Global Instrumentation
M12 Telemetry System

Instructions for Use

℞ Only

Restricted Intended Use:

Federal US law restricts the sale of this device by or on the order of a licensed physician.

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SECTION 1 - NOTICES

Global Instrumentation, LLC makes no representations or warranties with respect to the contents or use of this manual, or with respect to any Global Instrumentation, LLC hardware or software.

Federal US law restricts sale of the device identified in this manual to, or on the order of, a licensed physician.

Global Instrumentation, LLC assumes no responsibility for any injury, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or indications for use published in this manual.

Responsibility of the Customer

The user of this system is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards. This manual must be kept in a safe place to prevent its deterioration and/or alteration. The user and Global Instrumentation, LLC authorized personnel must have access to this manual at any time.

The user of this device must periodically check the transmitters and monitors, their functionality, and the integrity of their accessories.

Equipment Identification

Global Instrumentation LLC equipment is identified by serial and part numbers on the side, back, or bottom of the device. Care should be taken so that these numbers are not defaced.

The device and accessory product labeling is applied showing the unique identification numbers along with other important information printed on the label.

The labeling format is as follows:

- Date of manufacture label: year manufactured
- Serial number label: provides the sequence number of manufacture
- Lot number labeling: last 4 digits provides the week and year of manufacture (example: WWYY, where WW is week of manufacture and YY is year of manufacture)

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LIMITED WARRANTY INFORMATION

Global Instrumentation, LLC (“Company”) warrants, for a period of twelve (12) months that all Products, other than as set forth below, under normal use and operation, will operate substantially in accordance with the functional descriptions or specifications in the applicable User's Instructions or Documentation or Directions for Use.

- Software upgrades and hardware repairs are so warrantied for ninety (90) days.
- Reusable products, such as patient cables, lead-wires, charging cables, mounts, and other spare parts, are so warranted for a period of ninety (90) days.
- Single-use products are warranted for a period of ninety (90) days.

In the event of a breach of this Limited Warranty by the Company, the customer may return the defective Product to Global Instrumentation and, in the event the Company determines, in its sole and absolute discretion, that such Product is defective, the Company shall, in its sole and absolute discretion, either:

1) repair or replace the product, or
2) refund to customer the price paid, therefore.

This Limited Warranty is valid only if (a) all equipment/spare parts are approved for use with the Product by the Company and are installed according to instructions provided by the Company or its authorized distributors; (b) the Products are properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements and applicable written instructions of the Company; (c) all replacements and repairs are made by the Company or by persons expressly authorized by the Company; (d) the Products have not been configured, modified or adjusted other than by the Company or by persons expressly authorized by the Company and (e) the Products have not been subject to misuse, negligence, accident or use for something other than their intended purpose or in violation of applicable laws or regulations.

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This Limited Warranty applies only to items manufactured by the Company and does not cover components manufactured by others unless expressly set forth herein. The Company shall not accept any returned Products that are incomplete or damaged (other than as covered by this Limited Warranty). The Limited Warranty period on each repaired or replaced item in fulfillment of this Limited Warranty shall be limited to the unexpired portion of the original Limited Warranty period on the item so replaced or repaired. The Company shall have no warranty obligations to any items hereunder unless it determines, in its sole and absolute discretion, that such item is defective under the terms of this warranty.

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THE CUMULATIVE LIABILITY OF THE COMPANY TO CUSTOMER OR ANY OTHER PARTY FOR ANY LOSS OR DAMAGES RESULTING FROM ANY CLAIMS, DEMANDS, OR ACTIONS, ARISING OUT OF OR RELATING TO THIS LIMITED WARRANTY OR THE PRODUCTS, WHETHER FORESEEABLE OR UNFORESEEABLE, (INCLUDING, BUT NOT LIMITED TO, CLAIMS FOR LOSS OF DATA, GOODWILL, LOSS OF MONEY OR USE OF THE PRODUCTS, INTERRUPTION IN USE OR AVAILABILITY OF DATA, STOPPAGE OF OTHER WORK OR IMPAIRMENT OF OTHER ASSETS), WHETHER IN BREACH OF WARRANTY, BREACH OF CONTRACT, MISREPRESENTATION, NEGLIGENCE, STRICT LIABILITY, RELIANCE, TORT OR OTHERWISE, SHALL NOT EXCEED THE PRICE CUSTOMER PAID FOR THE PRODUCTS. IN NO EVENT SHALL THE COMPANY BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR EXEMPLARY DAMAGES OR LOST PROFITS, EVEN IF THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Customer's use of the Products constitutes acceptance of this Limited Warranty, which shall be governed by the laws of the State of New York, and all matters related hereto brought and resolved in the Courts located in Onondaga County, New York.

SECTION 2 - SAFETY INFORMATION

WARNING: Warning statements in this manual identify a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

CAUTION: Caution statements in this manual identify a condition or practice which, if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

NOTE: Provides information to further assist in the use of the telemetry system.

Familiarize yourself with these warnings and cautions. Additional warnings and cautions are also found throughout the directions for use.

Safety Regulations

The M12A Telemetry Central Station cannot be classified as Medical Electrical Equipment according to the definition of safety standard IEC 60601-1. The M12A Telemetry Central Station, together with the M12RT Telemetry Transmitter and all accessories that have a physical or logical connection with it, forms part of a Medical Electrical System.

WARNINGS

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse, or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Global Instrumentation service for additional training options.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the M12 Telemetry System could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, The M12 Telemetry System and the other equipment should be observed to verify that they are operating normally.
- The essential performance System (latency in or loss of the wireless connection, excessive signal noise, etc.) of the M12 may be lost or degraded due to Electro-Magnetic disturbances.
- Leave 5 ft (1.5 m) of open area around the patient during patient hookup and removal. The M12A Telemetry Central Station and accessories must always be kept a minimum of 5 ft (1.5 m) away from the patient. The operator shall not touch the M12A Telemetry Central Station and accessories and the patient simultaneously.
- This equipment must not be connected to any other equipment that is not compliant with EN60601-1, or a possibility exists that combined leakage currents could exceed safe limits.
- Do not use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer.
- The M12 Telemetry system and it's accessories (including the M12RT Telemetry Transmitter and patient cable) must be no closer than 30 cm (12 in) to any stationery or portable RF communication equipment, including antennas.

M12A Telemetry Central Station Warnings

- The M12A Telemetry Central Station is not designed to be used in the environment where the patient is undergoing a medical procedure as defined in IEC 60601-1 (1.5 m from the patient).
- The M12A Telemetry Central Station is not battery operated. For uninterrupted use, an appropriate uninterruptible power supply (UPS) is required. The wireless network (telemetry) as well as any active network components such, as switch and firewall, should also have the capability to remain operational in cases of general power outages. The M12A Telemetry Central Station is designed to continue operation with the last stored settings after a power interruption; however, loss of stored data is possible if power is interrupted to the system that stores the data. When using a backup power source such as a UPS, periodically check it to ensure it is properly functioning per the manufacturer's recommendations and specifications.

- The various parts of the M12 Telemetry monitoring system (telemetry receiver computers, control and display computers, storage computers, and printers) are all connected through a specific Ethernet data network. This network must be installed according to all applicable standards and may only be logically or physically connected to the outside world through a specific routing device available from Global Instrumentation, LLC. Any other data path can lead to serious security risks and interruptions of monitoring. Other devices must not be connected to the M12 Telemetry data network.
- In the case of an M12 Telemetry Central system with additional central stations for display and control of the same patient channels in multiple locations, silencing or pausing of alarms will cause the alarm to be silenced or paused at all the locations. Be certain that alarms are silenced or paused by the clinician having direct responsibility for the care of the given patient.
- Install all computer equipment with adequate space around ventilation vents. Clean and remove accumulated dust on ventilation openings and remove dust regularly from the inside of the system. The last operation must be performed by adequately trained and authorized personnel, and with the system turned off.
- The M12A Telemetry Central Station provides an alarm volume adjustment. Be sure to set the volume at a level that alarms can be heard above the ambient noise level in the environment of use. Setting alarm volumes too low can impede recognition of alarm signals.
- The M12A Telemetry Central Station must be connected to a properly grounded power terminal, and the electrical installation must comply with the local safety requirements for the environment where it is used.
- The M12A Telemetry Central Station requires more than one mains outlet. Fix multi-socket outlets properly, do not leave them on the floor, and organize the cabling in such a way that normal work is not hampered, and safety is not compromised.
- Regularly check all mains power cables for damage and proper connection. Do not use equipment with a damaged power cord.
- The on/off switch of the M12A Telemetry Central Station is deactivated and can only be used for emergency power down by depressing it for a period greater than 4 seconds. Normal shutdown of the M12A Telemetry Central Station should be done by using the password-protected configuration window. Should the M12A Telemetry Central Station computer not respond to emergency power shutdown, proceed to

unplug the M12A Telemetry Central Station from power, wait 60 seconds and plug back in.

- The M12A Telemetry Central Station components are not waterproof. Avoid spillage of liquids from penetrating the system or submersion of components and transmitters into a liquid. In case of accidental spillage, turn the computer off and let dry thoroughly.
- Portable and mobile RF communications equipment can affect medical electrical equipment or systems as well as the M12A Telemetry Central Station and its accessories.
- The M12RT Telemetry Transmitter and IT Network the device is connected to should be securely configured and maintained per the IEC 80001 standard, or an equivalent network security standard or practice.
- Do not install third party software on the M12A Telemetry Central Station.
- Do not connect any external audio device to the M12A Telemetry Central Station.
- Do not block the speaker of the M12A Telemetry Central Station computer.
- Ensure virus protection software is installed on the system to prevent ramifications of a possible virus or malware.

M12A Telemetry Central Station Alarm Related Warnings

- Various alarm conditions require the operator to set limits that vary per patient. The M12A Telemetry Central Station supports the selection of appropriate alarm settings when a patient is set up for telemetry monitoring. The operator should check these settings after each patient begins telemetry monitoring to ensure whether the chosen alarm limits are appropriate for the individual patient. Inappropriate alarm limits render the alarm system ineffective.
- Adjust the alarm thresholds to patient conditions after telemetry monitoring has started. Incorrect alarm threshold settings are a frequent cause of false alarms and lower the attention level to the genuinely important alarms.
- M12A Central Repeater Station does not produce audible alarm signals and may not be used to substitute any alarm functions of M12A Telemetry Central Station.
- During Preview Mode, patient alarms are not active at the M12A Telemetry Central Station. Active monitoring, including alarm activity, will not begin until the Preview Mode period expires or if the start monitoring command is performed.
- The leading cause of patient death or serious injury reported with the use of patient monitoring equipment is failure to respond to alarms notifying the user of an adverse

change in patient condition. If you are relying on visual alarm notifications, maintain a clear line of sight and remain within 4 m of the M12A Telemetry Central Station. If you are relying on audio alarm notifications, make sure that you can hear audio alarms from where you are. Set the volume as needed considering the environment and ambient noise levels. Verify that the alarm is audible to a clinician working at the maximum distance from the M12A Telemetry Central Station system

- If the system or one of its subsystems become inoperable during telemetry monitoring, a technical alarm sounds, and a message is displayed on the M12A Telemetry Central Station. In case of hardware or software failure that causes the sound generator or display subsystem to fail, the software watchdog unit generates a continuous beep. Periodic checks of the monitoring display screen are recommended to ensure proper functioning.
- Do not pause or turn off a visual or audible alarm if patient safety might be compromised.
- It is the operator's responsibility to set alarm limits as appropriate for each individual patient.
- Alarm volumes other than high may not be heard by the operator. Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions. It is recommended that the audible alarm levels of high, medium and low are tested within the use area of the M12A Telemetry Central Station to confirm the audible signals can be heard over the noise of the ambient environment. The testing and configuration of volume settings should be done during installation and not modified unless specific environmental changes have occurred within the operational area of the M12A Telemetry Central Station.
- Setting alarm limits to extreme values can render the alarm system useless.
- Simultaneously using similar systems with similar alarm sounds in the same area can cause the user to improperly interpret alarms. Do not simultaneously use multiple similar systems, with similar alarm sounds, in the same area.
- The display supplied with the M12A Telemetry Central Station has a separate power switch and power-on indicator. If no image appears on the display screen, check the display screen power indicator. Alarm sounds are not affected by the status of the display screen. Do not connect a sound-capable display monitor such as a LCD TV to the M12A Telemetry Central Station.

ECG Warnings

- It is important that clinicians understand and communicate to all staff using the System that any arrhythmia analysis program is an effective tool to assist in patient care, but arrhythmia analysis systems are unable to achieve 100 % accuracy for all morphologies and occurrences of QRS and PVC detection. Thus, continuous close physical surveillance and clinical interpretation of cardiac data must still be an integral part of every patient's care. Clinicians must review all data obtained from the System before implementing therapy based on the data.
- Computer assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable, and a qualified physician shall review the interpretations before treatment, or non-treatment, of any patient. This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment. Certain arrhythmias or pacemaker signals could adversely affect heart rate.
- Ensure patients connected to the system are kept under close surveillance, especially patients prone to arrhythmia events. Use the System only in conjunction with close surveillance by trained clinicians.
- Peripheral equipment and accessories/spare parts that touch the patient must comply with all appropriate safety, EMC, and regulatory requirements.

M12RT Telemetry Transmitter Warnings

- Removal of the M12RT Telemetry Transmitter battery cover for battery replacement shall be performed by facility professional staff.
- Do not perform servicing or maintenance of the M12RT Transmitter while in patient use.
- Electrostatic discharges may generate short interference on the ECG tracings.
- The M12RT Telemetry Transmitter utilizes standard wireless telemetry per the IEEE 802.11 standard. The wireless network supporting the M12RT and for use with the M12A Telemetry Central Station must be installed and tested in accordance with Global Instrumentation's guidance and network requirements. Also refer to Global Instrumentation's Manufacturer Disclosure Statement for Medical Device Security (MDS2) documents for the M12A Telemetry Central Station and M12RT Telemetry Transmitter.

- The M12RT Telemetry Transmitter should not be connected to any other equipment that applies currents or electrical signals to the patient or the performance of this or other equipment could be affected.
- Do not operate this product with MRI (Magnetic Resonance Imaging) equipment.
- The Transmitter should not be used on patients who are linked to heart / lung machines.
- The Transmitter should not be used on patients when an electrosurgical unit is being used.
- Any M12RT Telemetry Transmitter which has been dropped or damaged should be checked by qualified service personnel to ensure proper operation prior to use.
- Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.

Accessories, Cables, and External Connections Warnings

- ECG electrodes may cause skin irritation. Examine the skin for signs of irritation or inflammation and avoid placements of the electrode in those areas.
- Do not use the M12RT Telemetry Transmitter and electrodes on patients with known allergic reactions to adhesives or hydrogels or with family history of adhesive skin allergies. Patients may experience skin irritation. If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Transmitter and electrodes from the patient's chest.
- Utilizes ECG electrodes, which can damage skin if used improperly. The transmitter should be used by or in consultation with a health care provider familiar with proper placement and use of electrodes. Apply electrodes to intact, clean skin only. Do not apply electrodes over an open wound, lesion, infected or inflamed skin.
- Inspect the M12RT Telemetry Transmitter and accessories/spare parts before each use. Ensure that all modules and cables are in good working condition and have not exceeded the expected useful life.
- Keep the M12RT Telemetry Transmitter, patient cable and accessories/spare parts clean/disinfected, especially those components that touch patients.
- The conductive parts of electrodes and associated connectors for type CF applied parts, including the neutral electrode, should not contact any other conductive parts including earth.
- Discard electrodes after one use.

- Use of accessories, spare parts, and cables other than those specified may result in degraded electromagnetic compatibility performance of this device.
- Connect patient cable lead wires only to the patient electrodes.
- Using not approved cables and accessories/spare parts may affect performance.

Defibrillation & Electrosurgery Warnings

- The M12RT Telemetry Transmitter has not been designed for use together with electrosurgery equipment.
- The M12RT Telemetry Transmitter and patient cable is defibrillator protected in compliance with IEC 60601-2-27 standards if used with Global Instrumentation-approved patient cables. Defibrillation while using-non approved patient cables may damage the device beyond repair and cause a safety hazard to the patient.
- During defibrillation, keep the discharge paddles away from ECG and other electrodes, as well as other conductive components in contact with the patient. Avoid contact with any accessories connected to the M12RT Telemetry Transmitter and accessories/spare parts.

Pacemaker Warnings

- For patients with a pacemaker, consult supervising physician before use.
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance, patients should be continuously attended to. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument
- When Pacer detection is disabled, the pacemaker signals could adversely affect heart rate indications or alarms. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance, patients should be continuously attended to. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- For patients with a pacemaker, maintain a minimum of 6 inches between the M12RT Telemetry Transmitter and pacemaker, consult supervising physician before use. Remove the M12RT Telemetry Transmitter from the patient in the event you suspect the M12RT Telemetry Transmitter is affecting the pacemaker.
- Keep all pacemaker patients under close observation. Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely solely upon rate meter alarms.

NOTES

- The M12 Telemetry System contains electronic records including ECGs which can be exported to other applications. The M12 Telemetry System can be part of a system that is compliant with the electronic records requirements of part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11) as stipulated by the US Food and Drug Administration's (FDA). The user of the M12 Telemetry System must ensure full compliance to this as required.
- The M12 Telemetry System implements certain features such as username, passwords, and audit trails. By design, the M12A Telemetry Central Station system is accessible and available for use upon power-up without any user authentication. Subsequent interaction within the M12A Telemetry Central Station will require user authentication. The facility deploying and using the system is responsible for ensuring appropriate safeguards are put in place to protect patient health information (PHI). This includes a mixture of physical and IT-based mechanisms to secure PHI from unauthorized access. The M12 Telemetry System including printers generating reports must be placed in a physical location that is secure (e.g., nurse’s station). M12A Review/Admin and M12A Central Repeater Stations may be placed in less secure locations but must implement proper username/password access policies as required.

CAUTIONS

- The M12RT Telemetry Transmitter must be installed as part of a system in conjunction with the M12A Telemetry Central Station and in accordance with guidance and minimum characteristics per requirements provided by Global Instrumentation.
- Ensure that the M12RT Telemetry Transmitter and all reusable accessories/spare parts are properly cleaned/disinfected according to approved methods between each patient use.
- **DO NOT** use acetone, ether, freon, petroleum derivatives, or other solvents to clean the Transmitter. Refer *to* ***Section 25 - Maintenance and Service*** in this manual for proper cleaning techniques.
- **DO NOT** submerse, autoclave, or steam clean the Transmitter or the patient cable. Refer to “Maintenance” in this manual for proper cleaning techniques.
- Instruct patients to avoid exercise immediately following application of electrodes and thereafter avoid activities or environments that result in excessive perspiration, at this

may result in loss of skin contact by the electrode and result in a decreased period of recording.

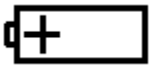
- Always ensure that the appropriate electrode placement is employed for the lead configuration selected.
- Use good quality skin surface ECG electrodes intended for long-term patient monitoring. Use Ambu BlueSensor L or VL series electrodes or electrodes functionally equivalent to these.
- Verify that dates on applicable accessories/spare parts have not expired.
- Make periodic visual checks on the M12RT Telemetry Transmitter and accessories/spare parts, including cables and electrode wires to confirm they are clean, not damaged, and safe to use. Perform periodic tests of the equipment and accessories/spare parts (by the clinical operator).
- Do not operate, store, or transit the M12RT Telemetry Transmitter in conditions outside of the listed environment specifications. Exceeding the environmental limits may cause the device to malfunction and/or become inoperable.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.
- The performance of the M12RT Telemetry Transmitter may be compromised by excessive motion.
- Touching the adhesive on the bottom of the electrode can reduce adhesive wear duration.
- If the electrode is removed from its pouch, the useful life of the electrode hydrogel becomes limited. Take care to remove the electrode from the pouch only when ready to apply the electrode to the patient.
- The electrodes used with the M12RT Telemetry Transmitter are intended for single-use only.
- Off the shelf electrode shall be handled and stored in accordance with the requirements of the electrode manufacturer.
- The Transmitter is not waterproof. The patient should not shower, swim, or take baths while wearing the Transmitter.
- DO NOT let soap or water come into contact with the Transmitter connector pins.
- To prevent possible damage to the device, do not use sharp or hard objects to depress the M12RT Telemetry Transmitter buttons, only use fingertips.

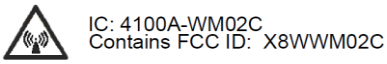
- Inserting the Secure Digital (SD) Card into the M12RT Telemetry Transmitter backwards or upside down may damage Secure Digital Card Interface.
- When handling a M12RT Telemetry Transmitter that has been worn by a patient use appropriate handling procedures (e.g. gloved hands).
- Prevent liquid from penetrating the M12RT device and do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation. Do not sterilize the device or ECG cable with Ethylene Oxide (EtO) gas.
- In the event of a cybersecurity concern involving the M12RT Telemetry Transmitter or the M12A Telemetry Central Station application, refer to the instructions for use or contact Global Instrumentation, LLC.
- When necessary, dispose of the M12RT Telemetry Transmitter, its components, and accessories/spare parts (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- Federal law restricts this M12 Telemetry System to sale by or on the order of a physician.

NOTES

- Preparation is important for the proper application of ECG electrodes and operation of the device.
- Always ensure that the appropriate electrode placement is employed for the lead configuration selected.
- It is the responsibility of the medical facility to provide the patient with instructions during use. Refer *to* ***Section 6.6 - General Wearing Instructions to Provide the Patient*** within this user manual.
- The patient cable life expectancy is twelve months of continuous use with proper care.
- No preliminary or ongoing scheduled periodic calibration by the user or Global Instrumentation personnel is required. The design for the device is such that the system contains no elements requiring calibration.
- Any serious incident that has occurred in relation to the device should be reported to Global Instrumentation, LLC and the competent authority of the Member State in which the user and/or patient is established.

SECTION 3 - EQUIPMENT SYMBOLS AND MARKINGS

	Warning statements in this manual identify a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.
	Caution statements in this manual identify a condition or practice which, if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.
CE 2797	Meets or exceeds Council Directive 93/42/EEC, MDD, Class IIb (FUTURE)
CE	Meets or exceeds Council Directive 93/42/EEC, MDD, Class I (FUTURE)
MET c us E114281	MET Labs NRTL (Nationally Recognized Test Laboratory) tested to comply with AAMI ES 60601-2, CSA C22.2 No. 60601-1
	Defibrillator-proof Type CF Applied Part Meets or exceeds requirements of MDR 2017/745 for medical devices
	Type CF Applied Part Meets or exceeds requirements of MDR 2017/745 for medical devices
	Battery Polarity. Use “AA” (LR6) type batteries
	Secure Digital Memory Card Interface
	Do not re-use. Indicates a medical device that is intended for one use.
	Use By; with Year-Month-Day defined below symbol
IP22	Protected from touch by fingers and objects greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical.
	Keep from direct sunlight
	Temperature Range (see Environmental Conditions)

	Humidity Range (see Environmental Conditions)
	Altitude Range (see Environmental Conditions)
	This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Japan Radio Law
	This equipment contains specified radio equipment that is certified by the FCC for Non-Ionizing Radiation
	Serial Number
	Reference Number
	Lot Number
	A data matrix (GS1) code is a two-dimensional barcode consisting of the product GTIN DI and PI numbers for the Transmitter
	No Latex
	Manufacturer – Global Instrumentation
	Patient Call Button
	Date of Manufacture, where “YYYY” is the year the device was manufactured
	Keep dry
	This end up
	Fragile, glass
	Recycling Symbol - Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European

	Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).
℞ Only	CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.
	MRI Unsafe (ASTM F2503-13); Do not operate this product with MRI (Magnetic Resonance Imaging) equipment.
	Medical Device
	Follow the instructions for use (IFU) – mandatory action. A copy of the instructions for use is available on this website. A printed copy of the IFU can be ordered from Global Instrumentation for delivery within 7 calendar days.

SECTION 4 - INTRODUCTION

NOTE: Read all directions for use before using the M12 Telemetry System. Follow all the instructions while using the M12 Telemetry System.

4.1 Purpose

NOTE: This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.

NOTE: Instruction for use documents are available through the support page of our website at www.globalinstrumentation.com as well as accessible through the Help About menu in the M12A Review and Admin software application. Click on the "Documentation" button in the Help About screen. PDF viewing software is required to open and print instructional material.

4.2 Audience

This manual is designed to be an aid for setting up and operating your new GI M12 Telemetry System and is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

4.3 Product Use and Purpose

The M12 Telemetry System is intended for monitoring of ECG cardiac signals for multiple patients within a healthcare facility or clinical pharmacology unit. The system can receive, display, and store data from multiple telemetry transmitters.

A typical centralized telemetry monitoring system will consist of three main components: the ECG telemetry transceivers, compatible network access points comprising an antenna network and the compatible Central Station software application running on a dedicated PC.

The M12RT Telemetry Transmitter is a prescription device intended for use as a patient worn telemetry transceiver for continuous transmission of ECG data. A graphic color LCD will offer display of ECG waveforms, demographic data, and other information.

During telemetry monitoring, the M12A Telemetry Central Station is continuously attended and provides primary monitoring of patients including display of values and waveforms, alarm generation and management, data storage, patient management, and report printing functionality. Patients are monitored through telemetry and may ambulate through a defined area of the healthcare facility.

The data and analysis provided by the M12A Telemetry Central Station is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various cardiac rhythm patterns.

4.4 Indications for Use

The M12A Telemetry Central Station is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult and adolescent patients (11 to 17 years) within a professional healthcare facility or clinical environment. Centralized monitoring involves the display and management of data from networked patient telemetry transmitters including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation.

The M12A Central Station with resting 12-lead ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and adolescent patients when connected to a transmitter with 12-Lead ECG monitoring enabled.

The M12RT Telemetry Transmitter is intended for use with the M12A Telemetry Central Station to monitor ECG on ambulatory and non-ambulatory adult and adolescent patients using wireless communication over the M12 telemetry network.

The M12RT Telemetry Transmitter can deliver ECG data using a 10-lead cable.

4.5 Contraindications

The M12R Telemetry System, including the M12RT Telemetry Transmitter, is not intended for home care use or the following hospital environments:

- Hyperbaric chambers
- Environments containing CT equipment
- Environments containing MRI equipment
- In the vicinity of electro-surgical equipment

The M12A Telemetry Central Station is not designed to be used in the environment where the patient is undergoing a medical procedure as defined in IEC 60601-1 (1.5 m from the patient)

Patient population

The M12R Telemetry System, including the M12RT Telemetry Transmitter, is not intended for use on pediatric or infant patients (under the age of 11 years).

4.6 Environments of Use

This device is intended for use in health care environments only.

The M12 Telemetry System is intended to be used in an environment where patient care is provided by healthcare professionals, i.e. physicians, nurses, and technicians,

trained on the use of the system who will determine when use of the system is indicated, based upon their professional assessment of the patient's medical condition.

Note: in some healthcare settings, such as clinical research facilities, the individuals under monitoring may be referred to as subjects rather than patients.

4.7 User Requirements

Professional User Group

The user group operates the product in accordance with the intended use. The user of the GI M12 Telemetry System shall have the following type of experience.

- Knowledge of operating a Windows PC based operating system including mouse and keyboard.
- Users of the M12RT Telemetry Transmitter and M12A Telemetry Central Station are physicians, or clinical technicians and staff who are under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm, and arrhythmia.
- For users performing subject hookup of the M12RT Telemetry Transmitter, they shall have experience on how to properly perform an ECG electrode preparation for a patient.
- For users performing maintenance operations on the software, database, and data files should have previous experience in those specific operations.

Lay-User Group

The lay-user group consists of patients who are prescribed to undergo real-time ECG monitoring using the M12 Telemetry System. The patient is required to wear the M12RT Transmitter for several hours to multiple days to accommodate a monitoring period sufficient to provide an adequate duration of ECG data based on the direction of the overseeing healthcare provider.

4.8 System Description

The GI M12 Telemetry System is comprised of the M12A Telemetry Central Station and the M12RT Telemetry Transmitter. Optional M12A Review/Admin Stations, M12A Telemetry Repeaters and server can be added based on facility needs.

The M12A Telemetry Central Station can perform telemetry monitoring using the M12RT Telemetry Transmitter integrated with a wireless network infrastructure installed in the healthcare organization's facility.

The systems intended functions include:

- Real-time 10-wire (12-lead) ECG signal display
- Real-time analysis program runs on three selectable ECG channels
- Automatic monitoring of arrhythmias including display of a single-channel waveform for each patient
- Visual and audible alarms of events, arrhythmias, and set parameters with adjustable priorities
- Graphical trend review
- 12-lead ECG report printing with selectable rhythm strip
- ECG signal data storage with full-disclosure storage and appraisal

Through telemetry, patients using transmitters are monitored while moving in a designated area. To guarantee proper signal transmission in various situations, install an antenna network as per facility requirements.

M12A Telemetry Central Stations may be set up in a variety of system configurations to support the acquisition and storage of real-time patient monitoring data.

Optional data storage is available for on or off premise storage. This increases storage capacity as well as allowing storage to duplicate data disks when continuous and complete ECG capture is critical. This is valuable for institutions that collect ECG data for research purposes. This capability may also be important for other medical facilities.

Networked printers are used for automatic or manual printouts of 12-lead ECG, ECG rhythm, and reports.

The M12A Telemetry Central Station provides the means for users to manage patient records with associated patient demographics and assign each to a particular M12R Telemetry Transmitter for obtaining cardiac physiological information. Physiological data obtained from the telemetry devices are viewable and stored continuously for up to 96 hours.

Alarm monitoring and management, including definition of alarm limits, as well as data trending and reporting are available. Full disclosure supports review of the data on a particular patient including review of 12-lead ECG waveforms and other data and waveforms for obtained parameters.

