# Clarus 40M

## Mobile Cardiac Monitor


Operator Manual

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# Description

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

The Clarus 40M is a battery operated ambulatory electrocardiograph recorder for use in mobile cardiovascular telemetry. It is capable of storing up to 4 channels of patient ECG data acquired from surface electrodes adhered to the body for up to 30 days of continuous recording. The Clarus 40M employs a rechargeable lithium polymer battery to achieve such an extended recording duration.

The Clarus 40M provides the ability to automatically detect and record pacemaker pulses as well as several common arrhythmias in accordance with the applicable standards of the International Electrotechnical Commission (IEC).

The Clarus 40M contains an internal cellular modem to allow access to the patient ECG data and analysis results. Any piece of data recorded on the device may be queried wirelessly during the course of the study. Additionally, data transmissions may be triggered automatically or manually as a result of arrhythmia analysis, or manual patient input, respectively.

The Clarus 40M provides a multitude of options to control recording parameters such as bit resolution, sampling rate, and frequency response as well as analysis parameters such as heart rate thresholds. These settings may be updated wirelessly during the course of a study to allow the device to dynamically adapt to the needs of the operator.

The Clarus 40M does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibilities of a trained healthcare professional or physician.

# Indications for Use

The Clarus 40M is intended for use by individuals who are at risk of having cardiac disease and those that have intermittent symptoms indicative of cardiac disease and demonstrated a need to be monitored on a continuing basis. The ECG recordings can be uploaded to monitoring center in a variety of ways - transmitted via Cellular RF Modem, via RF, via TTL, or flash card to an FTP storage location or software package to be read by a healthcare professional.

Patients include, but at are not limited to, those requiring monitoring for

a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACS, PSVT) and ventricular ectopy,
b) evaluation of brady-arrhythmias and intermittent bundle branch block including after cardiovascular surgery and myocardial infarction, and
c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

Data from this device may be used by another device to analyze, measure, or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Patients with symptoms that may be due to cardiac arrhythmias.

These may include, but are not limited to, symptoms such as

a) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded,
b) dyspnea (shortness of breath). Patients with palpitations with or without known arrhythmias to obtain correlation or arrhythmias with symptoms.

Patients who requiring monitoring of the effects of drugs to control ventricular rate in atrial arrhythmias (e.g. atrial fibrillation). Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive central) to evaluate possible nocturnal arrhythmias.

Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or flutter. Data from this device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

# Contraindications

The Clarus 40M is not intended for use under the following conditions:

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.

NOTE: The Clarus 40M does not provide interpretive or diagnostic statements. Interpretation and diagnosis is the responsibility of a trained healthcare professional or physician.

# Recorder Components

**Figure 1**

1. Accessory Cable Connector
2. Color Touchscreen
3. Patient Event Button


*Front view of the Clarus 40M.*

**Figure 2**

1. Serial Number


*Back view of the Clarus 40M.*

# Equipment Symbols

| | |
|---|---|
|  | Consult the Directions for Use |
|  | Type BF device |
|  | Electrically Isolated |
|  | Manufacturer Info |
| **Rx Only** | Prescription Only |
| **IP22** | Device has ingress rating of IP22 in accordance with IEC 60529 |
|  | 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). If this product is contaminated, this directive does not apply. |

# Precautions

- Use only cables provided by TZ Medical with the Clarus 40M.
- Disconnect patient leads before defibrillation.
- To reduce the risks of strangulation or asphyxiation do not leave electrode cables accessible to infants or children. Carefully route the electrode cables to reduce the possibility of entanglement or strangulation during use.
- False positive and false negative pacer pulse detects may occur when using Pacemaker Pulse Detection.
    - False positives – may result from poor electrode connection to the patient or a large amount of electrical interference from nearby source.
    - False negatives – may occur with pacemakers that are bipolar because of a weak pacemaker pulse signal at the patient's skin.
- When viewing the ECG data, the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- To achieve the best recording results, instruct patients to stay away from heavy electrical equipment or other sources of electromagnetic interference. This includes equipment such as electric blankets and heating pads.
- Avoid exposing device to water or excessive moisture.
- Do not expose device to extreme temperatures (beyond the limits shown in the environmental specifications).
- Do not allow conductive parts of the Clarus 40M patient electrodes to contact other conductive parts including earth.
- Allow 2 hours for the Clarus 40M to warm from the minimum storage temperature or to cool from the maximum storage temperature before operating the device.
- The Clarus 40M device should only be connected to a PC certified to IEC 60950-1 when using the USB Cable (PN: H3R-0025).
- Changes or modifications made to this equipment not expressly approved by TZ Medical may void the FCC authorization to operate this equipment.

