CIRCA Temperature Monitoring System™
Model CS-1000
Software Version 2.1

CIRCA Scientific, Inc.
14 Inverness Drive East, Suite H-136
Englewood, CO 80112 USA
+1 303-951-8767

Patent www.circascientific.com/en-us/patents

EU REP
MedNet EC-REP IIb GmbH
Borkstrasse 10,
48163 Muenster, Germany

CE 2797

CS-ART002 Rev. 06
(2025-07-08)

TABLE OF CONTENTS:

1. GENERAL WARNINGS & CAUTIONS:

Caution is 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, and damage to the device or damage to other property.

Warning is 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.

- The monitor is designed for use with CIRCA Scientific Interconnect Cables, Temperature Probe, 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 the S-Cath™ temperature probe. 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.
- 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 13 “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 7F “Data Transfer to USB”.
- Shut down system per section 6 “Shut Down Instructions”. 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 $\geq$ 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

***Notice**: 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.*

2. INTENDED PURPOSE:

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

2A 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 is applicable to the device and can be used as the parameter to measure the performance of the device. In addition, 'reduced risk of esophageal thermal injury' can be considered as the indirect clinical benefit of the device.

2B Contraindications: there are no known contraindications associated with the equipment or its accessories.

2C Limitations: system should only be connected to the CIRCA Esophageal Temperature Monitoring Probes for temperature reading, but not other temperature monitoring probes.

2D 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.

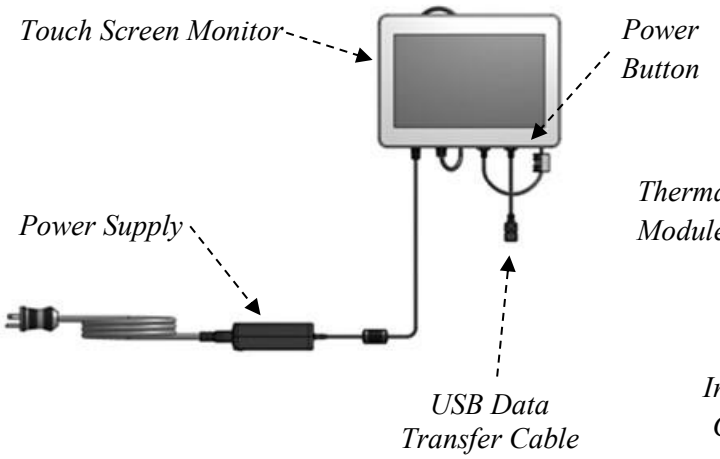
2E Intended Patient Population: adult patients of both men and women indicated as clinically suitable and in need to undergo cardiac ablation prescribed by a suitability qualified clinician.

3. SYSTEM DESCRIPTION:

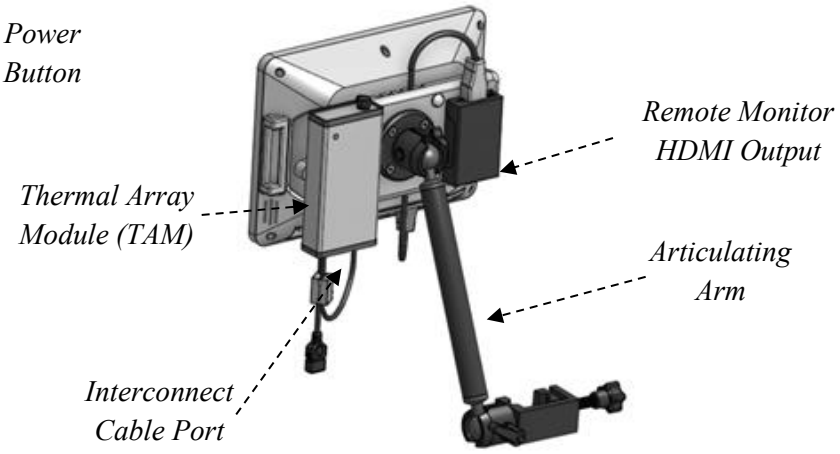
3A: HARDWARE

– The CIRCA Scientific 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 Cable, Temperature Probe (Applied Part), and Accessories only.

FIGURE 1: SYSTEM EQUIPMENT



Monitor (Front View)



Monitor (Back View)

Temperature Probe (Applied Part, Sold Separately)

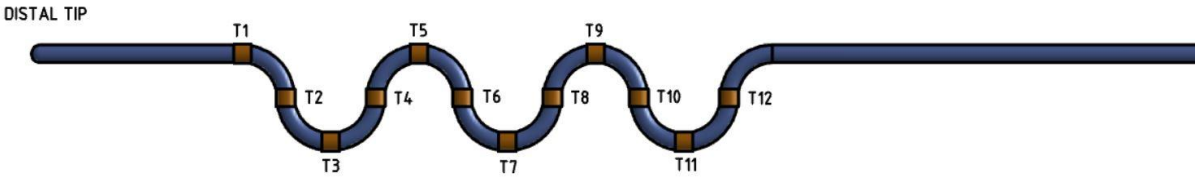
USB Data Transfer Drive

Interconnect Cable (Sold Separately)

Temperature Standard (Sold Separately)

NOTE: 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 on distal end of the probe.

FIGURE 2: TEMPERATURE PROBE SENSOR LOCATIONS



3B: SOFTWARE/DISPLAY

- The monitor displays 12 temperature probe sensor readings (°C), the maximum and minimum temperature of all sensors, a monitoring status indicator and contains a two-tiered alarm system with user-selected volume levels.
- The Monitoring Indicator will flash a green light when the system is operating properly and monitoring temperatures.
- The monitor features the following three screens:

FIGURE 3: MAX/MIN GRAPH

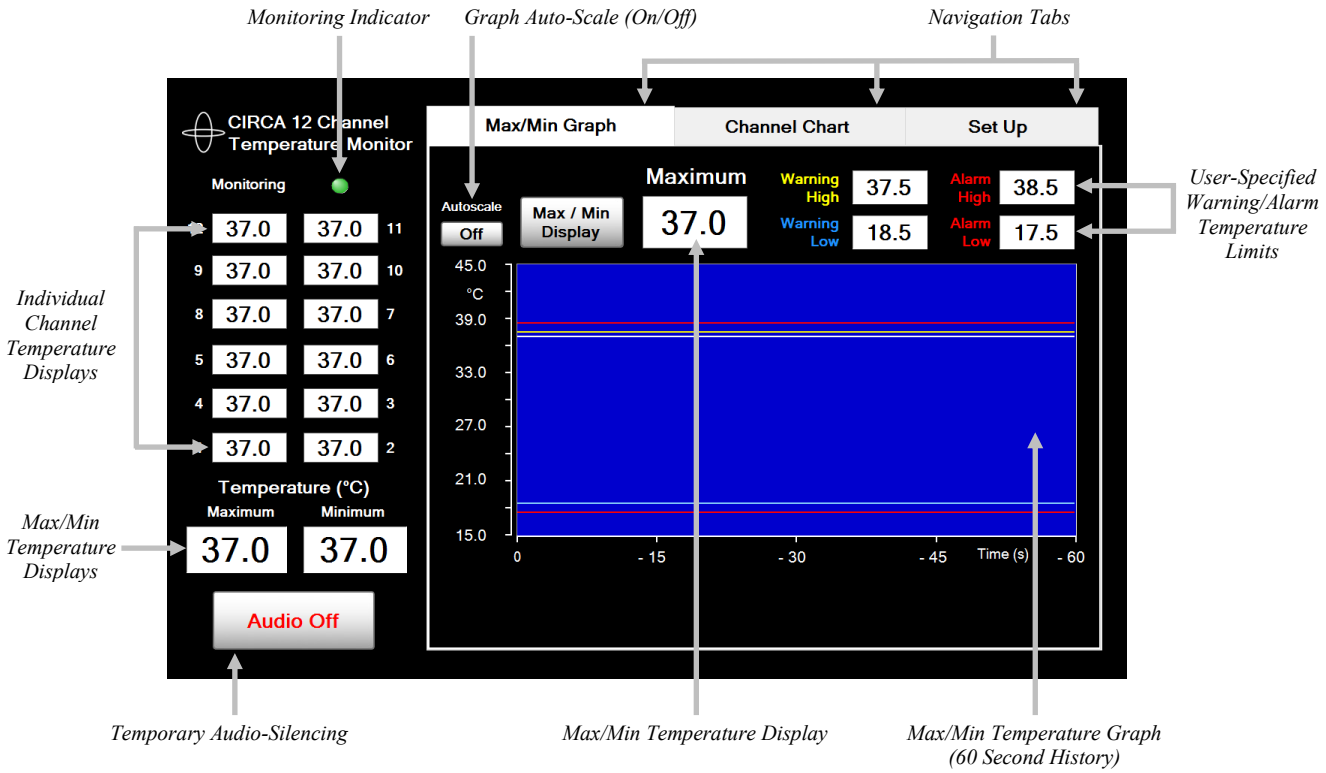


FIGURE 4: CHANNEL CHART

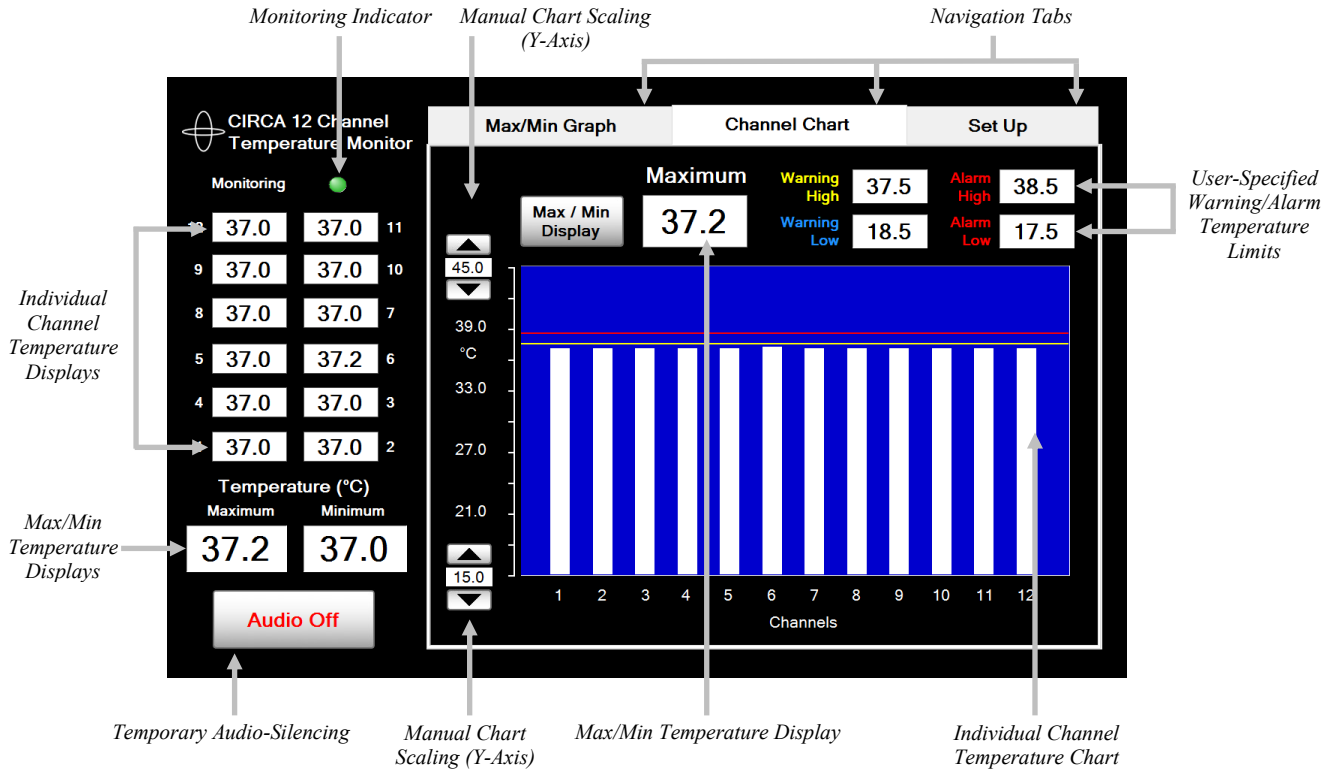
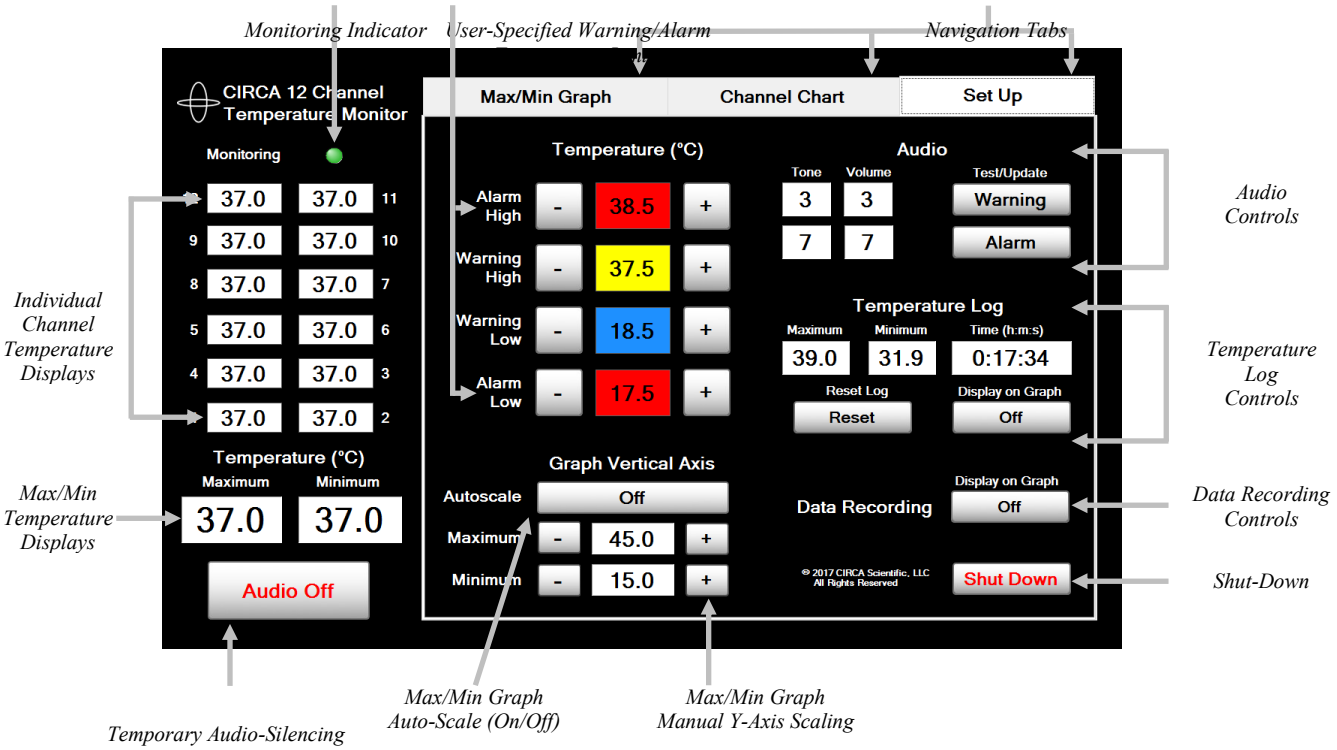


FIGURE 5: SET UP



3C: ALARM SYSTEM

- The alarm system provides visual and audible feedback when a sensor temperature is equal to, above or below the user-selected values.
- The alarm system is intended to provide operator feedback regarding temperature compared to user-selected levels only; it does not provide physiological alarm conditions.

WARNING HIGH & ALARM HIGH

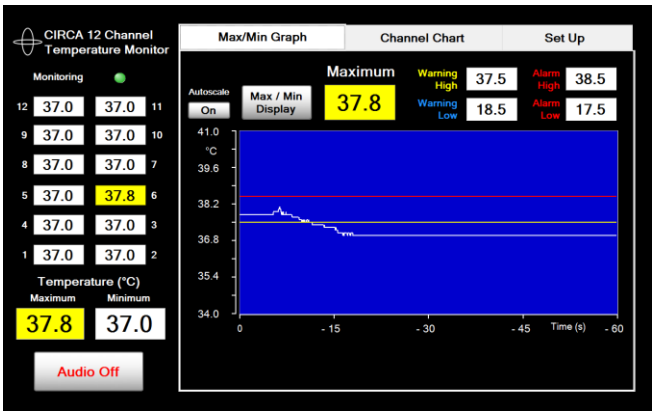
- The visual and audible signals are triggered when a sensor temperature is equal to or above the set value.
- Warning and Alarm values are set by the operator (see "Section 4: Set Up Instructions").

WARNING HIGH is a lower priority than ALARM HIGH.

WARNING HIGH is identified by **YELLOW**.

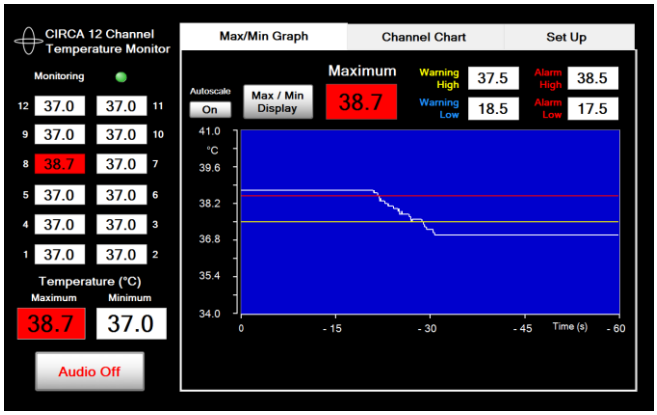
ALARM HIGH is identified by **RED**.

FIGURE 6: WARNING HIGH SIGNAL



- Individual channel temperature display backgrounds change to YELLOW to indicate a WARNING HIGH condition.
- Maximum temperature display backgrounds flash YELLOW to indicate a WARNING HIGH condition.

FIGURE 7: ALARM HIGH SIGNAL



- Individual channel temperature display backgrounds change to RED to indicate an ALARM HIGH condition.
- Maximum temperature display backgrounds flash RED to indicate an ALARM HIGH condition.

WARNING LOW & ALARM LOW

- The visual and audible signals are triggered when a sensor temperature is equal to or below the set value.
- Warning and Alarm values are set by the operator (see "Section 4: Set Up Instructions").

WARNING LOW is a lower priority than ALARM LOW.

WARNING LOW is identified by **BLUE**.

ALARM LOW is identified by **RED**.