M12 Telemetry System Central Monitoring Overview

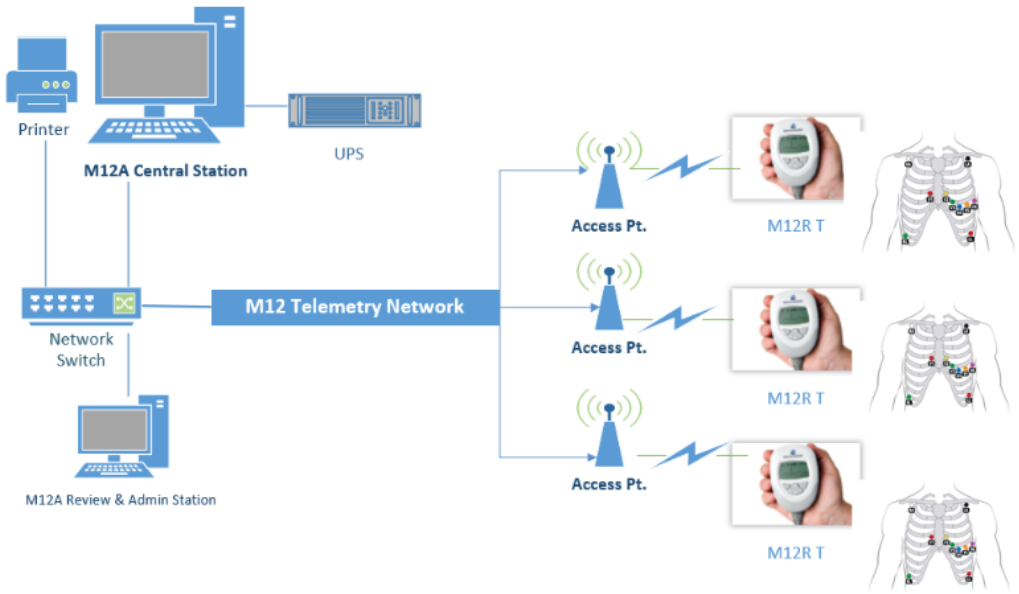


Figure 1 – M12A Telemetry Central Station configuration with wireless telemetry and M12RT Telemetry Transmitters.

CAUTION: All M12 Telemetry System hardware and screen representations shown in these instructions for use are examples only. Actual product or screens may differ slightly.

NOTE: The M12A Telemetry Central Station is not intended for use in the patient's vicinity.

M12A Review & Admin Station

The M12A Review & Admin Station is software run on a pc workstation that provides the following functionality in support of telemetry patient monitoring:

- Configuration of telemetry monitoring parameters for the central station including alarm configuration
- Creating and saving monitoring protocols
- Creating new patient listings with demographic information
- Uploading of SD Card data from the M12RT Telemetry Transmitter following the completion of a monitoring session
- Supporting various administrative tasks such as user management, device management, report configuration, and report archival
- Trends and alarm review for a monitoring session under acquisition
- Viewing and printing telemetry monitoring reports following the completion of a monitoring session.

The M12A Review & Admin software is run on a dedicated workstation connected to the M12 Telemetry Network or to the healthcare delivery organization's wireless network through a firewall router. Multiple M12A Review and Admin stations can be configured to meet the needs of an organization.

12A Central Station – Watchdog Device

The M12A Telemetry Central Station is intended for continuous use. An internal software Watchdog functionality emits a loud and continuous audible alarm in case of system failure.

Display

Each M12A Telemetry Central Station or M12A Telemetry Repeater Station can be equipped with up to four external displays. For display specifications, see ***Section 20 - Technical Specifications*** in this manual.

Mouse and Keyboard

The mouse can be used to select a screen element by moving the cursor on the element and then clicking on it. A keyboard is used to type text into a data entry field.

M12A Telemetry Central Station –Speakers

The M12A Telemetry Central Station computer uses internal speakers to produce audible alarms. See ***Section 20 Technical Specifications*** in this manual.

Optional System Components

- **M12A Telemetry Repeater Station:** A display station where monitoring channels are repeated and can be displayed, printed, and reviewed. Alarms are visual only and are not audible. Alarm control is managed at the M12A Telemetry Central Station. The M12A Telemetry Repeater station is used to extend the view of patient monitoring information within a facility to enhance workflow.
- **Additional data storage:** Stores real-time data and simultaneously copies the data to a set of Redundant Array of Independent Disks (RAID) for increased storage capacity and data security in situations where complete data collection is critical. All system data storage for M12A Telemetry Central Station workstations on the M12 Telemetry Network is performed at this networked server when it is a component of the M12 Telemetry System.
- **Network printer (print server):** The printer must be plugged into the AC power outlet through the appropriate power cord that is in compliance with local regulations. Please refer to the printer manufacturer's user manual for information, warnings, commands, and intended use.

M12 Telemetry Network

The M12 Telemetry network allows for the connection and exchange of data between the system components. Ethernet cable is used to connect all devices to the multi-port switch through an internal or external wall connection. All network devices are outside of the patient area.

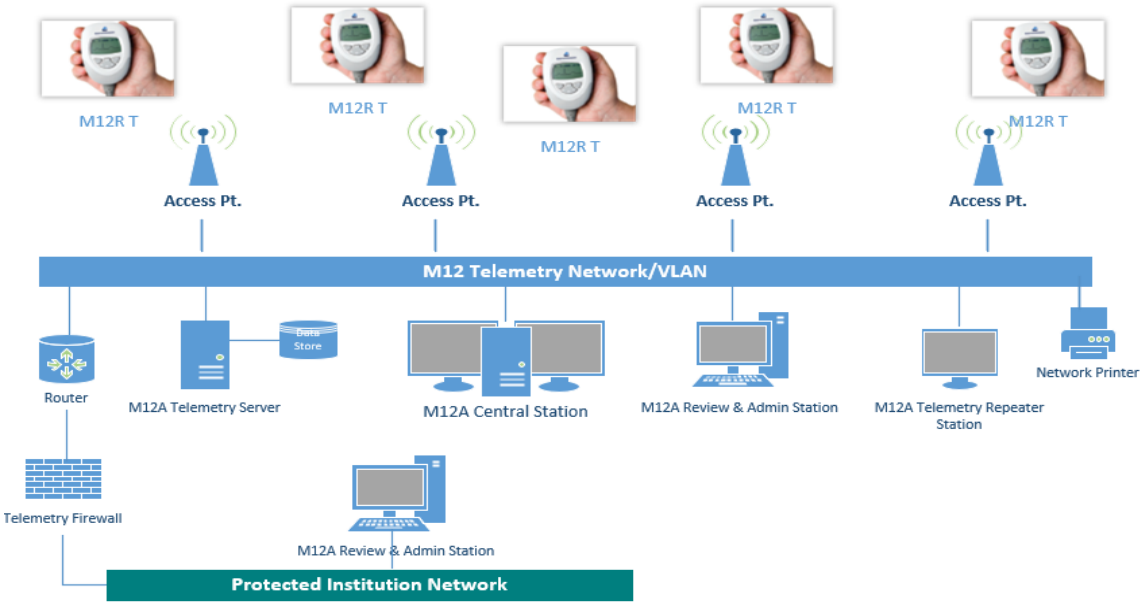


Figure 2 – M12 Telemetry System

The M12 Telemetry Network's router and firewall is used to isolate the system from the institution network. A secure firewall router is used for any M12A Review & Admin Stations that are located outside of the M12 Telemetry Network. Other applications that access M12A Telemetry Central Station data such as the M12A Enterprise Software Application for Holter analysis are networked in this way.

The M12A Telemetry Repeater Station is installed within the M12 Telemetry Network and does not allow user access to any other Microsoft® Windows® programs. It will automatically start when the M12A Telemetry Central Station is started, the same as any other dedicated node on the system.

M12A Telemetry Central Station Connections

See ***Section 20 - Technical Specifications*** for specifications on the M12A Telemetry Central Station workstation.

Peripheral Workstation Component Interconnect

NOTE: Hardware and connections shown below are subject to change.

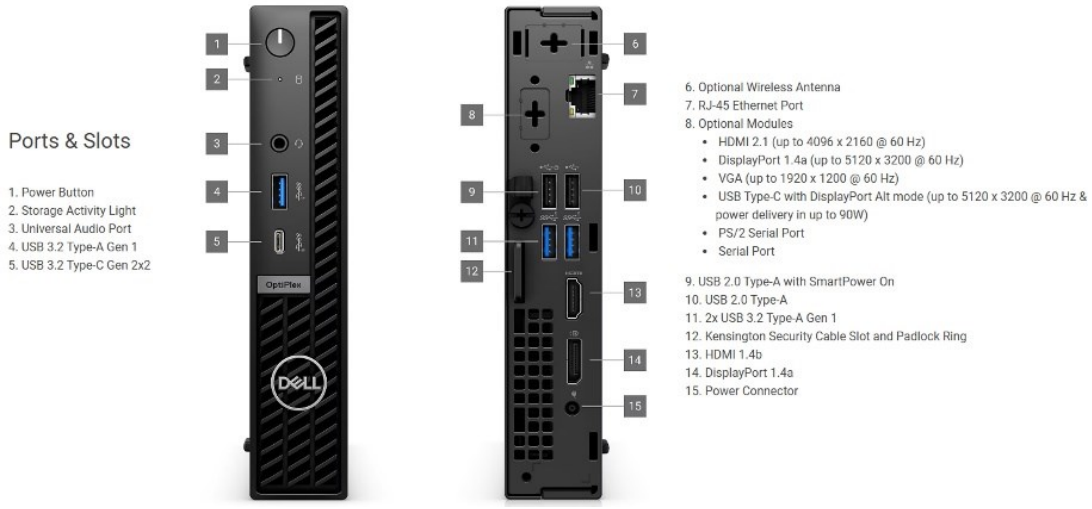


Figure 3 – M12A Telemetry Central Station PC

WARNING: Always make sure the system is turned off before connecting or disconnecting any cable.

Installation and Connections

Installation must be carried out by a Global Instrumentation, LLC authorized service representative in possession of current service and installation documentation. The M12A Telemetry Central Station requires specific settings based on the number and configuration of transmitters, the network layout, the type of printer, etc., as well as user preferences. The network printer requires specific settings and an installation driver. A package of cables, adapters, wire wraps, and labels are included with the system. Ensure these are available to installation personnel who will connect all accessories safely and in compliance with EMC and local safety requirements. Performing maintenance operations on the software, database, and data files should only be conducted by Global Instrumentation technical support personnel in collaboration with the clinical facilities IT/technical staff. Refer to ***Section 25 – Maintenance & Service***.

SECTION 5 - M12RT TELEMETRY TRANSMITTER

5.1 M12RT Telemetry Transmitter Description

The M12RT is a battery-operated patient worn transceiver that operates within IEEE 802.11 Wi-Fi technology, which utilizes the M12A Telemetry Central Station as the primary monitoring display and alarm source.

The M12RT Telemetry Transmitter has a color display allowing for operational conveniences such as a battery level indicator, Wi-Fi signal strength and M12A Telemetry Central Station slot information. While in normal operation, the display can show ECG waveforms, demographic data and other status information.

Figure 4 – M12RT Telemetry Transmitter

5.2 Transmitter Overview

The M12RT Telemetry Transmitter provides a means to acquire and transmit simultaneous ECG data to a M12A Telemetry Central Station monitoring system while allowing the patient to be ambulatory within the range of the wireless network.

The M12RT uses two (2) AA alkaline batteries. A new set of AA batteries is used for each patient monitoring session.

The following equipment is necessary to use the M12RT:

- Two (2) AA alkaline or lithium disposable batteries
- GI SD Card
- M12RT Patient Cable
- M12R Carrying Case
- Electrodes (compliant to ANSI/AAMI EC 12 standards)

- M12A Telemetry Central Station Monitoring System (including: M12A Review & Admin Workstation and GI specified 802.11 wireless access points and network infrastructure.

5.3 Available Configurations

The M12RT is offered in a 10-lead wire ECG configuration.

5.4 Operating Controls and Indicators

The operating controls and indicators of the M12RT are shown in the following diagrams:

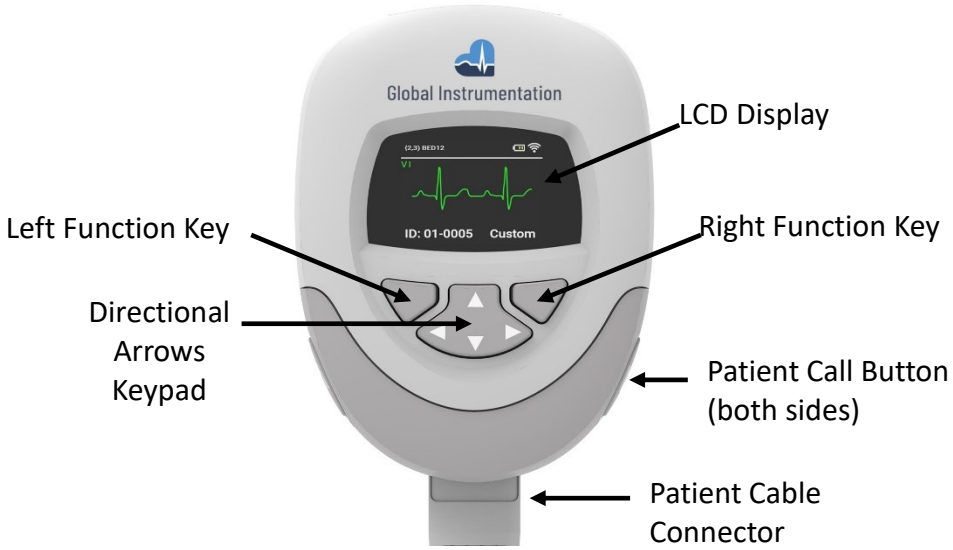


Figure 5 – M2RT Primary Display View

M12RT Front Button Pad

The front button pad is used for the following:

- Left Function Key – press to wake up the LCD display if in sleep mode. Will open the primary display view. Press again to place the display in sleep mode.
- Right Function Key – press to wake up the display if in sleep mode. Will open the secondary display view. Press again to place the display in sleep mode.
- Directional Arrow Keys
  - In Primary View: Up/Down arrow keys allows scrolling to view each ECG waveform
  - In Secondary View: Left/Right arrow keys allows scrolling of secondary data screens

Patient Call Button

The patient call buttons allow the patient to send an alert to the M12A Telemetry Central Station to request attention from a clinical staff member. This alert will appear in the patient-associated tile on the M12A Telemetry Central Station display. To initiate the alert the patient must press both buttons simultaneously. A short beep will emit from the device.

M12RT Primary Display View

The M12RT primary display view will appear when the transmitter is activated.

Information shown in this view include:

- Patient ID number
- ECG waveform
- ECG lead indicator (V1 shown)
- Battery level indicator
- WIFI icon with signal strength
- Error code field
- Central station slot designator
- Custom field (optional)

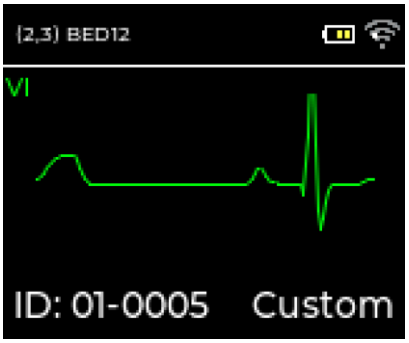
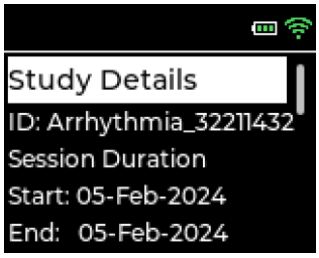


Figure 6 – M2RT Primary Display View

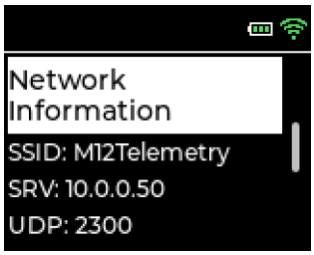
NOTE: The display on the M12RT will go into sleep mode and go blank after 5 minutes of last activity to preserve battery power. Press the left function key to activate the display.

M12RT Secondary Display View

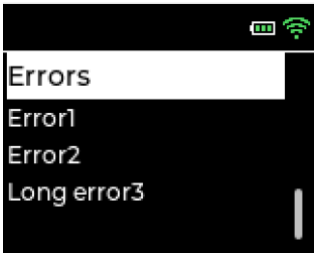
Pressing the right function key will bring up the secondary display view on the M12RT. The views available include:



Study/Protocol Information



Network Information



Error Code

Figure 7 – M2RT Secondary Display Views

5.5 M12RT Back View & Information

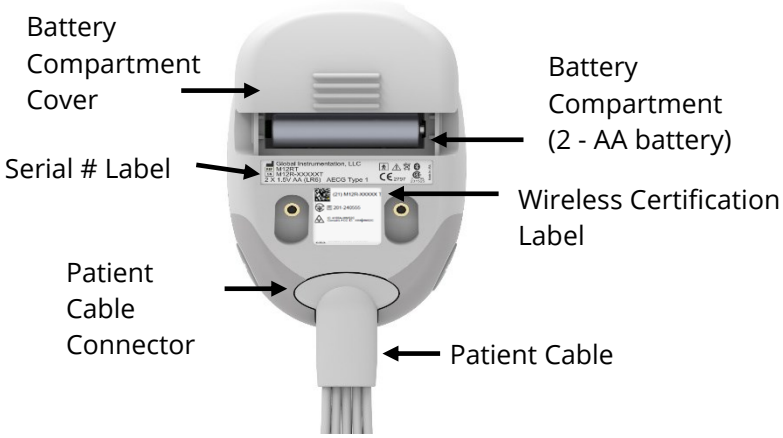


Figure 8 – M12RT Back View

Back Label

The label on the rear of the transmitter provides device model number and serial number.

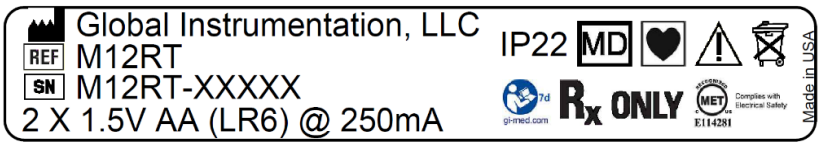


Figure 9 – Serial # Label

5.6 SD Card & Batteries

A Global Instrumentation SD Card and a fresh set of AA batteries are utilized in every monitoring session.

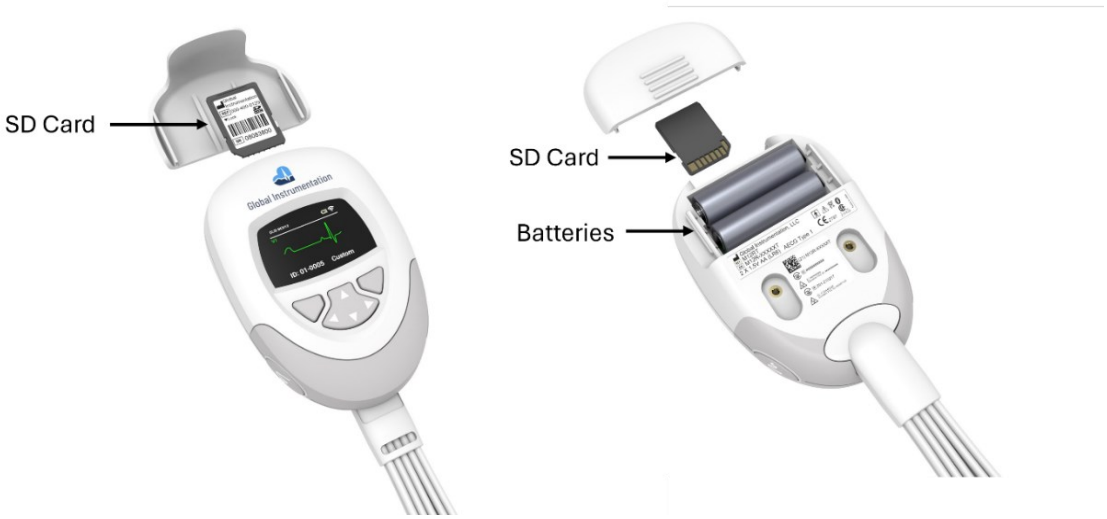


Figure 10 – SD Card & Battery

SD Card Use

A Global Instrumentation SD Card is configured via the M12A Telemetry Central Station and inserted in the M12RT for every monitoring session. The configuration of the SD card contains the patient's demographic data and parameters for monitoring. During the recording period, the SD card will store the patient's ECG signals in memory.

- Each SD Card is individually serialized.
- The card is reusable, and an existing data set may be over-written if permission is allowed.

At the conclusion of the monitoring session the data in the SD Card will be uploaded to the M12A Review & Admin Station to serve as a supplemental source of patient ECG data.

NOTE: At the start of a new monitoring session, **you must insert the SD Card into the M12RT Telemetry Transmitter before inserting the batteries.**

Battery Use

The M12RT Telemetry Transmitter uses two AA batteries for power. A fresh set of batteries is required at the start of each monitoring session and will need to be replaced one or more times depending on the monitoring session duration. A typical set of new AA batteries will last approximately 24 hours during monitoring.

Battery Compartment – Security Cover

A battery compartment security cover is provided. The cover fits over the M12RT Transmitter battery cover and is secured in place using two screws (provided). This cover is used to prevent access to the battery compartment by patients and untrained personnel and prevent accidental removal of the batteries.

Figure 11 – M12 Telemetry Transmitter Battery Compartment Security Cover

Attach the security cover following activation of the device. The cover will need to be removed when inserting new batteries into the transmitter.

5.7 Hot Swap Battery Function

The M12RT contains a permanent internal back up battery to provide continued power to the transmitter when the AA batteries become depleted. This allows the M12RT to continue real-time monitoring for a short duration while the AA batteries are being replaced. The internal lithium battery is used to power the device during battery hot swap period. See ***Section – 9.2 Replacing Batteries During a Monitoring Session*** for more information on battery replacement.

5.8 M12R Carrying Case

WARNING: The M12RT is not intended to be worn directly against the patients' skin, but rather should be worn outside the patient's garments, and within the carrying case.

A reusable nylon carrying case is offered for use with the M12RT Telemetry Transmitter. The case is designed to fit the contours of the M12RT and accommodate extended wearing of the device while the patient is ambulatory or stationary.

The carrying case comes with a belt and a shoulder strap which can be used together or individually. The placement of the case is at waist level with the patient cable then placed under the bottom edge of the patient's shirt or scrub top.

Figure 12 – M12RT Carrying Case

The carrying case features a clear vinyl cover to allow view of the LCD display and the sides of the case are accessible for the patient to access the patient call buttons.

5.9 M12RT Telemetry Transmitter Patient Cables

The M12RT Transmitter is utilized with a lightweight 10 lead patient cables that utilizes standard ECG snap electrodes. The patient cable conforms to the AAMI/AHA standard. The patient cable is user replaceable.

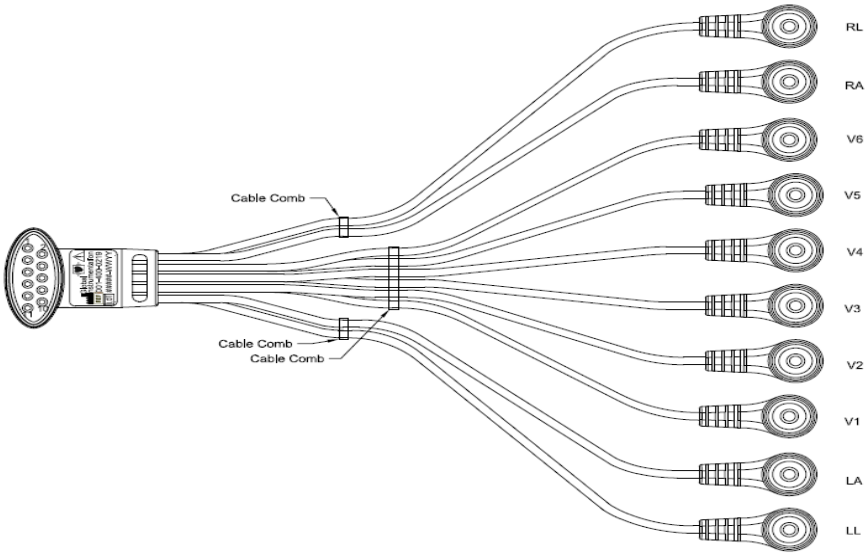


Figure 13 – M12RT 10 Lead Patient Cable

5.10 M12RT Accessories & Spare Parts

Item	Part Number
M12RT Telemetry Transmitter (no accessories/spare parts included)	001-400-0217
M12RT Telemetry Transmitter System Kit; includes: M12RT Telemetry Transmitter, 1 GI SD Card (000-400-0129), 10-Lead Cable AHA – 36 inch (#001-400-0219), carrying case - with belt and shoulder strap (#001-400-0224)	001-400-0226
M12RT Telemetry Transmitter System Kit; includes: M12RT Telemetry Transmitter, 1 GI SD Card (000-400-0129), 10-Lead Cable AHA – 24 inch (#001-400-0221), carrying case - with belt and shoulder strap (#001-400-0224)	001-400-0227
M12RT, 10 Lead Patient Cable – 36 inch (AHA - Defib)	001-400-0218
M12RT, 10-Lead Patient Cable – 24 inch (AHA - Defib)	001-400-0219
GI SD Card (with Bar Code & Serial Number)	000-400-0129
M12R Carrying Case (with belt & shoulder strap)	001-400-0027

SECTION 6 - PATIENT PREPARATION FOR ECG HOOK-UP

6.1 Quality ECG Data Acquisition

Obtaining quality ECG data is important in continuous ECG monitoring. A quality ECG signal depends largely on the patient prep and electrode placement. Good contact between the electrodes and the patient's skin and correct placement of the electrode can help ensure obtaining quality ECG data.

A good quality ECG contains:

- Clearly discernible P waves, QRS complexes, and T waves.
- Steady, even, crisp baseline.
- Absent of respiratory variability, artifact, noise, and other interference.

A good quality ECG may enhance the performance of the arrhythmia algorithm and may lessen false erroneous alarm notifications.

A poor-quality ECG may be caused by many factors:

- Poor site preparation.
- Poor electrode application or failure to refresh electrodes regularly.
- Patient movement.
- Interference by other equipment in the room.
- Poor quality ECG becomes synonymous with artifact and interference in the ECG waveforms.

A poor-quality ECG may manifest itself in several ways:

- Fast baseline artifact.
- Erratic baseline.
- Sharp “spikes.”
- Rolling, wandering waveforms as seen with patient breathing patterns.
- Difficult to discern P waves or atrial fib waves from noise.
- Inability to discern P waves, QRS complexes, T waves.

Artifact and interference in the ECG waveforms may be caused by using accessories, lead wires, and ECG cables other than those specified to work with the M12RT. Always use accessories, lead wires, ECG cables, and other accessories specified to work with the M12RT.

6.2 Skin Preparation

Skin preparation is essential to perform before electrode attachment to ensure good signal quality when recording patient data. Poor skin-to-electrode contact may cause noise to be included in the recording or loss of signal which can affect the analysis of the ECG data. Low amplitude signals may also be the result of poor skin-to-electrode contact.

To prepare the skin:

1. Determine where electrodes will be placed on the torso (refer to ***Section 6.3 - Electrode Placement***).
2. Remove any hair from the area where electrode(s) will be placed using a razor or shaver.
3. The electrode application site should be clean and dry. The preferred method of cleaning is with soap and water plus drying the skin with a dry cloth or gauze.
4. Attach the electrodes to the lead wires before attaching them to patient.
5. Do not apply any lotions or creams after cleaning the body area for electrode application.

NOTE: Cleaning the skin with isopropyl alcohol should be avoided or limited to situations in which electrode adhesion is an issue (diaphoresis, excessively oily or lotion-covered skin), since it may dehydrate the skin, thus causing skin impedance to increase.

IMPORTANT: Ensure skin is completely dry before electrode application.

6.3 Electrode Placement

To apply electrodes:

1. Use pre-gelled, Ag/AgCl disposable electrodes.
    a. Do not use electrodes after their expiration date, or if the gel has dried out.
        - Store electrodes in an airtight container.
        - Electrodes dry out if not stored properly leading to loss of adhesion and conductivity.
    b. Always use the same electrodes. Do not mix electrode brands or types. Using different types of electrodes may cause baseline artifact and noise in the ECG tracing.
2. Apply the electrodes in the following manner:

a. Attach the electrode to the ECG lead wires prior to attaching the electrode to the patient's chest.
b. Place the electrode in the properly prepared, correct location.
c. Gently press the electrode adhesive to the patient's skin until the entire outer surface of the electrode is adhered to the patient's chest.
d. Once the electrode adhesive is attached, gently press the gel area to ensure proper gel to chest contact. Avoid dislodging the gel as the displaced gel can increase baseline artifact and noise in the ECG tracing.
e. Test for firm electrode contact by slightly tugging on the electrode to check for adhesion amount the entire electrode surface. If the electrode moves freely, change the electrode. If the electrode does not move easily, a good adhesion contact has been obtained.
f. Connect the 10 lead snap connectors on the M12RT Patient Cable to the appropriate electrodes. All cable lead snap connectors are labeled with lead designators.

Refer to the Electrode Location section below for guidance on the anatomical landmarks on the chest for electrode placement.

NOTE: You have the discretion to connect the M12RT Patient Cable prior to the M12RT Telemetry Transmitter being configured for use or hold the attachment of the cable until the transmitter is ready to activate and use with the patient.

