Thermogard HQ™

Temperature Management System

ZOLL®

OPERATION MANUAL

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

601357-001 Rev 5
6/2024

Patent: www.zoll.com/patents

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1. Safety Information

Overview

Safety is of primary concern to ZOLL. This chapter provides information on safely using the Thermogard HQ™ system. You must read and understand the information in this chapter before operating the system. Always follow the warnings, cautions, and notes throughout this document.

If you have questions about the safe or effective use of the system, contact ZOLL.

Warnings, Cautions, and Notes

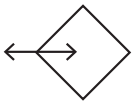
This document uses the following conventions to indicate important information:

WARNING. Warnings indicate events or conditions that can result in serious injury or death or severe damage to the equipment.

Caution. Cautions indicate information for safe operation, proper performance, or avoiding actions that may result in damage to the equipment.

Note. Notes clarify understanding, aid in the proper operation of the product, and prevent problems or errors from occurring.

Symbols

Symbol	Definition	Symbol	Definition
	Alternating current		Authorized Representative
	Batch Code		Catalog number
	Caution	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Connector for the data acquisition cable		Consult instructions for use
	Country of manufacture		Danger: Keep hands and fingers away
	Dangerous voltage warning		Date of Manufacture

Symbol	Definition	Symbol	Definition
	Deflation syringe		Do not allow liquids to spill on the product or package.
	Do not push or pull on the display head		Do not resterilize
	Do not reuse		Do not stack
	Do not use if package is damaged		Follow instructions for use
	Fragile contents		Fuse
Hi	The high patient temperature alarm limit		Importer
Lo	The low patient temperature alarm limit		Manufacturer
	Medical device		MR Unsafe
	Off		On
	Potential Equalization Conductor. This is a safety measure to prevent earth current loops in equipment		Protective earth (ground)
	Quantity		Serial number
	Sterile barrier		Sterilized using irradiation

Symbol	Definition	Symbol	Definition
CH REP	Swiss authorized representative		Top facing up
TrakLo	Alternate low patient temperature alarm limit		Type B applied part. Defibrillator protected
	Type BF applied part. Defibrillator protected	UDI	Unique device identifier
	USB		Use-by date
	Wi-Fi		Weight

General Safety Precautions

WARNING. Systemic hypothermia risks. Systemic hypothermia may cause cardiac arrhythmia, patient shivering, or other system or organ complications. Systemic hypothermia should only be utilized under the supervision of a qualified physician.

When treating a patient with the system, qualified medical staff must routinely and closely monitor the patient and must comply with the following procedures:

- Remain near the patient throughout the procedure. Address any audible and visual alarms from the console.
- Always verify the function of the console prior to insertion of an IVTM™ (Intravascular Temperature Management) catheter. In the event of a malfunction, have other means of cooling available.
- When combining the use of the system and other adjunctive means of cooling, observe the patient closely.
- Do not use the system in conjunction with other temperature maintenance devices that have an automatic temperature controller (e.g., dialysis device). Temperature oscillations may occur that are dangerous to the patient.
- Performing installation, operation, or maintenance procedures other than those described in this manual may create hazards and void the warranty.
- Sterile components are designed for a single use only. If unauthorized disposable components are used, proper operation cannot be guaranteed and the patient may be harmed.
- Proper aseptic technique must be used while making all sterile connections to the system.
- Never operate damaged or leaking equipment.
- Never operate the console without coolant fluid in the coolant well.
- Never use any fluid other than a ZOLL-approved 50% propylene glycol / 50% deionized water mixture as coolant.
- Never operate the equipment while smoking or in the presence of open flame.
- Avoid touching the patient simultaneously with metal parts in the console.
- When using the Thermogard HQ system for surface cooling, the patient's temperature and skin condition must be checked, especially areas in contact with the pad, every 20 minutes, or as directed by a physician. Patients vary in degree of sensitivity to cold, heat and pressure. Patients at greatest risk are those uncon-

scious or incapacitated, persons on prolonged therapy, diabetics, children, persons with insensitive skin areas or poor circulation. Focus attention on all bony prominences.

- Thermogard HQ™ Surface Start-Up Kits for surface cooling (non-sterile) are not compatible with IVTM catheter use (sterile).
- The ZOLL Coolgard and Thermogard consoles are MR Unsafe and, thus, these consoles are not allowed in the MR system room. Therefore, the catheter must be disconnected from the console prior to moving the patient into the MR system room.

WARNING. Projectile hazard.

WARNING. Electric shock risk during cardiac defibrillator discharge. The console's protection against the effect of the discharge of a cardiac defibrillator is partially in the patient temperature probe. To prevent potential hazards to the patient or operator, use the console in conjunction with the approved patient temperature probes listed in "Specifications" on page 97.

