead of a conventional wired phone connection using a desktop modem, a cellular phone can be used to transmit traces to the viewer or to OB **TraceVue**.

At the time of printing, the Nokia 6210GSM is the only cellular phone to date that has been validated for use with the monitor.

Customers may use any other modem after they have successfully verified several trace transmissions.

Parallel I/O Communications Interface

Caution
General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices. The RS-232 and parallel connectors on the monitor are electrically isolated to permit safe connections to non-medical devices, which should be connected with a cable of sufficient length to prevent the non-medical equipment from contacting the patient.

If a non-medical device is connected to the serial port, a recorder or printer connected at the same time to the parallel port should be located outside the patient vicinity, as the two interfaces are not isolated against eachother.

The parallel communications port is used to connect the FM-2 to the Recorder or to a standard PCL Level 3 printer. Supported printers that have been validated at the time of printing are:

- HP Deskjet 640c
- HP Deskjet 840c
- HP Deskjet 990 CXi
- HP Deskjet 980 CXi
- HP Deskjet 960c
- HP Deskjet 840c
- HP Deskjet 640c
- HP Deskjet 350
- HP Photosmart 1215

A standard PC parallel printer cable is used (IEEE-1284 compliant). This is supplied with the recorder.

Although the same cable is used to connect the monitor to the Recorder or a PCL Level 3 printer, a different protocol is used for communicating between the monitor and the Recorder. This protocol does not conform to the IEEE 1284 norm, and is actually a serial connection.

3
Tests and Error Codes

Service Philosophy

If the monitor detects a problem, it displays an error screen that shows an error reference number, and monitoring is discontinued. In addition, the errors are written to the error log (see Table 3, "FM-2 Error Codes," on page 23).

Read the system error log to determine whether the fault lies in the hardware or firmware. These problems can be repaired by board replacement or unit exchange. Do not attempt component-level board repair.

Overview of the Service Tests

A brief overview of the service tests that are used to verify performance following repairs or during routine maintenance follows. All tests can be performed without removing the covers of the monitor.

- Visual Test (see page 20)
- Power-On Self Test (see page 20)
- Performance tests for transducers, to check the processing of the signal from the transducers (see "Testing Transducers" on page 90)
- Safety Tests

  These test the electrical safety of the monitoring system and must be carried out after upgrades and repairs. You must use a safety testing analyzer.

  - System Safety Test (see page 89)
  - Safety Test Blocks (see Table 21, "Test and Inspection Matrix," on page 81)

Checking the Battery

Before testing the monitor after repair or service, ensure that the battery itself is not at fault. See "Battery Charging and Maintenance" on page 82.

Visual Test

Visually inspect the monitor and its accessories after a repair, and also on a regular basis as part of routine maintenance. Ensure that the monitor, cables, line cords, transducers and instruments have no visible evidence of damage that may affect patient safety or monitoring performance. Do not use if there is any sign of damage.

FM-2 Power-On Self-Test

When the monitor is turned on, it automatically performs a diagnostic self-test. The self test continues during normal operation also. If the monitor fails its self test, it will display an error screen, and will discontinue all monitoring functions. In this case, it should be turned off and removed from service.

What Happens During the Power-On Self Test

- The executable program is loaded from flash memory into Random Access Memory (RAM).
- A checksum algorithm is run to test the program just loaded into RAM.
- If the checksum test passes, the watchdog timer is started. The purpose of the watchdog is to check that **all** tasks running concurrently on the monitor are operating correctly.

- The watchdog timer is allowed to time out, and the interrupt expected to occur is verified to have occurred. Software will detect a watchdog failure if the watchdog timer does not expire within a specified amount of time.

Performing the Power-On Self Test

1. Press the On/Off button .

2. Initially the LCD screen illuminates, but is blank.

3. After two or three seconds, the monitor plays a two-tone power-on jingle while performing the Power-On Self Test. At this point, the monitor displays the start-up screen, showing the Agilent logo, bootcode version and the application version.

4. Upon successful completion of the Power-On Self Test, the display will show the main monitoring screen.

5. If an error is detected, the monitor will display the error screen.

6. The error number is stored in the error log (see Table 3, "FM-2 Error Codes," on page 23).

If the Power-On Self Test fails, try to cycle power again. If it fails again, then exchange the monitor.

Performance Test for Transducers

This tests the signal path to and from the transducers.

1. Turn on the monitor and the recorder or printer.

2. Connect one or two US cables and the TOCO transducer.

3. Check that the display acknowledges the connected transducers in the appropriate frames.

Also refer to "Testing Transducers" on page 90.

Error Handling

There are two types of error that you may see: those that the monitor cannot self-detect, and those that it can self-detect.

- If an operational error occurs that is not self-detected, the monitor shuts down. There will be no audible or visual warnings or indicators.
- If a self-detectable error occurs, the monitor will do the following:
  - Display the error screen
  - Sound an error tone
  - Discontinue all monitoring functions

Error Codes

The error codes are primarily intended for diagnostic use at the factory. The errors, their explanation, and any service action required are shown in the following table.

Table 3   FM-2 Error Codes

Error Code	Explanation	Action
1	Monitor's memory has become corrupt	Replace the monitor
2	Invalid internal software state in the monitor	
3	Unable to acquire a software resource (queue, semaphore, etc.)	
4	Stack overflow	
5	Bad parameter value passed to a function	
6	Software is in an unexpected state	
7	Software assertion was false (coding error)	
8	A task failed to check in with the watchdog timer	
9	The CRC of the software in memory is invalid	
10	A voltage is out of range	Check the battery and the power supply for correct operation. Replace if necessary
11	Watchdog timer is not functioning	Replace the monitor
12	System received too many resets	
13	Recorder's software version number is incompatible with the monitor	
14	Flash memory type is incompatible with the software	
15	Phase lock loop lost lock (non-critical error)	No action required

Table 3   FM-2 Error Codes

Error Code	Explanation	Action
16	Failed to allocate requested memory	Replace the monitor
17	A problem with the Codec has been detected	
18	High half-word of flash failed to program	
19	Low half-word of flash failed to program	
20	High half-word of flash failed to verify	
21	Low half-word of flash failed to verify	
30	Error in communications micro-controller	Check the side connector PCB. Replace if necessary.
50	Corrupt patient record (trend file)	None: factory diagnostic information only
51	Corrupt file system	
52	Attempt to read a deleted file	
53	File system wrapped memory	
54	Attempt to read a corrupt file	
55	Failed to create a file	
70	File corrupted - FM-2 viewer communication error	None: factory diagnostic information only
71	Invalid Patient ID - FM-2 viewer communication error	
72	Invalid sequence number - FM-2 viewer communication error	
73	Remote error - FM-2 viewer communication error	
1xx	Algorithm errors	None: factory diagnostic information only
2xx	Printer errors	
3xx	Fatal Operating system errors	
4xx	Fatal processor exceptions	

4
Power-up Default Settings and the Service Menu

Introduction

This section discusses use of the Power-up Defaults Menu to configure power-on default settings, and the Service Menu to obtain service-related information about the monitor.

Power-up Defaults Settings

These are parameters which can be changed by the user. The power-up defaults allow you to create a power-up default for many settings in the monitor. Power-up defaults are the settings in effect each time the monitor is powered on.

The power-up default settings are configured at the factory prior to shipment. Some of the parameters are stored when the monitor is powered down, and these are classified as "saved through power cycle". The factory default values are defined in Table 4.

Table 4   Power-Up Default Settings

Parameter	Factory Default	Saved Through Power Cycle
US trace separation	`"0"BPM`	No
TOCO Baseline set-point	5	Yes
All alarm settings	-	Yes
Modem: Initialization string	`-----`	Yes
Modem: Phone number	`-----`	Yes

Table 4   Power-Up Default Settings

Parameter	Factory Default	Saved Through Power Cycle
Data transfer	`Disabled`	Yes (if real-time transfer)
Data Transfer Destination	`Recorder/ Printer`	Yes
Recorder: Paper speed	`3 cm/minute`	Yes
Recorder: Paper style	`US`	Yes
Time format	12 hour	Yes
Date	"today"	Yes
Date format	mm/dd/yy	Yes
Patient ID	time/date encoded	No
Language	Configured language	Yes

Service Menu

The purpose of the Service Menu is to allow factory, field-service, and hospital biomedical technicians access to a series of test and system-related information screens for the purpose of verifying monitor performance or troubleshooting problems.

To access the Service Menu, press the navigation knob when the Power Status Frame is selected. The following can be viewed from the Service Menu:

Table 5   Service Menu Entries

Menu Item	Explanation
View Error Log	Displays the error log menu
View A/D Values	Displays the Analog-to-Digital (A/D) Menu
System On-Time	Elapsed system on-time (expressed in hours). System on-time is not reset to 0 after the battery is replaced, but is retained. This value is saved through power cycles.
Language	English German Spanish Italian Portuguese French Russian Simplified Chinese Traditional Chinese Japanese
Demo Mode	Choice of On or Off

The Service Menu lists the test and system-related information screens. Selection of an item in the menu will invoke that test or information screen. The test and information screens that appear in the Service Menu are as follows:

- Error Log
- System Analog-to-Digital (A/D) Values

Error Log

This screen displays the eight most recent error code types, logged by the monitor. After eight error code types have been logged, the oldest error code type will be deleted as new error code types are added. Adjacent to each error code will be an entry which is the number of occurrences of that error. This means that if there are many occurrences of one type of error code, that one error code won't overwrite the other seven error codes.

Next to the occurrence field is the time and date of the most recent occurrence of the error code. Error codes may not be changed or reset in this screen. When in the Error Code screen, the **Return** item is always highlighted; a press of the wheel will return the user to the Service Menu. Rotating the wheel while in the Error Code screen will have no effect.
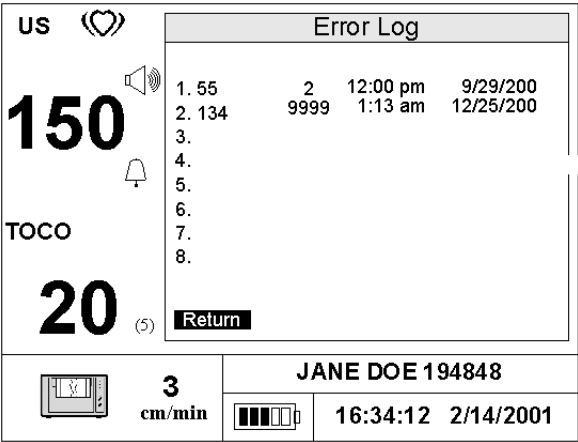

Figure 2   Error Log

Refer to "Error Codes" on page 23, for more information on error codes.

System A/D Values

For the end user or service personnel, the system A/D values require no interpretation.

The A/D screen displays the current value of each analog-to-digital (A/D) channel in volts. The A/D channels read DC voltages, for example, power supply voltages and battery voltage. The A/D values displayed are static, being acquired when the screen is first displayed.

