

Clarus 40L

Mobile Cardiac Monitor



Operator Manual

Contents

Device Overview	4
Description	4
Indications for Use	5
Contraindications	5
Recorder Components	6
Equipment Symbols	7
Precautions	8
Operation	9
Initial Device Setup.....	9
Power on the Device	9
User Interface.....	10
Network Status.....	11
Shutting Off	12
Adjusting the Settings	13
Starting a Study	15
Electrode Application	17
Marking an Event	18
Monitoring a Study	20
Receiving Messages	21
Ending a Study.....	22
Removing Patient Data	23
Patient Use Precautions	24
Patient Responsibilities	24
Maintenance	25
Charging	25
Storage	26
Cleaning.....	26
Testing.....	26
Troubleshooting	27
Error Messages.....	27
Specifications.....	28
TZ Medical Warranty.....	31
Limited Warranty	31
Obtaining Warranty Service	31
Accessories	32

Wireless Compliance.....33

EMC Precautions.....35

Description

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

The Clarus 40L 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 40L employs a rechargeable lithium polymer battery to achieve such an extended recording duration.

The Clarus 40L 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 40L 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 40L 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 40L 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 40L 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 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 40L 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 40L 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/Charging port
2. Color Touchscreen
3. Power Button



Front view of the Clarus 40L.

Figure 2

4. Serial Number



Back view of the Clarus 40L.

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 40L.
- 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 40L patient electrodes to contact other conductive parts including earth.
- Allow 2 hours for the Clarus 40L to warm from the minimum storage temperature or to cool from the maximum storage temperature before operating the device.
- The Clarus 40L 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

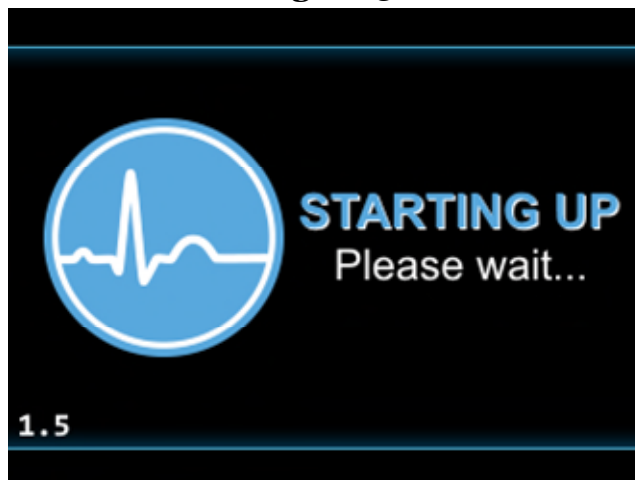
Initial Device Setup

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

Power on the Device

To power on the Clarus 40L, hold down the circular power button, as shown in Fig. 1, for at least one second. After approximately three seconds, the Clarus 40L will vibrate and the screen will light up displaying the Starting Up screen provided in Fig. 3. The Starting Up screen will last approximately five seconds before the device automatically redirects itself to the Welcome display, as shown in Fig. 4.

Figure 3

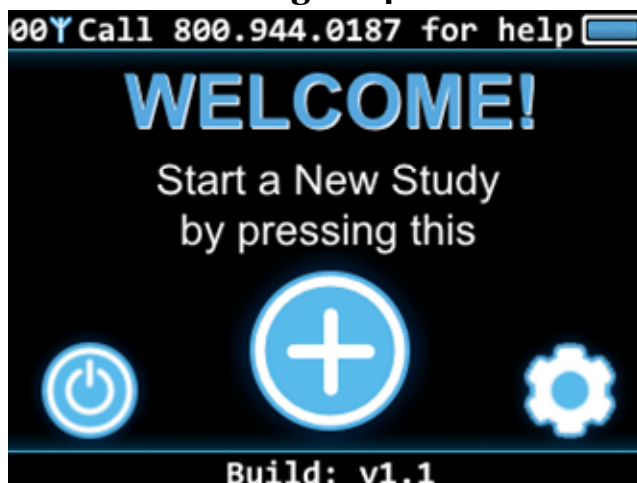


*The Starting Up screen that is displayed
when powering on the Clarus 40L.*

User Interface

The Clarus 40L 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 4



The welcome screen is displayed on startup.

The status bar found at the top of the display on the Clarus 40L displays a user-configurable message, the battery status, number of pending uploads (discussed in more detail on page 10), and the network status (discussed in more detail on page 10).

Press the power icon to power off the device, press the gear icon to adjust the device's settings, or press the plus icon to start a new 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.