Guidance and Manufacturer's Declaration– Electromagnetic Emissions

The Thermogard HQ console is intended for use in the electromagnetic environment specified below. The customer or user of the console should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The Thermogard HQ console uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF Emissions CISPR 11	Class A	The console is suitable for use in all establishments other than domestic establishments and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. **Note.** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR B is normally required), this equipment might not offer adequate protection to radiofrequency communication services. You may need to relocate or re-orient the equipment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Table 1.1. Guidance and Manufacturer's Declaration–Electromagnetic Emissions

Electromagnetic Immunity Declaration (EID)

The Thermogard HQ console is intended for use in the electromagnetic environment specified below. The customer or user of the console should ensure 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	± 8kV contact ± 15 kV air	± 8kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be 30% or higher.
Electrical fast transit/burst IEC 61000-4-4	±2 kV for power supply lines ±1kV for input/output lines	±2 kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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 > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, we recommend that the console be powered by an uninterruptable power supply or a battery.
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
Power frequency (50/60 Hz) magnetic field 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment guidance
Conducted RF immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 150 kHz to 80 MHz $d = 1.2\sqrt{P}$, 80 to 800 MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.7 GHz
	6 Vrms in ISM bands within 150 kHz and 80 MHz	6 Vrms in ISM bands within 150 kHz and 80 MHz (see Note 3)	
	80% AM at 1 kHz	80% AM at 1 kHz	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-3	3V/m 80 Mhz to 2.7 GHz	3V/m	Where P is the maximum 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 electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1. At 80 Mhz and at 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. **Note 3.** The frequency range between 100-150 kHz is associated with interference from low frequency RFID equipment. **Note 4.** The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz tested are 6.765 MHz to 6.975 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. **Note 5.** Tested for immunity to RF interference from transmitters operating at 125 kHz, 134.2 kHz and in the frequency ranges between 3.155 MHz to 3.4 MHz and between 7.4 MHz to 8.8 MHz.			

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts 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 console is used exceeds the applicable RF compliance level above, the console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the console.
2. Unless otherwise noted, over the frequency ranges 150 kHz to 80 Mhz, field strength should be less than 10 V/m.

Note. The following degradation associated with essential performance are not allowed during testing: component failure, changes in programmable parameters, resets to factory defaults, changes in operating modes, false alarms, cessation or interruption of any intended operation, even if accompanied by an alarm, initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm, error of a displayed numerical value sufficiently large to affect diagnosis or treatment, noise on a signal in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals.

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

Radiated maximum output power of the equipment (in Watts)	Separation distance according to frequency of transmitter (in meters)			
	150 kHz to 80 MHz inside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz inside ISM bands $d = 1.2\sqrt{P}$	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	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts according to the transmitter manufacturer.
Note 1. At 80 MHz and at 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.

Test Frequency (MHz)	Band[1] (MHz)	Service[1]	Modulation[2]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
Equipment: Valid test levels for professional healthcare facility						
385	380 –390	TETRA 400	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[2] 217 Hz	2	0.3	28
745						
780						
810	800 – 960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[2] 18 Hz	2	0.3	28
870						
930						

Table 1.2. Guidance and Manufacturer Declaration - Immunity to RF Wireless Communications

Test Frequency (MHz)	Band[1] (MHz)	Service[1]	Modulation[2]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[2] 217 Hz	2	0.3	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[2] 217 Hz	2	0.3	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation[2] 217 Hz	0.2	0.3	9

Table 1.2. Guidance and Manufacturer Declaration - Immunity to RF Wireless Communications

1. For some services, only the uplink frequencies are included.
2. The carrier shall be modulated using a 50% duty cycle square wave signal.
3. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Wireless Output Declaration

Wi-Fi Protocol	801.11a/b/g/n
Frequency Band	2.4 GHz and 5 GHz
Authentication	WPA2, PEAP and EAP-TLS

Table 1.3. Supported Wi-Fi protocols, frequencies, and authentication methods

Standard	Frequency Range	Effective Radiated Power	Modulation Type	Data Rates
802.11b	2412-2462 MHz	27 mW	CCK[1] and DSSS[2]	1, 2, 5.5, 11 Mbps

Table 1.4. Wireless Output Declaration

Standard	Frequency Range	Effective Radiated Power	Modulation Type	Data Rates
802.11g	2412-2462 MHz	52 mW	OFDM[3]	6, 9, 12, 18, 24, 36, 48, 54 Mbps
802.11n	2412-2462 MHz	55 mW	OFDM[3]	MCS0 through MCS15 6.5, 13, 19.5, 26, 39, 52, 58.5, 65, 78, 104, 117, 130 Mbps
802.11a	5180-5320 MHz 5500-5700 MHz 5745-5825 MHz	47 mW	OFDM[3]	6, 9, 12, 18, 24, 36, 48, 54 Mbps
802.11n	5180-5320 MHz 5500-5700 MHz 5745-5825 MHz	43 mW	OFDM[3]	MCS0 through MCS15 6.5, 13, 19.5, 26, 39, 52, 58.5, 65, 78, 104, 117, 130 Mbps

Table 1.4. Wireless Output Declaration (Continued)

1. CCK: Complementary Code Keying
2. DSSS: Direct Sequence Spread Spectrum
3. OFDM: Orthogonal Frequency Division Multiplexing

Caution. Equipment such as electromagnetic security systems, cellular telephones, RFID readers or other in-band transmitters can emit strong signals that interfere with Wi-Fi signals. The interference could result in loss of Wi-Fi connection between the console and the Wi-Fi access point. The console may fail to transfer log files to the ZOLL cloud server if it is unable to maintain a stable Wi-Fi connection. However, the console's ability to treat patients would not be impacted by the loss of Wi-Fi connection. If the problem persists, reorient the console or move it away from the other devices causing the interference.