FIGURE 8: WARNING LOW SIGNAL

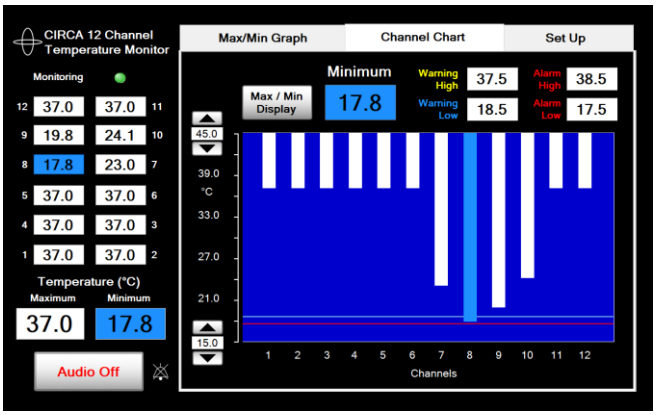
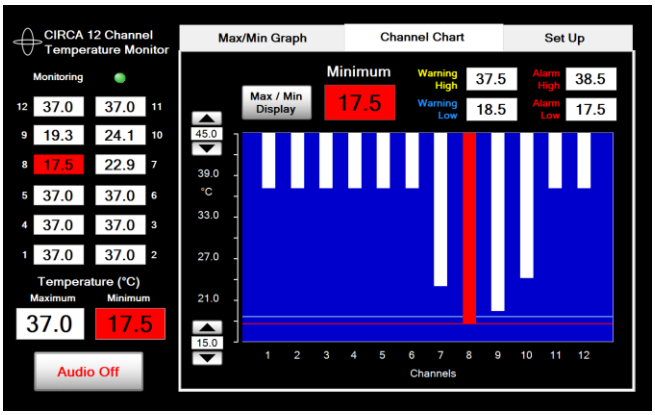


FIGURE 9: ALARM LOW SIGNAL



- Individual channel temperature display backgrounds change to BLUE to indicate a WARNING LOW condition.
- Minimum temperature display backgrounds flash BLUE to indicate a WARNING LOW condition.
- Individual channel bars on the Channel Chart change to BLUE to indicate a WARNING LOW condition.

- Individual channel temperature display backgrounds change to RED to indicate an ALARM LOW condition.
- Minimum temperature display backgrounds flash RED to indicate an ALARM LOW condition.
- Individual channel bars on the Channel Chart change to RED to indicate an ALARM LOW condition.

4. SET UP INSTRUCTIONS:

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

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

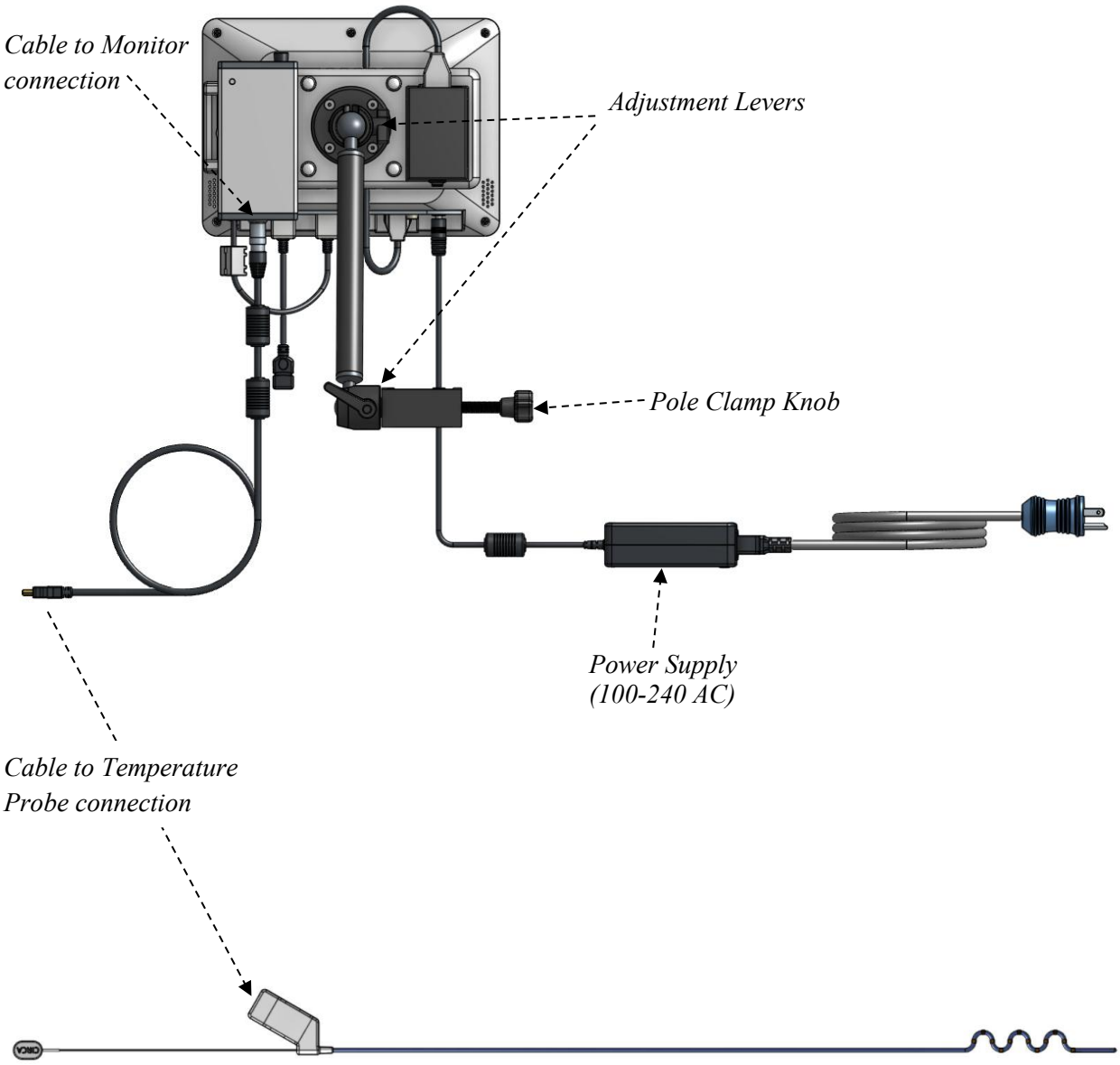
NOTE: Intended position of the Operator to observe the Alarm Signal is within an approximate distance of 4.5 feet (1.4 meters).

3. Plug power cord into power outlet.
4. Connect interconnect cable to monitor (connection located on back of monitor) by aligning snap-fit connectors and pushing firmly.
5. Connect temperature probe to interconnect cable by aligning linear connector and pushing firmly.

WARNING: To avoid the risk of electric shock, this equipment MUST be connected to a supply mains with protective earth ONLY.

6. Press Power Button 2 seconds to switch monitor on.
7. During start-up, the monitor will deliver a test audible alarm (3 beeps). If no audible signal is heard, sound system is defective. Refer service of monitor to Circa Scientific.
8. Verify temperatures are displayed on the monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor (see Section 8 for troubleshooting help).
9. Proceed to operating instructions in Section 5.

FIGURE 10: SET UP CONNECTIONS



5. OPERATING INSTRUCTIONS:

USER PROFILE: This device is intended to be used by trained medical professionals.

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.

1. Select the "Set Up" tab to set desired warning and alarm temperature limits. Default settings include:
    a. Alarm High Limit: 38.5°C
    b. Warning High Limit: 37.5°C
    c. Warning Low Limit: 18.5°C
    d. Alarm Low Limit: 17.5°C
    e. Max/Min Graph Autoscale ON
2. Set desired warning/alarm temperature limits:
    a. Touch "+" and "-" buttons adjacent to warning/alarm identifiers to change temperature limit values.

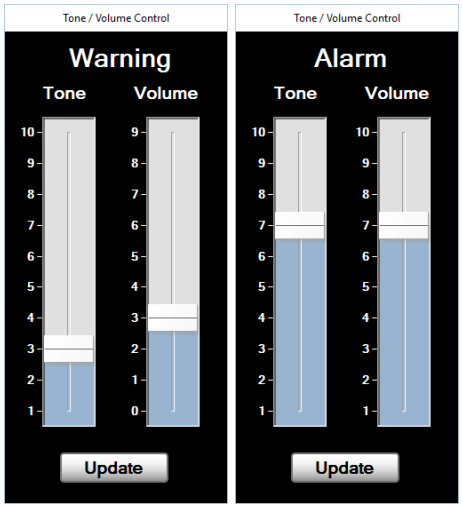
NOTE:
- "WARNING HIGH" temperature limit cannot be set equal to or greater than "ALARM HIGH" temperature limit.
- "WARNING LOW" temperature limit cannot be set equal to or less than "ALARM LOW" temperature limit.

3. Set desired warning and alarm tones and volumes:
    a. Touch "WARNING" or "ALARM" buttons to hear and update audible tone and volume settings.
    b. Touch bar graph level to desired setting then press "UPDATE" button to save and exit.

NOTE: Warning volume cannot be set equal to or greater than alarm volume.

NOTE: All user-selected values are retained; the last settings used before shut down will be recalled upon start-up.

FIGURE 11: TONE & VOLUME SETTINGS



4. Manually scale Channel Chart:
    a. Select the "Channel Chart" navigation tab.
    b. Press the "UP" and "DOWN" arrows at the base and top of the chart's Y-axis to manually scale the Channel Chart.
5. Once Set Up is complete, select desired screen (either "Max/Min Graph" or "Channel Chart") to view temperatures measured by the CIRCA S-CATH™.
6. Touch "MAX/MIN DISPLAY" button on either "Max/Min Graph" or "Channel Chart" screen to toggle between graph plots of maximum and minimum temperatures.
    a. "MAXIMUM" plots the maximum temperature of the 12 individual channels on the graph.
    b. "MINIMUM" plots the minimum temperature of the 12 individual channels on the graph.

