MRI Compatible 12-Lead Electrocardiograph Monitor

G30000

INSTRUCTIONS FOR USE

Version 2315
English

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Table of Contents

Introducing the MiRTLE MRI ECG Monitor

1.1 *Device Overview*

The MiRTLE system is an MRI-compatible 12-lead electrocardiograph which helps cardiologists, electrophysiologists, and radiologists understand the health of their patients during an MRI scan. Specific design features, which address the MRI safety concerns of standard 12-lead ECG monitors, allow traditional electrode placement for diagnostic-grade ECGs. Further design features remove the gradient induced interference allowing continuous monitoring during the imaging sequence.

As shown in **FIGURE 1** below, the MiRTLE system includes a Patient Acquisition Module that sits on the bed with the patient and connects to the electrodes via the patient cable. The battery powered Patient Acquisition Module converts the ECGs for digital transmission via a fiber optic cable to the Control Room Monitor located in the control room. The Control Room Monitor performs: the digital signal processing to cleanse the ECG signals of gradient interference; beat detection; and cleansed ECG visualization.

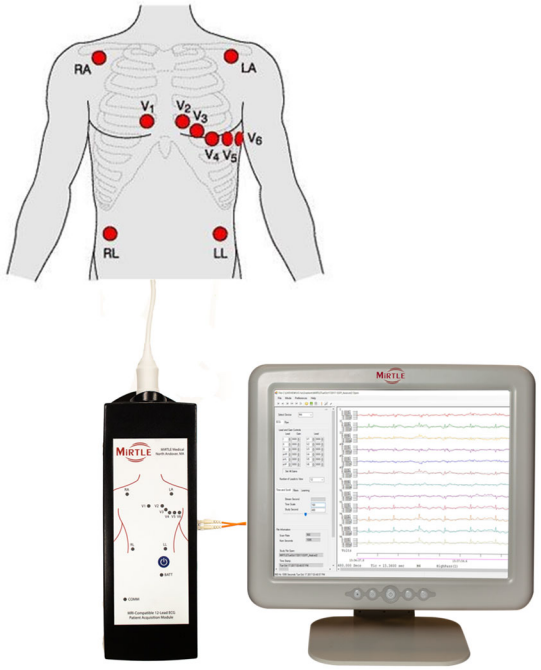


FIGURE 1

1.2 *Who This Manual is For*

This manual is for trained healthcare professionals using the MiRTLE Magnetic Resonance Imaging (MRI) Compatible Electrocardiography (ECG) monitor. This manual describes how to install and use the monitor, cables, patient electrodes and Control Room Monitor. Become familiar with all instrumentation and instructions, including warnings and cautions, before using the monitor on patients. Read and retain any and all instructions for usage that come with any accessories to be used with the monitor, as they contain important information about the use, care, and cleaning of those accessories that is not included in this manual.

You Should Be:

- Trained in the use of Magnetic Resonance Imaging (MRI) equipment
- Trained in the use of Electrocardiography (ECG) monitors
- Trained in the interpretation of ECG plots
- Familiar with medical devices and standard patient monitoring procedures

In This Guide:

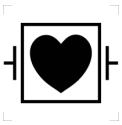
- **Warnings** alert you to potentially serious outcomes, adverse events, and/or safety hazards. Failure to observe warnings may result in user and/or patient injury.
- **Cautions** alert you to instances in which special care or attention is necessary for the safe and effective use of the product. Failure to observe cautions may result in minor to moderate user and/or patient injury, damage to the product, or damage to property.
- **Notes** provide suggestions to optimize monitor performance or clarify monitor usage
- **Monitor** or **MiRTLE** refers to the MiRTLE MRI Compatible ECG Monitor as a whole. **Patient Acquisition Module** (PAM), refers to the MiRTLE MRI ECG device or unit that connects to the patient via the patient cable. **Control Room Monitor** (CRM) refers to the computer that is connected to the MiRTLE MRI PAM, and **Screen** or **Display** refer to what is seen on the computer monitor's display, such as ECG plots.

1.3 *Safety Information*

The following information is vital to ensure the safety of the patient, operator, and any additional individuals who may interact with the MiRTLE System for the duration of the monitor's service life.

This following sections describe the use of any terms and symbols as well as the responsibilities of the manufacturer and of the user.

1.4 *Symbols*

Table 1: MiRTLE Symbol Definition		
Icon	**Standard**	**Definition**
	93/42/EEC	Conforms to the European Medical Device Directive
	IEC 60417-5336	Defibrillation-proof CF applied part – direct, floating, defibrillation-proof
	IEC 60417-5172	Electrical Class II equipment, in which the protection against electrical shock relies on double or reinforced insulation
	IEC 62570	MR-safe – safe for use within the MR field
	IEC 62570	MR-conditional – conditional use in an MR environment as explained in “Instructions for Use”
	IEC 62570	MR-unsafe – do not use in an MR environment
	ISO 7010-W001	Caution – general warning sign
	IEC 60878-1641 ISO 7010-Safety01	Follow operating instructions
	ISO 7010-M002	Refer to instruction manual
		Application software status – OK / Good
		Application software status – Warning
		Application software status – Off / Error
		Application software – save to disk

1.5 *Definitions*

BPM	Beats per minute	IFU	Instructions for Use
CRM	Control Room Monitor	MHD	Magneto-hydro Dynamic
DSP	Digital Signal Processing	OSK	On-Screen Keyboard
ECG	Electrocardiograph	PAM	Patient Acquisition Module
GUI	Graphical User Interface	VESA	Video Electronics Standards Association
GIV	Gradient induced voltage		

1.6 *Hazards and Cautions*

Table 2: MiRTLE System specific Warnings	
Warning Title	**Description**
Grounding	The grounding plug on the power cord must be used, with the power cord supplied with the MiRTLE System being connected directly from the monitor to a wall socket. The grounding prong must not be defeated or avoided with 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 MiRTLE System. Electrodes attach to the ends of the ECG cable lead wires, which are placed on the patient. 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.
Electromagnetic Interference including RFID	Electromagnetic fields, such as those potentially generated by electrical medical equipment and personal electronic devices, may interfere with the operation of the MiRTLE System such that the monitor may not function as desired, readings may be skewed, or otherwise distorted. Should the MiRTLE System be affected by electromagnetic interference, contact MiRTLE Medical, LLC, to request service.

Table 2: MiRTLE System specific Warnings	
Warning Title	**Description**
Hazardous Situation: Explosion	To reduce the risk of explosion, the MiRTLE System should not be used in the presence of flammable anesthetics or oxygen
Patient Cable and Lead wires	Only the patient cables and leads that are provided with the MiRTLE System should be used. If the provided patient cables or leads become damaged or otherwise unfit for use, contact MiRTLE Medical, LLC, 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. To minimize leadwire heating, leadwires must not be looped and should be placed in the center of the patient's abdomen and down in between their legs. The patient cable is a defibrillation-proof applied part which incorporates current-limiting devices in the trunk cable's yoke.
Electrodes	The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.
Defibrillation	The MiRTLE System is designed with defibrillation protection allowing a patient to be defibrillated while connected. Defibrillation protection requires use of MiRTLE Medical specified cable, lead wires and electrodes. When defibrillating a patient, follow all precautions for MiRTLE and the defibrillator device. During defibrillation, the ECG traces will saturate and then recover in under five (5) seconds in accordance with AAMI/ANSI EC13 and IEC 60601-2-27.
Electrosurgery	The MiRTLE System can be used during electrosurgery, provided the equipment being used is in good working order, meets appropriate safety standards, is properly grounded and is operated correctly in the appropriate manner and environment. Improperly grounded equipment can be a safety hazard and can also cause interference to the ECG signal and result in a noisy ECG signal waveform and inaccurate heart rate measurements. Electrosurgical unit overloads may cause damage to this device.
Instructions For Use (IFU)	To ensure safe and efficient operation of the MiRTLE System all instructions for use must be followed. Instructions for use include any instructions and steps included in this manual, as well as the

Table 2: MiRTLE System specific Warnings	
Warning Title	**Description**
	instructions for use found in the user manuals for additional accessories. It is significant to note that the instructions for use and operation of the MiRTLE System pertain solely to the MiRTLE System. These instructions do not replace, or bypass established medical procedures for patient care. The patient should be monitored and evaluated by relevant qualified medical personnel (physicians, nurses, etc.) regularly to ensure patient safety and to intervene or treat the patient as necessary.
MHD Interference	The MiRTLE System will display magnetohydrodynamic (MHD) interference when the patient is in the bore, altering the ECG signal during the ST portion of the ECG plus baseline wander into the next cardiac cycle. The physician must account for this interference and should remove the patient from the bore if any concerning ECG morphologies are present. MHD does not impact the heart rate accuracy.
Accuracy	The MiRTLE System may display erroneous heart rate values when pacemaker spikes, arrhythmias, or artifacts are present. Displayed heart rate values should be verified by a qualified physician.
Pacemaker Patients	Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Keep pacemaker PATIENTS under close surveillance.
Pacemaker Pulse Rejection	The MiRTLE System correctly detects, flags, and rejects pacemaker pulses to the maximum amplitude, width, and overshoot in accordance with IEC 60601-2-27. The MiRTLE System does not flag pacemaker pulses during MRI imaging.
Heart Rate Meter	The MiRTLE System calculates a new heart rate for each detected heartbeat and averages the heart rate over the most recent six heart beats. If no heartbeat is detected after three seconds, the heart rate display will blank with the default “HR” indicator. The MiRTLE System responds to a step change in heart rate in 2 seconds when increasing from 80 to 120 BPM and in 6 seconds when decreasing from 80 to 40 BPM in accordance with IEC 60601-2-27.

Table 2: MiRTLE System specific Warnings	
Warning Title	**Description**
No Alarms	The MiRTLE System does not provide visual or audible alarm signals. A qualified physician or clinical operator should always be present and monitoring the patient's ECGs. The MiRTLE System does not alarm for tachycardia.
Tall T-Wave Rejection	The MiRTLE System correctly rejects tall T-waves up to a maximum amplitude of 0.6 mV.
MR Conditional	The MiRTLE PAM and ECG cable may be safely used in the MR environment without cool down periods. Do not exceed a static magnetic field of 3.0T. Device operation may be impacted if PAM is located within field strengths greater than 40 mT (400 gauss).
Loss of Mains Power	The MiRTLE System incorporates battery backup for the Control Room Monitor which powers the monitor for up to 10 minutes of continuous operation during the loss of mains power. The user need not take any action to maintain normal device operation during a 30-second power outage.
Device Damage or Accidental Fall	In the event that a fall or other damaging event occurs, the Beat Detection System should be immediately disconnected from the patient and from the power supply and must be inspected to determine if any parts have been damaged. MiRTLE Medical should be contacted immediately and a qualified MiRTLE Medical service personnel should be called in to inspect the internal components of the Beat Detection System. Following inspection and servicing, if the Beat Detection System is deemed safe for use and operates normally in-service testing, then the Beat Detection System is acceptable to use and free from risk. If the Beat Detection System does not function following inspection, then the Beat Detection System must be returned to MiRTLE Medical for repairs and/or replacement.
Unauthorized Modifications to Device	This device must be checked and calibrated periodically. A malfunctioning device must not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated must be replaced immediately. Refer the device to qualified service personnel for repair or replacement. This device or any of its parts must not be repaired by the user. The device shall not be altered in any way. The user has the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than authorized service personnel.

1.7 *Intended Use*

The MiRTLE MRI-compatible 12-Lead electrocardiograph is intended for the acquisition, display, and recording of the electrical activity of the heart (ECG) and heart rate display during MRI scans including scanner synchronization for cardiac gated sequences.