FCC Notice

Contains FCC ID: PVH0965

ZOLL has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. See 47 CFR Section 15.21.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. See 47 CFR Section 15.19(a)(3).

The user is cautioned to maintain 20 cm (8 inches) of space from the product to ensure compliance with FCC requirements.

Note. Harmful Interference is defined by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Canada, Industry Canada (IC) Notices

Contains IC: 5325A-0965

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

FCC/IC/EU: The 5150MHz to 5250MHz band is limited to indoor use only.

Transportation, Shipping and Storage Conditions

When shipping or storing the console, follow these recommendations:

- Do not allow liquids to spill on the console or its packaging.
- Drain coolant from the console.
- Keep in a cool, dry place.
- Fragile contents, handle with care.
- Always handle and store with the top facing up.

When transporting the console around the hospital, follow these recommendations:

- Move the console by the handle only; do not push or pull on the display head.
- Request assistance from another person to lift the front wheels of the console when moving it over a threshold. Use the handle to gently pull the console over the obstacle while your assistant stabilizes the front of the unit.

WARNING. Tipping hazard. The console may tilt in case of transport outside its crate and over a threshold.

Ignition of Flammable Anesthetic Mixtures

The console is not category AP or APG equipment and must not be used in oxygen-rich environments or environments where flammable anesthetic gas mixtures are present.

Electrical Hazards

This equipment has been tested and found to comply with the EMC limits of the international standard IEC 60601-1-2. These limits are designed to provide reasonable protection against interference in a typical medical installation. The equipment can radiate radio frequency energy if not installed in accordance with the instructions, and may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Always comply with the following:

- To avoid the risk of electrical shock, do not remove any panels of the product.
- Refer servicing to qualified personnel.
- Never operate equipment with damaged power line cords.

The Thermogard HQ console requires special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this manual.

Portable and mobile RF communications equipment can affect the Thermogard HQ console.

Caution. Dangerous Voltage. Electric shock hazard. Always turn off the console and disconnect the power line cord from the source before performing any service or maintenance procedures, or before moving the console.To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

WARNING. The potential equalization conductor should be connected to the potential equalization bus bar of the electrical installation when available. Refer to the requirements in the IEC 60601-1 standard.

Primary Patient Temperature Probe (T1) Failure

The console relies upon the patient temperature reading from an YSI-400 type thermistor connected to the primary patient temperature probe connector (T1). There are rare failures of this type of thermistor that cannot be detected by the console with 100% reliability. Failure of the T1 patient temperature probe can result in either patient hypo- or hyper- thermia. Death or serious injury to the patient may result. A secondary patient temperature probe (T2) connection is therefore built into the console. For patient safety, either use both the T1

and T2 connections or employ the T1 patient temperature probe with an independent frequent check of patient core temperature.

WARNING. Never clinically use a resistor in place of the T1 patient temperature probe. ZOLL may supply fixed value resistors and variable resistor test boxes (e.g the TP-400 FOGG Box) for testing, training and demonstration purposes. These can be plugged into the T1 patient temperature probe connector on the front of the console to represent a patient. Never use this device, or other method, to circumvent the normal patient temperature feedback control when the console is connected to the patient. Doing so exposes the patient to the hazards associated with hypo- or hyper- thermia. Death or serious injury may result.

Configuration Changes

WARNING. No modification of this equipment is allowed.

Caution. Certification requirements for external equipment connected to the console interfaces. Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the console standard IEC 60601-1. Any person who connects additional equipment to the signal input part or the signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1.

Priming the Start-Up Kit Before Intravascular Use

WARNING. Do not prime the Thermogard HQ™ Start-Up Kit while connected to a ZOLL IVTM catheter. During the priming operation, the air-trap alarm is disabled. Air present in the saline line may be circulated through the catheter. Before priming the circuit or during troubleshooting for possible leak, disconnect the heat exchange catheter, then connect the IN and OUT Luers of the Start-Up Kit together.

Air Entry Into the Tubing Circuit

Air entry may occur with the failure of any part of the Start-Up Kit or Surface Start-Up Kit, between the fluid bag and the outflow of the pump. There are no known safety risks of air entering the Surface Start-Up Kits. However, using the Start-Up Kit with a ZOLL heat exchange catheter, the integrity of the catheter prevents air entry into the patient. In the rare event of a second, simultaneous failure of the catheter, air entry into the patient is possible.

Air entry into the tubing circuit will usually, but not always, be associated with an air trap alarm that stops the console. **Always investigate air trap alarms**. The cooling circuit is a closed loop. Usually air trap alarms indicate a breach somewhere in this closed loop (occasionally an air trap alarm can be caused by condensation forming on the air trap exterior). With any air trap alarm, check both the integrity of the catheter or surface pad and the Start-Up Kit or Surface Start-Up Kit.