None of the displayed values may be changed or reset in this screen.When in the A/D screen, the **Return** item is always highlighted; a press of the wheel will return the user to the Service Menu. Rotating the wheel while in the A/D screen will have no effect. The A/D Values screen appears as follows:
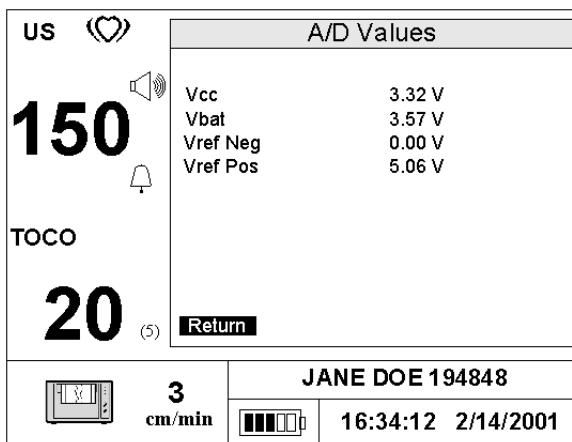

Figure 3   System A/D Values

Note—**The screenshot above shows untypical system A/D values that are not representative of normal operation.**

5
Troubleshooting

General

This section provides a guide for qualified service personnel in locating the possible cause of an apparent malfunction of the monitor or its accessories. Use of built-in diagnostics, flow charts, and step-by-step procedures are provided as aids in the troubleshooting process.

The chapter leads you to a probable field replaceable assembly or component. Items that are serviceable only at the factory are also identified, as well as instructions for their return for repair/replacement.

The initial analysis determines whether the apparent malfunction is caused by a replaceable accessory, or by a replaceable assembly within the monitor case.

Initial Trouble Diagnosis

The first step in diagnosing a possible malfunction is to duplicate, if possible, the symptoms of the reported malfunction. Thereafter, it is important to categorize the problem as either one of two types, as illustrated in Figure 4. They are:

- Totally inoperative condition, or
- Degraded operation.

The totally inoperative condition is indicated by the failure of the monitor to respond to the power ON front-panel action, or by complete loss of monitoring functions during operation. Contact your local Agilent Response Center.

Degraded operation performance might be indicated by the appearance of artifacts in the display, or by gaps in the pixel display, by intermittent actions, or by obviously inaccurate measures of fetal activity, etc.
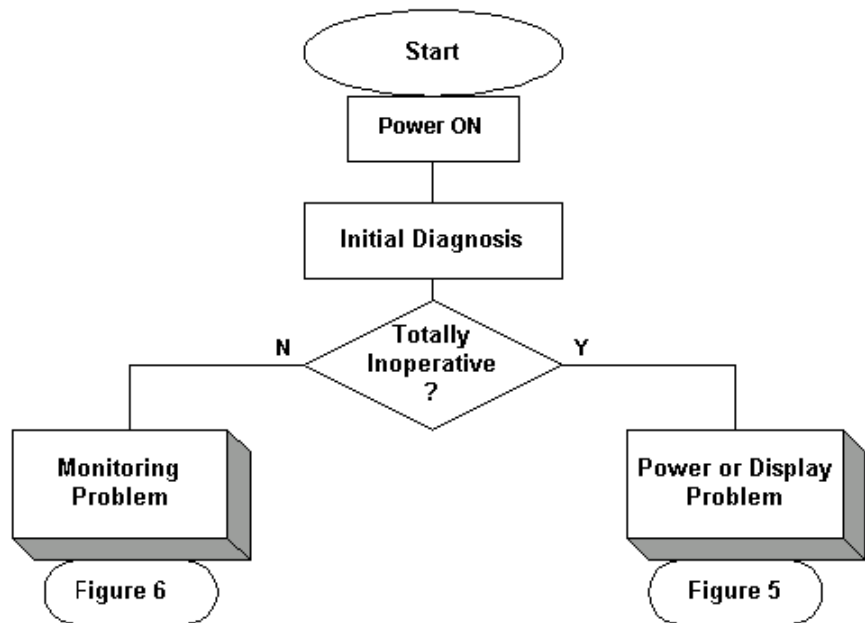
Figure 4   Diagnosing Malfunction - Initial Diagnosis

Power Problem Diagnosis

Diagnostic Flow Chart

The flow chart of Figure 5 shows a sequence of actions and decisions you can use after the initial diagnosis of a "total failure" as a power supply or display problem.

Note—**If the apparent "total failure" is caused by a malfunctioning display backlight, you may see a faintly lit display with the appropriate Power-On Self Test message. The troubleshooting under these circumstances is described in this section.**
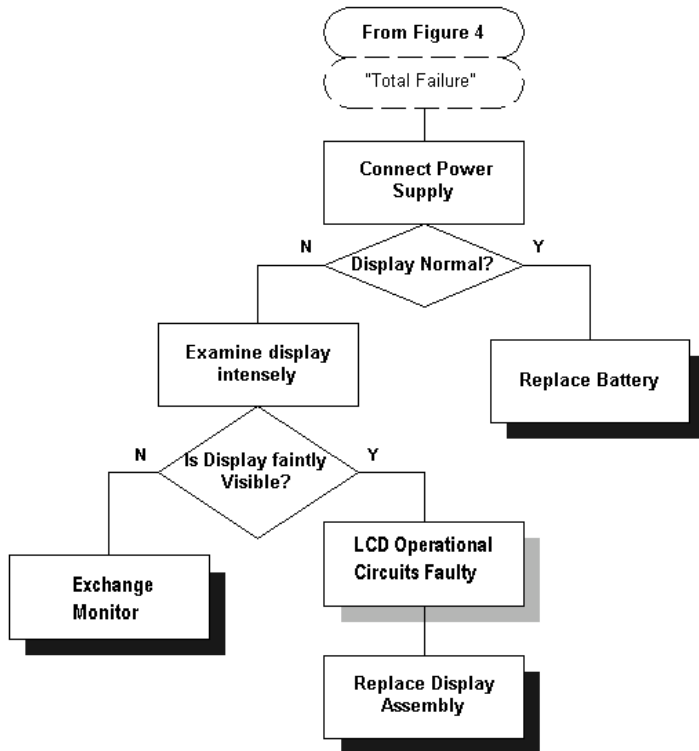

Figure 5   Power Diagnosis - Power Supply or Display

Diagnostic/Repair Actions

Examine Display Intensely   Reduce background room illumination. If only the back light fluorescent tube or its high voltage driver has failed, the display may be faintly visible.

Refer to page 50 for removal procedures.

Replace Battery   Refer to page 43.

Exchange the Monitor   If the display is not at all visible, and there is total failure, exchange the monitor.

Monitoring Degradation Problems

Diagnostic Flow Chart

Figure 6 illustrates a logical sequence of troubleshooting diagnostics when the monitor appears to be operative, but the displayed results are suspect for any number of reasons. The resulting diagnosis will result in replacing either the monitor or the transducers.
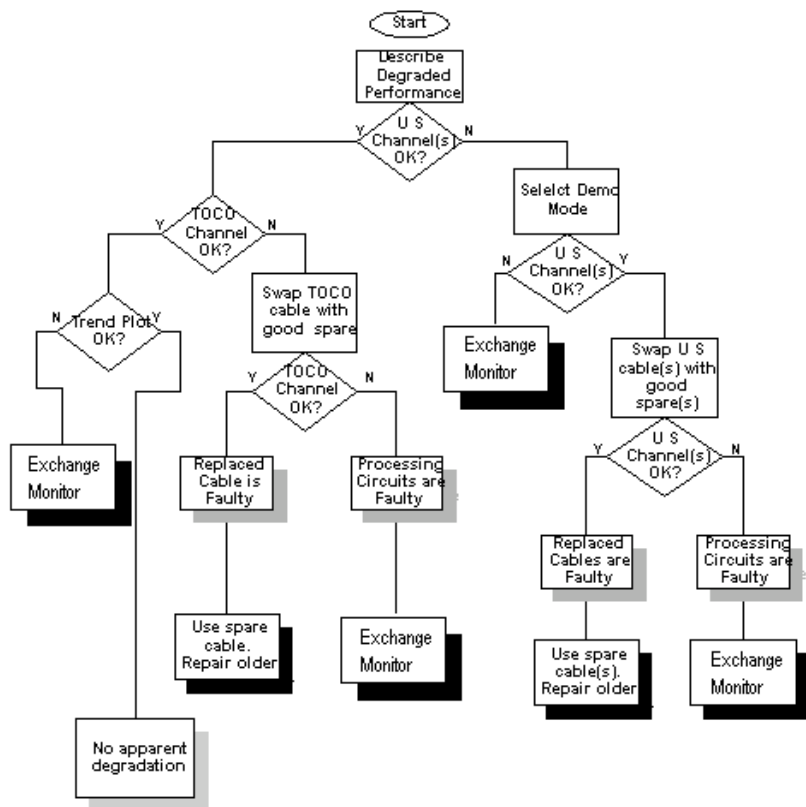

Figure 6   Monitoring Degradation, Diagnostic Flow Chart

Diagnostic Repair Actions

Describe Degraded Performance
Examine the display after an apparently successful power up sequence and self-test.

Consider, first, the appearance of artifacts, gaps, or general quality of the display.

Note the values being reported in the numerical frames (FHR(s)) and TOCO). Are they clearly unreasonable?

Swap Transducers
Use a spare transducer that is free of defects and meets factory specifications. At facilities where more than one monitor is installed, it may be convenient to borrow a transducer that is working satisfactorily with another monitor.

Exchange the Monitor
If the monitoring problems persist, or there is total failure, exchange the monitor.

6
Disassembly/Reassembly Guide

Warning
Performance verification: do not place the monitor into operation after repair or maintenance has been performed, until all performance tests and safety tests listed in Chapter 8 of this service manual have been performed. Failure to perform all tests could result in erroneous monitor readings, or patient/operator injury.

Warning
Energized circuits are accessible with the covers open. Do not work on the monitor with the covers open. Only qualified service personnel should open or disassemble the monitor.

Introduction

Warning
Before attempting to open or disassemble the monitor, disconnect the power supply from the monitor.

Warning
High voltage is generated by the LCD backlight driver. Do not operate the monitor with the covers open.

Caution
Observe ESD (electrostatic discharge) precautions when working within the unit.

Caution
Important for disassembly! When disassembling the monitor, make sure that the battery leads are disconnected. Otherwise, it is likely that circuit damage will occur.

The monitor can be disassembled down to all major component parts, including:

- PCBs
- battery
- cables
- function buttons
- chassis enclosures

Remember to store all screws, nuts, washers and other parts in a safe place for later refitting.

How to Use this Chapter

The step-by-step procedures that are used to access replaceable parts of the monitor are illustrated in the Disassembly sections which follow. These describe and photographically illustrate procedures for disassembling the monitor to enable removal and replacement of suspected defective assemblies and components.

The monitor consists of two main assemblies:

- The front case assembly
- The rear case assembly

The main PCB assembly is separable from the front case assembly.

All part numbers and exploded views of some assemblies are found in Chapter 7, "Spare Parts".

Tools Required

Caution
When reassembling, be sure to follow torque-limits instructions. Excessive torque may damage the plastic screw mountings or case.