Figure 5



Power Icon (Shut Off)

Figure 6



Plus Icon (New Study)

Figure 7



Gear Icon (Settings)

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 8



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

Figure 9



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

Figure 10



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

Figure 11



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

Shutting Off

There are two ways to turn off the Clarus 40L:

- 1) Start by pressing the power icon, provided in Fig. 5, on the Welcome screen. The device will be automatically redirected to a display as shown in Fig. 12. To confirm the shutdown press the power icon in the middle of the screen.

Figure 12



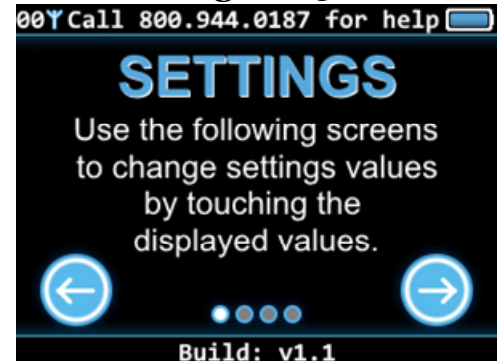
Confirm the shutdown command by touching the power icon again.

- 2) Alternately, the device may be powered off at any time by pressing and holding the power button for approximately five seconds or until the display shuts off. This latter method is not preferred.

Adjusting the Settings

After pressing the gear icon (settings button) provided in Fig. 7 on the Welcome screen, the device will automatically be directed to the first page of the settings menu with the display provided in Fig. 13. While on this screen, pressing the bottom-left arrow button will redirect the device back to the Welcome screen. Pressing the bottom-right arrow button will allow the user to navigate forward to the second page of the settings menu with the display shown in Fig. 14.

Figure 13



First page of the settings menu.

The second page of the settings menu allows the user to change the Study Length, Wireless Holter, and MCT Mode settings of the device by touching the respective white box. While on the second page of the settings menu, pressing the bottom-left arrow button will redirect the device back to the first page of the settings menu, while pressing the bottom-right arrow button will allow the user to navigate forward to the third page of the settings menu with the display shown in Fig. 17.

Study Length: Changes study length duration.

Wireless Holter: Uploads information through a network.

MCT Mode: Transmits trend information to be billed as MCT.

Figure 14



The second page of the settings menu.

If the user touches the white box respective to the Study Length setting, the display shown in Fig. 15 will show on the device screen. Pressing the X button will result in returning to its previous study length setting, as well as returning to the second page of the settings menu.

NOTE: The check cannot be pressed until a number has been input.

Figure 15

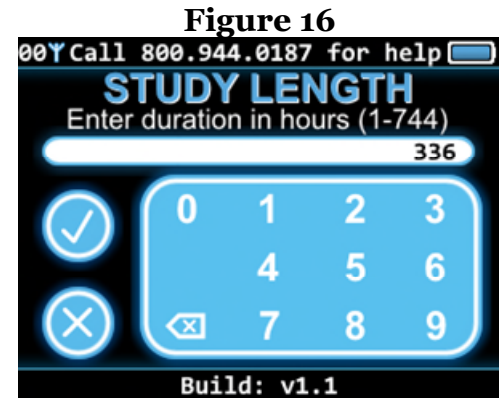


Display previous to setting study length.

Adjusting the Settings (continued)

The check will light up as shown in Fig. 16 after a study length number has been input. After the correct study length has been input, press the check in order to save the new study length and return to the second page of the settings menu. Pressing the X button will result in returning to its previous study length setting, as well as returning to the second page of the settings menu.

NOTE: Other number input settings (Current Time, Current Date, PIN Code) can be completed through the same steps provided for Study Length.



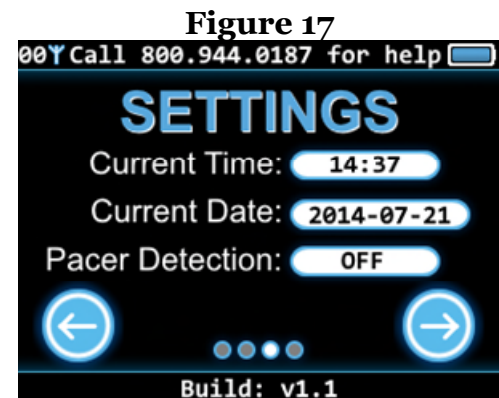
Display after setting study length.

The third page of the settings menu allows the user to change the Current Time, Current Date, and Pacer Detection settings of the device by touching the respective white box. While on the third page of the settings menu, pressing the bottom-left arrow button will redirect the device back to the second page of the settings menu, while pressing the bottom-right arrow button will allow the user to navigate forward to the fourth (final) page of the settings menu with the display shown in Fig. 18.