Leakage

Catheter intraluminal or balloon leakage

WARNING. Intraluminal leakage (between the saline lumen and infusion lumens) or balloon leakage is a potential catheter failure mode. In the event of such a failure, sterile saline from the cooling circuit is introduced into the patient. Intraluminal leakage or balloon leakage is typically associated with a fluid loss alarm once the saline bag has been depleted and stops the system. **Always investigate fluid level alarms.** The cooling circuit is a closed loop system – usually fluid loss alarms indicate a breach somewhere in this closed loop. With any fluid loss alarm, check both the integrity of the catheter and the Start-Up Kit (see below).

WARNING. If you notice a depleted saline bag or an air trap alarm, do not replace the saline bag prior to identifying the location of the leak and taking the appropriate mitigation. Check for system leaks according to the instructions in the 'Check for a Start-Up Kit or Surface Start-Up Kit leak' and 'Check for a catheter leak' sections below. (Note that a leak could be external or internal.)

Replacing the saline bag repeatedly without investigating the leak or loss of saline may result in unintended infusion of saline into the patient. Saline infusion may lead to the following adverse effects: local swelling that can cause subsequent local tissue damage; systemic fluid overload that can lead to dependent edema and subsequent skin breakdown; internal organ fluid overload, with subsequent overloading of the brain, lungs or heart. In some cases, this fluid overload may lead to life threatening events.

Caution. The console emits an alarm when the saline bag is empty. The bag must be completely empty and additional saline must have drained between the saline spike and the air trap for the saline level in the air trap to drop sufficiently to trigger the alarm.

Check for a Start-Up Kit or Surface Start-Up Kit leak

1. Check the air trap for condensation. If the air trap shows signs of condensation, wipe the air trap and reinstall it in the console. In the case of an air trap alarm, verify that the air trap alarm is cleared after this step.
2. Carefully check the fluid path from the fluid bag to the console for any leaks. Check if there is fluid on the floor, console, or the patient's bed.
3. If there is any fluid on the floor, console, or the patient's bed, check that the connections between the Start-Up Kit or Surface Start-Up Kit and the heat exchange device (catheter or surface pad) are not cracked or damaged and that the connections are tight enough to prevent leaks. Note that the Start-Up Kit connection to catheters uses Luers and the Surface Start-Up Kit connection to a surface pad uses ¼" quick disconnect connectors.
4. If you find a leak in the Start-Up Kit or Surface Start-Up Kit, replace it and see if there is also a leak in the heat exchange device (catheter or surface pad).
5. If you do not find a leak in the Start-Up Kit or Surface Start-Up Kit, there is likely a leak in the catheter or surface pad. Investigate further.

Check for a catheter leak

1. Disconnect the Start-Up Kit from the catheter. Properly cap both the catheter and Start-Up Kit using an aseptic technique.
2. Fill a sterile 10 mL slip tip syringe with sterile saline.
3. Connect the syringe to the IN Luer of the catheter and disconnect the OUT cap. Infuse 10 mL of saline – the saline should flow out the OUT Luer. If the saline does not flow out of the OUT Luer, a catheter leak is indicated.
4. Cap the OUT Luer and pull 5 cc of vacuum. Sustain for at least 10 seconds. Up to 4 mL of saline (not blood) should enter the syringe and you should be able to maintain the vacuum. If traces of blood are seen in the syringe or vacuum cannot be maintained, it indicates a catheter leak.
5. If you find a leak in the catheter, replace the catheter.
6. Replace the saline bag and re-prime the Start-Up Kit.
7. Ensure leak-tight Luer connections to the Start-Up Kit and continue the therapy.

Check for a surface pad leak

If using a surface pad, check it for leaks and replace as necessary. If necessary, the Surface Start-Up Kit fluid bag may be refilled with additional water.

WARNING. Never clinically circumvent the air trap alarm. ZOLL may use an air trap simulator fixture for testing, training and demonstration purposes. These are fluid filled air trap assemblies that are separate from a standard Start-Up Kit assembly. Never use this device, or other method, to circumvent the air trap alarm when

the console is connected to the patient. Doing so exposes the patient to the hazards associated with air embolism should the catheter fail. Death or serious injury may result.

Interference

If the console does cause interference with other devices, which can be determined by turning the console off and on, try to correct the interference by one or more of the following steps:

- Reorient or relocate the receiving device.
- Increase the separation between the console and device.
- Connect the console into an outlet on a circuit different from that to which the other device(s) is connected.

Product Label

An identifying label is attached to the outside of the console near the power cord inlet.

The label provides safety information and identifies the manufacturer, model, serial number, power requirements, fuse capacity, and manufacturing date for the console.

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2. Introduction

Use of the System

WARNING. Patients must be continuously monitored. Patients being treated with the system must be checked frequently (hourly) when the system is operating. It is possible for malfunctions or misuse of the system to result in patient injury or death.

The Thermogard HQ™ Temperature Management System comprises:

- An external heat exchange console (Thermogard HQ™ console)
- A heat exchange device
  - An IVTM™ (Intravascular Temperature Management) catheter
  - A compatible ZOLL surface pad
- A corresponding tubing kit
  - For use with an IVTM catheter:

    A sterile heat exchanger and tubing circuit (Thermogard HQ™ Start-Up Kit)
  - For use with a ZOLL surface pad:

    A non-sterile heat exchanger and tubing circuit (Thermogard HQ™ Surface Start-Up Kit)

The system enables patient temperature regulation with feedback control. The catheter, surface pad, Start-Up Kit, and the Surface Start-Up Kit are single-use disposable devices.