# Initial Device Setup

The Clarus 40M is delivered ready for use. Please consult with your software provider to determine if any additional configuration is required for your specific use case.

# User Interface

The Clarus 40M employs a graphical user interface consisting of a color touchscreen for configuration and patient hookup procedures. The menus on the device can be navigated by gently touching and releasing the graphical buttons on the display.

**Figure 3**


*The welcome screen is displayed on startup.*

The status bar found at the top of the display on the Clarus 40M displays a user-configurable message, the battery status, number of pending uploads, and the network status.

Press the power icon (bottom left) to power off the device, press the gear icon (bottom right) to adjust the device's settings, or press the plus icon (center) to start a study. If the patient ID setting has been set to a value other than 0, the bottom bar will display this value. Otherwise, the bottom bar will display the current firmware version of the device.

# Network Status

The network status is always displayed in the upper left-hand corner of the screen. The number of pending transmissions counts up to 99, and a blue antenna icon is shown when the device is connected to the network. The device will periodically turn off its modem to save power. In this case, no icon will be displayed next to the pending transmission count. It will also display a dash icon when searching for a network or a red antenna icon if it gets rejected by the network.

**Figure 4**


*The device has 7 pending transmissions, and it is searching for a network to which it can connect.*

**Figure 5**


*The device is connected to a network and currently uploading 7 pending transmissions.*

**Figure 6**


*The device's request to connect was rejected by the network, but it still has 7 pending transmissions.*

**Figure 7**


*The device is not connected to any network or searching, but it has 7 pending transmissions.*

# Shutting Off

After pressing the power icon on the welcome screen, confirm shutdown by pressing the power icon in the middle of the screen. Alternately, the device may be powered off at any time by pressing and holding the patient event button until the display shuts off. This latter method is not preferred.

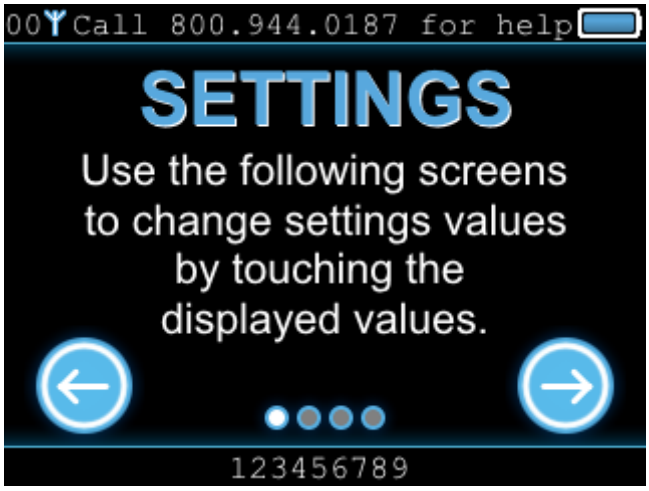
**Figure 8**


*Confirm the shutdown command by touching the power icon again.*

# Adjusting the Settings

After pressing the gear icon on the welcome screen, touch the arrow icons in the bottom corners to navigate the setting menus. The dots at the bottom-center of the screen indicate location within the settings menus. Pressing the right arrow on the last setting screen will return to the welcome screen.

**Figure 9**




*The first page of the settings menus.*

**Figure 10**


*The second page of the settings menus.*

To change a setting, touch the displayed value to bring up a keypad on the screen. Follow the on-screen instructions regarding proper formatting for each setting.

NOTE: When setting the sample rate, the Clarus 40M will accept entry of any value between 250 and 4000. However, the actual sample rate will be rounded up to one of the following values: 250, 500, 1000, 2000, or 4000 Hz.

