CIRCA SCIENTIFIC

CIRCA Temperature Monitoring System™

CE 2797

EC REP

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Contents

1.0 Introduction

1.1

Intended Purpose

Intended Purpose: Display continuous temperature measurement (°C) from 12-sensor temperature probe for esophageal monitoring during cardiac ablation procedures.

Clinical benefits: as this is a temperature-monitoring device, there can be no direct clinical benefits attributed to the device. The clinical benefits associated with the overall procedure are applicable to the device and can be used as the parameter to measure the performance of the device.

Contraindications: there are no known contraindications associated with the equipment or its accessories.

Limitations: patients with dysphagia and other esophageal diseases/abnormalities.

Intended users: the target user group is trained medical professionals. The probe is placed and used by a trained medical professional, e.g., surgical nurse, anesthesiologist, cardiologist, electrophysiologist, or ENT physician.

Intended patient population: adult patients of both men and women indicated as clinically suitable and in need to undergo cardiac ablation prescribed by a suitably qualified clinician.

1.2

General Warnings & Cautions

Note
A statement that provides important information, emphasizing or supplementing the main text. The information does not relate directly to issues that may cause injury to patients or users, or damage to the system.

Caution
A statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property.

Warning
A statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

Warning No modification of this equipment is allowed.

- The monitor is designed for use with CIRCA Scientific Interconnect Cables, Temperature Probes, and Accessories only. Incompatible components or replacement parts can result in degraded performance and could lead to damage to the unit. No modification of this equipment is allowed.
- Part of defibrillation-proof protection is provided by CIRCA Scientific Temperature Probes. Do not use with any other applied part.
- Only equipment complying with the requirement of IEC 60601-1 for medical equipment patient protection should be used within the patient environment. Other equipment not complying with patient protection should be used outside the patient environment.
- Additional equipment connected to the monitor must be certified to respective IEC or ISO safety standards. When connecting external equipment to monitor, make sure that the whole combination complies with safety standard for Medical Electrical Systems according to IEC 60601-1 3rd edition (clause 16) and with the requirements of local laws and governing agencies. Hospital personnel who connect additional equipment configure a medical system, and are therefore responsible for the system complying with the requirements for Medical Electrical Systems.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Never pour any liquid into an opening on the equipment. Do not use the equipment in an oxygen rich environment or in the presence of flammable anesthetics. This may cause fire, combustion, or electrical shock.
- Do not cover the openings. Overheating may occur as the openings on the enclosure are for air convection.
- If the equipment is not in use, disconnect it from the power source to avoid damage by transient overvoltage.
- Never open the equipment. No user serviceable parts inside. There is a danger of shock if incorrectly serviced. There is a danger of explosion if battery is incorrectly replaced. Refer servicing to CIRCA Scientific.

Note: Any serious incident that occurs in relation to this device should be reported to CIRCA Scientific and the Competent Authority of the Member State in which the user is established.

- Equipment is not to be serviced or maintained while in use with a patient or otherwise while in use. Refer servicing to CIRCA Scientific.
- This equipment needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be put into service according to the EMC information provided in Section 9 “Electromagnetic Compatibility”.
- Do not connect accessory equipment that has not been approved by CIRCA Scientific to the analog and digital interfaces for signal input or output. Personnel who connect additional equipment configure a medical system which may result in degraded performance and damage to the unit.
- Do not connect monitor to hospital network and do not use any USB Data Transfer Drive other than that supplied by CIRCA Scientific. Improper connection may result in infiltration of malware and viruses and voids the warranty of the CIRCA Scientific Temperature Monitor.
- Do not store USB Data Transfer Drive connected to the USB Data Transfer Cable. Ensure Protective Port Cover is inserted into USB Data Transfer Cable and only removed for data transfer per Section 2.3 “Data Archive.”
- Shut down system per Section 4.7 “System Shut Down”. Improper shut down by unplugging the power supply may result in damage to the unit.
- Do not use the device if any of the 12 temperatures displayed are meaningfully lower than 37°C (<35°C), in absence of particular justifying situations, or a difference ≥ 2°C is among the twelve displayed values.

Potential Adverse Events:

Potential risks for serious incidents associated with the use of the CIRCA Temperature Monitoring System include:

- Electric shock
- Esophagus thermal injury

1.3

Cybersecurity Transparency

Caution
Do not connect monitor to hospital network and do not use any USB Data Transfer Drive other than that supplied by CIRCA Scientific. Improper connection may result in infiltration of malware and viruses and voids the warranty of the CIRCA Scientific Temperature Monitor.

- The intended use environment is a hospital operating room with no interaction between the CS-1000 and any other device including communication via wired or wireless methods. The CS-1000 does not require any form of network connection at any time.
- Do not connect monitor to hospital network and do not use any USB Data Transfer Drive other than that supplied by CIRCA Scientific. Improper connection may result in infiltration of malware and viruses and voids the warranty of the CIRCA Scientific Temperature Monitor.
- High-level security features rely on network isolation which prevents the CS-1000 from gaining any form of network access. Networking ports and features are physically blocked where possible and disabled by the underlying Windows operating system. Strict operating system user permissions are used to restrict access to re-enabling these features.
- There are no user-configurable options or security features that require user interaction with the underlying operating system or connection to a network.
- The CS-1000 application was developed with an active power on self-test system. Should anomalies be detected in the device file system, the application will attempt to automatically restore the file system to a known good state. Should this operation succeed, a message will be displayed announcing this operation and alerting the user that changes made to settings should be verified as recent changes may not be saved. Should the operation fail, the CS-1000 will not load the temperature monitoring application and will require repair.
- A digital Software Bill of Materials (SBOM) is available on a continuous basis by asking a representative. The items listed in the SBOM do not require update therefore the revision level can be considered static.
- To securely decommission a CS-1000 the device should be returned to the manufacturer.

1.4

Symbols Key

This document and the device's product labels contain various symbols that draw attention to important information about this device. An explanation of each is given to the right.

Symbol	Description	Reference
	Manufacturer	ISO 15223-1 5.1.1
	Authorized Representative in the European Union	ISO 15223-1 5.1.2
	Date of Manufacture	ISO 15223-1 5.1.3
	Batch Code	ISO 15223-1 5.1.5
	Catalogue Number	ISO 15223-1 5.1.6
	Serial Number	ISO 15223-1 5.1.7
	Temperature Limits	ISO 15223-1 5.3.7
	Humidity Limits	ISO 15223-1 5.3.8

Symbol	Description	Reference
	Atmospheric Pressure Limits	ISO 15223-1 5.3.9
	Caution	ISO 15223-1 5.4.4
	Medical Device	ISO 15223-1 5.7.7
	Stand-By	IEC 60417-5009
	Direct Current	IEC 60417-5031
	Alternating Current	IEC 60417-5032
	Defibrillation-Proof Type CF Applied Part	IEC 60417-5334
	For Indoor Use Only	IEC 60417-5957

Symbol	Description	Reference
	European Conformity / Conformité Européenne	EU MDR 2017/745
	Consult Instructions for Use / Consult Temperature Probe Instructions for Use / Consult Temperature Monitoring System User Manual	ISO 15223 - 1 5.4.3
	Do not use with any other applied part. Part of defibrillation proof protection is provided by the CIRCA temperature probe.	ISO 7010-W001
	Bell Cancel. Indicates Temporary Audio Silencing Feature is active and all audible signals are inactive only until another event occurs.	IEC 60417-5576
	Centre-Positive. Indicates that the center (tip) of the output plug is Positive (+) and the barrel of the output plug is Negative (-).	—
	Waste Electrical and Electronic Equipment. Directive These products are not to be discarded together with non-electrical or non-electronic products.	IEC 60417-6414

2.0 System Description

2.1

Hardware

The CIRCA Temperature Monitoring System consists of a touch-screen monitor with articulating arm and power supply. The monitor is to be used with CIRCA Scientific Interconnect Cables, CIRCA Temperature Probes (Applied Part, Direct Mode), and CIRCA Accessories only.

Figure 2A: Monitor (Front View)

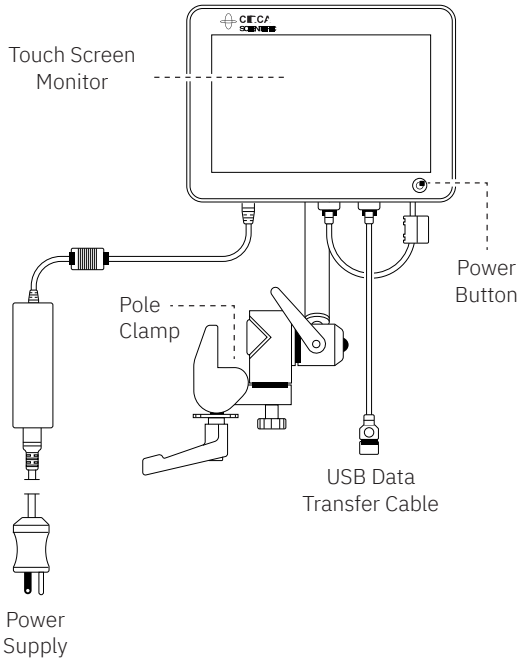


Figure 2B: Monitor (Back View)

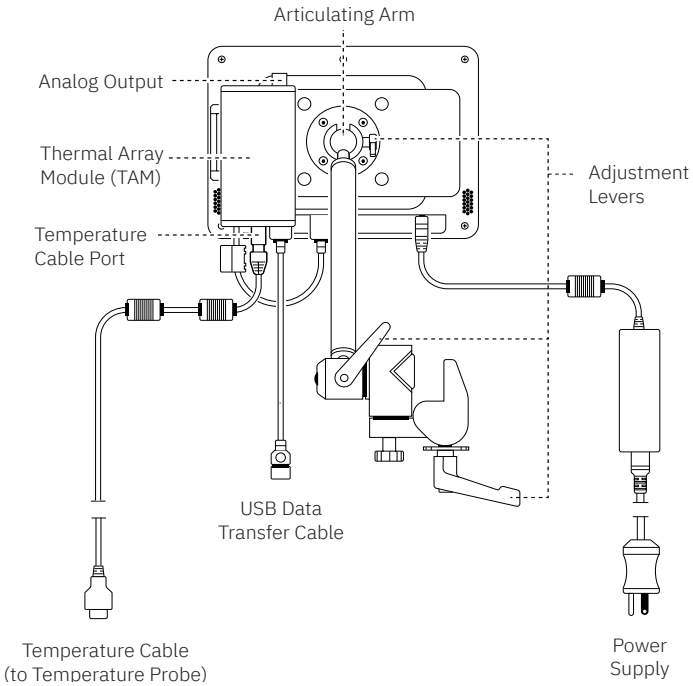


Figure 2C: Monitor (Bottom View)

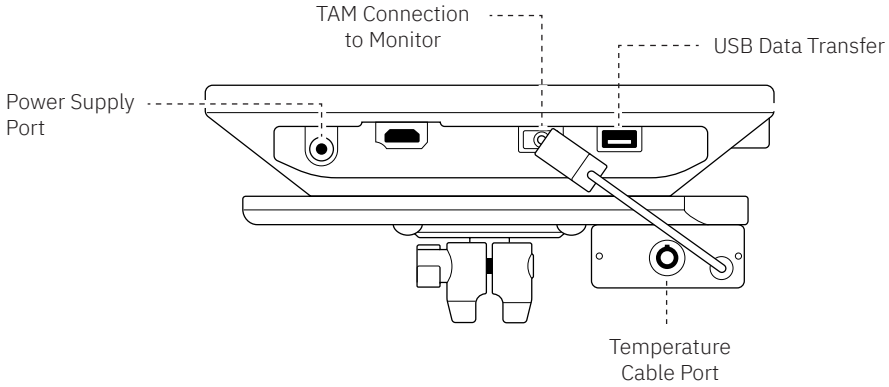


Figure 2D: Monitor (Side View)

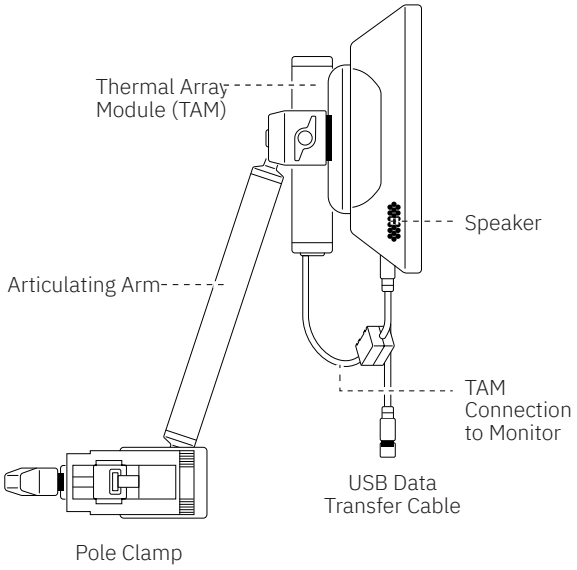


Figure 2E: CIRCA Temperature Probes (Applied Parts, Sold Separately)

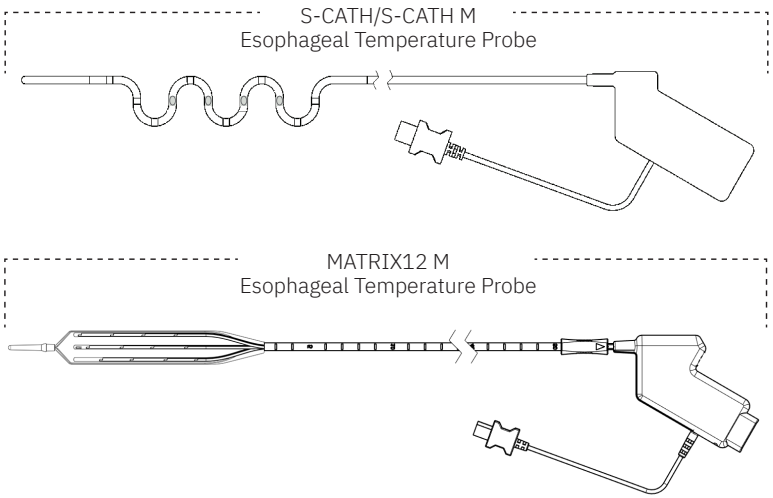


Figure 2F: CS-103 CIRCA Temperature Cable (Sold Separately)

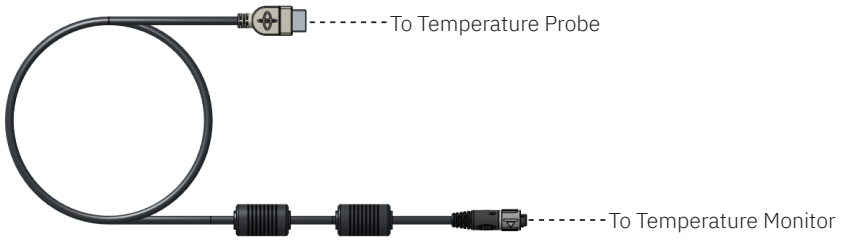


Figure 2G: CS-100 CIRCA Mapping Cable (Sold Separately)

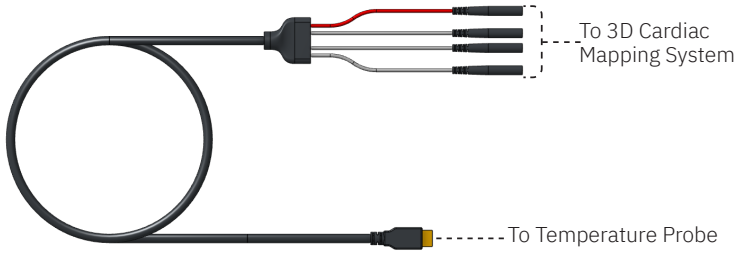


Figure 2H: CS-104 CIRCA Temperature Standard

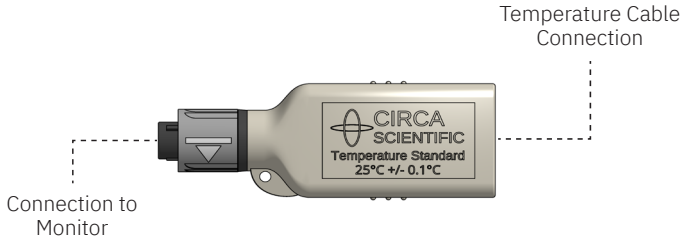
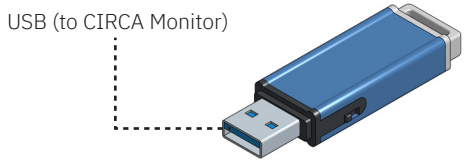


Figure 2I: CS-1083 CIRCA Data Transfer Drive (128 GB, Included with Monitor)*



*Actual USB may vary.

2.2

Applied Parts

S-CATH/S-CATH M Esophageal Temperature Probes

- The CIRCA S-CATH Esophageal Temperature Probe consists of twelve (12) temperature sensors placed along an S-Curve.
- Numbered channels 1 through 12 correspond to each sensor located within the S-Curve of the CIRCA S-CATH. Channel number begins with Sensor 1 located most distally on the probe (see Figure 2K).
- The CIRCA S-CATH is connected to the CIRCA Temperature Monitoring System via the CS-103 CIRCA Temperature Cable. (see Figure 2F).
- CIRCA S-CATH Probes are Direct Mode thermometers suitable for continuous operation.
- The CIRCA S-CATH M Esophageal Temperature Probe with Electrodes additionally includes four electrodes within the S-Curve, which may be utilized for visualization on 3D cardiac mapping systems (refer to S-CATH M Instructions for Use for additional detail).
- The CIRCA S-CATH M is connected to a third-party 3D cardiac mapping system via the CS-100 CIRCA Mapping Cable (see Figure 2G; refer to S-CATH M Instructions for Use for additional detail).