This manual provides operating instructions for the console, Start-Up Kit, and Surface Start-Up Kits.

Catheter, surface pad, and Surface Start-Up Kit components are referenced where necessary to ensure proper use with system components. Refer to the catheter, surface pad, or Surface Start-Up Kit Instructions for Use for additional information.

Operating Life

The operating life of the console is five years.

The operating life of the disposables varies by model. Refer to the individual product labeling.

Caution. The Start-Up Kit and Surface Start-Up Kit lifetime is seven days. The designed operating lifetime for these components is seven (7) days of continuous operation on a single patient. If a patient must be treated for a longer period, a new Start-Up Kit or Surface Start-Up Kit must be installed in the console. Failure to adhere to this time limit may cause the device to fail.

Caution. The Start-Up Kit and Surface Start-Up Kit are designed for single use only. Do not resterilize or reuse. Do not alter the product in any way.

Reuse of a single-use device may lead to product failures. Additional risks of reusing a single-use sterile intravascular device include but are not limited to:

- Potentially life threatening infection
- Toxic shock due to degradation of materials
- Increased risk of thrombosis
- Reduced heat exchange power

Functional Description

The console can be described in terms of three major components: a recirculating chiller, a roller pump, and a temperature control system. The console is connected to either the temperature-controlled catheter, or surface pad, by two small-bore plastic tubes. One tube supplies temperature-controlled fluid to the catheter or surface pad, and the other tube returns the fluid to the console. The fluid is pumped through a continuous recirculating loop by a roller pump inside the console. The fluid acts as an intermediate heat-transfer medium between the patient and the console. When connected to a catheter, sterile saline is used as the fluid because it is biologically compatible with the patient and in the unlikely event of a leak in the catheter, the possibility of harming the patient is reduced to a minimum.

Patient temperature feedback is used to control the console. The patient's temperature is measured by an indwelling YSI-400 thermistor temperature sensor. In response to the patient's measured temperature, the console employs both cooling and heating. Cooling occurs when the patient's temperature is above the set point target temperature. Based on the mode selected, heating occurs when the patient's temperature is below the set point target temperature. The amount of heating or cooling power is proportional to the difference in temperature between the set point target temperature and the patient's measured temperature.

A basic diagram of the system is illustrated in Figure 2.1, "Simplified Flow Diagram: Fluid Flows in a Closed-Loop Circuit".

1. Fluid bag
2. Start-Up Kit or Surface Start-Up Kit
3. Heat exchange device (catheter or surface pad)
4. Roller pump
5. Device outflow
6. Device inflow
7. Coolant well
8. Air trap
9. Coolant pump
10. Cooling engine and heater

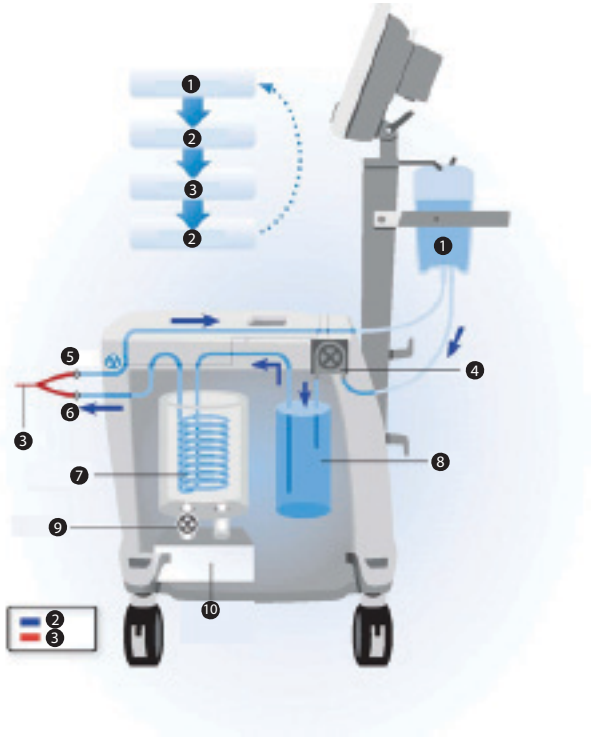

Figure 2.1. Simplified Flow Diagram: Fluid Flows in a Closed-Loop Circuit

Console Components

Controls and Display Screen

The display head contains four buttons and one knob used to select the settings on the screen. See Figure 2.2.

Display Screen

The display screen shows status, menus, messages, alarms, and patient temperature trend graphs.

The display head is attached to the mast by an adjustable swivel/tilt mounting clamp/lever. You can adjust the tilt and rotation of the display head and lock it into position by using the clamp/lever (Figure 4.65).

1. Display Screen
2. Alarm Indicator LED
3. Mute Button
4. Power On Indicator LED
5. Target Temp button
6. Pause / Resume treatment button
7. Mode / Rate button
8. Menu / Enter knob

Figure 2.2. Controls and Display Screen

Power Indicators

An LED on the control panel is illuminated when power is switched on. A second power indicator is mounted directly above the power switch on the rear of the console.