Pacemaker Patients

The M12RT contains special circuitry to detect pacemaker spikes. The spike detection points are transmitted with the ECG samples to the M12A Telemetry Central Station for processing. Refer to ***Section 9 – Conducting Telemetry Patient Monitoring*** for instruction on enabling pacer detection.

6.4 Electrode Location

10-Lead Placement (Reference Only)

AHA Lead	AHA Color	IEC Lead	IEC Color	Placement
RA	White	R	Red	Under the right clavicle, mid-clavicular line within the rib cage frame
LA	Black	L	Yellow	Under the left clavicle, mid-clavicular line within the rib cage frame
LL	Red	F	Green	Lower side of left ribcage as close to hip as possible

V1	Red	C1	Red	4th intercostal (IC) space at right border of sternum
V2	Yellow	C2	Yellow	4th IC space at left border of sternum
V3	Green	C3	Green	Midway between V2 and V4
V4	Blue	C4	Brown	5th IC space on left mid-clavicular line
V5	Orange	C5	Black	Left anterior axillary line at the horizontal level of V4
V6	Violet	C6	Violet	Left mid-axillary line at the horizontal level of V4
RL	Green	N	Black	Reference or ground lead. Electrode should be placed in a stable location on the body. Lower side of right rib cage recommended.

NOTE: All cable lead snap connectors are labeled with lead a designator. AHA cable V lead connectors have brown coloring. IEC cable V lead connectors have white coloring.

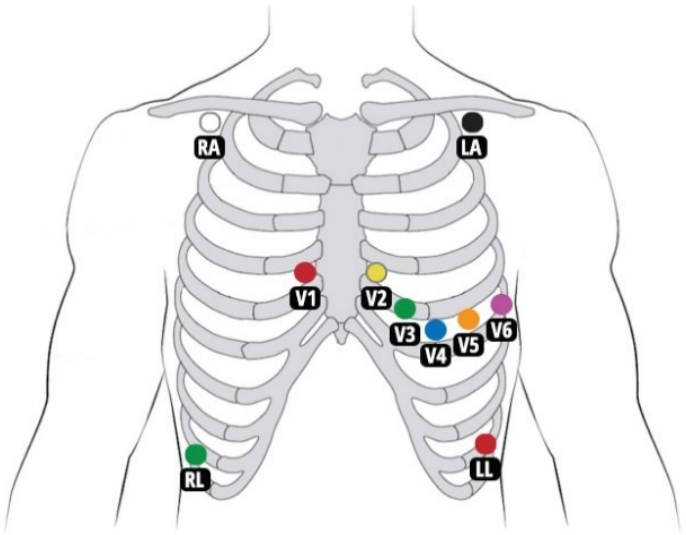


Figure 14 – 10-Lead (AHA) Placement

6.5 Checking ECG Electrode and Lead Wire Signal Quality

Following patient hook-up and activation of the M12RT Telemetry Transmitter, the LCD window of the M12RT will display the patient's ECG tracings.

Check to ensure the ECG tracing is free of artifact and noise with a clean ECG baseline as patient condition permits. If the ECG contains artifact or noise, review the steps for proper electrode site preparation and placement and repeat these steps to obtain proper ECG signals.

6.6 General Wearing Instructions to Provide the Patient

CAUTION: The M12RT Telemetry Transmitter is not waterproof. Do not shower, bathe, or while wearing the M12RT Telemetry Transmitter.

CAUTION: Instruct patients to avoid activities or environments that result in excessive perspiration, as this may result in loss of skin contact by the electrode and result in a decreased period of recording.

1. The patient should not remove the electrodes unless skin irritation or an allergic reaction develops.
2. The patient should not disconnect the patient cable from the device or disconnect lead wires from the electrodes.
3. The patient should keep the M12RT dry and not expose the device to water or fluids via bathing, showering or when handling liquids.
4. The patient should push both of the patient call buttons simultaneously if requiring attention by a clinical team staff member. This action is referred to as using the patient call button. After activating the patient call button, the following will occur:
    a. A patient call alert will be sent to the M12A Telemetry Central Station and a patient call technical alarm will be registered at the central station.
    b. Instruct the patient that following the patient call button press a clinical staff member will come to assist them on a timely basis.

6.7 Completion of Monitoring Session

CAUTION: When handling a Transmitter that has been worn by a patient use appropriate handling procedures (e.g. gloved hands).

1. Disconnect the Patient Cable electrode snaps from the electrodes on the patient's body.
2. Remove the pouch from the patient w/ the M12RT Telemetry Transmitter and patient cable.
3. Remove the electrodes from the patient by gently lifting the edge of the electrode and slowly peeling the electrode from the patient's skin.
4. NOTE: It is recommended to use petroleum jelly, baby oil, or an adhesive removal wipe between the skin and electrode to ease removal (example Uni-Solve Adhesive Remover Wipes; # 402300; manufactured by Smith & Nephew).
5. Discard the electrodes according to local regulations. The M12RT Telemetry Transmitter SD card contains the patient's ECG recording and will be used in a subsequent step.

6. Remove the battery and SD card from the transmitter. Data on the SD card will be uploaded to the M12A Telemetry Central Station to provide a backup source of the patient's ECG data. Refer to ***Section 10 SD - Card Upload***.

NOTE: Handle the SD card carefully and ensure the SD card data upload is completed promptly following removal from the M12RT Telemetry Transmitter

SECTION 7 - USING THE M12A TELEMETRY CENTRAL STATION - OVERVIEW

7.1 Turning on the M12A Telemetry Central Station Workstation

NOTE: The M12A Telemetry Central Station is intended to always be kept powered on and running during use. The content below is only for use if the central station is powered down.

NOTE: Should the mains (AC) power supply to the M12 Telemetry System be interrupted, the M12A Central Station will display the technical alarm – UPS ACTIVE, to indicate the central station is operating from the uninterruptible power supply (UPS).

The ON/OFF switch is located on the front side of the CPU. When the switch is depressed, the workstation will power on. To turn on the display screen, locate the main switch (usually on the bottom border of the screen).

Access to certain features and tasks in the M12A Telemetry Central Station may require entry of credentials including username and password.

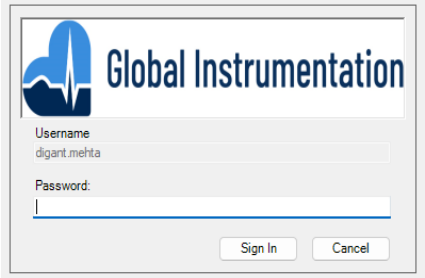


Figure 15 – M12A Telemetry Central Station Login Screen

Login credentials and access permissions for various functions of the M12A Telemetry Central Station and M12A Review and Admin station are controlled and managed in the M12A Review and Admin application.

Additionally, entry of credentials will be required when changing the settings of an actively monitored patient and other activities affecting the monitoring session.

NOTE: The login procedure described above is also used to log into the M12A Review & Admin Station.

NOTE: The power-up sequence takes several minutes and then the main display appears.

Central Station: Multi-Patient Display Screen

The M12A Central screen is divided into sub-screens, each showing a single patient. This screen is called the “multi-patient display”. An example is shown in Figure 17. In the multi-patient display, the entire screen displays real-time status of all connected

patients including waveforms sent from telemetry transmitters. A maximum of 16 patients can be assigned to one display monitor.

Figure 16 – M12A Telemetry Central Station multi-patient screen

NOTE: Normally, the waveform traces are drawn smoothly and continuously. Occasionally, you may observe a brief halt followed by the waveform catching up. This is usually due to momentary communication delays through the network between the M12A Central and the transmitters. The system is designed to work through such delays without data loss. However, if this occurs frequently, contact your network administrator or Global Instrumentation to check the condition of the network.

Moving the Cursor

The on-screen arrow is the mouse cursor used to activate all functions. For example, if you want to acknowledge and silence an alarm, move the cursor with the mouse over the alarm reset icon (only visible if there is an alarm present) and click left the mouse button.

7.2 Multi-Patient Display Detailed View

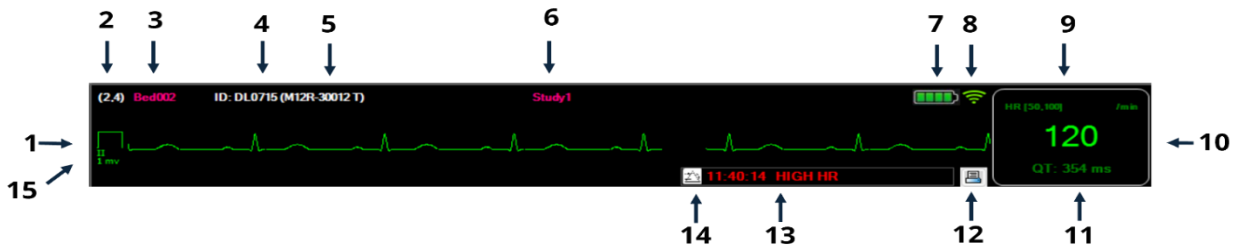


Figure 17 - Detailed view of an individual patient tile within the multi-patient

Multi-Patient Tile Elements

Item	Description	Detail
1	ECG Waveform	5 seconds of waveform data
2	CS Slot	Central station slot ID (column, row)
3	Telemetry Location	Telemetry location designation assigned to patient
4	Subject ID	Patient ID number configured during setup
5	Device Serial #	Serial number of M12RT
6	Protocol ID	Name/number of monitoring protocol assigned to patient
7	Battery Level Icon	Displays power level of M12RT battery
8	Wireless Signal	Signal strength of wireless connection between M12RT and central station
9	HR Thresholds	The high and low heart rate thresholds set for the patient
10	Heart Rate	Patient heart rate
11	QT Interval	Average QT segment interval (ms) of displayed ECG
12	Print Icon	Mouse click initiates print out of 12-lead ECG report (10 seconds prior to click)
13	Alarm/Event Message	Alarm or Event designation. color will vary based on type of alarm
14	Alarm Acknowledge Control Symbol	Used to acknowledge alarm and silence audible alarm signal
15	ECG Lead Name and Gain Setting	Selectable ECG lead view. Gain setting configurable for x.25, x.5, x1, x2, x4 scaling factor with calibration mark set to 1 millivolt. Sweep speed is fixed at 25 mm/seconds.

Heart Rate Range Exceeded

Should the heart rate of the patient exceed the measurement limits of the system, the following symbols will be shown in place of the heart rate reading.

Figure 18 – Heart Rate Limits Exceeded

The up arrows indicate the upper heart rate range of 300 bpm has been exceeded. The down arrows indicate the heart rate has dropped below the limit of 20 bpm.

7.3 Single-Patient Display View

A mouse double-click anywhere on a patient's tile reduces the multi-patient display to half width and opens the selected patient-related information on the right half of the screen in the Traces view. A heavier white outline will appear around the smaller view on the left.

Patient-related functions will be explained later in this manual. Click on Close to return to the multi-patient display screen.

Figure 19 – Expanded Single-Patient View

Single-Patient Display Fields

When a patient is selected and opened, there are 5 fields that can be used for review. All fields contain information for the selected patient. If another patient is selected, the information in the fields will change to that of the selected patient. Physical location and central station slot designations are displayed above the fields.

NOTE: The Patient Data field is not available at the M12A Telemetry Repeater Station

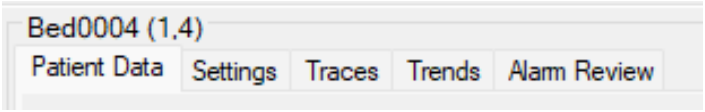


Figure 20 – Fields available in the single-patient display.

Patient Data Field

The patient data field provides a view of subject demographic information configured for the patient.

This field supports:

- View subject demographic information entered for the patient
- Allows entry of a patient related note. The note will appear under the “Note” column of the Inbox and open report.
- Allows start of monitoring session
- Allows ending of a monitoring session

- Allows pausing of alarms for a set time duration and cancelling of a pause. Refer to ***Section 13 Telemetry Monitoring Configuration*** for more information on pausing patient alarms.

Figure 21 – Patient Data field

Credential entry and authentication is required to end a monitoring session.

Settings Field

The Settings Field will provide a listing of the settings configured under the monitoring protocol established and assigned to this patient.

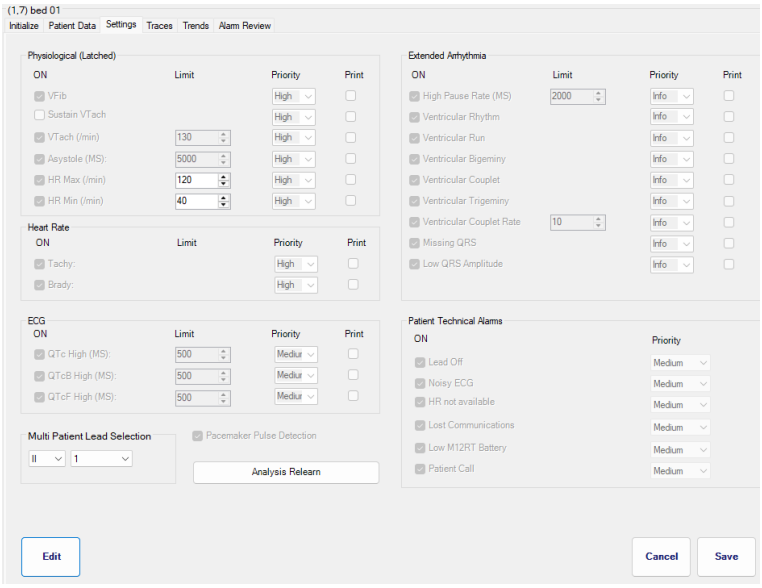


Figure 22 – Settings Field

The **Edit** button allows for the adjustment of selected settings for an actively monitored patient. Credential entry and authentication is required to change the settings for an actively monitored patient. Refer to ***Section 13 – Telemetry Monitoring Configuration.***

The Settings field in the single-patient view also supports the following ECG-related controls:

- **Multi-Patient Lead Selection:** this control allows the change of the patient's ECG lead that will be displayed in their multi-patient view tile.
- **Analysis Relearn:** In a case where the system incorrectly identifies the patient's normal beats, it may be necessary to relearn the rhythm. Click on the "Analysis Relearn" button to enable the analysis program to relearn the ECG rhythm profile.

Traces Field

The traces Field will display the real-time 12-lead ECG recording and associated parameters including heart rate and QT interval. Sweep speed is fixed at 25 mm/seconds.

Figure 23 – Traces

Tasks that can be performed in this view include:

- Printing of ECG report
- Acknowledging alarms
- Force a relearn of ECG analysis
- Save a 10 second safety ECG Report (save to Inbox)
- Save a 10 second ECG extraction (save to Inbox)

Trends Field

The trends field supports viewing of graphical trends for the heart rate and QT interval data with accompanying ECG waveforms for the patient.

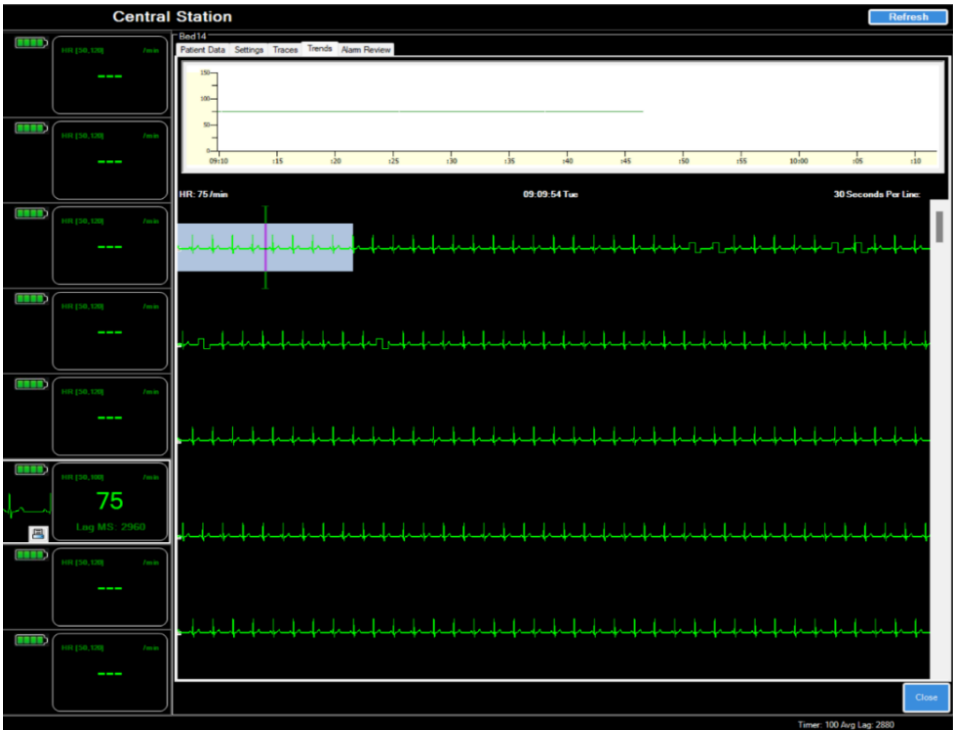


Figure 24 – Trends Field

Click on the drop-down menu at the bottom of the Traces field to select trend data options.

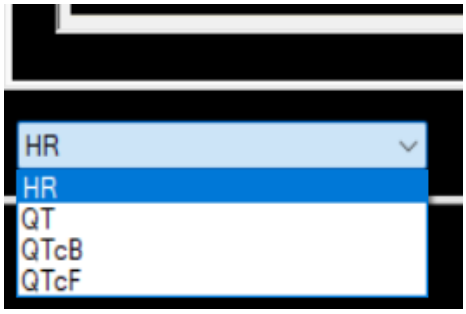


Figure 25 – Trend Selection Menu

Click on any time point in the upper trend graph to view the ECG waveform for that interval. The CG waveform view that corresponds to the alarm time will appear. This is selectable as:

- 3-lead ECG (7 seconds) of the three analysis leads
- 3-lead full disclosure view (30 seconds per line)
- 12 x1 lead view (10 seconds)

Double-click on the waveform to alternate between the formats listed above.

Alarm Review Field

Figure 26 – Alarm Review

This Field provides support for the following:

- Review physiological and technical alarms in order of occurrence. The most recent alarms will appear at the top.
  - Allows filtering by categories - physiological, technical, or all alarms
  - Filter by specific physiological alarm or technical alarm type (such as arrhythmia type)
- To navigate between the alarms listing you may:
  - Use your mouse scroll button to move up and down across the full listing of alarm.
  - Use your mouse to click on an alarm listing to view the waveform
  - The up & down arrow keys on your keyboard can also be used to move across and view each alarm waveform
- ECG waveform view that corresponds to the alarm time will appear. This is selectable as:
  - 3-lead ECG (7 seconds) of the three analysis leads
  - 3-lead full disclosure view (30 seconds per line)
  - 12 x1 lead view (10 seconds)

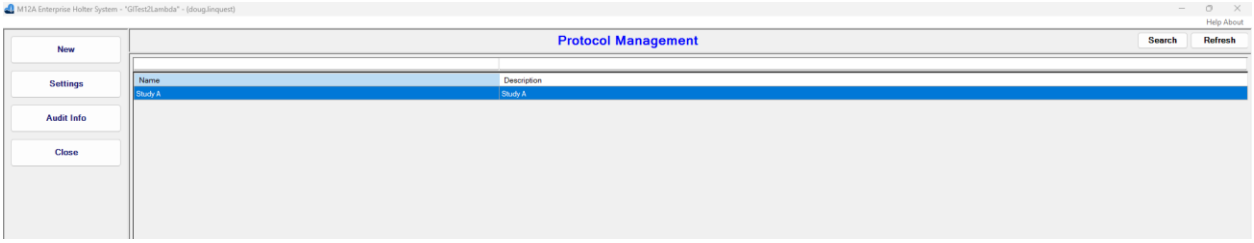
Double-click on the waveform to alternate between the formats listed above.
Click **Close** to return to the multi-patient display screen.

SECTION 8 - PROTOCOL MANAGEMENT

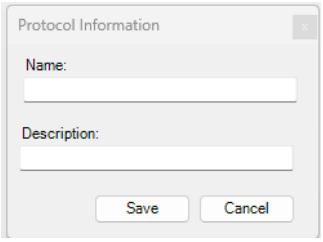
Protocol configuration and management is conducted at the M12A Review and Admin Station. New protocols are configured by selecting settings across the areas described below and saved. The global organizational telemetry monitoring parameters are the default basis of each new protocol with certain parameters being configurable.

When a new patient is being added for central monitoring at the M12A Telemetry Central Station, a protocol will be assigned to the patient.

Login credentials and access permissions to create and edit protocols within the M12A Review and Admin station are required.

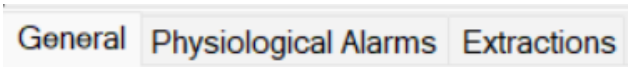


The **New** button will allow for creating the name and description of a new protocol.



The **Audit** button will open a screen providing a summary of all changes made by users to the highlighted protocol.

To configure or edit a protocol, click on the **Settings** button which will provide access to the specific settings under the categories:



8.1 General

The General settings field under Protocol Management allows for the selection of a color identifier to be assigned to a given protocol.

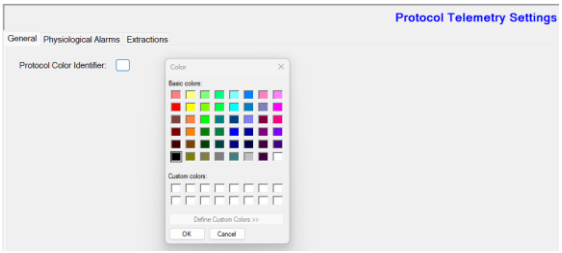


Figure 27 – Protocol Color Identifier

Click the “Ok” button to save your color selection.

The color that is chosen for the protocol will be matched to the protocol ID number and Telemetry Location field that appears in the patient tile of the central station under active monitoring. Refer to ***Section 7.2 - Multi-Patient Display Detailed View***.

8.2 Physiological Alarms

Alarms are generated for signals coming from the M12RT Telemetry Transmitter or from IT components of the telemetry system. Physiologic alarm settings are first configured on a default organizational basis (see ***Section 13 – Telemetry Monitoring Configuration***).

When starting a new patient on monitoring, the alarm limits, priorities, and printouts are automatically assigned to the patient based on the protocol settings.
For a specific protocol, certain alarms and parameters can be adjusted to match the needs of the protocol.

The alarms that can be adjusted are:

- Physiological Latched - HR Max and HR min limits
- Heart Rate - Tachy & Brady limits
- ECG – QTc High limits

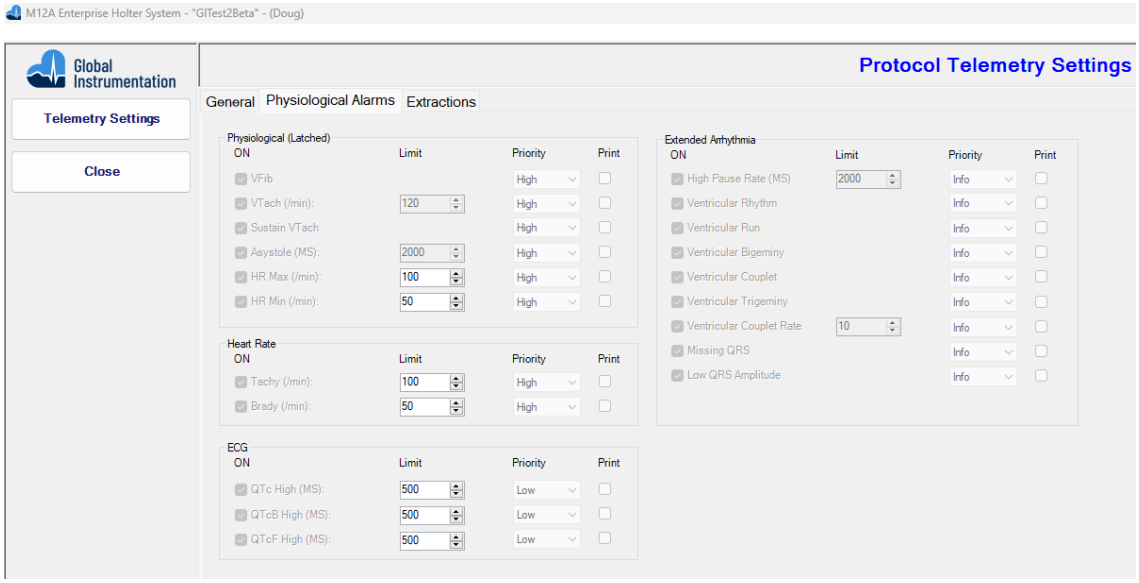


Figure 28 – The Physiologic Alarm Settings screen

Any changes to the three alarm areas listed above are made will be automatically saved once the “Close” button is clicked.

For a detailed description of alarm event criteria, refer to ***Section 12 – Alarm Details***.

NOTE: Alarm settings cannot be changed in an M12A Telemetry Repeater Station

WARNING: Adjust the alarm thresholds to patient conditions after monitoring has started. Incorrect alarm threshold settings are a frequent cause of false alarms and lower the attention level to the genuinely important alarms.

8.3 Subject Demographics

Refer to **Section 14.2 – Subject Demographics** for a description of custom fields that can be used to customize specific subject demographic elements for protocol use.

SECTION 9 - CONDUCTING TELEMETRY PATIENT MONITORING

9.1 Starting a Monitoring Session at the M12A Telemetry Central Station

The process of starting a monitoring session on a new patient is outlined below. The flow chart below provides an overview of the process with the assumption that a monitoring protocol has been created and available for use during initialization of the SD card.

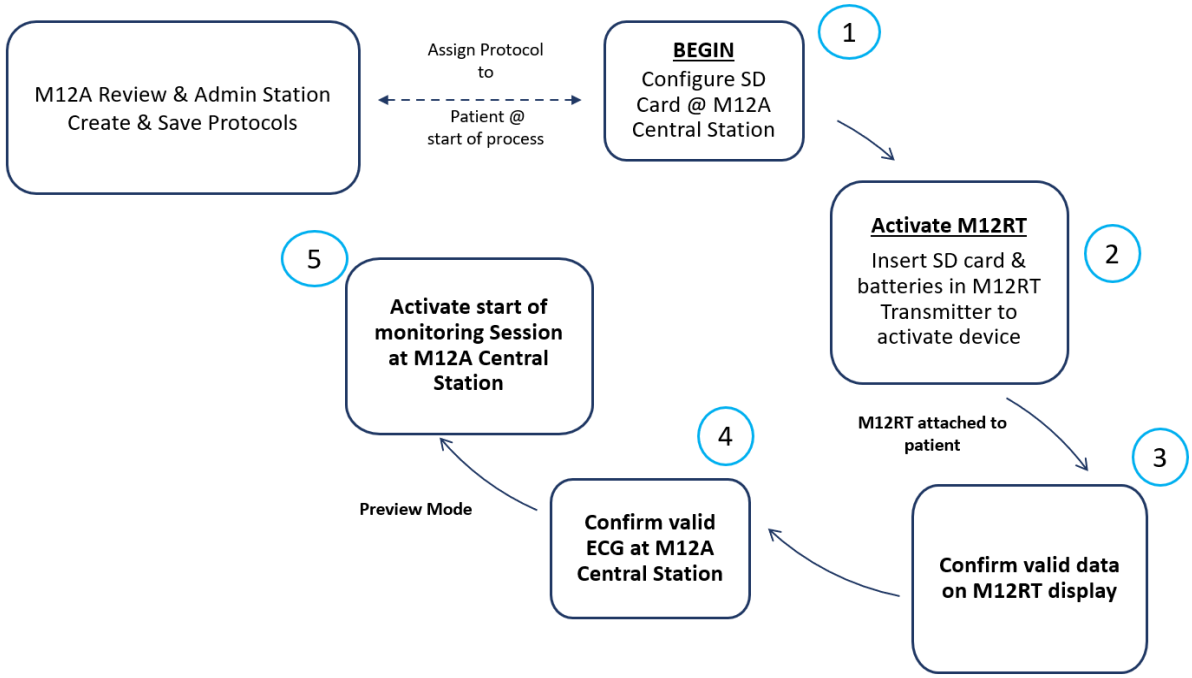


Figure 29 – Flowchart of starting a patient monitoring session

Follow the steps below to start a new patient monitoring session.

STEP 1 - Configuring the GI SD Card

Ensure the M12A Telemetry Central Station is powered ON and displays an available patient monitoring slot.

Have a GI SD Card inserted in SD card slot/reader of the computer.

Left double-click on an available patient tile window on the M12A Telemetry Central Station multi-patient view. The authentication window will appear. The user will enter the required credentials and click “Sign In”.

The single-patient display will open to the Initialize tab featuring a Monitoring Start Wizard.

The next step is to complete the subject demographics field.

1. **Enter Subject Demographics**

Search for an existing subject or enter in a new subject ID and associated demographic data.

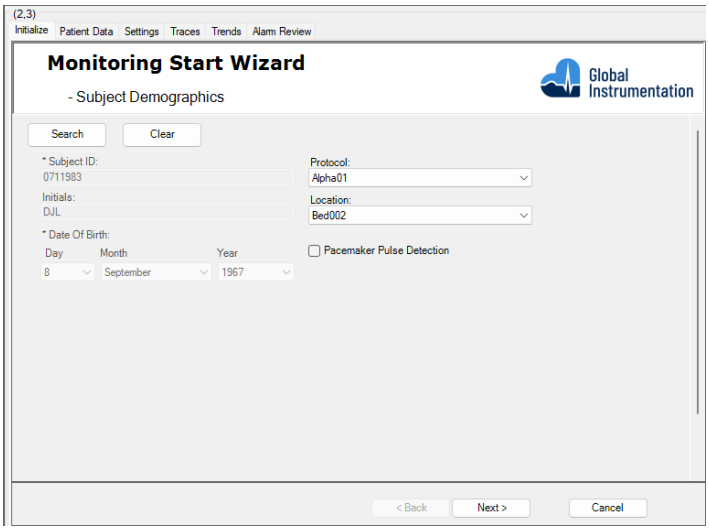


Figure 30 – Subject Demographics window

Select the Protocol (refer to ***Section 8 - Protocol Management***) you wish to associate with this subject.