The following tools are required:

- small/medium, Phillips-head screwdriver
- A torque-sensitive tool, with a torque range to 1.1 Nm (10 in-lb.); accuracy ±0.1 Nm (±1 in-lb.)
- needle-nose pliers or Tinnerman tool
- 10 mm socket driver (for wheel encoder nut)

- 3/16" socket driver

The rear case assembly consists of a molded plastic case, in which the battery is stored. The speaker housing is mounted on the back of the rear case assembly, and also forms the cover for the battery. Through-holes in the case cover are provided for the rear-panel connectors, that are mounted on the rear connector board.

Fuses

There are no customer or field-replaceable fuses.

Closed Case Disassembly/Reassembly Procedures

This section describes the items that may be removed without disassembling the main case of the monitor.

The speaker housing is attached to the back of the rear case. The speaker housing also acts as the battery cover. To gain access to the battery, first remove the speaker housing (see "Removing the Speaker Housing" on page 41).


Caution
Important for disassembly! When disassembling the monitor, make sure that the battery leads are disconnected. Otherwise, it is likely that circuit damage will occur.

Caution
Important for reassembly! If the internal battery cable has been disconnected, pay very careful attention to the polarity of the cable before reattaching. The red wire connects to the +ve terminal, the black wire connects to the -ve terminal. If the battery cable polarity is reversed, circuit damage will occur. Circuit damage caused by reversed polarity is not covered by the warranty.

Removing the Speaker Housing

Step 1. Place the monitor on its front panel, being careful not to place the unit on any surface that will damage the display.

Step 2. Using the Phillips-head screwdriver, unfasten the two screws securing the speaker housing. The speaker housing also acts as the battery cover.
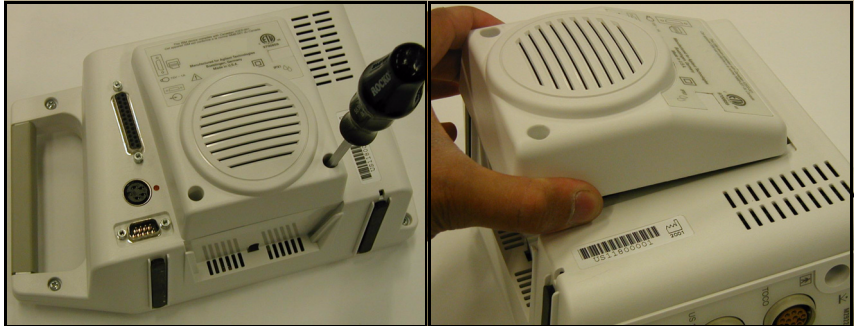

Step 3. Gently lift the bottom (screw) end of the speaker cover just enough for the battery pad (attached to the inside of the speaker housing) to clear the bottom of the rear case. At the same time, slide the speaker housing towards the bottom of the rear case to free the two lugs holding the top of the speaker housing. The speaker housing is now free of the rear case, but with the wires still connected.

Step 4. Carefully disconnect the speaker wires by sliding the spade connectors off the speaker terminals.

Step 5. The speaker housing is now completely free of the rear case.

Replacing the Speaker Housing

Step 1. Connect the speaker cables by pushing the spade terminals onto the speaker terminals in the speaker housing. Check that they are secure. The wires are not coded for polarity, as the polarity is uncritical.


Speaker housing lugs

Speaker terminals
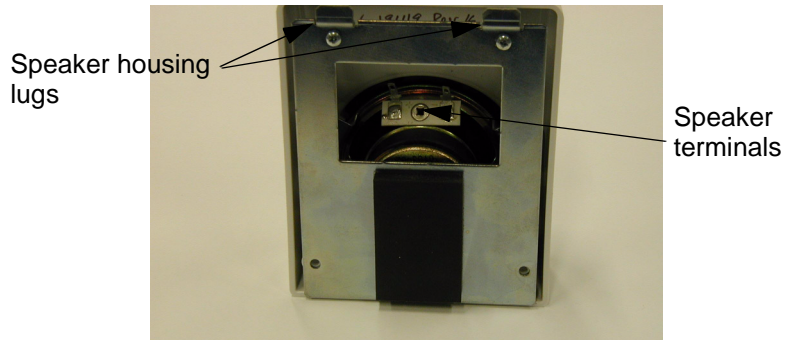
Step 2. Refit the speaker housing by sliding the two metal lugs at the top end of the speaker housing under the lip at the top of the battery housing aperture until it stops.

Step 3. Secure the speaker housing with the two fastening screws. Torque the screws to 0.7 to 0.9 Nm (6 to 8 in. lb).

Caution
Do not overtorque the screws, as the plastic screw mountings or the casing may be damaged.

Removing the Battery

Step 1. Place the monitor upside down so that its top is resting on the work surface. In this position, the monitor leans back at a convenient angle that allows easy removal of the battery with the aid of gravity.

Step 2. While the monitor is in this tilted position, the battery will normally fall partly out of its housing. If it does not, then apply a little pressure on the terminal-end of the battery (nearest the work surface). This should cause the battery to fall partly out of the case.
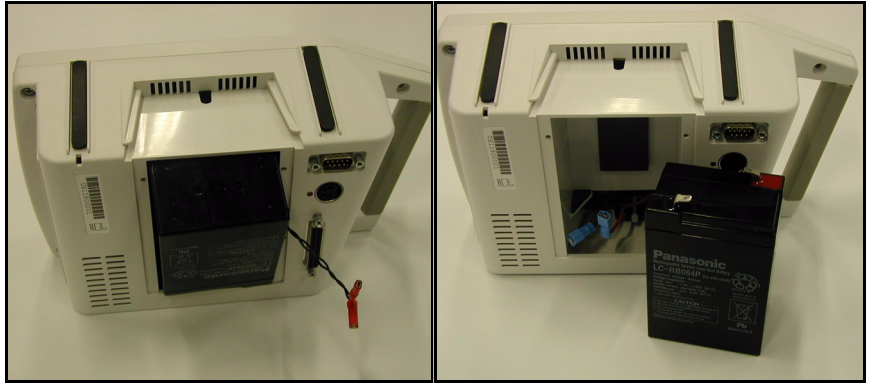
Step 3. Carefully remove the battery from the monitor. Take care not to put too much stress on the battery wires as you take the battery out of the case.

Step 4. Disconnect the battery cables by sliding the spade connectors off the battery terminals.

Caution
During reassembly, pay very careful attention to the polarity of the battery cable before reattaching. The red wire connects to the +ve terminal, the black wire connects to the –ve terminal. If the battery cable polarity is reversed, circuit damage will occur. Circuit damage caused by reversed polarity is not covered by the warranty.

Replacing the Battery

Step 1. Connect the battery cables to the replacement battery, paying careful attention to cable polarity. Connect the red cable to the positive terminal, marked in red. Connect the black cable to the negative terminal, marked in black.

Step 2. Carefully place the new battery into the battery housing.

Step 3. Reconnect the speaker and refit the speaker assembly. (See "Replacing the Speaker Housing" on page 42).

Battery Disposal

Refer to practices and procedures used at the local institution when disposing of the battery.

Please conform to any local laws and requirements governing the disposal of lead acid batteries.

Separation of Front and Rear Case Assemblies

Separation

This section describes the procedures required to separate the front and rear case assemblies of the FM-2 monitor.

Step 1. Remove the speaker housing (see "Removing the Speaker Housing" on page 41).

Step 2. Remove the battery (see "Removing the Battery" on page 43).

Step 3. Remove the four screws fastening the rear case assembly to the front case assembly using a Phillips-head screwdriver.

Step 4. Separate the front and rear case assemblies.
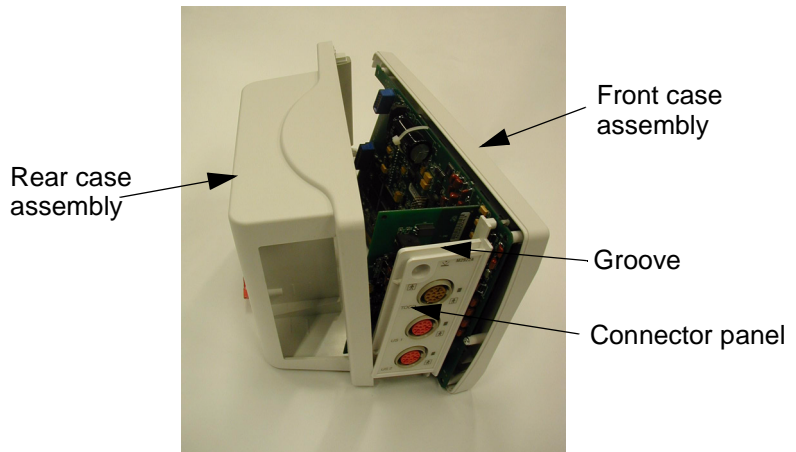
Note—**The US and Toco sockets protrude slightly from the face of the connector panel on the side of the monitor. While separating the front and rear case assemblies, you may feel some resistance at the connector panel end of the monitor, in which case gently raise the handle end of the rear case assembly to help to clear the sockets.**

Step 5. If the silicone tubing seal is to be replaced, remove it.

Reassembly

Step 1. Ensure that the cables for the speaker and the battery are correctly routed and accessible from the rear of the case for later connection.

Step 2. Confirm that the patient connector PCB is firmly mated to the main PCB. (There should be no gap between the bottom of the patient connector PCB and the main PCB).

Step 3. Carefully align the groove in the connector panel with the edge of the corresponding opening in the rear case moulding. Take care that it stays aligned while you push the front and rear case assemblies together. When the reassembly is complete, the edge of the case opening should sit evenly in the groove of the connector panel.

Step 4. Align the ridge in the front case assembly with the groove in the rear case assembly.

Step 5. Check that the four screw holes align correctly.

Step 6. Drive in the four screws that hold the front and rear assemblies together. Torque the screws to 0.7 to 0.9 Nm (6 to 8 in. lb).

Caution
Do not overtorque the screws, as the plastic screw mountings or casing may be damaged.

Step 7. Refit the battery (see "Replacing the Battery" on page 44).

Step 8. Refit the speaker housing (see "Replacing the Speaker Housing" on page 42).

Front Case Disassembly/Reassembly Procedures

This section describes how to remove/replace items from the front case assembly.

The front case assembly includes the replaceable molded front-case, the main PCB, the LCD assembly, the front-panel keypad and the navigation wheel.

First separate the front and rear case assemblies as described in the section "Separation of Front and Rear Case Assemblies" on page 45.

Removing the Navigation Wheel

The wheel is a friction fit on the stem of the encoder. The encoder is attached to the main circuit board and has a threaded moulded base just below the rotating stem of the encoder. The threaded base accepts a 10 mm nut which fastens the encoder assembly to the front bezel.

Step 1.   From the front, remove the wheel by grasping the sides of the wheel firmly and pulling straight back from the monitor.

   If the wheel is not easily removable by hand, a small flat-headed screwdriver may be used to gently pry off the wheel. If necessary, apply some adhesive tape to the front cover and/or the head of the screwdriver to prevent any damage.