Alarm Indicators

The console typically notifies users of alarm conditions in two ways. When an alarm occurs, the screen displays an alarm message, and there is an alarm tone (beep). You can temporarily mute the alarm beep, but cannot turn it off.

If the nature of the failure prevents the console from displaying an alarm message, the alarm indicator on the control panel is illuminated.

Control Buttons

The display head features four pushbuttons that are used to control console functions. Each time a button is pressed, there is a “click” sound.

Target Temp

Press the Target Temp button to display a screen that allows you to set the patient’s target temperature. You can set a target temperature between 31° C and 38° C (87.8° F and 100.4° F).

Mode/Rate

Press the Mode/Rate button to display a screen that allows you to set the cooling/warming rate (in degrees per hour) or the mode. You can set a cooling/ warming rate between 0.10ºC/hr and 0.65ºC/hr (0.18ºF/hr and 1.17ºF/hr). You can also set Max Power or Fever Control mode.

Pause/Resume treatment

Press the Pause/Resume treatment button to toggle the operation of the console between Standby (the pump is stopped) or Run.

An alarm or fault can place the console into Standby automatically. After remedying the condition that caused the alarm, press this button to return to Run.

Mute Button

Press the Mute button to silence the alarm beep for two minutes. If the alarm condition has not been cleared during this two-minute period, the alarm beeps again.

Menu/Enter Knob

The Menu/Enter ≡↵ knob is a dual-function control knob and button.

Press the knob to display a menu screen or to make a selection.

Turn the knob to scroll between selections or to scroll temperature trend graphs.

Recirculating Chiller

The chiller consists of an air-cooled refrigeration system, reservoir heater, circulation pump, stainless steel reservoir, reservoir cover, and a temperature controller.

Temperature Controller

The temperature controller uses input from the patient's temperature probe and the target temperature selected on the console to regulate the coolant temperature of the recirculating chiller. The temperature controller constantly adjusts the coolant temperature by means of a closed-loop control system. The controller cools or heats the coolant, in a range between 0° and 42° C (32° and 107.6° F), to achieve and maintain the target temperature selected on the console. The console constantly displays the measured patient temperature and the target temperature.

You can also select the rate at which the console achieves the target temperature.

Temperature Probe Connectors

The front of the console features T1 and T2 connectors, which are used to connect patient temperature probes. The primary patient temperature probe is plugged into the T1 connector. The secondary patient temperature probe is plugged into the T2 connector.

Figure 2.3. Temperature Probe Connectors

Roller pump

Fluid is circulated through the heat exchange coil and the catheter or surface pad by a high-performance, compact roller pump. It pumps by peristaltic action on the tubing installed in the pump head. The pump rotation speed is accurately controlled by an electronic speed control system.

WARNING. Finger injuries. Be careful when inserting the roller pump tubing that you do not catch your fingers with the roller. When the console is operating, do not attempt to circumvent the safety interlocks on the roller pump lid. Do not place fingers or foreign objects into the pump raceway when the pump is turning. The roller pump has sufficient torque to severely damage a finger.

If a tubing leak or failure occurs in the pump raceway when using the Start-Up Kit with an IVTM catheter, saline solution will cause corrosion in the moving parts of the rotor. Contact your ZOLL service representative.

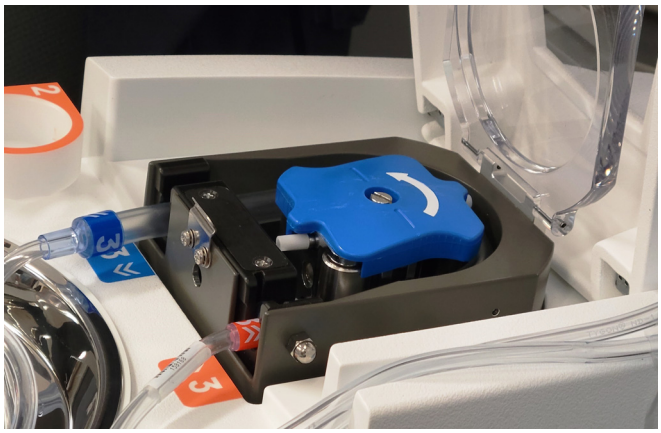

Figure 2.4. Roller pump

Prime button

The Prime button is located on the right side of the pump. The Prime button operates the pump to prime the tubing with fluid from the fluid bag. Press and release the Prime button to activate it for two minutes (blue light on). To deactivate the Prime button and stop the pump, press again (blue light off).