Select the Location identifier (refer to ***Section 13.1 – General Settings***) you wish to associate with this subject.

Pacemaker Pulse Detection – if the patient being monitored has a pacemaker, check the Pacemaker Pulse Detection box to enable the pacemaker detection functionality.

Click **Next**.

2. **M12RT SD Card Configuration**

The **SD Card Configuration** window will appear.

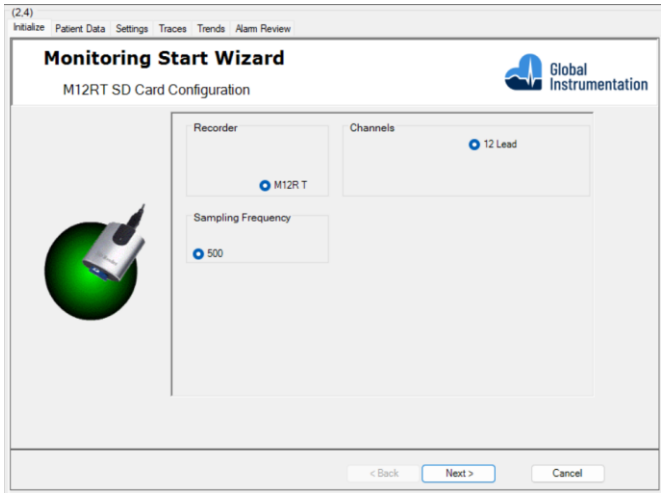


Figure 31 – SD Card Configuration window

This view will provide a summary of the M12RT configuration parameters for the monitoring session. Click **Next** to configure the SD card with the monitoring parameters and associated patient demographics.

If the M12A Telemetry Central Station application reads the SD card as having data in memory that has not been uploaded, the following message will appear.

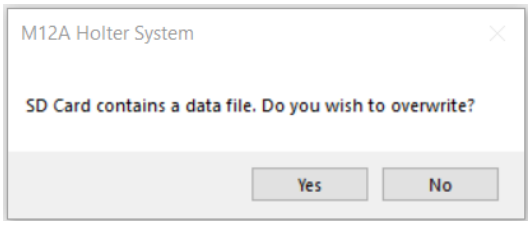


Figure 32 – SD Card Data Message

If you are unsure or concerned that the patient data file has not been previously uploaded and saved properly, stop, and exit the configuration process and re-attempt to upload. The M12A Telemetry Central Station application is configurable to control access to overwriting existing data on SD cards.

NOTE: All patient demographic and configuration information stored on the card is encrypted.

NOTE: If an SD card is not inserted or readable by the application, the card reader Icon will flash indicating the need to insert a card.

Figure 33 – Insert SD Card Alert Icon

Double-click on the icon to view the SD card path that is chosen and modify the choice for the correct path if necessary.

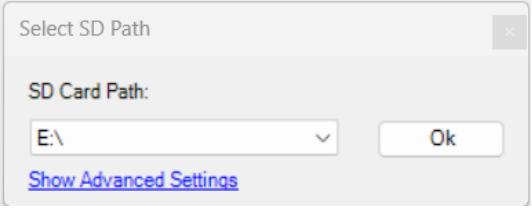


Figure 34– SD Card Path Selection

3. Complete SD Card Configuration

The final step in the Monitoring Start Wizard sequence is to remove the SD Card from the PC or SD card reader and proceed to enable the M12RT Telemetry Transmitter to activate.

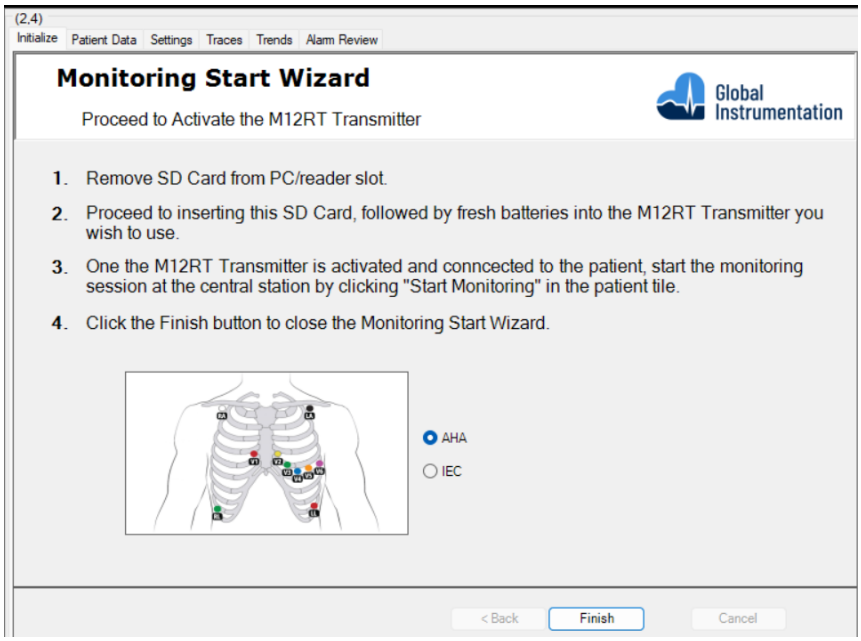


Figure 35 – Finish SD Card Configuration Window

You may proceed with activating the M12RT Telemetry Transmitter with you at the central station or at the patient's side.

The M12A Telemetry Central Station patient tile for the SD card you have just configured will now indicate "Waiting for M12RT". Proceed to activate the M12RT Telemetry Transmitter and hook up to the appropriate patient.

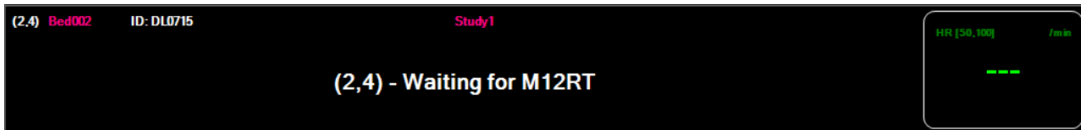


Figure 36 – Central Station Tile Prior to Transmitter Activation

STEP 2 – Activating the M12RT for Patient Monitoring

Following the completion of SD Card configuration, you should proceed to activate the M12RT Telemetry Transmitter for patient monitoring.

1. Prep the patient's skin and attach the monitoring electrodes and M12RT Patient Cable to the patient. Have a carrying pouch available for use. Refer to ***Section 6 – Patient Preparation for ECG Hookup***.
2. Connect the M12RT Telemetry Transmitter to the M12RT Patient Cable.

3. Remove the M12RT battery door and insert the SD Card into the transmitter with the label side of the SD Card facing forward and the beveled corner of the card on the lower left side. Gently press the SD Card into the slot until it clicks into place.

   NOTE: You must insert the SD Card into the M12RT Telemetry Transmitter **BEFORE** inserting the batteries.

Figure 37 – Inserting SD Card in M12RT Telemetry Transmitter

4. Insert two (2) new AA batteries into the batter compartment and reattach the battery door.
5. The M12RT will progress through a self-diagnostic start-up. At completion of the start-up sequence the M12RT will connect to the M12 Telemetry Network and initiate data stream to the M12A Telemetry Central Station. The following screen will appear.

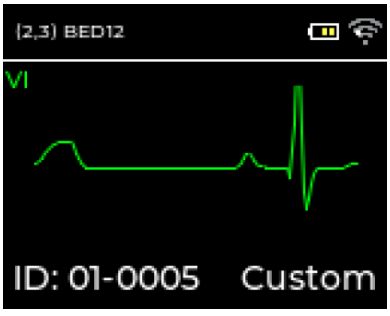


Figure 38 –M12RT Telemetry Transmitter Display

At the completion of the start-up sequence the message “PVIEW” will appear on the display indicating that the monitoring session is now in Preview Mode (see Step 4).

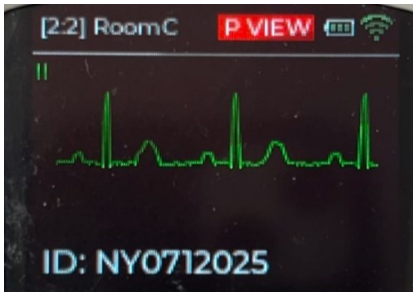


Figure 39 –M12RT Preview Mode Message

STEP 3 – Confirm Valid Data on the M12RT Display

Check the following information on the M12RT display to confirm readiness for a new monitoring session:

- **Patient ID Confirmation** – confirm patient ID listed on the M12RT display matches the patient you are working with.
- **ECG signal quality** – you can use the **Up Arrow** & **Down Arrow buttons** to scroll through each ECG lead. If an ECG lead is disconnected or not providing a quality signal, a lead-off indication will be shown.
  If a lead-off alert indication is shown, check the electrodes and lead-wire snap connections and correct as needed. The M12RT can also be configured, via the M12A Review & Admin Station, to provide an audible alert at the device if a lead off condition occurs.
- **Battery level** – do not initiate a new monitoring session without the battery indicator showing full. If less than full, replace the existing batteries with new.
- **Wireless (WIFI) active** – the WIFI icon should be visible.

If you do not have the configured SD card inserted in the M12RT as instructed above, the transmitter will not complete its startup process, and the display will post the following message.

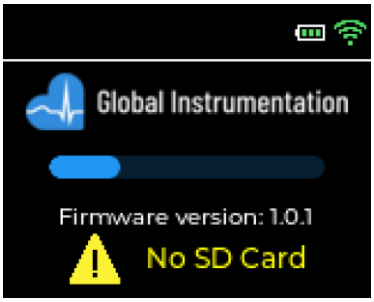


Figure 40 – No SD Card Inserted in M12RT Telemetry Transmitter

Remove the batteries from the device, insert the configured SD card, re-insert the batteries and the M12RT will complete the start-up mode.

WARNING: Active monitoring, including alarm activity, will not begin until the Preview Mode period expires or the start monitoring command is performed.

NOTE: Refer to ***Section 20 – Troubleshooting for the Clinician*** for more information resolving issues related to initiating a new monitoring session.

STEP 4 – Preview Mode - Confirm Valid ECG at the M12A Telemetry Central Station

Upon completion of activating the M12RT Telemetry Transmitter, telemetry data will automatically be sent to the M12A Telemetry Central Station via the wireless network.

Visually confirm that the patient's ECG data is being received at the central station.

The central station tile for the new monitoring session will post a message that the session is in Preview Mode. While in Preview Mode, the patient's ECG data is not being saved to the central station and alarm support has not been activated.

Figure 41 – M12A Telemetry Central Station Tile Indicating Preview Mode

The Preview Mode will end, and full monitoring will start within a maximum of 30 minutes. *Refer to* ***Section 13 – Telemetry Monitoring Configuration*** for information on setting the preview mode duration.

STEP 5 – Activate Start of Monitoring at the M12A Telemetry Central Station

To finalize the start of the new monitoring session, perform the following steps:

1. Confirm that a valid ECG signal is appearing in the patient assigned slot on the central
   station multi-patient display.
2. Execute the Start Monitoring command. You may do this by:
   a. Click on the **Start Monitoring** button to the left of the Preview Mode message.
      -or-
   b. You may Left double-click the patient's tile to open the single-patient view. Click on the **Start Monitoring** button.

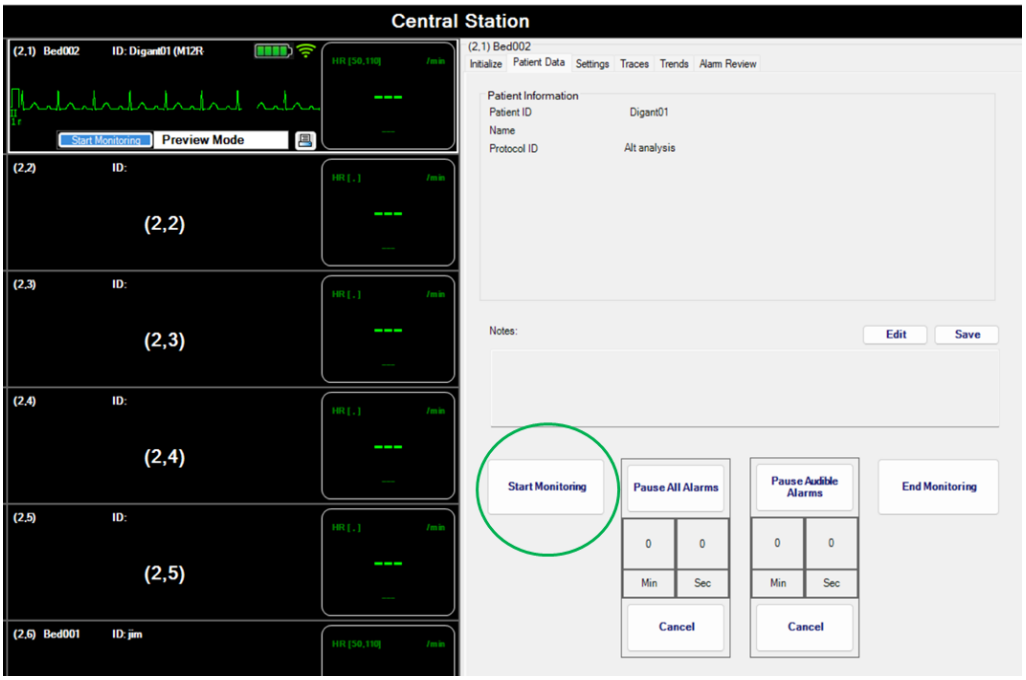


Figure 42 – Start Monitoring Selection

This will initiate recording and storage of the monitoring data, and all alarm capabilities will become active.

WARNING: Adjust the alarm thresholds to patient conditions after monitoring has started. Incorrect alarm threshold settings are a frequent cause of false alarms and lower the attention level to the genuinely important alarms.

9.2 Replacing Batteries During a Monitoring Session

WARNING: Removal of the M12RT Telemetry Transmitter battery cover for battery replacement shall be performed by facility professional staff.

When the low battery alert is displayed on the transmitter or the low battery alarm is displayed on the central station, you will need to insert fresh batteries.

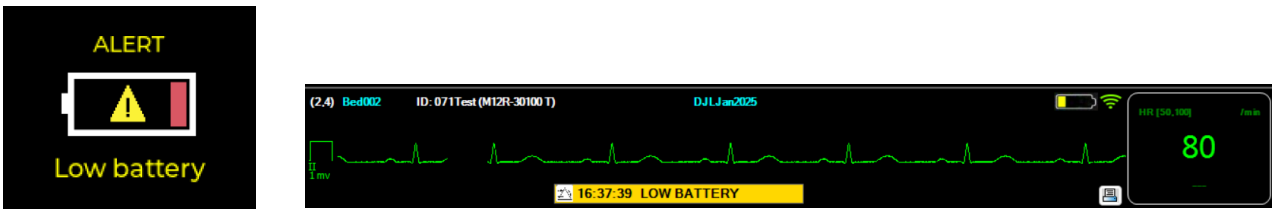


Figure 43 – Low battery alert on M12RT Transmitter and M12A Central Station

The M12RT Telemetry Transmitter allows you to remove the depleted AA batteries while retaining power through a permanent internal backup battery. This allows monitoring to continue during the battery change.

When you remove the AA batteries, the message below will appear:

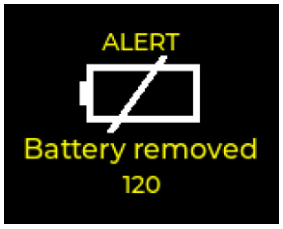


Figure 44 – Battery removed alert

The internal backup battery can power the M12RT for 2 minutes (120 seconds). A digital timer counting down the 120 seconds is on the bottom of the alert message above. The timer will start at 120 seconds and count down in 1 second steps to zero, at which time you no longer have the ability to insert new batteries. You must complete the battery swap in this time window to ensure the monitoring session does not end. If the batteries are not replaced before the internal battery loses charge, the patient monitoring will be ended and cannot be resumed under the current session.

Once fresh batteries are inserted, the M12RT screen will resume displaying the patient's waveform.

NOTE: The AA batteries in the M12RT will need to be replaced approximately every 24 hours.

9.3 Ending a Telemetry Monitoring Session at the M12A Telemetry Central Station

To end a patient monitoring session:

1. On the multi-patient display, double-click on the desired patient window.
2. Select the **Patient Data** tab.
3. Click on the **End Monitoring** button. User authentication will be required to proceed.

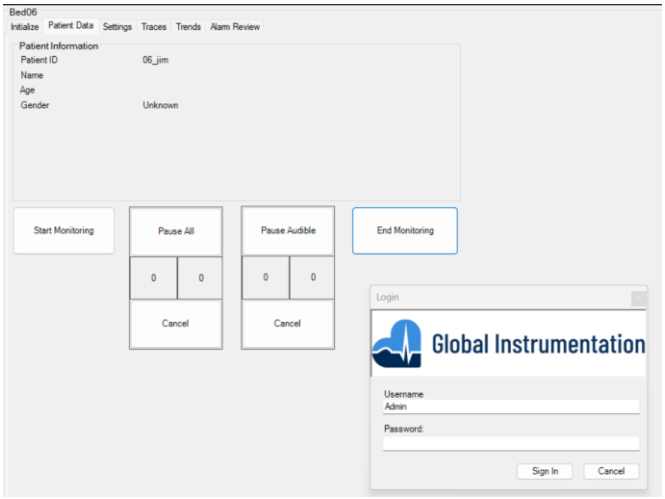


Figure 45 – Authentication to End Patient Monitoring

4. The following message box will appear:

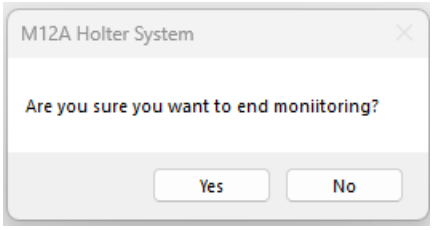


Figure 46 – Confirmation to End of Monitoring

Click **Yes** to end the monitoring session.

Once the monitoring session is ended at the central station, the M12RT Telemetry Transmitter associated with that patient will display the following message.

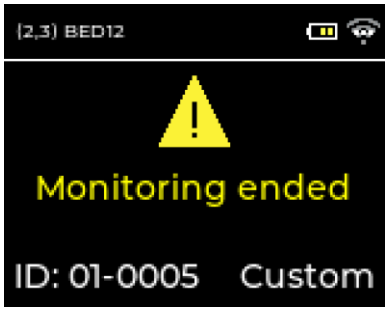


Figure 47 – M12RT Display – End of Monitoring

NOTE: Once a monitoring session is stopped, it cannot be restarted.

NOTE: All waveform collection and alarm activity is ceased once a monitoring session is ended.

NOTE: The maximum monitoring period is 96 hours and the M12RT will discontinue monitoring at that point.

Once ended, the telemetry monitoring session data and the telemetry monitoring report are available for review at the M12A Review and Admin Station.

9.4 Removing M12RT from Patient

Once the monitoring session has been completed you will remove the M12RT Telemetry Transmitter, patient cable, and electrodes from the patient. Refer to ***Section 6.7 – Completion of Monitoring Session.***

IMPORTANT – The SD card that is removed from the M12RT Telemetry Transmitter contains a secondary recording and source of the patient's ECG data. Handle carefully and proceed to instruction in ***Section 10 - SD Card Upload.*** Ensure the SD card upload is completed promptly following removal from the M12RT Telemetry Transmitter.

SECTION 10 - SD CARD UPLOAD

The SD card upload is performed at the M12A Review and Admin Station. Upon uploading, the patient ECG data from the SD card will overlay the data that was wirelessly collected during the monitoring session. This will allow any gaps in data that may have occurred during wireless monitoring to be filled by the complete data set recorded to the SD card.

10.1 Retrieving Recording & Uploading Transmitter Data

Once the monitoring session is completed, remove the batteries from the transmitter and remove the SD card. Place the SD card into the PC and it should automatically upload.

Upload Sequence

When the upload begins, the lower right corner of the screen will show the progress and status of the upload to the computer.

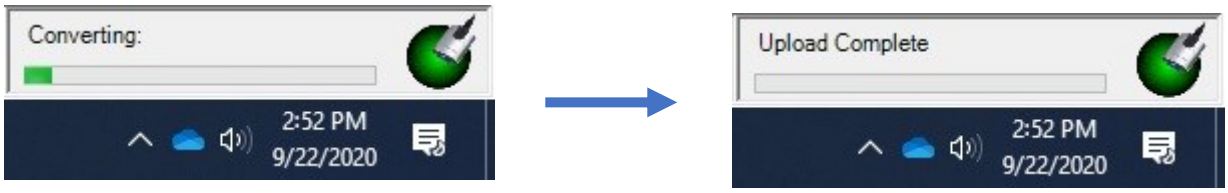


Figure 48 – Central Station SD Card Upload

Following the upload to the M12A Telemetry Central Station PC, you will also see (in the bottom left-hand corner of the screen) indications of the data being uploaded to the M12 Telemetry Server. Please note example below.

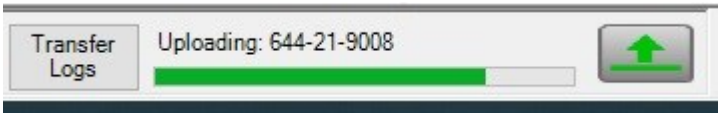


Figure 49 – Data Upload to M12 Telemetry Server

Reports that have been successfully uploaded will appear in the Inbox with a status showing “Full-100%”. If the status shows “Acquire” or “Uploading” then the report may still be transferring or has failed the upload process. If a report fails, the application may need to be restarted before it can successfully be uploaded.

Refer to ***Section 18 – Accessing Telemetry Reports*** for details on accessing the acquired telemetry reports.

SECTION 11 - ALARMS

This section describes alarm functions and alarm settings.

11.1 Understanding Alarms

Alarms triggered by a patient's ECG data that appears abnormal, or due to technical issues encountered by the transmitter or system are sent to the M12A Telemetry Central Station.

11.2 Alarm Categories

The M12A Telemetry Central Station alarms can be classified into two categories: physiological alarms and technical alarms.

- **Physiological alarms** – are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.
- **Technical alarms** – are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems.

Apart from the physiological and technical alarm messages, the central station will show some messages telling the system status.

11.3 Alarm Priorities

Alarms on the M12A Telemetry Central Station are divided into four priority levels: high (red), medium (yellow), low (cyan), and informational events (white) according to alarm importance. High, medium, and low alarm events are both audible and visual with different messages for each. Informational alarms are visual messages only.

The M12A Telemetry Central Station supports an intelligent alarm system and ensures that the highest priority alarms are displayed first. Within the same priority group of alarms (ex. High) there is additional priority logic assigned to each alarm. Refer to ***Section 11.10 – Overlapping Alarms.***

NOTE: The interburst interval is approximately 3 seconds for high and medium priority alarms. The interburst interval for low priority alarms is approximately 300 seconds (5 minutes).

COLOR	PRIORITY	VISUAL EXAMPLE	Alarm Audio Tone
Red	High	VTACH	10-pulse tone
Yellow	Medium	LEAD OFF	3-pulse tone
Cyan	Low	QTcB High	2-pulse tone
White	Information	PRINTER OFF	No audible tone

Refer to ***Section 12 – Alarm Details*** for listing of alarms and default priority settings.

The priority levels are classified as follows:

- High priority alarms: indicate a life-threatening situation and require immediate response

- Medium priority alarms: indicate abnormal ECG rhythm or a device malfunction and require a prompt response
- Low priority alarms: indicate a discomfort condition, a device malfunction, or an improper operation and require you to be aware of this condition.
- Information: additional information on the patient or the system status.

All high priority latched alarms are pre-set and fixed.

The priority of some alarms can be changed by the operator based on clinical need.

11.4 Latched and Non-Latched Alarms

Latched alarms indicate either life-threatening or serious conditions such as an asystole or ventricular fibrillation. Life-threatening alarm audible and visual indicators continue (even if the alarm condition is no longer valid) until the operator acknowledges the message and silences the alarm.

Non-latching alarms indicate advisory conditions and continue for as long as the event exists and will disappear automatically shortly after the clinical condition is resolved. The visual and audible alarm signals stop automatically when the alarm condition ends. You can also silence non-latching alarms manually.

Refer to ***Section 12 – Alarm Details*** for information on latched and non-latched alarms

11.5 Physiological Alarm Display

When a physiological alarm is generated, a blinking alarm message appears in the corresponding window. The message will continue to be displayed until the cause of the alarm disappears.

Figure 50 – Physiological alarm display in patient view of multi-patient display

The time listed to the left of the alarm type description is the time at which the alarm was first detected. Should the cause of the first alarm condition be resolved prior to acknowledgement, and a new alarm of the same type occurs, the time of the new alarm start will be displayed. The icon is displayed in front of the alarm message to identify the control to acknowledge and silence the alarm. You may click the acknowledge icon or anywhere in the alarm message field to acknowledge the alarm.

NOTE: Alarm event timing can differ from alarm presentation times due to overlapping higher priority alarms, or built-in presentation delays to avoid false alarms on short, clinically non-relevant events.

NOTE: There are no audible alarms on the M12A Telemetry Repeater Station.

11.6 Technical Alarm Display

Technical alarms are designated as:

- System Technical Alarm – related to functionality or performance of the overall telemetry system.
- Patient Technical Alarm – related to performance issues of the M12RT Telemetry Transmitter or monitoring conditions specific to the individual patient.

Figure 51 – Technical Alarm display in patient view of multi-patient display

System technical alarms will appear in the upper left corner of the central station display in a highlighted box (in figure above the alarm is UPS ACTIVE). Patient technical alarms will appear in the specific tile of the patient (in figure above the alarm is LOW BATTERY).

Refer to ***Section 12 – Alarm Details*** for more information on technical alarms.

11.7 Alarm Indicators

When an alarm occurs, the M12A Telemetry Central Station gives different visual or audible alarm indications as shown below.

Alarm Indicator	High Priority Alarm	Medium Priority Alarm	Low Priority Alarm	Information
Alarm Tone Pattern	10-pulse tone (5 beeps - half second pause – 5 beeps – 3 second pause – repeat)	3-pulse tone (3 beeps – 3 second pause – repeat)	2-pulse tone (2 beeps – 5 minute pause – repeat)	None
Alarm Message Field	**Red box**/Black text -alternating when alarm is active -Stationary when alarm condition is still present but acknowledged by operator	**Yellow box**/Black text -alternating when alarm is active -Stationary when alarm condition is still present but acknowledged by operator	**Cyan box**/Black text -stationary when alarm is active and following acknowledgement by operator	**White box**/Black text -stationary when alarm is active and following acknowledgement by operator

NOTES:

- Alarm time is displayed for latched physiological alarms only.
- The audible and visual alarms given by the M12A Telemetry Central Station comply with IEC 60601-1-8 standards. The facility or institution employing the use of the central station should give adequate training to the operators.
- When multiple alarms of different priority levels occur simultaneously, the central station selects the alarms of highest priority and provides alarm tones accordingly.

11.8 Alarm Status Symbols

Apart from the alarm indicators described in the above table, the following symbols are displayed on the central station screen to indicate current alarm status associated with a patient.

-  : the alarm reset control symbol. To be used to execute an alarm reset.
-  : the audio pause symbol, indicating that audible alarms are paused
-  : the audio off symbol, indicating that audible alarms are turned off.

11.9 How to Acknowledge and Silence Alarms

Certain priority alarm events will also generate an audible signal along with the blinking alarm message field.

Figure 52 – Alarm Message

Clicking on the alarm acknowledge icon , or anywhere in the alarm message field, indicates your acknowledgement and will silence the audible alarm.

The acknowledge icon will disappear while the alarm message will stay on the screen to remind you that the cause of alarm is still present. Additionally, the audio off symbol will appear in the patient tile view.

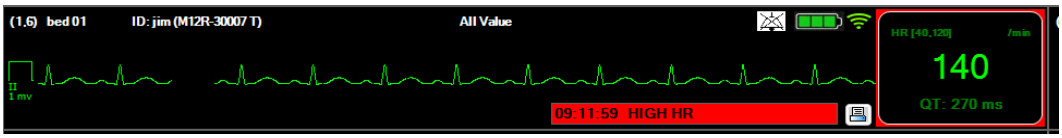


Figure 53 – Alarm Acknowledged

For a non-latched alarm, the visual alarm message will remain for 20 seconds after the cause of an unacknowledged physiological alarm disappears. This allows noticeable alarm presentation duration for conditions that last a short time. Technical alarms and acknowledged physiological latched alarm presentations disappear immediately after the cause goes away.

11.10 Overlapping Alarms

When several alarms occur within a short period of time and the system is busy displaying or printing a previous alarm printout, M12A Central will store the alarm events in memory and will automatically print them after the previous printout has finished. If more than one alarm is active, the auditory and visual indication of the highest priority alarm will be active. If more than one alarm with the same priority is active, the auditory and visual indication of the most recent alarm will be active.