Step 2.   Use a 10 mm hex socket or suitable closed spanner to unscrew the fastening nut on the outside of the front bezel.
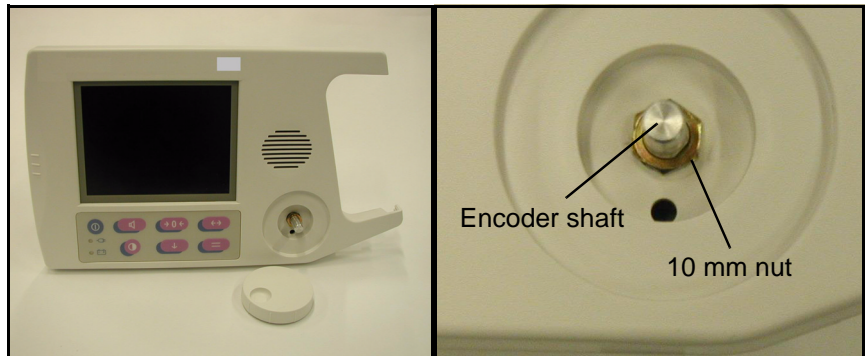
Replacing the Navigation Wheel

Step 1. If the front case assembly has been disassembled, refit the LCD assembly (see "Replacing the LCD Assembly" on page 51) and the main circuit board (see"Replacing the Main PCB Assembly" on page 52) to the front case assembly.

Step 2. Screw the 10 mm nut onto the threaded base of the encoder switch from the outside of the front bezel, initially by hand.

Caution

Do not overtorque. If excessive torque is applied to the encoder nut, damage will occur to the encoder switch. Do not exceed the maximum allowable torque setting.

Step 3. Using a torque-sensitive tool, torque the nut to 0.2 Nm (28.3 oz. in.).

Step 4. Push the navigation wheel onto the shaft of the encoder.

Removing the Main PCB Assembly from the Front Case Assembly

Step 1. Remove the navigation wheel (see "Removing the Navigation Wheel" on page 47).

Step 2. Place the front case assembly with the bezel face down on the work surface. Take care not to damage the display.

Step 3. Disconnect the backlight power supply cable connector from J4 on the main PCB.

Step 4. Disconnect the keypad ribbon cable connector from J6 on the main PCB. To remove the cable from the connector, first release the locking cap to loosen the cable. Slide the cable out, leaving the cap loosely seated in the connector.

Step 5. Use a Phillips-head screwdriver to remove the screw holding the main PCB assembly in place in the front cover assembly.

Connector J7 is on the underside of the board here

Keypad ribbon cable at J6 on main PCB

Backlight power supply at J4 on main PCB
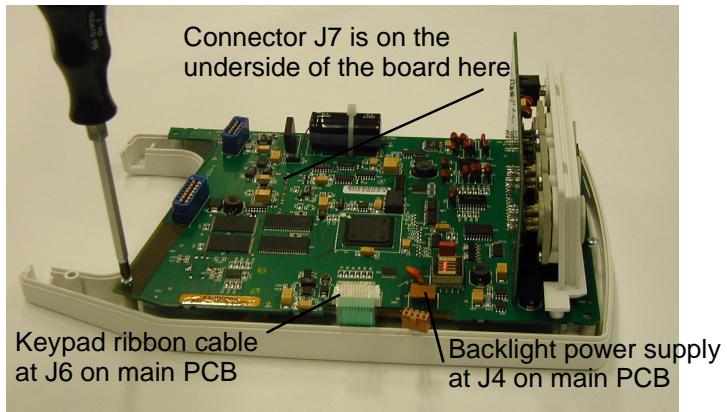
Step 6. Remove the main PCB by gently pulling upwards to disconnect the multipin LCD assembly connector at J7 on the main PCB. Pull straight up to avoid bending the pins.

There are now three separate items:

• Front case assembly

• Rear case assembly

• Main PCB assembly
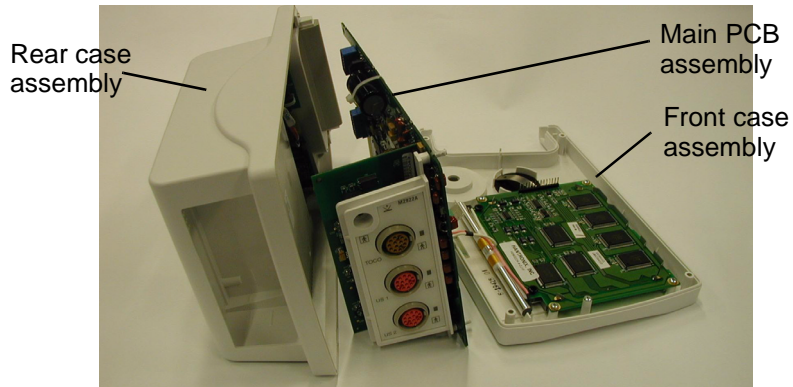
Removing the LCD Assembly

Warning
High voltage is generated by the LCD backlight driver. Do not operate the monitor with the covers open.

The Display Kit (M2922-64004) comes with a replacement display window, which should be replaced when the LCD assembly is replaced.

Step 1.   Use a Phillips-head screwdriver to unfasten the four corner screws.
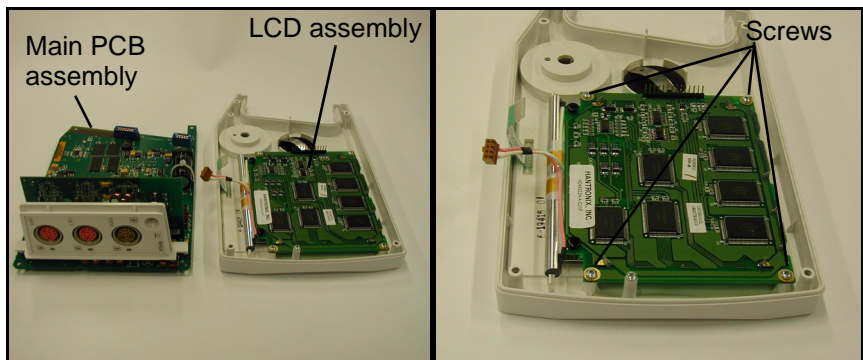
Step 2.   Remove the LCD assembly, providing access to the display window.

Step 3. Remove the display window by carefully prying up one corner and then peeling back.

Front bezel

LCD assembly
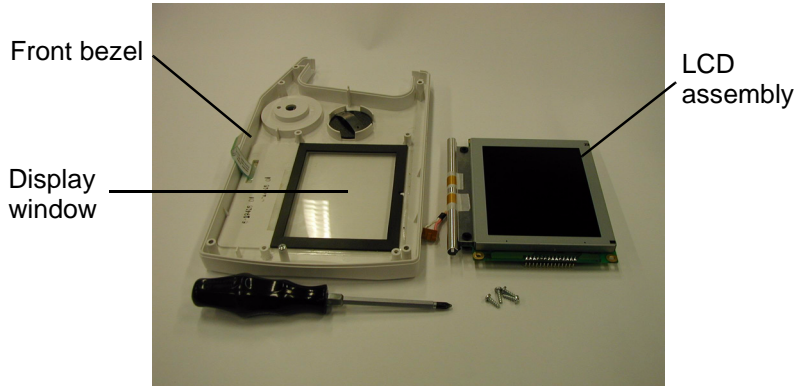
Display window

Replacing the LCD Assembly

Step 1. Fit the new display window with its gasket to the inside of the front bezel. The display window comes with its own double sided adhesive.

Step 2. Position the LCD assembly so that the holes in each corner align with the four screw mounts on the inside of the front bezel.

Step 3. Using a Phillips-head screwdriver, fasten the LCD assembly with the four fixing screws.

Replacing the Main PCB Assembly

Step 1. If the LCD assembly has been removed, first replace it. (See "Replacing the LCD Assembly" on page 51).

Note—**There are two notches on the main PCB, used for location purposes. One is at the patient connector panel end, and the other is on the opposite end. There are two corresponding guides in the front cover.**

Step 2. Align the location notch at the patient connector end of the main PCB with the guide in the front cover, while keeping the opposite end of the main PCB slightly raised and clear of the LCD connector pins (J7 on the main PCB).

Step 3. At this stage, check that the cables and connectors for the LCD backlight power supply and the front keypad do not get trapped underneath the main PCB, but are free and accessible from the side of the main PCB.

Step 4. With the guide in the front cover still located in the notch at the patient connector end of the main PCB, carefully align the connector J7 on the main PCB with the corresponding pins on the LCD assembly.

Step 5. Press down gently until the connector at J7 on the main PCB is fully seated on the pins on the LCD assembly. Check that the notch at the handle end of the main PCB aligns with the guide in the front cover, and that the fixing holes in the main PCB align with the four screw mounts in the front cover. This will confirm that the J7 connector is correctly located. Also check that the navigation wheel shaft is centred in the hole in the plastic bezel recess, so that the refitted wheel does not bind with the case.

Step 6. Using a Phillips-head screwdriver, fasten the fixing screw to the screw mount in the front cover at the handle end, nearest to the navigation wheel/encoder switch.
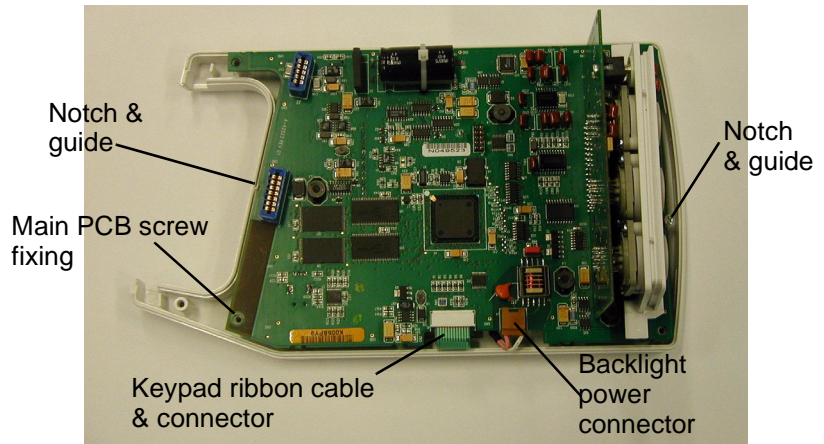
Step 7. Reconnect the backlight power supply connector to J4 on the main PCB. It is only possible to fit the connector one way round.

Step 8. Reconnect the keypad ribbon connector by inserting the ribbon cable fully into the connector at J6 on the main PCB through the locking cap which was left loosely fitted to the connector during disassembly. Slide the locking cap forward to secure the ribbon cable.

Removing the Keypad

The keypad is attached to a recess in the front cover assembly by an integral double sided adhesive.

Step 1.   From the face of the front bezel, carefully pry up one corner of the keypad, then peel it away from the front cover.

Note—The keypad is made up of a number of different layers, which may separate during removal. Ensure that all layers are removed completely before a replacement is fitted.

Replacing the Keypad

Step 1.   Ensure that the recess in the front bezel for the keypad is clean.

Step 2.   Thread the ribbon cable through the slot in the front cover.

Step 3.   Carefully align one end of the keypad with the corresponding edge of the recess in the front bezel, and carefully stick the keypad down, working from one end to the other to avoid air bubbles.

Rear Case Disassembly Procedures

This section describes the items that may be removed/replaced on the rear case assembly of the monitor. First separate the front and rear assemblies as described in the section "Separation of Front and Rear Case Assemblies" on page 45.

Removing the Rear Connector PCB and the Interface Board

The interface PCB is connected at right angles to the rear connector PCB, and is separable from it.