**Figure 11**


*The third page of the settings menus.*

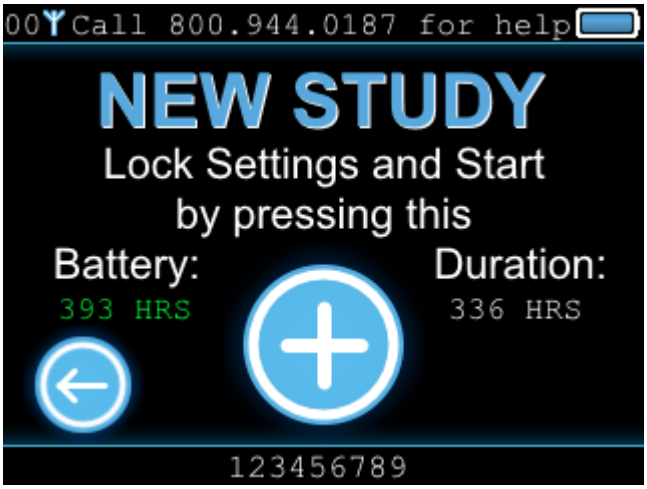
**Figure 12**


*Setting the clock.*

# Starting a Study

After pressing the plus icon on the welcome screen, confirm start of the study by pressing the plus icon in the center of the screen. As the Clarus 40M is design to operate for the duration of the study on a single battery charge, the device will not allow the study to start if there is insufficient battery life to accommodate the intended recording duration. Please contact your software provider if you wish to perform longer studies that will require recharging during the study. The device can be configured for this use case, but it does not support it by default.

**Figure 13**




*This device is ready to start a new study.*

**Figure 14**


*This battery is too low to start this study.*

# Starting a Study (continued)

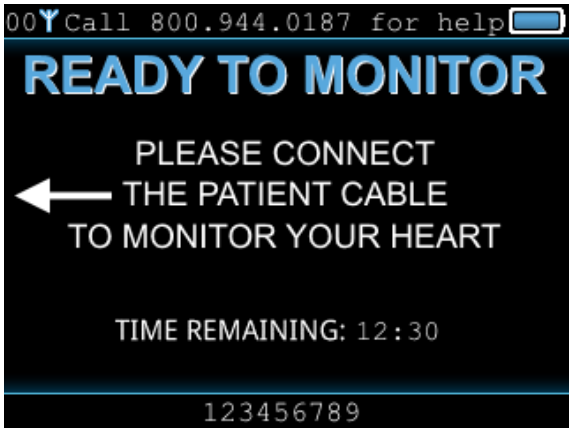
If the PIN Code setting was set to a value other than 0, the device will now prompt the patient to enter the PIN Code. This is generally used when the patient is not present when the device is configured. If this is the case, the device can be powered down for shipment by pressing and holding the patient event button until the screen turns off. When the patient receives the device, they can power it on by pressing the patient event button for 1 second. After the device boots, they can follow the on-screen instructions to enter the correct PIN (provided separately to the patient).

**Figure 15**


*The PIN Code screen.*

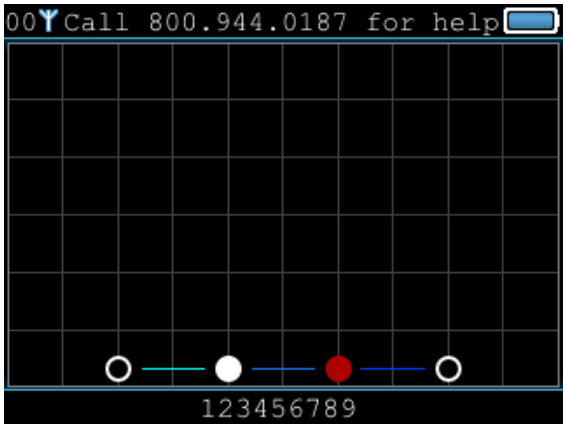
After the PIN has been entered (or if the PIN Code setting was set to 0), the device will indicate that it is ready to monitor and prompts the patient to connect the patient cable to the device. It is recommended that the patient connect all electrodes prior to connecting the cable to the device, as the device will launch a signal quality screen displaying tracings from all channels supported by the cable. The legend at the bottom of the screen may be used to identify which electrode, if any, needs correction.