MiRTLE is intended for use by trained healthcare professionals.

MiRTLE is intended for use under the direct supervision of a cardiologist or electrophysiologist.

MiRTLE is intended for use in MRI rooms and MRI electrophysiological prep areas in a hospital environment.

1.8 *Essential Performance*

The MiRTLE electrocardiograph accurately represents cardiac electrical activity, beat detection, and heart rate display as specified by the performance requirements of 60601-2-27. The MiRTLE electrocardiograph also outputs an MRI scanner synchronization signal (also known as gating or triggering).

1.9 *Indications for Use*

The MiRTLE electrocardiograph is indicated for use under the direct supervision of a cardiologist or electrophysiologist to observe the electrical activity of the heart (electrocardiography, ECG) and heart rate of patients for the duration of magnetic resonance imaging (MRI) scans within 1.5 and 3.0 Tesla scanners. The MiRTLE electrocardiograph provides MRI scanner synchronization for cardiac gated sequences The MiRTLE electrocardiograph is indicated for use in adults and children ages 2 years and above.

1.10 *Contraindications for Use*

The MiRTLE ECG is ***not*** intended for:

- MRI scanners with a magnet field strength greater than 3.0 Tesla
- Use in domestic establishments

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

1.11 *MRI Safety Information*

A person monitored with the MiRTLE MR-Compatible 12-Lead ECG may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	MiRTLE MR-Compatible 12-Lead ECG
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Limits on Scan Duration	2 W/kg whole-body average SAR for (60) minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of (10) minutes if this limit is reached
MR Image Artifact	The presence of the leadwires does not produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with parameter	

1.12 *Responsibilities*

MiRTLE is responsible for the safety, performance, and life-cycle maintenance of its electrocardiograph only if:

- The user installs and operates the device in strict accordance with the instructions for use
- Annual device maintenance is performed by MiRTLE Medical or its authorized representatives
- The user attaches approved accessories only as recommended by MiRTLE Medical

Unpacking and Checking Shipment

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

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 instrument and accessories.

2.2 *Check the Contents*

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

TABLE 3: G30000 DEVICE CONTENTS

PART NUMBER	SYSTEM COMPONENTS & ACCESSORIES	QUANTITY
Package 1 – PAM carrying case		
GR1000	MiRTLE Patient Acquisition Module	1
GA1100	MiRTLE Patient ECG Cable Consists of: GA1200 Trunk Cable GA1310 Lead-set	 1 1
GA2110	10m (33') Fiber Optic Cable	1
GA5100	Battery, rechargeable	2
Package 2 – Monitor		
GR4000	MiRTLE Control Room Monitor	1
	Power Supply	1
	Power Cord	1
	Monitor Mouse	1
	Monitor Touch Screen Pointer	1
Package 3 – Additional Accessories		
RRC-SMB-UBC -M-EU	Battery Charger, medical grade, EU power cord	1
	Monitor VESA stand & screws	1
GA3010	Gating Output Cable – Universal	1
GA3110	Gating Output Cable – Siemens	1

FIGURE 2

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 MiRTLE Medical for repair or replacement arrangements.

2.4 *Repacking*

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

2.5 *PAM Case*

The Patient Acquisition Module and its accessories are provided in a hard-shell protective storage case as shown in Figure 2. It is recommended to store the module and its accessories in the case when not in use.

The MiRTLE MRI Compatible ECG Monitor

12-lead ECGs are the standard of care for detecting acute ischemia as well as for a variety of functional heart diseases. With MRI's increasing role in detecting central-nervous system and orthopedic diseases, patients with ischemic history are increasingly referred for MRI exams. In addition, there are now more situations, such as trauma (stroke, spinal injury) or pediatric imaging, where MRI is performed on sedated or anesthetized patients, which require advanced ECG monitoring. Interest is also growing in MRI-guided interventions and surgery, where patients lie in the magnet for more time, and the level of risk, such as of an acute ischemic event (restricted blood flow), or incurring Ventricular Tachycardia (rapid heartbeat) or Ventricular Fibrillation (cardiac arrest), is inherently greater. For such interventions, rapid detection of cardiac events by the doctor is a pre-requisite, as a prelude to life support (defibrillation, CPR). The MiRTLE MRI ECG Monitor provides a solution for the ECG monitoring of patients for the duration of MRI scans.

3.1 *Getting to Know Your MiRTLE MRI ECG Monitor*

The MiRTLE electrocardiograph system includes a patient acquisition module that sits on the bed with the patient, which connects to the electrodes via the patient cable. The battery powered PAM converts the ECGs for digital transmission via a fiber optic cable to the Control Room Monitor located in the control room. The Control Room Monitor performs: the digital signal processing to cleanse the ECG signals of gradient interference; beat detection; and cleansed ECG visualization. The MiRTLE MRI electrocardiograph system consists of four major components as described in the following sections.

FIGURE 3

3.2 *MiRTLE Patient Acquisition Module (PAM)*

The MiRTLE Patient Acquisition Module is MR Safe. The PAM's control panel includes the following controls and status indicators:

a. lead-off indication for all 10 electrode connections

b. power button

c. battery status indicator

d. communications status indicator

FIGURE 4

The MiRTLE Patient Acquisition Module's side panels include the fiber optic communications connection on the right side and patient cable connection on the top side.

FIGURE 5

The MiRTLE Patient Acquisition Module includes the following LED indicators:

TABLE 4: MiRTLE PAM LED DEFINITION

INDICATOR	LED COLOR	OPERATION	DEFINITION
Lead Off	Red	Off	Good connection to patient
		On	No connection to patient RL only indication if all connections to patient are bad
BATT Battery	Green	Off	Device off Battery charge < 12% No battery installed
		On	Device on Battery charge > 20%
		Flashing fast	Device on Battery charge < 20%
		Flashing slow	Device on Battery charge < 15%
COMM Communication	Red	On	No connection
	Blue	On	Communications link found
	Green	On	Communications with CRM active
	Blue & Red	On	Battery charge < 12% Communication off

3.3 *MiRTLE Battery*

The MiRTLE Battery is custom designed for MRI safety. The battery is rechargeable and includes charge indicators on the left side of the battery, short-circuit protection, and a hard-plastic shell. The battery label includes a pull tab to assist removal of the battery and is reinforced for longevity.

FIGURE 6

3.4 *MiRTLE Patient Cable*

The MiRTLE Patient Cable is custom designed for MRI safety. The cable consists of a trunk cable with a yoke connection (GA1200) to the carbon-fiber lead set (GA1310). The lead set is AHA color coded for traditional 12-lead electrode placement. The lead set disconnects at the yoke for replaceability. The MiRTLE Patient Cable is defibrillation-proof, ANSI EC53 compliant, and intended for multi-patient use.

FIGURE 7

3.5 *MiRTLE Control Room Monitor*

The MiRTLE Control Room Monitor is a medical-grade workstation computer with integrated fiber optic communications to the Patient Acquisition Module. The MiRTLE Control Room Monitor includes: a power button on the face, touch screen interface, solid state drive, fiber optic communications port, GB Ethernet port, USB ports, and battery backup. The MiRTLE Control Room Monitor is powered by a medical-grade external power supply. The MiRTLE Control Room Monitor battery provides 10 minutes of uninterrupted operation in the event of mains power loss. Battery recharging is automatic. A fully depleted backup battery will recharge in 4 hours and requires no user action to change.

FIGURE 8

WARNING

- CRM is NOT MR Safe
- Do not bring CRM Inside the MRI room

3.6 *Connected Devices*

The MiRTLE MRI Compatible 12-lead electrocardiograph is a standalone device which requires no other devices used in combination to meet its intended purpose. MiRTLE provides two outputs to assist other devices by providing: a) safe traditional electrode placement for diagnostic ECGs; and b) improved ECG signals in the presence of MRI gradient interference. The devices tested and approved for connection to MiRTLE are listed below. Note that Imricor's Advantage-MR EP is not FDA cleared for clinical use.

Signal	ECG Output	Scanner Synchronization Output	
Manufacturer	Imricor, Inc. (Burnsville, MN, USA)	Siemens AG, Siemens Healthcare GmbH (Erlagen, DE)	Koninklijke Philips N.V. Philips Healthcare (Best, NL)
Model	Advantage-MR EP Recorder/Stimulator	Magnetoms Aera / Skyra / Avanto / Verio	Ingenia
Connection	GB Ethernet to Advantage workstation via CAT 6 cable	5V TTL to EXT Trigger input, RCA connector on bottom front of Magnetom	5V TTL to EXT Trigger input, BNC connector on side of Magnetom

4

Basic Operation

This chapter gives you an overview of the MiRTLE System and its operational functions. It takes you step by step through the use of the MiRTLE System to monitor heart rate.

Prior to installation in an MRI environment basic operation knowledge of the system is warranted. This operation can be performed with a human subject outside the MRI. After unpacking the following steps are performed for basic operation of the MiRTLE System.

TABLE 5: MIRTLE VERIFICATION OPERATIONS CHECKLIST

STEP	TASK	CHECK BOX WHEN DONE
1	Verify packing contents	❑
2	Clear an area to perform the verification	❑
3	Charge the Patient Acquisition Module's battery	❑
4	Install the battery in the PAM	❑
5	Connect the ECG lead wires to the ECG trunk	❑
6	Connect the ECG trunk cable plug to the PAM	❑
7	Connect the fiber optic cable to the PAM	❑
8	Attach the VESA stand to the Monitor with provided screws	❑
9	Connect the MiRTLE Monitor to AC mains using the supplied power cord	❑
10	Connect the mouse to the monitor in one of the USB connectors	❑
11	Connect the fiber optic cable to the monitor	❑
12	Prepare the patient for ECG monitoring	❑
13	Press the power button on the PAM, ensure that the Power LED illuminates.	❑
14	Press the power button on the Control Room Monitor, ensure the monitor boots to Windows and then loads the MiRTLEView application.	❑
15	Ensure that MiRTLEView has connected with the PAM by observing the plot window and looking at PAM status.	❑

TABLE 5: MIRTLE VERIFICATION OPERATIONS CHECKLIST		
STEP	TASK	CHECK BOX WHEN DONE
16	Monitor the patient	❑
17	After approximately 25 secs beat detection should be activated	❑
18	Once finished, select “Close Live” from the toolbar and exit the application; the data will be automatically saved by the MiRTLEView	❑
19	Power-off the PAM and Control Room Monitor	❑
20	Remove the cables and electrodes from the patient and the PAM	❑
21	Clean patient cable and PAM	❑
22	Properly store PAM, patient cable, and fiber optic cable in carry case	❑

4.1 *Charge the PAM Battery*

Prior to the power-on of MiRTLE, charge the battery in the provided charger. The battery charger is NOT MR Safe. Charge the battery outside of the MRI room.

Please refer to the battery charger user manual for any other charger LED colors or blinking patterns as they indicate a fault condition. A fully charged PAM battery provides 12 hours of operation. Charge time of a depleted battery is 3 hours. Please refer to the battery charger user manual for battery reconditioning procedures.

If the charger’s LED never turns green or if the battery’s LED never reaches five bars, the battery should be replaced. Contact MiRTLE Medical Support to replace the PAM battery.