Step 1.   From outside the rear cover, use a 3/16 socket driver to remove the two standoff fasteners of the RS-232 connector, and also the two standoff fasteners of the parallel connector.
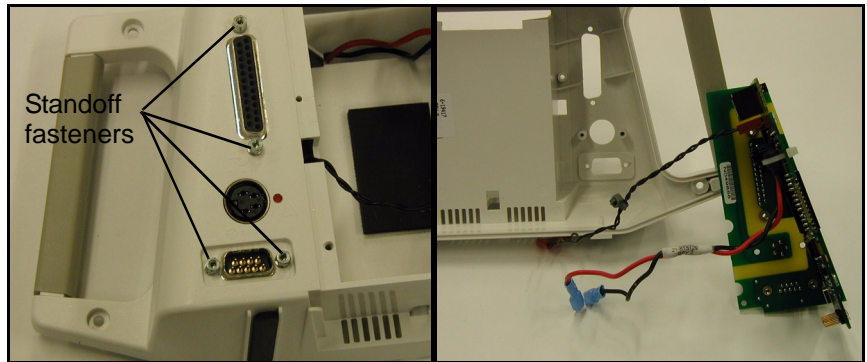
Step 2.   From inside the rear cover, remove the rear connector PCB and the interface PCB connected to it.

Removing the Interface PCB from the Rear Connector PCB

Step 1. Using a Phillips-head screwdriver, remove the two screws on the connector side of the connector PCB.
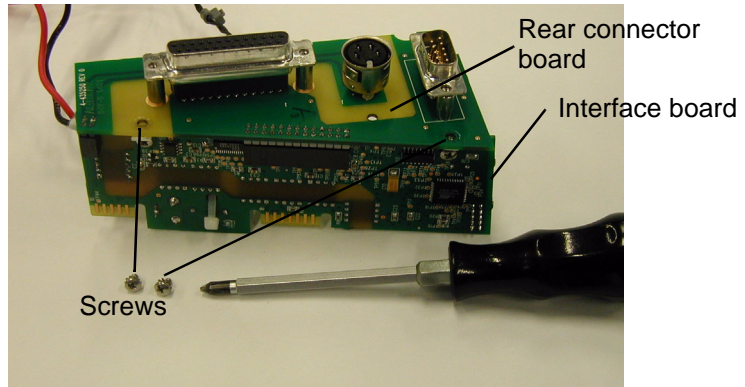
Step 2. Separate the two boards by disconnecting the two multi-pin connectors at J1 and J2 on the rear connector PCB. Ensure that you pull straight, with no twisting action, so that the pins do not get bent.
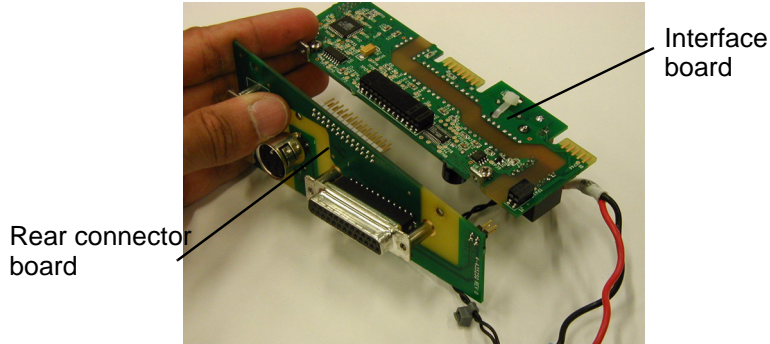
Replacing the Interface PCB on the Rear Connector PCB

The refitting procedure is the reverse of the removal procedure.

Replacing the Rear Connector/Interface PCB Assembly

Step 1. Place the rear connector/interface PCB assembly into the dedicated recess inside the rear case assembly. See that the RS-232, parallel and power supply connectors fit into their respective slots in the rear case.

Step 2. From outside the rear case, use a 3/16 socket driver to refit the two standoff fasteners of the RS-232 connector, and the two standoff fasteners of the parallel port to secure the rear connector PCB in place.

Step 3. Ensure that the speaker cable connector is secure on the interface PCB. Check that the two pins on the board are perpendicular to the board, or leaning slightly towards the connector latch. This will ensure a firm connection.

Step 4. Route the cables for the speaker and the battery.

Speaker cable connector
Connector latch
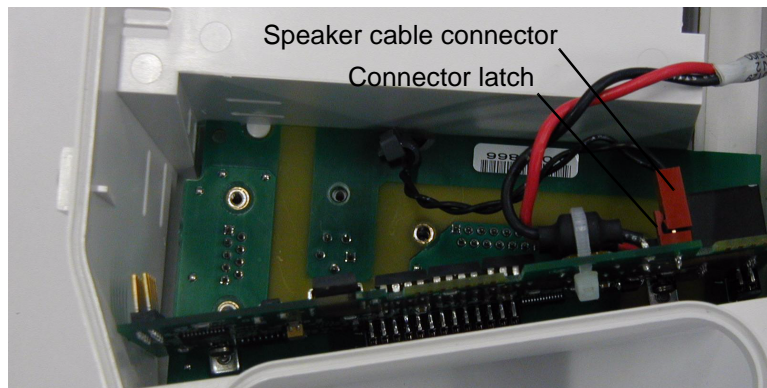
Removing the Handle

Each end of the handle is a friction fit on a cross-shaped boss.

Step 1. Use flat-bladed screwdriver to carefully pry one end of the handle.

Step 2. When the end of the handle has begun to loosen from the boss, use the same technique to begin to pry up the other end.

Step 3. Alternately apply this prying action between each end of the handle until the handle is free of the rear case.

Removing the Foot Cushions

The foot cushions are attached with an adhesive to the bottom surface of the rear cover, and can be removed by lifting one end of the foot and peeling off.

Foot cushions
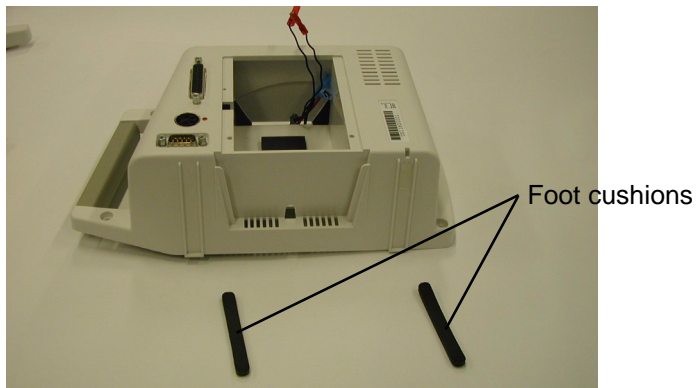
Main PCB Disassembly Procedures

This section describes the items that may be removed/replaced from the main PCB assembly of the monitor. The main PCB assembly is separable from the front case assembly.

Step 1. First separate the front and rear assemblies as described in the section "Separation of Front and Rear Case Assemblies" on page 45.

Step 2. Then remove the main PCB assembly from the front case assembly, as described on page 49.

Removing the Side Panel and Side Connector PCB

Step 1. Use needle-nose pliers or a Tinnerman tool to remove the two Tinnerman fasteners securing the white plastic side panel to the underside of the main PCB.

Tinnerman nut
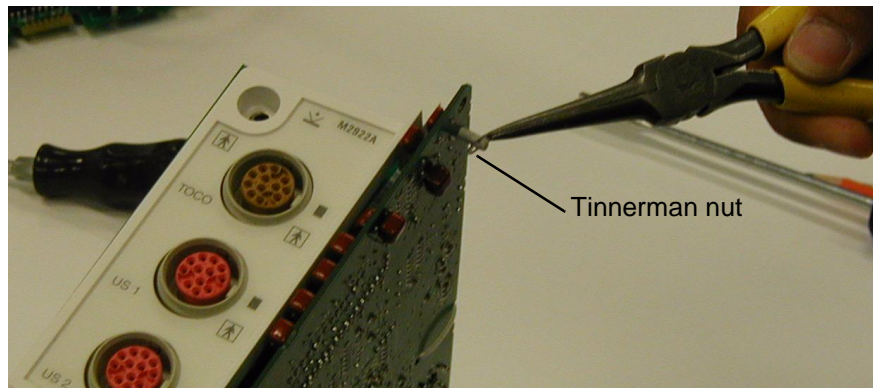
Step 2. The side panel is attached by screws to the side connector PCB. Remove this assembly from the main PCB by pulling it straight up, disconnecting the multipin connector at J3 on the main PCB.

J3
on
main
PCB
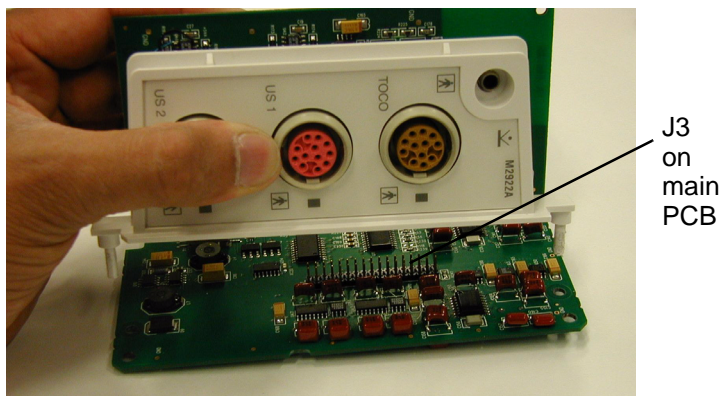
Step 3. Use a Phillips-head screwdriver to remove the six screws that secure the side panel to the socket surrounds. Access to the screws is gained through the holes in the side connector PCB.
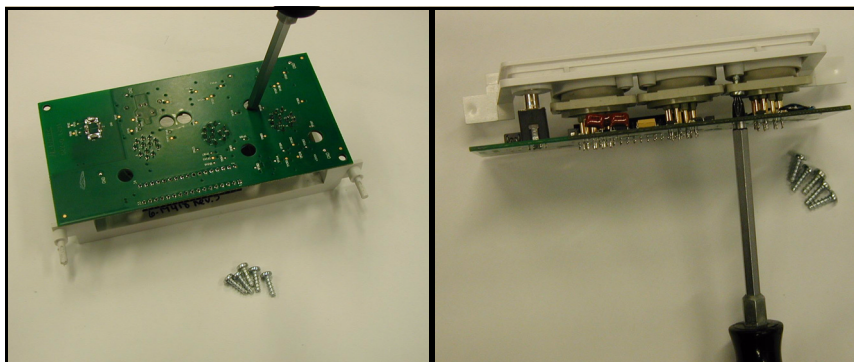
Step 4. Remove the side panel from the side connector PCB.

Replacing the Side Panel/Side Connector PCB

Step 1.   Place the side panel on the side connector PCB so that the sockets on the side connector PCB fit the holes in the side panel.

Step 2.   Using a Phillips-head screwdriver, fasten the side connector PCB to the side panel using the six screws.

Step 3.   Align the studs on the bottom of the side panel with the holes on the main PCB. Also align the pins at J3 on the main PCB with the corresponding multipin connector on the side connector PCB.

