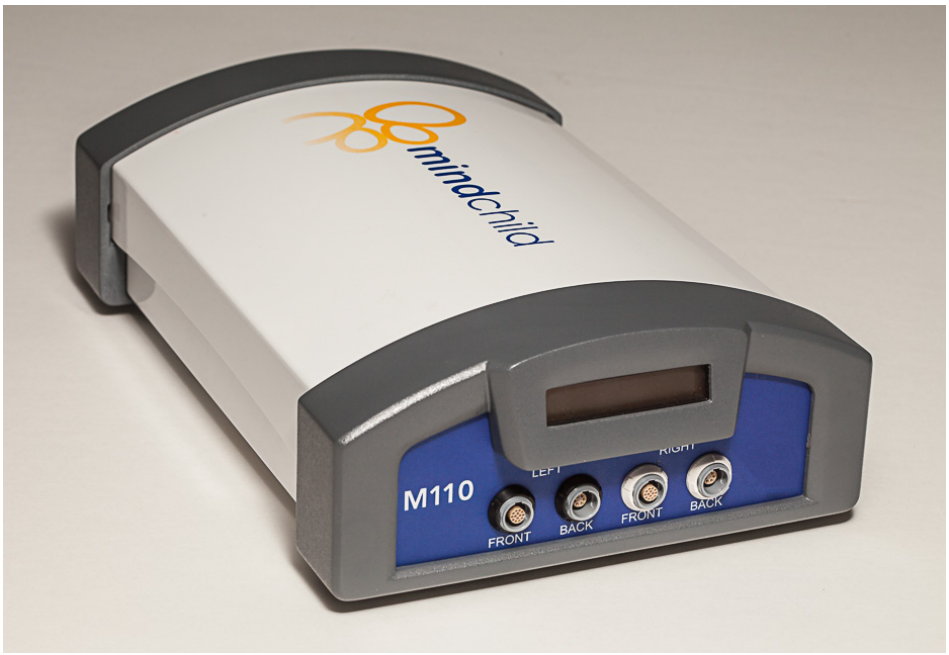


Meridian M110 Fetal Monitoring System
User & Service Manual

MindChild Medical, Inc.

23MOU110 V1902

MindChild Medical, Inc. Contact Information

Service Calls and Product Support

To inquire about product support or request service, call the number below:

(978) 566 - 1421

Ordering Product Parts and Accessories

Order accessories or other parts (including manuals, electrode patches, cables, etc.) from:

MindChild Medical, Inc.
1600 Osgood Street
Suite #2017
North Andover, MA 01845
Phone: (978) 975 - 1160
Fax: (978) 688 - 8875
support@mindchild.com

The following information is needed before requesting parts, accessories, and service:

- The name of the part/item
- Either the part number of the defective part **OR** the model and/or serial number of the equipment

Questions, Comments, and Concerns

Any additional questions, comments, concerns, or problems may be addressed by contacting MindChild Medical, Inc., using the contact information listed under Ordering Product Parts and Accessories.

Table of Contents

1. Introduction

1.1. Who this Manual is For

This manual is intended to be used by trained healthcare professionals using the Meridian M110 Fetal Monitoring System. It describes how to set up, use, and maintain the monitor, cables, and patient electrodes.

Familiarize yourself with all instructions, including warnings and cautions, before monitoring patients. Read and keep the Instructions for Use (IFU) that come with any accessories, as these contain important information about the accessories' applications, care and cleaning that is not included in this manual.

If using the Meridian M110 Fetal Monitoring System, you should be:

- Trained in the use of fetal heart rate (FHR) monitors
- Trained in the interpretation of FHR readings
- Familiar with using medical devices
- Familiar with standard fetal monitoring procedures

In this manual:

- A **WARNING** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in injury to the user/operator or patient.
- A **CAUTION** alerts you to where special care is necessary for the safe and effective use of the monitor. Failure to observe a caution may result in minor or moderate personal injury, damage to the monitor, or damage to other property.
- A **NOTE** is either a suggestion to optimize performance or a comment to clarify monitor usage.
- "**Monitor**" and "**M110**" and "**Meridian M110**" refer to the entire Meridian M110 Fetal Monitoring System Monitor boxed unit.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

1.2. Intended Use

The MindChild Meridian M110 Fetal Monitoring System is intended to be used to monitor the heart rate and contraction pattern of a singleton fetus during labor and delivery.

The Meridian M110 Fetal Monitoring System is intended for use by trained health care professionals.

The Meridian M110 Fetal Monitoring System is intended for use in delivery rooms and intrapartum testing areas in a hospital environment.

1.2.1. Essential Performance

The essential performance of the Meridian M110 Fetal Monitoring System is defined as follows:

1) Fetal heart rate within ±5 bpm accuracy for 90 percent of the time averaged over a three to five-minute window
2) Uterine activity start time and end time within ±30 seconds for 90 percent of the time

1.2.2. Indications for Use

The Meridian M110 Fetal Monitoring System is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR), maternal heart rate (MHR), and uterine contractions (UA). The Meridian M110 Fetal Monitoring System acquires and displays the FHR and UA from abdominal surface electrodes that detect the fetal ECG signals, maternal ECG signals, and of uterine muscle contraction signals. Tracings of FHR and UA are displayed onto a primary fetal monitor.

The Meridian M110 Fetal Monitoring System is indicated for use on women who are at ≥ 37 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The MindChild Meridian is intended for use by health care professionals in a clinical setting.

1.2.3. Contraindications

The Meridian M110 Fetal Monitoring System is **not** intended for:

- Use as a primary patient monitor, fetal or maternal, or as an ECG monitor
- Use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI).

- ECG measurements on patients connected to external electrical stimulators or with cardiac pacemakers
- Use in domestic establishments
- Use in establishments connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.

1.3. Safety Information

The following information is vital to ensure the safety of the patient, operator, and any additional individuals who may come into contact with the Meridian M110 Fetal Monitoring System for the duration of the monitor's lifecycle. This section describes the use of any terms and symbols as well as the responsibilities of the manufacturer and of the user.

1.3.1. Hazards and Cautions

1.3.1.1. M110 Symbol Definitions

TABLE 1: M110 SYMBOL DEFINITION

Icon	Standard	Definition
	IEC 60878-2497	Caution – MR Unsafe
	IEC 60878-5333	BF applied part – body, floating
	IEC 60417-5172	Electrical Class II equipment, in which the protection against electrical shock relies on double or reinforced insulation
	ISO 7010-W001	Caution – general warning sign
	IEC 60878-1641 ISO 7010-Safety01	Follow operating instructions
	ISO 7010-M002	Refer to instruction manual

1.3.1.2. Meridian M110 Monitor – Specific Hazards

The following hazards have been identified for the Meridian M110 Fetal Monitoring System. Additional hazards, hazardous situations, and risks may be found in Risk Management documents, which may be obtained from MindChild Medical, Inc., upon request. Read this user manual and service manual prior to operating the Meridian M110 Fetal Monitoring System.

Warnings

TABLE 2: M110-SPECIFIC WARNINGS	
Warning Title	*Description*
Accidental Spills	Should liquids or fluids of any kind be spilled on or near the monitor, immediately disconnect the monitor from the power supply and from the main monitoring unit. Inspect the monitor for damage, and arrange for maintenance and servicing if and as needed
Accidental Drop	Should the Meridian M110 Monitor fall to the floor, inspect the device for damage. If any of the connectors are cracked or broken; or the LCD display is cracked or broken; or the device does not power on; contact MindChild Medical to request service by a qualified MindChild Medical technician.
Clinical Use – EMG Precautions	The Meridian M110 Monitor deploys electromyography (EMG) technology to assess uterine activity. However, the safety and effectiveness of EMG for uterine activity monitoring have not been established for the following patient populations: preterm gestations (i.e, less than 37 weeks gestation); antepartum; and multiple gestations.
Clinical Use – EMG Timing	In general, use of a non-invasive, external monitor to assess contraction timing, as it relates to fetal heart rate tracing, should not be used in place of an invasive IUPC monitor where more definitive information is needed to make clinical decisions.
Clinical Use – EMG False Positives	The Meridian M110 Monitor deploys electromyography (EMG) technology to assess uterine activity. However, this technology may interpret other muscular activity, such as early uterine activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract and certain maternal movement involving the abdominal muscles, as uterine activity and therefore produces a “false positive” baseline deflection. Detection of these muscular activities typically produces low amplitude deflections above the baseline which are dissimilar to typical actual contractions. For example, in the following Meridian M110 Monitor tracing using uterine EMG, there are deflections above the baseline in the tracing that do not correspond to uterine contractions in the simultaneously monitored IUPC tracing. The additional deflections are identified by arrows in the Meridian M110 EMG plot.

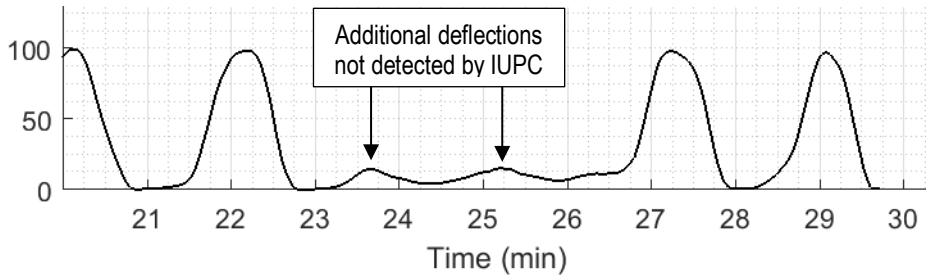
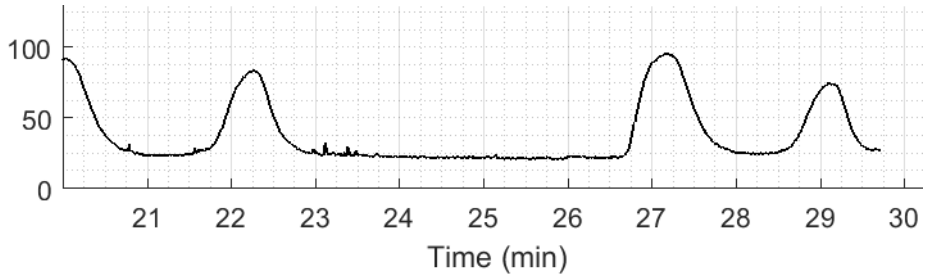
TABLE 2: M110-SPECIFIC WARNINGS	
Warning Title	*Description*
	EMG Plot Generated by M110  **IUPC Comparison Plot** 
Conductive Connections & Parts	Ensure that the patient is not conductively connected to any applied parts. Ensure that any conductive parts from the lead electrodes and their associated connectors do not contact any other conductive parts.
Defibrillation and Defibrillation Protection	The Meridian M110 Monitor is not intended for use during defibrillation. Remove all patches and electrodes from the patient before performing defibrillation, otherwise harm to the patient or the user can result. Please refer to Section 8.9 for more details.
Electrical Shock	To reduce the risk of electrical shock, read this manual and all instructions for use, including the instructions for use for any and all accessories, prior to operating the Meridian M110 Monitor. Do not remove the monitor's cover or expose any internal monitor parts. Should the monitor require servicing, contact MindChild Medical to request service by a qualified MindChild Medical technician.
Electro-surgery	The Meridian M110 Monitor is not designed to be used during electro-surgery. The surgical devices used in such procedures may affect the readings taken by the M110.
Magnetic Resonance Imaging	The Meridian M110 Monitor must not be exposed to a Magnetic Resonance Image (MRI) environment. The device may present a risk of projectile injury due to ferromagnetic material that can be attracted by the MRI core. The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MRI scanner.
Grounding	The grounding plug on the power cord must be used, with the power cord supplied with the Meridian M110 being connected directly from the M110 to a wall socket. The grounding prong must not be defeated or avoided with

TABLE 2: M110-SPECIFIC WARNINGS	
Warning Title	*Description*
	adapters, plug modifications, or otherwise. The defeat or avoidance of the grounding prong may cause a dangerous shock hazard to both the patient and the user/operator.
Connections	Follow all instructions for use and installation instructions. Connect cables properly. The cables have been designed such that improper connection can be avoided, as each cable has a certain number of pins can only be connected to the port with the same number of pin connections. Patient cables connect to the Meridian M110 Monitor. Patches and electrodes attach to the ends of the patient cables, which are placed on the patient. A UA/DECG cable connects from the back of the M110 to the main monitor being used. The M110's power cord connects from the back of the unit to an AC mains wall socket. Cables should only be connected to their proper connections. Do not plug electrode cables/leads into the power cord or wall socket (or vice-versa). Do not use an extension cord. The Meridian M110 Monitor is designed to be used as an accessory monitor, attached to a primary monitor. The user/operator should refer to the primary monitor for patient messages and alarms. Accessories should be ordered through MindChild Medical, Inc., and connected and used according to the relevant instructions for use, provided with the accessories.
Electromagnetic Interference	Electromagnetic fields, such as those potentially generated by electrical medical equipment and personal electronic devices, may interfere with the operation of the Meridian M110 Monitor such that the monitor may not function as desired, readings may be skewed, or otherwise. Should the Meridian M110 Monitor be affected by electromagnetic interference, contact MindChild Medical, Inc., to request service.
Hazardous Situation: Explosion	To reduce the risk of explosion, the Meridian M110 Monitor should not be used in the presence of flammable anesthetics or oxygen
Patient Cables and Leads	Only the patient cables that are provided with the Meridian M110 Monitor should be used. If the provided patient cables or leads become damaged or otherwise unfit for use, contact MindChild Medical, Inc., for replacement cables. Using cables and leads not provided with the monitor may create inappropriate electrical connections that may cause patient or user/operator shock or death.
Leakage	If multiple monitors are simultaneously connected to the patient, the resulting leakage current may exceed allowable limits.
Instructions For Use (IFU)	To ensure safe and efficient operation of the Meridian M110 Monitor, all instructions for use must be followed. Instructions for use include any instructions and steps included in this manual, as well as the instructions for use found in the user manuals for additional accessories.