FIGURE 12: MAXIMUM MODE

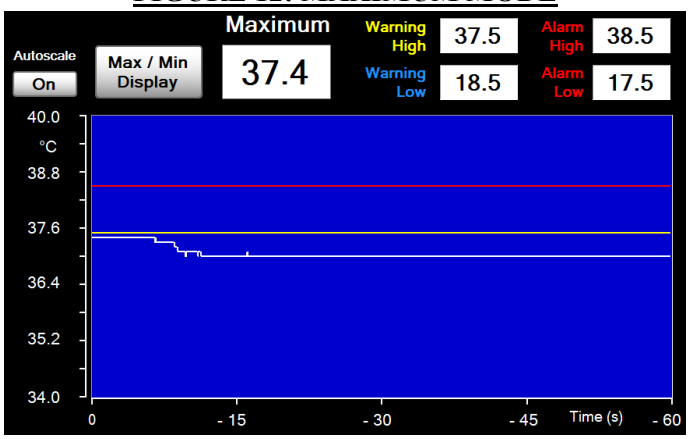
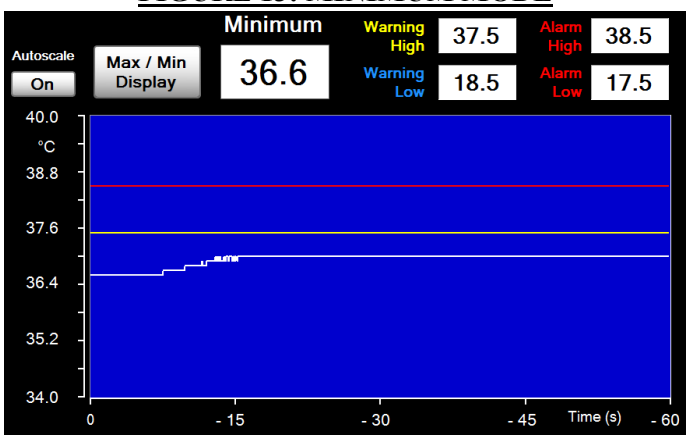


FIGURE 13: MINIMUM MODE



7. Disconnect probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

NOTE: After disconnecting, the message "NO VALID TEMPERATURE DATA. PLEASE CHECK PROBE" will appear on the screen.

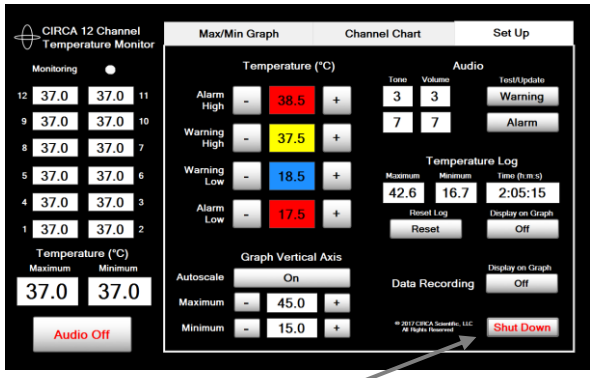
8. Prepare temperature probe for patient use per temperature probe's Instructions for Use.
9. Once temperature probe is placed in the patient and connected to the interconnect cable, temperature data will display for all 12 sensors.

CAUTION: 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.

6. SHUT DOWN INSTRUCTIONS:

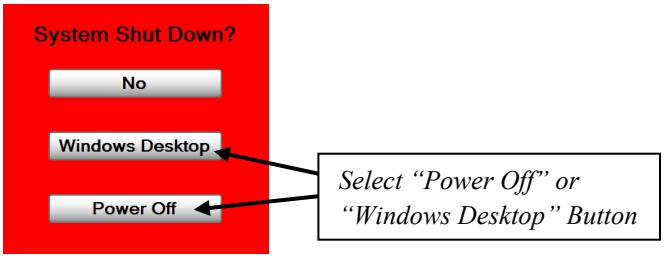
To shut down monitor:

1. Select the "Set Up" Navigation tab.
2. Press the "SHUT DOWN" button located on the lower right corner of the screen.



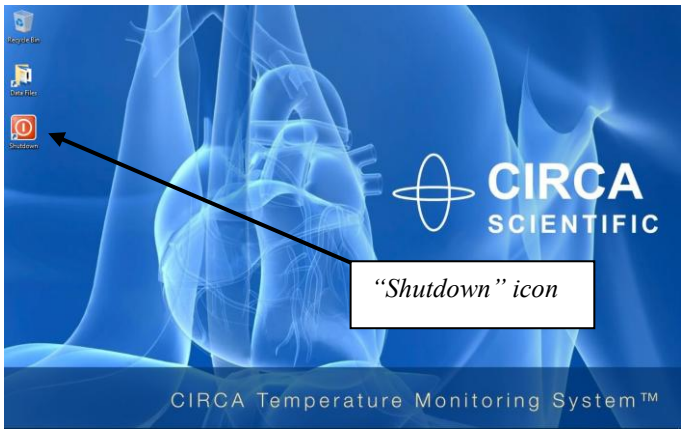
Select "Shut Down" Button

3. Confirm shut down by selecting either "Power Off" or "Windows Desktop". Otherwise, select "NO" to return to Set Up screen.



Select "Power Off" or "Windows Desktop" Button

4. If "Power Off" was selected the device will shut down. After selecting "Windows Desktop", the program will exit to the Windows Desktop.
5. Double tap the red "Shutdown" icon.



"Shutdown" icon

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

7. SPECIAL TOPICS: OPTIONAL FEATURES

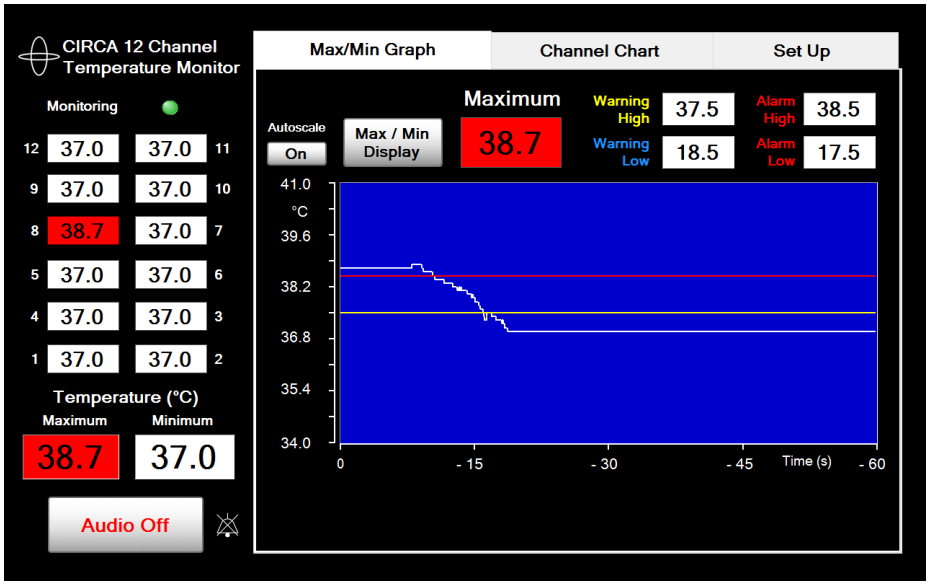
7A: AUDIO SILENCING

- AUDIO OFF inactivates all audible signals, only until another event occurs.
- Examples of events include:
  - Maximum temperature increasing from warning to alarm level.
  - Temperature dropping below warning or alarm values then increasing to a value equal to or above the user-specified temperature limits.

To activate Temporary Audio Silencing:

1. Press the "AUDIO OFF" button in the lower left corner of any screen.
2. When the Audible Silence feature is activated, the AUDIO OFF symbol will appear temporarily, adjacent to the "AUDIO OFF" button in the lower left corner of the screen.

FIGURE 14: AUDIBLE SILENCE FEATURE



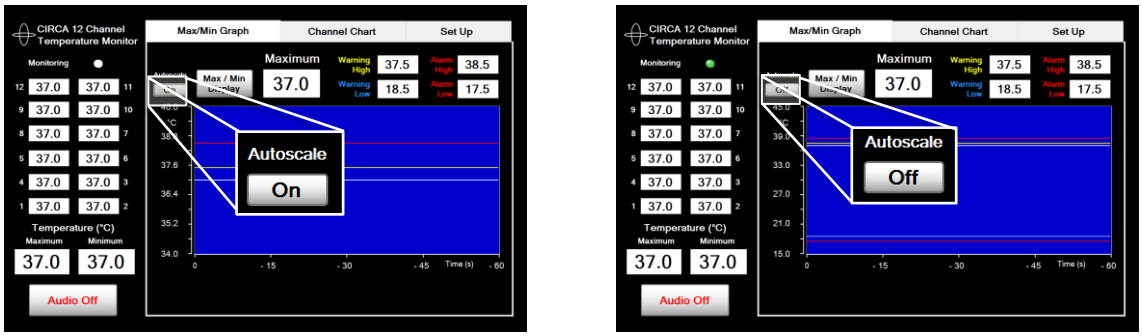
7B: AUTO-SCALING

- Default settings include an auto-scaling feature that adjusts the Max/Min Temperature Graph's Y-axis to approximately ± 2°C of the maximum or minimum temperature being plotted.
- Auto-scaling may be turned off by the user at any time, allowing the user to manually set upper and lower Y-axis limits for the Max/Min Temperature Graph.