Step 4.   Push down until the pins at J3 on the main PCB are fully mated with the multipin connector on the side connector assembly. There should be no gap between the bottom of the side connector PCB and the main PCB. Ensure that the side connector PCB is perpendicular to the main PCB.

Step 5.   From underneath the main PCB, fit a new Tinnerman nut to each of the two side panel studs located in the holes on the main PCB. Ensure that the side panel PCB remains perpendicular to the main PCB surface, and that the side panel is held firmly by the Tinnerman nuts.

7
Spare Parts

Introduction

Spare parts, along with part numbers, are listed in the tables that follow. "Item No." corresponds to the callout number in Figure 7 through Figure 11. The "Page Ref." indicates the page number of the relevant disassembly procedures in Chapter 6.

Small Parts Kit

Most small parts and hardware (screws, and so forth) can be found in the Small Parts Kit, Part Number M2922-64003. The Small Parts Kit is supplied with every major spare part.

Exchange Parts

Monitor (M2922A)

Table 6   Exchange Assemblies - M2922A

Exchange Part No.	Description
M2922-68000	Entire monitor
M1355-69011	TOCO Transducer
M1356-69011	US Transducer

Recorder (M2925A)

Table 7   Exchange Assemblies - M2925A

Exchange Part No.	Description
M2925-68110	Recorder 100V, 120V
M2925-68220	Recorder 220V, 240V

Non-Exchange Parts

Table 8   Non-Exchange Assemblies - M2922A

Item No.	Part No.	Description	Page Ref.
1	M2922-66505	Connector board	59, 61
2	M2922-66510	Interface board	56
3	M2922-40003	Battery	43, 44
4	M3921-60406	Navigation wheel	47
-	M2922-64001	Housing kit	-
5A & 5B	M2922-64004	Display assembly kit	50, 51
6	M2922-64002	Speaker kit	41, 42
7	M2922-44301	Key pad	54
-	M2922-64003	Small parts kit	-
8	M2922-60511	Rear connector board	55, 57
-	M3921-61000	Power supply 100V - 120V	
-	M3921-61010	Power supply 220V - 240V	
-	M1380-61624	Serial interface cable to PC, OB **TraceVue** and FM-2 viewer	-
-	15249A	Event marker	-

Supplies and Accessories

Table 9   Supplies and Accessories - M2922A

Part No.	Description
M1356-43203	Transducer knob adapters (3-pack)

Breakdown of Spare Parts Kits by Component

M2922-64003 - Small Parts Kit

Table 10   M2922-64003 Small Parts Kit

Component Description	Quantity
Screw, mach Phillips-head 4-40 X 3/16	4
Screw, tri-lob, Phillips-head 6 X 1/2	6
Ring retaining ext, 1/8 shaft	2
Screw, tri-lob, Phillips-head 4 X 3/8	17
Retaining ring for wheel	1
Screw locking kit	2

M2922-64001 - Housing Kit

Table 11   M2922-64001 Housing Kit

Component Description	Quantity
Small Parts Kit[1]	1
Front case	1
Louver cover plate	1
Handle	1
Rubber feet (cushions)	2
Speaker retainer spring	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M2922-64002 - Speaker Kit

Table 12   M2922-64002 Monitor Speaker Kit

Component Description	Quantity
Small Parts Kit[1]	1
Speaker housing	1
Bracket R/A 4-40	1
Speaker retainer	1
Speaker	1
Cable - speaker assembly	1
Gasket - speaker	1
Pad - battery, front/rear	1
Label - rear	1
Pad - battery, front/rear	1
Pad - battery, right	1
Pad - battery, left	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M2922-40003 - Battery Kit

Table 13   M2922-40003 Battery Kit

Component Description	Quantity
Small Parts Kit[1]	1
Battery, 6V 4AH lead acid, sealed	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M3921-60406 - Knob (Navigation Wheel) Kit

Table 14   M2922-60406 Knob (Navigation Wheel) Kit

Component Description	Quantity
Knob	1
Ring retaining 3/8" shaft	1

M2922-44301 - Keypad Kit

Table 15   M2922-44301 Keypad Kit

Component Description	Quantity
Small Parts Kit[1]	1
Keypad - switch, membrane	1

1. For contents of the hardware mounting kit, refer to Table 10 on page 66.

M2922-64004 - Display Kit

Table 16   M2922-64004 Display Kit

Component Description	Quantity
Small Parts Kit[1]	1
LCD assembly	1
Window display with gasket	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M2922-66505 - Side Connector PCB Kit

Table 17   M2922-66505 Side Connector PCB Kit

Component Description	Quantity
Small Parts Kit[1]	1
Side PCB, with twin ultrasound, and one Toco sockets	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M2922-66510 - Interface PCB Kit

Table 18   M2922-66510 Interface PCB Kit

Component Description	Quantity
Small Parts Kit[1]	1
Interface PCB	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

M2922-66511 - Rear Connector PCB Kit

Table 19   M2922-66511 Rear Connector PCB Kit

Component Description	Quantity
Small Parts Kit[1]	1
Rear connector PCB	1

1. For contents of the Small Parts Kit, refer to Table 10 on page 66.

Assembly Drawings

REAR LABEL

CONNECT SPEAKER CABLE FROM INTERFACE PCB TO SPEAKER TERMINALS

2 REQD: TORQUE TO 0.3 - 0.6 Nm (3 - 5 in. lbs)

MANUFACTURING LOGO TO FACE OUTWARDS TOWARDS SPEAKER HOUSING

SPEAKER HOUSING ASSEMBLY (SEE SHEET 6)

4 REQD: TORQUE TO 0.3 - 0.6 Nm (3 - 5 in. lbs.)

INTERFACE AND REAR BOARD ASSEMBLIES (SEE SHEET 4)

J1 & J2 ON MAIN PCB CONNECTS TO PCB PINS ON I/F PC

NOTE POLARITY CONNECT BATTERY CABLES FROM I/F PCB (SHEET 4) RED TO (+) TERMINAL BLACK TO (-) TERMINAL

REAR CASE ASSEMBLY (SEE SHEET 3)

SIDE BOARD ASSEMBLY (SEE SHEET 5)

FRONT CASE ASSEMBLY (SEE SHEET 2)

Figure 7   Assembly Drawing (Sheet 1) - Top Level Assembly
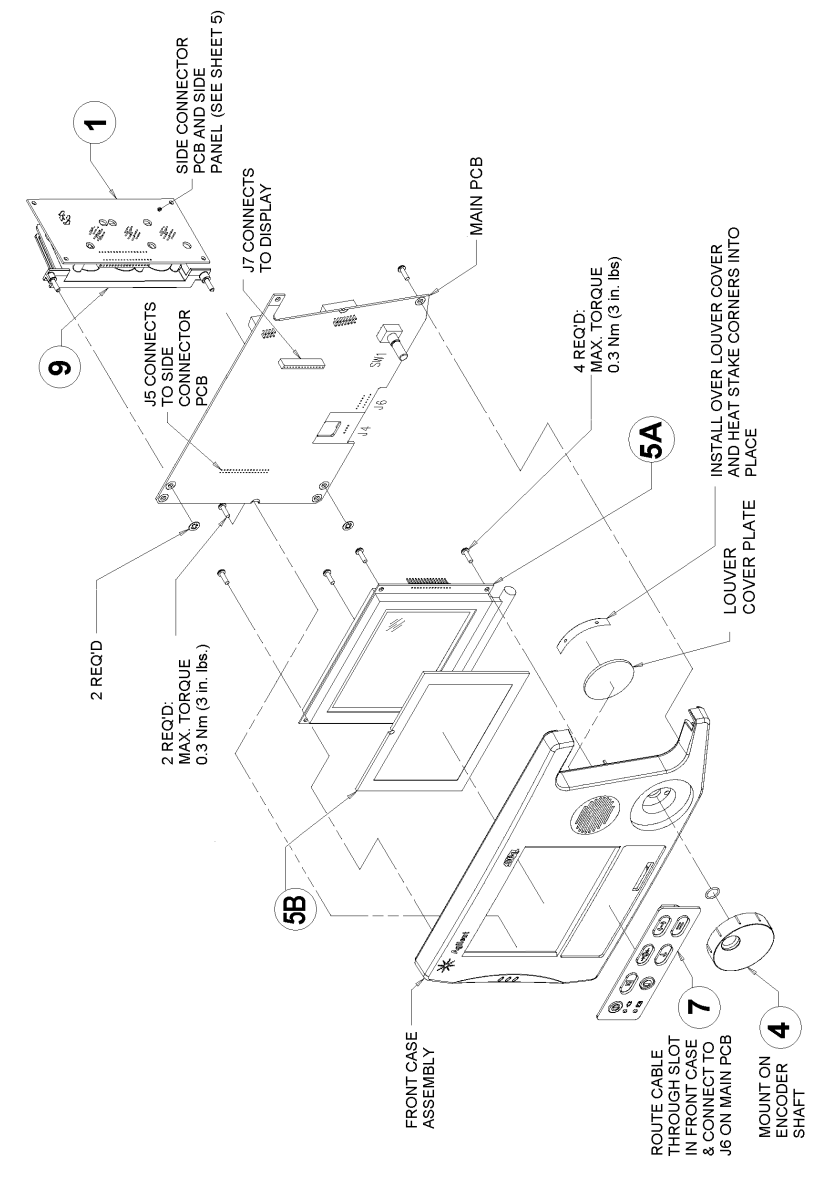
Figure 8   Assembly Drawing (Sheet 2) - Front Case Assembly
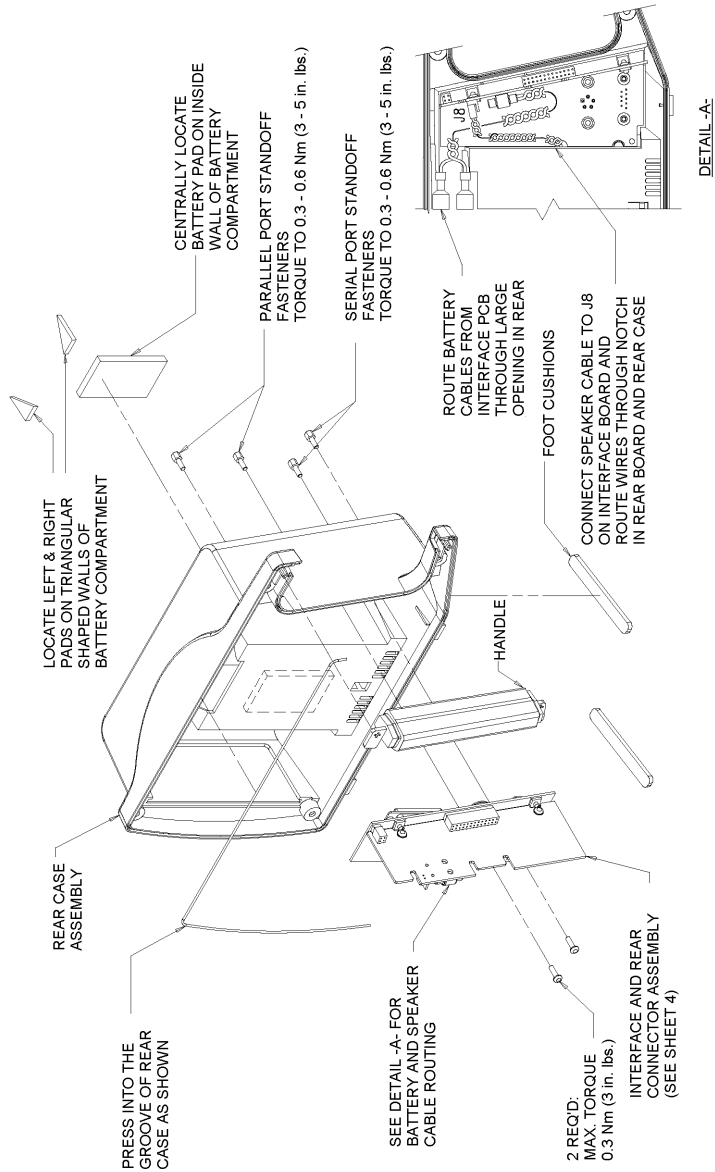
Figure 9   Assembly Drawing (Sheet 3) - Rear Case Assembly
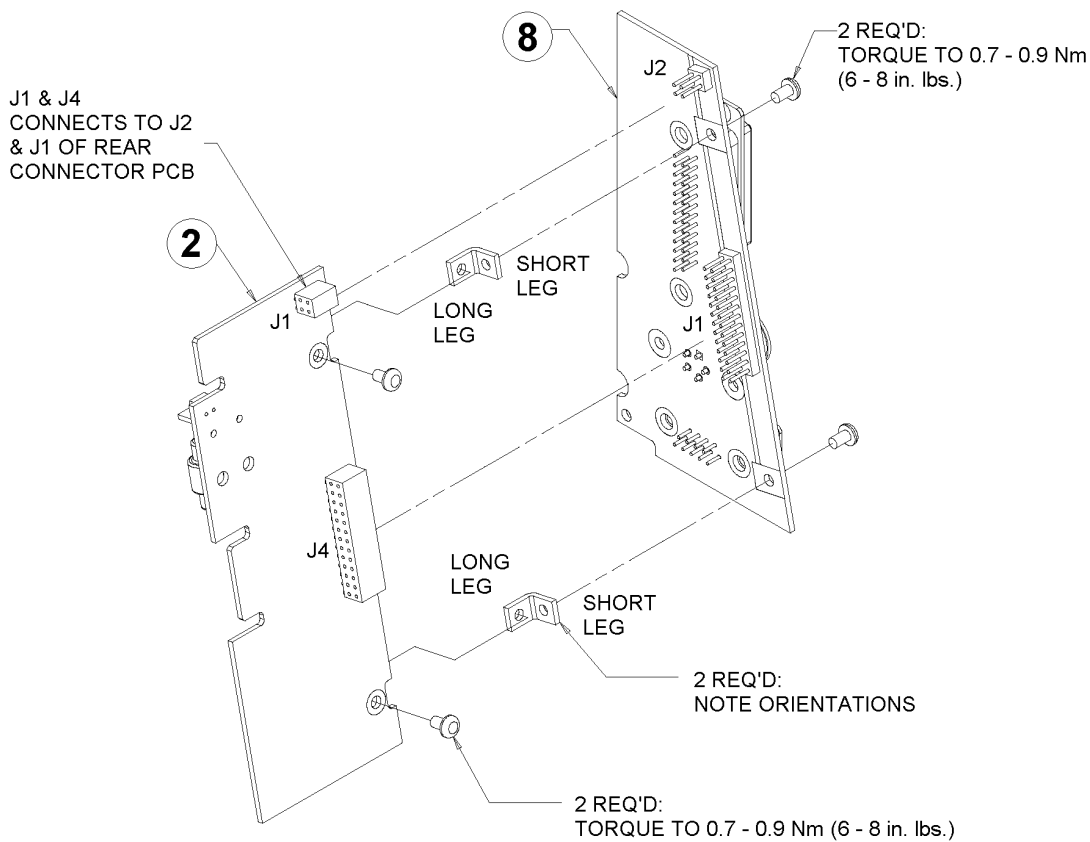
Figure 10   Assembly Drawing (Sheet 4) - Interface PCB/Rear Connector PCB