TABLE 2: M110-SPECIFIC WARNINGS	
Warning Title	*Description*
	It is significant to note that the instructions for use and operation of the Meridian M110 pertain solely to the safe and efficient use of the M110. These instructions do not replace or bypass established medical procedures for patient care. The patient should be monitored and evaluated my relevant qualified medical personnel (physicians, nurses, etc.) regularly to ensure patient safety and to intervene or treat the patient as necessary.
Patients with Pacemakers	The Meridian M110 Monitor is not intended for use on patients who have pacemakers.
Radiofrequency Interference	The Meridian M110 Monitor was designed to be used in a controlled environment – a hospital. The user of the device can help prevent electromagnetic interference by adhering to the recommended distance between the monitor and RF transmitting equipment, such as an RFID reader.
Use of Simultaneous Devices	The Meridian M110 Monitor was designed to be used as an accessory to a primary monitor such as a GE Corometrics or a Philips Avalon monitor. Meridian M110 electrodes connect from the patient to the M110, and a cable connects from the M110 to the primary monitor. The use of more than one device that connects via electrodes from the patient to an additional monitor or device may create interference or improper operation of one or more of the monitoring devices.
Strangulation	To reduce the risk of patient and user/operator strangulation, ensure that all patient cables and leads are properly positioned and placed away from the patient's head.
Water Births	The Meridian M110 is not intended to be used during water births, in whirlpool or submersion water baths, during showers, or in any other circumstances that involve the immersion of the mother in water. Use in such circumstances may result in electrical shock for the patient, user/operator, or both.
Disposal	The Meridian Disposable fECG Electrode Array or patches, should be disposed of appropriately. The Meridian M110 Monitor should be disposed of appropriately, and only after thorough inspection and cleaning. Refer to the Maintenance section of this manual for proper disposal instructions.

 **Cautions**

TABLE 3: M110-SPECIFIC CAUTIONS	
Caution Title	*Description*
Servicing	To ensure the safe and efficient performance of the Meridian M110 Monitor, follow the instructions for maintenance outlined in the Maintenance chapter of this manual.
Testing	The Meridian M110 Monitor and relevant accessories should be inspected daily, and cleaned and inspected following their use on each patient. The M110 should be tested regularly by qualified MindChild Medical, Inc., personnel.
Usage Environment	The Meridian M110 Monitor is intended for use in a clinical or hospital environment by qualified medical personnel. The monitor is not intended to be used during MRI scans, electro-surgery, or on patients with pacemakers. The M110 has not been tested for use in x-ray or imaging environments, and as such should not be used in these environments.
Locating the Meridian M110	The Meridian M110 Monitor is intended to be used as an accessory monitor with specified units included in the M110 of this manual.
Installation	Install the Meridian M110 Monitor on a horizontal surface.
Performance	Should any problems or causes for concern be encountered when using the M110, discontinue use **immediately** and contact MindChild Medical, Inc., to request service.
Pinching and Pinch Points	Care should be taken when connecting patient cables and leads to patient electrodes, as the cable pinch connectors may create a pinch-point.
Static Electricity	The Meridian M110 Monitor should be handled in such a manner as to avoid the build-up and discharge of static electricity. Static electricity may affect the safe and efficient performance of the M110.
Tripping Hazard	Care should be taken when arranging cables and leads and when using the M110 monitor in order to prevent a tripping hazard.

1.3.2. Responsibilities

1.3.2.1. Responsibilities of MindChild Medical, Inc.

MindChild Medical, Inc., is responsible for the assembly, extensions, readjustments, modifications, repairs, and all service of the Meridian M110 Monitor. MindChild Medical, Inc., is additionally responsible for the safety, reliability, and performance of the M110 in the following circumstances:

- The conditions for use as described in this manual and relevant specification documents are met.

  - Specification documents are available upon request from MindChild Medical, Inc.
  - Conditions for use include the qualifications of the User/Operator, the monitor usage environment (including location of the monitor, connection to power mains, environmental conditions, etc.), and the nature of patient observation and monitoring
- The Meridian M110 Monitor is used in accordance with the instructions for use included in this manual.

1.3.2.2. Responsibilities of the User/Operator

It is the responsibility of the user/operator to ensure that the Meridian M110 Monitor is used in accordance with the previously described Intended Use, Indications for Use, and Contraindications for use. It is the responsibility of each hospital or institution to ensure that relevant, qualified Labor and Delivery physicians and staff are trained in all aspects of the Meridian M110 Monitor.

It is the responsibility of the user/operator and of the hospital or institution to ensure that visual assessments and regular maintenance of the monitor are completed, users/operators are aware of individual patient histories and conditions, and that knowledge of the monitor is combined with knowledge of patient conditions and health to ensure proper care and monitoring of both the mother and the fetus.

It is the responsibility of the user/operator and the hospital or institution to establish a regular maintenance schedule to ensure the safe and effective use of the Meridian M110 Monitor. Failure to properly maintain the M110 may result in equipment failure and potential health hazards to the patient, user/operator, or both. It is the responsibility of the user/operator to report the need for service to MindChild Medical, Inc. Any unauthorized attempts to service or repair the Meridian M110 Monitor while the monitor is under warranty voids the warranty. Please refer to the Warranty and Service Sections of this manual for further instructions.

1.3.3. References to any Persons, Places, and Institutions

Any references to any persons, places, institutions, hospitals, or other entities within this manual are intended only to aid in user/operator comprehension of the Meridian M110 Monitor’s use, functions, and maintenance. Any similarity of such references to persons, living or dead, or to medical institutions, present or past, is purely coincidental.

1.4. Confirm Fetal Life Before Using the Monitor

Fetal monitoring technology available today is **not always** able to differentiate a fetal heart rate (FHR) signal source from a maternal heart rate (MHR) source in **all** situations. Therefore, you should confirm fetal life **by independent means** before starting to use the fetal monitor. For example, fetal life can be confirmed by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscope, stethoscope, or Pinard stethoscope.

If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography. Continue to confirm that the fetus is the signal source for the FHR during monitoring.

NOTE: Be aware that the MHR can exhibit features that are very similar to those of a FHR trace, even including accelerations and decelerations. MHR can be misidentified as the FHR when using abdominal electrodes, especially when the MHR is over 100 bpm. Do not rely solely on trace pattern features to identify a fetal source. The M110 provides both FHR and MHR displays to reassure the user that the device has correctly identified individual heart rates.

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2. The MindChild Meridian M110 Monitor

The MindChild Medical, Inc., Meridian M110 Monitor, as seen in Figure 1 below, is a fetal heart rate monitoring device which also monitors uterine activity. The Meridian M110 is ***not*** a Patient Monitor or an ECG Monitor. The Meridian M110 Fetal Monitoring System is an accessory that ***aides*** an OB/GYN during the labor and delivery process by monitoring the fetal heart rate and contractions only, and does not monitor the patient (mother). The product is designed to be used with specified main/primary fetal monitoring units with a DECG input. The Meridian M110 is used as an accessory to a main/primary fetal monitor replacing the Doppler/FSE and Toco/IUPC sensors on those monitors. The M110 is designed to be used in a hospital environment by trained medical staff. Fetal heart rate is displayed based on fetal ECG measured from the maternal abdomen. Maternal heart rate is locally displayed (M110 device only) to confirm independent heart rate tracking of the fetus. Uterine activity is based on uterine muscle activity (EHG) measured from the same sensors on the maternal abdomen.

The MindChild Meridian M110 is isolated from the patient and is primarily a listening device. No electrical stimulus is transmitted to the patient by any of the patient connections. The patient connections are off-the-shelf medical grade components and are FDA approved. These factors make the Meridian M110 inherently safe for the user.

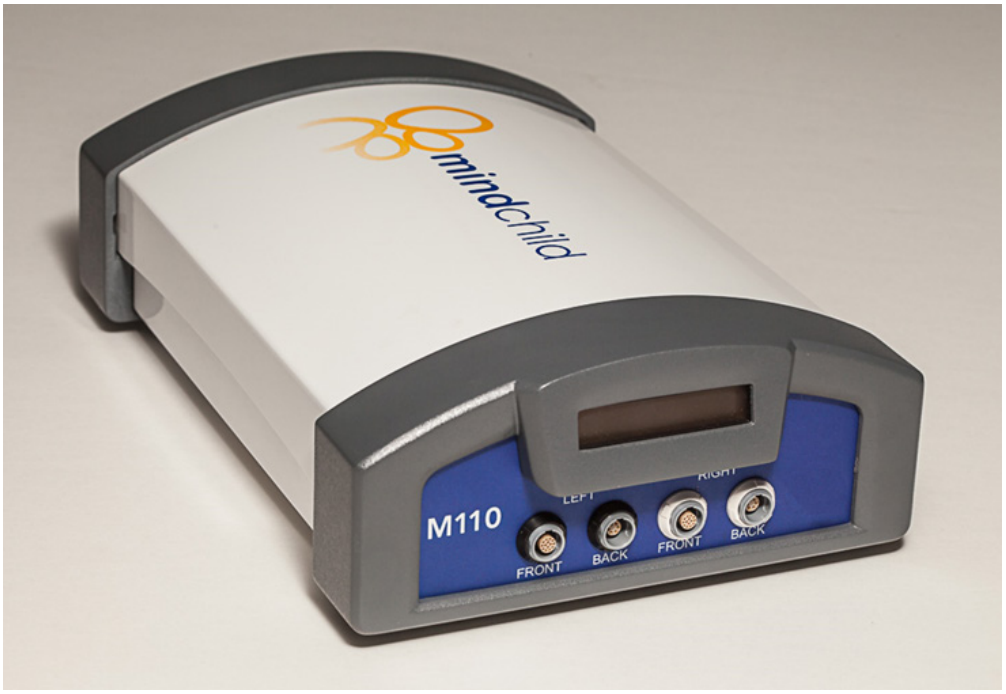

Figure 1. The Meridian M110 Fetal Heart Rate Monitor

2.1. Front Panel

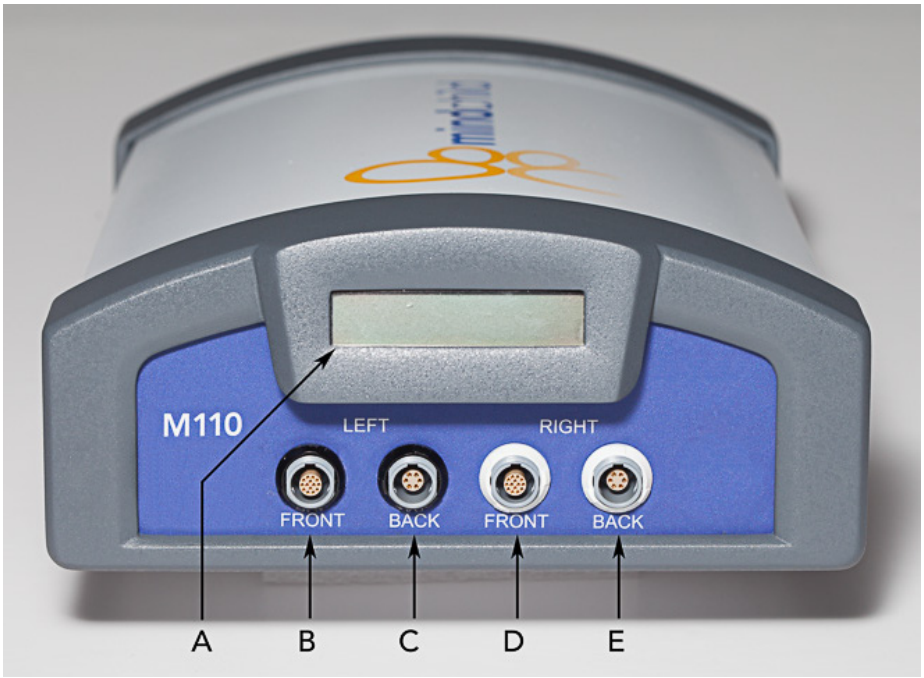

Figure 2. Front Panel of the Meridian M110 Monitor

TABLE 4: M110 FRONT PANEL

Front Panel Feature	Name	Description
A	LCD Screen	Displays startup messages (software version number, MindChild initialization, etc.), fetal and maternal heart rate, and system messages (FHR/MHR weak/no signal etc.).
B	Cable Connector for Left Abdominal Patch Cable	Connection port for the cable connected to the patch placed on the left front of the patient and maternal ECG
C	Cable Connector for Left Side/Back Patch Cable	Connection port for the cable connected to the patch placed on the left side/back of the patient
D	Cable Connector for Right Abdominal Patch Cable	Connection port for the cable connected to the patch placed on the right front of the patient
E	Cable Connector for Right Side/Back Patch	Connection port for the cable connected to the patch placed on the right side/back of the patient

2.2. Rear Panel

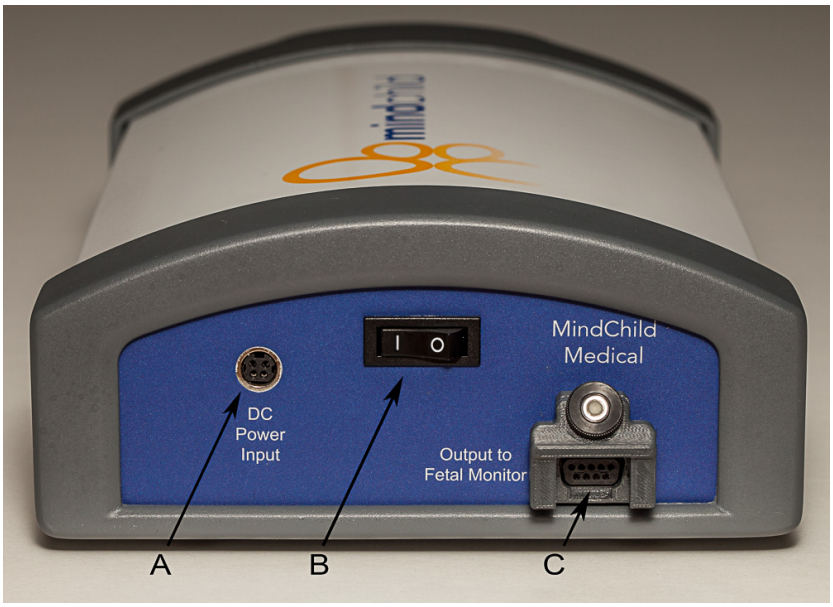

Figure 3. Rear Panel of the Meridian M110 Monitor

TABLE 5: M110 REAR PANEL		
Rear Panel Feature	Name	Description
A	Power Cord Socket	Power supply connection port
B	Power On/Off Switch	Pushing the power switch so that the I is depressed, turns on the monitor; and pushing the power switch so that the O is depressed, turns off the monitor
C	DECG/Uterine Activity Output Interface	Connection interface for interconnection cable that connects to the main/primary monitor; sends DECG and uterine activity signals to the primary monitor such that the primary monitor presents fetal heart rate and maternal contractions

2.3. Connection to a Primary Monitor

The Meridian M110 Monitor interconnects to the main/primary monitoring unit by means of the Output Interface located on the rear panel of the M110. The M110 and main/primary monitor interconnecting cable is included with the unit and contains three connectors: a DB9 M110 connector; a proprietary UA connector; and a proprietary DECG or FHR connector.