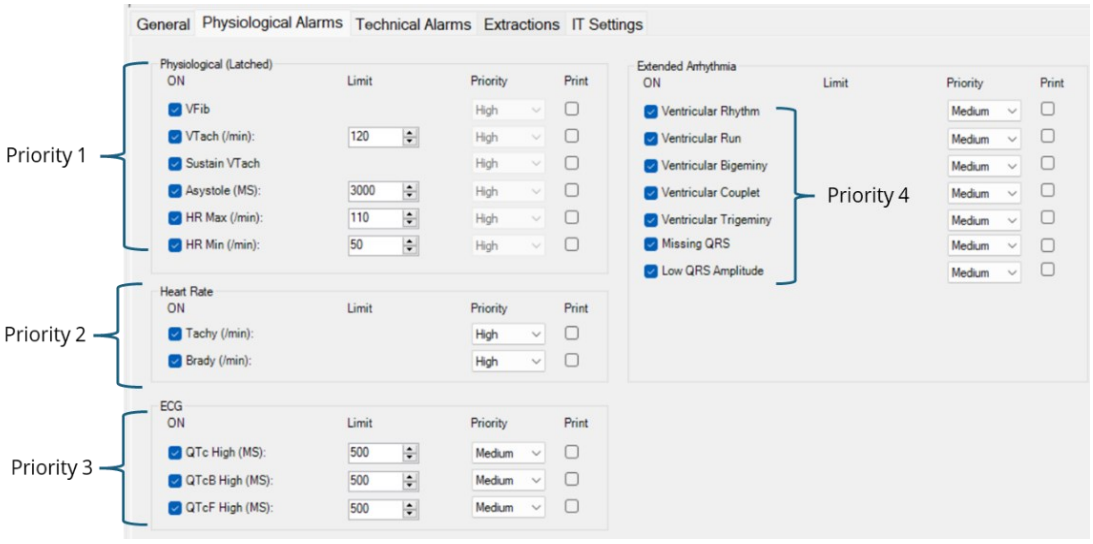


Figure 54 – Alarm Priority sequence for overlapping alarms

Physiological latched alarms will always be treated as the highest priority followed in descending order shown on the settings field below (VFib descending to HR Min in priority).

Priority levels will then move by group in rank order of Heart Rate (tachy/brady), ECG, and Extended Arrythmias. Within any of these groups, a medium priority alarm will take priority over a low priority alarm, regardless of position in the settings view.

For visual presentation, unacknowledged alarms have precedence over acknowledged alarms, depending on the priority.

11.11 Alarm and Event Messages

Due to the available screen space, some alarm and event messages are abbreviated. Longer messages are displayed on the Alarm Review event list and on printouts. Refer to **Section 12 – Alarm Details** for a list of all alarms, detailed alarm event criteria, and explanations.

11.12 Pausing Alarms

You can pause the alarm function on individual patients if this capability is enabled in the global telemetry settings of the organization. Refer to ***Section 13 – Telemetry Monitoring Configuration.***

To pause a specific patient's alarms, double-click on their tile on the central station display to open the single-patient expanded view. The Patient Data field will appear.

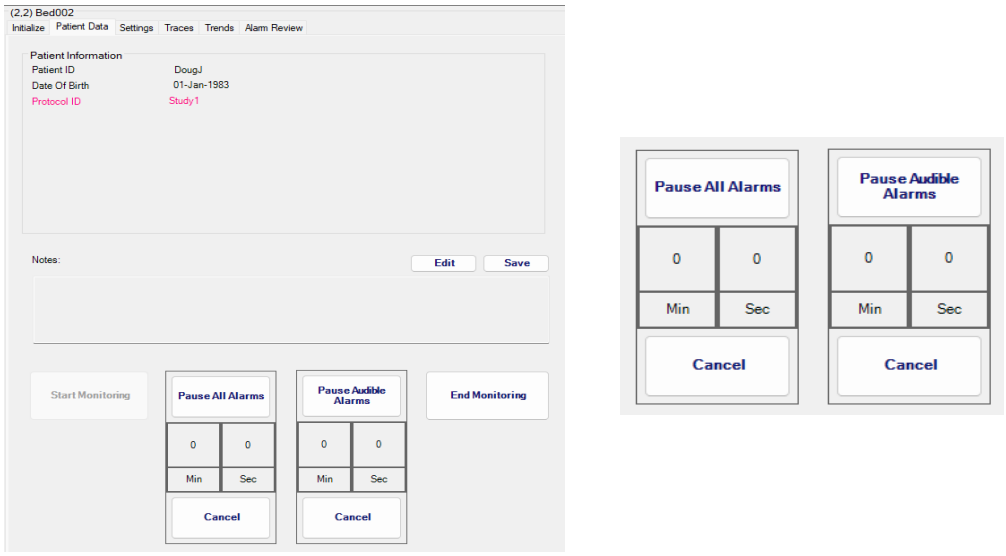


Figure 55 – Patient Data Field - Alarm Pause Controls

The two options for alarm pause are:

- Pause All – this will pause both visual and audible patient alarms. During a Pause All alarm period, all patient active alarms are terminated, and no alarm information is collected by the system until pause period expires or is cancelled.
- Pause Audible – this will pause only the audio alarms and visual alarms will stay active and alarm data will be collected by the system.

The duration of the alarm pause will be pre-configured by the organization for either 5, 10, 15, or 30 minutes.

Once an alarm pause is started, an indication for time remaining on the pause will be shown both in the pause control section of the Patient Data field and in patient monitoring tile. The audio pause symbol will also be displayed.

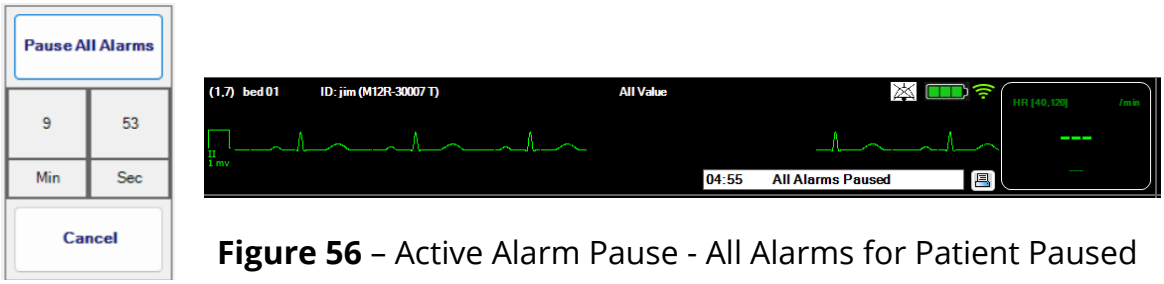


Figure 56 – Active Alarm Pause - All Alarms for Patient Paused

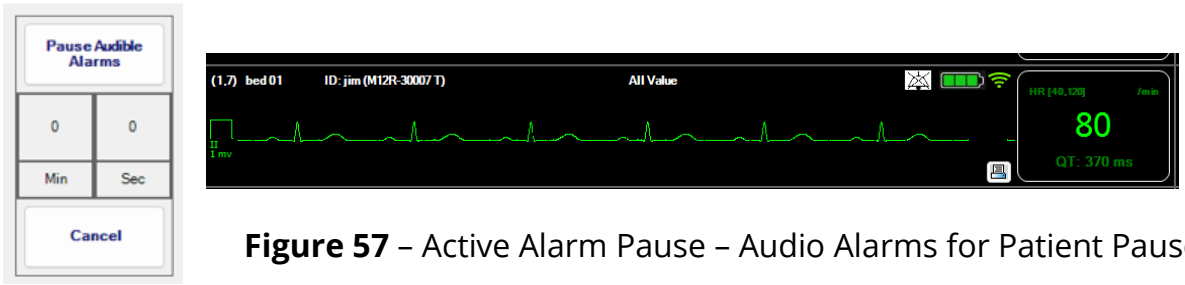


Figure 57 – Active Alarm Pause – Audio Alarms for Patient Paused

If you wish to extend the pause duration beyond the first-time segment, you may click the pause button again to start a fresh pause time segment (5,10,15, or 30 minutes depending on organizational configuration). This applies to the use of either the Pause All or Pause Audible control.

Immediately following the end of the pause period, the alarms will be automatically enabled.

11.13 Changing Alarm Limits

When monitoring begins, alarm limits, priorities, and printouts are automatically assigned to the patient based on the Protocol assigned to the patient.

NOTE: Most alarm limits cannot be changed by the operator during an active monitoring session. This is by design and intended to ensure patient safety.

To change alarm limits, double-click on the active patient tile to open the expanded single-patient view for the patient. Click on the **Settings** tab, and then click on the Edit button. Entry of user credentials will be required to authenticate. Prior to credential entry, all alarm fields will appear greyed-out indicating no adjustments are permitted.

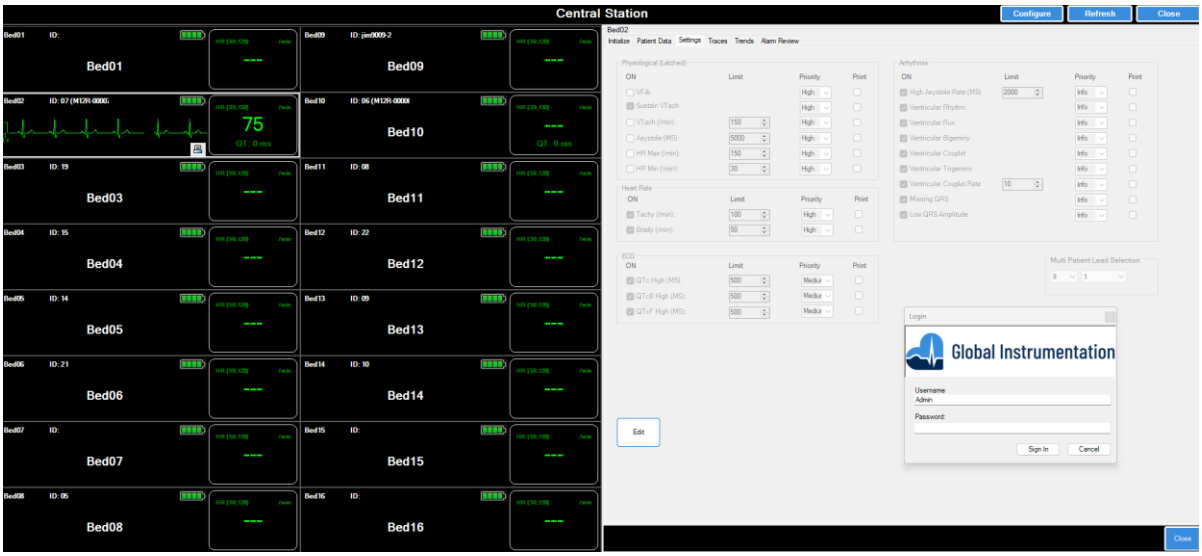


Figure 58 – Settings field in M12A Telemetry Central Station

Following authentication, the alarm limits that are adjustable will no longer be shaded.

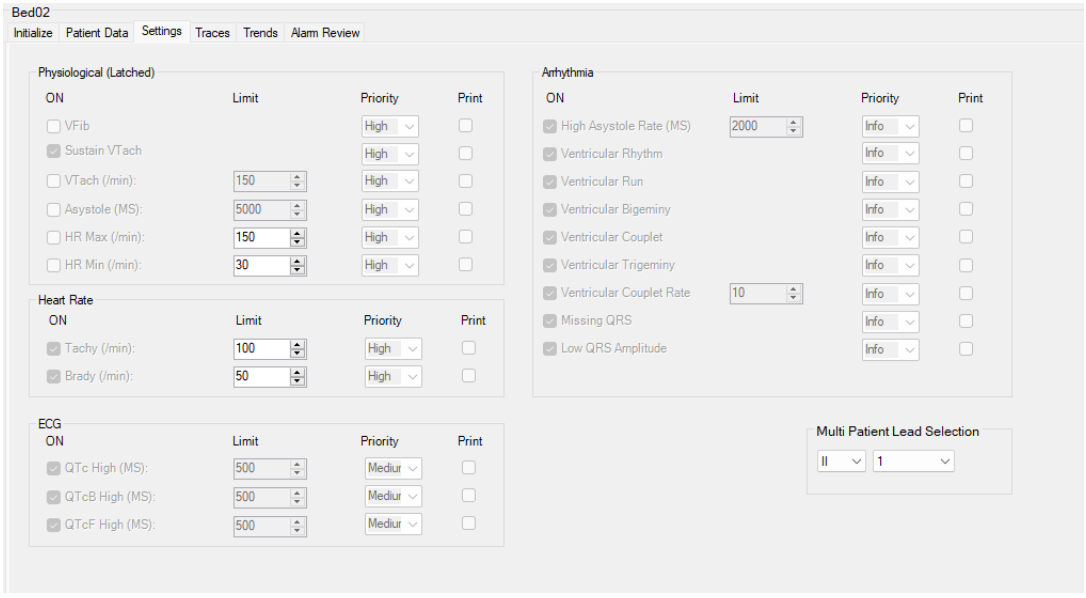


Figure 59 – Adjustable Alarm Settings field in M12A Telemetry Central Station

In the image above the alarm limits that can be adjusted are heart rate (max bpm & min bpm) and the Tachy/Brady alarms.

Once the alarm limits have been updated click on the **Save** button to save changes. New alarm limits become active after you have clicked on **Save.**

NOTE: The alarm groups are the same as the alarm categories of the alarm event list in the Alarm Review tab. For a complete list of alarm group assignments, see ***Section 12 - Alarm Details.***

WARNING: Inappropriate limit settings may render an alarm ineffective and cause serious danger to the patient. Choose limits appropriately and based on the individual patient.

11.14 Changing Alarm Priorities

Alarm priorities are not adjustable once active monitoring of a patient has started. Certain Alarm priorities are adjustable at a global level when the central station is configured. See ***Section 13 – Telemetry Monitoring Configuration*****.** Additionally, certain alarm priorities are adjustable from the default settings at the protocol level. Refer to ***Section 8 – Protocol Management.***

SECTION 12 - ALARM DETAILS

This section concerns alarm settings for telemetry monitored patients and provides further and more detailed information on system criteria regarding alarms. The table below lists all telemetry monitoring alarms and their principal characteristics.

The M12A Telemetry Central Station alarms can be classified into two categories: physiological alarms and technical alarms.

- **Physiological alarms** – are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.
- **Technical alarms** – are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems.

Apart from the physiological and technical alarm messages, the central station will show some messages pertaining to the system status.
Column definitions for the section 12.1 table are:

Message	The alarm message displayed on the central station screen.
Group	The alarms are broken into groups to which the alarm belongs as used in the Alarm Settings page.
Description	Detailed description of the cause of the alarm
Factory Default Priority	The priority set in the factory default alarm profile: Information (white), Low (Cyan), Medium (Yellow) or High (Red)
Range Limits	Minimum & maximum value of possible limit settings, if applicable, and factory default setting
Max. Limit	Maximum value of possible limit settings, if applicable
Delays	Delay in seconds after which the alarm is presented. This delay presents the sum of signal filter delays, algorithm detection delays, delays inserted to prevent false alarms and any other processing delays. These values have been measured in reasonable worst-case conditions. Wherever applicable, the measuring methods mentioned in the ANSI/AAMI standard EC 13 have been used.

NOTE: NA in tables below indicates not applicable.

If a power outage to the M12 Telemetry System occurs, all patient alarm settings will be automatically restored regardless of the power outage duration. The patient telemetry monitoring session current alarm setting information is maintained in a database and re-applied when the system recovers from the power outage.

12.1 Physiological Alarms

Message	Group	Description	Factory Default Priority	Range Limits (Resolution)	Factory Default Limit	Delay (seconds)
ASYSTOLE	Physiological (Latched)	Asystole – no detectable beat (QRS complex)	High (Latched)	Variable threshold setting: 2000 – 8000 MS	4000 MS	6 seconds + threshold
VFIB	Physiological (Latched)	Ventricular Fibrillation - a fibrillatory waveform persisting for greater than 4-seconds	High (Latched)	Not Adjustable	NA	8 seconds
VTACH	Physiological (Latched)	Ventricular Tachycardia with a duration of more than the number of beats limit and above the rate limit	High (Latched)	Variable threshold setting: 100 to 200 bpm +/- 3 bpm for 6 consecutive beats	Threshold default: 150 bpm +/- 3 bpm for 6 consecutive beats	10 seconds
HIGH HR	Physiological (Latched)	Heart rate is above the maximum limit	High (Latched)	50 - 250 bpm	120 bpm	10 seconds
LOW HR	Physiological (Latched)	Heart rate is below the minimum limit	High (Latched)	30 – 150 bpm	50 bpm	10 seconds
SUST VTACH	Physiological (Latched)	Sustained VTACH w/ a duration of more than 15 sec.	High (Latched)	Extension of Ventricular Tachycardia for > 15 second or longer.	15 sec	10 + 15 seconds
BRADYCARDIA	Heart Rate	Heart rate is below the bradycardia setting for a minimum of 15 seconds	High	10 bpm below the minimum heart rate limit	40 bpm	10 + 15 seconds
TACHYCARDIA	Heart Rate	Heart rate is above the tachycardia setting for a minimum of 15 seconds	High	30 bpm above the maximum heart rate limit	150 bpm	10 + 15 seconds
QT High	ECG	QT (no correction) above limit	Low	Range is 300 to 600 (ms)	500 ms	7 x 10 seconds
QTcB High	ECG	QTc (Bazett correction) above limit	Low	Range is 300 to 600 (ms)	500 ms	7 x 10 seconds
QTcF High	ECG	QTc (Fridericia correction) above limit	Low	Range is 300 to 600 (ms)	500 ms	7 x 10 seconds
VENT RHYTHM	Extended Arrhythmias	Ventricular Rhythm with 6 or more successive ventricular beats with rate below VTACH limit and no VTACH alarm	Information	Not Adjustable	6 ventricular beats	10 seconds + 3 beats
VENT RUN	Extended Arrhythmias	3 to 5 successive ventricular beats with rate above VTACH limit and no VTACH alarm	Information	Not Adjustable	3 ventricular beats	10 seconds + 3 beats
BIGEMINY	Extended Arrhythmias	Bigeminy - A beat pattern of N, V, N, V, N, V, N has been detected	Information	Not Adjustable	NA	10 seconds + pattern beats
VENT COUPLET	Extended Arrhythmias	2 successive ventricular beat sequence - N, V, V, N (pattern)	Information	Not Adjustable	NA	10 seconds
TRIGEMINY	Extended Arrhythmias	Trigeminy - a beat pattern of N, N, V, N, N, V, N, N, V, N has been detected	Information	Not Adjustable	NA	10 seconds + pattern beats

MISSING QRS	Extended Arrhythmias	R-R interval is greater than or equal to 180% of the average R-R interval	Information	Not Adjustable	NA	10 seconds
LOW QRS AMP	Extended Arrhythmias	QRS voltage is below 1.5 times that of the detection threshold.	Information	Not Adjustable	NA	60 seconds

12.2 Technical Alarms

Message	Group	Description	Priority (Factory Default)	Delay (seconds)
LEAD OFF	Patient Technical	One or more electrode is disconnected	Medium	10 seconds
LOST COMMS	Patient Technical	Signal from active transmitter not detected for period of time (30 seconds or more)	Medium	30 seconds
NOISY ECG	Patient Technical	Excessive artifact detected in ECG signal	Medium	10 seconds
LOW M12RT BATTERY	Patient Technical	M12RT Transmitter battery is low	Medium	30 seconds
HR NOT AVAIL	Patient Technical	Heart rate is not received by the system for a period of time	Medium	30 seconds
PATIENT CALL	Patient Technical	Patient has pressed the patient call buttons on M12RT	Low	10 seconds
STORAGE FULL	System Technical	The system storage space has reached capacity limit	Low	NA
STORAGE LOW	System Technical	Less than 24 hours storage space is available on storage disk	Low	NA
UPS ACTIVE	System Technical	System is running from UPS power	Low	TBD
PRINTER OFF	System Technical	The network printer is offline	Information	TBD
SERVICE ERROR	System Technical	System software functionality Issue	Information	TBD

12.3 Operator Patient Alarm Logs

The M12T Telemetry System includes alarm logging functionality that records patient-related alarm activity that can be accessed during active monitoring and following the conclusion of a patient telemetry monitoring session.

The patient alarm log includes the following for each patient telemetry session:

- Start and end date and time of each alarm occurrence (including high, medium, low, and information priority), the alarm priority setting, and the associated alarm limit (if applicable) that was exceeded to trigger the alarm.
- All patient alarm pause activity, including the date and time of the pause and the duration of the pause (inactive) period.
- All user inserted notes and comments to the alarm log of a specific patient. The date and time of the comment entry by the user is recorded and available under the report audit log. The user ID is included in the audit log notation.

All patient-related alarm activity is retained permanently in the system alarm log record. A user may designate an alarm as omitted for reporting purposes using the M12 Telemetry System alarm review and reporting functionality, however all alarms remain visible and are never deleted from the alarm log record.

Accessing the Patient Alarm Log

During active monitoring, a patient alarm log can be viewed at the M12A Central Station by opening the single-patient view for a given patient and opening the Alarm Review field.

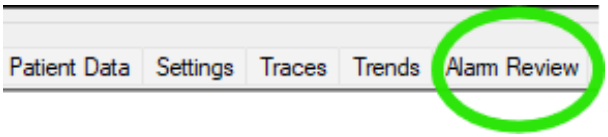


Figure 60 – Alarm Review Field on M12A Central Station

Refer to ***Section 8.3 Single Patient Display View***.

Following the completion of a patient monitoring session, the Alarm Review field is accessible at the M12A Review and Admin Station.

A printed patient alarm log report can be generated from the M12A Review and Admin Station.

NOTE: Access to the patient alarm log, during real-time monitoring and post-monitoring, is controlled by permissions. Users must authenticate with credentials to perform editing (alarm classification) and adding notes.

12.4 Organizational Patient Alarm Log

In addition to the operator patient alarm logging described above, the Organizational Patient Alarm Log can be exported and printed for each patient. The Organizational Patient Alarm Log includes a variety of information on the patient-specific monitoring session, including:

- All Operator Patient Alarm Log information contained in Section 14.3.
- All changes made to the alarm settings of a specific patient by the user/operator.
- The start and stop time of the monitoring session.
- Alarm acknowledgement activity by users.

NOTE: The information contained in the Organizational Patient Alarm Log is permanent and not editable.

Access to Organizational Patient Alarm Logs is controlled by permissions. Refer to

An Organizational Patient Alarm Log is accessed from the Inbox of the M12A Review and Admin station by right-clicking on a patient/subject report listing and then clicking on “Audit Information” from the dropdown menu.

This log report is not editable in any manner and may be exported for printing and review.

The Organizational Patient Alarm Log is accessible during an active monitoring session or after completed session. There is no limit to the size of the report audit log. Each patient monitoring session creates a new alarm log file. The M12 Telemetry Server can be upgraded with increased memory capacity based on the activity and requirements of the facility.

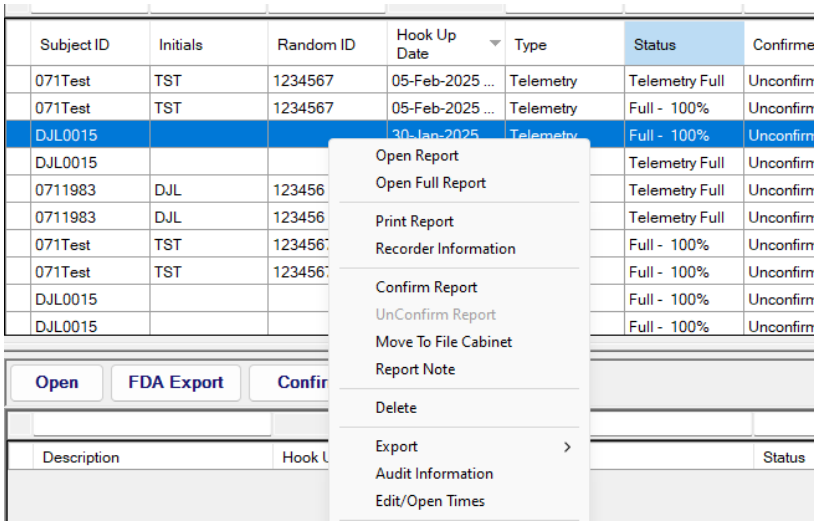


Figure 61 – Accessing Report Audit Log

12.5 System Technical Alarm Logs

A system-based technical alarm log (non-patient specific) is accessible via the systems setting – Telemetry System Log. This log report is not editable in any manner and may be exported for printing and review.

12.6 Log Retention and Server Capacity

All alarm log data including Operator Patient Alarm Logs, Organizational Patient Alarm Audit Logs, and System Technical Alarm Logs are centrally stored on the M12A Telemetry Server and are recovered should the following occur:

- Powering down or loss of power at the M12A Central Station PC.
  - The data and time of the power cycle is stored within the System Technical Alarm log.

  - The full alarm log data is retained on the M12 Telemetry Server.
- Total loss of power to the M12A Telemetry Central Station and M12 Telemetry Server.
  - All alarms logs are stored within server and preserved.

NOTE: System technical alarms will trigger if server capacity is reaching the storage limits.

Alarm Log Capacity

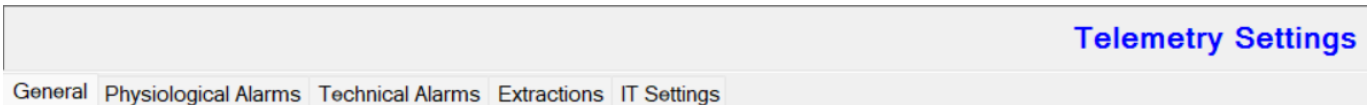
There is no limit to the size of the alarm logs. Each patient monitoring session creates new alarm log files. The M12 Telemetry Server can be upgraded with increased memory capacity based on the activity and requirements of the facility.

SECTION 13 - TELEMETRY MONITORING CONFIGURATION

The configuration of default parameters for telemetry monitoring at the M12A Telemetry Central Station is done using the M12A Review and Admin Station.

NOTE: Making changes to the Telemetry Monitoring configuration will require adequate credentials and authentication.

To access the telemetry monitoring configuration area of the M12A Review and Admin Station click on the Settings button and then click on the Telemetry Settings button.



The tabs in the image above contain fields for configuring various parameters for telemetry monitoring.

CAUTION: User actions can interrupt monitoring, destroy data, or change alarm modality. Use the Alarm configuration fields only if properly instructed and authorized.

NOTE: Clicking on the Close button will save changes made to any settings field.

13.1 General Settings

The General Settings field is used to configure various settings for telemetry monitoring.

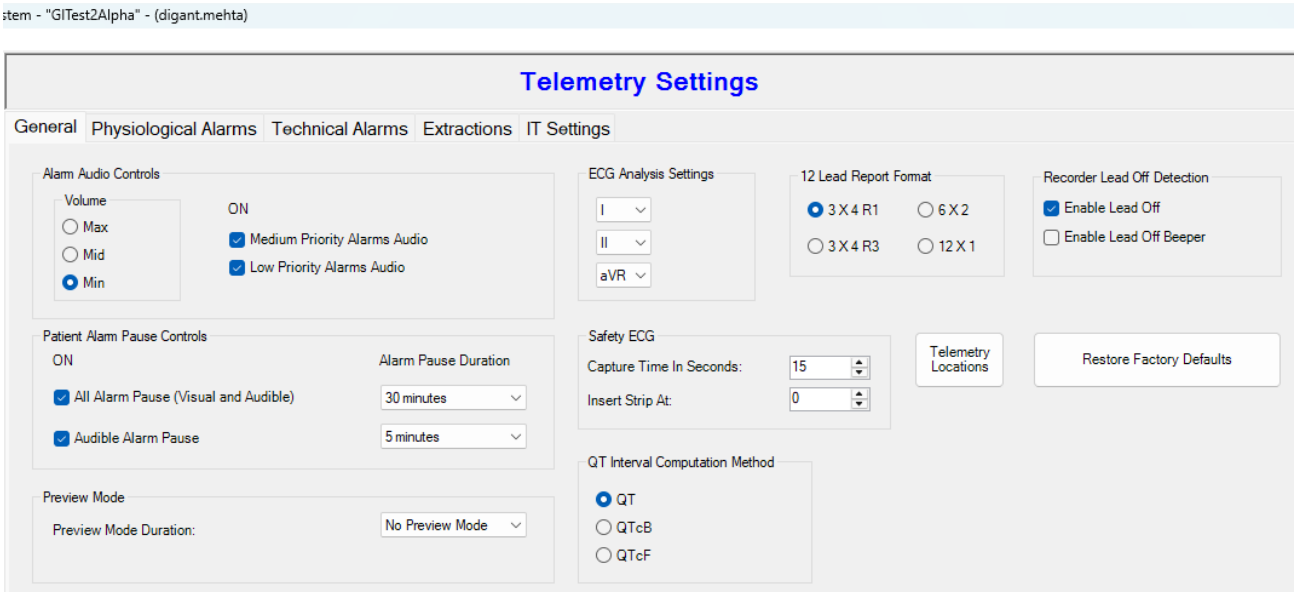


Figure 62 – General Settings field – M12A Review & Admin Station

Alarm Audio Controls

- Volume – sets the alarm audio volume for the speakers at the central station
- Medium and Low Alarm audio on/off control – allows the choice to enable or disable audio alarms for medium and/or low priority designated alarms.

Patient Alarm Pause Controls

This field allows enabling or disabling the ability to pause alarms for individual patients being monitored. The two options for alarm pause are:

- Pause All Alarms – this will pause both visual and audible alarms
- Pause Audible Alarms – this will pause only the audio alarms and visual alarms will stay active.

Use the drop-down menu to choose the duration of the alarm pause. Options are 5, 10, 15, or 30 minutes.

- When only audible alarms are paused, alarm occurrences will still be collected and documented in the system.
- When Pause All is chosen, all active alarms will be terminated, and no alarm information is collected by the system.

WARNING - Do not pause or turn off a visual or audible alarm if patient safety might be compromised.

Preview Mode Duration Settings

The Preview Mode is configured to provide a short period of time at the start of a new patient monitoring session, in which data from the activated M12R Transmitter will be displayed at the M12A Telemetry Central Station, without data storage or alarm capability being activated.