6 REQ'D
MAX. TORQUE 0.3 Nm
(3 in. lbs.)
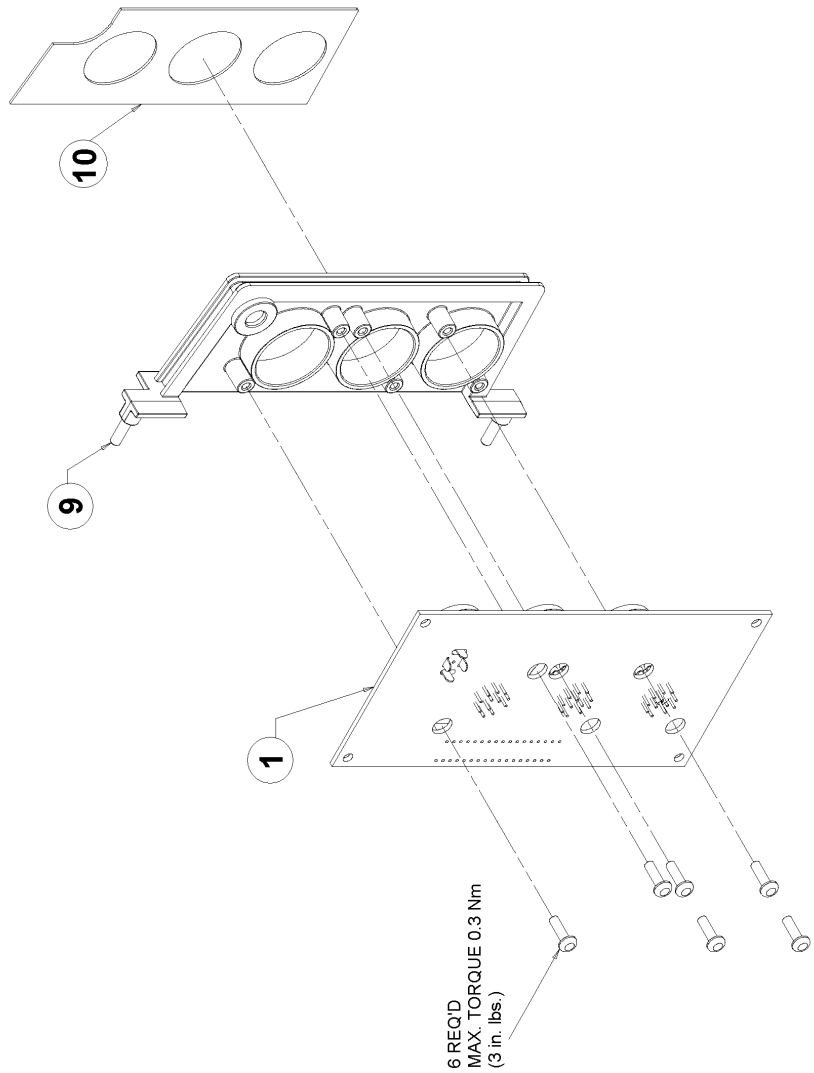
**Figure 11   Assembly Drawing (Sheet 5) - Side Connector PCB/
Panel/Label**

Assembly Drawings

Test and Inspection Matrix

Warnings

Warning
EXPLOSION HAZARD! Do not use the FM-2 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

Warning
SHOCK HAZARD! The power-receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the power supply or accessory to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

Warning
SHOCK HAZARD! Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

Warning
Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specification performance and possible safety hazards.

Cautions

Caution
Use care when transporting or moving the monitor to assure that the attached patient cables are stored so that they will not be damaged in the move.

Caution
Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.

Caution
Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

Caution
Never use sharp or pointed objects to operate the front-panel switches.

Caution
General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices. The RS-232 and parallel connectors on the monitor are electrically isolated to permit safe connections to non-medical devices, which should be connected with a cable of sufficient length to prevent the non-medical equipment from contacting the patient.

If a non-medical device is connected to the serial port, a recorder or printer connected at the same time to the parallel port should be located outside the patient vicinity, as the two interfaces are not isolated against each other.

Introduction

This chapter contains maintenance and safety information for the FM-2 antepartum fetal monitor and its accessories.

All checks that require the instrument to be opened must be made by qualified service personnel. Please contact your local Agilent representative when you wish safety and maintenance checks to be carried out.

To ensure that your monitor functions properly and safely, you must adhere to the standards stated in this manual.

When to Perform Tests Blocks

Table 20 shows which test blocks to perform after repair and preventive maintenance tasks.

Table 20   FM-2: When to Perform Test Blocks

Service Event		Test Block(s) Required (See Table 21 on page 81)
Installation	The product is *customer installed.* Refer to the *Instructions for Use.*	Visual and Power On
Preventive Maintenance	Preventive maintenance is limited to exchanging the battery	Power On Safety Tests
Repairs	Unit Exchange	Visual and Power On
	Unit opened	Visual and Power On
	Front End Connector Board exchanged	Power On Performance Tests for Transducers Safety Tests
	Rear Connector Board exchanged	Power On Safety Tests
	Power Supply exchanged	Power On
	Battery exchanged	Power On Safety Tests

Table 21   Test and Inspection Matrix

Test Block Name	Test	Expected Results	What to Record
Visual Test (See 20)	Inspect exterior of fetal monitor for damage.	No Visual Damage	V:P or V:F
Power-On Self-Test (See 20)	Power on the monitor	Displays Normal Monitoring Screen Configuration and emits tones	PO:P or PO:F
Safety Tests:			
• **Safety Test 1** (See 86)	Enclosure Leakage Current - S.F.C. Open Supply	All Safety Test results are in range of Table 22 on page 87	S:P or S:F
• **Safety Test 2** (See 88)	Patient Leakage Current - S.F.C. Open Supply	All Safety Test results are in range of Table 23 on page 89	S:P or S:F

Key to Table: P = Pass   F = Fail

Battery Charging and Maintenance

Before attempting to perform any tests, it is important to verify that the battery is charged and functional.

Using the Battery

You can run the monitor for approximately six hours on battery power at room temperature of 25° C from a fully charged battery (with a minimum of two hours monitoring at 10° C from a fully charged battery). The age of the battery, operating temperature and number of recharge cycles affects this. A battery life cycle is approximately 200 charge/discharge cycles.

Low Power Warning

A low power warning occurs when the battery power is running low. The battery fuel gauge flashes, and a repetitive audible tone sounds. Remaining monitoring time is typically 30 minutes with a new battery at room temperature of 25° C. In an older monitor, in which the battery has had a number of recharge cycles, it may occur when fewer minutes remain.

The warning continues until the low power condition disappears (when you connect the monitor to an AC power supply) or until the system stops functioning because of the low power. You cannot silence it, and you cannot adjust its volume.

The monitor retains any stored fetal traces, even if it shuts down because of lack of battery power.

Recharging the Battery

Use the power supply to recharge the battery from an AC power source. This takes a maximum of 14 hours when monitoring simultaneously, or eight hours if no monitoring occurs. Typical times are 11 hours if you are monitoring simultaneously, or 4.75 hours if no monitoring occurs.

Storing

A stored battery loses capacity over time. To minimize loss of capacity, recharge the battery at least every six months. A battery typically has three to five years shelf life.