FIGURE 9

4.2 *PAM Battery Installation and Removal*

To install and remove the rechargeable battery from the Patient Acquisition Module, perform the following steps:

TABLE 6: INSTALLING & REMOVING PAM BATTERY	
STEP	ACTION
1.	Turn the PAM over, see **FIGURE 10**
2.	Slide the door latch down to release the battery door
3.	Open the battery door, see **FIGURE 11**
4a.	To install the battery, grab the battery face up with the contacts at the top; place the battery into battery compartment with the top of the battery placed underneath the battery door hinge; slide the battery up to seat in its connector
4b.	To remove the battery, grasp the battery's tab and pull straight down. The battery will release from its connector and slide away from its connector. The battery may be removed from the PAM.
5.	Close the battery door ensuring that the latch is secured

FIGURE 10

FIGURE 11

WARNING

- Remove the battery from the PAM if the device is not likely to be used within 24 hours
- It is recommended to always remove the battery after use to charge and store the battery in its charger

4.3 *Connect the ECG lead wires to the ECG trunk*

To prepare the PAM module for patient data acquisition the ECG trunk cable is connected to the ECG lead wire set. The connection is keyed so the lead wire set will only fit in one orientation with the connection labels adjoining each other.

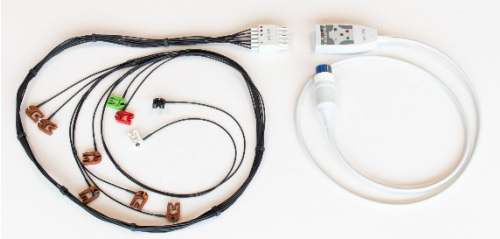


FIGURE 12

FIGURE 13

4.4 *Connect the ECG trunk cable plug to the PAM*

To connect the ECG trunk cable to the PAM insert the trunk cable instrument plug into the PAM

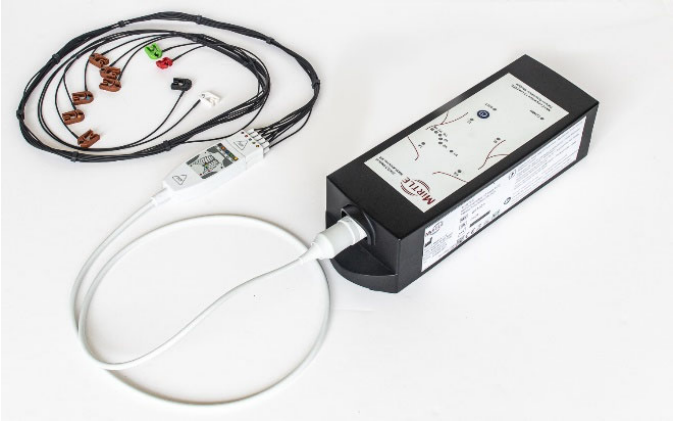


FIGURE 14

4.5 *Connect the fiber optic cable to the PAM*

For transmission of the patient data from the PAM to the monitor first connect one end of the provided fiber cable into the PAM connection port on the side of the unit. The LC duplex connector can only be inserted in one orientation thereby preventing communication errors.

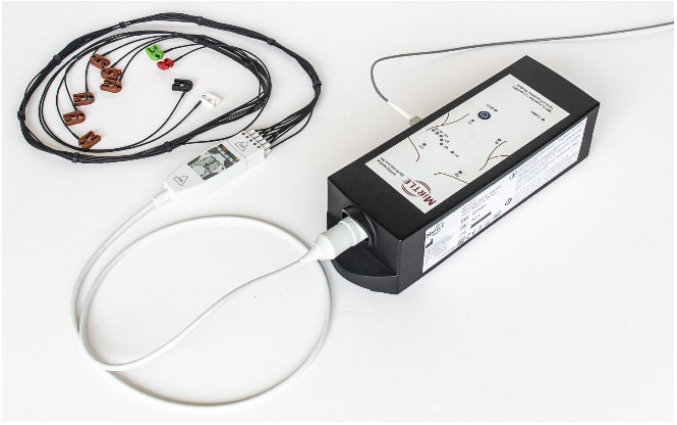


FIGURE 15

4.6 *Attach the VESA stand to the Monitor with provided screws*

To use the monitor on a tabletop, a VESA stand is provided along with 8 fastening screws. The VESA mount allows the user to wall mount or swing-arm mount the monitor if desired (alternate mounts not included). Use the following description to mount the included stand to the monitor for tabletop use:

TABLE 7: ASSEMBLY INSTRUCTIONS FOR VESA STAND

STEP	ACTION
1.	Place the CRM face down on a table as shown in **FIGURE 16**
2.	Using a small Phillips head (cross-head) screwdriver, remove the two screws from the Connection Panel Guard as shown in **FIGURE 16** and remove the guard itself as shown in **FIGURE 17**
3.	Remove the VESA stand cover by grabbing the cover as shown in **FIGURE 18** and slide the cover up as shown in **FIGURE 19** to remove it from the stand.
4.	Place the VESA stand on the CRM as shown in **FIGURE 20**, aligning the holes
5.	Insert and tighten all 8 screws as shown in **FIGURE 21**
6.	Install the VESA stand cover by placing it over the mount and sliding down towards the bottom of the CRM as shown in **FIGURE 22**

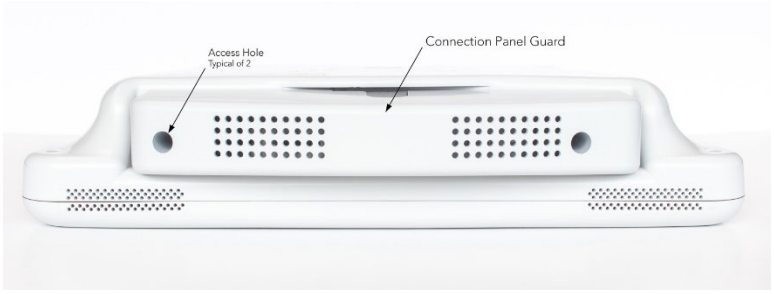


FIGURE 16

FIGURE 17

FIGURE 18

FIGURE 19

FIGURE 20

FIGURE 21

FIGURE 22

4.7 *Connecting the MiRTLE Monitor to AC Mains*

The monitor power supply allows you to operate the monitor from an AC (alternating current) power source of 100-240 VAC and 47-63 Hz. Power is connected to the bottom side of the monitor.

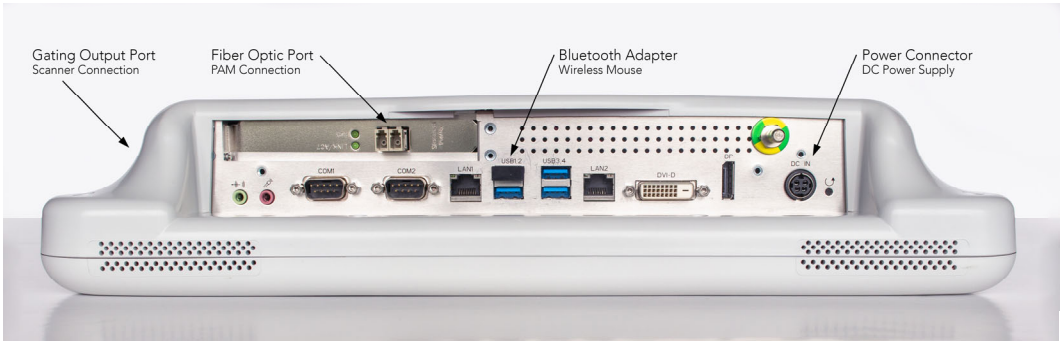


FIGURE 23

FIGURE 24

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 power supply uses 1 MOOP to provide isolation from mains supply.

4.8 *Connect Fiber Optic & Gating Cables*

The fiber optic cable connects the Patient Acquisition Module in the MRI room to the monitor. The fiber optic cable uses LC connectors at both ends easing connection. There is a single orientation to the connector. The cable will snap into place. Figure 15 shows the fiber cable connected to the PAM. Figure 23 shows the location of the LC connector on the CRM.

The gating cable connects to the MRI scanner in the MRI room. Connect the BNC side of the gating cable to the left side of the CRM (as seen from the rear of the CRM). Figure 24 shows the fiber and gating cable connected to the CRM.

4.9 *Confirm mouse operation*

A wireless mouse is supplied with the monitor. Confirm that the Wi-Fi adapter is installed in the USB port as shown in Figure 23. Turn the mouse power on and verify that the pointer on screen responds to mouse movements.

4.10 *Prepare the Patient for ECG Monitoring*

Monitoring electrodes are placed on the patient's chest and torso in the prescribed pattern shown in Figure 26.

What you will need:
10 Radiolucent Monitoring Electrodes

CAUTION Use only MR-safe ECG electrodes.

Prepare the skin: 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). If alcohol is used, allow it to dry prior to electrode application. Excessive hair at the site should be removed by clipping. Preparing the skin with NuPrep skin prep gel is recommended to improve ECG signal quality.

Place the electrode: The foam tape backing is exposed by peeling the protective layer away and discarding it as shown in Figure 25. Place the electrode on the patient and use gentle pressure to ensure contact of the entire electrode surface to the skin. Repeat for each of the nine remaining electrodes.

FIGURE 25

4.11 *Placing the Chest and Torso Electrodes*

Place the chest and torso electrodes in the designated positions for 12-Lead ECG data collection as follows in Figure 26 and as described in Table 8:

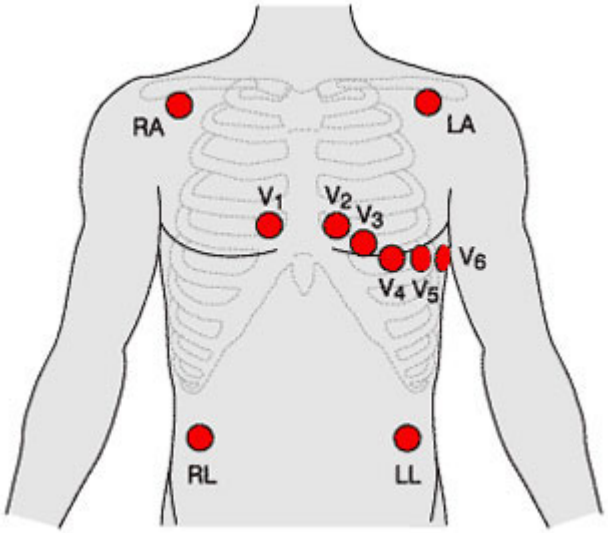


FIGURE 26

TABLE 8: 12-LEAD ELECTRODE PLACEMENT

COLOR	NAME	ELECTRODE PLACEMENT
White	RA	Second intercostal space lateral right side
Black	LA	In the same location where RA was placed, but on the left side
Green	RL	Lower right lateral chest or right leg
Red	LL	In the same location where RL was placed, but on the left side
Brown/Red	V_1	In the fourth intercostal space just to the right of the sternum
Brown/Yellow	V_2	In the fourth intercostal space just to the left of the sternum
Brown/Green	V_3	Between leads V_2 and V_4
Brown/Blue	V_4	In the fifth intercostal space (between ribs 5 and 6) in the mid-clavicular line
Brown/Orange	V_5	Horizontally even with V_4, in the left anterior axillary line
Brown/Purple	V_6	Horizontally even with V_4 and V_5 in the mid-axillary line

4.12 *Connect the ECG Cable to the Patient*

Connect all the pinch connectors to the previously placed electrodes on the patient, matching the pinch connector's label to the specific location. Refer to Table 8 below for color coding of the pinch connectors to aid in correct connection. Verify each connection by confirming that all lead-off LED indicators are off. If RL is not connected, all ten lead-off LEDs will be on.