The purpose of the Preview Mode is to allow adequate time for the patient transmitter hookup to be completed following the configuration of the M12RT SD card.

The options for Preview Mode duration are:

- No Preview Mode
- 5 Minutes
- 10 Minutes
- 15 Minutes
- 30 Minutes

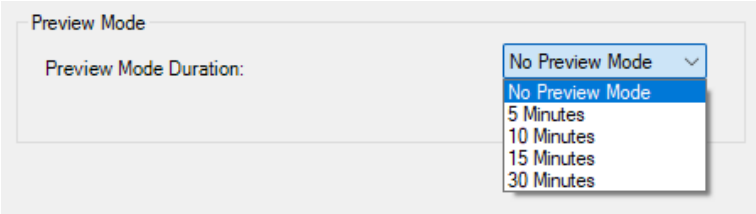
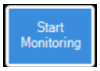


Figure 63 – Preview Mode

Preview Mode will automatically end, and full monitoring capability start, at the end of the Preview Mode duration or when the user manually clicks on the 

button on the patient's tile at the central station.

If "No Preview Mode" is selected, full monitoring support will begin immediately following activation of the 12RT Transmitter.

WARNING - During Preview Mode patient alarms are not active at the M12A Central Station. Active monitoring, including alarm activity, will not begin until the Preview Mode period expires or if the start monitoring command is performed.

Refer to ***Section 9 – Conducting Telemetry Patient Monitoring*** for information on starting a patient monitoring session.

ECG Analysis Settings

The ECG Analysis Settings provide the user with the ability to customize which default ECG channels are analyzed by the M12A Telemetry Central Station during monitoring. (Note: following the end of a live monitoring session, telemetry reports can be opened and reanalyzed later with different channel selections).

Safety ECG Settings

The Safety ECG setting field supports the selection of the total capture time for the 12-lead safety ECG (up to 300 seconds/5 minutes) and the time to insert the 12-lead strip within the duration chosen.

QT Interval Computation Method

Provides the user with the ability to select between QT (non-corrected), Bazett, or Fridericia formula for QTc display.

12 Lead Report Format

The 12-Lead Report Format controls the format of which 12-lead strips are displayed and printed.

- 3 x 4 R1 – 3 rows by 4 columns with 1 rhythm lead (first analysis lead).
- 3 x 4 R3 – 3 rows by 4 columns with 3 rhythm leads (all three analysis leads).
- 6 x 2 – 6 rows by 2 columns.
- 12 x 1 – All 12 leads in a separate row.

The 12 Lead R1/R3 Lead Selection controls the selection of R1 and R3 leads for the 3 x 4 R1 and 3 x 4 R3 formats.

The sweep speed is fixed at 25 mm/seconds.

Telemetry Locations

Clicking on the Telemetry Locations button will open a field that allows the creation and editing of facility location identifiers (ex. bed, room, floor) that can be associated with a patient under monitoring. During the start of a new patient monitoring session a location identifier chosen from the list will be assigned to the patient.

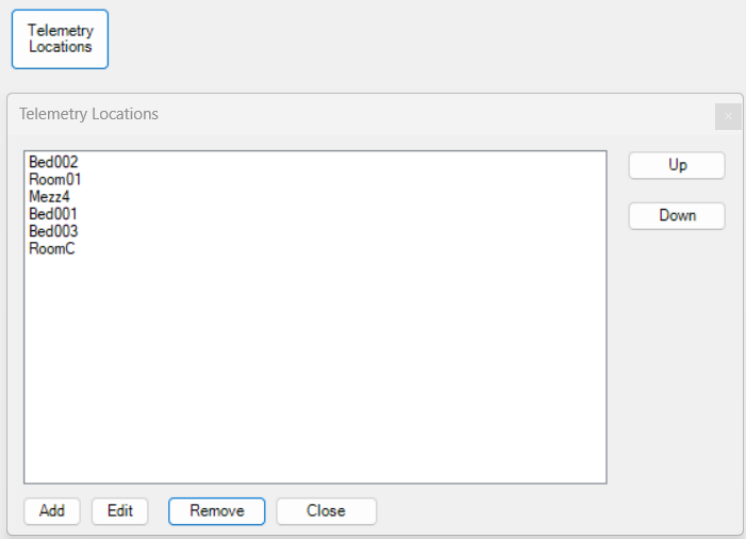


Figure 64 – Telemetry Locations

Transmitter Lead Off Detection

This setting field enables lead off alert functionality and controls how the M12RT Telemetry Transmitter will provide feedback if the patient cable lead wire(s) create a lead off condition.

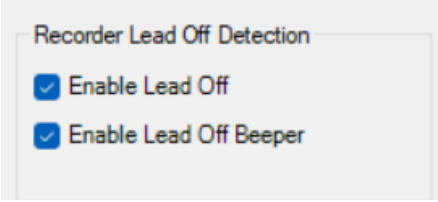


Figure 65 – Transmitter Lead Off Controls

- Enable Lead Off – if checked, lead off detection is enabled in the system including the ability for a technical alarm at the central station. Additionally, the transmitter provides a visual alert of the lead off condition on the device display.
- Enable Lead Off Beeper – If checked, the M12RT Telemetry Transmitter will provide an audible beep alert of the lead off condition.

The “Enable Lead Off” selection must be activated to support the technical alarm setting for lead off alarming at the central station. Refer to ***Section 13.3 Technical Alarms.***

Restore Factory Defaults

Clicking the Restore Factory Defaults button will allow you to choose a reset of the general settings, physiological alarm settings, and technical alarm settings to the original settings as provided by Global Instrumentation at the time of manufacture. Refer to ***Section 20.6 Alarm Groups*** for information on the default settings.

13.2 Physiological Alarms

The Physiological Alarms Settings are configured using the field illustrated below.

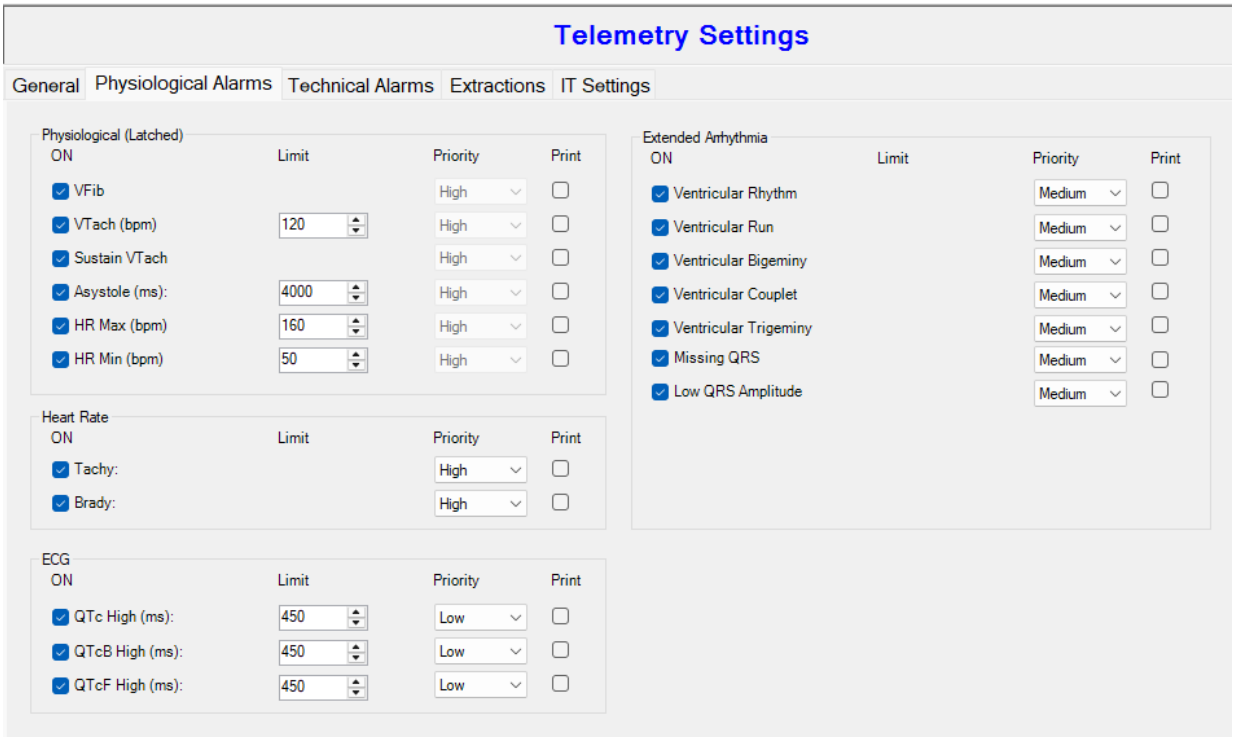


Figure 66 – Physiological Alarms Settings – M12A Review & Admin Station

Alarms are enabled or disabled using the check boxes to the left of each alarm type. A blue check in the box indicates the alarm is configured to be on and active.

The recommended practice is to enable all the alarms listed in the Physiological (Latched) alarms group for patient monitoring. Enabling alarms in the other alarm groups is viewed as more discretionary based on the oversight of the responsible clinical organization and specifics of patient population and/or clinical conditions being considered.

Certain parameters are preset relative to the configuration of physiological alarms.

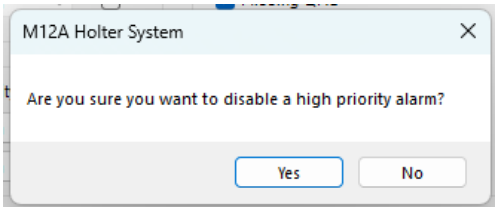
- Physiological (Latched) alarms are set and fixed at the high priority level
- The Heart Rate alarm group can be set at any of the four priority levels – Info, Low, Med, High
- The alarm groups of ECG and Extended Arrhythmia can be set at priority levels – Info, Low, and Medium
- Certain alarms allow adjustment of the parameter threshold limit that would trigger an alarm

To set or adjust alarm parameters use the following setting controls:

- **On/Off Setting** – click each alarm that you want active. An active alarm will have the blue highlight in the check box and the check mark showing.
- **Threshold Limits** – certain alarms allow for setting of thresholds for which that specific parameter will need to exceed to trigger the alarm.
- **Priority** – the priority level for which the alarm will be assigned.
- **Print** – checking the Print box for a given alarm will initiate an auto-print of the alarm event, with associated ECG tracing, if the alarm triggers.

Refer to ***Section 12*** – ***Alarm Details*** for more information on the alarm parameters.

NOTE: If a user attempts to turn off a high-priority designated alarm, the following field will appear requiring confirmation that disabling of the alarm is intended.



WARNING: Do not pause or turn off a visual or audible alarm if patient safety might be compromised.

13.3 Technical Alarms

Technical alarms are designated as:

- System Technical Alarm – related to functionality or performance of the overall telemetry system.
- Patient Technical Alarm – related to performance issues of the M12RT Telemetry Transmitter or monitoring conditions specific to the individual patient.

Technical alarms are enabled or disabled using the check boxes to the left of each alarm type. A blue check in the box indicates the alarm is configured to be on and active.

The priority of technical alarms can be set at the levels of Info, Low, or Medium.

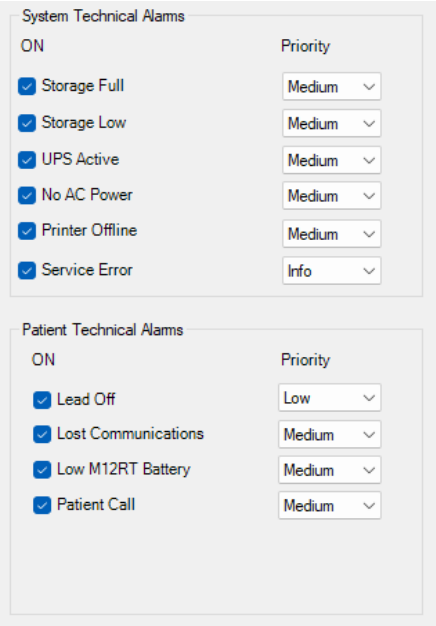


Figure 67 – Technical Alarms

13.4 IT Settings

Supports the setting of IT specific items for the telemetry monitoring system.

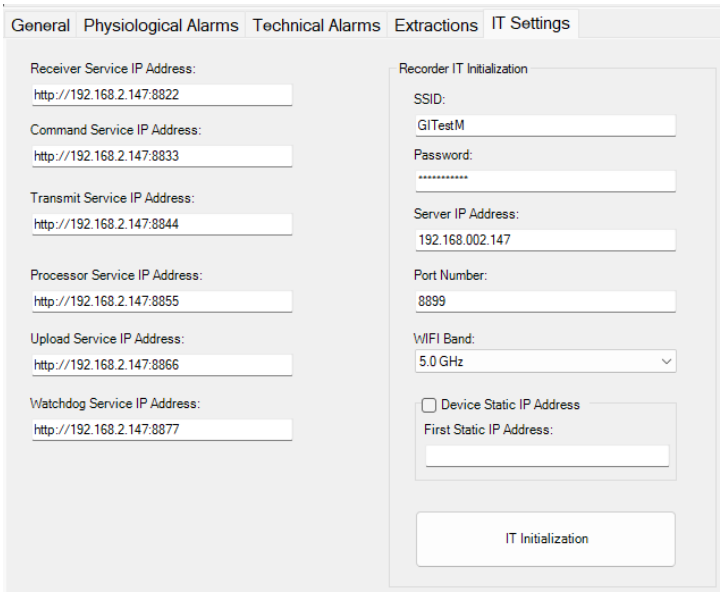


Figure 68 – IT Settings

The IT Settings are used to manage the Wi-Fi communications and server configuration elements. Access to these field are permission controlled. Consult Global Instrumentation Technical Support for assistance with these settings.

13.5 M12 Telemetry System Reboot or Restart

Central Station Reboot/Restart

When the M12A Telemetry Central Station must be rebooted or restarted, Global Instrumentation recommends that patients connected to transmitters are supervised by clinical personnel during the reboot or restart process.

The M12A Telemetry Central Station is the primary monitoring means to view M12R Transmitter patient data. If devices are monitored on only one central station, they will not be actively monitored during a reboot or restart, however all the data will continue to be received at and stored on the M12 Telemetry Server. If a second (redundant) central station is in use, all functionality will persist while the first central station is offline.

Once the M12A Central Station is back online the central station automatically resumes patient monitoring and, via communication with the server, backfills all data received from the transmitters as well as updating the trending information.

NOTE: Rebooting or manually power cycling the central station computer should only be considered a final course of action when performing troubleshooting.

M12A Telemetry Server Reboot/Restart

NOTE: Maintenance on the M12A Telemetry Server should be done only when there are no active patient monitoring sessions.

When the M12A Telemetry Server must be rebooted or restarted, Global Instrumentation recommends that patients connected to transmitters are supervised by clinical personnel during the reboot or restart process.

If the M12A Telemetry Server losses power or becomes inoperable, all new telemetry monitoring data will not be available. The M12A Central Station(s) will display a message that server communication is offline. Upon resumption of server activity, full monitoring data collection and functionality will resume.

NOTE: All data prior to the server outage will be retained and available.

NOTE: During the server outage, the M12RT Transmitter will continue to record and store data on the SD card. Upon completion of the monitoring session the SD card can be uploaded and all monitoring data gaps created during the server outage will be viewable from the M12A Review and Admin Station. Refer ***Section 10 – SD Card Upload***.

13.6 Data Archival and Storage

The M12 Telemetry System supports archival of patient monitoring records including ECG data, alarms, logs, and other session information. Archiving of older data sets stored on the M12 Telemetry System will free up capacity for performing new

monitoring sessions. Once monitoring session data sets are archived, they may later be restored if access to data is required.

SECTION 14 - ADDITIONAL SETTINGS

The M12A Review and Admin Station supports the configuration of additional settings for telemetry monitoring workflow and data management.

14.1 Facility Configuration

The Facility Configuration Page screen allows the user to configure information relative to the facility where the M12 Telemetry System is in use. A facility name, multiple information entries, and an icon can be set up. Each of these fields will appear on the summary page printout.

To access the facility configuration field of the M12A Review and Admin Station click on the Settings button and then click on the “Facility Configuration” button.

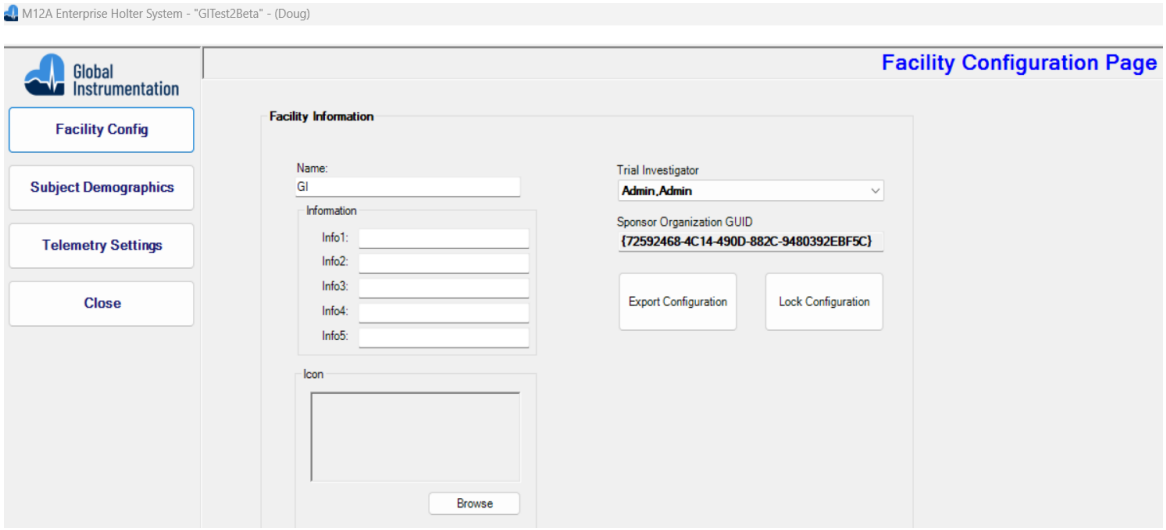


Figure 69 – Facility Information

The facility configuration page allows exporting the configuration as an XML File. In addition, the page also allows locking the configuration settings thereby preventing any changes to the configuration.

14.2 Subject Demographics

The Subject Demographics is a list of all the subject information fields that can be entered when configuring a monitoring session as well as all the information that is displayed in a report.

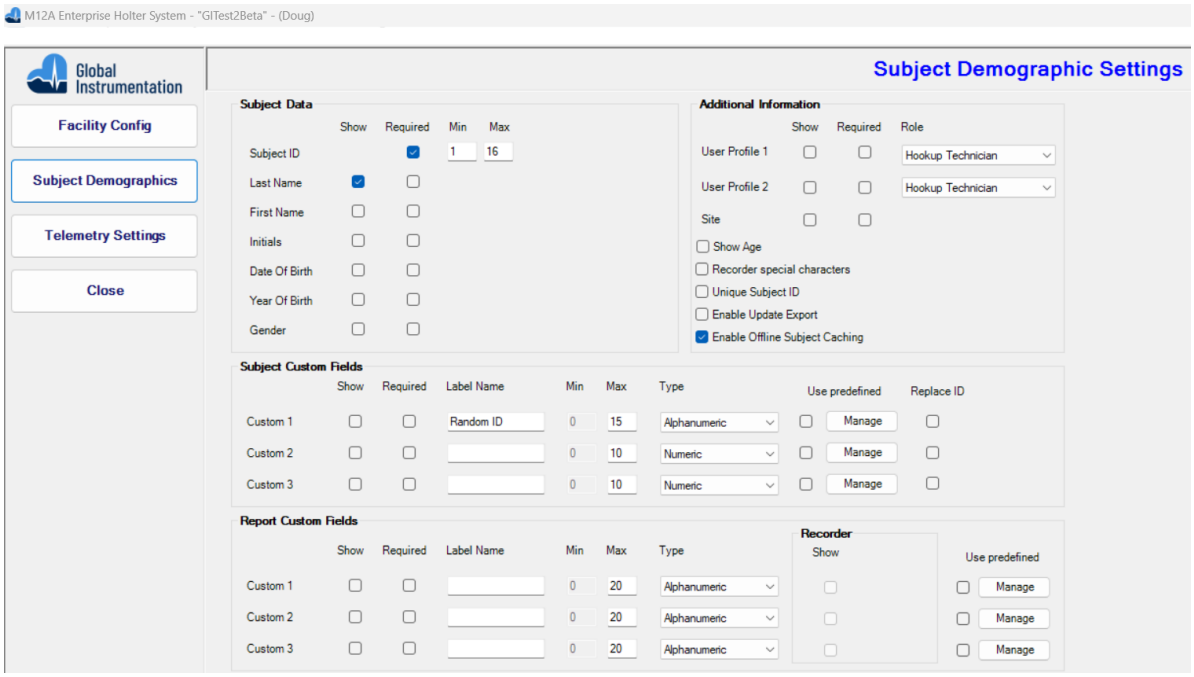


Figure 70 – Subject Demographics

Each field can be tagged as “Show” which makes it appear on all pages that show demographics and if shown, it can be tagged for “Required” which forces the field to be mandatory. Some fields also provide entry for the minimum and maximum number of characters that can be entered.

Three Custom fields can be entered into the system which support a customized label and entry data type from the list: numeric, alpha, and alphanumeric.

The system allows the configuration of either entering in date of birth or year of birth for subject demographics.

The “Additional Information” section contains options for User Profile 1 and 2. These fields allow a system’s Role to be selected. The Role name will then appear as part of the demographic entry with a list of all users assigned to the particular role.

Within the “Report Custom Fields” are subgroups for “Recorder”. When an entry in the “Recorder” group is set to “Show”, it will appear on the transmitter display.

The “Show Age” checkbox can be used to display “Age” vs “Date of Birth” for a subject.

The “Unique Subject ID” checkbox can be used to enable/disable the requirement for a unique subject id.

The “Enable Update Export” checkbox can be used to enable/disable export of Subject XML file when changes are made to the subject demographics.

Within the “Report Custom Fields” group are available checkboxes to enable the use of predefined values. Using this approach the Fields will be available as a pull-down menu on the demographic entry. These fields can be pre-populated by clicking on the “Manage” button.

Within the “Subject Custom Fields” group are available checkboxes to enable the use of predefined values. Using this approach the Fields will be available as a pull-down menu on the demographic entry. These fields can be pre-populated by clicking on the “Manage” button.

SECTION 15 - SUBJECT MANAGEMENT

Each time a patient monitoring session is performed, a new subject is created with the demographics specified. These subjects are saved in the system to identify the report and for reuse later with the same individual. The Subject Management screen gives the user a way to pre-configure subjects or edit the information for existing subjects.
Refer to ***008-700-0154 (M12A Enterprise Administration Guide)*** for information on subject management functionality.

SECTION 16 - SECURITY MANAGEMENT

To control and restrict access to certain areas of the system, roles are defined within the Security Management screen. When users are created or edited, they can be assigned any of the roles in the system. The permissions associated with each role are then inherited by the user granting access to various features.
Permissions specific to use of the M12 Telemetry System include:

- **Tele - Org Default Settings:** Supports setting and updating of all organization default settings for General settings, Physiological Alarm settings, and Technical Alarms settings.
- **Tele – Org Default IT Settings:** Supports setting and updating all areas of organizational default IT settings.
- **Tele – Protocol Management**: Supports creating new protocols and editing settings of existing protocols.
- **Tele – Active Monitoring Mgmnt:** Supports access to all commands/controls and changeable settings for an actively monitored patient.
- **Tele – Patient Alarm Log Mgmnt:** Supports the ability of a user to edit alarm classifications and add notes/comments to an alarm entry.

Refer to ***008-700-0154 (M12A Enterprise Administration Guide)*** for additional information on security management functionality.

SECTION 17 - USER MANAGEMENT

User management is a feature for creating users authorized to log into the system. Users are created with a unique username, personal information, and what roles they are assigned. The User Management screen can then be used to edit, disable, and reset users after they are created.

Refer to ***008-700-0154 (M12A Enterprise Administration Guide)*** for information on user management functionality.

SECTION 18 - ACCESSING TELEMETRY REPORTS

Report review and printing will be conducted at the M12A Review and Admin Station.

18.1 Finding a Report

All telemetry related reports within the M12A Review and Admin Station application are stored in one of two locations, the Inbox or File Cabinet. The Inbox contains all reports by default. This means that any time a new report is created through a hookup or upload, an entry will be created within the table in the Inbox. Once a report has been reviewed and finalized, or the user wants it to be archived then the report can be moved to the File Cabinet.

Both views contain a list of operations on the left side and a table containing each of the reports on the right. Each column identifies information that is being shown for the report. These columns can be clicked on to sort the list ascending or descending and just above the columns are entry fields that can be used to filter the selection to the entered text.

If the report is currently opened by another user, a lock indicator will be shown (if configured) and the report status will read open. Hovering over the lock indicator will show which user is currently editing it, and on what computer (this applies to M12A Enterprise version application only).

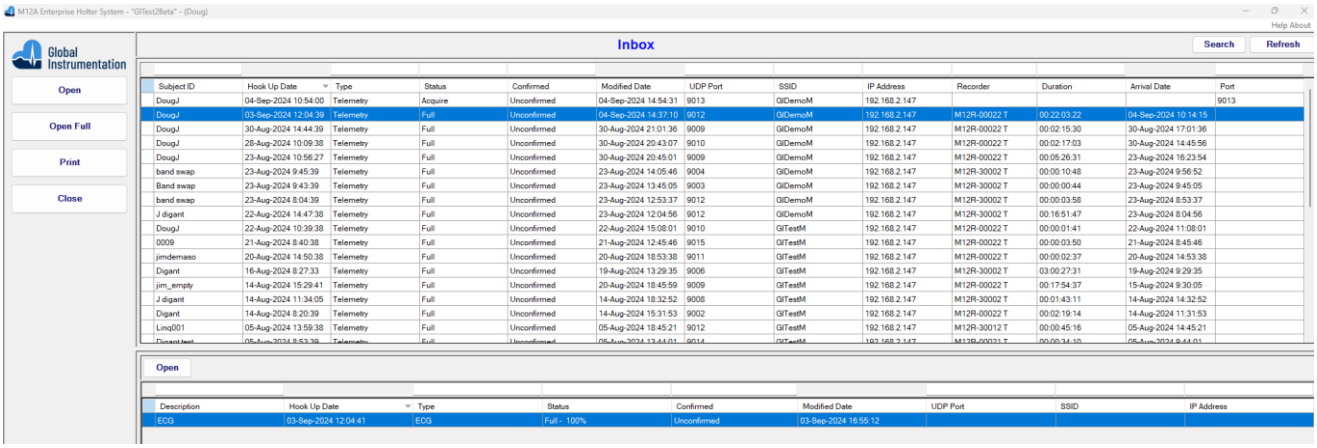


Figure 71 – Inbox

18.2 Inbox

The M12A Telemetry Review & Admin Inbox window contains all telemetry reports that have not been moved to the File Cabinet. Each time a new monitoring session is initiated, a report entry will be created in the list showing information about the date, type ("Telemetry" for telemetry monitoring, or "ECG" for ECG capture reports", etc.), status ("Acquire" for in progress monitoring, "Full" for complete reports, "Processing" for reports uploading after a monitoring session has ended. Once uploaded, that report becomes available for viewing, editing, printing, and other operations.

The reports that are locally cached will display a status of Full – 100%, these reports will open very quickly.

Telemetry Inbox – Status Designations

The Inbox assigns each patient monitoring sessions a status designation as follows:

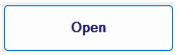
- "Acquire" – patient monitoring is still active and in session.
- "Processing" – active monitoring session has ended, and the report is being generated.
- "Telemetry Full" – this indicates that telemetry report residing in the Inbox is based on the data collected during the wireless transmission from the M12RT to the M12A Telemetry Central Station.
- "Full" – this indicates that the SD card data, from the M12RT, has been uploaded and has overlayed the data collected through wireless transmission.

IMPORANT - It is highly recommended that following the end of a monitoring session that the SD card is uploaded to create the final telemetry report. During wireless telemetry transmission there is the potential that data packets can be missed or dropped due to issues with the wireless network or the patient going out of range of the network. In comparison, the data that is written directly to the SD card during the monitoring session is not subject to wireless variables and is the most reliable source for the full patient data set.

Inbox Sections

The Inbox is divided into two sections. The upper section provides the listing for all telemetry sessions under active monitoring, and all completed full duration telemetry reports. The lower section includes all individually captured ECG reports including Safety ECG and Extraction ECG reports.

Accessing Active Patient Monitoring Information from the Inbox

The M12A Review & Admin Station supports an informational view of each single-patient monitoring session still under acquisition. By clicking on the 

button of a patient listing in "Acquire" status, the following views of the patient monitoring session are available:

- Patient Data
- Settings
- Trends
- Alarm Review

The data presented will match that as described in ***Section 7.3 Single-Patient Display View*** for the same named fields. However, this view from the M12A Review and Admin Station is for informational access only and not intended for real-time monitoring. The information and functionality presented from this view excludes alarming, pausing of alarms, starting and ending monitoring, and changing any of the alarm settings for the patient.

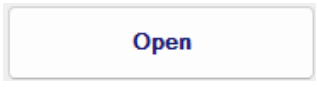
18.3 File Cabinet

The File Cabinet window lists the tests that are no longer in need of active attention and have been manually moved to this new location. Most of the same functions that were available in the Inbox are still available in the File Cabinet allowing a user to review and/or edit older reports if needed.