Figure 2J: S-CATH Esophageal Temperature Probe

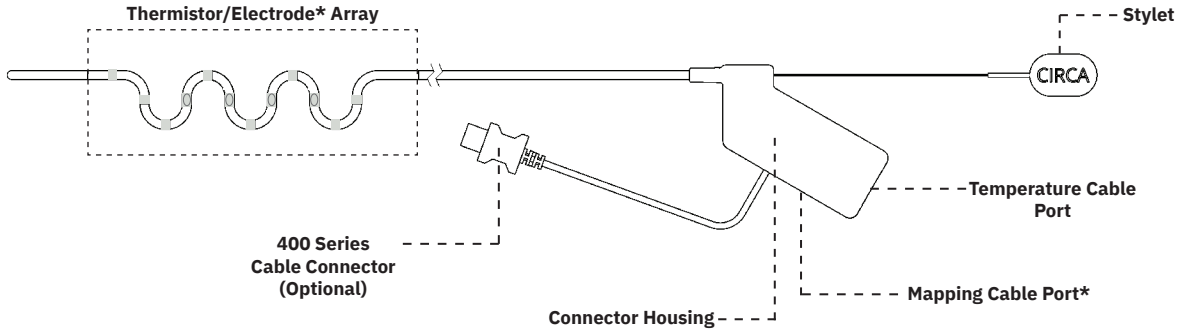
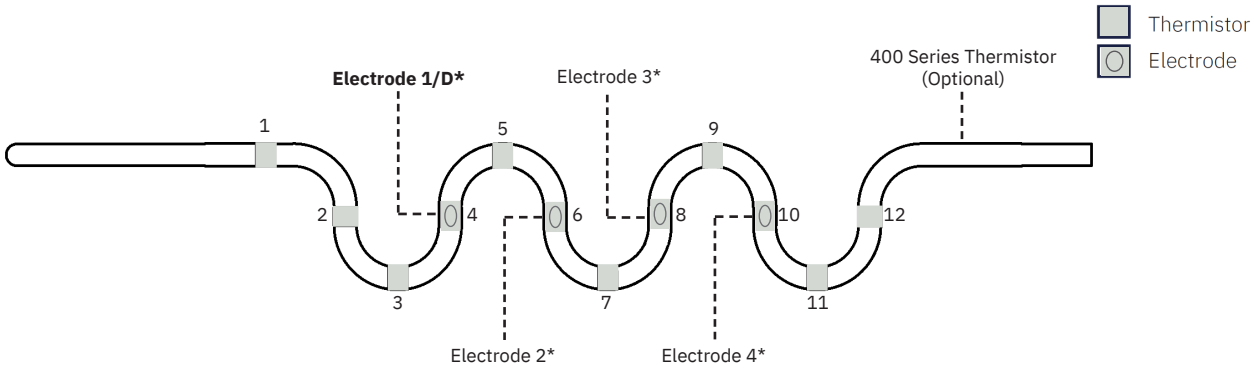


Figure 2K: S-CATH Thermistor & Electrode* Locations



*S-CATH M Probe Only

2.2

Applied Parts

MATRIX12 M Esophageal Temperature Probes

- The CIRCA MATRIX12 M Esophageal Temperature Probe consists of twelve (12) temperature sensors placed along a flexible array.
- Numbered channels 1 through 12 correspond to each sensor located within the temperature array. (See Figure 2M below for thermistor locations).
- The CIRCA MATRIX12 M is connected to the CIRCA Temperature Monitoring System via the CS-103 CIRCA Temperature Cable (see Figure 2F).
- CIRCA MATRIX12 M probes are Direct Mode thermometers suitable for continuous operation.
- The CIRCA MATRIX12 M Esophageal Temperature Probe additionally includes four electrodes within the temperature monitoring array, which may be utilized for visualization on 3D cardiac mapping systems (refer to MATRIX12 M Instructions for Use for additional detail).
- The CIRCA MATRIX12 M is connected to a third-party 3D cardiac mapping system via the CS-100 CIRCA Mapping Cable (see Figure 2G; refer to MATRIX12 M Instructions for Use for additional detail).

Figure 2L: MATRIX12 M Esophageal Temperature Probe

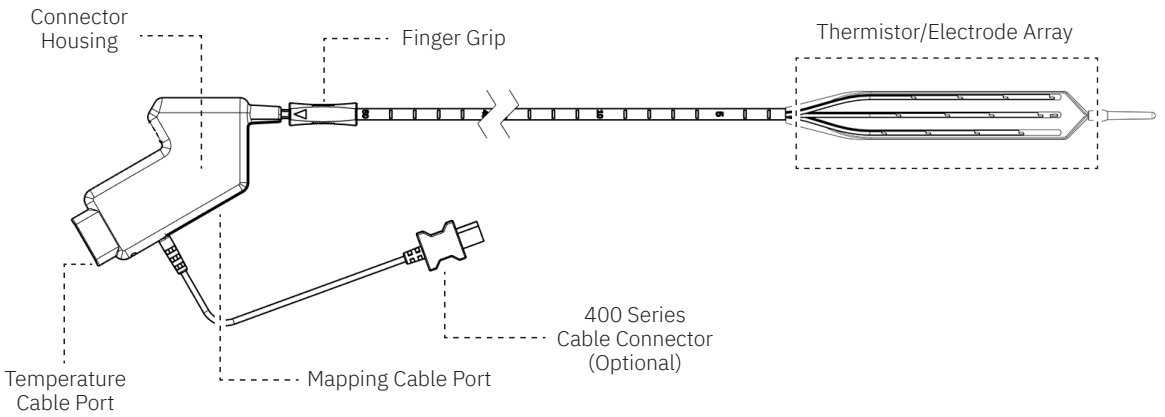
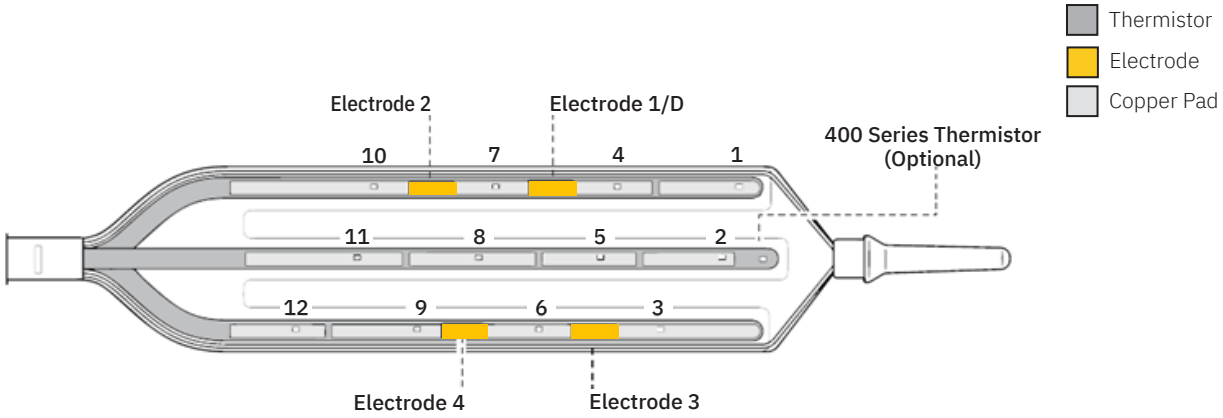


Figure 2M: MATRIX12 M Thermistor & Electrode Locations



Note
Upon initial start-up, users may be required to input the monitor serial number found on the back of the unit.

2.3

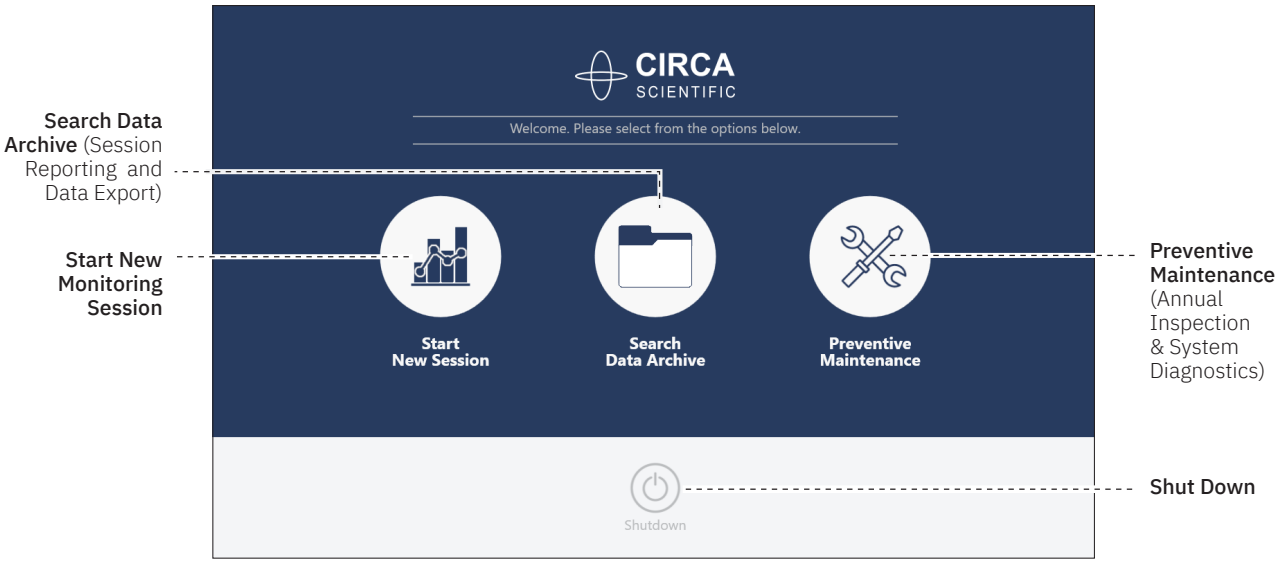
Software/Display

Main Menu

The CIRCA Temperature Monitoring System features three (3) operating modes, which may be selected and navigated between from the Main Menu (see Figure 2N). Screen navigation and Set Up are controlled by touch screen.

- Active Monitoring Session (See Section 4 for additional detail)
- Data Archive (See Figure 2R for additional detail)
- Preventive Maintenance (See Section 7 for additional detail)

Figure 2N: Main Menu Screen



Active Monitoring Session

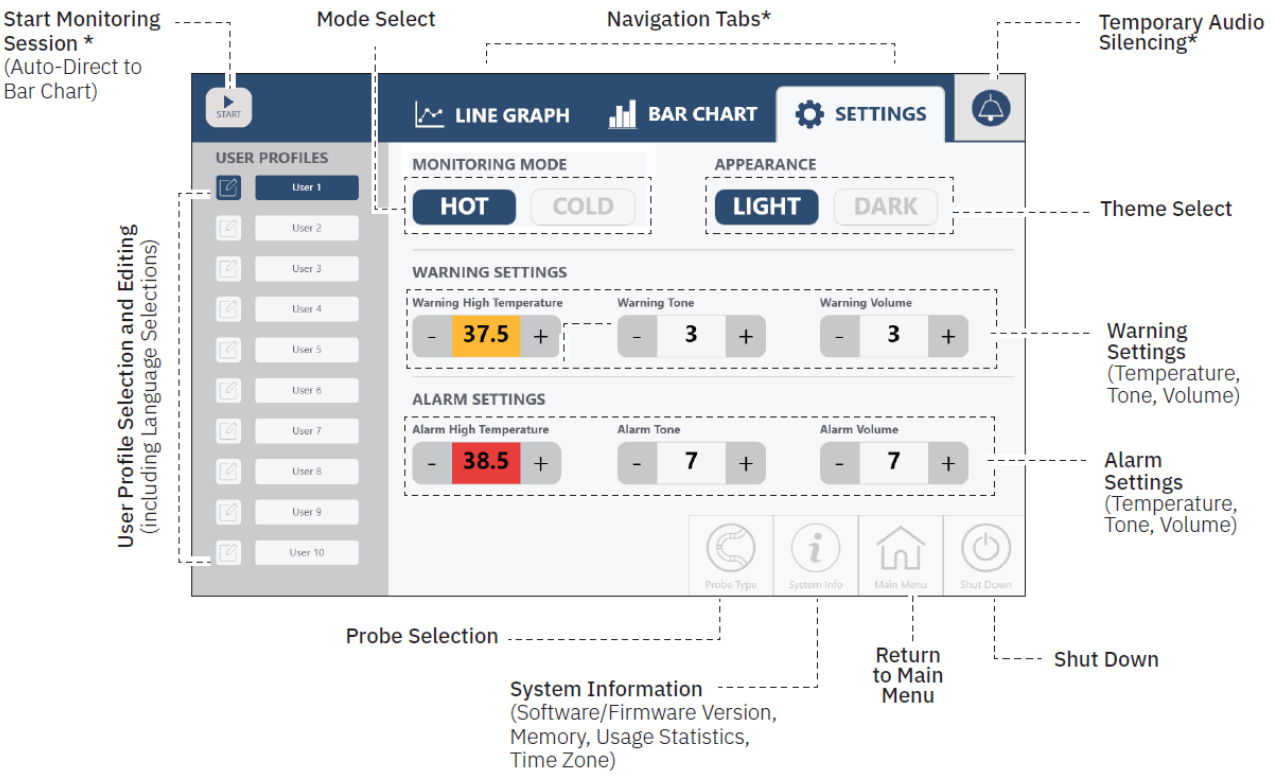
During an Active Monitoring Session, the CIRCA Temperature Monitor displays continuous temperature readings (in °C) from each of the connected CIRCA Scientific Temperature Probe's twelve (12) sensors. The Monitoring Indicator (colon in Session Timer) will flash when the system is actively monitoring temperatures.

The following three (3) screens may be accessed during an active monitoring session:

- Settings (see Figure 2O),
- Bar Chart (see Figure 2P)
- Line Graph (see Figure 2Q).

Operators may toggle between these views touching one of the navigation tabs near the top of the screen. Common elements between screens are marked with an asterisk in the figures that follow.

Figure 2O: Settings Screen



**Common elements shared between Active Monitoring Session Screens.*

Figure 2P: Bar Chart Screen

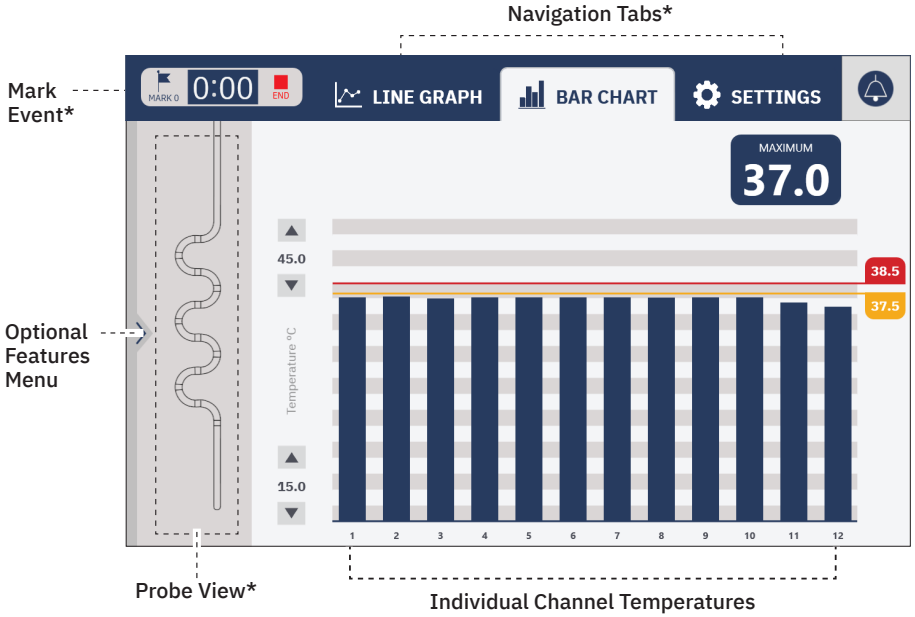
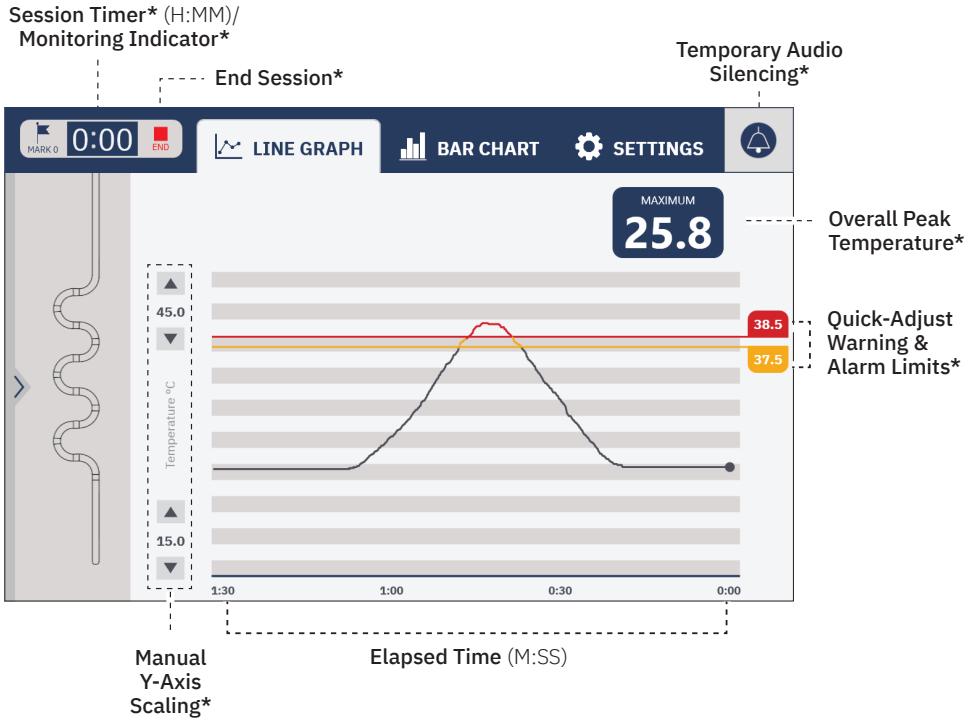


Figure 2Q: Line Graph Screen



Common elements shared between Active Monitoring Session Screens.