Route the lead wires bundles down the center of the patient's chest. Avoid any individual lead wire or lead wire bundle looping. If any individual lead wire is too long, minimize the excess length by taping the wire to the center of the patient's chest. Avoid running the lead wires at the patient's side. Place the trunk cable's yoke between the patient's legs. Position the yoke towards the patient's feet until all slack in the lead wires is removed.

4.13 *Power-on the Unit*

Power-on the MiRTLE MRI ECG Monitor by pressing the power button on both devices located: a) on the top of the Patient Acquisition Module; and b) on the front of the Control Room Monitor.

4.14 *Beat Detection*

After connecting the electrodes and before entering the MRI, check that the signal in all channels are free of obvious noise. Once the signal has stabilized, verify beat detection on the CRM display.

In general, if there are issues with the beat detection that do not resolve within 30 seconds:

1. Check the channel signal quality for interference (flat-line, excessive noise, excessive baseline wander, intermittent spikes)
2. Once satisfied with the quality, ask the subject to stay still to avoid motion-related noise.
3. If beat detection is inaccurate, the application will continue to learn. Wait to move the patient inside the bore until detection is correct.

Please refer to section 6.10 for more details regarding beat detection and display.

4.15 *Monitoring*

The monitoring session can last as long as necessary, for the duration of the MRI and beyond. Live patient data will continue to be collected as long as the monitor is in operation.

4.16 *Electrode Removal Instructions*

Loosen one side of the electrode. Grasping the electrode's full width, slowly and gently pull it back over itself. Keep the electrode close to the surface of the patient's skin as you pull it back and support the skin immediately adjacent to the adhesive being removed. Discard the electrodes in a sanitary disposal.

Installation and Operation in the MRI Environment

Prior to operation of the MiRTLE System within the MRI environment and use of the product to monitor patients, become familiar with the operation details of both the instrumentation and the software as detailed in the following section.

5.1 *Installation*

Installation should be carried out by qualified service personnel, either by the hospital's biomedical department or MiRTLE Medical Support.

The installation instructions given in this chapter contain the steps in preparing the monitor for use within the MRI environment.

For a list of conventions used in this guide, see Chapter 4, "Basic Operation".

5.2 *Installation of the System in the MRI Environment*

TABLE 9: INSTALLATION OVERVIEW TASKS

STEP	ACTION
1.	Install the PAM battery and locate the PAM module at the MRI bedrail furthest away from the MRI bore (foot of the bed)
2.	Locate the MiRTLE CRM and battery charger in the MRI control Room and connect the CRM and battery charger to AC mains using the supplied power cord and power supply for each device respectively
3.	Install and connect the fiber optic cable using the supplied cable (See "Installing and Connecting the Fiber Optic Cable") through an overhead conduit or the MRI penetration panel to the CRM
4.	Connect the Gating cable from the CRM through the MRI penetration panel to the scanner gating input. Refer to scanner manufacturer's manual for the location of the external trigger input.

5.3 *Device Installation*

5.3.1. **Locating the MiRTLE Patient Acquisition Module**

The MiRTLE Patient Acquisition Module is designed to be placed horizontally on the MRI bed rail, near the patient's feet. The Patient Acquisition Module should not move with the patient as the bed moves into the bore. Velcro straps are provided with the PAM to facilitate mounting on the bed rail.

FIGURE 27

FIGURE 28

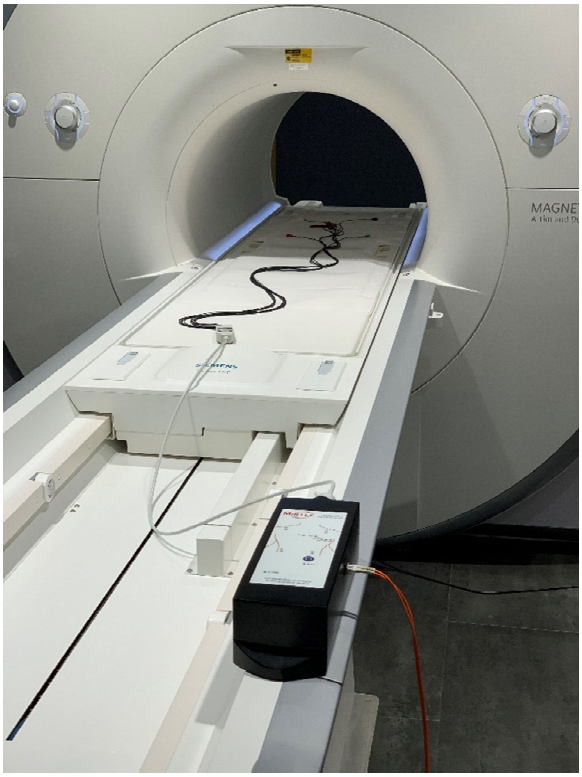


FIGURE 29

5.3.2. **Locating the MiRTLE Control Room Monitor**

The MiRTLE Control Room Monitor must be installed in the MRI control room in a hospital environment. Under no circumstances should the MiRTLE Control Room Monitor be placed in the MRI room as it is not MRI safe. Place the Control Room Monitor on a desktop where the user can see the display to monitor the patient's ECG. A mouse and monitor touch screen pointer are provided to ease operation of the monitor.

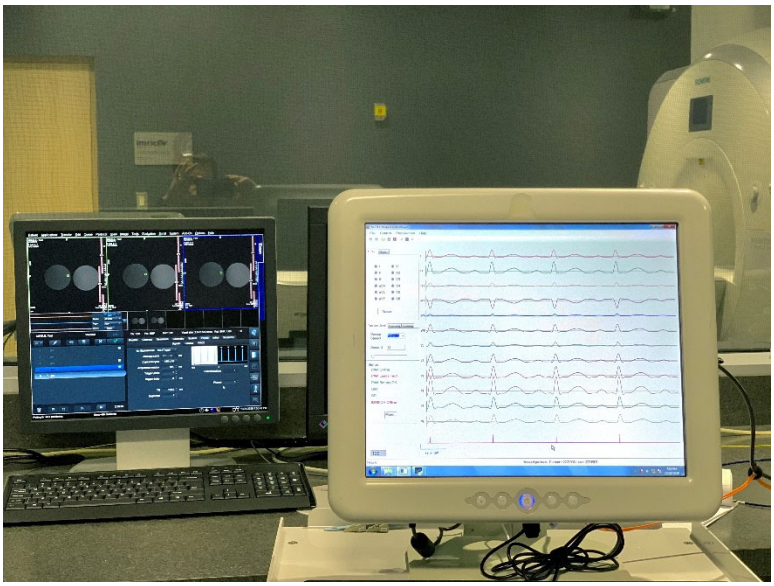


FIGURE 30

5.3.3. **Installing the MiRTLE Fiber Optic & Gating Cables**

The fiber optic cable that connects the MiRTLE CRM to the PAM and the gating cable that connects the MiRTLE CRM to the scanner may be installed two ways: in an overhead conduit or through the penetration panel. It is preferred that both cables be installed by a hospital electrician in an overhead conduit. From the ceiling of the MRI room, drop the fiber optic cable down to the foot of the MRI bed for connection to the PAM. Connect the fiber optic cable to the PAM. From the ceiling of the MRI room, drop the gating cable down to the left front floor for connection to the scanner. For Siemens scanners, connect the RCA end of the cable to the scanner's External Trigger input. For Philips scanners, connection is to be made by Philips service personnel as the connection is not externally accessible to the user.

For a temporary installation, run the cables through a porthole into the MRI room and tape or cover in a cable cover the two cables to prevent the risk of tripping.

WARNING

- Tripping hazard
- Inside the MRI room, secure the fiber optic and gating cable on the ground with tape or use a cable cover to prevent entanglement with the user or patient
- Do not run cables through doorway

Detailed Operation within the MRI Environment

TABLE 10: PATIENT MONITORING OVERVIEW TASKS	
STEP	ACTION
1.	Connect the Gating cable from the monitor to the scanner gating input.
2.	With the patient on the MRI bed and prior to insertion into the MRI bore, attach electrodes to the 10 locations and connect the MiRTLE ECG cable
3.	Power-on the PAM and the CRM
4.	When the CRM is done booting, MiRTLEVIEW will automatically launch and begin plotting ECG traces.
5.	Verify valid lead settings and clean patient ECG traces
6.	After approximately 25 seconds of MiRTLEVIEW operation, verify beat detection and scanner synchronization (if using).
7.	Move the patient into MRI scanner bore
8.	Run MRI protocols as desired while continuously monitoring the patient's cardiac activity.
9.	When patient monitoring is complete, power-off the PAM by pressing the power button on the top of the unit, then remove the patient cable and electrodes from the patient.
10.	Power-off the CRM by first exiting the MiRTLEView application, then either pressing the power button on the front of the CRM or select Windows – Power – Shutdown from the Windows Start icon.
11.	Clean and disinfect the patient cable and PAM as described in section 8.2 of this manual.
12.	Remove the patient cable and battery from the PAM. Store the PAM and patient cable in the supplied case. Place the battery in the charger.

6.1 *MiRTLEView Software*

MiRTLEView is a Windows application which runs on the MiRTLE Control Room Monitor. It has two modes of operation: Live Mode and Retrospective Mode. In Live Mode, it receives data and status from a MiRTLE Patient Acquisition Module via the fiber optic cable. In Retrospective Mode, a file containing previously accumulated data may be viewed.

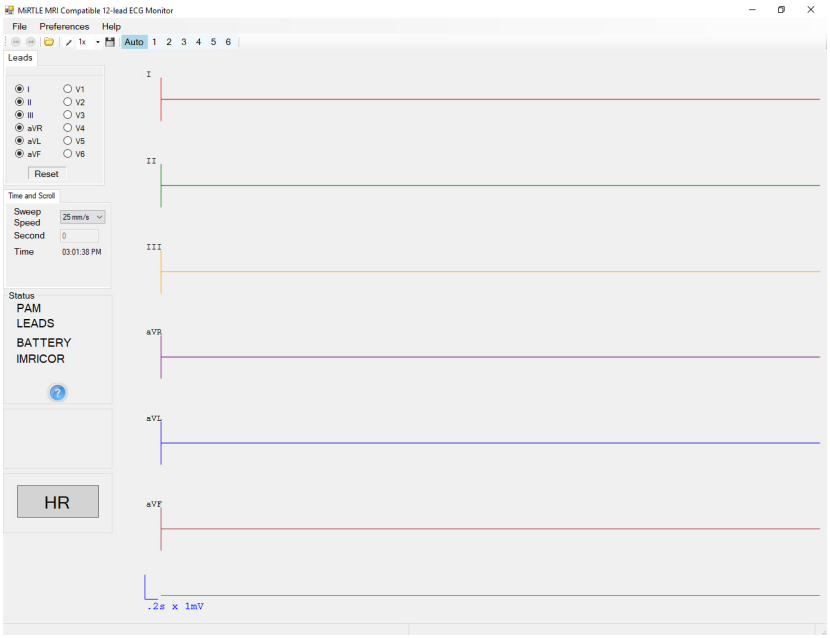


FIGURE 31

6.2 *Running MiRTLEView*

MiRTLEView comes up in Live Mode ready to receive from the PAM when the CRM is powered up.

6.2.1. **Live Mode**

MiRTLEView receives data from the PAM and displays it in the plot window. You can change what MiRTLEView displays without affecting the live data being collected. For example, you can change display parameters such as which leads to view, gain, and sweep speed.