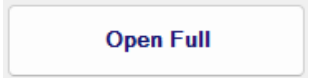
18.4 Inbox/File Cabinet Operations

To perform an action on a report, select the report by clicking on the row within the table and choose the button associated with the action. Reports that appear with the status "Acquire" or "Processing" have not been uploaded yet and will not work with the above actions until the report has been fully uploaded to the system.

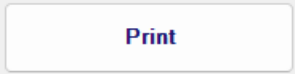
The Inbox and File Cabinet screens provide controls for the following list of actions:



Open Button – opens the selected report for viewing and or minor report editing.



Open Full Button – Downloads all the report files from the server before opening the report. Provides better performance for extensive report editing.



Print Button – Print Button – Prints the selected report

Close Button – Closes Inbox/File Cabinet screen and returns to Main Menu.

To perform an action on a report, select the report by clicking on the row within the table and choose the button associated with the action. In addition to the buttons on the left side of the screen, a menu will appear when a report is right clicked showing many of the same functions as well as a few additional options.

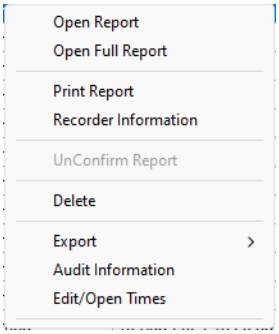


Figure 72 – Report Drop-Down

Opening and printing work as described above. In addition, the right click menu gives the user the ability to view M12RT Telemetry Transmitter information, confirm as well as unconfirm a report, export into additional formats, delete a report (permanently removes the report), view the audit information, or schedule the report to be downloaded at a particular time on the Enterprise system. A report note can be added/deleted/viewed for a report. The ability to execute the above actions are based on the permissions available to the user.

18.5 Searching for a Report

The Search button 

allows the user to narrow down the amount of information downloaded from the server and to find a report quickly.

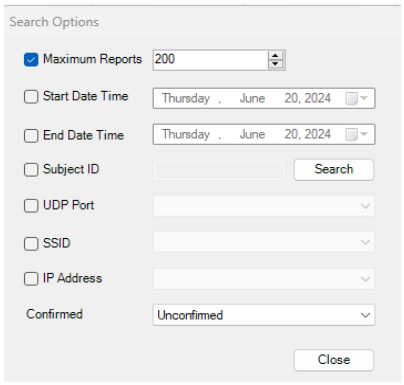


Figure 73 – Report Search

The search allows various options to limit the number of reports displayed within the Inbox.

SECTION 19 - TROUBLESHOOTING FOR THE CLINICIAN

The following charts contain information to assist the clinician with troubleshooting by providing possible solutions. Whenever the suggested solutions to not resolve the issue, contact Global Instrumentation technical support for assistance.

General Troubleshooting

Trouble	Possible cause and solution
Noisy ECG signal	• Check that the electrodes are in good contact with the skin. • Check that the ECG lead wires are connected securely to the electrodes. • Check that patient is not undergoing excessive movement. • Check that patient is relaxed. Tension can cause muscular interference. • Check that there is no clothing rubbing or pulling on the related wires or electrodes.
No ECG signal is displayed on the M12RT Telemetry Transmitter	• Confirm that the configured SD card has been properly inserted into transmitter followed by correct insertion of 2 AA batteries.
No ECG signal is displayed at the central station	• Confirm that the M12RT Transmitter has been properly activated • Check that telemetry transmitters are not outside the range of the Wi-Fi network.
The M12RT Telemetry Transmitter is activated, however the Central Station patient tile continues to display “Waiting for M12RT”	• Transmitter is not communicating to the WiFi network • Check device display for error messages and consult your facility or Global Instrumentation technical support
M12RT Transmitter will not activate	• Confirm that you have configured the SD card properly via the central station Monitoring Start Wizard. • Confirm the SD card is inserted properly in the transmitter. • Confirm that the SD card was inserted in the transmitter before the batteries were inserted. If unsure, remove the batteries and SD card and repeat the sequence in proper order.
Square Waves are showing on central station display	• Check for disconnected patient cable lead wires • Check the surrounding area for any possible cause of RF interference.
Faulty Alarms or Arrhythmias	• Check status of the patient • Check that all electrodes are attached • Check the QRS morphology to see if there is a change. If yes, select “Analysis Relearn” in the Settings field for the patient under monitoring. • Select Traces to display all 12 ECG leads. Determine if a signal issue is occurring on one more lead. Check the electrode and lead wire adhesion on the patient. Replace electrode(s) if necessary.

M12RT Telemetry Transmitter Specific Troubleshooting

Trouble	Possible cause and solution
"No Configuration File" message on device display	• An SD card has been inserted that was not properly configured via the Monitoring Start Wizard. Reconfigure the SD card properly. Refer to Section 11.
"No IT Info" message on device display	• Indicates the IT configuration file was not found on the SD Card • Attempt to reconfigure the SD card
"IT Info Not Valid" message on device display	• Indicates the content of the encrypted IT configuration files are invalid • Attempt to reconfigure the SD card
M12RT Error Message –"No WiFi"	• The device cannot connect to the WiFi.
M12RT Error Message – "NoIP"	• The device is not configured with specific IP address to start communicating.
M12RT Error Message – "NoDATA"	• Device is not actively communicating with the CS
M12RT Error Message – "NoCMD"	• Device is not communicating with the CS
M12RT Lead Off Error Message – including: LeadRA, LeadLA, LeadLL, LeadV1, LeadV2, LeadV3, LeadV4, LeadV5, LeadV6	This indicates that one or more ECG leads has lost a signal. Check that each leadwires on patient cable are securely connected to electrodes on the patient.

Network Transmission Troubleshooting

Trouble	Possible cause and solution
Any of the following: 1. Intermittent ECG traces on the Central Station 2. Low signal strength indication on Wi-Fi signal icon	Possibly due to poor WLAN network coverage. Check with IT administrator to correct issues

SECTION 20 - TECHNICAL SPECIFICATIONS

20.1 System

Mode of Operation	Continuous

20.2 M12RT Telemetry Transmitter - General

Category	Description
Instrument Type	Digital mobile transmitter with ECG
Dimensions	4.4 x 3.1 x 1.4 inches (112 x 78 x 36 mm)
Weight	14 oz. (396 grams) with batteries and patient cable
Input Channels	Continuous 12-lead signal acquisition and transmission with 10-wire cable
ECG Leads Transmitted	10-wire: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Device Classification	EU Class: Class IIb IEC Type: Type CF
Applied Parts	Patient cable, Ag/AgCl disposable electrodes
Special Functions	ECG display, lead-off, battery notification, multi-purpose call
Defibrillator Protection	Complies with IEC 60601-2-27 and/or IEC 60601-2-25; excludes section 201.12.1.101.14 of IEC 60601-2-27– Synchronization pulse for cardioversion)
Function Keys	Keypad for: display navigation; display wake-up; multi-purpose call
Display Type	Anti-glare color OLED
Display Size	1.75 inches (4.4 cm) diagonal, active area
Display Resolution	160 x 128 pixels
Battery Type	• AA (size LR6) batteries; user-replaceable; disposable • 3.7V (@ 170 mA) Lithium polymer (LiPO) internal battery for supply back up (LiPO battery charge rate 20mA/hour; charge time of <10 hours)
Battery Run-Time	Up to 26 hours (when configured with a high-performance alkaline battery; (example - Duracell Optimum) (AA batteries may require replacement during monitoring session) **NOTE:** The battery life listed above my be shortened by the following factors: • Wireless signal interference • Frequent turn on/off cycling of the M12RT display • Wireless network coverage does not meet the technical specifications (see section ***20.8 M12 Telemetry Network***)
Monitoring Session Duration	Up to 96 hours
Communications	Network: 802.11 a/b/g/n
Auxiliary Output	Not supported

20.3 M12RT Telemetry Transmitter – Environmental

Category	Description
Temperature	Operating Temperature: +10°C to +40°C Non-Operating (shipping/storage) Temperature: -20°C to +50°C
Humidity	Operating Humidity: 15% to 95% (non-condensing) Non-Operating (shipping/storage) Humidity: 15% to 95% (non-condensing)
Altitude	Operating Atmospheric Pressure of 700 hPa to 1060 hPa Non-Operating (shipping/Storage) Atmospheric Pressure of 700 hPa to 1060 hPa
IP Classification	IP22 – This device is protected from touch by fingers and objects greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical.

20.4 ECG Specifications

Category	Description
ECG	12-lead ECG with specific 10-wire patient cable
Simultaneous Leads Available	10-wire: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Analysis Channels	3 channels, any combination
Monitoring Period & Report Durations	Continuous monitoring & storage up to 96 hours
Storage Capacity & Period	– GI SD Card part number 000-400-0129 – Internal (user removable) full-size 8 GB SD Card (minimum transfer rate of 20MB/s) – Data remains valid for >5 years or until SD card is initialized for reuse.
ECG Digital Sampling Rate	500 sps
Pacemaker Detection	Pacer detection: ±2mV to ±700mV and durations of 0.5ms to 2.0ms Pacer Detection is defaulted to ECG-II (pacer detection only available on leads RA and LL)
Pace Pulse Rejection	When tested in accordance with the IEC60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. - Amplitude: ±3 mV to ±700 mV @ width: 0.1 ms to 2 ms - Rise time: 10 µs to 100 µs - No overshoot This rejection capability also applies when an atrial paced pulse with identical amplitude and duration precedes a ventricular pace pulse by 150 ms to 250 ms.
A/D Conversion	16 bits

A/D bit Resolution	0.5 µV
Frequency Response	0.05 Hz – 175 Hz @ 500 sps (±0.015 sps)
Dynamic Range	+/-300 mV (0.5uV p-p noise)
Beat Detection	Sensitivity 99.94%, positive predictivity 99.91% (AHA/MIT database)
Beat Recognition	Normal, ventricular, artifact
Heart Rate Measurement	Range: 20-300 bpm; Resolution: 1 bpm HR accuracy of +/-2 bpm or +/-1%, whichever is greater Note: if the heart rate detection goes below 20 bpm a triple down direction arrow symbol will appear. If heart rate detection goes above 300 bpm a triple up arrow symbol will appear.
HR Averaging	Heart rate calculation is based on the average of the last 12 valid RR intervals if at least 3 out of 12 RR intervals are valid. Paced beats and PVCs are included in the heart rate calculation.
Tall T-wave rejection capability	When the test is performed based on Clause 201.7.9.2.9.101 b) 2) of IEC60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV (12 mm) of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Response time to heart rate change	Meets the requirements of IEC60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 bpm to 120 bpm: less than 11 seconds overall from 80 bpm to 40 bpm: less than 11 seconds overall
Response to irregular rhythm (special waveforms)	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: • Ventricular bigeminy (3a): 80 ± 1 bpm • Slow alternating ventricular bigeminy (3b): 60 ± 1 bpm • Rapid alternating ventricular bigeminy (3c): 120 ± 1 bpm • Bidirectional systoles (3d): 90 ± 1 bpm
Time to alarm Tachycardia (special waveforms)	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC60601-2-27: • Waveform B1 (x0.5, x1.0, x2.0 gain) time to alarm less than 10 seconds • Waveform B2 (x0.5, x1.0, x2.0 gain) time to alarm less than 10 seconds
Applied Currents	Lead connection failures are detected by a 0.4V bias current, which is applied to each patient electrode connection through a 40 Meg-ohm resistor with respect to the reference electrode. RL drive for noise suppression; Applied currents not to exceed the safe limit leakage currents defined in IEC 60601-1.
Recovery from Defibrillation Discharge	Within 5 seconds, compliant with IEC 60601-2-25 and/or IEC 60601-2-27.
Electrodes	Compatible with Ag/AgCl disposable electrodes that comply with the EC12 performance standard

20.5 M12A Telemetry Central Station – Alarms

Category	Description
Number Alarm Levels	4 (high, medium, low, and information only)
Visual Alarm Presentation	Color-coded text message by priority (red, yellow, cyan, white) Blinking, for active alarm Stationary when alarm condition is still present and acknowledged by operator
Audible Alarm Presentation	Speakers - 3 volume settings SPL ranges (measured according to IEC 60601-1-8:2012) within a radius of 1 meter: – Max audible alarm sound volume: 63.5 dB (±15dB) – Mid audible alarm sound volume: 58.0 dB (±15dB) – Min audible alarm sound volume: 52.5 dB (±15dB) The alarm volume decibel level settings listed above are fixed and not adjustable by the user organization

20.6 Alarm Groups

The following Alarm Groups are supported in the M12A Telemetry System. Information below in parentheses indicates the factory default settings for each alarm.

Category	Description
Physiologic (Latched)	**High Priority Only** Asystole (high priority/latched) Ventricular Fibrillation (high priority/latched) Ventricular Tachycardia (high priority/latched) Sustained Ventricular Tachycardia (high priority/latched) High Heart Rate (high priority/latched) Low Heart Rate (high priority/latched) (default setting: all enabled On)
Heart Rate	**High/Medium/Low/Information; on/off (user selectable)** Bradycardia (high priority) Tachycardia (high priority) (default setting: all Enabled On)
Extended Arrhythmias	**Medium/Low/Information; on/off (user selectable)** ventricular rhythm, ventricular run, ventricular bigeminy, ventricular couplet, ventricular trigeminy, missing QRS, low QRS amplitude (default settings: priority - information; all Disabled)
ECG	**Medium/Low/Information; on/off (user selectable)** QT High (low priority) QTc Bazett High (low priority) QTc Fridericia High (low priority) (default setting: all Disabled)

Technical Alarms - System	**Medium/Low/Information; on/off (user selectable)** Storage Full (low priority) Storage Low (low priority) UPS Active (Low priority) Printer Offline (information) Service Error (Information priority) (default setting: all Enabled On)
Technical Alarms – Patient Related	**Medium/Low/Information; on/off (user selectable)** Lead Off (med priority) Lost Communications (med priority) Low M12RT Battery – transmitter (med priority) Patient Call (low priority) (default setting: all Enabled On)

20.7 M12 Telemetry System – System Requirements

Components	Requirements
M12A Telemetry Central Station Workstation	
Central Station PC/CPU	• CPU: 4 cores and 2.9 GHz minimum • Memory: 16 GB minimum • Hard disk 1: 250GB minimum; RAID 1 disks; SSD preferable • Hard Disk 2: 2000GB minimum; Raid 1 disk; SSD preferable • Network adapter: 1000BASE-T (minimum) self-adapting wired only connection • Ethernet 802.3 • USB ports: four or more
Display	• 24-inch or 27-inch ordinary display with 1280×1024 resolution • Support for up to four displays
Operating System	• Support Windows 11 (version 24H2 or newer)
Antivirus	• Required and should be managed by Organization IT Support
Graphic Card	• Support dual or multiple displays
Printer	• Support A4 or Letter paper size; resolution greater than 300 dpi
Peripherals	• Keyboard and mouse
Speaker	• Internal to computer • Give alarm tones (45 to 70 dB) and alarm tones comply with IEC 60601-1-8
UPS	• Uninterruptible power supply – sized adequately for 60 minutes or longer backup runtime; facility/organization IT supported
Firewall Rules	• Specific Firewall rules are applied for inbound and outbound

M12A Review & Admin Workstation	
PC/CPU	• CPU: dual cores and 2.0 Ghz minimum • Windows 11; compatible with all major service pack updates (version 24H2 or newer) • Memory: 8 GB minimum • 1000 GB hard drive minimum; Additional hard size required for storing temporary data files. • USB ports: three or more
Display	• 24-inch or 27-inch ordinary display with 1280×1024 resolution
Printer	• Support A4 or Letter paper size; resolution greater than 300 dpi
Peripherals	• Keyboard and mouse
M12A Telemetry Server	
Core Server	• Memory: 16 GB RAM minimum • Storage: – Hard Disk 1: 250GB hard drive minimum for OS. Raid 1 – Hard Disk 2: Telemetry (short term data) 4 TB: Raid 1 – Hard Disk 3: Data (long term storage) 16 TB: Raid 5,6,10, – Hard Disk 4: Log files 1 TB: Non-Raid minimum • Network: Dual 1000BASE-T, self-adapting wire only connections.
Operating System	• Windows 2022 Server (64-Bit) SP1 or higher
Other	• SQL Database Compatibility – SQL 2017 (remote SQL) – SQL 2019 (remote SQL) – SQL 2019 Express (built-in SQL)
UPS	• Uninterruptible power supply – sized adequately for 60 minutes or longer backup runtime. Supported by organization IT staff.
Server	• Physical or virtual • Physical can be racked
Antivirus	• Required and should be managed by the facility/organization IT support staff
SSL	• SSL certificate is used for web service hosting, all inter communication from Devices to server, and from Server to CS and Review/Admin stations. SSL certificate purchase and replacement are managed by an organizational IT group.
Ports	• 64 ports for receiving data from M12R T devices • 64 ports for transmitting data to CS, Repeaters and review/admin stations. • 10 other ports used for stream communication, commands, management, etc.
Firewall Rules	• Specific Firewall rules are required for inbound and outbound rules.
Hard Drive space Storage Requirements	• Telemetry data storage (short term) requires at a minimum 1 GB per patient per 24-hour recording.

	• Date storage (long term) requires: – 300 MB for each 12-Lead 24-hour monitoring period – 0.1 MB for each 10 second 12-lead ECG recording

20.8 M12 Telemetry Network

Server/ Central Stations/ Repeaters network requirement

Category	Description
VLAN Telemetry	• Dedicated VLAN for Server, Central Stations, Repeaters and optional for Review/Admin stations
Digital local area network:	• IEEE 802.3, 1000 BASE T
Network protocol:	• IPV4 only
Data exchange protocol	• TCP, HTTPS, HTTPS Encrypted SOAP
Distance switch-station	• Max 100 m
Cable	• Cat 6 or higher
Connectors	• RJ-45
Router IP addressing	• Fixed or DHCP; Preferably fixed for Server, Central Stations, and Repeaters

M12RT Device WIFI AP Network Requirements

Category	Description
VLAN WIFI	• Dedicated VLAN for all M12RT transmitters.
SSID	• Dedicated SSID for all M12RT Transmitters • SSID name length max is 32 bytes • SSID Password max length is 48 bytes
SSID Radio parameters	• Channel width 20 MHz for 5GHz band
Access Points	• Multiple access points preferably POE with direct wired connections back to network switches. • Ideally configured using star wired connection (POE) into a minimum of two network switches. Adjacent AP should be on different network switch
Routes	• WIFI access points should only be allowed to send/receive data to specific server in VLAN Telemetry above. Within VLAN WIFI, no other inbound or outbound communication ports should be opened. No M12RT to M12RT (peer to peer) device communication is required or should be enabled.
Digital local area network:	• IEEE 802.3, 1000 Base T
Network protocol:	• IPv4 only
Data exchange protocol	• TCP
Distance switch-station	• Max 100 m

Cable	• Cat 6 or higher
Connectors	• RJ-45
Router IP addressing	• Fixed or DHCP

20.9 M12RT Wireless Module

The M12RT Transmitter uses a WiFi wireless module to enable transmission of ECG data across the wireless network.

Operating characteristics are:

- Frequency Band: 5GHz
- Modulation: 802.11 a/b/g/n/ac/ax
- Max Output Power: 19 dBm.
- Typical Range: 100 Meters/330 Feet (Minimum range of 30 Meters/100 Feet)

The wireless communication system automatically determines QoS environment and will adapt to the environment using spread spectrum techniques. To avoid possible effects from RF sources in the vicinity of the M12RT Transmitter maintain a minimum distance of one foot from RF sources (e.g., electromagnetic security systems, cellular telephones, RFID or other in-band transmitters).

Summary of EMC and telecommunications standards which device meets includes:

- EMC: IEC 60601-1-2:2014+AMD1:2020
- FCC ID: X8WWM02C
- ISED ID: 4100A-WM02C
- CE, UK, Australia: Compliant
- JapanTELEC: 201-240555

20.10 Conformance to Regulatory/Electrical Safety Standards

The M12 Telemetry System conforms to the following standards:

Category	***Standard No.***	***Standard Title***
Essential Performance	IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
	AAMI EC57	Testing And Reporting Performance Results Of Cardiac Rhythm And ST Segment Measurement Algorithms
Safety	IEC 60601-1	Medical Electrical Equipment - General Guidelines for Safety 3rd edition
Safety & Essential Performance	IEC 60601-1-14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Safety & Essential Performance	IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

EMC	IEC TS 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
Safety & Essential Performance Usability	IEC 60601-1-6	Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
	IEC/EN 62366-1	Medical devices - Application of usability engineering to medical devices
Safety & Essential Performance Alarms	EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
Safety Electrical	AAMI EC53	ECG Trunk Cables and Patient Lead wires
Biocompatibility	ISO 10993-1	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
Software Validation	IEC 62304	Medical device software - Software life-cycle processes
Risk Management	ISO 14971	Medical Devices - Applications Of Risk Management To Medical Devices

SECTION 21 - SECURITY RECOMMENDATIONS

Global Instrumentation makes the following security recommendations:

- Physical security of the M12RT Telemetry Transmitters is recommended and is the responsibility of the operating organization.
- Physical security of the information technology closet is recommended and is the responsibility of the operating organization.
- Restrict physical access to unused ethernet ports on the M12A Central Station.
- The operating organization should restrict physical access to unused USB and serial ports on the M12A Central Station.
- Global Instrumentation relies on the medical device isolation mechanism of the VLANs and the proper configuration, implementation, and use of the operating organization's security measures to prevent the introduction of malware onto the M12 Telemetry network.

SECTION 22 - CYBERSECURITY CONSIDERATIONS

Global Instrumentation provides the following security information and recommendations:

- Global Instrumentation recommends always following network security best practices, such as:
  - Maintaining software
  - Perform regular backups to the M12A Telemetry Server
  - Segmenting via firewalls
  - Closing unused ports
  - Restricting user permissions
  - Limiting third party access
  - Monitoring network activity
  - Termination of multicast communication with Infinity devices
  - rejection of new unicast connections

  Without these measures there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.

- Global Instrumentation recommends that the responsible organization operate the M12A Central Station and M12RT Transmitter devices on separate, isolated, VLANs to reduce risk from network security vulnerabilities. Use of QoS with M12RT Transmitters is required to ensure optimal network data transmission.
  Without these measures there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.

- To enhance network and device security, restrict physical access of the following to authorized users only:
  - M12 Telemetry network
  - M12RT Transmitter devices
  - Accessories

  In addition, physical access must also be restricted to:
  - Unused Ethernet ports
  - Unused USB ports
  - Unused serial ports

The sections below provide additional information related to the M12 Telemetry System information structure and data exchange to assist in your security and cybersecurity protection planning .

22.1 Third-Party Software (SBOM)

Vendor Name	Version	Description
Microsoft Windows 11	10.0.26100 (24H2)	Operating System M12A Telemetry Central, Review & Admin Station Clients
Microsoft Windows Server 2022	10.0.20348	Operating System to host M12A Telemetry Server Components
Microsoft .Net Framework	4.8.04161	Microsoft components required to run M12A Telemetry Server Components M12A Telemetry Central, Review & Admin Station Clients
Microsoft IIS		Microsoft components required to run M12A Telemetry Server Components
Microsoft SQL Express	10.0.20348	Microsoft components required to run M12A Telemetry Server Components

NOTE: if additional information on the M12 Telemetry System SBOM is required, please contact Global Instrumentation.

22.2 Network Ports & Services

Part 1 - Network Port Filtering

Appropriate port filtering rules will be set for VLANs configured for M12A Telemetry System.

The following is the recommended port filtering on the two VLANS required for the M12A Telemetry components.

Port Filtering - M12A Telemetry Network VLAN (Primary-VLAN)

Filter	Inbound /Outbound	Source	Destination	Protocol	Port	Comment
Allow (Open)	Outbound	Primary-VLAN	GI Software Deployment Server IP (Trusted IP)	TCP	<443>	Allow GI Software Deployment Server IP
Allow (Open)	Inbound	Device VLAN	M12A Telemetry Server	TCP	9000 to 9064	-ECG Stream -Command port
Allow (Open)	Inbound	M12A Telemetry Server	M12A Admin/Review Station	TCP	443	General access to data
Allow (Open)	Outbound	Primary-VLAN	Microsoft Deployment Servers	TCP	Refer to windows update.	Windows Updates
Allow (Open)	Outbound	Primary-VLAN	Any	UDP	53	DNS for Windows Updates
Allow (Open)	Inbound	Primary-VLAN	Trusted IP list provided by GI	TCP	3389	RDP
Deny (Closed)	Both	Primary-VLAN	Any	Any	Any	Deny All Other Traffic

DNS Filtering - M12A Telemetry Network VLAN (Primary-VLAN)

GI recommend blocking all domains, using content filtering features in network management, EXCEPT the following:

- Microsoft domains for software updates (add wildcards for subdomains)
- WWW.globalinstrumentation.com for software upgrades and license management

Port Filtering - M12A Telemetry Network VLAN (Device-VLAN)

Filter	Inbound /Outbound	Source	Destination	Protocol	Port	Comment
Allow (Open)	Outbound	Device-VLAN	M12A Telemetry Server IP in Primary-VLAN	TCP	9000 to 9064	-Device ECG streams -Command Port
Deny (Closed)	Both	Device-VLAN	Primary-VLAN	Any	Any	Block Device VLAN devices to rest of Primary VLAN
Deny (Closed)	Both	Device-VLAN	Any	Any	Any	Block Device VLAN devices to Internet or others

Part 2 – Local Computer Firewall Rules

Windows Firewall Rules – M12A Telemetry Server

Inbound	Outbound	Protocol	Port Number	Application
Allow	Block	TCP	9000-9063	Devices ECG stream & Device Command
Allow	Block	TCP	9064-9075	Additional controls ports
Allow	Allow	TCP	443	HTTPS – General data

Firewall Rules – M12A Central Station and Repeater Station

Inbound	Outbound	Protocol	Port Number	Application
Allow	Allow	TCP	8000-8064	Display ECG stream with results

22.3 Sensitive Information and Data Transmitted

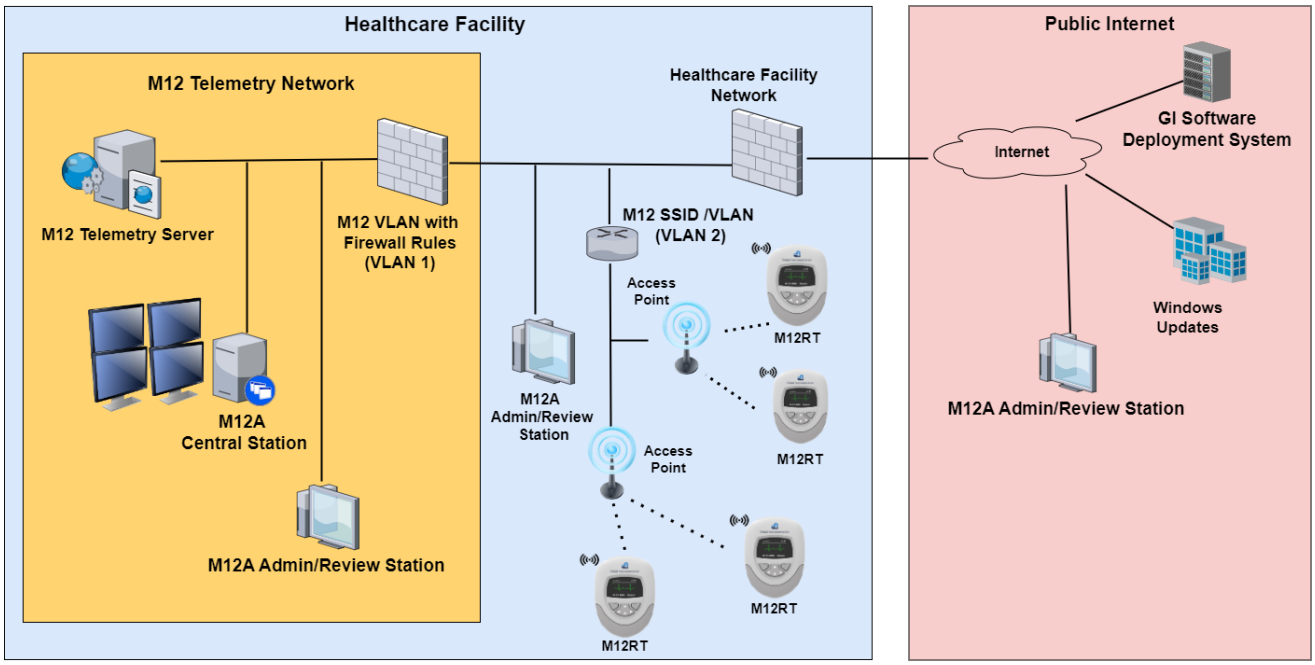
- Patient / Subject ECG waveform data (PHI) is transmitted from M12RT Transmitter to the M12A Telemetry Server. This transmission is fully encrypted.
- Patient / Subject ECG waveform data (PHI) relays from M12A Telemetry Server to the M12A Central or Review Station. This transmission is fully encrypted.
- Patient / Subject information, report files and other (PII) files may be sent from M12A Telemetry Server to the M12A Central or Review Station as requested. This exchange is fully encrypted.

22.4 Sensitive Information and Data Stored

- Patient / Subject ECG waveform data (PHI) is received by M12A Telemetry Server and is stored in proprietary format.
- Patient / Subject information, report files and other (PII) files generated on M12A Telemetry Server, except when stored in database, are stored in encrypted format on local drives.
- Patient / Subject information, report files and other (PII) files, received on M12A Central or Review or Admin Stations, are stored in encrypted format on local drives.

22.5 Network and Data Flow Diagram

The following diagram shows an example of the M12 Telemetry System network configuration.



* VLAN 1 - A private VLAN for M12 Telemetry System. Tightly controlled using Firewalll rules.