To inactivate auto-scaling:

1. Select the "Max/Min Graph" navigation tab.
2. Press "ON" button labeled "Autoscale" in upper left corner of the graph. The button will now display "OFF".

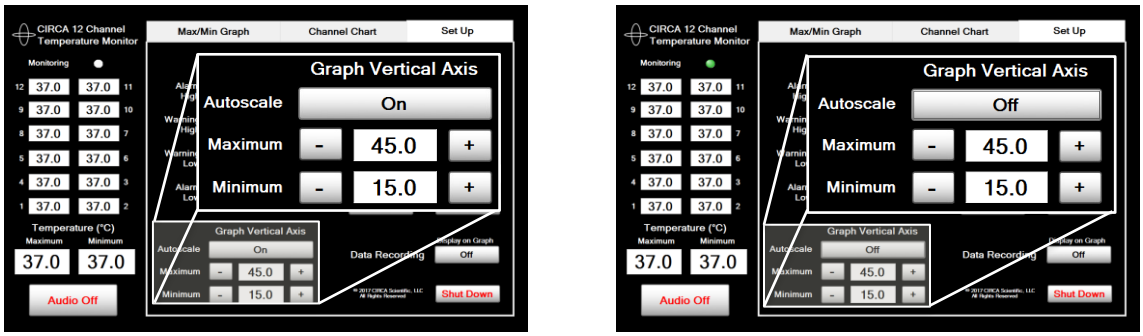
FIGURE 15a: AUTO-SCALING FEATURE (ON / OFF)



OR

1. Select the "Set Up" navigation tab.
2. Press the "ON" button, labeled "Autoscale" in the lower left corner of the screen. The button will now display "OFF".
3. Manually set upper and lower Y-axis limits for the Max/Min Temperature Graph using the "+" and "-" buttons below the "AUTOSCALE ON/OFF" button.

FIGURE 15b: AUTO-SCALING FEATURE (ON / OFF)



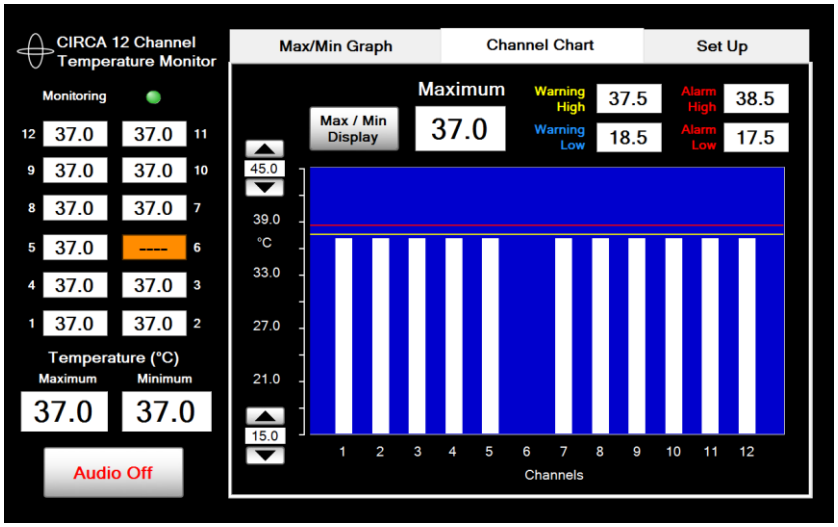
7C: CHANNEL DISABLING

- Users may manually disable a specific channel or channels from any screen.
- Individual channel temperature display backgrounds change to ORANGE to indicate a disabled condition.
- Corresponding Channel Charts will disappear for disabled channels.
- Disabled channels will be reactivated upon changing to a different CIRCA S-CATH™ probe.
- If 11 or more channels are disabled by the system or user, the system must be shut down and restarted to re-activate channels (see "Section 6: Shut-Down Instructions" for detailed instructions).

To manually disable a channel:

1. Press an individual channel temperature display background.
2. A message box will appear. Press "YES" to confirm the user's intent to disable channel.
3. The background color will change from WHITE to ORANGE to indicate the channel has been disabled.
4. Corresponding Channel Charts will disappear for disabled channels.
5. If the system (or user) disables up to 10 channels, disconnecting and reconnecting a new CIRCA S-CATH™ probe will clear (reset) all channels.
6. If the system (or user) disables 11 or more channels, the system will generate the message "ALL TEMPERATURE CHANNELS DISABLED. PLEASE SHUT DOWN AND RESTART SYSTEM". Restarting the system will clear (reset) all channels.

FIGURE 16: CHANNEL DISABLING FEATURE



7D: TEMPERATURE LOGGING

- The CIRCA Temperature Monitoring System includes a temperature-logging feature that displays the maximum temperature reached, minimum temperature reached, and time elapsed since the last user reset on the "Set Up" screen.
- The temperature log can be reset by the user at any time.

To display the temperature logging feature on the Max/Min Graph:

1. Select the "Set Up" navigation tab.
2. Press the "OFF" button, labeled "Display on Graph" on the right side of the screen under "Temperature Log". The button will now display "ON".

To reset the temperature log:

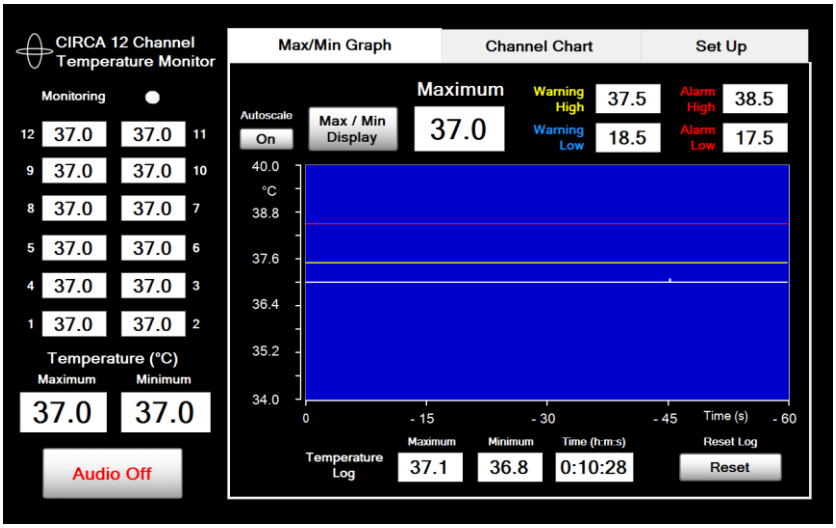
1. Press the "RESET" button next to "Temperature Log" label on the Max/Min Graph screen or the Set Up screen. The temperature log will be reset.

To hide the temperature logging feature on the Max/Min Graph:

1. Select the "Set Up" navigation tab.
2. Press the "ON" button, labeled "Display on Graph" on the right side of the screen under "Temperature Log". The button will now display "OFF".

   NOTE: Temperature Log information is still available to the user on the Set Up screen.

FIGURE 17: TEMPERATURE LOGGING FEATURE



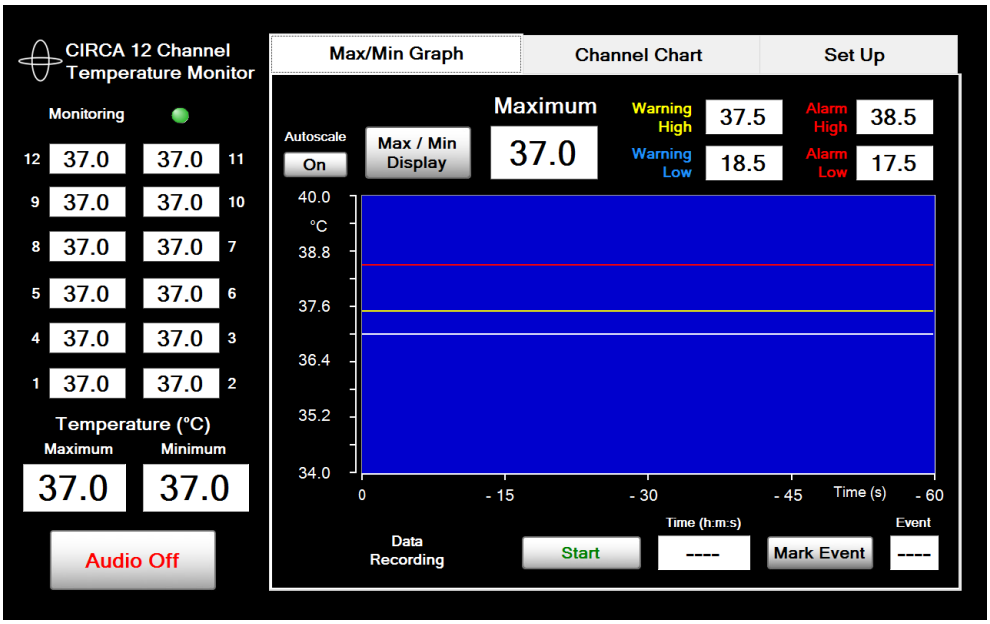
7E: DATA RECORDING

- The CIRCA Scientific Temperature Monitoring System is equipped with a data recording feature that enables users to record and export selected temperature data to a .csv (comma separated value) file via USB.
- The system stores data in up to 6 files. For instructions on transferring data files to USB, see "Section 7F: Data Transfer to USB".