Current Time: Current time (military time; 0-24 hours)

Current Date: Current date (YYYY-MM-DD)

Pacer Detection: Device creates a mark in ECG record when a pacemaker pulse is detected.

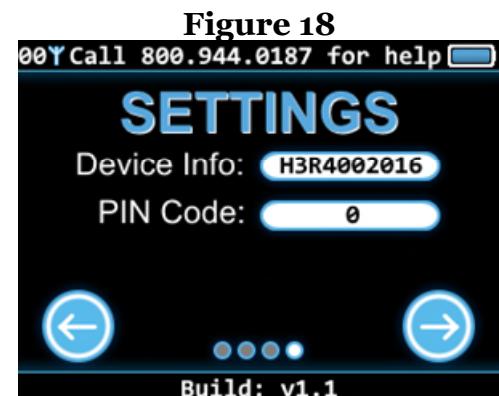


The third page of the settings menu.

The final page of the settings menu allows the user to view the Device Information and set a PIN Code for the device by touching the respective white box. While on the final page of the settings menu, pressing the bottom-left arrow button will redirect the device back to the third page of the settings menu, while pressing the bottom-right arrow button will allow the user to navigate back to the Welcome screen.

Device Info: Provides device information.

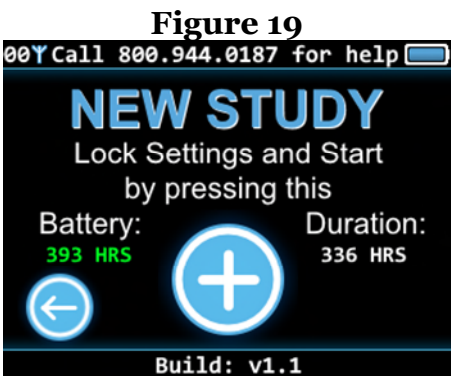
PIN Code: Input a PIN Code for a patient.



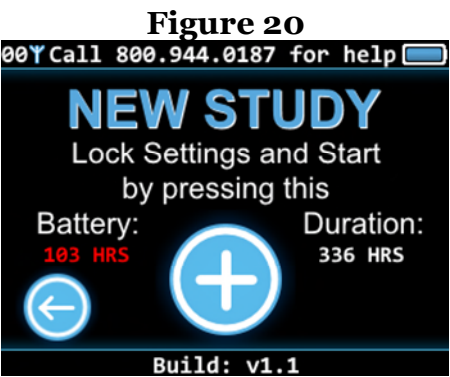
The fourth (final) page of the settings menu.

Starting a Study

To start a study, press the plus icon provided in Fig. 6 on the Welcome screen. The device will be directed to a screen with a display similar to Fig. 19 or Fig. 20. On this screen, confirm the start of the study by pressing the plus icon in the center of the screen. To return back to the Welcome screen, press the bottom-left arrow button. The length of the study that was manually added within the settings will be displayed under the “Duration” text as shown in Fig. 19 and Fig. 20. The remaining battery life of the Clarus 40L will be displayed under the “Battery” text as shown in Fig. 19 and Fig. 20.



This device is ready to start a new study.



The battery will have to be recharged during the study.

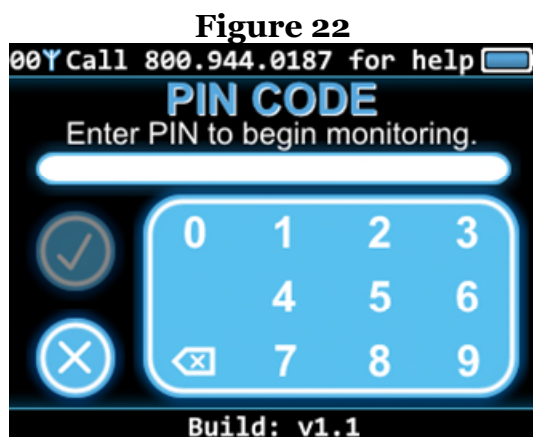


The PIN Code screen.

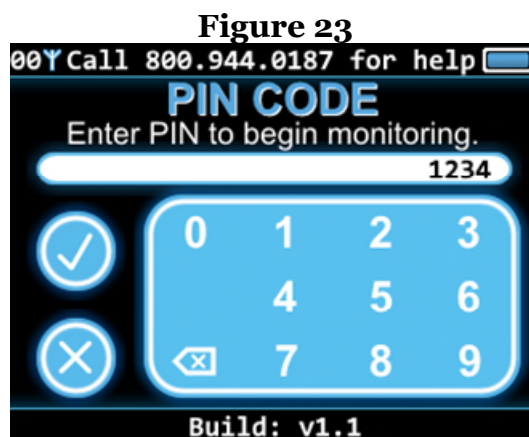
If the PIN Code setting was set to a value other than 0 while setting up the settings, the device will prompt the patient to enter the PIN Code as provided in Fig. 21. This is generally used when the patient is not present when the device is configured. If this is the case, the device can be powered down for shipment by pressing and holding the power button until the screen turns off. When the patient receives the device, they can power it on by pressing and holding the power button for at least 1 second. After the device boots, they can follow the on-screen instructions to enter the correct PIN. The PIN should be provided separately to the patient.