**Figure 16**




*Ready to monitor.*

**Figure 17**




*Signal quality can be evaluated on this screen.*

# Monitoring a Study

Once a study has been started, the Clarus 40M will silently record ECG data with no intervention from the patient. The patient can wake the display by briefly pressing the patient event button to view a status screen with instructions on how to mark an event.

**Figure 18**

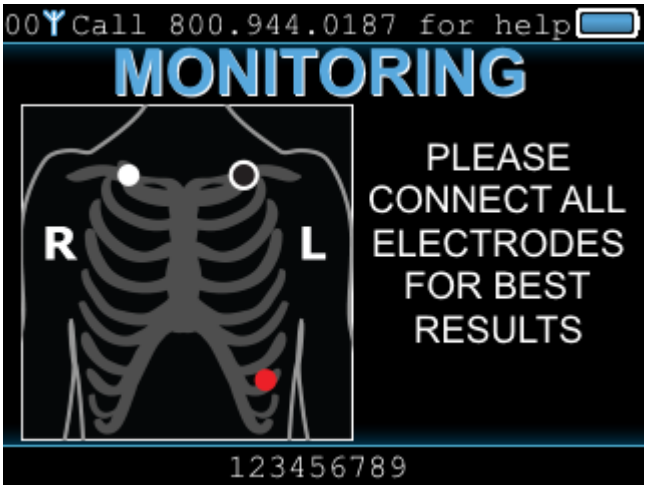

*Study progress and event instructions.*

**Figure 19**


*After an event has been successfully marked.*

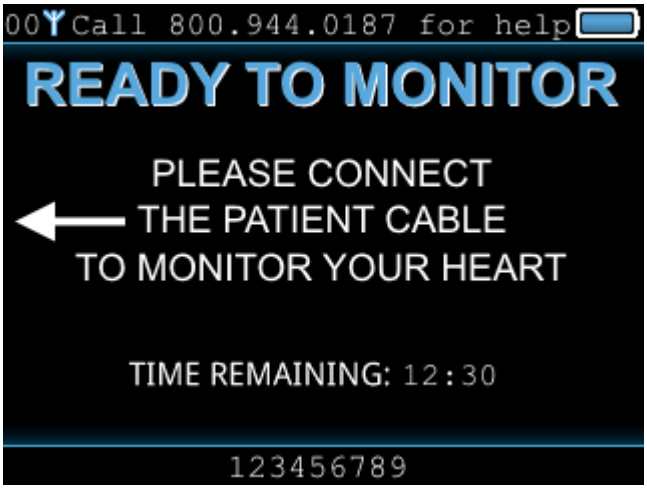
If electrodes become disconnected during the course of a study, the device will notify the patient by beeping and by displaying a message on the screen indicating the correct location of each electrode. The hookup diagram is keyed to the patient cable such that the proper diagram is always displayed, regardless of which patient cable is used. Disconnecting the patient cable from the recorder will stop the recording, should the patient need to remove the electrodes for some reason. The Clarus 40M will continue to record as long as the patient cable is connected, regardless of electrode status.

**Figure 20**




*An electrode has been disconnected.*

**Figure 21**

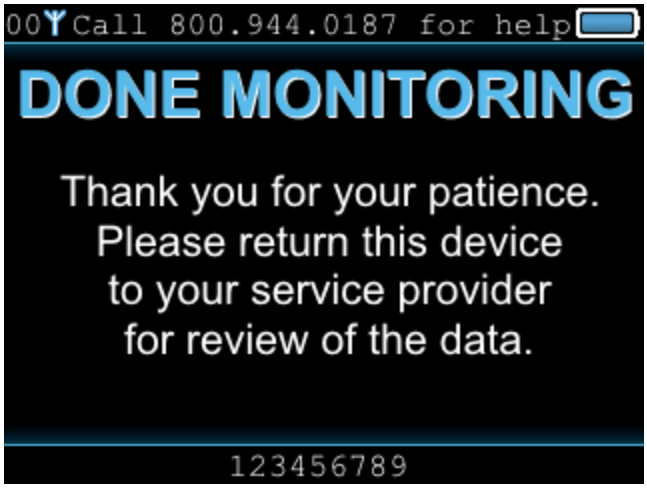



*The patient cable has been disconnected.*

# Ending a Study

The Clarus 40M will end the study once the pre-configured recording duration is reached. At this point, it will notify the patient that the recording is complete and that the device should be returned.