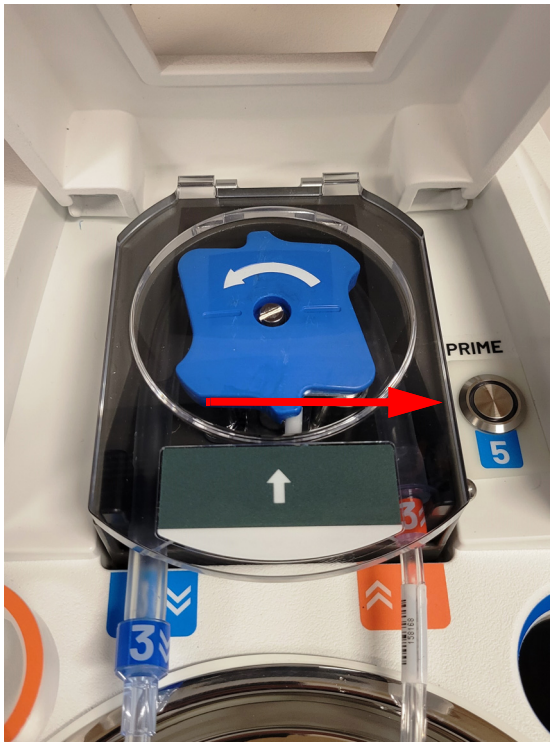

Figure 2.5. Prime button

Start-Up Kit and Surface Start-Up Kit

The Thermogard HQ™ Start-Up Kit for IVTM catheters contains a sterile heat exchange coil, air trap, saline delivery lines, saline bag connector, catheter connectors, and the roller pump tubing.

The Thermogard HQ™ Surface Start-Up Kit contains a non-sterile reservoir bag, heat exchange coil, air trap, water delivery lines, surface pad connectors, and the roller pump tubing.

Figure 2.6. Start-Up Kit

Setup Guide

A setup guide is located on the inside of the console cover. Use this guide to ensure that the Start-Up Kit has been installed correctly for use with IVTM catheters.

When using the surface pad with the Surface Start-Up Kit, see the Thermogard HQ Surface Setup Guide (ordered separately, 106942-001).

Figure 2.7. Setup Guide for use with IVTM catheters

Indications for Use - Intravascular Use - USA

The Indications for Use listed below have clearance within the USA for the following models of ZOLL IVTM® Thermal Regulation Systems:

- The Thermogard HQ™

These systems can be used with any of the IVTM Catheters. The indications for use are specific to the catheter. Please refer to the Indications for Use statement in the catheter specific Instructions for Use.

The Thermogard HQ™ Start-Up Kit (SUK) is intended to control patient core temperature using heat exchange fluid in conjunction with the Thermogard HQ™ console and ZOLL intravascular heat exchange catheters but does not have specific independent indications for use.

Indications for Use – Cool Line® Catheter

The Cool Line Catheter Model CL-2295A, when used with the ZOLL Thermal Regulation System, is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning—Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

* Fischer's exact test

For more details on the clinical trial results, refer to Physician's Manual – "Normothermia for the Neurocritically Ill Stroke Patient".

Indications for Use – ICY® Catheter

The ZOLL ICY Intravascular Heat Exchange Catheter Model IC-3893A, connected to the ZOLL Coolgard/Thermogard Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and

- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/ intensive care.

Indications for Use – Quattro® Catheter

The ZOLL Quattro Catheter Model IC-4593, connected to a ZOLL Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/ intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/ intensive care.

Indications for Use – Solex 7® Catheter

- In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care. (Maximum use period: 4 days)
- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care. (Maximum use period: 4 days)
- In fever reduction, as an adjunct to other antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated. (Maximum use period: 7 days)

Warning - Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. A randomized controlled trial of endovascular cooling in patients with fever associated with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

Indications for Use - Surface Use - USA

Temperature reduction in adult patients where clinically indicated, e.g. in hyperthermic patients.

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3. Receiving, Inspection, and Assembly

Overview

This chapter provides information on how to receive, unpack, and assemble the console. If your console was delivered and set up by a ZOLL representative, you may skip this chapter and go to Chapter 4.

Inspection for Damage

Each console is carefully inspected before it is shipped. When the carrier delivers your console, ensure that the shipping containers are not damaged. Visually inspect the outside of the shipping container for any damage. If damage is detected, notify ZOLL Customer Service and file a damage claim with the carrier.

Required Tools

To safely unpack, inspect, and assemble the console, the following tools are required:

- Phillips screwdriver[1]
- 3/16-inch Allen wrench[1]
- 5/32-inch Allen wrench[1]
- 7/64-inch Allen wrench[1]
- Scissors or box knife

Unpacking

Caution. Avoid lifting injury. The console weighs 107 lb (49 kg). Never attempt to lift the console without assistance. Use safe lifting practice when handling the equipment.

To unpack the console:

1. Cut and remove the straps from the carton and pallet.
2. Open the top flaps of the carton and remove the inner carton containing the display head, console handle, condensate pan, and other parts.
3. Remove the protective inserts and lift the outer carton up and off.
4. Use scissors or a box knife to carefully cut away the silver moisture barrier bag surrounding the console. Use care to avoid scratching the console.
5. With the help of an assistant, grasp the base of the console just above the casters, carefully lift the console off the platform, and set it on the floor. The console is heavy; do not lift or move it without assistance.
6. Open the Thermogard HQ Essentials Kit (Essentials Kit) and remove the Display guide, Setup Guide, Tools, Power Cord, Coolant, Documentation, and Maintenance boxes.

1. Included in the Thermogard HQ Essentials Kit.

Figure 3.1. Console unpacked and ready for assembly

Assembly

To assemble the unpacked console, follow these steps in the indicated order.

Handle

1. Attach the handle to the mast using the long bolt and the short screw provided. Use a 3/16-inch Allen wrench to tighten the bolt securely. Use a 5/32-inch Allen wrench to tighten the screw (see Figure 3.2). Do not lift the console by the handle.