Starting a Study (continued)

After the patient has pressed the check mark provided in Fig. 21 the user will then be able to enter their PIN Code which should be provided by their physician. In Fig. 22 it is noticed that the user cannot press the check mark until a number is input. Once a number has been put in, the check mark becomes visible as shown in Fig. 23. If the PIN Code is input incorrectly, or if the user presses the X button, the device will be redirected back to the Patient Verification screen provided in Fig. 21, the patient can then go through the same steps in order to input the correct PIN Code.

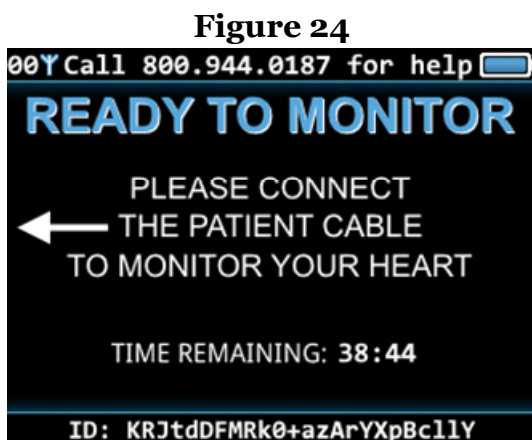


Display previous to patient inputting PIN Code.

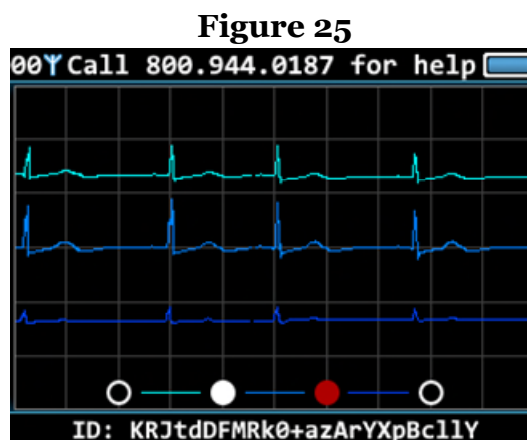


Display after patient inputs PIN Code.

After the PIN has been entered correctly (or if the PIN Code setting was set to 0), the display in Fig. 24 will be presented on the screen, indicating that the device is ready to monitor, prompting 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, as shown in Fig. 25. The legend at the bottom of the screen may be used to identify which electrode, if any, needs correction.



Ready to monitor.



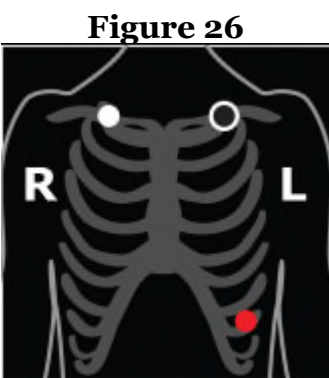
Signal quality can be evaluated on this screen.

Electrode Application

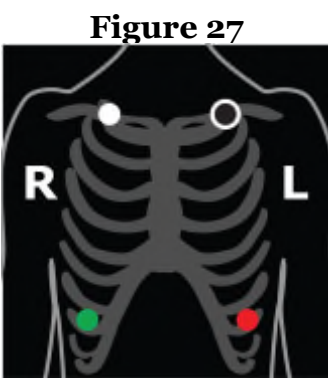
Employ the following procedure when applying electrodes to a patient and connecting them to the Clarus 40L:

- 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, pressing the border firmly to ensure consistent adhesion. Make sure to match electrodes to the selected configuration from the following figures or as instructed by the physician.
- 7. To alleviate tension on electrode snaps, loop patient lead wires and tape down.

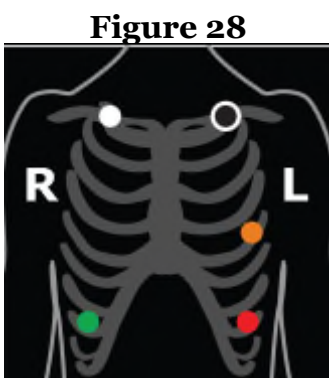
NOTE: When plugging cable into device, cord faces up (away from patient). The cable might need some force to be completely inserted.