Data Archive

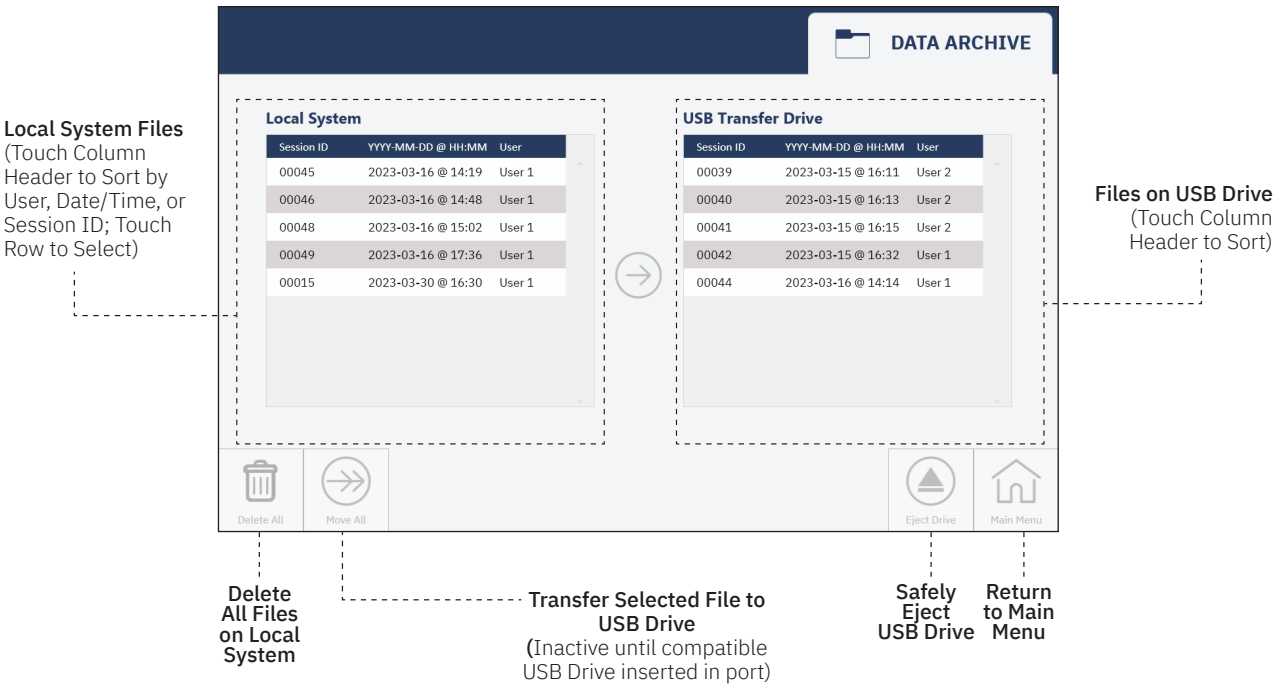
The CIRCA Temperature Monitoring System is equipped with an automatic data recording feature, enabling users to export data corresponding to a selected monitoring session to a .csv (comma separate value), .pdf, or .jpg file via the CS-1083 CIRCA USB Data Transfer Drive. Files may be sorted, selected, deleted, and/or transferred to the USB Drive from the Data Archive Screen.

Local System Storage Capacity
The Local System can store data up to 200 monitoring sessions. Users will be notified of the need to delete or transfer local files to free device memory at 190 session files.

File Transfer
Please note, file transfer is one-way (from the Local System to the USB Data Transfer Drive). Once a file is transferred off the local system, it cannot be restored back on the Local System.

File Deletion
Similarly, file deletion on the Local System is permanent. If a file is deleted from the local system in error, it cannot be recovered. The user will be prompted to confirm their intent to delete the file prior to proceeding.

Figure 2R: Data Archive Screen



Preventive Maintenance

The Preventive Maintenance Screen provides access to two (2) guided pathways to assist users when performing an Annual Safety Inspection and Accuracy Test (see Section 7: Preventive Maintenance) or System Diagnostics (see Section 6: Troubleshooting) when used in conjunction with the CIRCA Temperature Standard.

Figure 2S: Preventive Maintenance Screen

3.0 Set Up Instructions

Caution: The operator is responsible for checking the compatibility of the monitor, cables, and temperature probe before use. Ensure only CIRCA Scientific components and equipment are connected to the system before proceeding.

3.1

Hardware Set Up

1. Mount monitor to standard IV pole or similar rigid structure. Secure by tightening the Pole Clamp Lever.
2. Adjust monitor to desired position (tilt position and angle) using articulating arm adjustment levers.

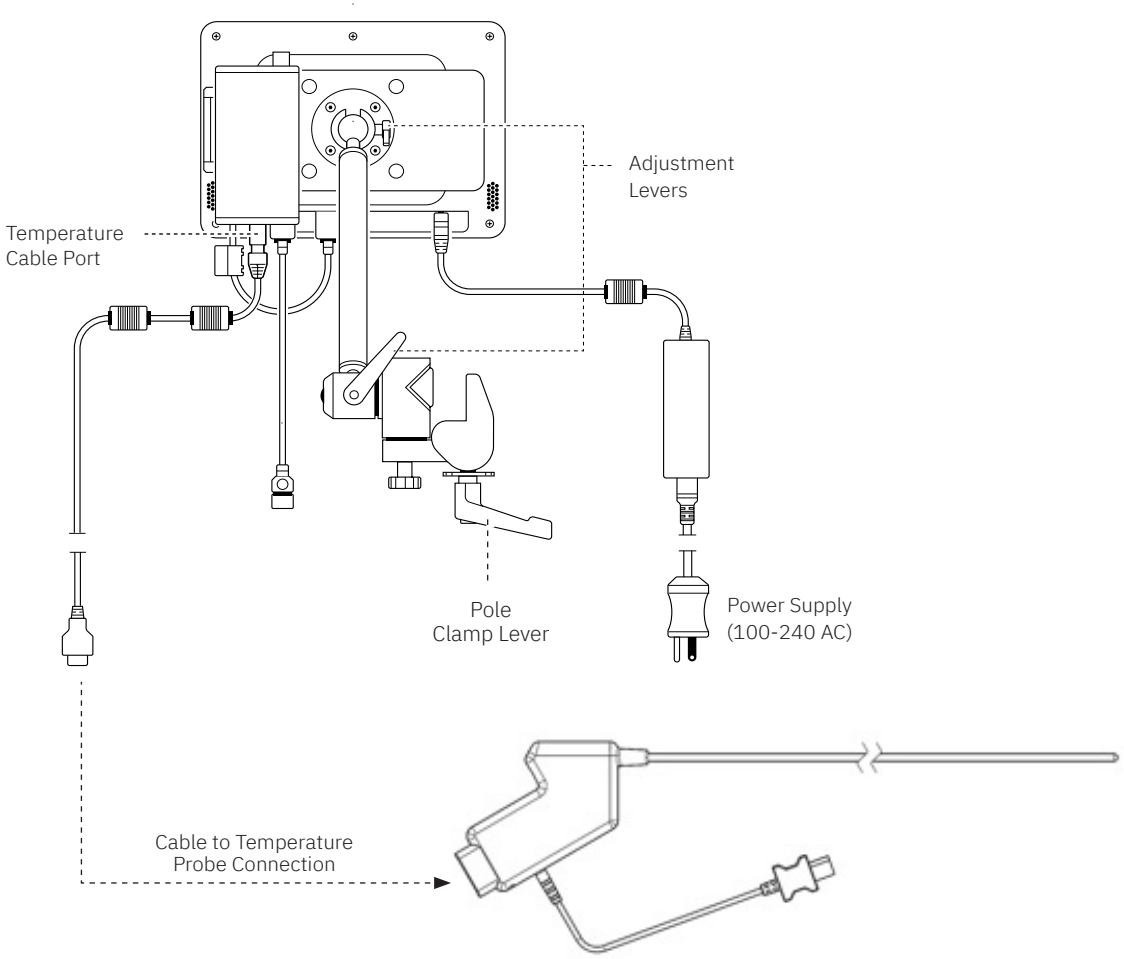
Note: Intended position of the operator to observe the Alarm Signal is within an approximate distance of 1.4 meters.

3. Plug power cord into power outlet.

Warning: To avoid the risk of electric shock, this equipment **must** be connected to a supply mains with protective earth **only**.

4. Connect Temperature Cable to monitor (connection located on back of monitor) by aligning snap-fit connectors and pushing firmly.
5. Press Power Button 2 seconds to switch monitor on.
6. Select “Start New Session” from the Main Menu to navigate to the Settings screen, and proceed to Software Set Up (see Section 3.3).
7. Once a new session has started, the monitor will deliver a test audible alarm (3 beeps). If no audible signal is heard, sound system is defective. Contact Technical Support to refer monitor for service at CIRCA Scientific.

Figure 3A: Set Up Connections



3.2

Storage & Transport

Do not leave this equipment in an environment where the storage temperature may go below -20°C (-4°F) or above 60°C (140°F). This could damage the equipment.

If shipping equipment, pack in original carton and packing materials. If original packing material is not available, cover monitor, pack with foam, and ship in sturdy box to prevent damage during transport.

Operating Humidity: 30% to 75%RH, non-condensing
Operating Pressure: 700 to 1033 hPa
Storage & Transport Humidity: 10% to 85%RH, non-condensing
Storage & Transport Pressure: 700 to 1033 hPa

Note: Screen navigation and Set Up are controlled by touch screen. Different screens may be selected by touching one of the navigation tabs near the top of the screen.

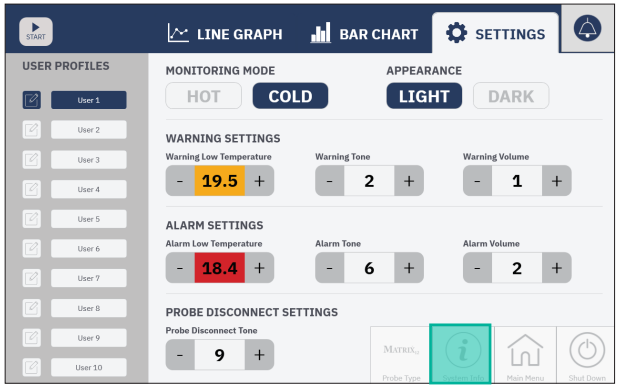
3.3

Software Set Up

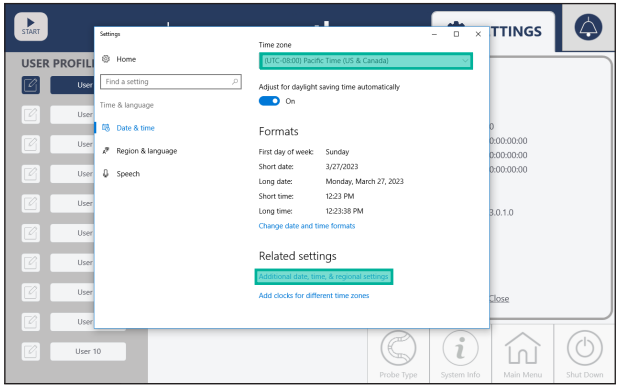
Set System Time Zone

1. From Settings Screen, select “System Information” in the bottom right-hand corner of the screen.
2. Touch “Edit” under “Time Zone UTC” to configure the system’s date and time settings to align with the physical location of the monitor.
3. Use the drop down to select the appropriate time zone. Then select “Additional date, time, and regional settings” (see Figure 3B, step 3).
4. Select “Set the time and date”:
   - Set Time Automatically
   - Set Time Zone Automatically
   - Adjust for daylight saving time automatically.
5. Select “Change date and time” button (see Figure 3B).
6. Use the Windows controls to adjust the date and time to the correct settings (see Figure 3B, step 4).
7. Close all Windows dialogue boxes by selecting “OK” or using the “X” in the top right corner of the box.

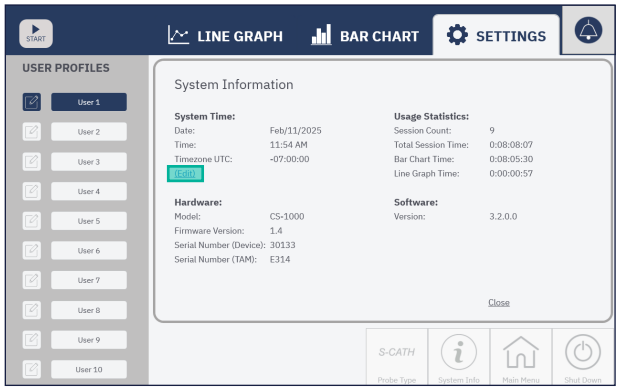
Figure 3B: Set System Time/Date



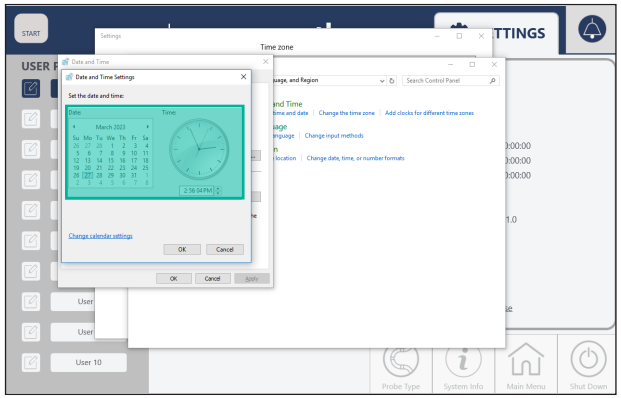
Step 1: Open System Info



Step 3: Set time zone and select additional settings



Step 2: Open Windows Date & Time Settings



Step 4: Manually adjust the date and time settings

User Profiles

Users can save preferred system settings by selecting a user profile on the left-hand side of the screen. User-profile associated settings include:

- System Language
- Preferred Monitoring Mode: Hot or Cold (Note: A single user profile will support preferences for both Hot and Cold modes)
- Preferred System Appearance: Light or Dark
- Warning Settings (Temperature, Tone, Volume)
- Alarm Settings (Temperature, Tone, Volume)
- Optional Features (see Section 5).

To create or edit a new user profile:

1. Touch the edit button to the left of an available user profile.
2. On the "Edit User Profile" Screen, use the on-screen QWERTY keyboard to type the desired name of the User Profile.
3. Select the preferred system language for the User Profile using the drop down menu in the lower right-hand corner of the "Edit User Profile Screen".
4. Select "Return" to return to the Settings screen.
5. Set Warning/Alarm temperature, tones, and volumes, as desired. All settings are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

Note: Once a monitoring session has been started, changes cannot be made to the User Profile without ending and restarting the session.

Set Warnings/Alarms

1. Select "Hot" mode to monitor temperature increases and maximum temperature. Select "Cold" mode to monitor temperature decreases and minimum temperature.
2. Set desired Warning and Alarm temperature limits by touching the "+" and "-" buttons adjacent to the temperature values. Default temperature limits are set to:
    - Warning High Temperature: 37.5°C
    - Warning Low Temperature: 25°C
    - Alarm High Temperature: 38.5°C
    - Alarm Low Temperature: 20°C

Note: Warning High Temperature Limit cannot be set equal to or greater than Alarm High Limit. Warning Low Temperature Limit cannot be set equal to or less than Alarm Low temperature limit.

3. Set desired Warning and Alarm tones and volumes. Warning and Alarm tones and volumes can be heard and adjusted by tapping on the "+" and "-" buttons next to the appropriate value to be adjusted. Default settings include:
    - Warning Tone/Volume: 3/3
    - Alarm Tone/Volume: 7/7

Note: Warning volume cannot be set equal to or greater than alarm volume. Auditory alarm signal volumes set less than ambient levels can impede recognition of alarm conditions.

Chart Scaling and Optional Feature Selection

1. Using the Navigation Tabs at the top of the screen, select either "Bar Chart" or "Line Graph".
2. Confirm desired probe is displayed in "Probe View" on left of screen. All twelve sensors on the image should appear **green.** If the sensors appear red or do not appear, probe is defective. Discard and replace probe.

Note: If a probe is not connected, the message "Probe disconnected" will appear on the screen.