6.2.2. **Retrospective Mode**

You can browse data files that contain previously recorded data. MiRTLEView displays data by reading from the disk file as needed. View a file by choosing “Open Data File” from the File Menu.
Once the data file is chosen, a second MiRTLEView application window is launched with a plot of the file data. The Menu Bar at the top of the retrospective window is colored in aqua to visibly differentiate the window from the live window. The retrospective window activates two controls not available in the live window. In the Time and Scroll section, the Seconds field allows direct entry of a value to jump to that point in the recording. The seconds entered is the start of the plot. A scroll bar is the second activated

control which allows faster movement through the recorded file. With the scroll bar as the active focus, the left and right arrow moves the plot one second back and forward respectively. Also, with the scroll bar as the active focus, page up and page down keys moves the plot one page back and forward respectively. This is identical to the forward and back icons in the tool bar.

The retrospective windows displays the open file name and the length of the file in seconds.

When viewing retrospective data files or “mpd” files, the information is a recording of the information displayed in real-time. No additional processing is performed in this view. For example, beat detection is what was detected in real-time, not a new detection of beats. Also, the ECG signals plotted are the results of the gradient removal processing when recorded. The retrospective view of recorded data can be thought of as a paper copy of the device’s output when it happened in real-time.

When done examining the recorded data, exit MiRTLEView’s retrospective window.

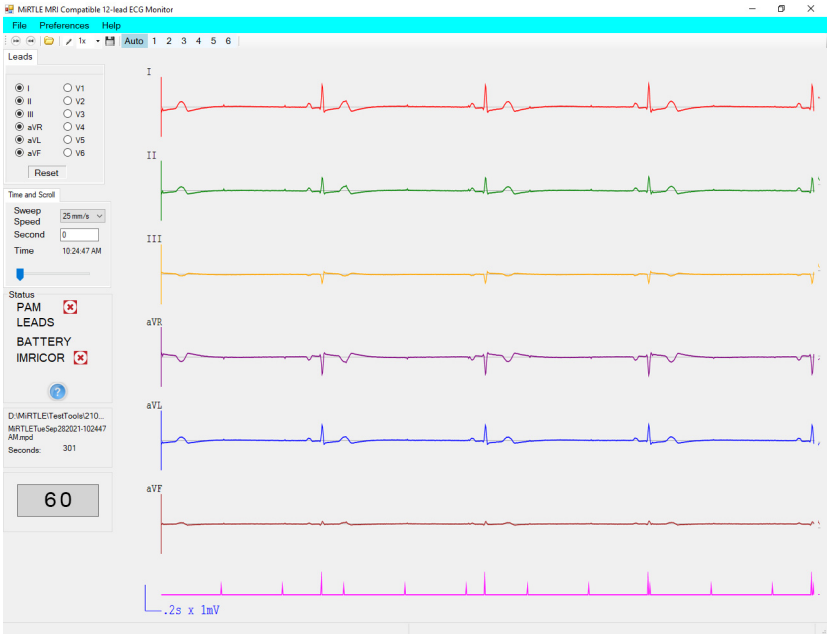


FIGURE 32

6.3 *Menu Selections*

When the **File Menu** is selected, a drop-down menu appears.

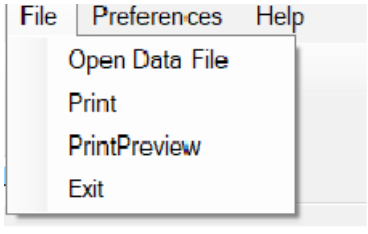


FIGURE 33

Open Data File: When selected, a file dialog box appears. You can browse to a directory then select the file to view. MiRTLEView automatically saves data to c:\Mirtle\ED3. Data will be brought into the viewer. It does not matter how large this file is as only the data required by the display is brought into memory. The second to view may be selected.

Print: When selected, a dialog box opens which allows you to select any printer to which you have previously connected. When you click the printer, the drawing (with a white background) is printed. The controls in the left-hand panel are not printed. The drawing is scaled so as to fill one normal printed page.

Print Preview: Shows the display to be printed.

Exit: This closes MiRTLEView. All files are closed. You can press Exit at any time. No data or files will be corrupted. The same action occurs if “X" in the upper right-hand corner is pressed.

When **Preferences** is selected, a drop-down menu appears.

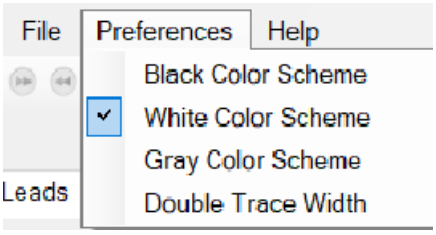


FIGURE 34

One of three color schemes may be selected: black, white, or gray.

Double trace width may also be selected. This doubles the thickness of the plot lines. If a checkbox appears next to it, double thickness is selected. If no check appears, single thickness is in effect.

When the **Help** is selected, a drop-down menu appears.

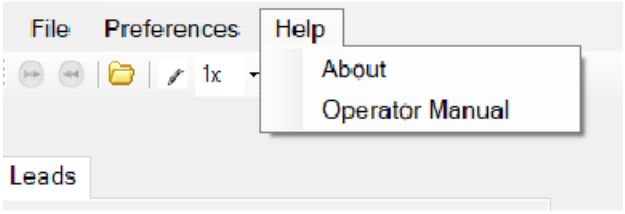


FIGURE 35

About displays a window identifying the MiRTLEView version and ownership information.

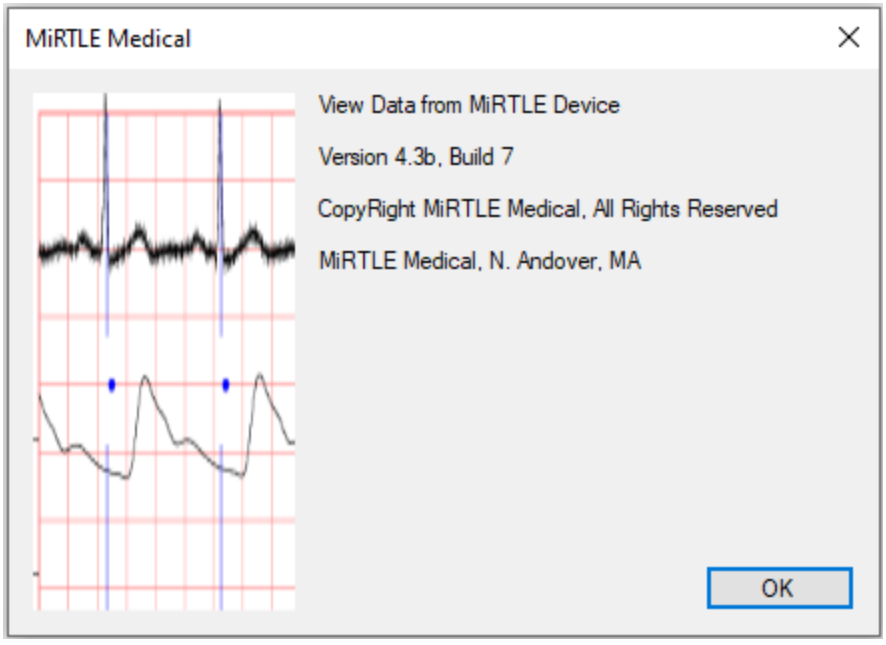


FIGURE 36

Documentation displays this Operators Manual.

6.4 *Tool Bar Buttons*

Whenever a button is grayed out, its functionality is unavailable.

Page Forward: When viewing a file, this button advances the display forward in time one page. Note: If the Sweep Speed is set to 250, you will advance one second per click. If the time scale is set to 25, you will advance by 10 seconds on each click. This button is not available for Live Mode.

Page Back: This button moves the display back in time one page. If the time scale is set for 250, you will page back one second per click. If the time scale is set to 25, you will page back 10 seconds each click. This button is not available for Live Mode.

Open Data File: This is a short cut for the function under the File Menu. When clicked, a file dialog box opens. After selecting the file, a second copy of MiRTLEView will open and the file data will be brought in for viewing. MiRTLEView in Live Mode continues to run.

Write Log Info Tool: This tool is only available in Live Mode. The user may enter data into the log file. As soon as this tool is selected, it puts a timestamp into the log file followed by "User Notes:" and pops up a window for data entry. When "Submit" is selected, the text is written. This feature is useful in order to log information about the session.

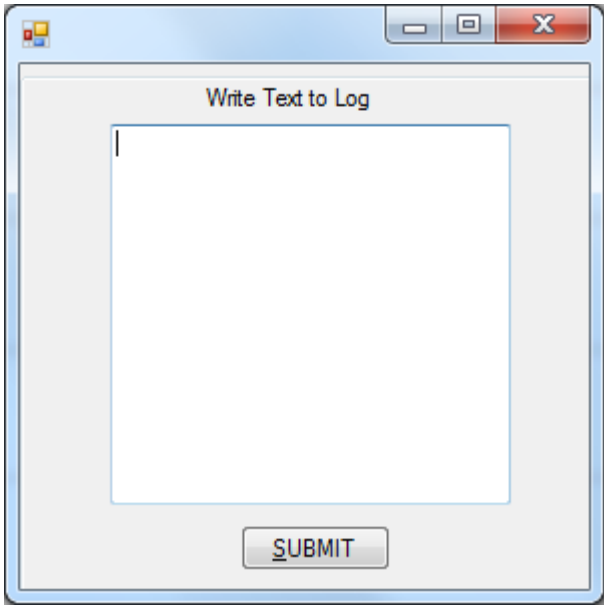


FIGURE 37

Gain Selector: Choose the gain you want the plotted data to be multiplied by: .5, 1, 2, or 4. The signal amplitude along with the 1 mV scale will change based on the selection.

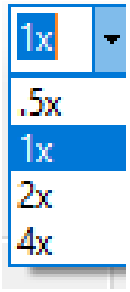


FIGURE 38

Start Saving Data: Start saving data to files.

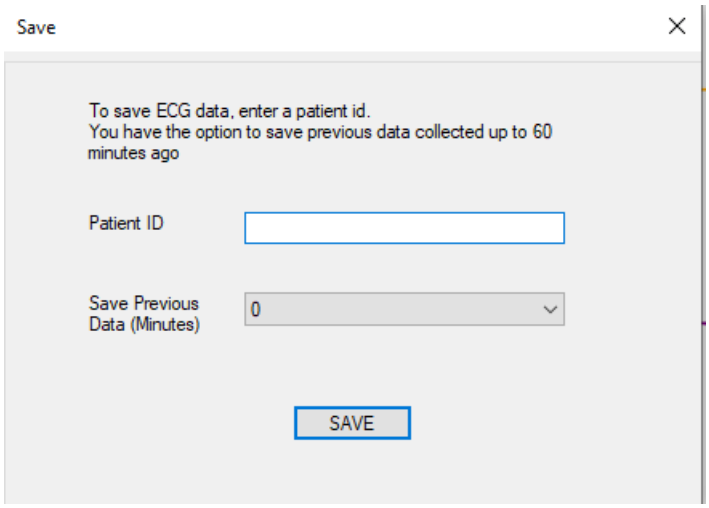


FIGURE 39

Files containing the ECG data are automatically deleted after thirty days but can be saved via this mechanism.

Files to be saved will be copied to the directory named Patient ID under C:\MiRTLE\Saves.
Files previously collected within the specified number of minutes selected under “Save Previous Data” will also be saved.

If this option is activated a disk icon appears on the Status window to indicate that files are being saved.

Click the Save icon a second time to stop saving to disk.