3-electrode (H3R-0017) hookup.



4-electrode (H3R-0077) hookup.



5-electrode (H3R-0019) hookup.

Electrode Color	Application Placement	Configuration
Black	LA	3-electrode; 4-electrode; 5-electrode
White	RA	3-electrode; 4-electrode; 5-electrode
Red	LL	3-electrode; 4-electrode; 5-electrode
Green	RL	4-electrode; 5-electrode
Brown	V5	5-electrode

Marking an Event

Once a study has been started, the Clarus 40L will silently record ECG data with no intervention from the patient. The patient can wake the display provided in Fig. 29 by briefly pressing the power button. This display allows the user to view the time remaining for the study as well as instructions on how to mark an event. After pressing the plus button, the display shown in Fig. 30 will be displayed on the screen.

NOTE: If the user does not touch the plus button or power button for approximately 20 seconds, the device screen will go back to sleep.

Pressing the bottom-left arrow will bring the user back to the previous screen displayed in Fig. 29. Pressing the lower-right arrow will bring the user to the Symptom Diary screen displayed in Fig. 31.

Use the up and down arrows to scroll through the symptoms list in order to place the correct symptom into the white box. While on the Symptom Diary screen, pressing the bottom-left arrow button will redirect the device back to the first page of the marking an even menu, while pressing the bottom-right arrow button will allow the user to navigate forward to the third page of the marking an event menu with the display shown in Fig. 32.

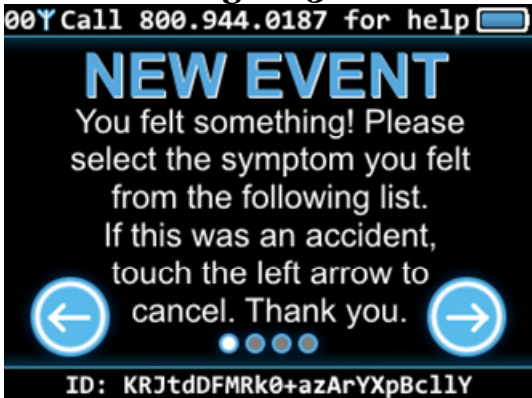
NOTE: The scroll cannot be used to go up and down the list, it merely provides a visual for where you are in regards to the list view.

Figure 29



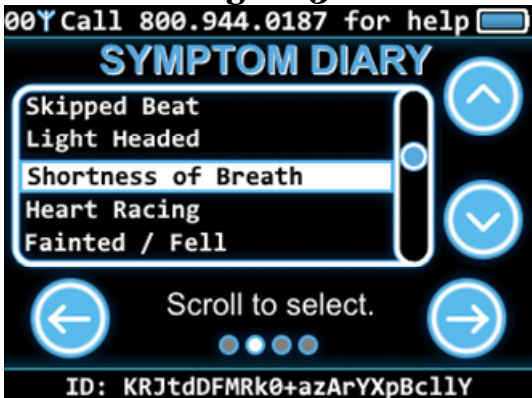
Study progress and event instructions.

Figure 30



First page of marking an event.

Figure 31



Second page (Symptom Diary page) of marking an event.

Marking an Event (continued)

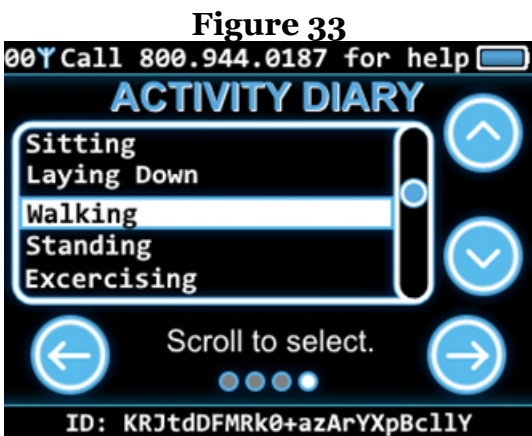
Pressing the bottom-left arrow will bring the user back to the previous Symptom diary screen displayed in Fig. 31. Pressing the lower-right arrow will bring the user to the Activity Diary screen displayed in Fig. 33.



Third page of marking an even.