3. Manually scale the Chart or Graph using the up or down arrows at the base and top of the chart's y-axis (or select "Auto-Scale" from the Optional Features Menu (See Section 5.3). Settings will be applied to both the Bar Chart and Line Graph screens.
4. Select desired Optional Features for monitoring session using fly-out menu on left-hand side of screen (See Section 5). Settings will be applied to both the Bar Chart and Line Graph screens. All settings are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.
5. Proceed to Operating Instructions (see Section 4).

Caution: The operator is responsible for checking the compatibility of the system before use. Ensure only items specified by CIRCA Scientific are connected as part of the system (see Figure 3C below).

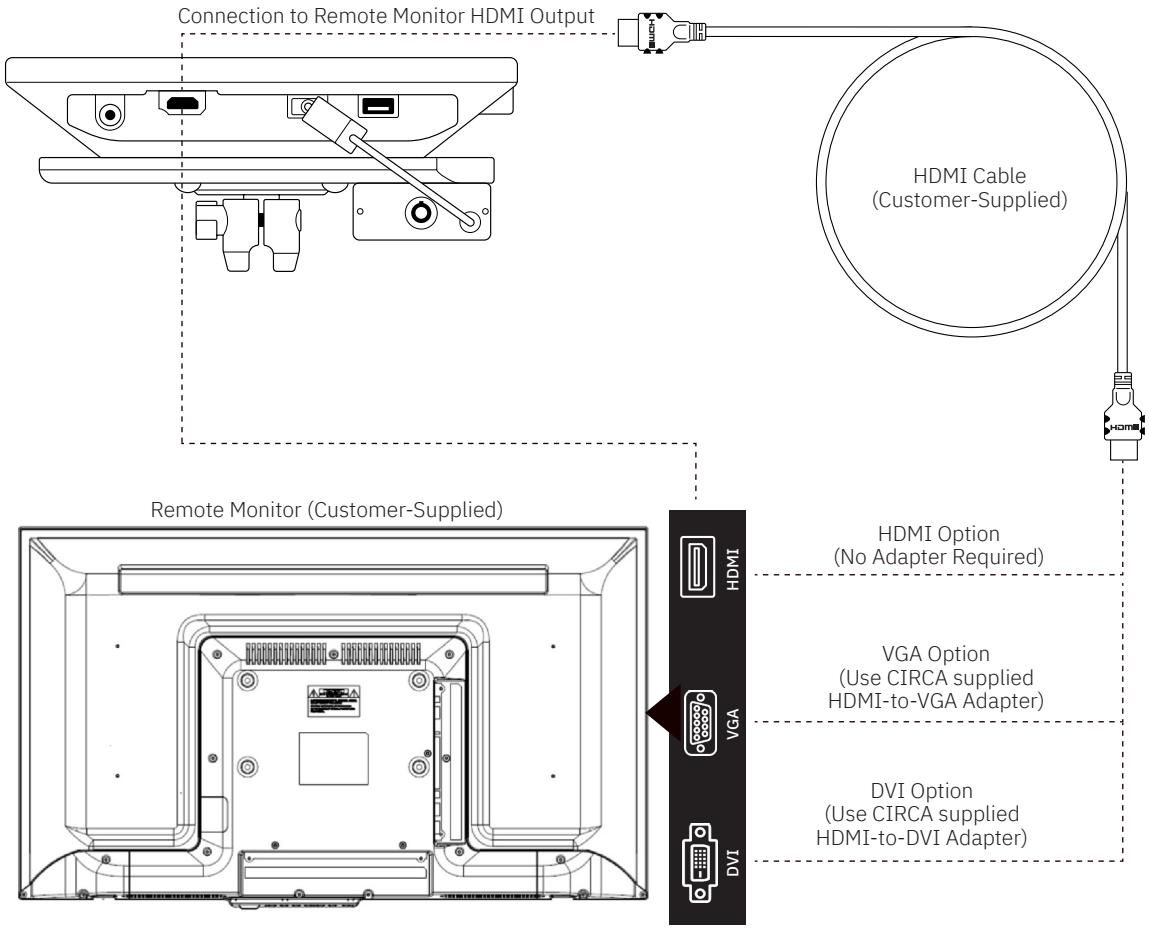
3.4

Remote Monitoring Set Up

The CIRCA Scientific Temperature Monitor may optionally be connected to a remote monitor via an HDMI-to-HDMI, HDMI-to-DVI, or HDMI-to-VGA connection. When properly connected, the CIRCA Temperature Monitor Display is cloned to the connected remote monitor.

1. Connect an HDMI cable (customer-supplied) to the Remote Monitor HDMI Output on the bottom or the back of the CIRCA Temperature Monitor.
2. Connect the other end of the HDMI cable to the remote monitor. If a DVI or VGA connector is required, also connect the appropriate in-line adapter (included with monitor).
3. Verify all parts of system are connected as shown in Figure 3C. Ensure connections are fully seated and secure.
4. Power on both the Remote Monitor and CIRCA Temperature Monitor.
5. Verify the same image is displayed on the CIRCA Temperature Monitor and the Remote Monitor. If no image is visible, verify connections are fully seated and resolve any error messages displayed.

Figure 3C: Remote Monitoring Connections



4.0 Operating Instructions

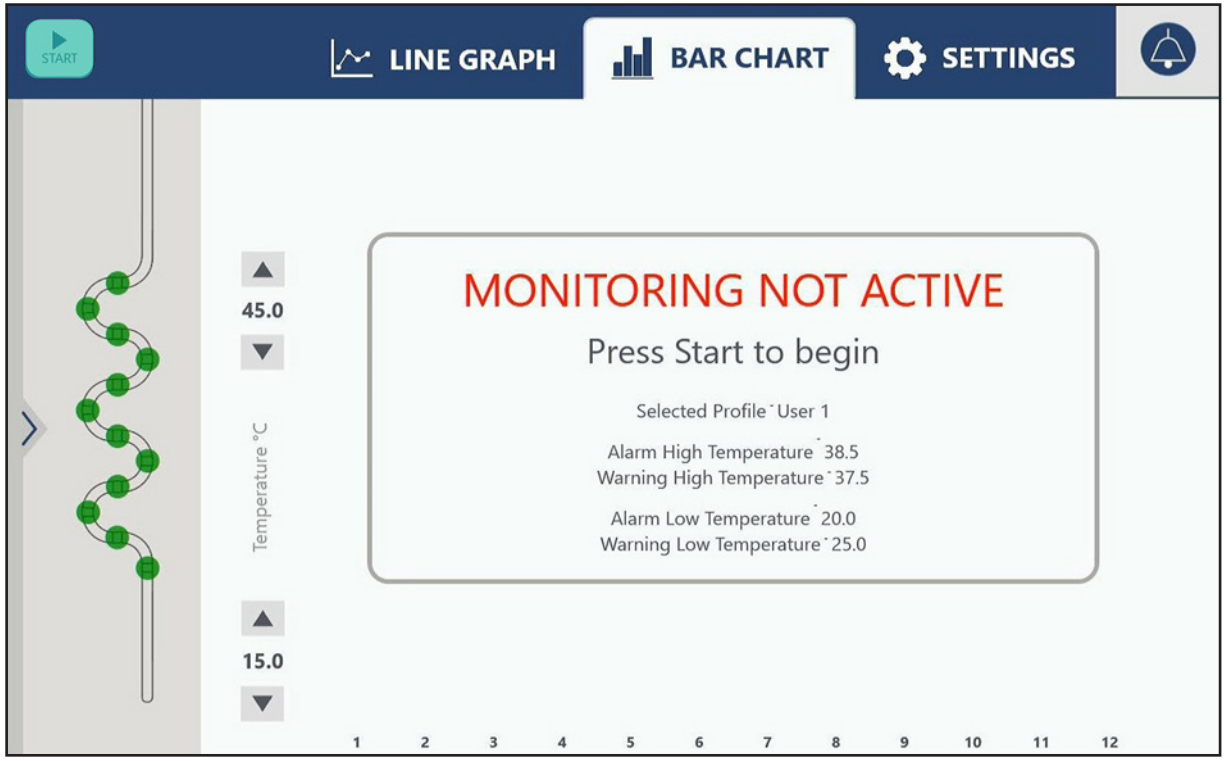
Warning: User **MUST** press "Start" to begin temperature monitoring.

4.1 Starting a Session

To Start a New Session:

1. Prepare temperature probe for patient use per temperature probe's instructions for use. Once placed in the patient's esophagus, connect Temperature Probe to Temperature Cable by aligning linear connector and pushing firmly.
2. Once temperature probe is placed, probe is connected to the temperature cable, and software settings are configured to user preferences, select desired Operating screen (either "Bar Chart" or "Line Graph") from the top-line navigation to start a new session.
   - The "Bar Chart" screen displays the temperature data from individual temperature sensors in a bar graph format. Each individual bar will move up or down independently corresponding to temperature rise or fall.
   - The "Line Graph" screen plots overall peak temperature over time and is displayed over a 90-second time period.
   - Users may change which screen is active during an active monitoring session by touching the respective navigation tab near the top of the screen.
3. Touch the "Start" button in the upper left-hand corner of the screen.
4. Enter a session ID, or use the ID automatically generated, and select "Start."
5. Verify temperatures are displayed on the monitor. If no temperatures are displayed, verify connections are fully seated and resolve any error messages displayed on the monitor (see Section 6 for Troubleshooting help).
6. Users can confirm active system monitoring at any time during a session by locating the flashing colon (":") in the session timer in the upper left corner of the screen. Duration is displayed in HH:MM format. If it is not flashing, temperature data is not being collected. End session and restart.

Figure 4A: Starting a New Session



Warning: User should verify that the alarm settings and/or User Profile are appropriate prior to patient monitoring.

Warning Indicators are lower priority than alarms and are visually identified by yellow elements.

- Audible signal sounds
- Background of Peak Temperature flashes **yellow**
- Sensor in Probe View flashes **yellow**
- Bar corresponding to thermistor changes to **yellow** (Bar Chart Only)
- Line changes to **yellow** (Line Graph Only)

4.2

Alarm System

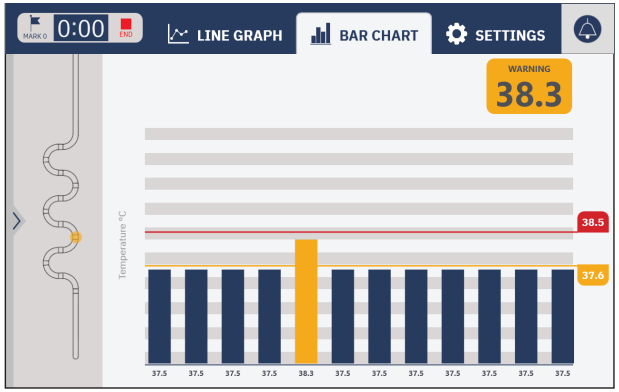
Description
The alarm system provides visual and audible feedback when the system detects a temperature value equal to or exceeding the user-selected threshold levels. Please note:

- The alarm system is intended to provide operator feedback regarding temperature compared to the user-selected levels only; it does not provide physiological alarm conditions.
- The interpretation and use of this data is at the sole discretion of the physician.

User-Selectable Warnings & Alarms
The CIRCA Temperature Monitor supports four (4) user-selected threshold values:

- Hot Mode: Warning High, Alarm High
- Cold Mode: Warning Low, Alarm Low

Figure 4B: Warning Signals in Hot Mode (Warning High)



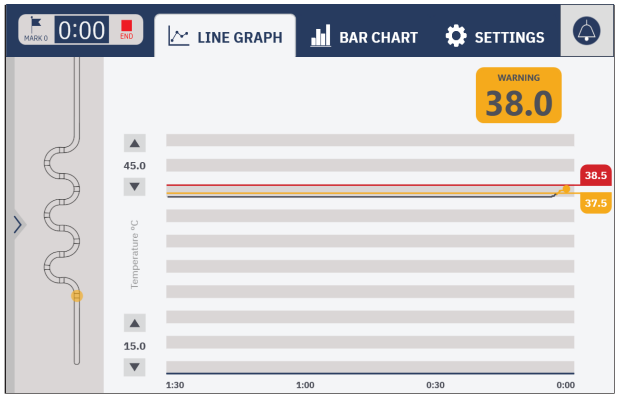
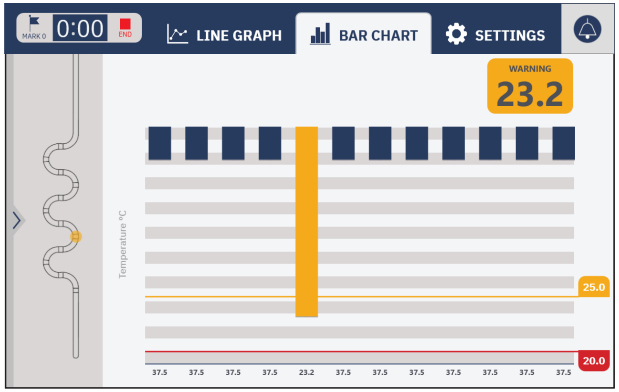
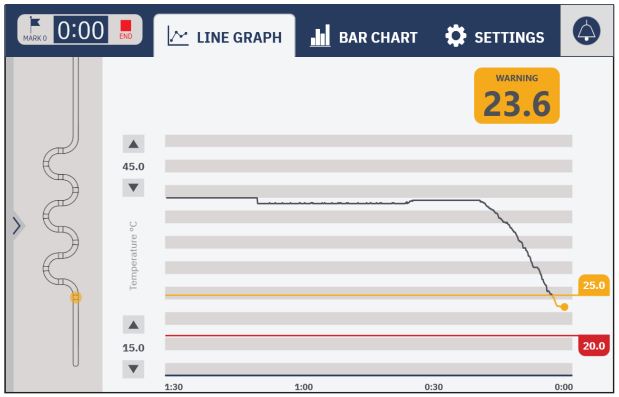


Figure 4C: Warning Signals in Cold Mode (Warning Low)





Alarm Indicators are higher priority than alarms and are visually identified by red elements.

- Louder audible signal sounds
- Background of Peak Temperature flashes **red**
- Sensor in Probe View flashes **red**
- Bar corresponding to thermistor changes to **red** (Bar Chart Only)
- Line changes to **red** (Line Graph Only)

Hot Mode: Warning High and Alarm High

In Hot Mode, visual and audible signals are triggered when the system detects a temperature **equal to or above** the set values (see Figure 4D).

Note: Though Warning Low and Alarm Low are hidden in Hot Mode, all four (4) threshold values are active at all times. Temperatures equal to or below these values will still trigger visual and audible alerts in Hot Mode.

Cold Mode: Warning Low and Alarm Low

In Cold Mode, visual and audible signals are triggered when the system detects a temperature **equal to or below** the set values (See Figure 4E).

Note: Though Warning High and Alarm High are hidden in Cold Mode, all four (4) threshold values are active at all times. Temperatures equal to or above these values will still trigger visual and audible alerts in Cold Mode.