To start data recording:

1. Select the "Set Up" navigation tab.
2. Press the "OFF" button, labeled "Display on Graph" on the right side of the screen under "Data Recording". The button will now display "ON".
3. Select the "Max/Min Graph" navigation tab.
4. Press the "START" button on the bottom of the screen to begin recording data. The system will only record data if the "START" button on the Max/Min Graph is pressed.
5. The user may mark events to tag specific data of interest by pressing the "MARK EVENT" button located on the bottom of the Max/Min Graph. The event number will advance up to 99 events.

FIGURE 18: START DATA RECORDING



To stop and save data recording:

1. Pressing the "STOP" button located on the bottom of the Max/Min Graph will save the data file automatically.
2. A message box will appear with the number of files saved and the file name. Press the "OK" button to close the message box.

NOTE: Improper shut down will result in loss of data.

FIGURE 19: STOP DATA RECORDING

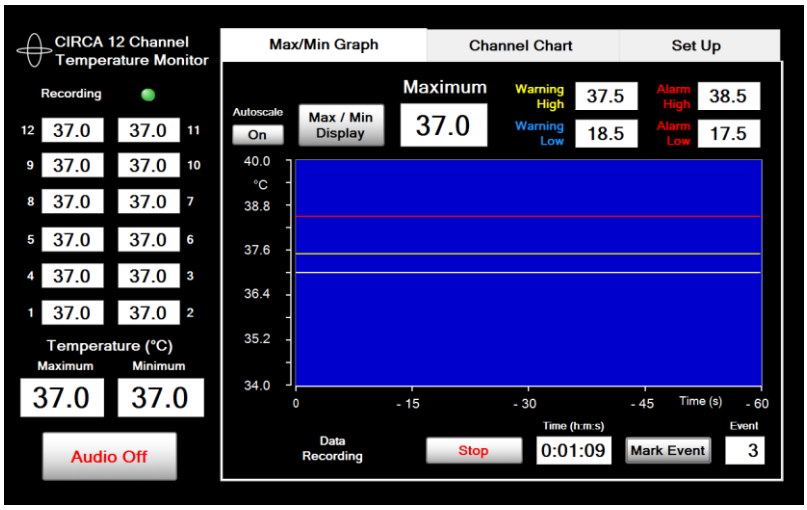
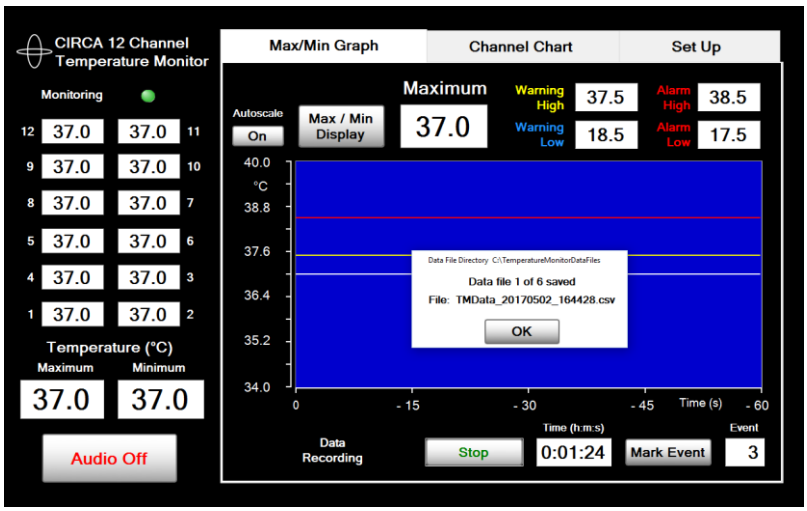


FIGURE 20: SAVE DATA RECORDING FILE



7F: DATA TRANSFER TO USB

- The CIRCA Temperature Monitoring System stores data in up to 6 data files that can be transferred to the user's computer via the CIRCA USB Data Transfer Drive for detailed data analysis.
- Only use the CIRCA Scientific USB Data Transfer Drive to transfer data from the system.
- Do not use USB Data Transfer Drive while Temperature Monitoring System is connected to patient or inside the patient environment.
- Do not touch the USB Data Transfer Cable connector and the patient simultaneously.

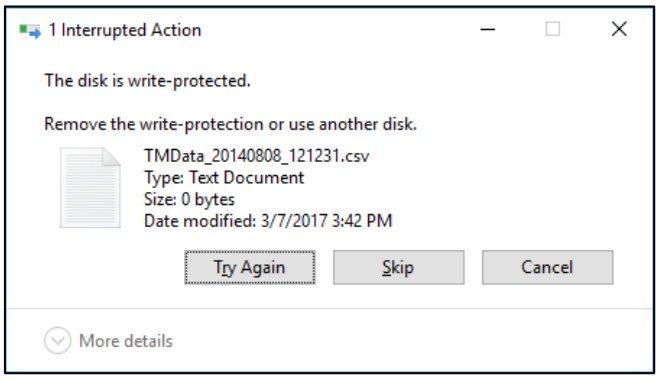
CAUTION: Use of accessories or replacement parts not supplied by CIRCA Scientific can result in degraded performance and could lead to damage to the unit.

WARNING: Use of any USB Data Transfer Drive other than that supplied by CIRCA Scientific may result in infiltration of malware and viruses and voids the warranty of the CIRCA Scientific Temperature Monitor.

To move data files to USB Data Transfer Drive:

1. Shut down the CIRCA Temperature Monitoring System to "Windows Desktop" (see "Section 6: Shut Down Instructions").
2. Remove Protective Port Cover from the USB Data Transfer Cable and Insert the CIRCA USB Data Transfer Drive with Write Protect on USB Data Transfer Drive LOCKED.
3. UNLOCK Write-Protect on USB Data Transfer Drive, ONLY when attached to the CIRCA CS-1000 Monitor, by moving the write-protect switch located on the side of the CIRCA USB Transfer Drive "UP".
    - Write Protect on USB Data Transfer Drive must be UNLOCKED (only when attached to the CIRCA CS-1000 Monitor), or the system will generate an error message as depicted in Figure 21, below.

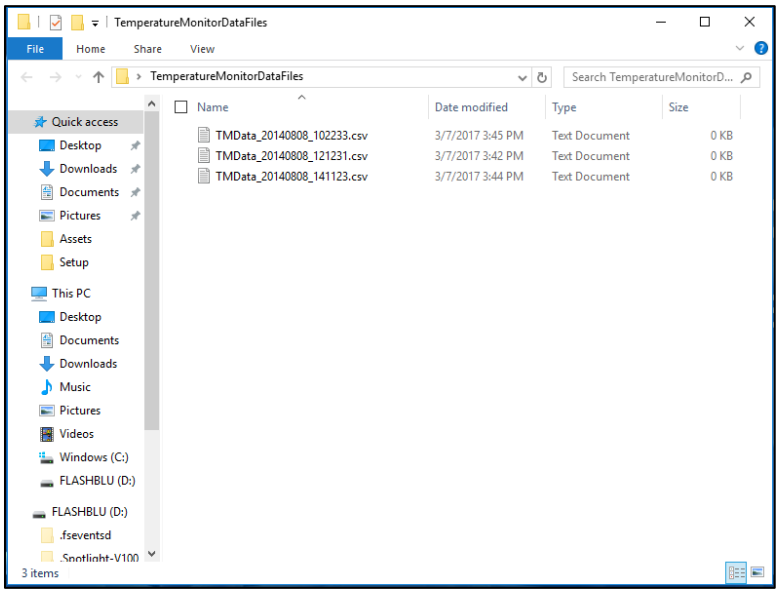
FIGURE 21: USB WRITE-PROTECTION ERROR MESSAGE



4. Select “DATA FILES” icon on Windows desktop (reference Figure 22 below) and a directory of data files will appear as shown in Figure 23, below.
    - File name format is: TMData_<Date>_<Time>.
    - Example Date (YearMonthDay): 20140729
    - Example Time (HourMinuteSecond): 213439
5. From this screen, users may view all existing data files on the monitor. From this screen users may delete data files, if necessary.

FIGURE 22: DESKTOP SHORT CUTS

FIGURE 23: DIRECTORY OF DATA FILES ON USB DATA TRANSFER DRIVE



6. Prepare the file(s) you wish to transfer by selecting them which will place a check in the box to the left of the file name as depicted in Figure 24 below.
7. At the top of the window select the “Home” tab then select the “Move to” button. Select “Choose location…” in the menu that displays as depicted in Figure 25 below.
8. In the “Move Items” dialog select the item “FLASHBLU (D:)” then select the “Move” button as depicted in Figure 26 below.
9. The files selected in step 6 will now be transferred to the USB Data Transfer Drive. DO NOT REMOVE THE USB DATA TRANSFER DRIVE WHILE A TRANSFER IS IN PROGRESS.