Preventive Maintenance

The only preventive maintenance task required for the monitor is battery exchange. Life expectancy of a battery depends on the frequency and duration of use. The battery should be replaced every two years.

Safety Testing

This section defines the test and inspection procedures applicable to the FM-2 fetal monitors. Use the tables in the following section to determine what test and inspection results must be reported after a repair has been carried out.

- **Test Blocks** in Table 20 tells you when to carry out the tests blocks

- **Test and Inspection Matrix** in Table 21 tells you the expected results of the tests and what to record.

Warning
Apply the safety test limits set by the local standards and statutes applicable to the country of installation, such as IEC 601-1, UL2601, CAN/CSA-C22.2 No. 601.1.M90.

The safety tests defined in this chapter are derived from local and international standards but may not be equivalent. They are NOT a substitute for local safety testing.

Caution
Successful completion of the patient safety tests does not ensure the correct and accurate functioning of the equipment.

Safety Test Procedures

The test procedures outlined in this section are to be used only for verifying the safe installation or service of the product. "Safety checks at installation refer to safety aspects directly related to the installation and setup activities and not to intrinsic safety features that have already been checked during final acceptance testing at the factory."
[FDA 97-4179 Medical Quality Systems Manual: A Small Entity Compliance Guide (QSR manual). First Edition December 1996. Chapter 14: Storage, Distribution and Installation. This document may be viewed at http://www.fda.gov.

When running safety tests on the peripheral components of the system, refer to the documentation included with those products.

When performing safety tests, you must use a standard safety tester. You can use testers complying with IEC 601-1 internationally. You may also use testers complying with any local standards and statutes applicable to the country of the installation. For safety test procedures see the operation instructions of the safety tester used.

If using the Metron safety tester use your local regulations to perform the test, for example

• in Europe: IEC60601-1/IEC60601-1-1

• in the US: UL2601-1

The Metron Report should print results as detailed in this chapter, along with other data.

Note—**For information and ordering guides for Metron products contact:**
Metron AS, Travbaneveien 1, N-7044 Trondheim, Norway
Tel. (+47) 73 82 85 00; Fax (+47) 73 91 70 09;
E-mail: sales@metron.no/support@metron.no
www: http://www.metron-biomed.com

There are two general categories of safety test:

• Ground integrity

• Electrical Leakage

Ground Integrity

The FM-2 is a Class 2, Type BF instrument. It has an external power supply, and is constructed with double insulation. The FM-2 does not require an isolated Earth Ground terminal, neither is one installed. No Protective Ground Continuity check is required.

Electrical Leakage

The following tests verify the electrical leakage of the monitor:

- Enclosure leakage Current
- Patient Leakage Current

Safety Test 1: Enclosure Leakage Current Test

Normal Condition

This test is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures leakage current of exposed metal parts of the Instrument Under Test. It tests both normal and reversed polarity.

For type BF and CF Applied Parts the test measures AP/GND.

Safety Test according IEC 601-1 (Clause 19).

Report the highest value.

Single Fault Condition (S.F.C.) Open Supply

This test is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures leakage current of exposed metal parts of the Instrument Under Test with one supply lead interrupted. It tests both normal and reversed polarity.

For type BF and CF Applied Parts the test measures AP/GND.

Safety Test according IEC 601-1 (Clause 19).

Report the highest value.

Test Steps
1. Connect the external power supply output cord to the monitor. Then connect the appropriate external power supply input power cord to the analyzer as recommended by the analyzer operating instructions.

2. Using the appropriate test cable, connect the analyzer to a fixing nut of the RS-232 connector on the back of the monitor.

3. Turn the monitor on.

4. Perform the test as recommended by the analyzer operating instructions.

The analyzer leakage current indication must not exceed the values listed in Table 22.

Table 22   Enclosure Leakage Current

Test Condition	Polarity	Maximum Leakage Current (µA)	
		IEC 601-1 ES1	AAMI/ANSI Standard
Normal	Normal	100 µA	100 µA
	Reversed	100 µA	100 µA
S.F.C.[1] (Open Supply)	Normal	500 µA	300 µA
	Reversed	500 µA	300 µA

1. S.F.C. = Single Fault Condition

Safety Test 2: Patient Leakage Current Test

Normal Condition

This test is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures patient leakage current from any individual patient connection to earth (power ground) in parallel. It tests both normal and reversed polarity.

Safety Test according IEC 601-1 (Clause 19).

Report the highest value.

Single Fault Condition (S.F.C.) Open Supply

This test is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures patient leakage current from any individual patient connection to earth (power ground) in parallel, with one supply lead interrupted. It tests both normal and reversed polarity.

Safety Test according IEC 601-1 (Clause 19).

Report the highest value.

Test Steps

This test requires a sample patient cable for each device parameter. These must be configured as recommended by the safety analyzer operating instructions.

1. Configure the electrical safety analyzer as recommended by the analyzer operating instructions.

2. Connect the appropriate external power supply input power cord to the analyzer as recommended by the analyzer operating instructions. Connect the external power supply output cord to the monitor.

3. Turn the monitor on.

4. Perform the test as recommended by the analyzer operating instructions.

For each test condition, the measured leakage current must not exceed that indicated in Table 23.

Table 23   Patient Leakage Current Values

Test Condition	Polarity	Maximum Allowable Leakage Current (µA)
		Type B & BF
Normal	Normal	100 µA
	Reversed	100 µA
S.F.C.[1] (Open Supply)	Normal	500 µA
	Reversed	500 µA

1. S.F.C. = Single Fault Condition

System Safety Test

Whenever you connect a monitor to an obstetrical system such as Agilent OB **TraceVue** you **must** perform the System Test. The System Test consists of the Enclosure Leakage Current tests (normal and single fault condition) as described on 86. You must run this test when connecting either a new or repaired monitor.

Testing Transducers

Testing Toco Transducers

Visual Check   Check the transducer for signs of damage. Ensure that there are no cracks in the transducer housing or dome, in the cable or the connector plug.

Electrical Check
1. Turn on the monitor.

2. Connect the transducer to the Toco socket.

3. Check that the display acknowledges the connected transducer in the Toco frame of the main monitoring screen.

4. Lay the transducer face up on a flat surface for a few seconds.

5. Set the Toco Baseline as follows:

    a. Highlight the Toco frame in the main monitoring screen by turning the navigation wheel.

    b. Press the wheel to enter the Toco Menu. The existing Toco Baseline will be displayed.

    c. If you need to change this, highlight the **TOCO Baseline** menu item, and press the navigation wheel. You will see a box containing the choices for setting the Toco Baseline.

    d. Highlight the desired Toco Baseline value by turning the navigation wheel, and select by pressing the wheel.

    e. Exit the Toco menu by highlighting Return and pressing the navigation wheel.

6. Zero the Toco by pressing the ⬭ button.

7. Turn the transducer over so that button is face down on the flat surface. Hold the cable at a point 25 cm from the transducer and ensure that the

transducer touches the flat surface only with the button and that the transducer is parallel to the flat surface.

8. The Toco display should read between 20 and 40 units above the Baseline.

Toco display = 5, 10, 15, or 20 depending on Baseline setting

Toco display = 20 - 40 Toco units above the Baseline

Flat Surface   Flat Surface
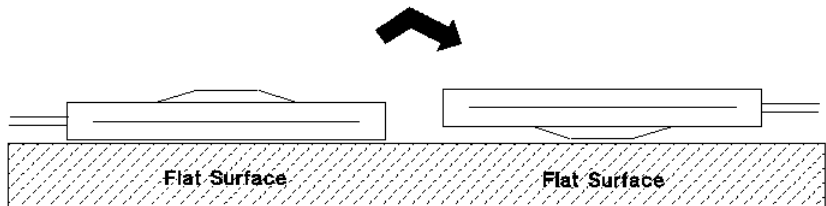
Figure 12   Testing a Toco Transducer

9. If the test fails, repeat with another transducer. If it still fails, refer to Chapter 5, "Troubleshooting".

Testing Ultrasound Transducers

Visual Check   Check the transducer for signs of damage. Ensure that there are no cracks in the transducer housing or dome, in the cable or the connector plug.

Electrical Check

1. Turn on the monitor.

2. Connect the transducer(s) to the US 1 or US 2 socket.

3. Check that the display acknowledges the connected transducer(s) in the Ultrasound frame of the main monitoring screen.

4. Increase the loudspeaker volume to an audible level.

5. Holding the transducer in one hand, move your hand repeatedly towards and then away from the surface of the transducer, or gently tap the transducer surface with your finger.
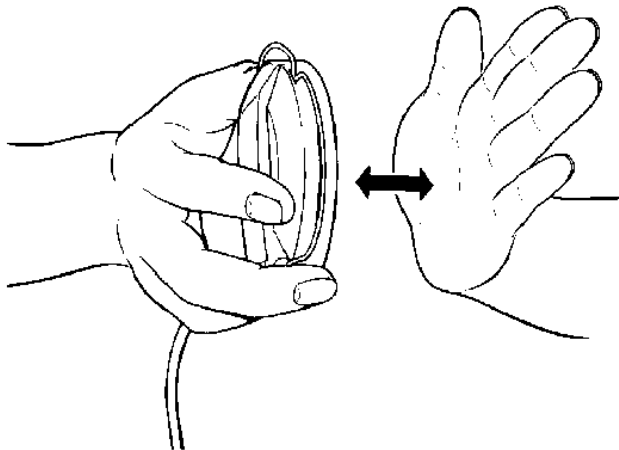
Figure 13   Testing an Ultrasound Transducer

6. Check that a noise is heard from the loudspeaker.

7. The transducer contains seven piezo-electric crystals.
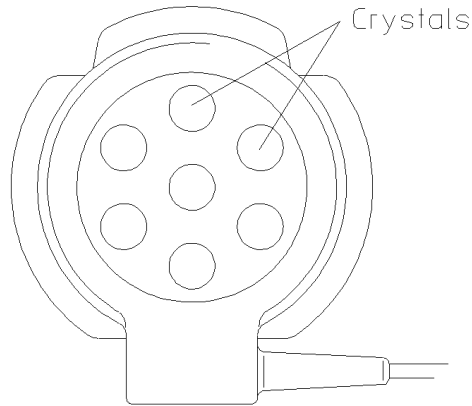
Figure 14   Position Of Crystals in an Ultrasound Transducer

8. Holding the transducer in one hand, move a flat-bottomed pencil or similar object repeatedly towards and then away from each crystal. The distance between the pen and the transducer surface should be about 2 to 3 cm.
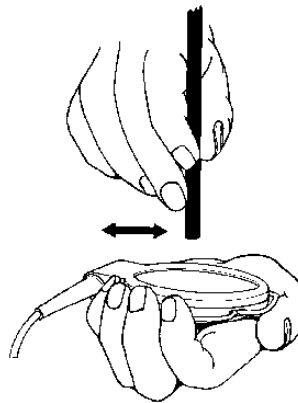
Figure 15   Testing the Crystals in an Ultrasound Transducer

9. Check that a noise is heard from the loudspeaker for each crystal.

10. If the test fails, repeat using another transducer. If it still fails, refer to Chapter 5, "Troubleshooting".

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