Figure 4D: Alarm Signals in Hot Mode (Alarm High)

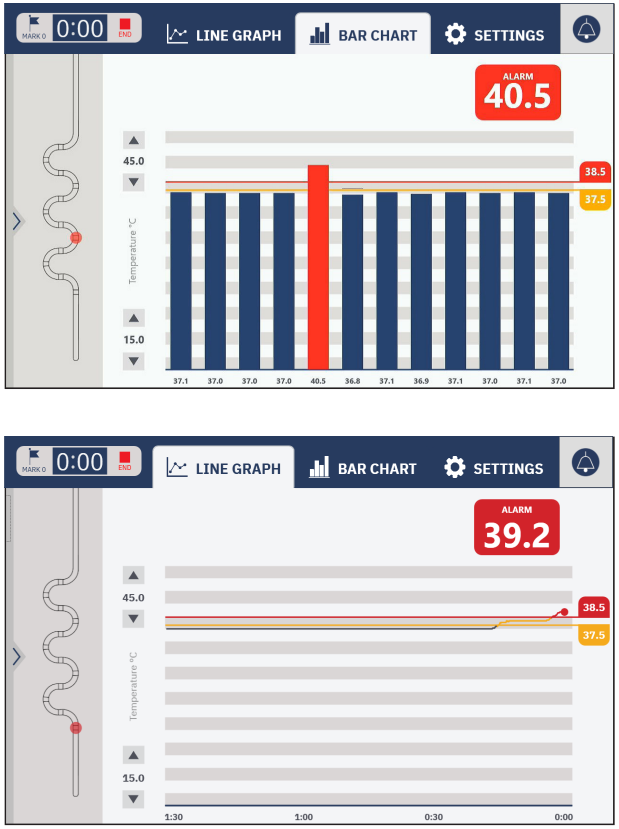
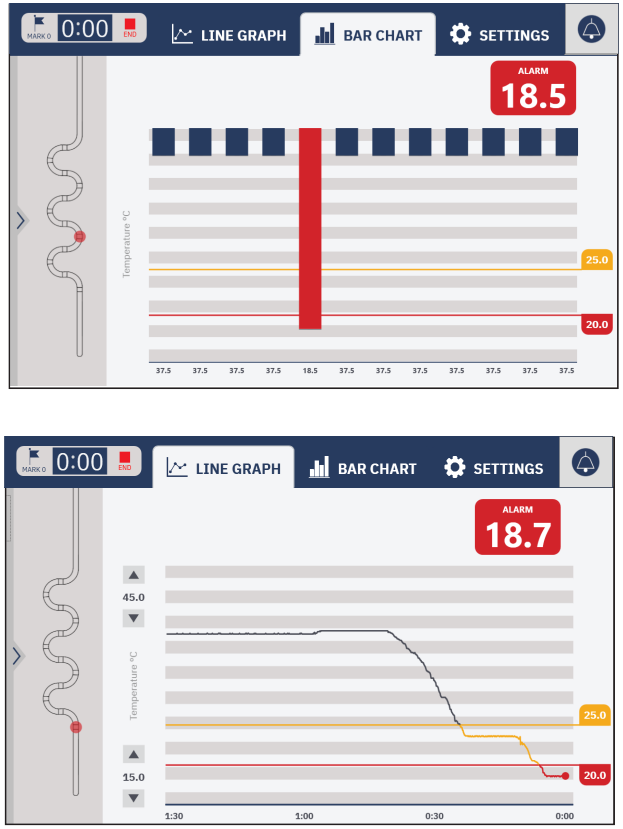


Figure 4E: Alarm Signals in Cold Mode (Alarm Low)



4.3

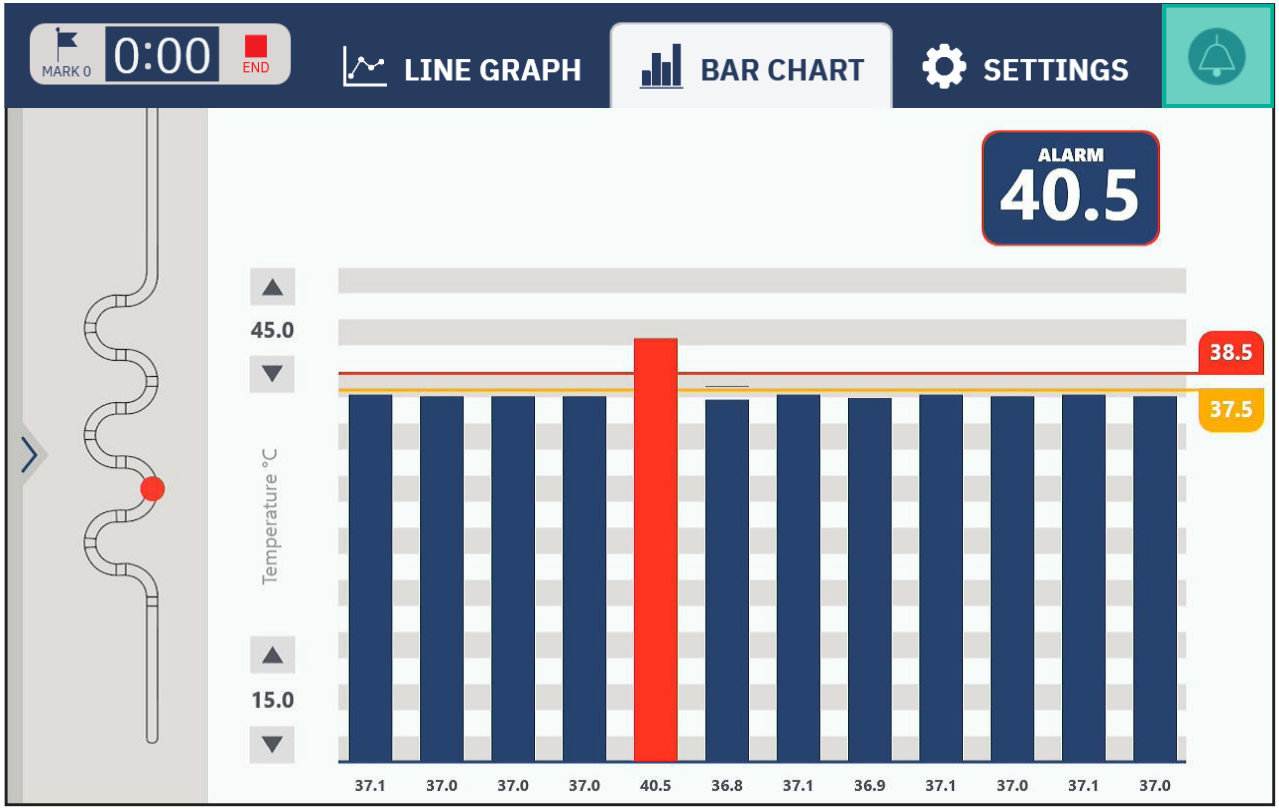
Temporary Audio Silencing

Description
The CIRCA Temperature Monitoring System is equipped with a Temporary Audio Silencing Feature that inactivates all audible signals, only until another event occurs. Examples of events include:

- Peak temperature increasing from warning to alarm level (Hot Mode)
- Peak temperature decreasing from warning to alarm level (Cold Mode)
- Temperature dropping below warning or alarm values then increasing to a value equal to or above the user-specified temperature limits (Hot Mode)
- Temperature increasing above warning or alarm values then decreasing to a value equal to or below the user-specified temperature limits (Cold Mode)

To Activate Temporary Audio Silencing:
1. Press the Audio Off (Bell Symbol) button in the upper right corner of any screen (see Figure 4F).
2. When the Audio Silence feature is active, an “X” will appear through the bell symbol in the upper right corner.

Figure 4F: Audible Silence Feature



4.4

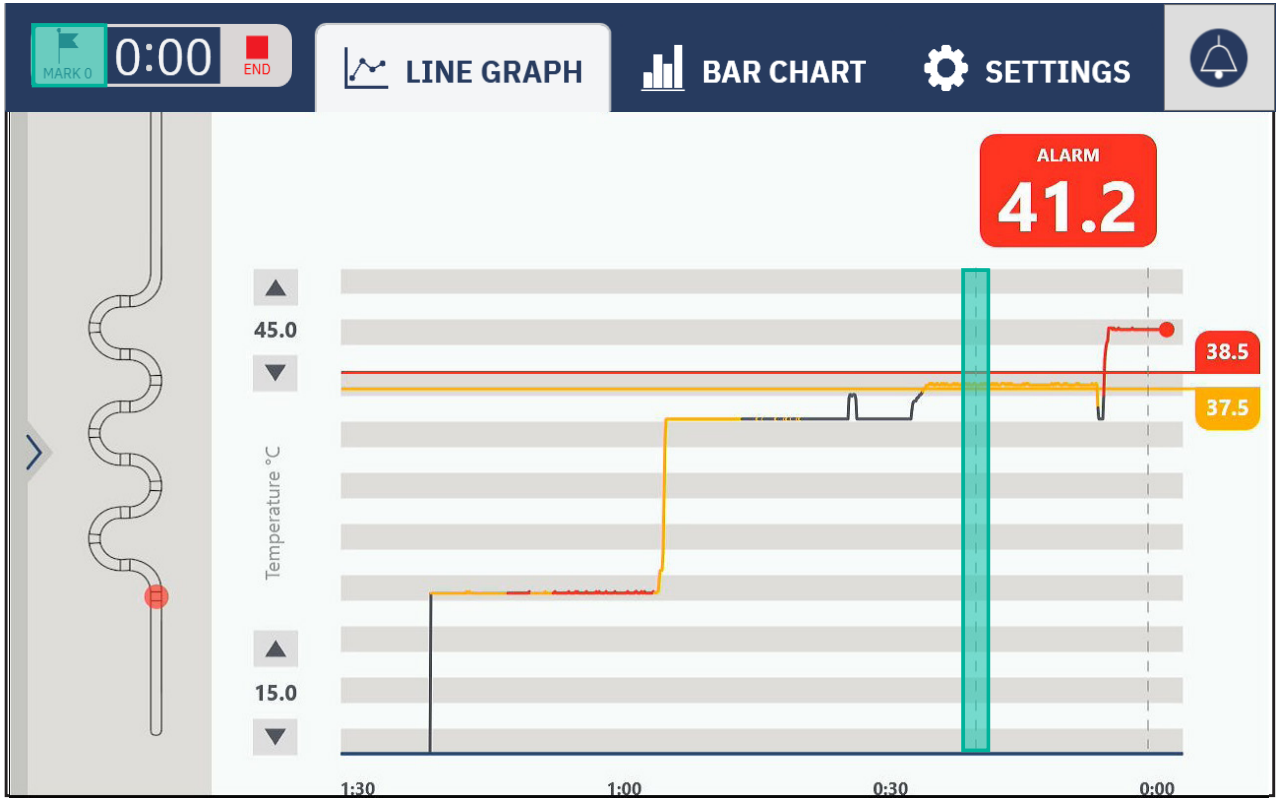
Event Marking

Description
Users may mark events to tag specific areas of interest at any time during an active monitoring session from either the Bar Chart or the Line Graph Screen. Events are noted in both the Session Summary Report and the .csv Data File for offline review/analysis.

To Mark an Event:

1. Touch the “Mark” button (Flag Symbol) in the upper left-hand corner of the screen.
2. When an event is successfully marked, an audible “click” will sound from the system and a vertical dashed line will appear on the Line Graph screen. Please note, no visual indicator will appear on the Bar Chart Screen.

Figure 4G: Marking an Event



4.5

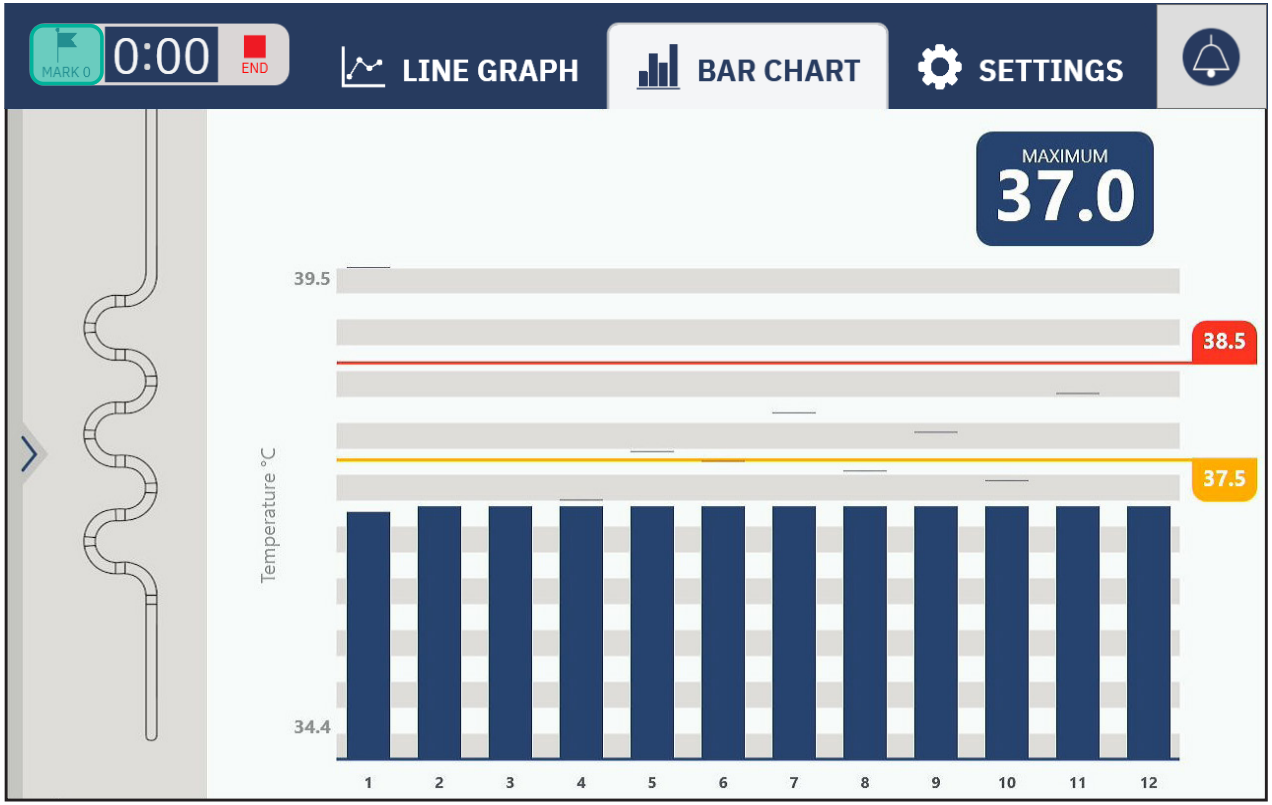
Ending a Session

To End a Session:

1. To end a session, tap “End” in the top left corner of the screen.
2. After a brief loading screen, a Session Summary Report will be displayed.
3. To return to the Main Menu, press “Home” in the lower right corner of the Summary Report screen.

Caution: Do not unplug or shut down the CIRCA Temperature Monitoring System while the Session Summary Report is loading. Improper Shut Down will result in loss of data.

Figure 4H: End Monitoring Session



4.6

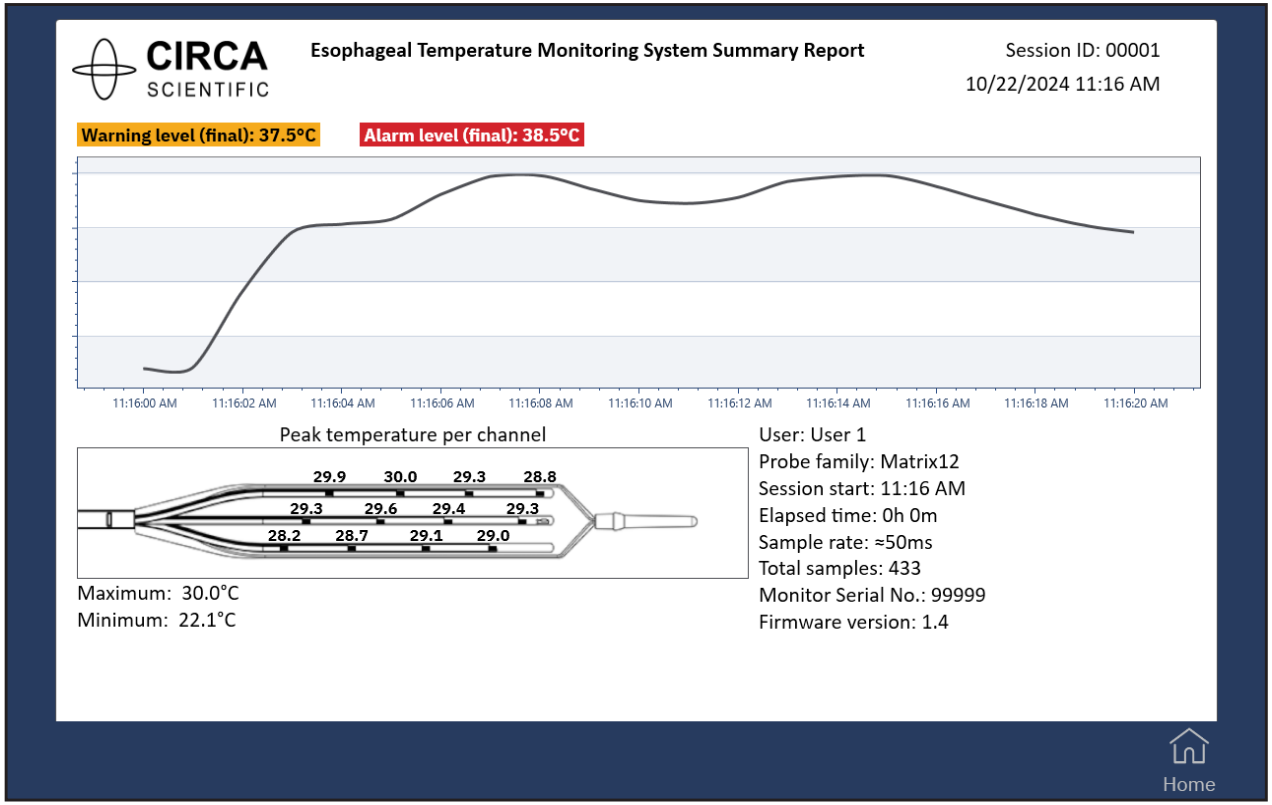
Session Summary Report

Description
Following the end of every session, a Session Summary Report is generated. This report provides users with information related to the procedure.

The report includes statistics on elapsed time, probe type, and a graph (For Reference Only) visualizing the entire length of the procedure, showing when temperatures reached warning or alarm levels.

Also included is an illustration of the probe showing the peak temperature per channel, as well as listing overall maximum and minimum temperatures, peak change rate and total area under curve for the session.

Figure 4I: Session Summary Report



Caution: Improper shut down by unplugging the power supply may result in damage to the unit.

4.7 System Shut Down

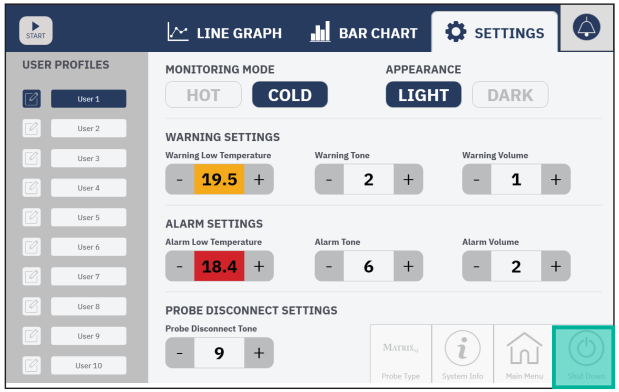
To Shut Down the CIRCA Temperature Monitoring System from the Settings Screen:

1. Select “Settings” Tab in top-line navigation.
2. Press the “Shut Down” button located in the lower right corner of the screen.
3. Confirm shut down by selecting “Ok,” or return to Settings screen by selecting “Cancel.”