FIGURE 24: SELECT FILE(S) TO TRANSFER

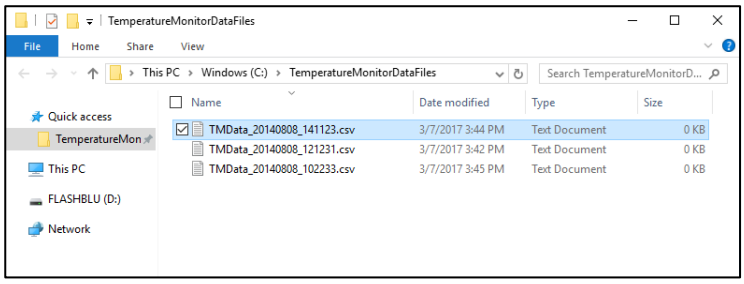


FIGURE 25: MOVE TO BUTTON AND LOCATION MENU

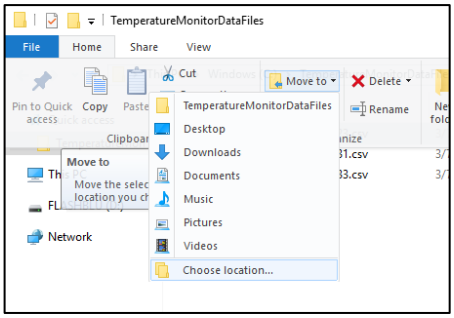
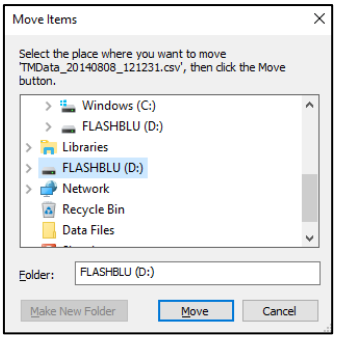


FIGURE 26: MOVE ITEMS DIALOG WITH MOVE BUTTON



To remove USB Data Transfer Drive:

1. Wait for all files to complete the transfer operation.
2. LOCK the Write-Protect on USB Data Transfer Drive by moving the write-protect switch located on the side of the CIRCA USB Transfer Drive “DOWN”.
3. Remove USB Data Transfer Drive from the USB Data Transfer Cable.
4. Reinsert Protective Port Cover into USB Data Transfer Cable.

NOTE: Improper removal of USB Data Transfer Drive may result in loss or corruption of data. Do not disconnect the USB Data Transfer Drive until all file transfers have been completed.

NOTE: Store USB Data Transfer Drive in a safe location for next use.

WARNING: Use of any USB Data Transfer Drive other than that supplied by CIRCA Scientific may result in system infiltration of malware and/or viruses and voids the warranty of the CIRCA Scientific Monitor.

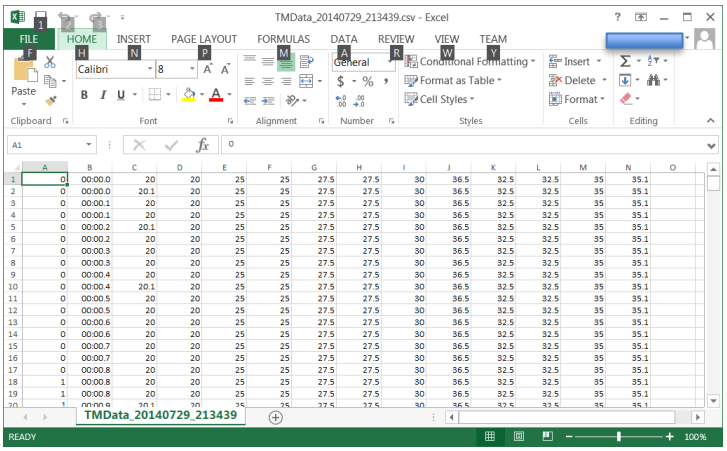
7G: DATA ANALYSIS IN MICROSOFT EXCEL®

- The CIRCA Temperature Monitoring System stores data in up to 6 data files that can be exported to Microsoft Excel® or other software for data analysis.
- **NOTE**: Data values recorded as -20.0°C or 90.0°C are default values for channels that have been disabled. These values should be excluded from data analysis.

To analyze data in Microsoft Excel®:

1. Insert LOCKED USB Data Transfer Drive into USB port on computer. DO NOT UNLOCK THE USB WRITE-PROTECT SWITCH WHEN CONNECTED TO NON-CIRCA SCIENTIFIC DEVICES.
2. A directory of data files will appear as shown in Figure 23, above.
3. Open Microsoft Excel® and select the desired data file for analysis (.csv format).
    - Row Definition: Each row in the data file has a unique time stamp and contains an event number and 12 temperatures.
    - Column Definition:
        - Column A: Event Number (0-99)
        - Column B: Time Stamp* (Hr:Min:Sec:mSec)
            - *Time Stamp requires special formatting
        - Column C: Temperature (Sensor 1)
        - Columns D-N: Temperatures (Sensors 2-12)

FIGURE 27: MICROSOFT EXCEL® DATA FILE



4. Save the file in an Excel® workbook format such as .xlsx on the host computer or a different storage device. DO NOT SAVE ADDITIONAL FILES TO THE CIRCA USB DATA TRANSFER DRIVE TO PROTECT THE CIRCA TEMPERATURE MONITORING SYSTEM FROM MALWARE/VIRUS INFILTRATION.
5. To format time stamp:

- Highlight Column B by right clicking at the top of the column.
- Select “FORMAT CELLS”.
- Under “CATEGORY,” select “CUSTOM” and enter the following into the Type Box: “h:mm:ss.000” as shown in Figure 28, below.
- Column B will now be reformatted with the modified time stamp, as shown in Figure 29, below.

FIGURE 28: FORMAT TIME STAMP

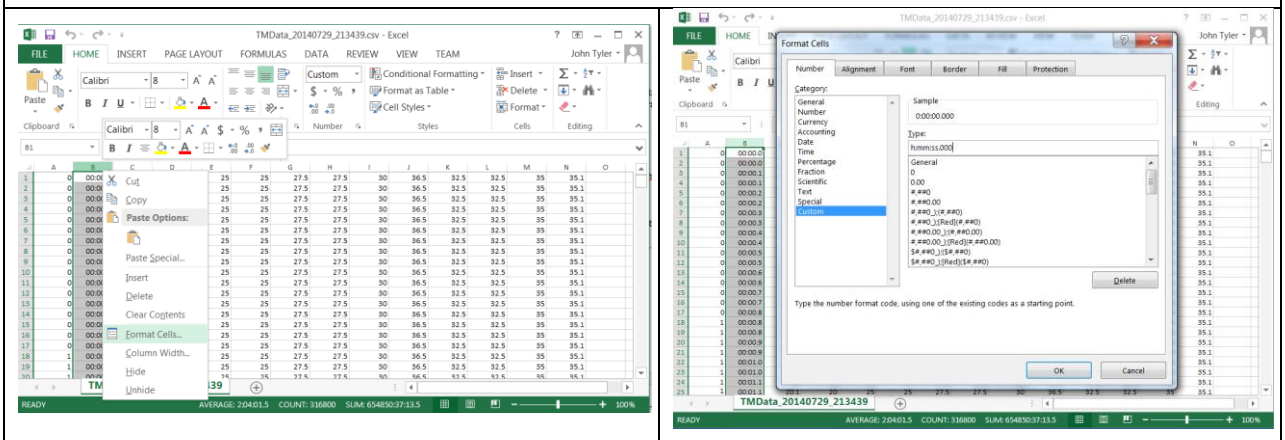
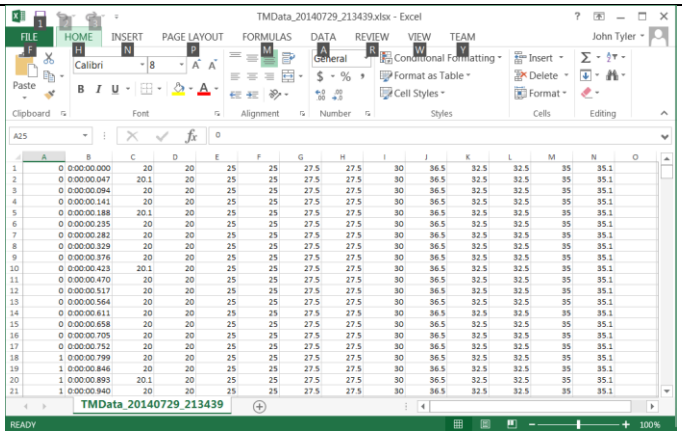


FIGURE 29: REFORMATTED TIME STAMP



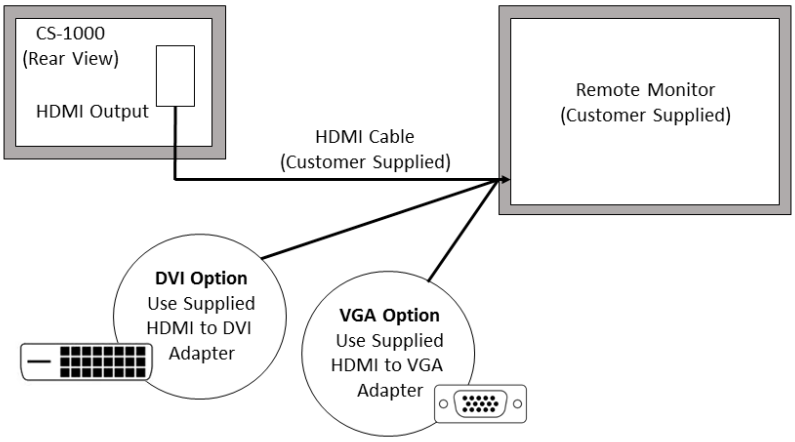
6. After the data has been saved in a spreadsheet format, it may be filtered and parsed by the user.
   - For example, to filter by event:
     a. Select the “DATA” tab.
     b. Select “FILTER”.
     c. Choose an Event Number such as “1” to view only the data associated with Event 1.