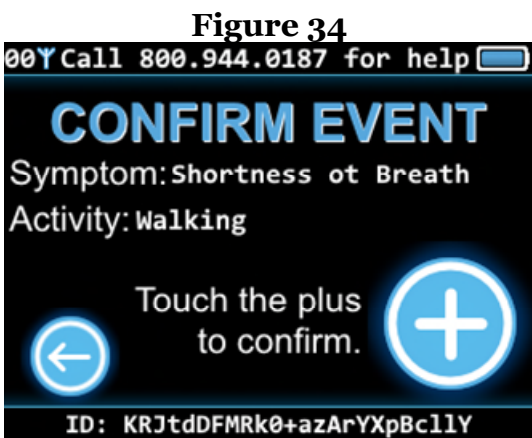
Use the up and down arrows to scroll through the activity list in order to place the correct activity into the white box. While on the Activity Diary screen, pressing the bottom-left arrow button will redirect the device back to the third page of the marking an even menu, while pressing the bottom-right arrow button will allow the user to navigate forward to the event confirmation page with a display provided in Fig. 34.

NOTE: The scroll cannot be used to go up and down the list, it merely provides a visual for where you are in regards to the list view.



Fourth page (Activity Diary page) for marking an event.

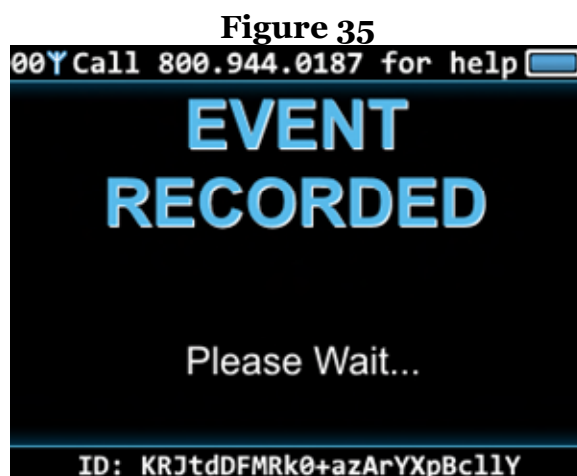
This page shows the user what Symptom and Activity were chosen for the event, allowing them to change if necessary. To change the symptom or activity, the user would need to hit the bottom-left arrow until the correct diary is displayed, in which they would need to select the correct text from the list provided, as explained previously. If the symptom and activity is correct, then the user can confirm the event by touching the plus button.



Event confirmation page.

Marking an Event (continued)

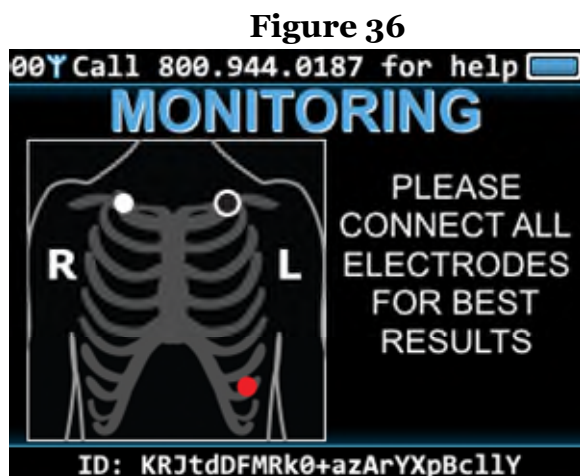
Once an event has been successfully marked, the display provided in Fig. 35 will be displayed on the screen and will vibrate for approximately three seconds. After those three seconds, the device will be redirected to the monitoring screen display provided in Fig. 29.



Event confirmation page.

Monitoring a Study

If electrodes become disconnected during the course of a study, the device will notify the patient by vibrating 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 40L will continue to record as long as the patient cable is connected, regardless of electrode status.



An electrode has been disconnected.



The patient cable has been disconnected.

Receiving Messages

The Clarus 40L can receive messages, similar to the one displayed in Fig. 38, at any time if the device is connected to a network. The message can be confirmed by pressing the bottom-right arrow.

Figure 38

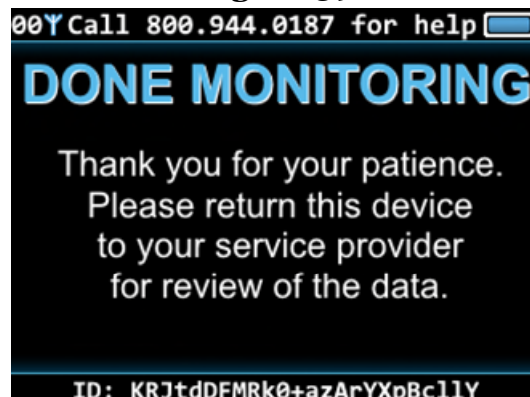


The device has received a message.

Ending a Study

The Clarus 40L 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 by vibrating and displaying the screen shown in Fig. 39, notifying the patient that the device should be returned.