To Shut Down the CIRCA Temperature Monitoring System from the Main Menu:

1. Press the “Shut Down” button located in the lower center of the screen.
3. Confirm shut down by selecting “Yes,” or return to Main Menu by selecting “No.”

Figure 4J: Shut Down from Settings Screen



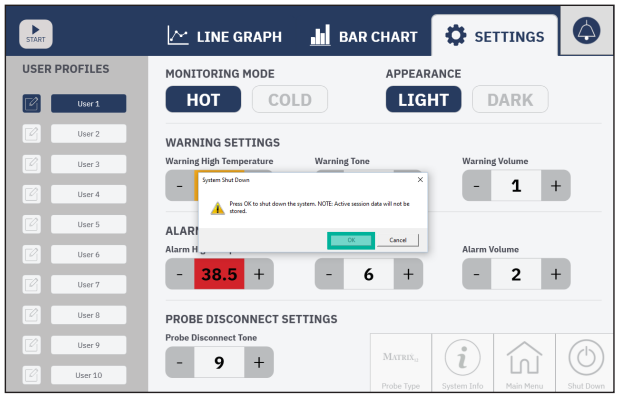


Figure 4K: Shut Down from Main Menu

5.0 Optional Features

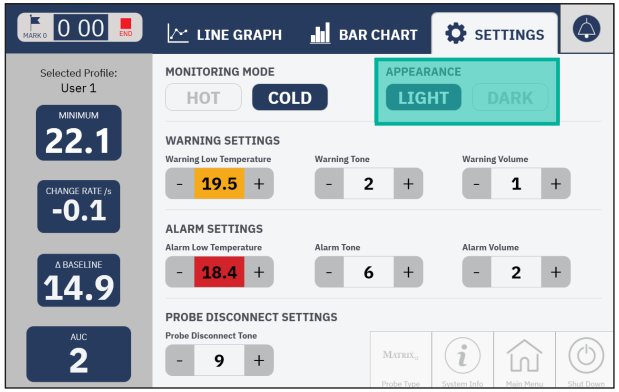
5.1

Appearance

The color profile of the display may be toggled between “light” (default) and “dark” appearance modes by tapping the “light” or “dark” buttons located in the right upper corner of the Settings screen.

Appearance preferences are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

Figure 5A: Light Mode



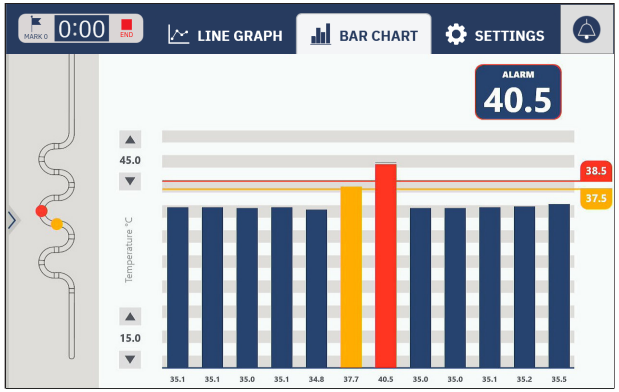
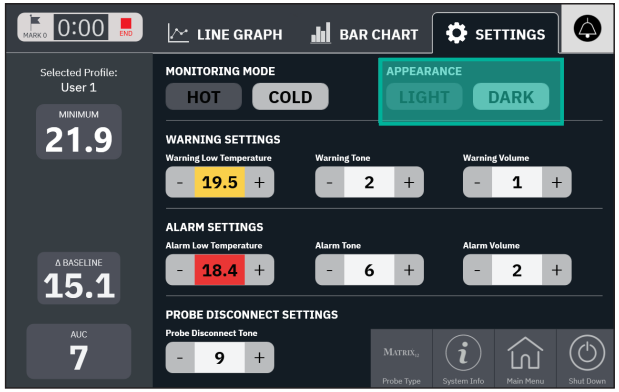
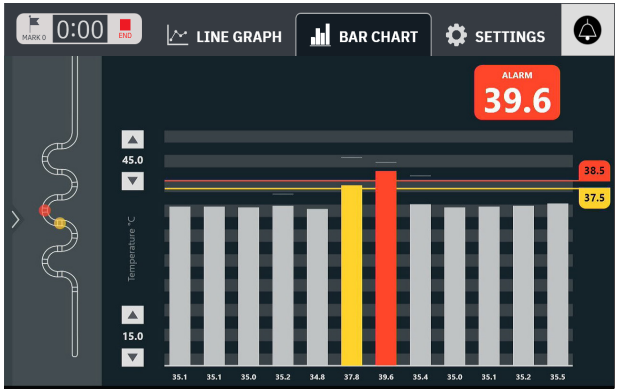


Figure 5B: Dark Mode





5.2

Remote Monitoring Setup

The CIRCA Scientific Temperature Monitoring System for Remote Monitoring consists of the CS-1000 Temperature Monitor and connecting components.

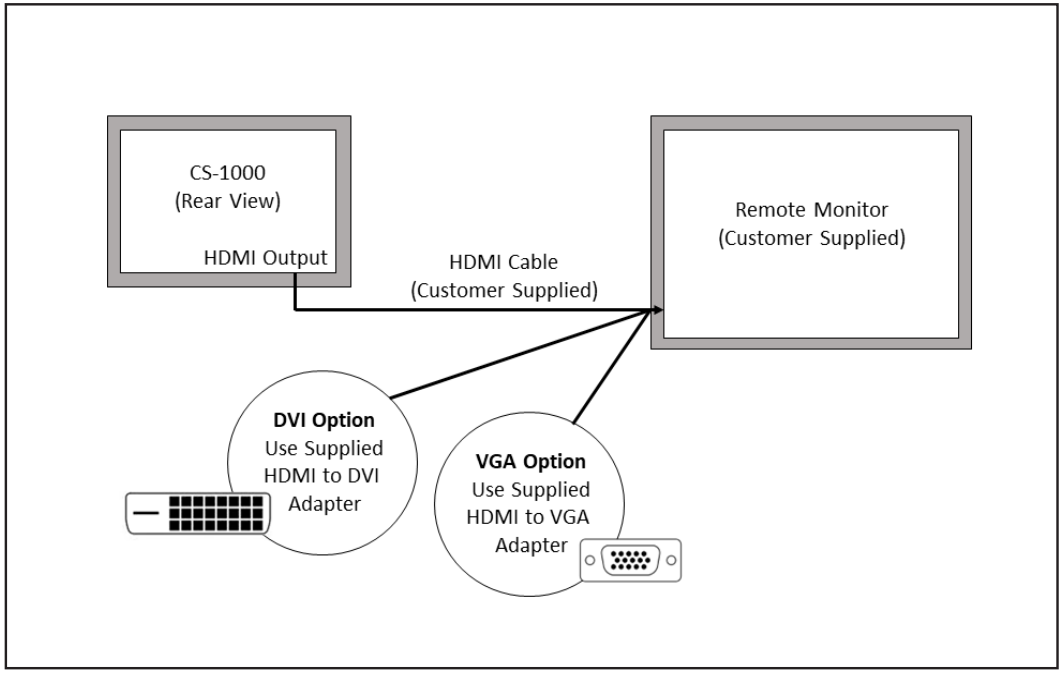
The intended use of Remote Monitoring is to clone the CS-1000 display to a remote monitor.

Setup Instructions:

The operator is responsible for checking the compatibility of the system before use. Ensure only items specified by CIRCA Scientific are connected as part of the system (see Figure 5C).

1. Connect an HDMI cable to the display output on the back of the CS-1000 Temperature Monitor labeled: Remote Monitor HDMI Output.
2. Connect the other end of the HDMI cable to the remote monitor. If a DVI or VGA connector is required also connect the appropriate included adapter.
3. Verify all parts of system are connected as shown in Figure 5C. Ensure connections are fully seated and secure.
4. Power on both the Remote Monitor and the CS-1000 Temperature Monitor.
5. Verify the same image is displayed on the CS-1000 Temperature Monitor and Remote Monitor. If no image is visible, verify connections are fully seated and resolve any error messages displayed on the CS-1000 Temperature Monitor.
6. Following session start, the CS-1000 Temperature Monitor will deliver a test audible alarm signal (3 beeps). If no audible signal is heard, sound or system connections are defective. Refer service to CIRCA Scientific.

Figure 5C: Remote Monitoring Setup



5.3 Chart Scaling

Note: Chart scaling settings/selections will be applied to both the Bar Chart and Line Graph Screens.

Note: Chart Scaling preferences are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile and monitoring mode is selected.

Manual Chart Scaling:
By default, users may manually set the upper and lower Y-axis limits for the Bar Chart and Line Graph according to their preferences. Default upper and lower axis values are as follows:

- Upper Y-Axis Limit: 45.0
- Lower Y-Axis Limit: 15.0

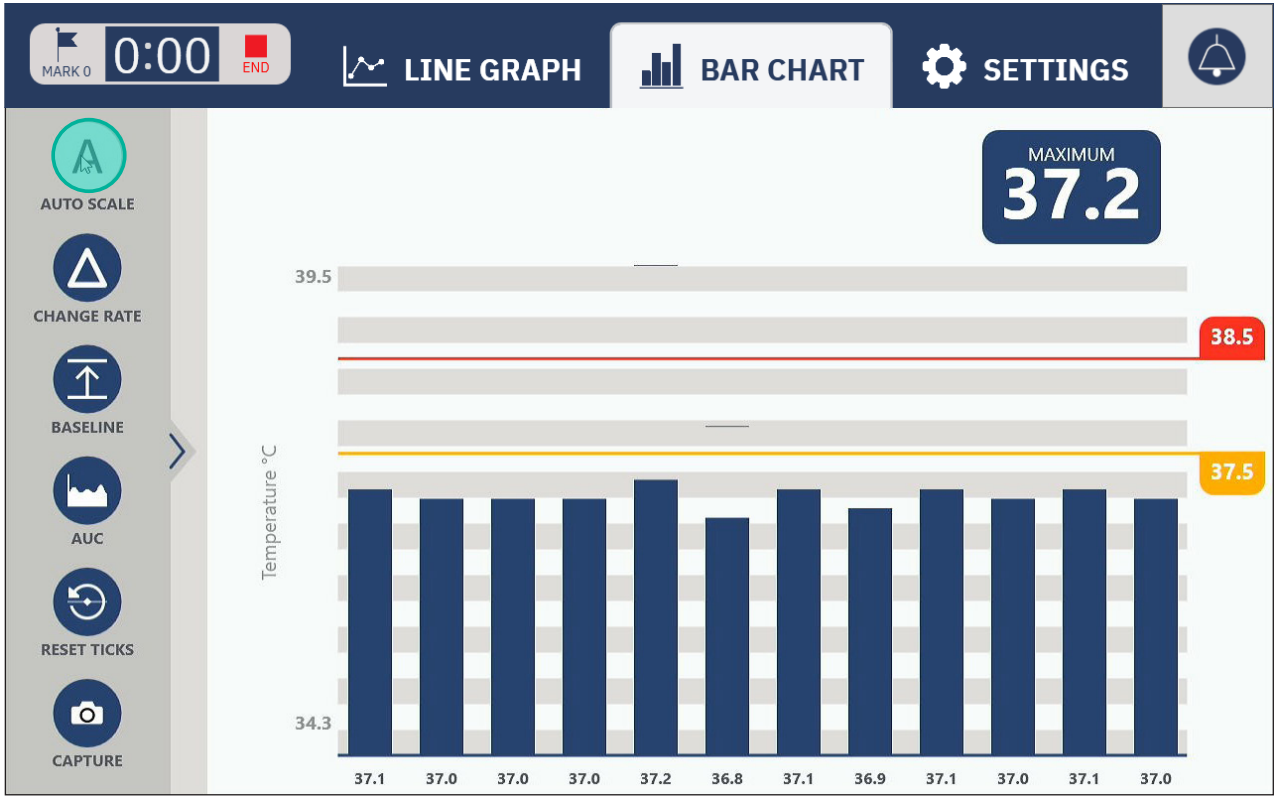
1. To adjust the scale of the Bar Chart or Line Graph, touch the up or down arrows at the base and top of the chart's Y-axis.
2. Selections will be applied to both the Bar Chart and Line Graph screens.

Automatic Chart Scaling:
Auto-scaling automatically adjusts the minimum and maximum Y-axis values of the Bar Chart and Line Graph within ±2°C of the maximum (hot mode) or minimum (cold mode) temperature detected by the System. To activate automatic chart scaling:

1. Tap the arrow on the left-hand side of the screen to open the "Optional Features" menu (see Figure 5D).
2. Select "Auto Scale" from the Optional Features Menu. When auto-scaling is enabled, the background of the button will change to white and the up and down arrows at the base and top of the chart's Y-axis will be hidden.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

To deactivate automatic chart scaling, repeat steps 1-3 above.

Figure 5D: Automatic Chart Scaling On



5.4 Change Rate

Users may optionally display a calculated value indicating the Maximum Rate of Temperature Change ("Change Rate") above the Bar Chart or Line Graph during an active monitoring session.

Change Rate is calculated by subtracting the overall peak temperature detected 1 second ago from the current overall peak temperature. It is a real-time measure of the slope of the line displayed on the Line Graph.

Please note, Change Rate is an informational field only and is not tied to the System's Alarm functionality. The interpretation and use of this data is at the sole discretion of the physician.

To Show Change Rate:

1. Tap the arrow on the left-hand side of the screen to open the "Optional Features" menu (see Figure 5E).
2. Select "Change Rate" from the Optional Features Menu. The Change Rate block will now be displayed above the chart or graph, next to the Peak Temperature.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

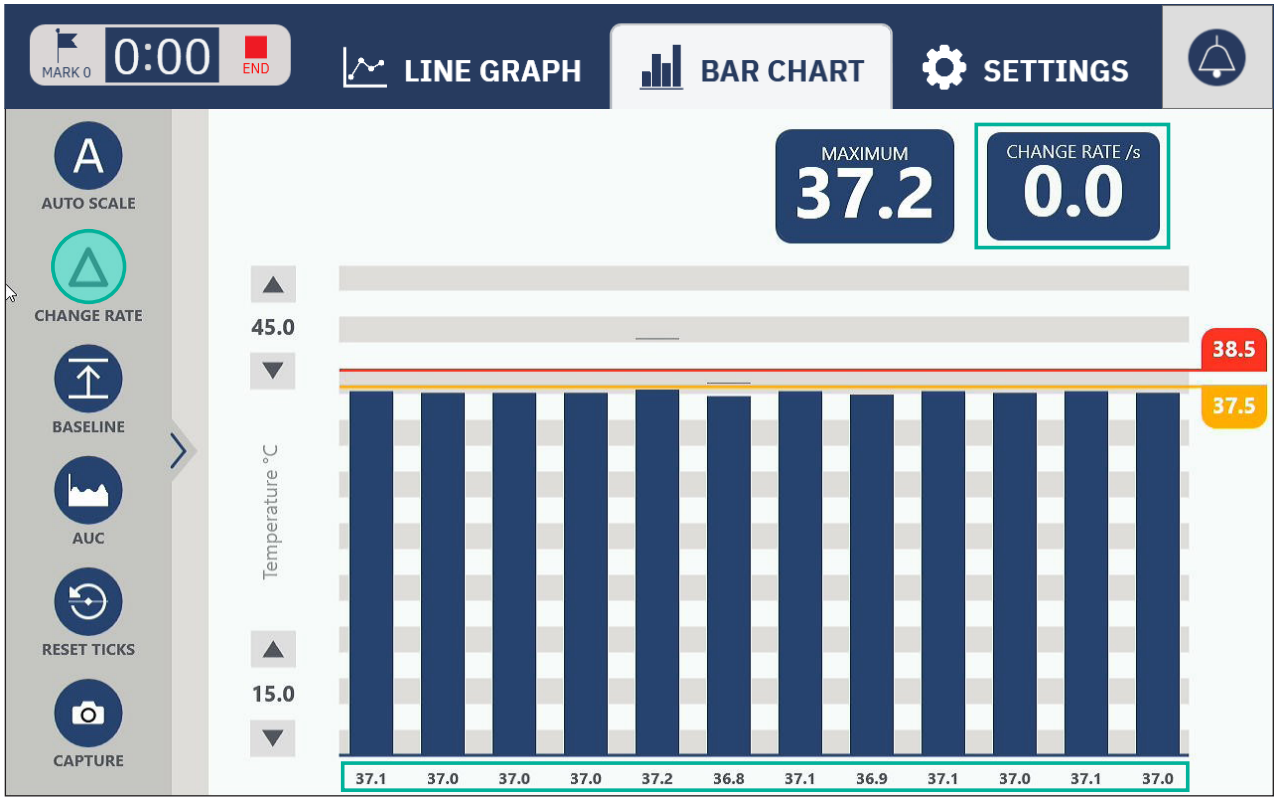
To hide Change Rate Block, repeat steps 1-3 above.

To Display Individual Channel Change Rate Values (Bar Chart Only): Tap the "Change Rate" block above the Bar Chart. Individual channel change rate values will be displayed below the X-Axis.

Note: Change rate is displayed as an informational field only and is not tied to the alarm system. Change rate thresholds cannot be defined, and the user will not visually or audibly be alerted based on this data.