Gradient Cleansing Manual Selection: Removal of the gradient interference is, by default, handled automatically. Should the user want to manually select specific gradient removal signal processing, buttons 1 through 6 may be selected to apply different signal processing techniques to cleanse the ECG signals of the gradient interference. Auto should be selected with the patient outside the MRI bore which will turn off all signal processing.

6.5 *The Left-Hand Panel*

The left-hand panel contains:

- Lead Display
- Time and Scroll
- Status
- File Information (in Retrospective Mode only)

6.6 *Lead Display*

This section contains lead controls which determine which leads are plotted. These controls may be changed at any time. Note that these are display options only. They do not control the collection of data.

The order that the lead is selected in determines the order it is plotted in. The Reset button restores the default lot display of 6 leads (I, II, III, aVR, aVL, aVF).

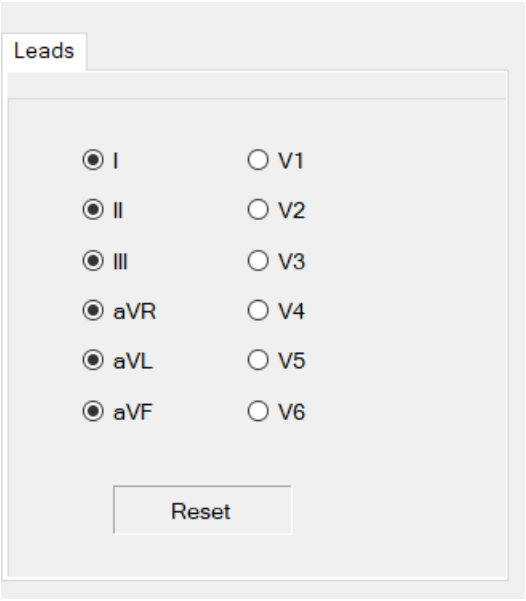


FIGURE 40

6.7 *Time and Scroll*

See Figure 41. This section contains the following:

- Sweep Speed
- Second
- Scroll Bar

Sweep Speed: represents how quickly the plot moves when in Live Mode. It represents the number of seconds of data compressed into one screen in Retrospective Mode. Four choices are given: 250 mm/s (1 second), 125 mm/s (2 seconds), 50 mm/sec (5 seconds), and 25 mm/s (10 seconds).

Study Second: represents the second being viewed with respect to the start of the file.
In Retrospective Mode, entering a number into the Study Second field causes the display to move to that second. Note: you must press “Enter” for it to take effect. It is not available in Live Mode.

The **Scroll Bar:** You can use the scroll bar to get to the second to view. The new second will then be reflected in the Study Second field. Correspondingly, when you change the Study Second field, the Scroll Bar will move. The scroll bar is not available in Live Mode.

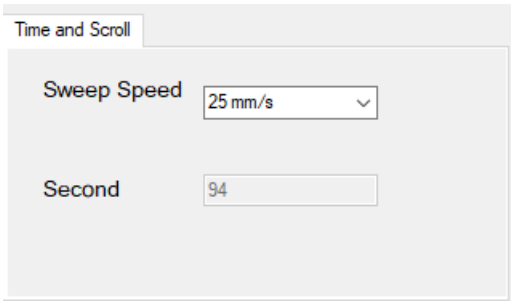


FIGURE 41

6.8 *Status*

This section displays PAM, lead, battery, Imricor, and filter status. A disk icon appears in this window if files are being saved. The "?" pops up a window that gives more detail.

OK Warning Off/Error

FIGURE 42

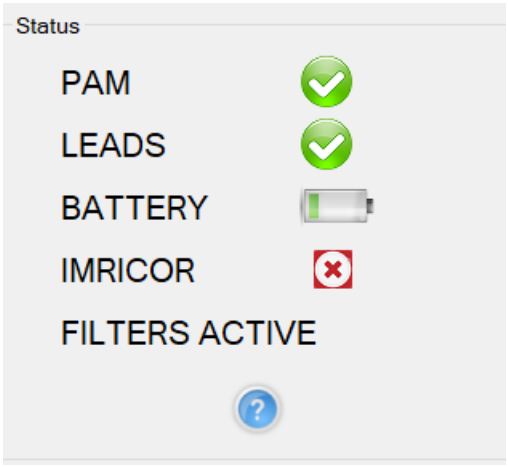


FIGURE 43

PAM indicates if the PAM is online.
Leads indicates if the PAM leads are connected, noisy, or disconnected.

Following are the icons displayed for battery level:

FIGURE 44

If the PAM battery charge drops below 20%, the warning icon is displayed. IF the PAM battery charge drops too low to operate, the Error icon is displayed and plotting stops.

If MiRTLE is configured to transmit ECG traces to Imricor's Advantage EP System, the green OK indicator appears when the two devices are communicating and the red Off indicator appears when the two devices are not communicating.

The Filters Active indicator appears when additional filtering is applied to the ECG traces to remove the MRI's interference. If the Filters Active indicator disappears, only the standard diagnostic-grade high pass and low pass filter are being applied.

 Pressing the question mark button brings up a status window showing more detail.

The status window shows information on the PAM and its battery:

- PAM firmware version and communications status from the PAM
- Battery status displays temperature, state of charge, and time to empty.
- Electrode connection status, OK (good connection), Warning (noisy), and Error (disconnected) icons are displayed on the diagram for each electrode.

Note that if the right leg (ground) electrode is disconnected, all electrodes will display an error. It is imperative to correct the electrode connection if either the warning or error icon is present. Correct operation cannot be guaranteed in the presence of poor electrode connections to the patient.

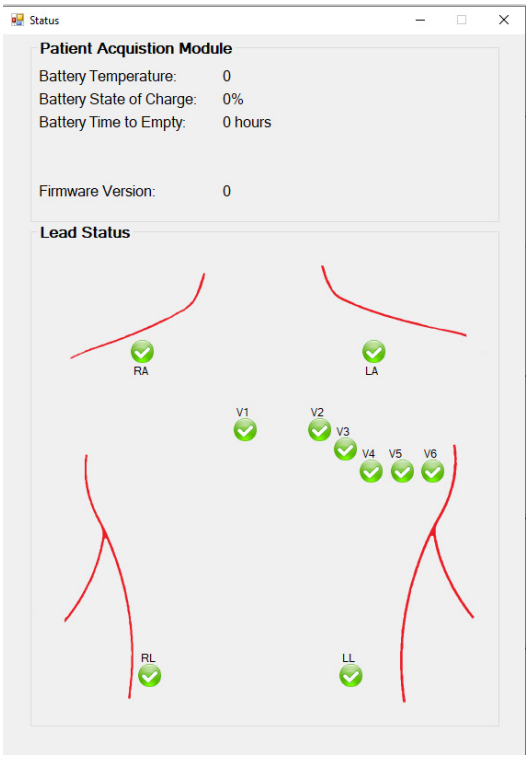


FIGURE 45

6.9 *File Information*

In Retrospective Mode, this section appears. It does not appear in Live Mode. It is read-only.

- File viewed
- Seconds in file

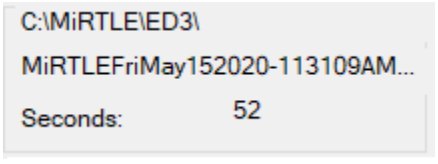


FIGURE 46

6.10 *Beat Detection*

Beat detection on a patient inside an MRI is extremely challenging. MHD and GIV interference renders traditional beat detection approaches useless. MiRTLE uses advanced signal processing techniques combined with VCG to detect beats. As such, a 20-second learning period of artifact-free ECG signals is required before beat detection begins to operate. This learning period can be both outside and inside the MRI bore. However, no cable or patient movement artifacts or GIVs should be present during this period.

The trace at the bottom of the screen, below all the ECG lead traces, is the beat and pacemaker flag indication. The amplitude of the spike indicates which type was detected. The small spike is the pacemaker flag and the taller spikes indicate a normal beat. The indicator trace in Figure 47 shows ineffective pacing with the heart rate at 30 BPM and pacing at 80 BPM.

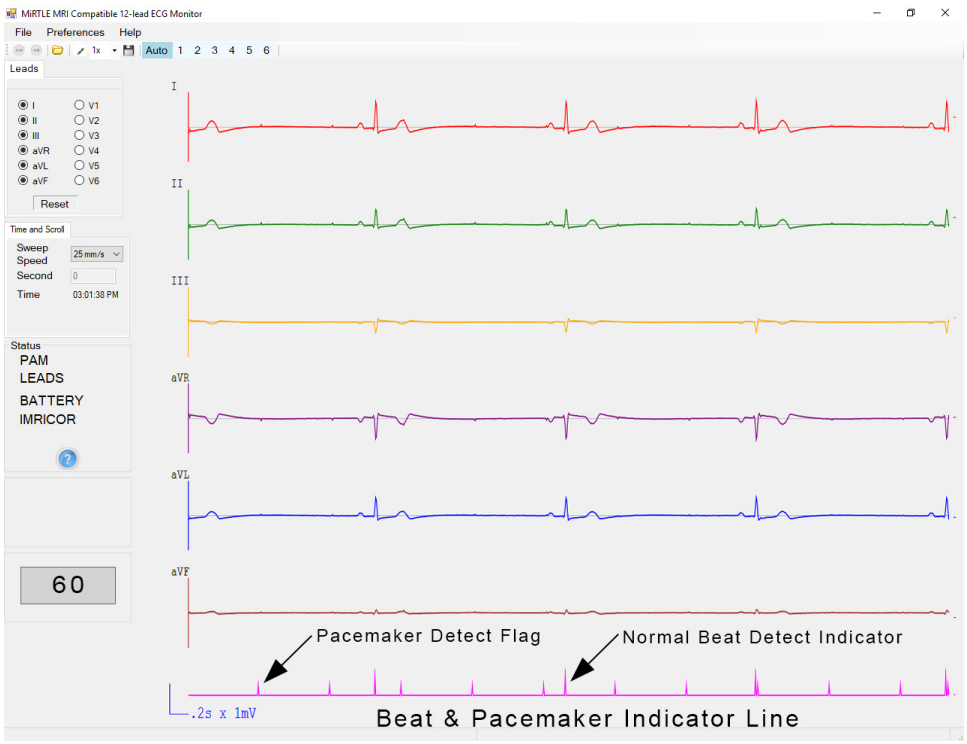


FIGURE 47

The heart rate indicator averages a new heart rate for each detected heartbeat and averages the heart rate over the most recent six heartbeats. The heart rate indicator responds to a step change in heart rate in 2 seconds when increasing from 80 to 120 BPM and in 6 seconds when decreasing from 80 to 40 BPM in accordance with IEC 60601-2-27.

Pacemaker pulses will be detected and excluded from the heart rate calculation. During imaging, pacemaker indication is suspended. Pacemaker indication automatically resumes immediately after imaging stops.

WARNING

- During imaging, pacemaker indication is suspended.
- Pacemaker indication automatically resumes immediately after imaging stops.

6.11 *Accessing Previously Saved Patient Data*

MiRTLEView data files, upon terminating the live session either by closing the program or by selecting the “Close Live” button from toolbar, are automatically saved by the program. The data files can be opened for review by reopening the program and selecting “Open Data File” from the “File” drop-down menu as described in the MiRTLEView Software section of this manual.

Data can be transferred where and when needed from the computer by any preferred means of data transport, such as a USB flash drive. Ensure that the computer receiving the data has the MiRTLEView program installed.

Data can be printed by selecting the “Print” option under the “File” drop-down menu as per the MiRTLEView Software section of this manual.