The Meridian M110 Monitor interconnects with GE Healthcare Corometrics monitors with cable M100-A290 and interconnects with Philips Healthcare Avalon monitors with cable M110-B290.

Figure 4. GE Interconnection Cable M100-A290

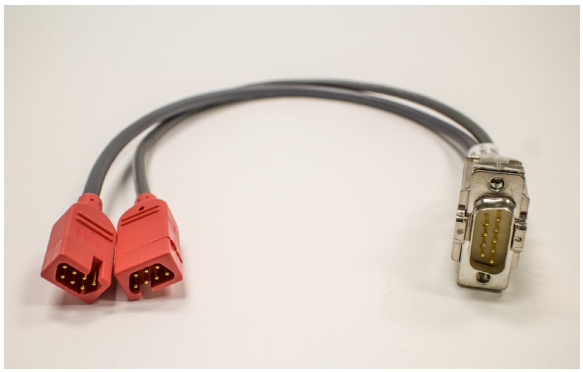

Figure 5. Philips Interconnection Cable M110-B290

2.3.1. Connecting the Output Cable to the Meridian M110 Device

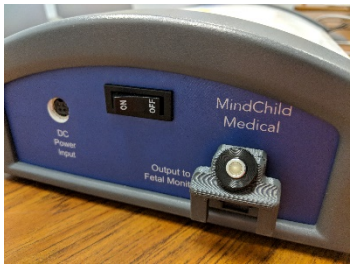

Figure 6. As shipped

Figure 7. Clamp removed

Figure 8. Cable secured

Perform the following steps to affix the Meridian Output Cable M100-A290 or M110-B290 to the Meridian M110 device.

TABLE 6: AFFIXING MERIDIAN OUTPUT CABLE TO M110	
STEP	ACTION
1.	Loosen and remove the retaining nut.
2.	Remove the back half of the clamp from the device.
3.	Connect the M100-A290 or M110-B290 cable's DB9 connector to the device.
4.	Slide the back half of the clamp over the cable aligning the bolt through the clamp's slot.
5.	Replace the retaining nut with the smaller diameter extension facing the device and tighten to secure the cable to the device.

2.3.2. Connecting to GE Healthcare Corometrics Monitors

Please refer to Figure 4 above depicting the three connectors of the M100-A290 Interconnection Cable.

Perform the following steps to connect the Meridian M110 Monitor to a GE Healthcare Corometrics 120 or 250 main/primary monitor using the supplied M100-A290 cable:

TABLE 7: AFFIXING MERIDIAN OUTPUT CABLE TO GE COROMETRICS	
STEP	ACTION
1.	Follow Section 2.3.1 above to connect and fasten the cable's DB9 connector to the M110
2.	Insert the cable's proprietary UA connector in the main/primary monitor's UA socket, located on the main monitor's front panel
3.	Insert the cable's proprietary DECG connector in the main/primary monitor's FECG/MECG socket, located on the main monitor's front panel

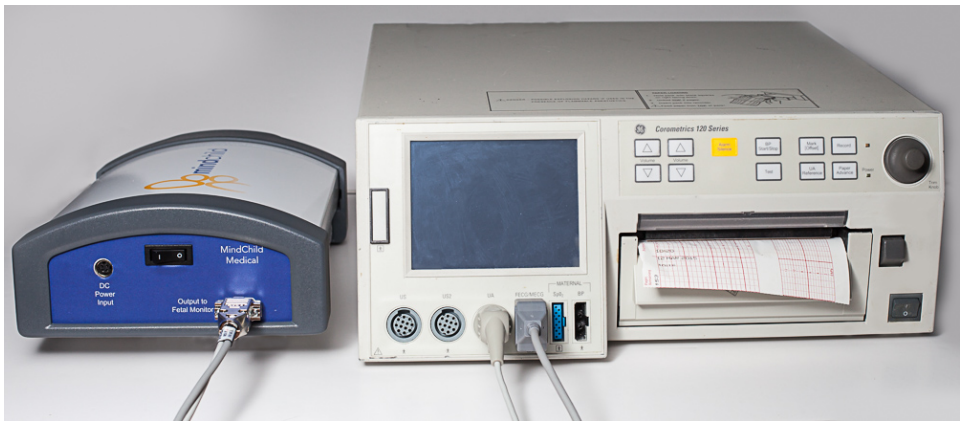

Figure 9a. M110 connected to a GE Corometrics 120 Fetal Monitor

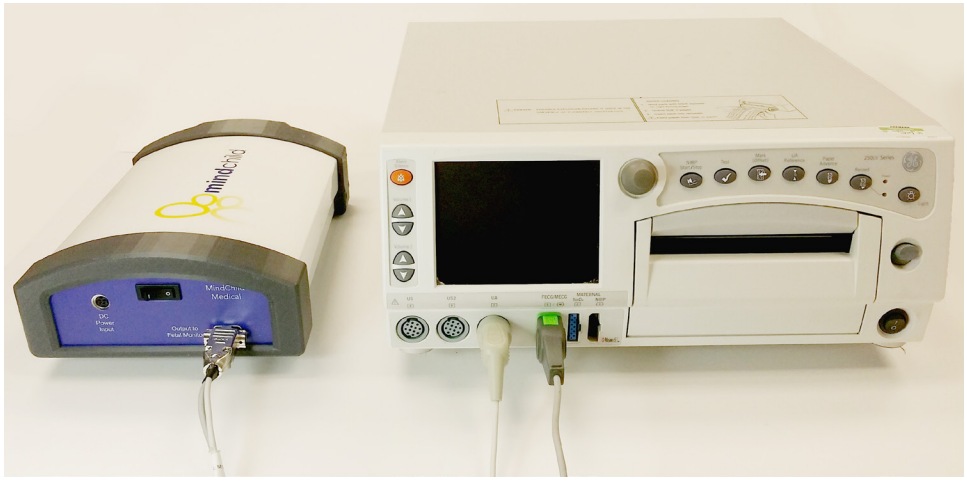

Figure 9b. M110 connected to a GE Corometrics 250 Fetal Monitor

2.3.3. Connecting to Philips Healthcare Avalon Monitors

Please refer to Figure 5 above depicting the three connectors of the M110-B290 Interconnection Cable.

Perform the following steps to connect the Meridian M110 Monitor to a Philips Healthcare Avalon 20/30/50 main/primary monitor using the supplied M110-B290 cable:

TABLE 8: AFFIXING MERIDIAN OUTPUT CABLE TO PHILIPS AVALON	
STEP	ACTION
1.	Follow Section 2.3.1 above to connect and fasten the cable's DB9 connector to the M110
2.	Using either red connector of the M110 Output Cable, plug the red connector into the Philips M2738A Patient Monitor cable
3.	Using the other red connector of the M110 Output Cable, plug the second red connector to a second Philips M2738A Patient Monitor cable
4.	Insert the two Philips M2738A Patient Monitor cables into any of the Philips Avalon Monitor's Fetal Sensor sockets

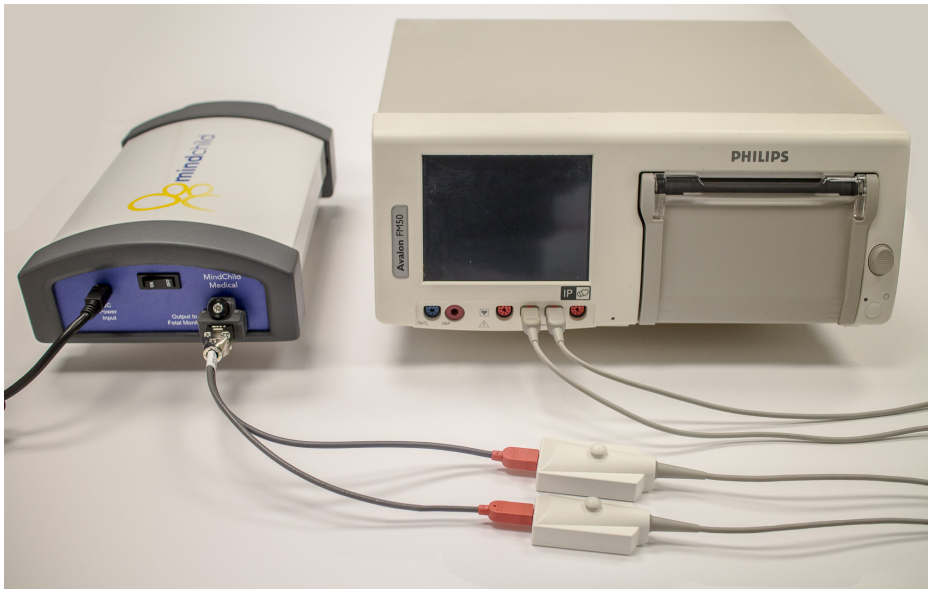

Figure 10. M110 connected to a Philips Avalon 50 Fetal Monitor

NOTE: Any of the red Fetal Sensor ports/sockets may be used.
The Philips Avalon will automatically detect the correct function of FHR and UA.

2.4. Accessories and Supplies

The Meridian M110 accessories are the custom cables and electrodes that complete the patient connections to the monitor. The electrodes are prearranged into four patches to facilitate proper placement location and to expedite both application and removal. These patches are available for purchase from MindChild Medical, Inc. All accessories listed here may not be available in all geographies. All accessories listed here are reusable, unless indicated otherwise.

2.4.1. Information on Latex

All Meridian M110 accessories are not made with latex unless indicated otherwise.

2.4.2. Cables

There are five patient connection cables included with the Meridian M110 monitor. The cables are made with bio-compatible materials and medical grade connectors. To assist in the proper connection of the four cables, each cable has two identifiers: 1) color, white is the patient's right side and black is the patient's left side; and 2) geometric pattern, circle is the left abdomen, cross is the right abdomen, triangle is the left side/back, and square is the right side/back. The red color coded cable is the patient leg cable for grounding the patient.

A sixth cable connects the Meridian M110 to the primary fetal monitor.

Figure 11. Front Left Electrode Connection Cable M2-1010

Figure 12. Front Right Electrode Connection Cable M2-1020

Figure 13. Back Left Electrode Connection Cable M2-0510

Figure 14. Back Right Electrode Connection Cable M2-0520

2.4.3. M110 Monitoring Cable Requirements

The Meridian M110 configuration provides non-invasive fetal monitoring via maternal abdominal patches and two individual electrodes.

TABLE 9: NON-INVASIVE FETAL MONITORING WITH ELECTRODES	
Cable Description	*Required connections*
Front Left Patch Cable	Maternal heart connection (Red electrode snap) and left abdominal patch connection (Black)
Front Right Patch Cable	Right abdominal patch connection (White)
Back Left Patch Cable	Left side/back patch connection
Back Right Patch Cable	Right side/back patch connection
Interconnection Cable from M110 to primary monitor	From the rear of the M110 monitor to the UA/DECG sockets on the main/primary monitor (see images and descriptions of the front and rear panels of the M110 and the section on connecting the M110 to a main/primary monitor, sections 2.2-2.4).

2.4.4. Patches and Electrodes

The Meridian M110 uses proprietary “Disposable Fetal ECG Electrode Arrays” or patches that are equipped with electrodes and adhesive foam backing.

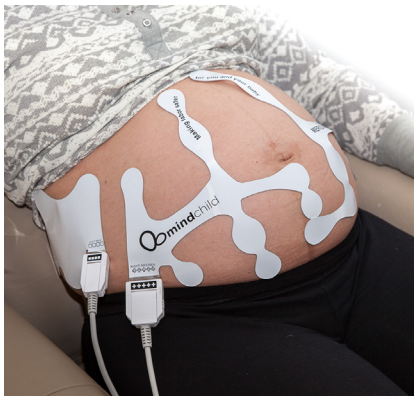

Figure 15. MindChild disposable patch electrodes on patient's abdomen and right side/back

Features:

- Adhesive foam-tape backing and proprietary sticky gel ensure excellent skin contact
- Sticky gel delivers excellent trace quality resulting in better patient information
- High performance adhesive offers instant adhesion and up to 24-hour wear with excellent patient skin care and comfort.
- Expedites placement and removal of electrodes
- Facilitates accurate placement of electrodes

2.4.5. Patient Protection

The Meridian M110 patient protection isolation barrier provides 4 KVDC of galvanic isolation for all the patient input connections. The cables that connect directly to a patient pass through this isolation barrier.

2.5. Primary Monitor Specifications

The following main/primary monitors are supported by the Meridian M110 Monitor:

- GE Healthcare: Corometrics 120 and 250 Series
- Philips Healthcare: Avalon Series FM 20, 30, & 50

2.6. Software Upgrades

Should a software upgrade be desired or required, contact MindChild Medical, Inc. for servicing. The current software version is listed upon monitor start-up on the front panel LCD screen.

WARNING:

- **Reuse:** Disposable accessories and supplies intended for single use, or single patient use only, are indicated as such on their packaging. Never reuse disposable accessories and supplies, such as sensors, electrodes and so forth that are intended for single use or single patient use only.
- **Approved accessories:** Use only Meridian M110-approved accessories.
- **Packaging:** Do not use a sterilized accessory if its packaging is damaged.
- **Protection against electric shocks:** Accessories listed in this chapter are NOT defibrillator proof.
- **Electro-surgery, Defibrillation and MRI:** The fetal/maternal monitors are NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all sensors and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the operator can result.