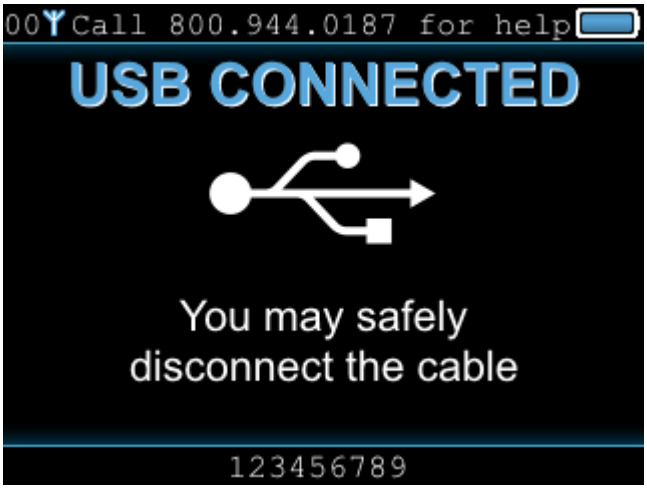
**Figure 22**




*The patient will be notified once the study is complete.*

The data from the Clarus 40M may be retrieved at any time by connecting the USB accessory cable between the Clarus 40M and a PC. No special steps are required when terminating a study early. After retrieving the data from the Clarus 40M, always make sure that all patient data has been removed from the device! When the USB cable is disconnected from the device, it should restart and display the welcome screen.

**Figure 23**




*The USB cable is connected.*

**Figure 24**

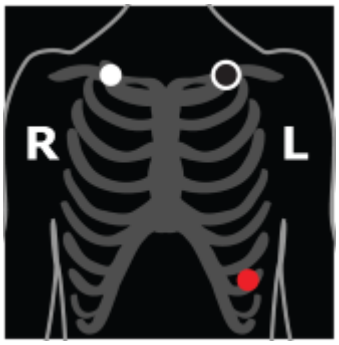

*The device should return to the welcome screen once the patient data has been removed.*

# Electrode Application

Employ the following procedure when applying electrodes to a patient and connecting them to the Clarus 40M:

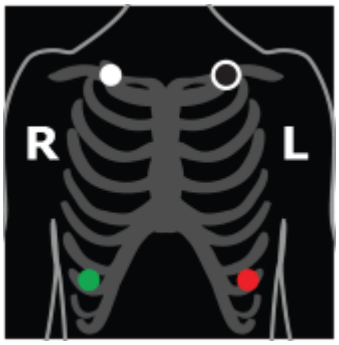
1. Select electrode sites to match the configured electrode configuration shown in the following figures or as instructed by the physician. Select areas over bone, avoiding muscle areas and breast tissue.
2. Clean electrode sites with alcohol and use a razor to remove hair.
3. Abrade electrode sites with a scrub pad or gauze. Allow sites to dry before applying electrodes.
4. Connect the patient lead wire to the electrode snap.
5. Remove the protective backing from the electrode.
6. Apply the electrode to the patient's skin, matching electrodes to the selected configuration from the following figures or as instructed by the physician.
7. Press adhesive border firmly for consistent adhesion.
8. To alleviate tension on electrode snaps, loop patient lead wires and tape down.

**Figure 25**




*3-electrode hookup*

**Figure 26**




*4-electrode hookup*

# Patient Use Precautions

The Clarus 40M contains sensitive electronic circuitry. Please observe the following precautions while using the Clarus 40M. Failure to do so may result in serious damage to the device.

### Avoid Exposure to Moisture

The Clarus 40M should not be used while swimming, showering, bathing, or participating in any aquatic activities. Use caution to avoid inadvertent submersion in water.

### Avoid Sharp Impacts

While the Clarus 40M has been designed to survive minor drops, it is possible to damage the internal structure, or outer casing, if the device suffers a sharp impact or is otherwise traumatized. Such use may irreparably damage the Clarus 40M and void its warranty.

### Avoid Pulling on Wires

Always disconnect cables from the device by grasping the rubberized connector, not by pulling directly on the wire. Yanking on the wires may result in irreparable damage to the cables.