Figure 39



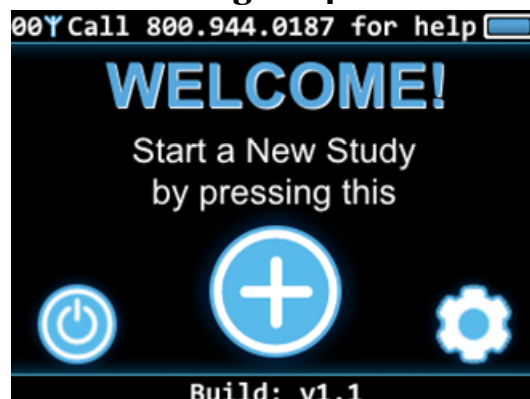
The patient will be notified once the study is complete.

Figure 40



The USB cable is connected.

Figure 41



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

The data from the Clarus 40L may be retrieved at any time by connecting the USB accessory cable (H3R-0025) between the Clarus 40L and a PC. No special steps are required when terminating a study early; once the device has been connected via USB, it will not record anymore ECG until the 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 if the patient data has been removed. Otherwise, it will restart and display the done monitoring screen.

Removing Patient Data

In order to use the device for another study, or if there was some misunderstanding in setting up the device, the Clarus 40L can be easily reformatted:

1. Using the Clarus USB cable (H3R-0025), plug the device into a computer.
2. Follow the steps provided by your software provider for retrieving the patient's data off of the device.
3. On your desktop, open the File Explorer tab so that you can view the plugged in device.
4. Right-click on the device and click the "Format..." button.
5. Under the "Format Options", ensure that the "Quick Format" is checked.
6. Click "Start" and wait until the device has been reformatted.
7. If a warning pops up saying that formatting will erase ALL data, click "OK"
8. After the format is complete, click "OK" on the pop-up and close out of the formatting screen.
9. Right-click on the device and hit "Eject" to safely remove the device from the computer.

The Clarus 40L device will now be reformatted where it can record a new study.

NOTE: Make sure that any recording has been uploaded to a computer before reformatting, or else the data will be lost.

Patient Use Precautions

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

Avoid Exposure to Moisture

The Clarus 40L should not be used while swimming, showering, bathing, or participating in any aquatic activities. In these situations, disconnect the cable from the device and place the device in a safe location. Use caution to avoid inadvertent submersion in water.

Avoid Sharp Impacts

While the Clarus 40L 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 40L 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 40L in order to ensure proper detection and analysis of your heart's symptoms.

Keep Electrodes Connected

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

Keep the Battery Charged

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


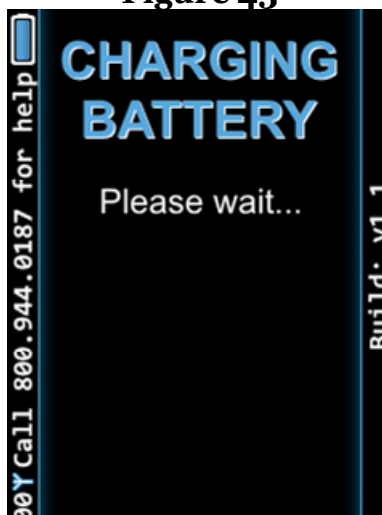
To charge the battery during a study, disconnect the patient recording cable and connect the Clarus 40L wall charger (H3R-0099). To charge the device between studies, you may either connect the device to the Clarus USB cable (H3R-0025) or insert the Clarus device into the Clarus 9-Device USB Charging Dock (H3R-0079) or the Clarus 9-Device Charging Dock (H3R-0205). The USB cable and 9-Device USB Charging Dock options provide USB access to device data. If the charging dock is not plugged in to an external power supply, then the display provided in Fig. 42 will appear on the device screen. While the Clarus 40L is charging, the screen will display the image provided in Fig. 43 and the blue LED on the charging dock will flash. The Clarus 40L will also indicate that the battery is charging with a charging battery icon () in the corner of the screen. When the charging has been completed, the display provided in Fig. 44 will appear on the screen and the blue LED on the charging dock will be solid.

Figure 42



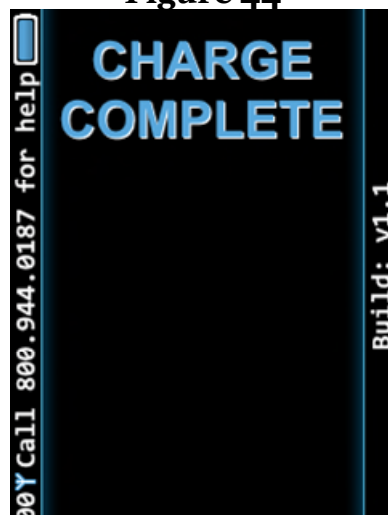
Charging dock not plugged in to external power supply.