3. Installation

Installation should be carried out by qualified service personnel, either by the hospital's biomedical department or by MindChild Medical, Inc., support technicians.

To prepare the Meridian M110 Monitor for use, follow the installation instructions given in this chapter.

For a list of conventions used in this guide, see Chapter 4, "Basic and Essential Operation of the Meridian M110."

Not all accessories and supplies may be available in all geographies. Contact MindChild Medical for details of availability.

3.1. Installation Checklist

Use this checklist to document your installation.

TABLE 10: INSTALLATION CHECKLIST

Step	Task	Check Box when Done Task
1	Perform initial inspection of delivery, unpack and check the shipment (see "Unpacking and Checking Shipment")	❑
2	Locate the Monitor as appropriate for your installation (See "Locating the Monitor")	❑
3	Connect the fetal monitor to AC mains using the supplied power cord (see "Connecting the Monitor to AC Mains")	❑
4	Connect the monitor to the chosen primary fetal monitoring unit	❑
5	Power-on the unit	❑
6	Confirm that proper start-up messages are displayed on the monitor's LCD screen	❑

3.2. Unpacking and Checking the Shipment

The monitor and any supporting options ordered are supplied packed in protective shipping cartons.

3.2.1. Initial Inspection

Before unpacking, visually check the packaging and ensure that there are no signs of mishandling or damage. Open the package carefully and remove the monitor and any accessories.

3.2.2. Check the Contents

Check that the contents are complete and that the correct options and accessories have been delivered.

TABLE 11: M110 COMPONENTS

System Components, Accessories and Supplies	Quantity
Meridian M110 Monitor Unit	1
AC Power Supply	1
Front Left Patch Cable	1
Back Left Patch Cable	1
Front Right Patch Cable	1
Back Right Patch Cable	1
Interconnection cable	1
User Manual	1

3.2.3. Claims for Damage

If the shipping cartons are damaged, contact the carrier. If any of the equipment is damaged, contact both the carrier and MindChild Medical, Inc., for repair or replacement arrangements.

3.2.4. Repacking

Retain the original packing carton material, in case you need to return equipment to MindChild Medical for service. If you no longer have the original packing materials, MindChild can advise you on alternatives.

3.3. Prior to the Operation of the Meridian M110 Monitor

The Meridian M110 fetal monitor provides ease of use to the user/operator and a solution for non-invasive fetal heart rate monitoring applications. Measurements are displayed on the primary monitor chosen by the hospital and/or medical staff qualified to use the monitor. Measurements are displayed as both graphic and numeric. The monitor is a boxed unit that is 31.75 cm x 21.6 cm x 9.8 cm (12.5” x 8.5” x 3.875”) (L x W x D) and which can be located at the qualified user/operator’s discretion: in the relevant hospital environment (intrapartum monitoring room, labor/delivery rooms, etc.), on a rolling cart, or permanently affixed to a horizontal surface for ease of use. The monitor is designed to be used in a hospital environment.

3.3.1. Locating the Meridian M110

The Meridian M110 Monitor is a boxed unit that is intended to be used as a Doppler replacement for a primary monitor for examinations and for the duration of labor and delivery in a hospital environment.

The Meridian M110 Monitor is best located:

a) near the patient for use in monitoring FHR during labor and delivery
b) adjacent to the primary monitor

In most installations, the recommended location of the Meridian M110 is:

a) to the patient’s left (for practical reasons but not required)
b) within four feet of the mother’s abdomen
c) to be placed on top of the primary monitor, either directly or on a shelf immediately above

The Meridian M110 includes rubber feet to reduce the chance of movement should the patient cables pull on the device. The Meridian M110 must be placed on a horizontal, non-slip surface. It is not recommended that the M110 be used in a vertical position at any time. The Meridian M110 is designed to be drip-proof when installed in the horizontal position.

CAUTION: Install the Meridian M110 on a horizontal surface.

3.3.2. Connecting the Monitor to AC Mains

The monitor is an electrical Class II device in which the protection against electric shock does not rely on basic insulation and a protective earth conductor, but on galvanic isolation.

The M110's power supply is a separable brick unit. The medical grade power supply operates the monitor from an AC (alternating current) power source of 100 to 130 V, consuming approximately 1.0 A, and a supply frequency of 60 Hz.

Step 1. Plug the power supply's three-prong connector to approved electrical outlet.

Step 2. Plug the power supply's DIN output connector to the M110's rear panel's "DC Power Input" socket.

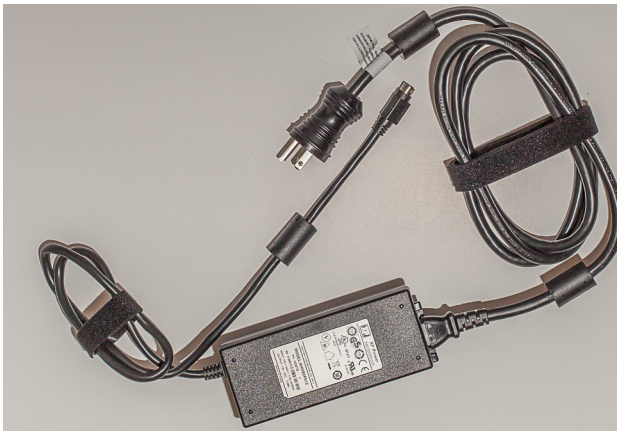

Figure 16. M110 Medical Grade Power Supply

Figure 17. Connecting Power Supply to M110's Rear Panel

WARNING:

- Always use the supplied power cord with the earthed mains plug to connect the monitor to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
- The protective earth conductor is required for EMC purposes. It has no protective function against electrical shock! The protection against electrical shock in this device is provided by double and/or reinforced insulation.
- Do not use AC mains extension cords or multiple portable socket-outlets.
- Maintenance of the system must be performed by authorized MindChild personnel in order to maintain the warranty.
- Do not use a device in the patient vicinity if it does not comply with IEC/EN 60601-1. The whole installation, including devices outside of the patient vicinity, must comply with IEC/EN 60601-1-1.

3.3.3. Power-On the Unit

After assertion of the power-on and connection to a primary monitor, the Meridian M110's LCD screen should display relevant messages as detailed in Section 5.2. System Messages.

3.3.4. Confirm Software Version

After the power initialization is complete, the software Version number of the Meridian M110 Monitor will be displayed on the monitor's LCD screen and can be confirmed to the packaging slip. The software version will read as M110.4.19.XX, where M110.4.19 refers to the device version and XX refers to the specific software version running on the Monitor.

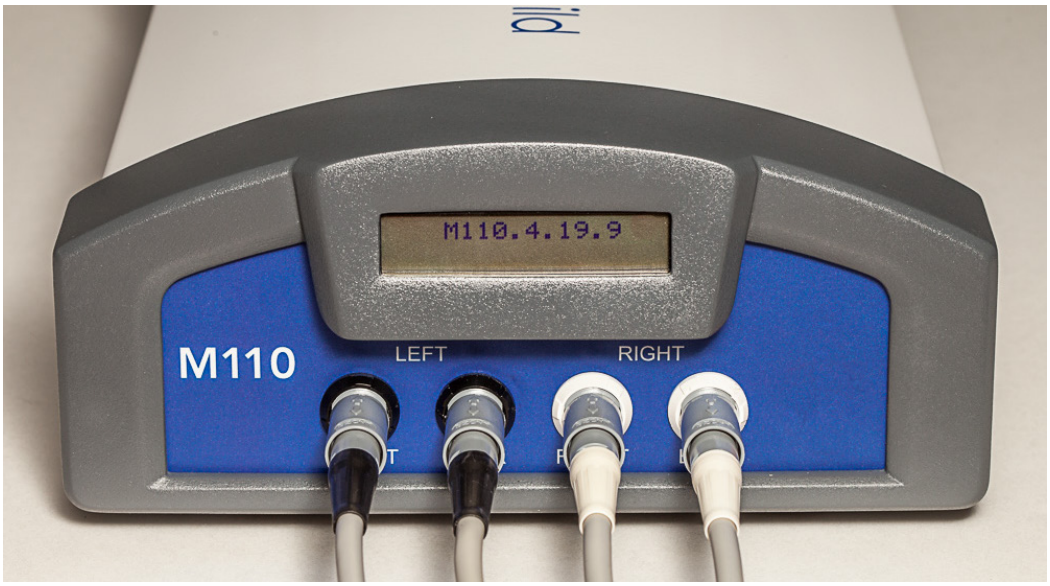

Figure 18. M110 Start-Up Screen #3: Software Version Number

4. Basic and Essential Operation of the Meridian M110

This chapter presents an overview of the Meridian M110 Monitor and its operational functions. It takes you step by step through the use of the M110 to monitor fetal heart rate.

4.1. Patient Monitoring

Confirm fetal life before you begin fetal monitoring. Familiarize yourself with the basic operation principles before you start to monitor a patient. Position the Meridian M110 and relevant primary monitor setup next to the patient bed.

4.1.1. Steps to Monitor a Patient

The following Step-Action table identifies the actions required to monitor a patient and the corresponding User Manual section explaining each action in detail:

TABLE 12: STEP TO MONITOR A PATIENT

STEP	ACTION	SECTION
1.	Connect the Meridian M110 Monitor to the desired primary monitor	2.3
2.	Prepare the patient's skin	4.1.2
3.	Place and fasten the patch electrodes to the patient (see Figure 25 through Figure 27 for placement)	4.1.3 – 4.1.5
4.	Connect the patient cables to the patches and electrodes	4.1.6
5.	Connect the patient cables to the M110	4.1.7
6.	Connect the Meridian M110 Monitor to AC mains and switch it on	3.3.2 – 3.3.3
7.	Confirm the LCD screen start-up messages	5.2
8.	Monitor the patient throughout labor and delivery	4.2
9.	Remove the cables from the patches and removal all patches and electrodes from the patient	4.3
10.	Power-off the Meridian M110	3.3.3
11.	Disconnect the monitor from the AC mains	3.3.2

4.1.2. Preparing the Patient's Skin for Monitoring

The performance of the Meridian Fetal Monitor is directly related to the quality of the electrical connection to the patient's skin by the electrodes. In most patients, skin preparation is not needed. But in some patients whose skin is not properly hydrated, has oily lotions applied, or has a thicker epidermal layer, a signal boosting procedure is required. And because you cannot determine the conductivity of the patient's skin beforehand, it is prudent to perform the signal boosting procedure on all patients prior to placing the disposable electrode patches.

Application sites must be clean, dry and free of any body lotions. Cleaning with isopropyl alcohol should be avoided or limited to situations in which electrode adhesion is an issue (e.g. excessively oily or lotion covered skin). Wash with warm soapy water and dry the application sites with a towel. If alcohol is used, allow it to dry prior to electrode application. Excessive hair at the site should be removed by clipping.

The materials required are a tube of Nuprep Skin Gel and four 4 x 4 gauze pads. Figure 19 below identifies in pink, the four locations on the patient to apply the skin gel.

The entire signal boosting procedure should take 3-4 minutes.

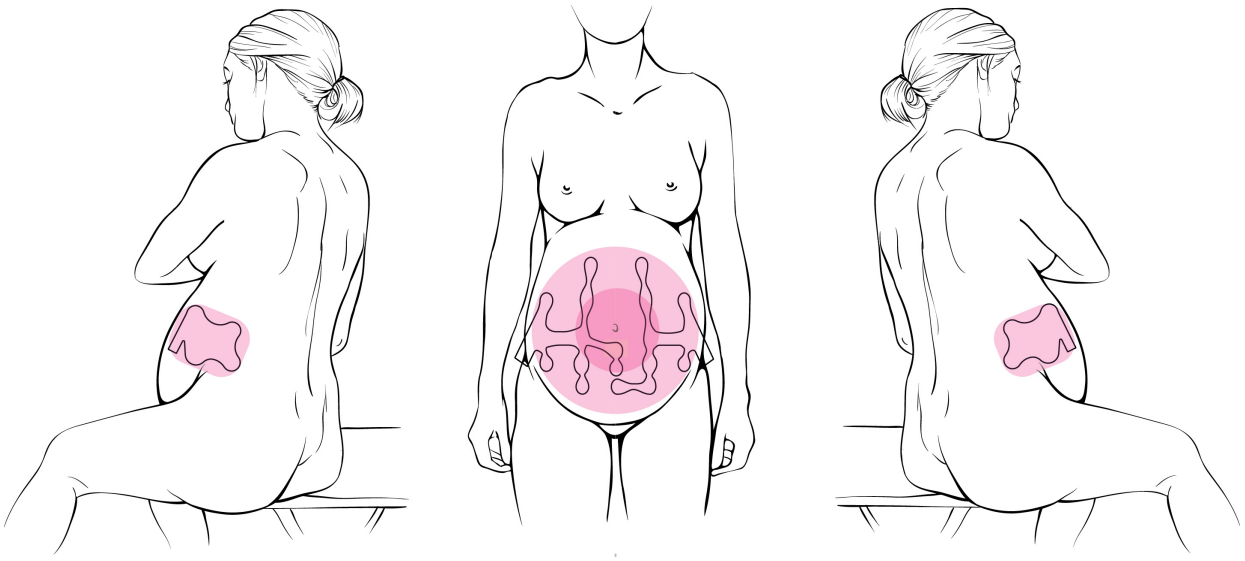

Figure 19. Four Skin Gel Application Locations

TABLE 13: SMALL AREA PROCEDURE – SIDE-BACK PATCHES	
STEP	ACTION
1.	Apply a nickel-sized drop of skin gel to a gauze pad.
2.	With medium pressure, apply the gel to the skin rubbing in a circular motion where the side/back patch will be placed. Rub 6-7 circles covering that entire location.
3.	Fold the gauze in half with the gel on the inside of the gauze, then wipe the area dry with the dry side of the gauze.
4.	Repeat steps 1-3 for the other side-back patch location using a new gauze pad.