Note: Dynamic temperature measure preferences are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

Figure 5E: Change Rate On



5.5

Change vs. Baseline

Users may optionally display a calculated “Change vs. Baseline” value indicating the difference between Real-Time Peak Temperature and the user-specified baseline value (in °C). When active, the “Δ Baseline” Block will be displayed above the Bar Chart or Line Graph, and a Baseline indicator (dotted line with “B” handle) will be displayed on the Bar Chart and Line Graph.

By default, baseline temperature is set to the maximum temperature detected at the time of feature activation in hot mode and to the minimum temperature detected at the time of feature activation in cold mode. Users may override default baseline temperature by touching the “B” handle located to the right of the Bar Chart or Line Graph and adjusting the desired value from the pop-up window. **Note: Baseline value is static, not dynamic, and will not be automatically adjusted throughout the procedure. It is not an indicator of core body temperature.**

Please note, Change vs. Baseline is an informational field only and is not tied to the System’s Alarm functionality. The interpretation and use of this data is at the sole discretion of the physician.

To Show Change vs. Baseline:

1. Tap the arrow on the left-hand side of the screen to open the “Optional Features” menu (see Figure 5F).
2. Select “Baseline” from the Optional Features Menu. The ΔBaseline block will now be displayed above the chart or graph, next to the Peak Temperature.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

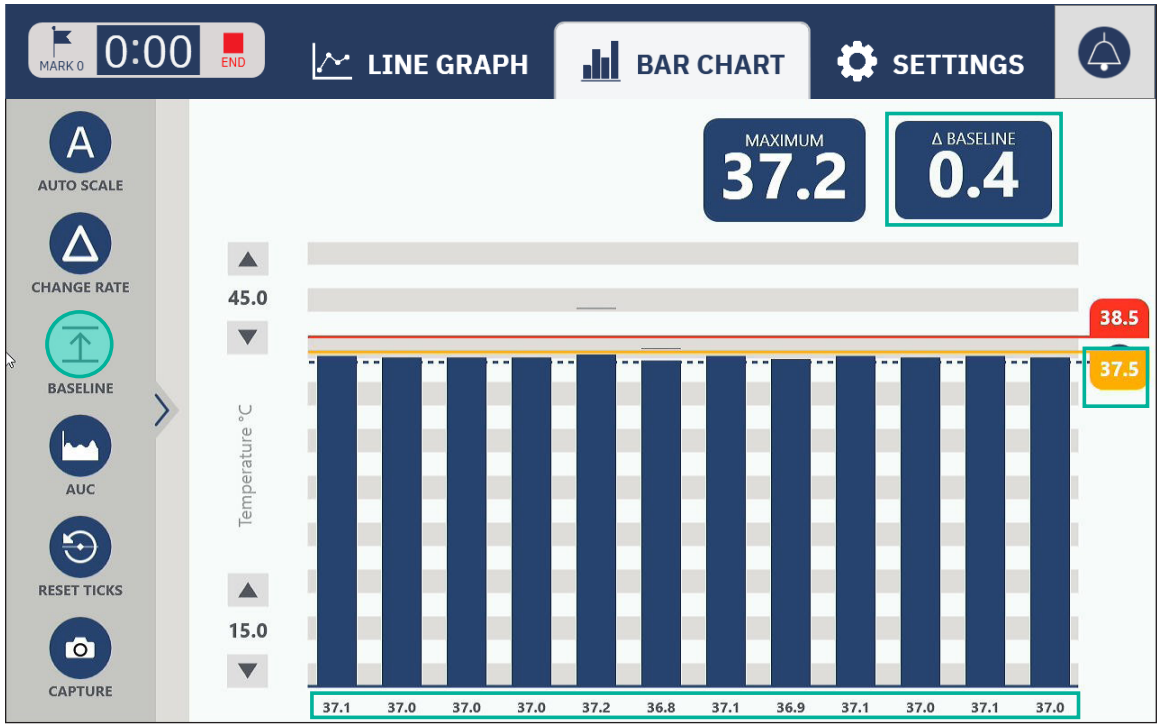
To hide the Change vs. Baseline Block, repeat steps 1-3 above.

To Display Individual Channel Change vs. Baseline Values (Bar Chart Only): Tap the “ΔBaseline” block above the Bar Chart. Individual channel change rate values will be displayed below the X-Axis.

Note: ΔBaseline is displayed as an informational field only and is not tied to the alarm system. Thresholds cannot be defined for dynamic temperature values, and the user will not visually or audibly be alerted based on this data.

Note: Dynamic temperature measure preferences are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

Figure 5F: Change vs. Baseline On



5.6

Area Under Curve (AUC)

Users may optionally display a calculated “Area Under Curve (AUC)” value, which is an estimation of the accumulated heat delivered to the esophagus during an active monitoring session (in K · seconds) during a procedure. It is calculated by using the trapezoidal role of integral approximation for the Peak Temperature Curve with an adjustable baseline threshold value, above or below which area is not calculated. This value is cumulative and is calculated at 1-second intervals.

When active, the “AUC” Block will be displayed above the Bar Chart or Line Graph. Users may set the AUC Threshold Value by touching the “AUC Block” above the Bar Chart or Line Graph and adjusting the desired value from the pop-up window. **Note: The AUC Threshold Value is not the same as the Baseline value used to calculate Change vs. Baseline.**

Please note, AUC is an informational field only and is not tied to the System’s Alarm functionality. The interpretation and use of this data is at the sole discretion of the physician.

To Show Cumulative AUC:

1. Tap the arrow on the left-hand side of the screen to open the “Optional Features” menu (see Figure 5G).
2. Select “AUC” from the Optional Features Menu.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

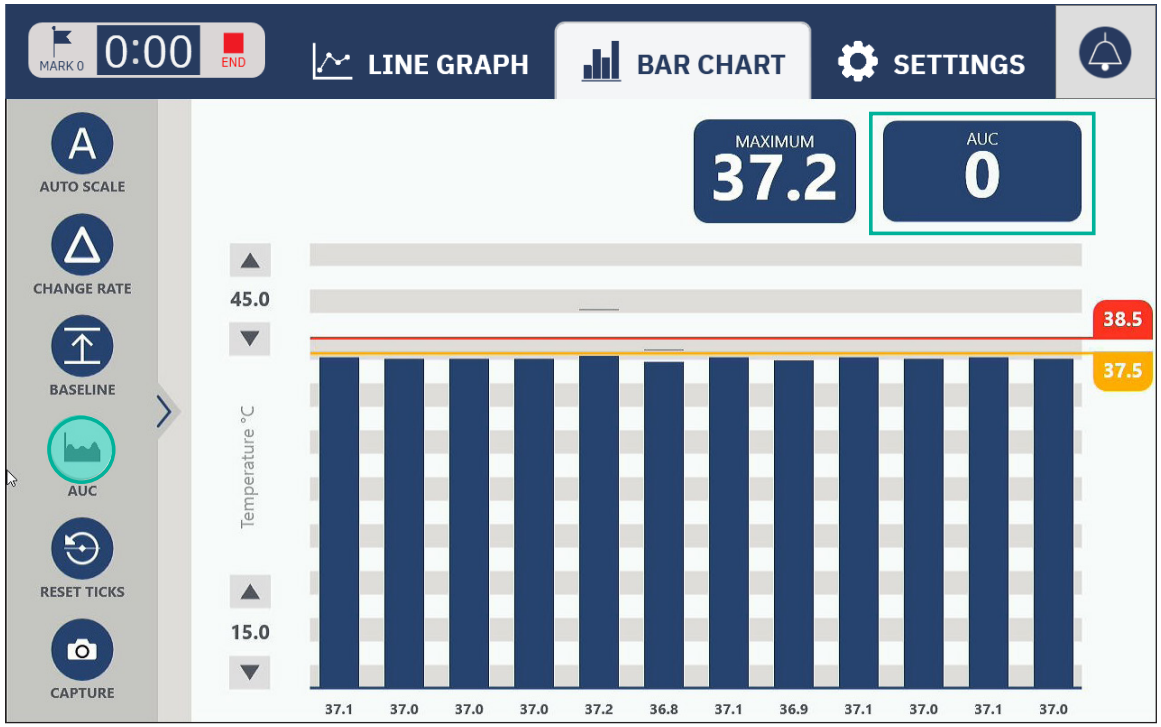
To hide the AUC Block, repeat steps 1-3 above.

Note: AUC is displayed as an informational field only and is not tied to the alarm system. Thresholds cannot be defined for dynamic temperature values, and the user will not visually or audibly be alerted based on this data.

Note: Dynamic temperature measure preferences are retained in the User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

Note: While monitoring is active, toggling between HOT and COLD modes will invalidate all AUC calculations.

Figure 5G: Area Under Curve On



Note: Optional feature preferences are retained in the active User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

5.7

Peak Channel Temperatures (Bar Chart Only)

Peak temperatures recorded by each of the temperature probe's thermistors are continuously tracked and marked on the Bar Chart Screen by a light grey tick mark, which appears over the bar corresponding to each channel.

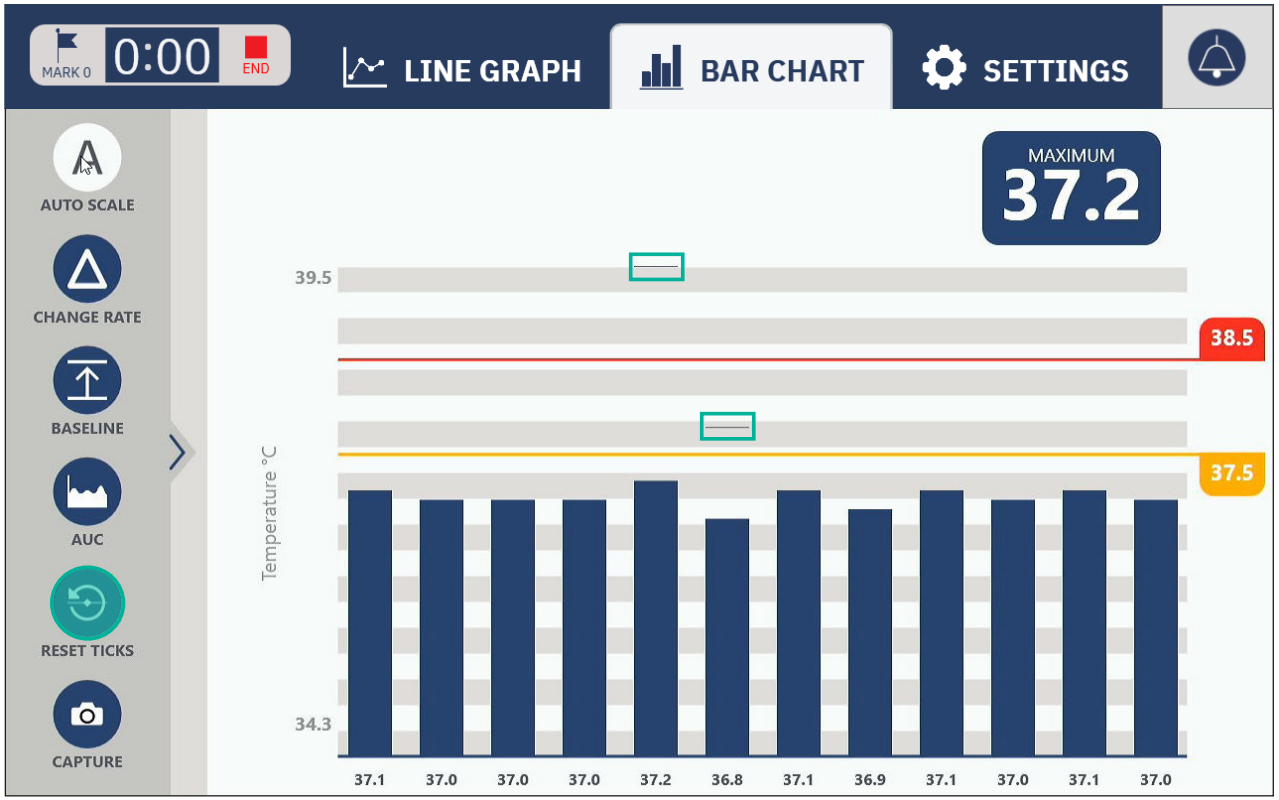
Users may reset Peak Channel Temperature Values by selecting "Reset Ticks" from the Optional Features menu, which will clear all existing tick marks and reset them to the current temperature detected by each channel.

Note: Resetting Peak Channel Temperatures during a session will also reset the Peak Channel Temperatures reported in the Session Summary Report.

To Reset Ticks:

1. Tap the arrow on the left-hand side of the screen to open the "Optional Features" menu (see Figure 5H; Bar Chart Only).
2. Select "Reset Ticks" from the Optional Features Menu.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

Figure 5H: Peak Channel Temperatures / "Tick Marks"



Note: Optional feature preferences are retained in the active User Profile and will be automatically recalled for the next monitoring session when the same user profile is selected.

5.8

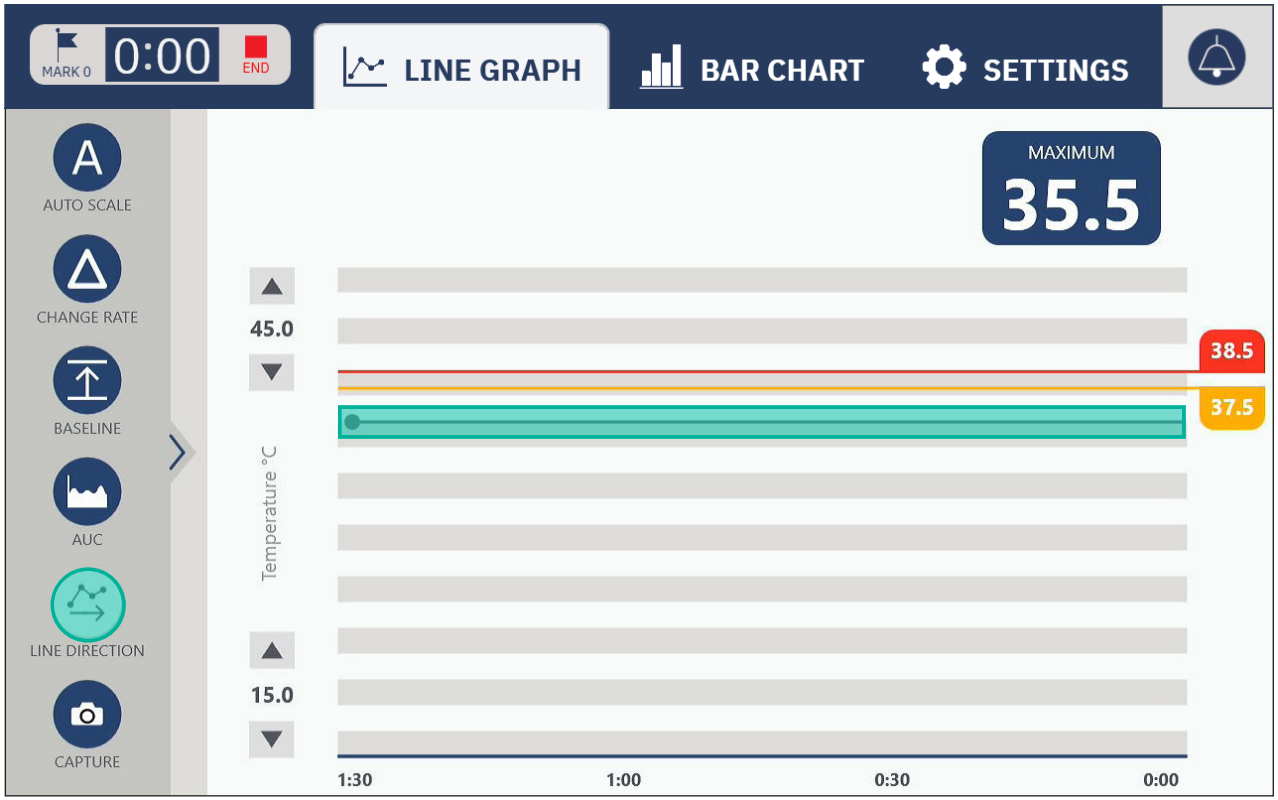
Line Direction (Line Graph Only)

Users can choose to format the Line Graph such that it reads right-to-left (newest information displayed on left-hand side of screen) or left-to-right (newest information shown on right-hand side of screen). By default, Line Direction is set to read right-to-left.

To Change Line Direction:

1. Tap the arrow on the left-hand side of the screen to open the "Optional Features" menu (see Figure 5I; Line Graph Only).
2. Select "Line Direction" from the Optional Features Menu.
3. Tap the arrow on the right edge of the Optional Features menu to return it to its original hidden position.

Figure 5I: Line Direction



6.0 Troubleshooting

6.0

Troubleshooting

Problem: Message

Resolution

1. Touch “OK” button.
2. Ensure USB Cable (back of monitor) is firmly seated in port. If loose, reconnect cable.
3. Shut Down from Windows Desktop.
4. Press Power Button 2 seconds to switch monitor on.

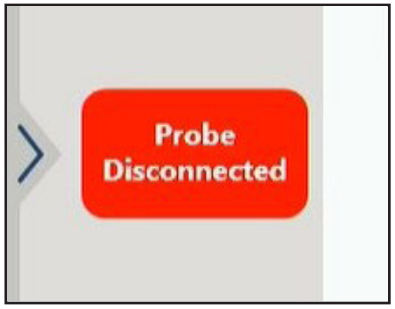
Problem:

Monitor does not boot up and BIOS Configuration resets to default.