# Patient Responsibilities

As the patient, it is your responsibility to fulfill the following responsibilities while using the Clarus 40M in order to ensure proper detection and analysis of your heart's symptoms.

### Keep Electrodes Connected

The Clarus 40M can only record data when it is properly connected to the electrodes on your body. The device will emit a short beep whenever it detects that one of the electrodes has been disconnected. If too many of the electrodes become disconnected, the Clarus 40M will stop recording and prompt you to reconnect the electrodes.

### Keep the Battery Charged

The Clarus 40M may need to be recharged during the course of the study. When prompted, disconnect the patient cable and connect the provided wall charger to recharge the battery.

### Report Any Heart-Related Events

Briefly press the wake button and then tap the plus icon on the screen to mark when you feel any heart-related symptoms. Follow the on-screen prompts to enter your symptoms.

# Charging

The Clarus 40M employs a rechargeable lithium-ion battery to meet the demanding power requirements of cellular data transmissions. This battery cannot be recharged in the device without interrupting the data recording.

To charge the battery during a study, connect the Clarus wall-charger. To charge the device between studies, you may either connect the Clarus USB cable or insert the Clarus device into the Clarus 9-Device Charging Dock (see Accessories list). The Clarus 40M will indicate that the battery is charging with an icon in the corner of the screen.

**Figure 27**

*The screen will display the charging indicator in the top left corner.*

# Storage

When not being used for recording data, the Clarus 40M should be shut off as shown previously. To wake the Clarus 40M after it has been powered down, press the wake button for 1 second. To maximize battery life, it is recommended that for long periods of storage that the device be stored at 50% battery charge in a cool environment.

# Cleaning

- **Do not** attempt to submerse, autoclave, or steam clean the Clarus 40M or the patient cable.
- **Do not** use solvents to clean the device.

Observe the following procedure to clean the Clarus 40M between patient uses:

1. Disconnect the patient cable.
2. Wipe the exterior of the Clarus 40M and its accessories with a damp cloth. Use mild detergent diluted in water. Take care not to allow water or moisture to enter the Clarus 40M, especially around the cable receptacle.
3. Dry with a clean cloth or paper towel.
4. Reconnect the patient cable to the device.
5. Clean the patient cable in the same manner before each procedure.

# Testing

The Clarus 40M recorder performs a comprehensive self-test each time it is powered on. In most cases this test will detect any potential problems prior to starting a recording session. In the unlikely event that an error occurs please provide the error details to your service provider for further instructions.

To verify the ECG signal path prior to deploying on a patient, simply start a recording then connect a patient cable between a patient simulator and the device. Observe the signal quality screen to verify expected signal shape. Before the signal quality screen disappears, be sure to disconnect the patient cable from the device.

# Error Messages

The Clarus 40M has been designed to detect and recover from error conditions automatically, if at all possible. Unfortunately, there are situations that may occur where the device simply cannot recover on its own. In such cases, the Clarus 40M will display an error message to the user with an error code.

**Figure 28**


*An error message displayed on the Clarus 40M screen.*

These errors can often be resolved connecting the Clarus 40M to a computer, erasing the recording memory and cycling the power. Please consult the troubleshooting guide for more specific information on dealing with error codes.

If the error message persists, the device will need to be returned to TZ Medical Inc. for servicing. See the Warranty section of this manual for instructions on returning a device for service.

# Specifications

## Functional

| | |
|---|---|
| ECG Channels | Up to 4 bipolar channels<br>- or -<br>2 bipolar channels and up to 2 unipolar channels |
| Sample Rate | 250, 500, 1000, 2000, or 4000 Hz |
| User Interface | Color touchscreen |

## Memory

| | |
|---|---|
| Total Recording Time | Up to 31 days, 7 days continuous (from full charge) |
| Media | 8GB internal |
| Data Retention | Over 10 years |

## Physical

| | |
|---|---|
| Dimensions | 3.90 x 2.36 x 0.81 inches (99.2 x 60.0 x 20.6 mm) |
| Weight | 4.17 oz. (118 g) |

## Electrical

| | |
|---|---|
| Input Impedance | > 10M Ohms |
| CMRR | > 60 dB |
| Signal Range | ± 430 mV |
| Resolution | (24 bits) |
| Frequency Response | 0 to 150 Hz |
| Pacemaker Detection | ANSI/AAMI/IEC 60601-2-47:2012 |