TABLE 14: LARGE AREA PROCEDURE – MATERNAL ABDOMEN	
STEP	ACTION
1.	**Figure 20:** Place one dime-sized drop of skin prep at each of 3, 6, 9, & 12 o'clock location approximately two inches above, below, and to the sides of the umbilicus.
2.	**Figure 22:** With medium pressure, start at one of the drops of gel with a clean gauze pad and rub the gel on the skin in a circular motion. Rub a 4-inch circle 2-3 times before sliding the gauze towards the next drop. Roughly 32 4-inch circles should be made to prepare the inner loop of skin on the abdomen.
3.	**Figure 21:** Place one nickel-sized drop of skin prep gel at each of 2, 4, 6, 8, 10, & 12 o'clock location approximately in a six-inch radius from the umbilicus.
4.	**Figure 23:** With medium pressure, start at one of the drops of gel with a clean gauze pad and rub the gel on the skin in a circular motion. Rub a 4-inch circle 2-3 times before sliding the gauze towards the next drop. Roughly 96 4-inch circles should be made to prepare the outer loop of skin on the abdomen. This should take approximately 45 seconds.

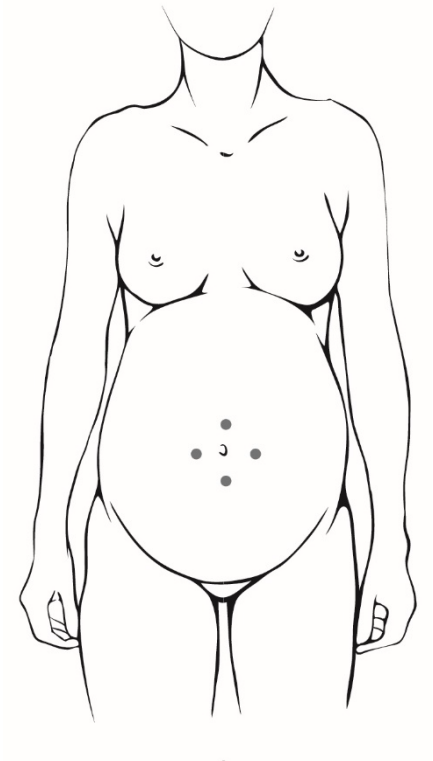

Figure 20. Abdominal Inner Loop Gel Application

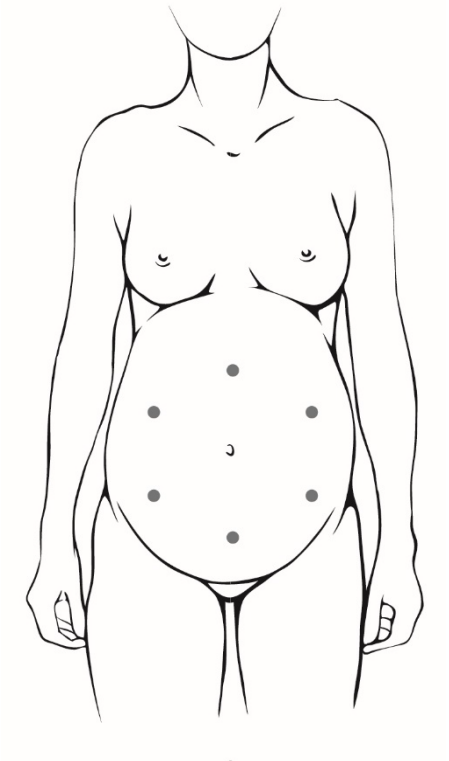

Figure 21. Abdominal Outer Loop Gel Application

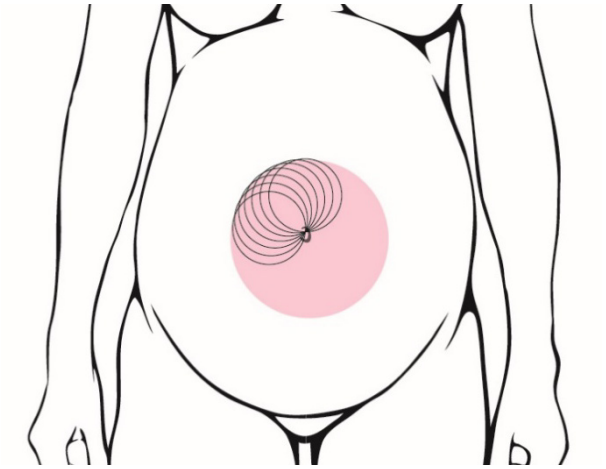

Figure 22. Abdominal Inner Loop Rubbing

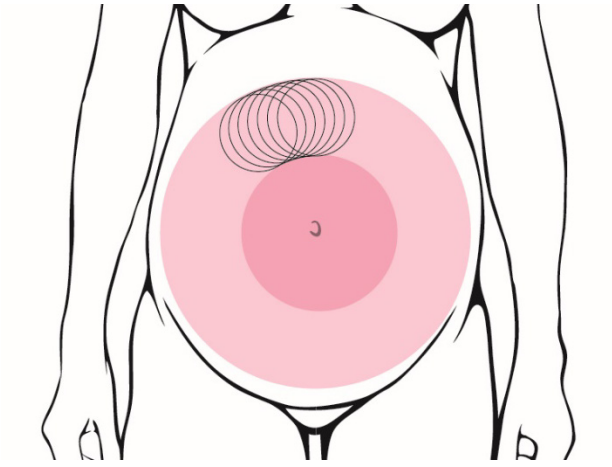

Figure 23. Abdominal Outer Loop Rubbing

4.1.3. Preparing for Electrode Placement on the Patient

The MindChild Monitoring Electrodes are placed on the patient's abdomen, top and sides, as shown in Figure 25 through Figure 27. The application of patient electrodes should be completed as follows; you will need one set of the MindChild Disposable fECG Electrode Array for each monitoring session.

Electrode Handling: The electrode's foam adhesive backing is exposed (Figure 24) by peeling the protective layer away and discarding. Place the patch on the patient and use gentle pressure to ensure contact of all electrode surfaces to the skin. Repeat for each of the patches. It is acceptable to reposition the patches within the first two (2) minutes of placement. Repositioning of any electrode after five (5) minutes is not recommended and a new patch should be used in its place.

Figure 24. Exposing the foam adhesive backing

WARNING: US federal law restricts this device to sale by or on order of a physician.

4.1.4. Placing the Abdominal Electrodes

Place the two front abdominal patches in the designated positions using the umbilicus and right and left midclavicular lines as guides. It is recommended to place the right abdominal patch first using the umbilicus as a guide. Place the left abdominal patch using the two electrodes of the right patch below the umbilicus as your second guide.

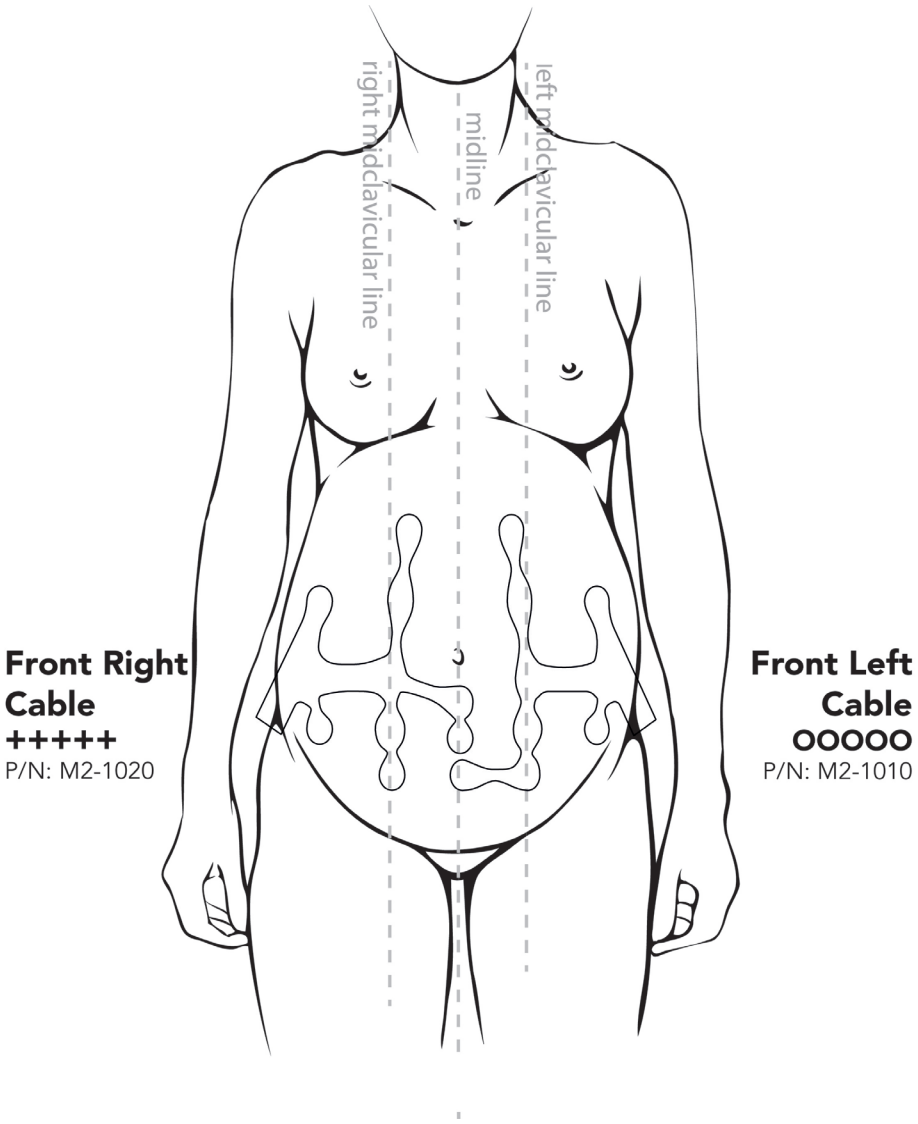

Figure 25. Front abdominal patch placement

NOTE: All patches and electrodes must be placed on the patient in the indicated locations.

4.1.5. Placing the Side Patches

With the patient in the upright sitting position place the right-side patch using the patient's auxiliary line and posterior superior iliac crest as guides shown below and then repeat for the left-side patch (Figure 26 and Figure 27).

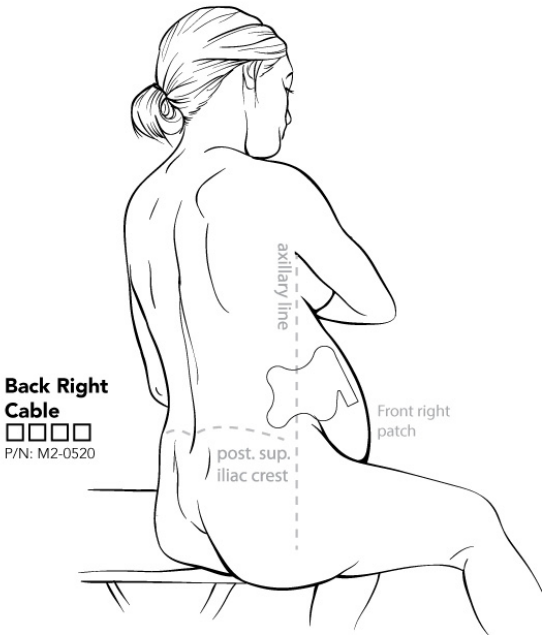

Figure 26. Right side and back patch placement

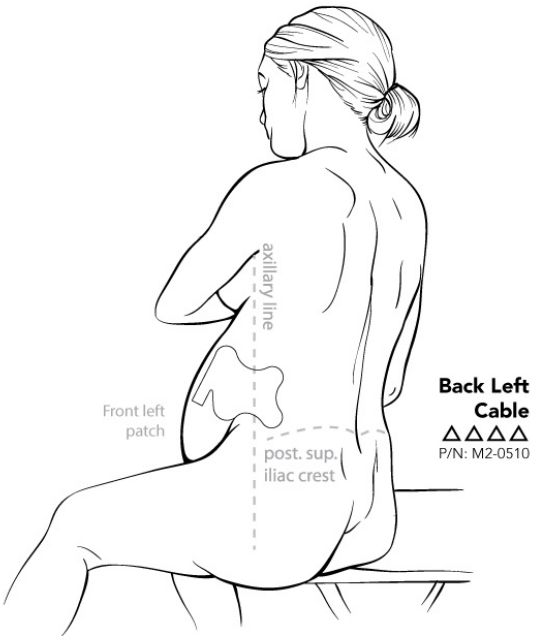

Figure 27. Left side and back patch placement

NOTE: All patches must be placed on the patient in the indicated locations.

4.1.6. Connecting Cables to the Patches and Electrodes

You will need one each of the following cables:

TABLE 15: M110 PATIENT CABLES

Cable	Part Number
Left Abdomen Patch Cable	M2-1010
Right Abdomen Patch Cable	M2-1020
Left Side/Back Patch Cable	M2-0510
Right Side/Back Patch Cable	M2-0520

To connect the cable to the patches, perform this procedure four times, once for each patch: lift the clip on the connector; insert the patch's tab fully into the connector until the tab's plastic guide on the top is flush against the connector; and finally lower the clip on the connector to lock the cable to the patch.

To assist in the proper connection of the four cables, each cable has two identifiers: 1) color, white is the patient's right side and black is the patient's left side; and 2) geometric pattern, circle is the left abdomen, cross is the right abdomen, triangle is the left side/back, and square is the right side/back.

4.1.7. Connecting Patient Cables to the Monitor

The cables are connected from the attached patient patches to the connector panel on the front of the Meridian M110.

The M110's connectors are color coded to match the cables. The cables are labeled to match the front panel socket labels to prevent misconnections. It is important that when connecting the electrode cables to the Meridian M110 Monitor, the connectors are grasped by the grey colored barrel and not by the cable or the colored (black or white) plastic. Grasping the cable connectors by the grey barrel ensures that the cables are connected correctly and completely. Correct cable connection has been achieved if an audible click is heard upon connector insertion.

WARNING: When connecting the cables to the Meridian M110, verify the cable connector bands are matched and the label nomenclature match on the panel and the socket labels. Misconnection of the cables to the connectors may result in improper measurements on the Meridian M110.