Resolution

1. The computer inside the monitor is provided with a battery-powered real-time clock circuit. The battery has no power.
2. Warning: There is a danger of explosion if battery is incorrectly replaced. Refer servicing to CIRCA Scientific.

Problem: Probe Disconnected Message



Resolution

1. Ensure temperature probe is firmly seated to interconnect cable and interconnect cable is firmly seated to monitor.
2. Replace probe and/or interconnect cable if no temperature data can be displayed after verifying connections.

6.0 Troubleshooting

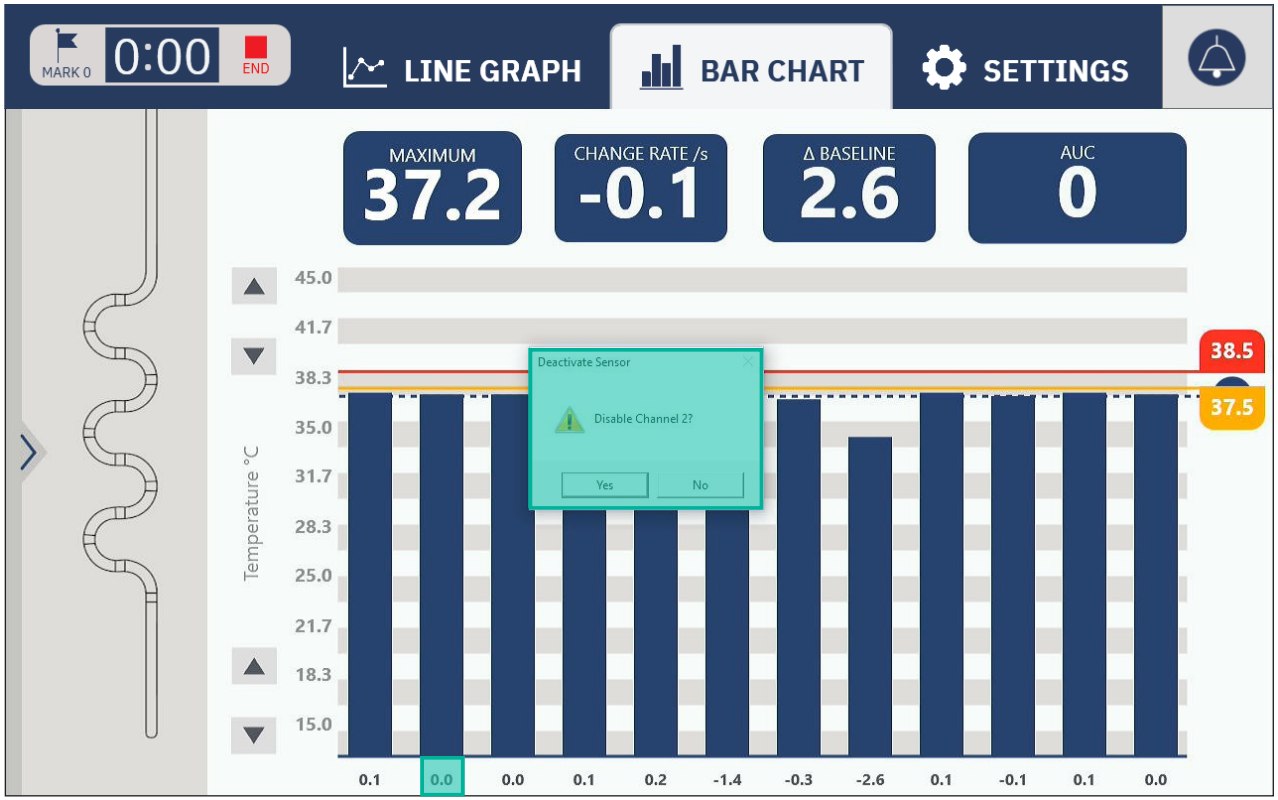
Problem:

"----" and orange background is displayed for an individual sensor temperature reading and an individual sensor chart (under "Channel Chart" display) is not present.

Resolution

1. No action required.
2. The four dashes ('----') and orange-colored graph indicate an individual sensor wire has failed or has been manually disabled.
3. Individual channels can be disabled by tapping on that channel's temperature reading below the X axis on the graph (Figure 6A).

Figure 6A: Channel Disabling



7.0 Preventive Maintenance

7.1

Cleaning and Visual Inspection

Cleaning and Disinfection (Temperature Monitor and Interconnect Cables)

1. Disconnect from power before wiping down.
2. Use a damp cloth. Do not use liquid or spray detergents.
3. Wipe outer surfaces with damp cloth and let dry. Do not rinse, soak, wash or sterilize.
4. If disinfection is required by hospital policy, apply non-abrasive/non-corrosive disinfection fluid to disposable cloth, wipe outer surfaces, and then let dry.
5. CIRCA Interconnect Cables may be disinfected using Sodium hypochlorite wipes or Quaternary ammonium wipes per the manufacturer's instructions and allowing to dry.

Visual Inspection (Temperature monitor and Interconnect Cables)

1. Visually inspect the monitor and all accessories at least once before each use.
2. Inspect the power cord, cables, and monitor for damage, wear, and loose components.
3. Particular attention should be made to the power cord and interconnect cable for insulation damage such as cuts, brittleness, cracking, and bare spots.
4. Do not use if equipment appears damaged.

Warning: To prevent shock, never open the equipment. Refer servicing to CIRCA Scientific.

Note: Do not use equipment if the inspections or test reveal a defect. The equipment has no serviceable parts.

7.2

Annual Inspection

The following test should be performed by hospital's equipment service department at least every 12 months:

1. Inspect the equipment and accessories for mechanical damage.
2. Inspect all labels and markings for legibility.
3. Check temperature accuracy with the following test:

Performing an Annual Inspection with CS-104, CIRCA Temperature Standard (see Figure 2H; available from CIRCA Scientific)

1. Connect Temperature Standard to Interconnect Cable.
2. Turn unit on, navigate to Preventative Maintenance Screen, then Annual Inspection
3. Observe results to confirm all sensors are passing with a green check mark. Passing indicates measurement error is not greater than 0.1C.

Figure 7A: Annual Inspection, Passing

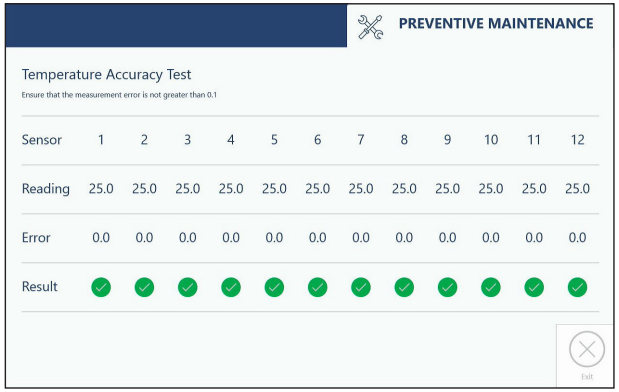
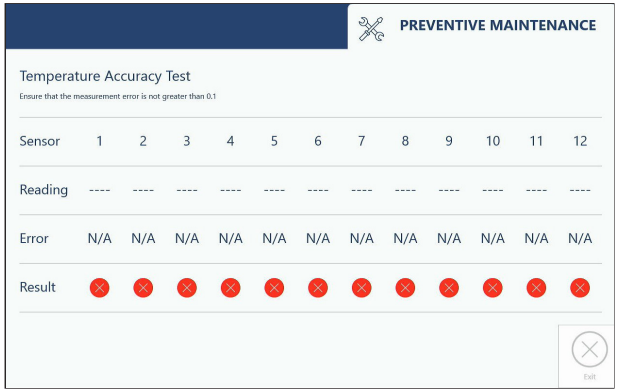


Figure 7B: Annual Inspection, Failing



Warning: To prevent shock, never open the equipment. Refer servicing to CIRCA Scientific.

Note: Do not use equipment if the inspections or test reveal a defect. The equipment has no serviceable parts.

7.3

System Diagnostics

System diagnostics can be performed at any time with the guided inspection to determine the root cause of any potential system issues including:

1. CIRCA Temperature Probe
2. CIRCA Interconnect Cable
3. CIRCA Monitor

Checking System Diagnostics:

1. Disconnect probe and connect Temperature Standard to Interconnect Cable.
2. Turn unit on, navigate to Preventive Maintenance Screen, then System Diagnostics.
3. Observe sensor readings (12) displayed on the monitor.
   - If sensors are passing, the probe was the issue
   - If sensors are failing, move onto step 4
4. Disconnect interconnect cable and connect circular end of Temperature Standard to Monitor.
5. Observe sensor readings (12) displayed on the monitor.
   - If sensors are passing, the cable was the issue
   - If sensors are failing, the monitor may be the issue, contact your representative

Figure 7C: System Diagnostics, Passing

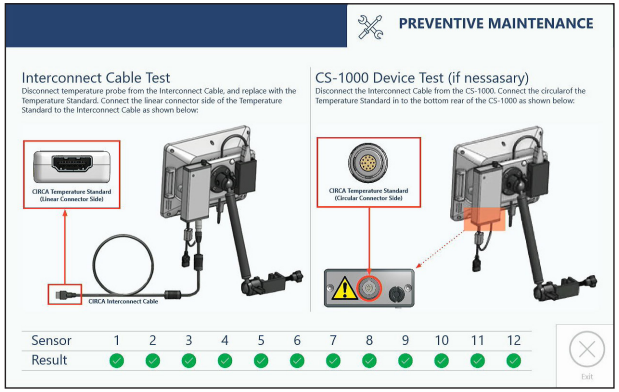
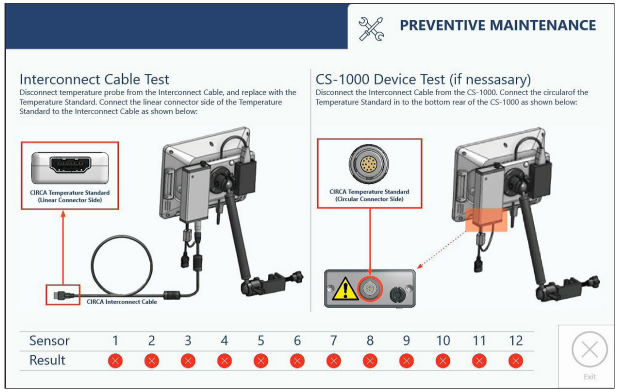


Figure 7D: System Diagnostics, Failing



8.0 Technical Specifications

8.0

Technical Specifications

Classification	Class I Defibrillation-Proof Type CF Applied Part Continuous Operation
Software	Revision level 3.2
Electrical (Mains)	Mains Supply Voltage: 100-240V AC ~ Mains Supply Frequency: 50-60 Hz Mains Rated Input: 1.6-0.7A
Electrical (Power Supply)	Output: 12V ⎓ 5A, 60W Max Use only Adapter Tech. Model ATM065-P120 power supply.
Electrical (Monitor Power Input)	Input Rating: 12V ⎓ 5A
Electrical (Safety and Electromagnetic Compatibility)	Safety: IEC 60601-1:2005 + A1:2012 + A2:2020 EMC: IEC 60601-1-2:2014 + A1:2020
User Settings	Alarm and Warning Temperature Levels in 0.1°C increments Alarm and Warning Tone 1 – 10 in single digit increments Alarm Volume 1 - 10 in single digit increments Warning Volume 0 – 9 in single digit increments Graph y-axis Minimum and Maximum in 1°C increments Setting range = 0.0°C to 55.0°C
Measurement Display	Update rate ≈ 50 milliseconds Graph time span = 60 seconds Accuracy = ± 0.1°C Precision = 0.1°C
Alarm System	Intended position of the Operator to observe the Alarm Signal is within an approximate distance of 4.5 feet (1.4 meters). Alarm Signal Sound Pressure Range = 45 to 85 dB
Physical	Dimensions (monitor): 10.3” W x 7.5” H x 3.5” D | 262 W x 191 H x 90 D (mm) Weight: 5.5 lbs. (2.5 kg)
Disposal	No special precautions are required. Dispose of equipment per hospital policy. EU Only: Products affected by the directive Waste of Electrical and Electronic Equipment (WEEE). These products are not to be discarded together with non-electrical or non-electronic products.
Environmental Specifications	Operating Temperature: 0˚C to 40˚C (32˚F~104˚F) Operating Humidity: 30% to 75%RH, non-condensing Operating Pressure: 700 to 1033 hPa Storage & Transport Temperature: -20˚C to 60˚C (-4˚F~140˚F) Storage & Transport Humidity: 10% to 85%RH, non-condensing Storage & Transport Pressure: 700 to 1033 hPa

9.0 Electromagnetic Compatibility

9.0

Electromagnetic Compatibility

The essential performance of the CS-1000 Temperature Monitoring System is accuracy and if accuracy is lost or degraded due to EM disturbances the operator can expect abnormal behavior such as sudden temperature fluctuation or an error message. In this event, identify the source of interference and, where possible, power it off or remove it. Power the CS-1000 off and back on.

The equipment may be affected by portable and mobile RF (Radio Frequency) communications equipment.

Warning: Use of cables and accessories other than those supplied and sold by CIRCA Scientific may result in increased emissions or decreased immunity of the equipment.

Warning: The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation. Normal operation is considered as absence of unusual, erratic variations in temperature readings.

Table 9A: – Guidance and manufacturer's declaration – Electromagnetic Emissions

The CIRCA Scientific CS-1000 Temperature Monitoring System is intended for use in the electromagnetic environment specified below.
The customer or the user of the CIRCA Scientific CS-1000 Temperature Monitoring System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CIRCA Scientific CS-1000 Temperature Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CIRCA Scientific CS-1000 Temperature Monitoring System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 9B: – Guidance and manufacturer's declaration – Electromagnetic Immunity

The CIRCA Scientific CS-1000 Temperature Monitoring System is intended for use in the electromagnetic environment specified below.
The customer or the user of the CIRCA Scientific CS-1000 Temperature Monitoring System should assure 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 ± 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods. At 0°. Voltage Dips >95% reduction, 0.5 period. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. Voltage Dips >95% reduction, 1 period. At 0°. Voltage Interruptions >95% reduction, 250/300 period.	Voltage Dips 30% reduction, 25/30 periods. At 0°. Voltage Dips >95% reduction, 0.5 period. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. Voltage Dips >95% reduction, 1 period. At 0°. Voltage Interruptions >95% reduction, 250/300 period.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CIRCA Scientific CS-1000 Temperature Monitoring System requires continued operation during power mains interruptions, it is recommended that the CIRCA Scientific CS-1000 Temperature Monitoring System be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Table 9C: – Guidance and manufacturer's declaration – Electromagnetic Immunity

The CIRCA Scientific CS-1000 Temperature Monitoring System is intended for use in the electromagnetic environment specified below.
The customer or the user of the CIRCA Scientific CS-1000 Temperature Monitoring System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CIRCA Scientific CS-1000 Temperature Monitoring System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3Vrms 80% AM (1kHz), 0.15-80MHz	3 Vrms	d = 1.2 √P
	6Vrms ISM Bands within 150kHz - 80MHz	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80-2700MHz, 80% AM at 1kHz	3 V/m	d = 1.2 √P 80 to 800 MHz d = 2.3 √P 800 MHz to 2.7 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment that include RF transmitters or that apply RF electromagnetic energy for diagnosis, i.e. 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.

(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 CIRCA Scientific CS-1000 Temperature Monitoring System is used exceeds the applicable RF compliance level above, the CIRCA Scientific CS-1000 Temperature Monitoring System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CIRCA Scientific CS-1000 Temperature Monitoring System.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note: If high frequency surgical equipment is used at the same time and interferes with the operation of the CIRCA Scientific CS-1000 Temperature Monitoring System, additional measures may be necessary, such as re-orientation of cables, relocation, and/or connecting the hospital grade power cable into a different grounded receptacle or separate grounded power source.

Table 9D: – Recommended separation distances between portable and mobile RF communications equipment and the CIRCA Scientific CS-1000 Temperature Monitoring System

The CIRCA Scientific CS-1000 Temperature Monitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CIRCA Scientific CS-1000 Temperature Monitoring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CIRCA Scientific CS-1000 Temperature Monitoring System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
W	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.7 GHz d = 2.3 √P
0.01	0.12 meters (4.7 inches)	0.12 meters (4.7 inches)	0.23 meters (9.1 inches)
0.1	0.38 meters (15.0 inches)	0.38 meters (15.0 inches)	0.73 meters (28.7 inches)
1	1.2 meters (3.9 feet)	1.2 meters (3.9 feet)	2.3 meters (7.6 feet)
10	3.8 meters (12.5 feet)	3.8 meters (12.5 feet)	7.3 meters (24.0 feet)
100	12 meters (39.4 feet)	12 meters (39.4 feet)	23 meters (75.5 feet)

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.

Table 9E: – Immunity to proximity magnetic fields

Test Frequency (Hz)	**Modulation**	**Level (A/m)**
134.2 kHz	Pulse Modulation (a) 2.1 kHz	65 (b)
13.56 MHz	Pulse Modulation (a) 50 kHz	7.5 (b)

(a) Carrier modulated using a 50% duty cycle square wave.
(b) rms, before modulation is applied.