6.12 *Disconnecting the MiRTLE MRI ECG Monitor from the Patient*

To disconnect the monitor from the patient, first disconnect all the cables from the patient’s chest and torso. To remove the electrodes, see the section above entitles “Electrode Removal and Replacement Instructions.” Following electrode removal, turn off the MiRTLE PAM by pressing the power button located on the top of the PAM. When the PAM is powered down, disconnect the PAM’s patient cable and fiber optic cable. Clean both cables and the PAM as described in the cleaning section below. Close MiRTLEView on the Control Room Monitor, and power down the Control Room Monitor by pressing the button on the bottom of the face

Troubleshooting

The following technical issues and errors can be amended by taking the included actions.

TABLE 11: TROUBLESHOOTING	
MESSAGE/ISSUE	ACTION TO RESOLVE
Unable to plot ECG traces when Control Room Monitor is powered on	Ensure that MiRTLE's application MiRTLEView is operational. If not, restart the Control Room Monitor. Ensure that the Patient Acquisition Module is turned on and the fiber optic cable is connected at both ends. If these steps do not resolve the problem, contact MiRTLE Medical.
The "seconds" indicator increments however no ECG traces are plotted	Ensure that the Control Room Monitor's disk drive has available space. If the disk drive is full, ECG plotting stops.
High gain value causes lead/channel signal displays to drop into other lead/channel signal displays	Decrease gain value
The status of all electrodes is red or Error	The right leg (ground) electrode is disconnected, verify that the right leg electrode and its connection are good.

Care and Cleaning

Use only MiRTLE Medical-approved substances and methods listed in this chapter to clean or disinfect your MiRTLE MRI Compatible ECG Monitor. Warranty does not cover damage caused by unapproved substances or methods.

MiRTLE Medical makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital'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 Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia, February 1989. See also any local policies that apply within your hospital and country.

8.1 *General Points*

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

Keep your monitor, electrodes, cables and accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use the equipment if you see signs of deterioration or damage. If you need to return any equipment to MiRTLE Medical, ***always*** decontaminate it first before sending it back in the appropriate packaging materials.

Observe the following general guidelines:

- Always follow carefully and retain the instructions that accompany the specific cleaning and disinfecting substances that you are using. Always dilute the cleaning substances appropriately according to the manufacturer's instructions or use the lowest possible concentration.
- Do not allow a cleaning of 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 PAM enclosure or cable connections.
- Do not immerse monitor in liquid; protect against water sprays or splashes.
- Never use abrasive materials on the monitor (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 your service personnel or MiRTLE service engineer.
- 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.

8.2 *Cleaning and Disinfecting*

Clean and disinfect the MiRTLE MRI Compatible ECG monitor PAM and cables after each use. Clean equipment before disinfecting. For accessories, see “Cleaning and Disinfecting Monitoring Accessories.”

The CRM does not require cleaning after each use. Follow hospital policy for when to perform CRM cleaning. Follow cleaning instructions below to clean the CRM.

Do not permit any liquid to enter the PAM case and avoid pouring liquid on the PAM when cleaning. Do not allow water and/or cleaning/disinfecting solution to enter the connectors of the PAM or cables.

Clean and disinfect the patient cable with the trunk and leadwires connected to each other Do not clean or disinfect the patient cable with the trunk and leadwires detached from each other. Should cleaning or disinfecting the cable pieces be necessary, avoid getting liquids on the electrical contacts of both cable pieces. Do not allow water and/or cleaning/disinfecting solution to enter the connectors of the ECG cable.

Clean with a lint-free cloth, moistened with warm water (40 C/104 F maximum) and soap. Soap used should be a diluted non-caustic detergent that is tenside or a phosphate-based cleaning agent (see “Cleaning Agents”). Do not use strong solvents such as acetone or trichloroethylene. After cleaning, allow the item time to fully dry. If excess moisture is present after cleaning, use a dry towel to absorb the moisture and facilitate drying. Once the item is fully dry, disinfect using only the approved disinfecting agents listed (see “Disinfecting Agents”).

CAUTION

- Solutions: Do not mix disinfecting solutions as hazardous gases may result.
- Skin Contact: To reduce the risk of skin irritation, do not allow a cleaning of 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 and 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 and regulations governing the use of disinfecting agents.

TABLE 12: PAM AND ECG CABLE CLEANING AND DISINFECTING

STEP	ACTION
1.	Remove PAM and cable from use. Keep the patient cable connected to the PAM.
2.	Remove all visible debris using with a lint-free cloth, moistened with warm water (40 C/104 F maximum) and soap.
3.	Check the PAM and cable for any residual debris. If any debris is present, repeat step 2 then re-examine the item before proceeding.
4.	Allow the items time to fully dry. If excess moisture is present after cleaning, use a dry towel to absorb the moisture.

TABLE 12: PAM AND ECG CABLE CLEANING AND DISINFECTING	
STEP	ACTION
5.	Disinfect the PAM and patient cable by thoroughly wetting it using CaviWipes disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal). Follow the Instructions for Use from the disinfectant manufacturer to properly disinfect the PAM and ECG cable.
6.	Allow the item time to fully dry before storing. If excess moisture is present after disinfecting, use a clean, dry towel to absorb the moisture.
7.	Check the PAM and patient cable for damage including cracks, tears, and cuts. Check the two cable connections for excess play while connected. There should be no movement in the lead wire to yoke connection and very little movement in the patient cable to PAM connection.
8.	Follow the storage procedure in Table 10 above.

8.2.1. **Cleaning Agents**

TABLE 13: CLEANING AGENTS	
Type	**Base**
Instrument Cleaner	Phosphates, Tensides

8.2.2. **Disinfecting Agents**

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

TABLE 14: DISINFECTING AGENTS	
Type	**Base**
Instrument Disinfectant	Glutaraldehyde, up to 3.6%
Surface Disinfectant	Ethanol, up to 70% 1- and 2- Propanol, up to 70%

8.2.3. **Cleaning and Disinfecting Monitor Accessories**

To clean and/or disinfect the fiber optic cable and gating cable, follow the same process listed above with the fiber optic cable disconnected from the PAM and gating cable disconnected from the scanner. Electrodes are single use and should be disposed of after use. Do not attempt to clean, disinfect, or reuse electrodes.

8.2.4. **Sterilizing**

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

Maintenance

WARNING

- **Maintenance 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.
- **Device in Use:** Do not service or maintain any part of the device while connected to or in use with a patient.
- **In Case of Problems:** If you discover a problem with any equipment, contact your service personnel, MiRTLE Medical, or your authorized supplier.
- **Electric Shock Hazard:** Do not open the monitor housing. Refer all servicing to qualified service personnel.

9.1 *Inspecting the Equipment and Accessories*

You should perform a visual inspection of the monitor, accessories, and set-up with the computer **before each use**, and in accordance with your hospital's policy.

With your monitor switched off:

1. Examine the 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.

9.2 *Inspecting the Cables and Cords*

1. Examine all system cables, the power plug, and the power 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 pinch connectors general condition. Make sure that there are no breaks in the insulation. Make sure that the pinch connectors can adequately clamp to an electrode.

9.3 *Maintenance Task and Test Schedule*

The following tasks are for MiRTLE Medical-qualified service professionals. Ensure that the tasks are carried out as indicated by the monitor's maintenance schedule, or as specified by local laws, whichever comes sooner. Contact a MiRTLE Medical-qualified service provider if your monitor needs a safety or performance evaluation. Clean and disinfect equipment to decontaminate it before performing testing or maintenance.

TABLE 15: MAINTENANCE & TEST SCHEDULE	
ACTION	FREQUENCY
Safety checks according to IEC 60601-1 and, where applicable, to national standards	• At least once every year, 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 measurements	At least once every year or if you suspect the measurement values are incorrect, contact MiRTLE Medical for service

MiRTLE G30000 MRI-Compatible 12-Lead ECG monitor contains no user-serviceable parts. All repairs must be performed by trained service personnel. All repairs on products under warranty must be performed by authorized personnel or in an authorized Service and Repair Center. Unauthorized repairs will void the warranty. Circuit diagrams, component part lists, descriptions, calibration instructions, and other information to assist service personnel in the repair of the serviceable parts of the device are available on request.

9.4 *Disposing of the Monitor*

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

Do not dispose of waste electrical or electronic equipment as unsorted municipal waste. Collect it separately so that it can safely and properly be reused, treated, recycled, or recovered.

Monitor:

- Recycle PCBs according to local laws
- Recycle the paper Operator's Manual

9.5 *Manufacturer's Information*

You can write to MiRTLE Medical at this address:

MiRTLE Medical LLC
1600 Osgood Street Suite 2017
North Andover, MA 01845
Contact us at: info@mirtlemed.com
Visit our website at: www.mirtlemed.com

9.6 *Expected Service Life*

The MiRTLE G30000 MRI-Compatible 12-Lead ECG monitor is expected to provide six (6) years of operation.

9.7 *Reuse Life*

With proper cleaning and disinfecting and normal use, the PAM's reuse life is no less than the expected service life of six (6) years of operation. The PAM provides an automatic power up self-check and will generate a message on the CRM of any failure. Should the PAM, its battery, or fiber optic cable fail, the CRM will generate a message and display the PAM or battery status in red.

With proper cleaning and disinfecting and normal use, the patient cable's reuse life is no less than the expected service life of six (6) years of operation. After each use, cleaning, and disinfecting, inspect the patient cable. The cable should be replaced if any of the following conditions occur:

- unacceptable deterioration such as corrosion, discoloration, pitting, or cracked jacket,
- cracks or other signs of damage to the connector including bent or damaged pins,
- loose connection of any gripper to an electrode stud.
- loose connection of lead wire set to trunk cable,
- or loose connection of trunk cable to PAM

9.8 *Battery Life Cycle*

Batteries have life cycles. The battery life is at an end when the equipment operating time. provided by battery power becomes much shorter than usual (i.e., when the total battery capacity has only 70 percent its initial capacity). For optimal battery life, please follow these guidelines:

- Do not store the batteries in a discharged condition. Always charge a battery to at least 40 percent of capacity before storing.
- Charge the batteries once a month when not in use.

Immediately remove any battery that has an expired life cycle and replace it with a new battery. To ensure the safety of operators and patients, observe the following warnings and cautions.

WARNING	Do not use a damaged battery. Periodically check batteries, stop using and replace any battery that exhibits abnormal heat, odor, color, deformation, or other condition. If a battery is punctured or if battery liquid leaks onto your skin or clothing, immediately wash the area and clothing with fresh water. If battery liquid gets into your eyes, do not rub your eyes; immediately flush your eyes with clean water and consult a physician.

CAUTION	• If the battery contacts become dirty, wipe it clean with a dry cloth before use. Do not immerse in a battery in water or other liquids. • Store batteries in a dry place, between 0 to 40°C (32 to 104°F). Do not expose a battery to temperatures above 60°C (140°F). • Do not short the external battery contacts. Keep metal objects away from the battery contacts. • Store each battery in a manner that prevents shorting with the container or another cell/battery. • Only use the MiRTLE Medical specified charger.