Figure 28. M110 Patient Cable Connections

Step 1: Connect the four patient cables to the appropriate socket on the Meridian M110 front panel as shown in Figure 28 above. Confirm that the color bands on the cables match the cable socket's color and the label on the cable matches the socket panel label.

Step 2: Route the cables to minimize any discomfort to the patient and to prevent any entanglement of the baby or doctor in the delivery procedure.

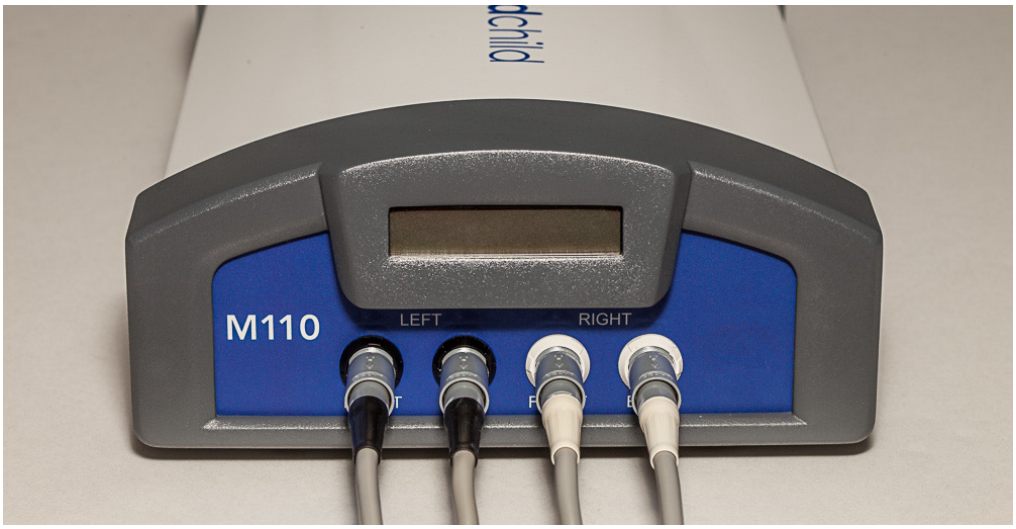

Figure 29. M110 with All Patient Cables Connected

Step 3: Confirm that all four cables are connected to the M110 as shown in Figure 29 above. You are now ready to monitor the patient.

4.2. Monitoring

The monitoring session can last as long as the delivery process requires. Patient data will continue to be processed as long as the monitor is connected and powered. To start the device, flip the switch on the back of the device from the “0” position to the “1” position.

NOTE:

- In the event where no fetal heart can be acquired the fetal heart rate value will blank and a message will activate. Upon acquisition of a valid fetal heart rate, the displayed value and output to the main monitor will automatically restart.
- When connecting cables or patient electrodes, interference may cause inaccurate fetal heart rates to be displayed. Discount these readings until all electrodes are placed on the patient.
- There is a 16 second delay from the actual ECG event to the time of the display of the fetal heart rate on the primary monitor.
- Should patient monitoring exceed 24 hours, all electrodes should be removed and replaced with new electrodes.
- The device stops monitoring after 48 hours. Should patient monitoring exceed 48 hours, cycle power on the device to begin a new 48-hour monitoring session.

4.3. Disconnecting the Meridian M110 from the Patient

To disconnect the monitor from the patient:

1. Turn off the Meridian M110.
2. Disconnect all the four cables from the patient’s patches.
3. Remove the patient patches and electrodes:
    a. Loosen one side of the electrode
    b. Grasp the full width of the electrode and slowly and gently pull it back over itself.
    c. Keep the electrode close to the skin’s surface as you pull it back, and support the skin immediately adjacent to the adhesive being removed.
4. Discard the electrodes in a sanitary disposal.
5. Disconnect the M110’s interconnection cable from the main/primary monitor.
6. Disconnect the AC power cord and move the unit to a safe area.

4.3.1. Patch Removal Procedure

The peel direction, peel rate and dwell time are all important factors that contribute to the removal of the adhesive from the skin. The peel direction should be between 150° and 180° (180° is folder over onto itself) in order to reduce peel force compared to peel angels of 90° and 120° (90° is lifting perpendicular to the skin).

The leading edge (the edge where the adhesive is contacting the skin) can be touched with a wet sponge in order to decrease adhesion. The following table provides several recommended procedures for removing the patches:

TABLE 16: PATCH REMOVAL

STEP	ACTION
1.	Loosen the edges of the adhesive patch.
2.	With the fingers of the opposite hand, push the skin down and away from the adhesive.
3.	Remove the adhesive patch low and slow back over itself in the direction of hair growth, keeping it horizontal and close to the skin surface (as close to 180° as possible).
4.	As the patch is removed, continue moving fingers of the opposite hand as necessary to support newly exposed skin.
5.	If adhesion is very strong, use a wet sponge to loosen the adhesive bond. After patch removal, consider using lotion, petroleum or mineral oil (if not reapplying an adhesive product to the same area) to improve patient comfort.

5. Alarms, Messages & Troubleshooting

The Meridian M110 Monitor provide system messages. System messages are indicators which refer to the Meridian M110 system operation.

5.1. Patient Alarms

The M110 does not provide patient alarms. All clinical conditions are alarmed by the main/primary fetal monitor. Please refer to the main/primary fetal monitor's user manual for patient alarms.

5.2. System Messages

The following messages are displayed on the LCD screen of the Meridian M110 Monitor when the algorithm computes data signals or encounters any issues.

- The Meridian M110 Monitor Application shall display the following messages upon start-up:
  - **MindChild** – upon M110 hardware boot-up
  - **MindChild Initializing** – upon operating system start-up
  - **M110.4.20.X** – upon acquisition application start-up (where X represents software version)

- **FHR XXX BPM** / **MHR XXX BPM** – fetal/maternal heart rate of XXX beats per minute (XXX represent the numerical heart rate), extracted using the Meridian M110 algorithm from electrode signals and displayed on the M110's LCD screen. This is the normal operating message, displayed when the device is operating with a good signal quality FECG and no system messages. Additionally, FHR only is sent to the main/primary monitoring unit connected by the Output Interface cable for display, plotting, and patient alarms. The M110 provides both FHR and MHR display to reassure the user that the device has correctly identified individual heart rates.

- **FHR --- BPM; MHR No Signal** – displayed when maternal signal is lost or cannot be detected and processed by the monitor and algorithm.

- **FHR --- BPM; FHR No Signal –** displayed when fetal signal is lost or cannot be detected and processed by the monitor and algorithm.

- **FHR --- BPM; MHR Weak Signal** – displayed when the algorithm detects a poor or weak maternal heart rate signal.

- **FHR --- BPM; FHR Weak Signal** – displayed when the algorithm detects a poor or weak fetal heart rate signal.

- **No Patient Connection** – displayed when algorithm's energy threshold has not been surpassed, in the event of electrode malfunction and in any other circumstances in which a signal cannot be obtained by the electrodes or processed by the algorithm.

- **Signal Interference** – displayed when the algorithm encounters external signal interference and cannot accurately read the FHR.

TABLE 17: M110 SYSTEM MESSAGES

LCD Screen Message (Line 1, Line 2)	Condition	Action	Expiration
L1: MindChild L2: {Clear}	Upon start-up	Display message	Upon OS message
L1: MindChild L2: Initializing	Upon operating system start-up	Display message	Upon application start-up message
L1: M110.4.19.X L2: {Clear}	Upon application start-up	Display message	Upon energy, FHR, or system message
L1: FHR XXX BPM L2: MHR XXX BPM	First FHR computation or system message expiration	Display message	Upon system message or power down
L1: FHR --- BPM L2: MHR No Signal	Algorithm's maternal signal lost TRUE	Display message	Algorithm's maternal no signal FALSE
L1: FHR --- BPM L2: FHR No Signal	Algorithm's fetal signal lost TRUE	Display message	Algorithm's fetal no signal FALSE
L1: FHR --- BPM L2: MHR Weak Signal	Algorithm's maternal signal poor TRUE	Display message	Algorithm's maternal signal weak FALSE
L1: FHR --- BPM L2: FHR Weak Signal	Algorithm's fetal signal poor TRUE	Display message	Algorithm's fetal signal weak FALSE
L1: No patient L2: connection	Algorithm's low energy threshold TRUE	Display message	Algorithm's low energy threshold FALSE

TABLE 17: M110 SYSTEM MESSAGES			
LCD Screen Message (Line 1, Line 2)	**Condition**	**Action**	**Expiration**
L1: Signal L2: Interference	Algorithm signal interference detection TRUE	Display Message	Algorithm's signal interference detection FALSE

5.3. Troubleshooting

TABLE 18: M110 MONITOR TROUBLESHOOTING

Problem	Possible Cause	Solutions
The M110 does not turn on and start up when the Power Switch is depressed in the on position	The monitor may not be connected to the power cord The M110's power cord may not be plugged into AC mains outlet	Ensure that the power cord is connected to the M110 monitor and plugged into an AC mains outlet.
	The power cord may be defective The AC mains outlet is defective	Replace the power cord Use a different outlet
	The fuse pertaining to that power cord has blown	If M110 fuse: contact MindChild Medical, Inc., to arrange for service. If hospital/institution fuse: contact the hospital's or institution's Biomedical Engineering Department or Maintenance Department
	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service
FHR is erratic or not recording properly or FHR is reading as "---" on M110 LCD screen	The patches and electrodes and/or their cables are not properly connected to the patient and to the M110	Ensure that the patches and electrodes are correctly attached to the patient, and that they are correctly and securely connected to the Meridian M110 Monitor.
	There is no FECG signal Defective patch or electrodes Defective cable(s) One of the leads is providing an inadequate signal Service required	Auscultate FHR Replace patches or electrodes Replace cable(s) Change/Adjust lead Call MindChild Medical, Inc. to arrange for service

TABLE 18: M110 MONITOR TROUBLESHOOTING

Problem	Possible Cause	Solutions
MHR is erratic or not recording properly or MHR is reading as "---" on M110 LCD screen	The patches and electrodes and/or their cables are not properly connected to the patient and to the M110	Ensure that the patches and electrodes are correctly attached to the patient, and that they are correctly and securely connected to the Meridian M110 Monitor.
	Defective patch or electrodes	Replace patches or electrodes
	Defective cable(s)	Replace cable(s)
	One of the leads is providing an inadequate signal	Change/Adjust lead
	Service required	Call MindChild Medical, Inc., to arrange for service
Primary monitor is not recording maternal contractions	The patches and electrodes and/or their cables are not properly connected to the patient and to the M110	Ensure that the patches and electrodes are correctly attached to the patient, and that they are correctly and securely connected to the Meridian M110 Monitor.
	Defective output cable	Replace output cable assembly
	No maternal contractions	Wait until maternal contractions commence
System Message: Weak Signal - Fetal	Patch connections and/or leg connected improperly.	Check connections as per Figure 25 through Figure 27 ensure leg electrode and all patches are connected properly.
Continued Weak or No Signal - Fetal	Patient obesity prevents FHR signal transmission	Use fetal scalp electrode to obtain FHR
System Message: Weak Signal – Maternal	MECG electrode or connection and/or left back/side patch connected improperly.	Check connections as per Figure 25 through Figure 27, ensure MECG electrode and left back/side patch are connected properly.
System Message: No Signal - Fetal	Patch connectors have disconnected	Check patch connections.
	Patient movement	Instruct patient to relax and wait for FHR display to return
System Message: No Signal - Maternal	MECG electrode connector has disconnected	Check maternal ECG electrode connection.
	Patient movement	Instruct patient to relax and wait for FHR display to return

TABLE 18: M110 MONITOR TROUBLESHOOTING		
Problem	**Possible Cause**	**Solutions**
System Message: Communications Fault 1, 2, 3, or 4	Software fault	Reboot system via powering down and then powering back up with the power on /off button. If fault reoccurs, call MindChild Medical, Inc. to arrange for service.
Enclosure Damage	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service
Plastic Bezel Damage	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service
Patient Connector Damage	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service
Power Connector Damage	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service
Output Connector Damage	The device fell to the floor	Call MindChild Medical, Inc. to arrange for service

6. Care and Cleaning

Ensure that the Meridian M110 Monitor is unplugged and disconnected from the AC power source. Detach all accessories from the monitor, and no not immerse the monitor or accessories in any liquid. Do not use abrasive cloths or cleaners to clean the monitor and monitor accessories. Use only the approved MindChild Medical, Inc., substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

MindChild Medical, Inc., makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital or institution's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public-Safety Workers" issued by the U.S. Department of Health and Human Service, the Public Health Service, and the Centers for Disease Control in Atlanta, Georgia in February, 1989. See also any policies that apply within your hospital, county, state, and country.

6.1. General Points

The electrodes and patient modules are sensitive instruments. Handle them with care.

Clean and disinfect the Meridian M110 fetal monitor and cables after each use. Keep your monitor, electrodes, cables and accessories free of dust and dirt. After cleaning and disinfecting, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to MindChild, **always** decontaminate the equipment first before sending it back in the appropriate packaging.

Observe the following general precautions:

- Always follow carefully and retain the instructions that accompany the specific cleaning and disinfecting substances you are using. Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not allow a cleaning or disinfecting agent to leave residues on any equipment surfaces. Wipe residues off with a cloth dampened with water, after allowing the appropriate time for the agent to work.
- Do not allow liquid to enter the monitor case.
- Do not immerse in liquid. Protect against water sprays or splashes.
- Never use abrasive material (such as steel wool or silver polish).

- Never use bleach.

Warning:

- Do not operate the monitor if it is wet. If you spill liquid on the monitor, contact MindChild Medical, Inc., immediately to request service.
- Do not perform underwater monitoring (for example, in a bath or shower) using wired electrodes.
- Place the monitor where there is no chance of contact with, or falling into water or other liquid
- Do not dry equipment using heating devices such as heaters, ovens (including microwave ovens), hair dryers and heating lamps.
- Failure to follow the cleaning and disinfecting steps outlined in this chapter may result in the melting, distortion, blurring, or fading of the monitor case, labels, and finishes.