## Environmental

| | |
|---|---|
| Operating Temperature | 0 C (32 F) to 45 C (113 F) |
| Operating Humidity | 10% to 95%, non-condensing |
| Storage Temperature | -25 C (-13 F) to 70 C (158 F) |
| Storage Humidity | 5% to 95%, non-condensing |
| Atmospheric Pressure | 70 kPa to 106 kPa |

## Battery

| | |
|---|---|
| Type | Single Cell, Lithium Polymer Rechargeable |
| Life | 7 days, from full charge |

## External Power Requirements

| | |
|---|---|
| Output Voltage | 5.0 VDC +/- 5% measured at the output |
| Output Current | 500 mA minimum |

## Wireless Transmission

| | |
|---|---|
| Service | Dual Band UMTS/HSPA+, Dual-Band GSM |
| Bands | 850/1900 MHz |

# Specifications

## Projected service life

The projected service life of the Clarus 40M and Clarus 9-device charging dock is 2 years on average based on the following assumptions:

- the typical 60 day shelf storage duration
- battery charge and discharge does not exceed 500 cycles for the service life of the device
- proper cleaning and maintenance per the operator manual

The projected service life of the Clarus 40M cables and electrodes is 90 days based on the following assumptions:

- operator manual suggested cleaning procedure is followed
- cable and snap electrodes are connected and disconnected correctly by grasping the connector overmold and not the strain reliefs

## Additional equipment classification information as required in EN 60601-1

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

IP22 - The EQUIPMENT is protected from 12.5 mm or greater foreign objects and vertical drip with the product tilted 15°.

Internally Powered Equipment

Mode of Operation – Continuous

## Conformance to Regulatory Standards

TZ Medical, Inc. declares that his device complies with the essential requirements of Article 3 of the R&TTE 199/5/EC Directive, if used for its intended use and that the following standards have been applied:

BS EN 62209-2: 2010
ETSI EN 301 489-1 V1.9.2
ETSI EN 301 489-7 V1.3.1
ETSI EN 301 511 V9.0.2

International Electrotechnical Commission (IEC)

IEC 60601-1: 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
IEC 60601-1-6:2010 (Third Edition) in conjunction with IEC 60601-1: 2005 (Third Edition)
IEC 60601-1-11:2015 (Second Edition) in conjunction with IEC 60601-1:2012 (Third Edition) + A1:2012
IEC 60601-2-47:2012 (Second Edition) in conjunction with IEC 60601-1:2005 (Third Edition)
IEC 62209-2: 2010
IEC 62366:2007 (First Edition) for use in conjunction with IEC 60601-1-6: 2010

# Limited Warranty

This TZ Medical product is warranted to be free from manufacturing and material defects for a period of two (2) years from the date of shipment from TZ Medical to the original purchaser ("Warranty Period"). If a hardware defect arises and a valid claim is received within the Warranty Period, TZ Medical will either repair or replace the defective product free of charge for parts or labor.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, patient cables, charging adapters, and batteries. This warranty does not apply to any product which TZ Medical determines has been modified or which has been damaged due to customer abuse or misuse (e.g. corrosion from water ingress or cracking of the LCD glass).

**Except for the express warranties stated above, TZ Medical disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of TZ Medical for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of TZ Medical products.**

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

Unauthorized modifications to TZ Medical products could void your warranty and alter the regulatory status of the device. Any resulting service required is not covered under our service agreements. Such modifications can affect the performance or safety of your device in unpredictable ways, and TZ Medical is not responsible for equipment that has been modified.

# Obtaining Warranty Service

To obtain repairs, the device should be shipped pre-paid to TZ Medical at the address shown below. Units that are repaired under warranty will be returned postage paid. Any device serviced by TZ Medical will be factory reset, removing all custom device settings and formatting all data storage devices.