7H: Remote Monitoring Setup Instructions

- 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.

Remote Monitoring Components:

Figure 30: Remote Monitoring Block Diagram

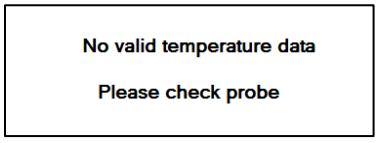
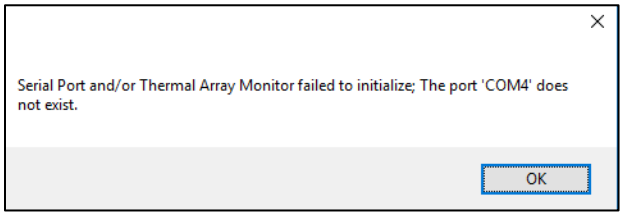


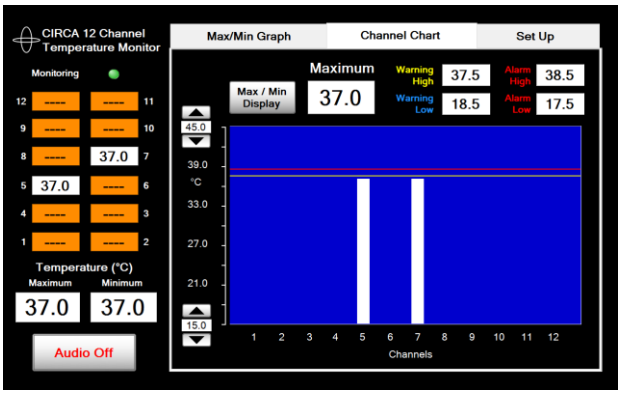
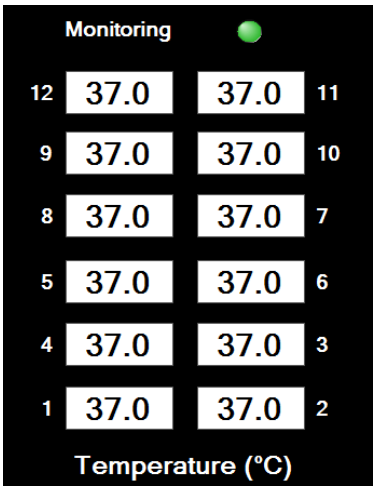
Setup Instructions

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 30 above).

1. Connect an HDMI cable to the display output on the back of 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 30. Ensure connections are fully seated and secure.
4. Power on both the Remote Monitor and the CS-1000 Temperature Monitor.
5. During start-up, *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.
6. 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*.

8. TROUBLESHOOTING:

Problem	Resolution
Message 	- Touch “OK” button. - Ensure USB Cable (back of monitor) is firmly seated in port. If loose, reconnect cable. - Shut Down from Windows Desktop. - Press Power Button 2 seconds to switch monitor on.
Message 	- Ensure temperature probe is firmly seated to interconnect cable and interconnect cable is firmly seated to monitor. - Replace probe and/or interconnect cable if no temperature data can be displayed after verifying connections.
Message 	- Touch “OK” button. - Ensure USB Cable (back of monitor) is firmly seated in port. If loose, reconnect cable. - Shut Down from Windows Desktop. - Press Power Button 2 seconds to switch monitor on.
Monitor does not boot up and BIOS Configuration resets to default.	- The computer inside the monitor is provided with a battery-powered real-time clock circuit. The battery has no power. - **Warning**: There is a danger of explosion if battery is incorrectly replaced. Refer servicing to Circa Scientific.

Problem	Resolution
"----" and orange background is displayed for an individual sensor temperature reading and an individual sensor chart (under "Channel Chart" display) is not present. 	- No action required. - The four dashes ('----') and orange-colored graph indicate an individual sensor wire has failed or has been manually disabled. - See "Section 7C: Channel Disabling" for detailed instructions on how to resolve a system- or user- disabled channel.
Frozen Screen: Monitoring indicator does not flash. 	- Shut down unit and re-start.

9. MAINTENANCE:

- Disconnect from power before wiping down.
- Use a damp cloth. Do not use liquid or spray detergents.
- Wipe outer surfaces with damp cloth and let dry. Do not rinse, soak, wash or sterilize.
- If disinfection is required by hospital policy, apply non-abrasive/non-corrosive disinfection fluid to disposable cloth, wipe outer surfaces, and then let dry.

Routine Visual Inspection

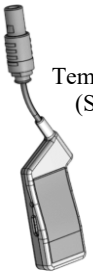
- Visually inspect the monitor and all accessories at least once before each use.
- Inspect the power cord, cables, and monitor for damage, wear, and loose components.
- Particular attention should be made to the power cord and interconnect cable for insulation damage such as cuts, brittleness, cracking,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

Annual Safety Inspection and Accuracy Test

- The following safety inspection and accuracy test should be performed by hospital's equipment service department at least every 12 months:
  - ❑ Inspect the equipment and accessories for mechanical damage.
  - ❑ Inspect all labels and markings for legibility.
  - ❑ Check temperature accuracy with the following test:

    Equipment: CIRCA Temperature Standard (Part Number: CS-1029, available from CIRCA Scientific)

    1. Connect Temperature Standard to Interconnect Cable.
    2. Turn unit on.
    3. Observe temperature readings (12) displayed on the monitor.
    4. Calculate the measurement error for each individual Output Temperature measurement by subtracting reading from 25.0°C.
    5. Ensure that the measurement error is not greater than 0.1°C.


Temperature Standard
(Sold Separately)

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

WARNING: to prevent shock, never open the equipment. Refer servicing to Circa Scientific.

10. 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.

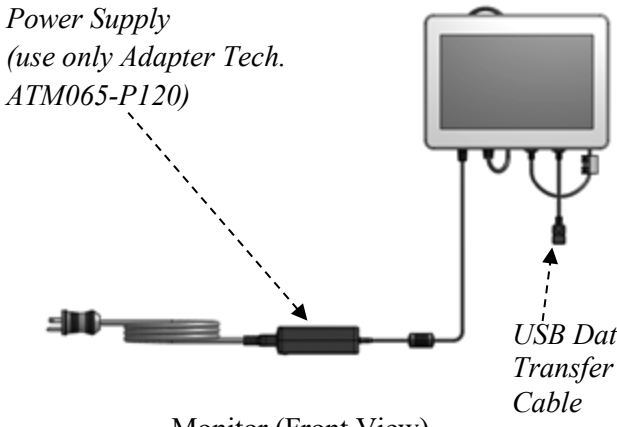
- If shipping equipment, pack in original carton and packing materials. If original packing material is not available, cover monitor, pack with foam, and ship in sturdy box to prevent damage during transport.

11. ACCESSORIES

- The monitor is designed for use with CIRCA Scientific Interconnect Cable, Temperature Probes, USB Data Transfer Drive, and Temperature Standard only. The Interconnect Cable, Temperature Probe, and Temperature Standard are sold separately.
- Contact CIRCA Scientific or Authorized Distributor for ordering information.
- The "Recorder" Port located on the back of the monitor is intended to connect with the 0 to 5V analog input of a recording device that is compliant with IEC 60601-1. Do not connect this port to any other device.

CAUTION: Use of accessories or replacement parts not supplied by CIRCA Scientific can result in degraded performance and could lead to damage to the unit.

WARNING: Use of cables and accessories other than those supplied by CIRCA Scientific may result in increased emissions or decreased immunity of the equipment and voids on the CIRCA Scientific Temperature Monitor.



Monitor (Front View)

Monitor (Back View)

Temperature Probe (Sold Separately)

Interconnect Cable (Sold Separately)

USB Data Transfer Drive

Temperature Standard (Sold Separately)

12. TECHNICAL INFORMATION:

Classification	– Class I – Defibrillation-Proof Type CF Applied Part – Continuous Operation
Software	– Revision level 2.1
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 = -19.9°C to 89.9°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

13. 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.
- **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.

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

Table 5 – 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 6 – 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 periods	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 periods	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 (50/60 Hz) magnetic field IEC 61000-4-8	30A(rms)/m	30A(rms)/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 7 – 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	80% AM (1 kHz) 3 Vrms, 0.15-80 MHz 6 Vrms in ISM Bands within 150kHz – 80MHz	3 Vrms 6 Vrms	d = 1.2 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m, 80 –2700 MHz, 80% AM at 1 kHz	3 V/m	d = 1.2 $\sqrt{P}$ 80 to 800 MHz d = 2.3 $\sqrt{P}$ 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 8 – 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 W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
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.

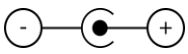
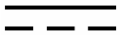
Table 9 – Immunity to proximity magnetic fields (IEC 61000-4-39)

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] r.m.s., before modulation is applied

14. SYMBOLS KEY:

	– Consult Instructions for Use		– Temperature limits
MD	– Medical device		– Humidity limitation
℞ Only	– Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		– Atmospheric pressure limits
	– Defibrillation-Proof Type CF Applied Part		– Caution: part of defibrillation proof protection is provided by the S-Cath™ temperature probe. Do not use with any other applied part
	– "Power" / "Off"		– 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.
	– Centre Positive. – Indicates that the center (tip) of the output plug is Positive (+) and the barrel of the output plug is Negative (-).		– For indoor use only
	– Alternating current		– Direct current
	– Manufacturer		– Date of Manufacture
REF	– Catalogue Number	SN	– Serial Number
CE ####	– "Conformité Européenne" – "European Conformity"	EU REP	– Authorized Representative in the European Union