6.2. Cleaning and Disinfecting the M110 Monitor

Clean and disinfect the Meridian M110 fetal monitor after each use. Clean equipment before disinfecting. For the cables and other accessories, please refer to “Cleaning and Disinfecting Monitoring Accessories” below.

Clean with a lint-free cloth, moistened with: warm water (40°C/104°F maximum) and soap or a diluted non-caustic detergent that is either a tenside or phosphate based cleaning agent (see “Cleaning Agents” table below). Do not use strong solvents such as acetone, alcohol, or trichloroethylene. Do not use abrasive cleaners of any kind. After cleaning, disinfect using only approved disinfecting agents listed (see “Disinfecting Agents” table below).

Do no permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning/disinfecting solution to enter the connectors of the monitor.

CAUTION:

- **Solutions:** Do not mix disinfecting solutions as hazardous gases may result.
- **Skin contact:** To reduce risk of skin irritations, do not allow a cleaning or disinfecting agent to leave residues on any of the equipment surfaces: wipe it off with a cloth dampened with water, after allowing the appropriate time for the agent to work, or before applying to a patient.
- **Hospital Policy:** Disinfect the product as determined by your hospital’s policy, to avoid long term damage to the product.
- **Local requirements:** Observe local laws governing the use of disinfecting agents.

6.2.1. M110 Monitor Cleaning & Disinfecting Agents

TABLE 19: APPROVED MERIDIAN M110 CLEANING & DISINFECTING AGENTS	
Type	**Base**
Cleaner	Mild soap (diluted) Phosphates Tensides
Disinfectant	Commercial diluted bleach Commercial diluted ammonia

WARNING: To avoid the risk of damaging the monitor and its accessories, do NOT use disinfectants containing additional active ingredients other than those listed.

6.3. Cleaning and Disinfecting Cables and Monitoring Accessories

To clean, disinfect and sterilize reusable sensors, cables, leads and so forth, refer to the instructions delivered with the relevant accessories.

The Disposable fECG Electrode Arrays are single use patient applied-part devices that do not require cleaning and should be disposed of following use.

The patient cables are re-usable. Care and cleaning of the cable and connector should be in accordance with the following recommendations:

- MindChild recommends cleaning of the cable jacket and connector with diluted bleach (See Cleaning and Disinfection Agents below).
- Solvent based products may dry out the cable's jacket and shorten the life of the product. For this reason, alcohol based solutions or other solvents should be avoided.
- Wipe first with a cloth dampened with the cleaning solution, then re-wipe with a cloth moistened with water only to remove any residue.
- Avoid contact of cleaning solution with any metal components and do not immerse the cable in the solution.

6.3.1. Patient Cables Cleaning & Disinfecting Agents

TABLE 20: APPROVED MERIDIAN PATIENT CABLES CLEANING & DISINFECTING AGENTS	
Type	**Base**
Cleaner	Mild soap (diluted)
Disinfectant	Sodium Hypochlorite 5.25% (bleach) diluted 10:1 Cidex™ Sporicidin™

6.4. Sterilizing

Do NOT sterilize the M110 monitor, patient cables, accessories or supplies unless otherwise indicated in the separate Instruction for Use that accompany the accessories and supplies.

7. Maintenance

7.1. Inspecting the Equipment and Accessories

A visual inspection of the monitor should be performed **before each use** of the monitor and in accordance a hospital's policy. With your monitor switched off:

1 Examine unit for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids that may have entered the housing, and that there are no signs of abuse.

2 Inspect all accessories (electrodes and cables). Do not use a damaged accessory.

WARNING:

- **Schedule:** Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- **In case of problems:** If you discover a problem with any equipment, contact MindChild Medical, Inc., to request service.
- **Electric shock hazard:** Do not open the monitor housing. Refer all servicing to qualified MindChild Medical, Inc., service personnel.

7.2. Inspecting the Cables and Cords

1. Examine all system cables and the power plug and cord for damage. Make sure that the prongs of the plug do not move in the casing. If damaged, replace it with an appropriate power cord.
2. Inspect the patient cables and connectors general condition. Make sure there are no breaks in the insulation. Make sure that the connector's tab open and closes properly.
3. Carry out performance assurance checks. Make sure that valid FHR output is provided when all cables are properly connected.

7.3. Maintenance and Service Schedule

The following tasks must be completed by the relevant qualified individuals. Ensure that these tasks are carried out as indicated by the monitor's maintenance schedule or as specified by local laws (whichever comes sooner). Contact MindChild Medical, Inc., to request a qualified service technician if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

TABLE 21: MAINTENANCE TASK AND TEST SCHEDULE

Maintenance and Test Schedule	To Be Performed By	Frequency
Visual Inspection Check for: Any physical damage Loose and/or frayed connectors and cables Marks, scratches, dents, or any other damage Legibility of any safety labels and inscriptions	Qualified individuals at the hospital or institution, including but not limited to: • Doctors • Physicians • Nurse Practitioners • Nurses • Intern physicians • Trained medical school graduate students	Before installation, before each use, and each time the monitor is serviced. Visually inspect the monitor at least annually. Do not use the Meridian M110 Monitor if it is damaged in any way. Contact qualified service personnel, such as hospital biomedical department personnel, or MindChild Medical, Inc., for repairs
Clean and disinfect the equipment		After each use.
Inspect: Patient Cables and Leads Monitor Exterior Power Cord		As Needed

TABLE 21: MAINTENANCE TASK AND TEST SCHEDULE		
Maintenance and Test Schedule	**To Be Performed By**	**Frequency**
Inspect: Patient Cables Monitor's Internal Battery Monitor Exterior Entire Monitor Power Cord Power Supply Voltages Circuit board Voltages	Qualified MindChild Medical, Inc., Personnel	Annually Calibrate power supply and circuit board voltages annually or if/when needed
Check Ground Continuity		As needed, but at least annually
Safety checks according to IEC 60601-1, and where applicable, to national standards		At least once every two years, or as specified by local laws. After any repairs where the power supply has been replaced (by an authorized service agent). If the monitor has been dropped, it must be repaired / checked by an authorized service agent.
Performance assurance for all measurement		At least once every two years, or if you suspect the measurement values are incorrect.

7.4. Testing the Meridian M110 Monitor

Contact MindChild Medical, Inc., to request qualified service personnel to perform necessary electrical safety tests, performance assurance tests, and regular maintenance tests.

7.4.1. Calibrating the Meridian M110 Monitor

The Meridian M110 Monitor does not require calibration. Should the M110 not operate to its specifications, contact MindChild Medical, Inc., to request service. Do not attempt to service or calibrate the monitor.

WARNING:

- **In case of problems:** If you discover a problem with any equipment, contact MindChild Medical, Inc., to request service.
- **Electric shock hazard:** Do not open the monitor housing. Refer all servicing to qualified MindChild Medical, Inc., service personnel.

7.5. Disposing of the Monitor

WARNING: To avoid contaminating or infecting personnel, the service environment or other equipment, make sure the equipment has been appropriately disinfected and decontaminated before disposal at the end of its useful life, in accordance with your country's laws for equipment containing electrical and electronic parts.

Recycle PCBs in accordance with local, state, and federal laws. Recycle the paper Operator's Manual (this document) with paper recycling. Retain original packaging materials for the storage and/or shipping of the Meridian Monitor. Upon the Monitor's end of service life, recycle unused packaging materials accordingly. Do not dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered.

7.6. Disposing of the Patches and Electrodes

Dispose the Disposable fECG Electrode Arrays and individual electrodes after use in compliance with the hospital's medical waste policy. Neither the patches or electrodes contain any hazardous waste materials.

7.7. Record any Maintenance, Servicing, and Repairs

Each time the Meridian M110 Monitor undergoes maintenance (regular and otherwise), servicing, or repairs, log the actions taken in the table on the following page. This table should not be completed directly but should instead be copied and completed as necessary and kept with other M110 documentation.

TABLE 22: MERIDIAN M110 MONITOR MAINTENANCE, SERVICING, AND REPAIRS LOG						
Meridian M110 Monitor Unit Serial Number: Institution Name:						
Date Request Made	Maintenance, Servicing, or Repair	Date Monitor sent out for Service or Date and Time of Technician Arrival	Technician			Date Monitor Received following Service or Date and Time of Completed Repair, etc.
			Name	Employer	Signature	

8. Specifications and Standards Compliance

The Meridian M110 monitor is intended to monitor a mother and her singleton fetus, which from an electrical safety point view are one person.

8.1. Environmental Specifications

The monitor may not meet the given performance specifications if stored and used outside the specified temperature and humidity ranges, as outlined in the following table.

TABLE 23: MERIDIAN M110 MONITOR ENVIRONMENTAL SPECIFICATIONS

Temperature Range	Operating	0°C to 45°C (32°F to 113°F)
	Storage	-20°C to 60°C (-4°F to 140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C/104°F
	Storage	<90% relative humidity @ 60°C/140°F
Altitude Range	Operating	-500 to 3000 m/-1640 to 43000ft.
	Storage	-500 to 13100 m/-1640 to 43000 ft.

8.2. Physical Specifications

The Meridian M110 Monitor volume dimensions are 31.75 x 21.6 x 9.8 cm (12.5” x 8.5” x 3.875”) (L x W x D) with a weight of approximately 2.95 Kg (6.5 lbs).

WARNING: **Explosion Hazard:** Do not use in the presence of flammable anesthetics, such as flammable anesthetic mixtures with air, oxygen or nitrous oxide. Use of the devices in such an environment may present an explosion hazard.

8.3. MTBF Specifications

The Meridian M110 Monitor is designed and manufactured in line with the best engineering and electronic practices available today. However, because of the widely differing ways in which our monitors are operated, the variable quality of the electrical supply and level of care they can receive in the field, the MTBF (Mean Time Before Failure) rating for these devices can vary greatly. The MTBF is conservatively calculated at 46,000 hours (approximately 5.25 years).

8.4. Expected Service Life

The Meridian M110 Monitor is expected to provide nine (9) years of operation.

8.5. Regulatory Standards and Compliance

8.5.1. Safety and Performance

The Meridian M110 monitor complies with the following major international safety and performance standards:

- IEC 60601-1: ed3.0 (2005-01), Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- AAMI 60601-1: ed3.0 (2005-01) North American Deviations
- CSA C22.1#60601-1: ed3.0 (2008-02)
- *IEC 60601-1-1: Part 1-1*, General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems
- *IEC 60601-1-6: ed3.0 (2010-01), Medical Electrical Equipment* – Collateral Standard: Usability
- *IEC 60601-2-49: ed2.0 (2011-02), Medical Electrical Equipment* – Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment
- *IEC 62366: ed1.0 (2007-10)*, Medical Devices – Application of Usability Engineering to Medical Devices
- *ISO 14971:2007*, Medical Devices – Application of Risk Management to Medical Devices

8.5.2. Electromagnetic Compatibility (EMC)

The device and its accessories, listed in the accessories section, comply with the following EMC standards:

- EN/IEC 60601-1-2: ed3.0 (2007-03)

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this book. Before using the device, assess the electromagnetic compatibility of the device with surrounding equipment.

CAUTION:

- Although the Meridian M110 is an electrical Class II device, it has a protective earth conductor which is needed for EMC purposes.
- Always use supplied power cord with the three-prong plug to connect the monitor to AC mains. Never adapt a three-prong plug from power supply to a two-slot outlet.

CAUTION: The use of accessories, electrodes and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

WARNING: Do NOT use cordless/mobile phones or any other portable RF communication system within the patient vicinity, or within a 1.0m radius of any part of the fetal monitoring system.

CAUTION: Fetal ECGs, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

8.5.3. Reducing Electromagnetic Interference

CAUTION: The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

The product and associated accessories can be susceptible to interference from continuous, repetitive, and additional RF energy sources as well as from power line bursts, even if the other equipment is compliant with EN 60601-1-2 emission requirements. Examples of other sources of RF interference include other medical electrical devices, cellular products, information technology equipment, and radio/television transmissions.

When electromagnetic interference (EMI) is encountered, for example, if you can hear spurious noises on the fetal monitor's loudspeaker, attempt to locate the source. Assess the following:

- Is the interference due to misplaced or poorly applied electrodes? If so, re-apply the electrodes correctly and according to the directions in this manual or in the Instructions for Use accompanying the relevant accessory.
- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical electrical equipment?

Once the source is located, there are a number of things that can be done to mitigate the problem:

1. **Eliminate the Source:** Turn off or move possible sources of EMI to reduce their strength.
2. **Attenuate the Coupling:** If the coupling path is through the patient leads, the interference may be reduced by moving and/or rearranging the leads. If the coupling is through the power cord, connecting the system to a different circuit may help.
3. **Add External Attenuators:** If EMI becomes an unusually difficult problem, external devices such as an isolation transformer or a transient suppressor may be of help. MindChild Medical, Inc., service personnel can be of help in determining the need for external devices.

Where it has been established that electromagnetic interference is affecting physiological parameter measurement values, a physician, or suitably qualified person authorized by a physician, should determine if it will negatively impact patient diagnosis or treatment.

8.5.4. System Characteristics

The phenomena discussed above are not unique to this system but are characteristic of patient monitoring equipment in use today. This performance is due to very sensitive high gain front end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.

8.5.5. Electromagnetic Emissions and Immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. See tables 13 to 16 for this detailed immunity information. See Table 17 for recommended minimum separation distances between portable and mobile communications equipment and the Meridian M110 Monitor.

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of and electromagnetic disturbance.

Caution should be exercised in comparing immunity levels between different devices. The criteria used for degradation are not always specified by the standard and can therefore vary with the manufacturer.

In the table below, the term “device” refers to the Meridian M110 fetal monitor together with its accessories. The table provides details on the electromagnetic emissions for the Meridian M110 monitor, how these emissions are classified, and the electromagnetic environments in which the Meridian M110 is specified to technically function.

TABLE 24: GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS		
Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 For the Meridian M110 with all accessories	Class A	The device is suitable for use in hospital environments only. It is not intended for domestic use or establishments that are directly connected to a low voltage power supply network.

8.5.5.1. Electromagnetic Immunity

The Meridian M110 Monitor is suitable for use in specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

TABLE 25: GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY			
Immunity Test	**IEC 60601-1-1 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Key: U_T is the a.c. mains voltage prior to application of the test level.			