TZ Medical
Sparked by your ideas

**TZ Medical, Inc.**
17750 SW Upper Boones Ferry Rd
Suite 150
Portland, OR 97224

**Phone:** **800.944.0187**
**Fax:** **503.639.0239**

# Accessories

The following accessories are available for use with the Clarus 40M.

| Part Number | Description |
|---|---|
| H3R-0017 | Clarus 3-Electrode Patient Cable |
| H3R-0025 | Clarus USB Data / Charging Cable |
| H3R-0027 | Clarus 40M Plastic Holster |
| H3R-0051 | Clarus Screen Protector |
| H3R-0077 | Clarus 4-Electrode Patient Cable |
| H3R-0079 | Clarus 9-device charging dock |
| H3R-0093 | Clarus TTM + Charging Supply |
| H3R-0099 | Clarus Charging Supply |

# Wireless Compliance

**FCC ID:** ZIMH40M

**FCC Compliance Statement**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. 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.

The Clarus 40M contains a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The exposure standard for wireless mobile devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

Before a device model is available for sale to the public, it must be tested and certified to the FCC that it does not exceed the limit established by the government-adopted requirement for safe exposure. The tests are performed in positions and locations (for example, worn on the body) as required by the FCC for each model. Changes or modifications made to this equipment not expressly approved by (manufacturer name) may void the FCC authorization to operate this equipment.

This device has been tested and meets FCC RF exposure guidelines when worn on the body using the Clarus 40M Plastic Holster (PN: H3R-0027). Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

The maximum reported body SAR is 1.06 W/kg per 1 g of tissue. The maximum reported extremity SAR is 1.12 W/kg per 10g of tissue.

The FCC has granted an Equipment Authorization for this wireless electro-cardiovascular monitor with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the “Display Grant” section of: http://transition.fcc.gov/oet/ea/fccid/ after searching on FCC ID: ZIMH40M.

**IC ID:** 9647A-H40M

**License Exempt (Canada)**

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio
exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le onctionnement.

# EMC Precautions

The Clarus 40M needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

List of all cables and maximum lengths of cables, transducers and accessories:

| Transducer / Accessories | Maximum Cable Length |
|---|---|
| Clarus 3-Electrode Patient Cable | 44.8 in (1138 mm) |
| Clarus 4-Electrode Patient Cable | 44.8 in (1138 mm) |
| Clarus 5-Electrode Patient Cable | 44.8 in (1138 mm) |
| Clarus USB Data / Charging Cable | 45.5 in (1156 mm) |

**Warnings!**

- The use of accessories and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Clarus 40M as replacement parts for internal components, may result in increased emissions or decreased immunity of the Clarus 40M.
- The Clarus 40M should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Clarus 40M should be observed to verify normal operation in the configuration in which it will be used.
- The Clarus 40M may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Clarus 40M does not have life supporting function
- Portable and mobile RF communications equipment can affect the Clarus 40M.

# EMC Precautions

| **Guidance and Manufacturer's Declaration - Emissions** | | |
|---|---|---|
| The ***Clarus 40M*** is intended for use in the electromagnetic environment specified below. The customer or user of the ***Clarus 40M*** should ensure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
| RF Emissions<br>CISPR 11 | Class B | The ***Clarus 40M*** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics<br>EN 61000-3-2 | Class A | |
| Flicker<br>EN 61000-3-3 | Complies | |
| **Guidance and Manufacturer's Declaration – Immunity** | | |
| The ***Clarus 40M*** is intended for use in the electromagnetic environment specified below. The customer or user of the ***Clarus 40M*** should ensure that it is used in such an environment. | | |
| Immunity Test | Compliance | Electromagnetic Environment – Guidance |
| ESD<br>IEC 61000-4-2 | ±6kV Contact<br>±8kV Air | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30% |
| Power Frequency<br>50/60Hz<br>Magnetic Field<br>IEC 61000-4-8 | 3A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

| **Recommended Separations Distances for the *Clarus 40M*** | | | |
|---|---|---|---|
| The ***Clarus 40M*** is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ***Clarus 40M*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the ***Clarus 40M*** as recommended below, according to the maximum output power of the communications equipment. | | | |
| Max Output Power (Watts) | Separation (m)<br>150kHz to 80MHz<br><br>D=(3.5/V1)(Sqrt P) | Separation (m)<br>80 to 800MHz<br><br>D=(3.5/E1)(Sqrt P) | Separation (m)<br>800MHz to 2.5GHz<br><br>D=(7/E1)(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 | 3.69 | 3.69 | 7.38 |
| 100 | 11.67 | 11.67 | 23.33 |