Appendix

A-1. MiRTLE Electrocardiograph Technical Specifications

Table 16: G30000 MiRTLE Electrocardiograph Monitor		
Category	Technical Specifications	
Model Number	GR1000	GR4000
Power Requirements	Patient Acquisition Module	Control Room Monitor
Voltage	7.2 VDC	100-240 VAC
Maximum Consumption	0.75 A	5 A
Frequency	DC	50/60 Hz
Supply	Rechargeable Battery	AC Plug
Physical Characteristics	Patient Acquisition Module	Control Room Monitor
Height	10.2 cm (4”)	40.6 cm (16”)
Width	7.6 cm (3”)	40.6 cm (16”)
Depth	33.0 cm (13”)	30.5 cm (12”)
Weight	2.95 kg (6.5 lbs.)	7.26 kg (16 lbs.)
Shipping Box	Patient Acquisition Module	Control Room Monitor (2 boxes)
Height	34.9 cm (13.75”)	55.9/33.0 cm (22/13”)
Width	43.2 cm (17”)	62.2/43.2 cm (24.5/17”)
Depth	19.1 cm (7.5”)	19.1/31.8 cm (7.5/12.5”)
Weight	3.63 kg (8 lbs.)	5.9/4.54 kg (13/10 lbs.)
Environmental Specifications	Operating	Storage
Temperature Range	0°C to 40°C (32°F to 104°F)	-20°C to 60°C (-4°F to 140°F)
Relative Humidity	<95% RH @ 40°C/104°F	10-90% RH @ 60°C/140°F
Altitude	-500 to 3000 m/-1640 to 9840 ft.	-500 to 3000 m/-1640 to 9840 ft.
Pressure	70 – 106 kPa (10.2 - 15.4 psi)	20 – 106 kPa (2.9 - 15.4 psi)
Performance		
Measurement Type	Electrocardiograph	
Measurement Sensor	Electrodes, radiolucent	
Measurement Range	30 – 350 BPM	
Accuracy	± 1 BPM	
Applied Part	Electrodes, quantity 10, Type CF defibrillation-proof	
Output Type	ECG trace, heart rate (HR), beat detected (BD)	
Output Resolution	HR: 1 BPM	BD: 30 ms
Output Rate	HR: 1 per second	BD: 1 per beat
Impedance	> 100MΩ	
Electrode Offset Tolerance	± 300 mV	
Dielectric Strength	5 kVA	
Defibrillator Protection	Yes	
Electro-surgery Protection	Yes	
Patient Alarms	None	
Tachycardia Alarm	None	
Pacemaker Display	Location flagged	
Pacemaker Rejection	±2 mV to ±700 mV, 0.5 ms to 2.0 ms	
Tall T-wave Rejection	0.6 mV	
MTBF	Typical (years)	Continuous (years)
GR1000 PAM	40.0	10.0
GR4000 CRM	6.1	3.1
GA1100 Patient Cable	6.0	1.5

Table 16: G30000 MiRTLE Electrocardiograph Monitor	
Category	Technical Specifications
Accessories	
PAM Battery Charger:	
Part Number	RRC-SMB-UBC
Type/Brand	14.7 VDC Charger
Manufacturer	MiRTLE Medical, LLC. (RRC)
Input	100-250 VAC, 50-60 Hz, 3.4 A
Output	14.7 VDC, 4.8A
Form Factor	Separable charger
Temperature Range	0 and +40 °C (32°F to 104°F)
Relative Humidity	<95% relative humidity @ 40°C/104°F
Altitude	-500 to 13100 m/-1640 to 43000 ft.
CRM Power Supply:	
Part Number	HPU101-105
Type/Brand	Switching Power Supply
Manufacturer	MiRTLE Medical, LLC. (Sinpro)
Input	100-240 VAC, 47-63 Hz, 0.5-1.2 A
Output	12 VDC, 8.5A
Form Factor	External power supply
Temperature Range	0 and +70 °C (32°F to 158°F)
Relative Humidity	<95% relative humidity @ 40°C/104°F
Altitude	-500 to 13100 m/-1640 to 43000 ft.
Cables:	
Part Number	GA1100
Type/Name	Patient electrode cable
Manufacturer	MiRTLE Medical, LLC. (Nicolay)
Length	300 cm (118”)
Temperature Range	0 and +45 °C (32°F to 113°F)
Relative Humidity	<95% relative humidity @ 40°C/104°F
Altitude	-500 to 13100 m/-1640 to 43000 ft.
Equipment Classification	
Type of protection against electrical shock	Class I equipment
Degree of protection against electrical shock	Type CF defibrillator-proof equipment
Degree of ingress protection	GR1000: IPX1 (vertical drip) GR4000: IPX1 (vertical drip)
Methods of sterilization	Non-sterilizable, use of surface disinfectants only
Mode of operation	Continuous operation

Table 16: G30000 MiRTLE Electrocardiograph Monitor	
Category	Technical Specifications
Certification(s) and Compliance with Standards	IEC 60601-1:2012-Ed.3.1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2014-Ed.4.0 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests IEC 60601-1-6:2013-Ed.3.1 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 60601-2-27:2011-Ed.3.0 Medical Electrical Equipment – Part 2-27: Particular Requirements for The Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment IEC 62304:2015 Medical device software - Software life cycle processes IEC 62366:2014 - Ed. 1.1 Medical devices – Application of usability engineering to medical devices ISO 10993-1:2016 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes ISO 14971:2007 Medical devices – Application of risk management to medical devices ASTM F2052-14 – Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Device in MR Environment ASTM F2503-13 – Standard Practice for Marking Medical Devices and other Items for Safety in the MR Environment ANSI / AAMI EC53 – ECG trunk cables and patient lead-wires 93/42/EEC, 2007/47/EEC - Medical Device Directive (MDD) 2002/96/EC – Directive on Waste of Electrical and Electronic Equipment 2006/66/EC – Battery Directive 2011/65/EC – Restriction of Hazardous Substances (RoHS2)

A-2. Supported Cables and Accessories

The following cables and accessories are supported by the MiRTLE Medical MRI Compatible ECG Monitor.

Table 17: Supported Cables & Accessories		
Item	Manufacturer	Part Number
Patient Cable, ≤ 3.0T	MiRTLE Medical	GA1100
Gating Output Cable, Universal	MiRTLE Medical	GA3010
Gating Output Cable, Siemens	MiRTLE Medical	GA3110
Fiber Optic Cable 30 FT	MiRTLE Medical	GA2100
Radiolucent Foam Electrodes	3M	2570
	ConMed	2700
	Kendall/Covidien	850
	Philips Healthcare	M2202A

A-3. Supported MRI Scanners

The following MRI scanners are compatible with the MiRTLE Medical MRI Compatible ECG Monitor.

Table 18: Supported MRI Scanners

Manufacturer	B0 Field	Model
GE Healthcare	1.5T	Optima MR450w Signa Artist Siga HDxt Signa Explorer and Explorer Lift Signa Voyager
	3.0T	Signa Architech Discovery MR 750w Siga PET/MR Signa Pioneer Signa Hero
Philips Healthcare	1.5T	Ingenia Ambition Ingenia Evolution Ingenia MR5300
	3.0T	Ingenia Elition X Ingenia Elition S
Siemens Healthcare	1.5T	Aera Altea Amira Avanto Sola
	3.0T	Skyra Lumina Vida

A-4. Electromagnetic Compatibility (EMC)

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

- EN/IEC 60601-1-2: ed4.0 (2014)

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 MiRTLE CRM is an electrical Class I 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's vicinity, or within a 1.0m radius of any part of the ECG monitoring system.

WARNING: Do NOT use RF emitters such as RFID within the patient's vicinity, or within a 1.0m radius of any part of the ECG monitoring system.

.

WARNING: Be aware that specific investigations or treatments may cause reciprocal interference. A physician, or suitably qualified person authorized by a physician, should determine if reciprocal interference will negatively impact patient diagnosis or treatment.

CAUTION: 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.

A-4.1 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, 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. MiRTLE 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.

A4.2 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.

A4.3 Electromagnetic Emissions and Immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. See Table 19Table 19 to Table 22 for this detailed immunity information. See Table 23 for recommended minimum separation distances between portable and mobile communications equipment and the MiRTLE 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 MiRTLE ECG monitor together with its accessories. The table provides details on the electromagnetic emissions for the MiRTLE monitor, how these emissions are classified, and the electromagnetic environments in which the MiRTLE is specified to technically function.

Table 19: 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 MiRTLE 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.

A4.3.1 Electromagnetic Immunity

The MiRTLE 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 20: 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.			

A-4.4 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 21: 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 22: Guidance and Manufacturer's Declaration: Electromagnetic Immunity		
Radiated RF Immunity Test EN/IEC 61000-4-3		
IEC 60601-1-2 Test Level over 80 MHz to 2.5 GHz	**Compliance Level**	**Electromagnetic Environment Guidance: Recommended Separation Distance (d) (in Meters, at Frequency Range Tested) for Ultrasound and ECG Measurements**
3.0 V/m	3.0 V/m	Over 80 MHz to 800 MHz: $d = 1{,}2\sqrt{P}$
		Over 800 MHz to 2.5 GHz: $d = 2{,}3\sqrt{P}$

Key:
d = Recommended separation distance in meters (m)
p = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer
E1 = Tested compliance level (in volts/meter) for the Radiated RF Immunity test IEC 61000-4-3

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 MHz 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}: $d = 2{,}3\sqrt{P}$

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 MiRTLE Medical Support.

A-4.4.1 Recommended Separation Distances from Other RF Equipment

The MiRTLE ECG 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 23: 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

A-4.5 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 +40 °C (32°F to 104°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 electrically conductive parts.

A-5. Product Warranty; Limitations and Exclusions

1.1 Limited Warranty

MIRTLE MEDICAL warrants that the MIRTLE MEDICAL Manufactured Equipment/Software described in the attached proposal, when delivered, properly installed, and used in accordance with MIRTLE MEDICAL's instructions, will conform to MIRTLE MEDICAL's most current version of the published specifications for such Equipment/software or to those specifications in effect as of the date the Equipment/Software was originally delivered to Customer in all material respects. Equipment or Software manufactured or developed by a company other than MIRTLE MEDICAL shall be sold only with the warranty and support provided by the original manufacturer. No additional warranty or support is offered by MIRTLE MEDICAL. As MIRTLE MEDICAL's sole responsibility and Customer's exclusive remedy in the event of any material nonconformity, MIRTLE MEDICAL shall, at its option, make a reasonable effort to repair or replace the Equipment/Software so it is conforming or shall reimburse Customer's purchase price for the pertinent parts of the Equipment/Software. Any claim based on the foregoing warranty must be submitted in writing in accordance with MIRTLE MEDICAL's standard procedures within three hundred and sixty-five (365) days after delivery of the Equipment/Software. Such warranty shall not apply to Equipment that has been modified or altered.

EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, MIRTLE MEDICAL MAKES NO WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE SYSTEM, THE DESIGN OR CONDITION OF THE EQUIPMENT OR SOFTWARE, OR ANY OUTPUT BASED ON USE OF THE SYSTEM. MIRTLE MEDICAL SPECIFICALLY DISCLAIMS, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EQUIPMENT MANUFACTURED BY COMPANIES OTHER THAN MIRTLE MEDICAL WILL BE WARRENTED AND SUPPORTED ONLY TO THE EXTENT WARRENTED AND SUPPORTED BY THE ORIGINAL MANUFACTURER.

1.2 Warranty Repairs

If, during the period described in Section 2.1, any Equipment/Software component fails to conform to the Warranty specifications that component will be replaced or repaired at MIRTLE MEDICAL. For warranty-covered repair work, if possible, a loaner component will be provided if the anticipated repair period is in excess of two weeks. Shipping expenses incident to repairs and loaner equipment will be paid by customer. If a loaner component cannot be provided, Customer's warranty will be extended an additional two days for every day their system is not operational.

1.3 Support After the Warranty Year

Support for products will be offered in accordance with the then current, support policies for the life of the product. Customer will be offered a service agreement at an additional cost covering Equipment repairs and service outside the warranty period. Repairs on a parts and labor basis are also available.