8.5.6. Finding Recommended Separation Distances

In the following table, **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and **d** is the recommended separation distance in meters (m).

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for frequency of the transmitter.

Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

TABLE 26: GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

Conducted RF Immunity Test EN/IEC 61000-4-6		
IEC 60601-1-2 Test Level Over 150 kHz to 80MHz	**Compliance Level**	**Electromagnetic Environment Guidance: Recommended Separation Distance (d) (in Meters, at Frequency Range Tested) for Ultrasound and ECG Measurements**
3.0 V_{RMS}	3.0 V_{RMS}	$d = 1{,}2\sqrt{P}$

Key:
d = Recommended separation distance in meters (m)
P = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer
V1 = Tested compliance level (in Volts) for the conducted RF Immunity test IEC 61000-4-6

Note: The device meets the compliance level of 3.0 V_{RMS} according to IEC 60601-1-2 over the specified test frequency range 150 kHz to 80MHz, the recommended separation distance in meters (d) is by the following equation:

$$d = \left(\frac{3{,}5}{V1}\right)\sqrt{P}$$ For a Compliance level of 3.0 V_{RMS}

$$d = 1{,}2\sqrt{P}$$

<table>
<tr><th colspan="3">TABLE 27: GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY</th></tr>
<tr><th colspan="3">Radiated RF Immunity Test
EN/IEC 61000-4-3</th></tr>
<tr><th>IEC 60601-1-2 Test Level over 80 MHz to 2.5 GHz</th><th>Compliance Level</th><th>Electromagnetic Environment Guidance: Recommended Separation Distance (d) (in Meters, at Frequency Range Tested) for Ultrasound and ECG Measurements</th></tr>
<tr><td rowspan="2">3.0 V/m</td><td rowspan="2">3.0 V/m</td><td>Over 80 MHz to 800 MHz:
$d = 1{,}2\sqrt{P}$</td></tr>
<tr><td>Over 800 MHz to 2.5 GHz:
$d = 2{,}3\sqrt{P}$</td></tr>
<tr><td colspan="3">Key:
d = Recommended separation distance in meters (m)
p = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer
E1 = Tested compliance level (in volts/meter) for the Radiated RF Immunity test IEC 61000-4-3</td></tr>
<tr><td colspan="3">Note: The device meets the compliance level of 3.0 V_{RMS} according to IEC 60601-1-2 over the specified test frequency range.
Over the frequency range 80 kHz to 800 MHz, the recommended separation distance in meters (d) is found by the following equation:
$$d = \left(\frac{3{,}5}{E1}\right)\sqrt{P}$$ For a compliance level of 3.0 V_{RMS}: $d = 1{,}2\sqrt{P}$
Over the frequency range 800 kHz to 2.5 kHz to 2.5 GHz, the recommended separation distance in meters (d) is found by the following equation:
$$d = \left(\frac{7{,}0}{E1}\right)\sqrt{P}$$ For a compliance level of 3.0 V_{RMS}: $d = 2{,}3\sqrt{P}$</td></tr>
</table>

Field strengths from fixed transmitters, such as base stations or radio (cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the device.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

If you require further information or assistance, please contact MindChild Support.

8.5.6.1. Recommended Separation Distances from Other RF Equipment

The Meridian M110 monitor in intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user/operator of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the monitor as recommended below, according to the maximum output power of the communications equipment.

TABLE 28: SEPARATION DISTANCE (D) IN METERS ACCORDING TO FREQUENCY OF TRANSMITTER AT IEC 60601-1-2 TEST COMPLIANCE LEVEL

Rated Maximum Output Power (P) of Transmitter (in watts)	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3,5}{E1}\right)\sqrt{P}$	800 MHz to 2.5 GHz $d = \left(\frac{7,0}{E1}\right)\sqrt{P}$
0.01	0.1	0.1	0.23
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0

8.6. Environment

Before operation, make sure that the monitor is free from condensation. Condensation can form when equipment is moved from one building to another and/or exposed to moisture and differences in temperature.

Use the monitor in an environment which is reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so forth. It operates within specifications at ambient temperatures between 0 and +45 °C (32°F to 113°F). Ambient temperatures that exceed these limits can affect accuracy of the system and can damage the components and circuits.

Ambient temperature ranges for storage are -20°C to +60°C (-4°F to 140°F) for the monitor.

WARNING:

- **Leakage currents:** If several items of equipment used to monitor a patient are interconnected, the resulting leakage current may exceed allowable limits.
- **ECG electrodes:** NEVER allow ECG electrodes to contact other electrical conductive parts.

8.7. Monitoring After a Loss of Power

After a power loss the Meridian M110 will automatically reboot as in the case of a clean start. Fetal heart rate monitoring will begin in approximately 30 seconds after power is restored.

The M110 does not store any patient data, therefore no file or file structure maintenance is required in the event of a power loss.

8.8. ESU and MRI

WARNING: The Meridian M110 is NOT intended for use during electro-surgery or MRI. Remove all electrodes, sensors, and accessories before performing electro-surgery or MRI, otherwise harm to the patient or the user can result.

WARNING: MR-unsafe!

Do not expose the device to a magnetic resonance (MR) environment.

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the device, which can heat during MR scanning.
- The device may generate artifacts in the MR image.
- The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

8.9. Defibrillation

WARNING: The Meridian M110 is NOT intended for use during defibrillation. Remove all electrodes, sensors, and accessories before performing defibrillation, otherwise harm to the patient or the user can result.

The Meridian M110 Monitor does not comply with the Defibrillation Protection Requirement of IEC 60601-1

Should a situation arise that defibrillation of a patient is required, MindChild requires that the M110 be disconnected from the patient. In order to accomplish this, two methods may be employed:

1) removal of all patches and individual external electrodes, or
2) if time is limited, the M110 can be disconnected from the patient by disconnecting the cable clips from all the patches.

In an abundance of caution, all cables leading to the M110 device should be cleared from the area prior to initiating defibrillation

8.10. Cardiac Pacemakers and Electrical Stimulators

WARNING: The fetal/maternal monitors are NOT intended for use for ECG measurements on patients connected to external electrical stimulators or with cardiac pacemakers.

9. Meridian M110 Monitor Parts

Information on the parts of the Meridian M110 follow. This information pertains and should be used in conjunction with the rest of this manual, and should additionally be used when ordering new parts in the event of damage or otherwise. Parts can be ordered by contacting MindChild Medical, Inc., using the contact information located at the beginning of this manual (on page 3).

9.1. Parts List

TABLE 29: MERIDIAN M110 MONITOR PARTS

Part	Manufacturer	Part Number or Serial Number	Comments
Meridian Monitor	MindChild Medical	M110	
12 VDC Medical Grade Power Supply	MindChild Medical	M100-P850	
AC Power Cord	MindChild Medical	M100-C060	
Front Left Patch Cable	MindChild Medical	M2-1010	
Front Right Patch Cable	MindChild Medical	M2-1020	
Back Left Patch Cable	MindChild Medical	M2-0510	
Back Right Patch Cable	MindChild Medical	M2-0520	
Interconnection Cable GE Healthcare	MindChild Medical	M100-A290	
Interconnection Cable Philips Healthcare	MindChild Medical	M110-B290	

Appendix

A-1. Meridian M110 Monitor Technical Specifications

TABLE 30: MERIDIAN M110 MONITOR		
Category	Technical Specifications	
Power Requirements		
Voltage	100-240 VAC	
Maximum Consumption	0.5 A	
Frequency	50/60 Hz	
Supply	Separable medical grade brick power supply, required as part of Medical Electronic (ME) System	
Physical Characteristics	Device	Boxed
Height	9.8 cm (3.875”)	30.5 cm (12”)
Width	21.6 cm (8.5”)	40.6 cm (16”)
Depth	31.8 cm (12.5”)	40.6 cm (16”)
Weight	2.95 kg (6.5 lbs.)	7.26 kg (16 lbs.)
Environmental Specifications	Operating	Storage
Temperature Range	0°C to 40°C (-4°F to 104°F)	-20°C to 60°C (-4°F to 140°F)
Relative Humidity	<95% RH @ 40°C/104°F	<90% RH @ 60°C/140°F
Altitude	-500 to 3000 m/-1640 to 9840 ft.	-500 to 13100 m/-1640 to 43000 ft.
Performance Fetal Heart Rate		
Measurement Type	Electrocardiograph, non-invasively from maternal abdomen	
Measurement Sensor	Electrodes	
Measurement Range	50 – 240 BPM	
Accuracy	± 5 BPM	
Applied Part	Electrodes, quantity 29, Type BF	
Output Type	FHR via LCD Display & DECG QRS replication	
Output Resolution	Display: 1 BPM	DECG: 0.05 - 0.95 BPM
Output Rate	Display: 1 per second	DECG: R-R interval
Beat to Beat Change	30 BPM	
Differential Input Impedance	> 100MΩ	
Electrode Offset Tolerance	± 300 mV	
Dielectric Strength	4000 Vrms	
Defibrillator Protection	None	
Electro-surgery Protection	None	
Patient Alarms	None	
Performance Uterine Activity		
Measurement Type	Electrohysterograph, non-invasively from maternal abdomen	
Measurement Sensor	Electrodes, same as above	
Measurement Range	0 – 100 Counts	
Accuracy	± 30 seconds	
Output Type	UA replication	
Output Resolution	UA: 1 Count	
Output Rate	UA: 1 per second	

TABLE 30: MERIDIAN M110 MONITOR	
Category	Technical Specifications
Accessories Power Supply: Type/Brand Manufacturer Form Factor Temperature Range Relative Humidity Altitude Cables: Type/Name Manufacturer Temperature Range Relative Humidity Altitude Electrodes: Type/Name Manufacturer Size Description Temperature Range Relative Humidity Altitude	 12 VDC Medical Grade Power Supply M100-P850 MindChild Medical, Inc. Separable brick power supply, required as part of ME System 0 and +45 °C (32°F to 113°F) <95% relative humidity @ 40°C/104°F -500 to 13100 m/-1640 to 43000 ft. Patient electrode cables M2-XXXX MindChild Medical, Inc. 0 and +45 °C (32°F to 113°F) <95% relative humidity @ 40°C/104°F -500 to 13100 m/-1640 to 43000 ft. MDPA1 Disposable fECG Electrode Array MindChild Medical, Inc. 300cm x 350cm (11.8” x 13.8”) Electrode array (4 patches) with twenty-nine hydrogel electrodes +15 to +35 °C (59°F to 95°F) <95% relative humidity @ 35°C/95°F -500 to 13100 m/-1640 to 43000 ft.
Certification(s) and Compliance with Standards	• IEC 60601-1: ed3.0 (2005-01), Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance • AAMI 60601-1: ed3.0 (2005-01) North American Deviations • CSA C22.1#60601-1: ed3.0 (2008-02) • IEC 60601-1-1: Part 1-1, General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems • IEC 60601-1-6: ed3.0 (2010-01), Medical Electrical Equipment – Collateral Standard: Usability • IEC 60601-2-49: ed2.0 (2011-02), Medical Electrical Equipment – Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment • IEC 60601-1-2: ed3.0 (2007-03) General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility • IEC 62366: ed1.0 (2007-10), Medical Devices – Application of Usability Engineering to Medical Devices • ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices

A-2. Supported Cables and Accessories

The following cables and accessories are supported by the MindChild Medical, Inc., Meridian M110 Fetal Monitoring System.

TABLE 31: SUPPORTED CABLES & ACCESSORIES

Cable	Manufacturer	Part Number
Front Left Patch Connection Cable	MindChild Medical	M2-1010
Front Right Patch Connection Cable	MindChild Medical	M2-1020
Back Left Patch Connection Cable	MindChild Medical	M2-0510
Back Right Patch Connection Cable	MindChild Medical	M2-0520
Interconnection Cable	MindChild Medical	M100-A290 M110-B290
Disposable fECG Electrode Array	MindChild Medical	MDPA1

Note that a set of four (4) patch connection cables are part number MCC01. A box of twenty (20) patches is part number MCD20 and five (5) boxes (100 patches) is part number MCD100.

A-3. Product Warranty; Limitations and Exclusions

Limited Warranty. MindChild warrants that the Monitor and the Software, when delivered, properly installed and used in accordance with MindChild's instructions, will conform in all material respects to MindChild's most current version of the published specifications or to those specifications in effect as of the date the Monitor and/or Software was originally delivered to the Customer. The foregoing limited warranty is referred to below as the "Warranty." Any equipment or software manufactured or developed by a company other than MindChild shall be provided only with the warranty and support provided by the original manufacturer or developer, and no additional warranty or support is offered by MindChild. Any claim based on the foregoing Warranty must be submitted in writing in accordance with MindChild's standard procedures no later than the earlier of (i) 60 days after discovery of such nonconformity or (ii) 1 year after the date of shipment (as the case may be, the "Warranty Period"). Such Warranty shall not apply if the Monitor or Software is modified or altered.

Warranty Repairs. As MindChild's sole responsibility and the Customer's exclusive remedy in the event of any material nonconformity during the Warranty Period, MindChild shall, at its option, make a reasonable effort to repair or replace the Monitor or Software so that it is conforming or shall reimburse Customer's purchase price for the pertinent parts of the Monitor or the Software. The Custom shall not continue to use the Monitor after providing notice of any Warranty claim.

THE FOREGOING STATES THE EXCLUSIVE REMEDY OF THE CUSTOMER, AND THE ENTIRE OBLIGATION OF MINDCHILD, WITH RESPECT TO ANY CLAIMS OF NON-CONFORMITY TO THE TERM OF THE FOREGOING WARRANTY.

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The total liability of MindChild (including its subcontractors and suppliers) for all claims, whether in contract, tort (including negligence and product liability), or otherwise, arising

out of, connected with, or resulting from the manufacture, sale delivery, resale, repair, replacement, or use of the Monitor or the Software shall not exceed the purchase price of the Monitor. This limitation of liability is intended to apply to all claims, including but not limited to those of research subjects, without regard to which other provisions of this Agreement have been breached or proven ineffective. In no event shall MindChild be liable for indirect, special, consequential or incidental damages, including (without limitation) damages for loss of revenue or profit.

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