Figure 43



Battery is charging.

Figure 44



Charging Complete.

Storage

When not being used for recording data, the Clarus 40L should be shut off as shown previously. To wake the Clarus 40L after it has been powered down, press the power button for at least 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 submerge, autoclave, or steam clean the Clarus 40L or the patient cable.
- **Do not** use solvents to clean the device. Examples include:
 - Ketones or Esters (Acetone, Methyl Ethyl Ketone [MEK], Ethyl Acetate, Benzyl Acetate)
 - Strong Bases (Ammonium Hydroxide, etc.)
 - Benzene
 - Mineral Spirits
 - Bleach (chlorine or hypochlorite)

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

1. Disconnect the patient cable. Patient cables are designed to be reusable after being properly cleaned.
2. Wipe the exterior of the Clarus 40L and its accessories with a damp cloth. Use mild detergent diluted in water or surface wipes such as PDI Super Sani-Cloth® Germicidal Disposable Wipes ("purple top"). Take care not to allow water or moisture to enter the Clarus 40L, especially around the cable contacts. Other acceptable cleaning agents: up to 97% isopropyl alcohol, up to 3% benzyl ammonium chloride.
3. Dry with a clean cloth or paper towel.
4. Clean the patient cable in the same manner before each procedure.

Testing

The Clarus 40L recorder performs a comprehensive self-test each time it is powered on. This test is designed to 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 40L has been designed to detect and recover from error conditions automatically. There are situations that may occur where the device simply cannot recover on its own. In such cases, the Clarus 40L will display an error message on the screen with an error code. An example of an error display is provided in Fig. 45.

Figure 45



*An example error message displayed
on the Clarus 40L screen.*

These errors can often be resolved through connecting the Clarus 40L to a computer, and reformatting the device (removing patient data) which erases the recording memory. If the error message persists, please contact your service provider as the device may 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 - or - 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 30 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

Ingress Protection	IP22
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	Multi Band LTE, Multi Band 3G HSPA/UMTS and Quad Band GSM
Bands	12 Band FDD-LTE, 7 Band 3G HSPA/UMTS, Quad Band 2G GSM

Specifications

Projected service life

The projected service life of the Clarus 40L 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 40L 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

Specifications

 Manufactured by TZ Medical, Inc. 17750 SW Upper Boones Ferry Rd STE #150 Portland, OR 97224	 EU Authorized Representative: CEPartner4U Esdoornlaan 13 3951 DB Maarn The Netherlands Tel: +31 (0)6-516.536.26	 0459
---	---	--

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 40L.

Part Number	Description
H3R-0017	Clarus 3-Electrode Patient Cable
H3R-0077	Clarus 4-Electrode Patient Cable
H3R-0025	Clarus USB Data / Charging Cable
H3R-0099	Clarus Wall Charger
H3R-0079	Clarus 9-Device USB Charging Dock
H3R-0205	Clarus 9-Device Charging Dock
H3R-0027	Clarus 40L Plastic Holster
H3R-0051	Clarus Screen Protector

Wireless Compliance

FCC ID: ZIMH40L

FCC Compliance Statement

This device complies with part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s).

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 40L 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 40L Plastic Holster (PN: H3R-0027). Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

The maximum reported body SAR is 1.31 W/kg per 1 g of tissue. The maximum reported extremity SAR is 1.76 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: ZIMH40L.

Directive 2014/53/EU Compliance Statement

Hereby, TZ Medical, Inc. declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0053>

Wireless Compliance

IC ID: 9647A-H40L

License Exempt (Canada)

Antenna Statement

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Licence 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 fonctionnement.

EMC Precautions

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

EMC Precautions

Guidance and Manufacturer's Declaration - Emissions			
The Clarus 40L is intended for use in the electromagnetic environment specified below. The customer or user of the Clarus 40L should ensure that it is used in such an environment.			
Emissions Test	Compliance	Electromagnetic Environment – Guidance	
RF Emissions CISPR 11	Class B	The Clarus 40L 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 EN 61000-3-2	Class A		
Flicker EN 61000-3-3	Complies		
Guidance and Manufacturer's Declaration – Immunity			
The Clarus 40L is intended for use in the electromagnetic environment specified below. The customer or user of the Clarus 40L should ensure that it is used in such an environment.			
Immunity Test	Compliance	Electromagnetic Environment – Guidance	
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%	
Power Frequency 50/60Hz Magnetic Field 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 40L			
The Clarus 40L is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Clarus 40L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Clarus 40L as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz 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