* VLAN 2 - A private VLAN where only M12RT devices can connect using WIFI

Figure 74 – M12 Telemetry System Environment Overview

22.6 Malware Protection

GI strongly recommends configuring Local Windows Policy on all computers to disable the (program) execution access for all removable media, to prevent malware injection from compromised removable media like USB/SD Card attached to the computers. The removable media should have read only access where required.

22.7 Software Updates and Patch Management

Global Instrumentation actively seeks out information to identify performance and/or security issues that require remediation.

- Internal Global Instrumentation testing teams identified defects or issues are forwarded to Global Instrumentation quality assurance department for investigation, analysis, and remediations.
- Customer identified defects or issues are reported to Global Instrumentation by calling Global Instrumentation Technical Support via phone (315-682-0272) of via email at giservice@gi-med.com.

When software or firmware updates are released to remediate identified defects, safety, or performance issues associated with the M12 Telemetry System, Global Instrumentation will communicate to customers by issuing a service bulleting and/or reaching out directly to the healthcare facility. The deployment of implementing the software update, depending on the technical nature of the update, may be conducted by one or all of the following methods:

- Download and install directly
- Get regular factory service
- Get field service

22.8 Authentication and Authorization

Login credentials and access permissions for various functions of the M12A Telemetry Central Station and M12A Review and Admin station are controlled and managed in the M12A Review and Admin application. Additionally, entry of credentials will be required when changing the settings of an actively monitored patient and other activities affecting the monitoring session.

To control and restrict access to certain areas of the system, roles are defined within the Security Management screen. When users are created or edited, they can be assigned any of the roles in the system. Refer to Section 16 – Security Management.

Passwords

Global Instrumentation recommends using custom “strong” passwords that are securely stored. The creation of strong passwords requires the user to use a password that is at least 8 characters long and must contain 1 lower case letter, 1 upper case letter and 1 digit. The system requires each user to reset their password every 120 days.

22.9 Network Controls

Global Instrumentation recommends the following network control processes:

- Setting up a separate SSID exclusive for M12RT transmitters and matched to M12RT Transmitter WIFI Network VLAN (Device- VLAN). All M12RT transmitters shall be set up to communicate over this SSID.
- Enabling WPA2 security protocol for WIFI segments of the network.
- Enabling strict MAC address-based filtering-based approach in all VLANS. Only the computers and devices added to respective VLAN should have their MAC addresses whitelisted.

- Enabling configuring STATIC IPs for all computers in M12A Telemetry Network VLAN (Primary-VLAN). Furthermore, all devices (M12RT transmitters) when added to M12RT Transmitter WIFI Network VLAN (Device- VLAN), should be set up to use a dedicated Static IP.
- Enabling Intrusion Detection and Intrusion Prevention in the network setup to avoid cybersecurity threats like DOS attacks or Malware injections.
- Using client isolation features in WIFI network to disable inter-communications between the devices (M12RT transmitters) latched to a WIFI network.

22.10 Encryption

Global Instrumentation recommends and implements the following encryption practices:

- Enabling Bitlocker or hard drive encryption protection for hard drive on all Windows computers in GI Telemetry System.
- Enabling WPA2 security protocol for enabling encryption of WIFI segments of the network.

Global Instrumentation enables the support for TLS 1.2 SSL protocol for encryption of communication over SOAP web services and communications between server and the clients.

22.11 Audit Logging

The table below provides a list of where log and audit information is stored.

Computer	Application	Type	Accessibility
M12A Telemetry Server	Telemetry Services	Logs	Located in *storage drive* GIMedical\GITelemetry
M12A Telemetry Server	M12A Server	Logs	Located in *storage drive* GIMedical\ GIHolter\GIHolterWAN\<study name>
M12A Telemetry Central/Review/Admin Station	M12A Application	Logs	Located in *storage drive* GIMedical\GIHolter\<study name>\Data\Log
M12A Telemetry Central/Review/Admin Station	System	Audits	Accessible by log into study using M12A Application.

22.12 Remote Connectivity

- Global Instrumentation recommends allowing RDP access to certain computers from trusted IPs and adding corresponding firewall rules as described in Network Ports and Services section for internal usage only.

- Based on user requirements, an M12A Admin/Review station can be set up outside the facility for remote use. Such access is enabled using the Port filtering rules described in the Network Ports and Services section.
- Global Instrumentation recommends blocking Inbound TCP Port for SQL Server remote access on the M12 Telemetry Server.
- GI recommends using SQL Server administration tools to disable remote access in addition to the TCP Port blocking.

22.13 Service Handling

Global Instrumentation recommends the following service handling practices:

- Implement role-based access control (RBAC) for service personnel to limit system access to authorized personnel based on job function, using unique, strong passwords.
- Regularly back up M12 Telemetry system data and verify its integrity to ensure business continuity in case of device failure, corruption, or cyberattack.
- When decommissioning components of the M12 Telemetry System, ensure the process follows established facility processes and guidelines that comply to HIPAA, state, and local regulations regarding data retention and privacy. This should include consideration of the following elements:
    - Data archival – extraction/export of data from the system and secure storage of archived data securely and in compliance with relevant regulations.
    - Decommissioning of hardware and software – Remove or destroy hardware components and uninstall software.

Consult Global Instrumentation for support on service handling recommendations and support.

22.14 Cybersecurity Incident Response

M12 Telemetry System settings may be compromised in the event of a cybersecurity attack or other configuration error. If a cybersecurity attack is suspected:

1. Isolate the affected unit(s) and/or components and disconnect from the network.
2. Immediately contact your healthcare facility biomedical and IT departments for support.
3. Power off and discontinue use of the affected devices or system components.

4. Do not place devices or components back into service until the situation is resolved.
5. Collect all logs.

In the event of a suspected cybersecurity attack, Global Instrumentation recommends that all logs are collected by the biomedical or IT department, Global Instrumentation service staff, or specialized service personnel.

22.15 End-of-Life and End-of-Support

Global Instrumentation will continue to provide support and service for the M12 Telemetry System throughout the service life of the product. This will include security updates, bug fixes/software updates, and technical support. At least 1 year prior to the expected end of service life, Global Instrumentation will notify customers of the intended end of service life date via a service bulletin.

22.16 Secure Coding Standards

Global Instrumentation implements robust security practices throughout the software development lifecycle, including secure coding guidelines, rigorous testing, and continuous monitoring. Key areas of focus include input validation, secure error handling, and strong authentication and authorization mechanisms.

22.17 System Hardening Standards

Global Instrumentation follows secure hardening coding standards for medical devices focus on building robust security into the software development lifecycle to mitigate cybersecurity risks. This involves implementing security controls throughout the design, development, and maintenance phases, adhering to relevant standards including ISO 13485, 21 CFR Part 820, IEC 62304, NIST, and FDA cybersecurity guidance.

SECTION 23 - PHYSICIANS GUIDE

23.1 Overview

The M12 Telemetry System performs continuous analysis of the ECG data. The analysis processing consists of the following sub-processing components:

- Signal Conditioning
- QRS Detection
- Beat Classification
- R to R measurement
- Heart Rate Calculation
- Asystole, Ventricular Tachycardia, and Ventricular Fibrillation detection.
- Various cardiac rhythm pattern detections

23.2 Signal Conditioning

The signal processing performed during the analysis is used to remove some of the noise and artifacts normally found during a monitoring session. The following types of noise and artifacts may occur:

- Drift – gradual baseline wander usually caused by respiration.
- Shift – sudden baseline changes in electrode skin impedance or external contact to electrode site.
- Rail – amplitude saturation of the signal.
- Continuous noise of a single frequency- usually associated with high electrode impedance and mains 50 or 60 Hz interference.
- Burst of noise- usually several frequencies mixed together due to electrical signals from active muscles.
- Spikes- large amplitude shifts of a short duration.

The analysis program applies to a collection of several filters to correct for these types of issues. These filters are optimized for the specific sub-process requirements.

23.3 QRS Detection and Feature Extraction

The analysis program detects each QRS for each channel. Each detected QRS has several locations identified including Isoelectric, Q, R, and S points. From these locations, additional measurements are made for the width, height, morphology, and noise assessment. These measurements are used for beat classification and are not provided for external review. A separate detection function is used to identify and detect VTach and VFib.

23.4 Beat Classification

The beat classification is performed by evaluating QRS detections, features, R-R intervals, and noise assessment. The outcome of the classification results in the following beat types:

- Normal
- Ventricular
- Artifact

23.5 Pattern Determination

Table 1: Ventricular event patterns

VTach (six or more Ventricular over the VTach Rate)	N-V-V-V-V-V-V-N
Vfib (4 or more seconds of Ventricular Fibrillation)	N-V-V-V-V-V-V-V-V-V...
Ventricular Couplet	N-V-V-N
Ventricular Run	N-V-V-V-N
Bigeminy	N-V-N-V-N-V-N
Trigeminy	N-N-V-N-N-V-N-N-V-N

The analysis program detects the following rate-related patterns:

Table 2: Rate-related event patterns

Event	**Definition**
Asystole	No heartbeats detected within threshold time (use configurable)
Low Heart Rate	Heart rate falls below minimum heart rate threshold (user configurable)
High Heart Rate	Heart rate is greater than high heart rate threshold (user configurable)
Tachycardia	Heart rate is above the tachycardia setting for a minimum of 15 seconds
Bradycardia	Heart rate is below the bradycardia setting for a minimum of 15 seconds

23.6 Heart Rate Calculation

The analysis program assigns an R-R interval to each detected QRS based on the time interval to the last labeled QRS. A QRS can be assigned with an unknown R-R interval if the region between the last detected QRS and current QRS contains artifact classifications. Artifact regions can be automatically classified by the analysis program.

The heart rate calculation is reported on each beat. The heart rate for a specific beat is based on the average of 12 previous valid R-R intervals. A valid heart rate will require at least 3 out of 12 valid R-R intervals. If the heart rate cannot be calculated, it will be assigned as an unknown heart rate.

The heart rate errors associated with one false positive detection (interpolated noise) would be a +8.3% increase in reported heart rate. A false negative detection (missed beat) would result in a -8.3% error in reported heart rate. The duration of time required to correct the heart rate calculation would be 12 beats.

SECTION 24 - M12RT TELEMETRY TRANSMITTER FIRMWARE UPDATES

Periodically, Global Instrumentation may release firmware updates available for the M12RT Transmitter to enhance performance or remediate a discovered performance issue. Firmware simply means the software that runs inside the M12RT Transmitter and controls operation of the recorder. You may become aware of the availability of a firmware update through a service bulletin provided by GI, or at your discretion you may check for available firmware updates perform the update by following the steps described below.

You will perform the M12RT firmware update starting from the main screen on the M12A Review and Admin Station.

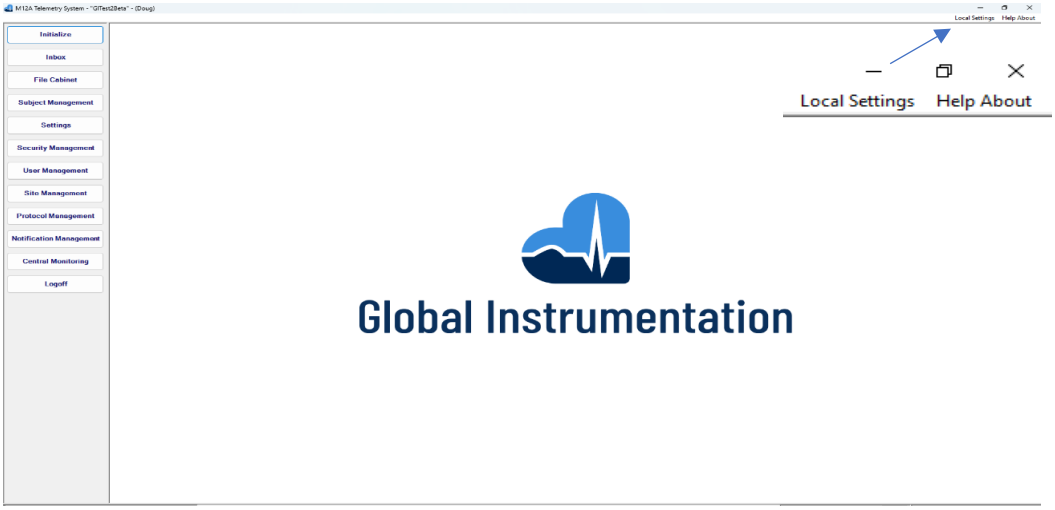


Figure 75 – M12A Review & Admin Main Screen

Click on the **<Local Settings>** in the upper right-hand corner of the screen to open the field shown below.

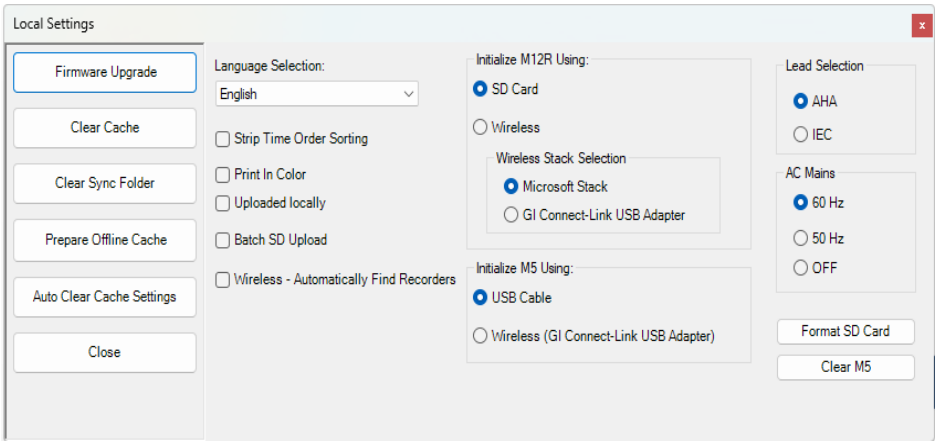


Figure 76 – Local Settings

Click on the **<Firmware Upgrade>** button on the Local Settings screen. The Firmware Upgrade screen will open.

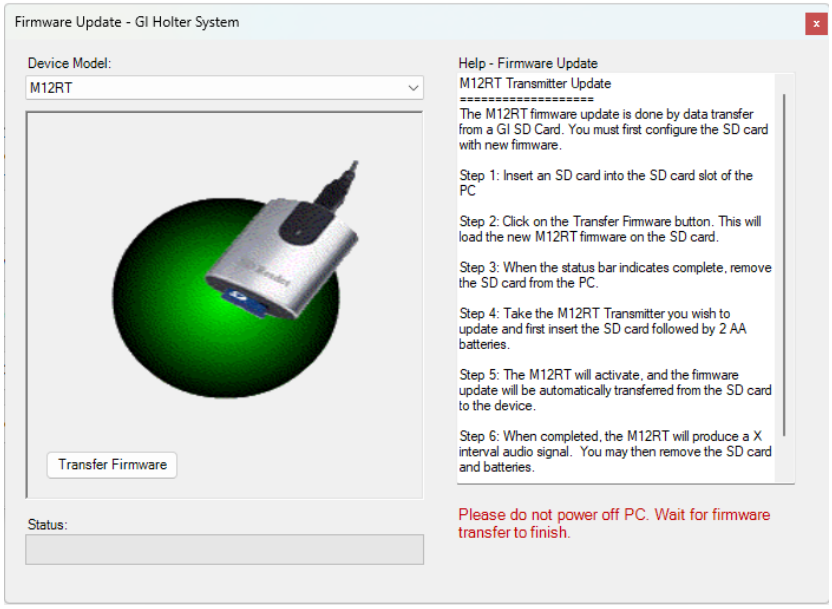


Figure 77 – Firmware Update

Note: should the firmware upgrade process not complete successfully, the M12RT Transmitter will provide an audible beeping sequence.

SECTION 25 - MAINTENANCE & SERVICE

25.1 Inspection

Your new M12RT Telemetry Transmitter, accessories, and M12A Telemetry Central Station components were carefully inspected before shipment. Please inspect all components upon delivery for any damage which may have occurred in transit.

- Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.
- Verify that all cables and connectors are securely seated.
- Check the M12RT Transmitter housing for any visible damage.
- Inspect cables and connectors for any visible damage.
- Inspect buttons, LCD or LED for proper function and appearance.

In case of any damage or abnormality, do not use the affected device or M12A Central Station. Contact your facility technical support staff or Global Instrumentation service personnel immediately.

25.2 M12RT and Accessory Cleaning Requirements

This section presents procedures for cleaning the M12RT Telemetry Transmitter and M12 Patient Cable. Global Instrumentation, LLC has validated these instructions to be capable of preparing your device and accessories/spare parts. Clean on a routine basis according to your facility's protocols and standards or local regulations.

CAUTION: Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation. Do not sterilize the device or ECG cable with Ethylene Oxide (EtO) gas.

WARNING: Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.

To protect patients against risk of cross-contamination, the M12RT Telemetry Transmitter, Patient Cable, and carrying case should be cleaned and disinfected in preparation for a new patient. Remove the transmitter from the carrying case and remove the patient cable from the transmitter before cleaning.

Approved Cleaners

For cleaning & disinfecting the M12RT Telemetry Transmitter, Patient Cable, and carrying case it is acceptable to use the following:

- Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes
- Dispatch® Hospital Cleaner Disinfectant Towels with Bleach
- CleanCide Wipes (Wexford Labs)
- 70% isopropyl alcohol solution applied to a clean cloth
- 10% chlorine bleach solution applied to a clean cloth

Cleaning the M12RT Transmitter

Follow the cleaning agent manufacturer's instructions to prepare the solution, if applicable. Use cleaning agent manufacturer’s instructions and recommendations to clean all exposed surfaces of the M12RT Telemetry Transmitter, carrying case, cords, and cables. Wipe all surfaces until no visible soil remains. Change the wipe or cloth throughout the cleaning procedure as needed.

- Wipe all sides of the M12RT Telemetry Transmitter and all sections of the Patient Cable thoroughly.
- Wipe and clean the full length of all cables including the M12 Patient Cable lead wire cables.
- It is acceptable to lightly wipe the metal connector components on the M12RT Telemetry Transmitter and M12 Patient Cable.
- Wipe and clean the inner and outer surfaces of the carrying case, belt, and shoulder strap.
- Allow all components to air dry prior to reuse or storage.
- Store the M12RT Telemetry Transmitter and Accessories/Spare Parts

Store the Transmitter and accessories/spare parts according to facility guidelines to keep the components clean, dry, and ready for service. Remove batteries prior to storing the Transmitter.

NOTES:

- Do not use solvents or abrasive cleaners or materials.
- Use caution with excess liquid as contact with metal parts may cause corrosion.
- Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
- Do not use excessive drying techniques such as forced heat.

- Global Instrumentation does not endorse any specific off-the-shelf wipes or liquids. However, products that only contain the disinfecting agents mentioned above are likely to be compatible with the device. Some products contain a mixture of agents and may have a detrimental effect if used intensively and frequently. Check the Material Safety Data Sheet of the product used for the list of ingredients.

25.3 Central Station Component – Preventative and Periodic Maintenance

The Preventative Maintenance for the M12A Telemetry Central Station will consist of periodic cleaning, inspection, and testing.

Network components such as ethernet switches and wireless access points should follow the preventive maintenance requirements recommended by their manufacturer.

1. With the system turned off, clean all system components (computer, display, keyboard, mouse, printer, etc.), in accordance with their manufacturer's instructions.
2. To properly clean a computer, start with the exterior: use a lint-free cloth to wipe down the case, monitor, keyboard and printer. For more stubborn stains, a small amount of rubbing alcohol on a cotton swab can be used to clean keycaps or other small areas
3. For dust buildup, use compressed air to blow out vents and ports.
4. Inside the computer, you can also use compressed air to remove dust from fans and components.

Inspection and preventive maintenance by authorized personnel is recommended every six months.

WARNING: Cleaning must be performed with the system turned off. Let all parts dry well before use.

NOTE: Refer to ***Section 22 – Cybersecurity Considerations*** for additional information on recommended software and IT related maintenance.

25.4 Testing M12A Telemetry Central Station Alarms

To test the functionality of the audible and visual alarms of the M12A Telemetry Central Station follow the steps below.

NOTE: This should only be done when there is no active telemetry patient monitoring occurring at the central station.

1. Click on the “Telemetry” button in the top right corner of the central station screen, then click on the “Alarm Testing” row. This will open the drop-down menu shown in figure 69.

   Each alarm that is configured in Telemetry Settings (refer to ***Section 13 – Telemetry Monitoring Configuration***) setting will trigger and display the associated alarm visual message and audible signal. Each configured alarm will activate, terminate, and then advance to the next highest priority alarm within the category selected. This feature is not available for use if the central station is being used for active patient monitoring.

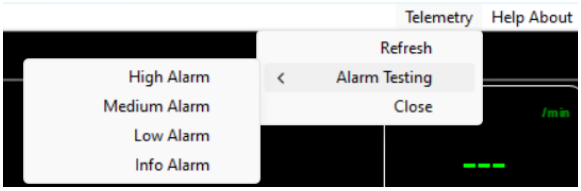


Figure 78 – Telemetry Drop Down

2. Next, click on any of the alarm priority selections listed. The upper left central station tile (1,1) will provide a visual test alarm field, and the associated audible alarm will sound (example below of high priority alarm).

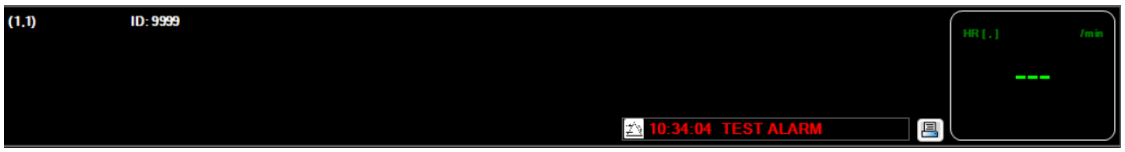


Figure 79 – Test Alarm View

3. The audible and visual alarm will persist for 30 seconds. You may proceed to test the full range of alarms from High Priority to Info as appropriate.

NOTE: The audible alarm volume emitted during this test will be based on the volume level set (high, medium, or low) in the telemetry monitoring configuration – General Settings. Refer to ***Section 13.1General Settings***.

NOTE: The M12A Telemetry Central Station will always force the Windows operating system sound setting level to the maximum value prior to sounding any audible alarm. The M12A Telemetry Central Station alarm audio settings will be maintained at the preset levels. Refer to ***Section 13.1 – General Settings.***

NOTE: The local user account for Windows 11 will have the Group Policy configured to prohibit access to sound settings. All M12A Central Station users will be restricted to

regular user account level and not any administrator account levels, whether for local accounts or domain accounts. This will block regular users from adjusting the Windows operating system sound settings.

25.5 Calibration

The M12RT Telemetry Transmitter does not require calibration.

25.6 Expected Life of Product

The expected life of the M12RT Telemetry Transmitter is approximately 3 years. It is recommended after three years of use that the M12RT Transmitter be returned to Global Instrumentation for essential performance and basic safety testing.

25.7 Service Policy

All repairs on products under warranty must be performed or approved by Global Instrumentation. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Global Instrumentation certified service personnel.

If the product fails to function properly or if you need assistance, service, or accessories/spare parts contact Global Instrumentation. For phone numbers or Web Site, see Page iii.

Before contacting Global Instrumentation, try to duplicate the problem, and check all spare parts and accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name and model number and complete description of the problem.
- Serial number of your product (if applicable).
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or accessories/spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required accessories/spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please contact Global Instrumentation. A representative will assist you in troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary returns.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as

the appropriate return address. An RMA number must be obtained by the Global Instrumentation prior to any return, contact Global Instrumentation (see Page i)

If you have to return goods for service, follow these recommended packing instructions:

- Remove all cables, batteries, spare parts and accessories products (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Global Instrumentation Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

25.8 Service Conditions

All service prices are based on work being performed during normal business hours (9:00 a.m. through 5:00 p.m. Eastern Time, Monday through Friday) via remote communication at Global Instrumentation's location in Manlius, New York only.

In the event on-site service or installation at customer's location is required, Global Instrumentation shall provide a specific quotation for such on-site service including time of services required. Such service shall be provided as set forth in a separate onsite agreement to be negotiated by the parties. Security and access for Global Instrumentation at the customer's location will be the responsibility of the Customer. Customer will accompany any Global Instrumentation employee or agent while on-site at a customer location. Customer cancellations of scheduled site visits will be provided to Global Instrumentation in writing no less than five (5) business days prior to such scheduled site visit. If the scope of work or the number of devices or office locations to be implemented changes at the customer's request from that specified in the applicable customer order, then prior to accepting any such changes, Global Instrumentation reserves the right to review and change the terms set forth therein, including, without limitation, pricing and any delivery requirements that are affected or impacted by such request.

25.9 Discarding the Equipment

Discard the M12RT Transmitter, spare parts and accessories, and IT components according to local laws. Please follow the state's recycling laws or your facility's recycling

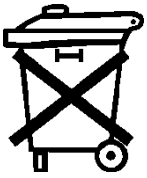
policy to ensure proper disposal of the products. For more information on recycling, call the Environmental Protection Agency or local authorities.

Disposal must be in accordance with the following steps:

1. Follow cleaning and disinfection instructions per instructions in this user manual section.
2. For computer components (M12A Telemetry Central Station and M12A Telemetry Server) delete all existing data related to patients, healthcare facility, physician, and healthcare providers. Data backup may be performed prior to deletion.
3. Segregate material in preparation for the recycling process
    - Components are to be disassembled and recycled based on type of material
        - Plastic to be recycled as plastic waste
        - Metal to be recycled as Metals
    - Includes loose components containing more than 90% metal by weight
    - Includes screws and fasteners
    - Electronic components, including the power cord, to be disassembled and recycled as Waste of Electrical and Electronic Equipment (WEEE)
        - Batteries to be dismantled from the device and recycled as per WEEE

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Global Instrumentation Technical Support for guidance on safe disposal protocols.

Waste of Electrical and Electronic Equipment (WEEE)



Attention: Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. See www.globalinstrumentation.com.

SECTION 26 - ELECTROMAGNETIC EMISSIONS AND IMMUNITY

26.1 Electromagnetic Emissions

The M12RT Telemetry Transmitter is intended for use in the electromagnetic environment specified below. The user of the Transmitter should be sure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 2	The M12RT Telemetry Transmitter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The M12RT Telemetry Transmitter is suitable for use in all establishments, including domestic establishments. The transmitter has no connection to the public low voltage power supply network.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

26.2 Electromagnetic Immunity

The M12RT Telemetry Transmitter is intended for use in the electromagnetic environment specified below. The user of the Transmitter should be sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± ±2kV, ±4kV, ±8kV, ±15 kV air	±8 kV contact ± 15 kV 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 C 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	
Surge C 61000-4-5	±1 kV differential Mode ±2 kV common mode	Not applicable	
Voltage dips [f) p) r)] IEC 61000-4-11	0% U_T; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 270° and 315° [q)] 0% U_T; 1 cycle and 70% U_T; 25/30 cycles [h)] Single phase: at 0°	Not applicable	
Voltage interruptions [f) i) o)] IEC 61000-4-11	0% U_T; 0,5 cycle [h)]	Not applicable	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Not applicable	

Note: U_T is the a.c. mains voltage prior to application of the test level.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in the ISM	3Vrms 6 Vrms in the ISM	Portable and mobile RF communications equipment should be used no closer to any part of the M12RT Transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = (1.17)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7GHz	3 V/m	$d = (1.17)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.33)\sqrt{P}$ 800 MHz to 2.5 GHz where 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). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Footnotes:

a Field strengths from fixed transmitters, such as base stations for 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 M12RT Telemetry Transmitter is used exceeds the applicable RF compliance level above, the M12RT Telemetry Transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the M12RT Telemetry Transmitter.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

The M12RT Telemetry Transmitter enclosure port immunity to proximity magnetic fields; Requirement levels are:

Test Frequency (MHz)	Modulation	Immunity Test Level (A/m)
30kHz [a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50 kHz	7.5 [c)]

a) This test is applicable only to the M12 Telemetry System intended for use in a home health care environment.

b) The carrier shall be modulated using 50% duty cycle square wave signal.

c) r.m.s., before modulation is applied.

The M12RT Telemetry Transmitter Proximity fields from RF wireless communications equipment; Requirement levels are:

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GNRA 460, FRS 460	Pulse modulation [c] ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTR Band 13, 17	Pulse modulation [b] 18 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900: DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1845				
1970				
2450	2400 to 2500	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5500				
5785				
If necessary to achieve the immunity test level, the distance between the transmitting antenna and the M12RT Telemetry Transmitter may be reduced to 1m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using 50% duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be the worst case.				

26.3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the M12RT Telemetry Transmitter

The M12RT Telemetry Transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Transmitter as recommended below, according to the maximum output power of the communications equipment.

Rated Max. Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (2.33)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

SECTION 27 - REGULATORY INFORMATION

27.1 FCC Information

This Model M12RT Telemetry Transmitter device contains FCC ID: X8WWM02C.

Per part 15.21 of FCC rules, you are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1) This device may not cause harmful interference.
2) This device must accept any interference received, including interference that may cause undesired operation.

27.2 FCC RF Radiation Exposure Statement

For body worn operation, this device has been tested and meets FCC RF Exposure guidelines that position the EUT a minimum of 0 cm from the body.

SAR Information

FCC 0.778W/kg @ 1g (Body)

27.3 Japan

This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Japan Radio Law.

27.4 Regulatory Compliance

The Customer is responsible for ensuring that the Products are used only in full compliance of all regulatory requirements imposed by countries where the products are being used. Customer shall comply with all applicable laws, regulations and government orders, including without limitation applicable export laws and regulations, and shall not export, re-export, divert or transfer, directly or indirectly, any Products or associated items to any country that is embargoed by executive order, unless Customer has obtained the necessary authorization.

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