

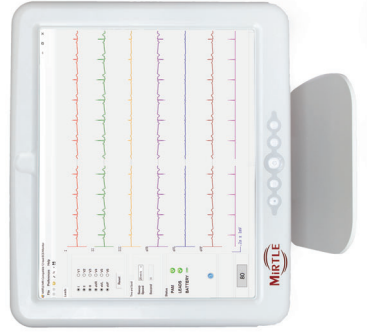


QUICK START GUIDE

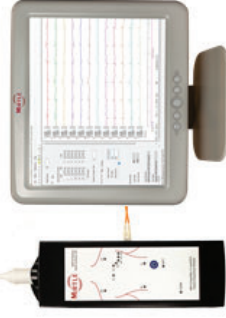
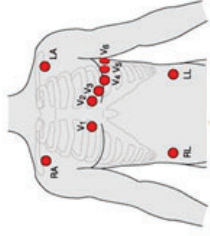


The Instructions for Use are located on the device. From within the software, select Help from the menu, and then select Instructions For Use.

The Instructions For Use may also be found at: www.mirtlemed.com/support



MRI-Compatible 12-Lead ECG



MedQ Consultants B.V.
Baanstraat 110
NL 6372 AH Landgraaf
+31 45 303 0006



MIRTL Medical, LLC
support@mirtlemed.com
978.918.7223
33GQ5001 V2125

PREPARATION: CHARGE & INSTALL PAM BATTERY IFU Sections 4.1 & 4.2

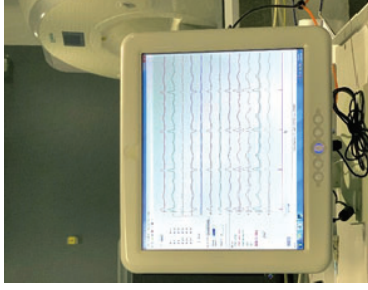
Prior to using the PAM, charge the battery in the provided charger. The battery charger is NOT MR Safe. Charge the battery outside of the MRI room. Turn the PAM over. Slide the door latch down to release the battery door. Open the battery door.

To install the battery, grab the battery face up with the contacts at the top; place the battery into the battery compartment with the top of the battery placed underneath the battery door hinge; slide the battery up to seat in its connector. Close the battery door ensuring that the latch is secured.



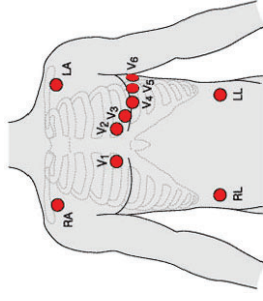
INSTALLATION: PLACE CRM IN CONTROL ROOM IFU Section 5.3.2

The CRM must be installed in the MRI control room in a hospital environment. Under no circumstances should the CRM be placed in the MRI room as it is not MRI safe. Place the Control Room Monitor on a desk-top 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.



USE: PREPARE PATIENT FOR MONITORING IFU Sections 4.10 & 4.11

Application sites must be clean, dry, and free of any body lotions. Excessive hair should be removed by clipping. Preparing the skin with NuPrep skin prep gel is recommended to improve ECG signal quality. Use only MR-safe ECG electrodes. Place the chest and torso electrodes in the designated positions for 12-lead ECG data collection as shown here. Connect patient cable to all ten electrodes. Verify connection by confirming that all lead-off LED indicators are off. If RL is not connected, all ten LEDs will be on.



INSTALLATION: CRM SETUP IFU Sections 4.6 to 4.8

Install the CRM stand with the eight screws provided.

Connect the power supply, fiber optic cable, and gating cable to the labelled connectors as shown below.



INSTALLATION: FIBER OPTIC & GATING CABLES IFU Section 5.3.3

The fiber optic cable that connects the CRM to the PAM and the gating cable that connects the 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. Also from the ceiling of the MRI room, drop the gating cable down to the left front floor for connection to the scanner.

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.

USE: POWER ON PAM & CRM IFU Section 4.1.3

Power on the MIRTLE MRI ECG Monitor by pressing the power button on both devices located: a) on the top of the PAM; and b) on the front of the CRM. When the CRM is done booting, the ECG application will automatically launch and begin plotting ECG traces.

USE: MONITOR THE PATIENT IFU Section 6

With the patient on the MRI bed and prior to moving into the MRI bore, instruct the patient to remain still to allow the beat detection unit to learn the patient's ECG. After approximately 25 seconds, verify beat detection accuracy and scanner synchronization (if using). If beat detection is inaccurate, the application will continue to learn. Wait before moving the patient inside the bore and instruct the patient to remain still until detection is correct.

Move the patient into MRI scanner bore.

Run MRI protocols as desired while continuously monitoring the patient's cardiac activity.

USE: POST PATIENT MONITORING IFU Section 8.2

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. Power-off the CRM by pressing the power button on the face of the CRM. Clean and disinfect the PAM and cables after each use. Remove the PAM battery and place in the charger for the next monitoring session.

USE: CONNECT FIBER OPTIC & GATING CABLES IFU Section 5.3.3

Connect the fiber optic cable and patient ECG cable to the PAM as shown in the picture immediately to the left.

Connect the RCA end of the gating cable to the scanner Ext Trigger port located at the left front bottom of the scanner as shown here.



INSTALLATION: PLACE PAM ON MRI BED & SECURE IFU Section 5.3.1

The PAM should be placed horizontally on the MRI bed rail, near the patient's feet. The PAM 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.