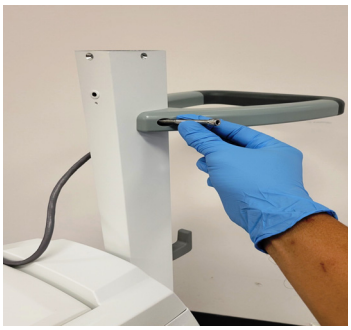


Figure 3.2. Use the long bolt and center screw to attach the handle

Display head

2. Carefully remove the display head from its packaging.
3. Attach the display head to the mast. Hold the pivot assembly perfectly vertical and slide it into the mast opening by applying even, gradual pressure. The pivot assembly fits into the mast only in one direction.

Figure 3.3. Attach the display head to the mast

4. Secure the display head to the mast by installing four screws in the holes provided at the top of the mast. Use a Phillips screwdriver to tighten the screws securely.

Accessory hooks

Note. Hooks and screws are in the Essentials Kit.

5. Attach the gray accessory hook to the front of the mast using the short bolt provided. Use a 7/64-inch Allen wrench to tighten the bolt securely.
6. Attach the other gray accessory hook to the rear of the mast using the same procedure.

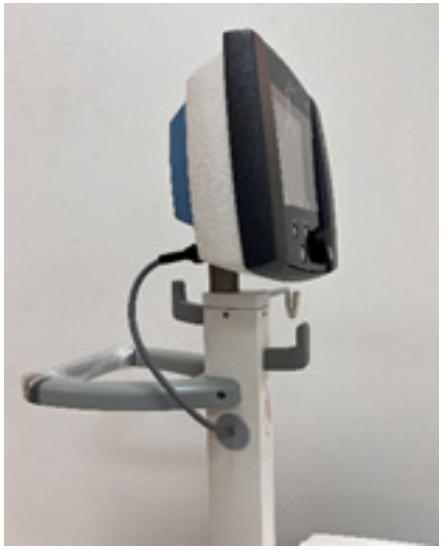


Figure 3.4. Console with front and rear accessory hooks attached

Control cable

7. Connect the control cable to the socket on the lower right rear corner of the display head. Align the plug with the socket and gently push the plug into the socket until it is seated. Turn the retaining collar approximately two full turns clockwise to lock the plug in the socket.

Figure 3.5. Plug the control cable Into the socket

Power cord

Note. Power cord is in the Essentials Kit.

8. Plug the female end of the power cord into the recessed power inlet connector. Wrap the power cord around the two cord hooks on the rear of the console.

Condensate pan

9. Remove the condensate pan from its packaging and install it in the slot under the front of the console. See Figure 7.1.

Saline bag insulating jacket

10. (Optional) Remove the saline bag insulating jacket (in the Essentials Kit) from its packaging and hang it on the saline bag hook.

Assembly is complete.

4. Operation

Overview

This chapter explains how to:

- Set up the console
- Start treatment
- Change patient target temperature and other settings
- Download treatment data

Operating States

The console has three operating states: Setup, Standby and Run.

Setup

When the console first powers on, it goes through a sequence of Power On Self Tests (POST) It tests its electronics, internal sensors, thermometer functions, and cooling engine. It is normal to hear two beeps during POST.

You can preset the coolant temperature so that the console is either cooling or warming the coolant in Setup.

Patient temperature alarms are not active in Setup.

Console self tests

The console performs self tests to check its own performance both at initial power-on and then hourly during operation.

Thermometer functions self test

The console checks the primary patient temperature monitoring circuit (T1) during Setup and then hourly against its internal high resolution calibration resistor. This is a quick test.

Cooling engine self test

During Setup and then every four hours, during Run, the console automatically tests its cooling engine and heating functionality. This test takes a few minutes.

The cooling engine self test briefly stops the roller pump to remove the heat load from the patient during the test. This is normal. The tests that are conducted depend upon the state of the console at the time of the test. The tests are:

Coolant Temperature	Heating Test	Cooling Test
<10 °C	✓	✖
10 °C - 38 °C	✓	✓
> 38 °C	✖	✓

✓ = will be performed ✖ = will not be performed

You do not see any screen messages unless there is an abnormal result, which triggers the appropriate alarm.

Sensor Checks

For the console to enter the next state, Standby, the following sensors must be checked and found normal. Any incomplete checklist items are unchecked in the System Setup window (Figure 4.6). When all checklist items are complete and checked, the console progresses to Standby.

Checklist item	If unchecked, do the following
Coolant well full	The coolant level is low. Fill the coolant well with coolant until the coolant level reaches the MAX line.
Roller pump lid closed	The clear plastic roller pump lid is not closed properly. Close the roller pump lid.
Air trap primed and placed in chamber	There is no Start-Up Kit or Surface Start-Up Kit installed or there is a large amount of air in the air trap chamber. See "Start-Up Kit or Surface Start-Up Kit" on page 60.
Prime button inactive	The Prime button is active (blue light on). Press the Prime button to deactivate it (blue light off). The Prime button must be inactive to proceed to Standby.

Table 4.1. Setup Sensor Checks

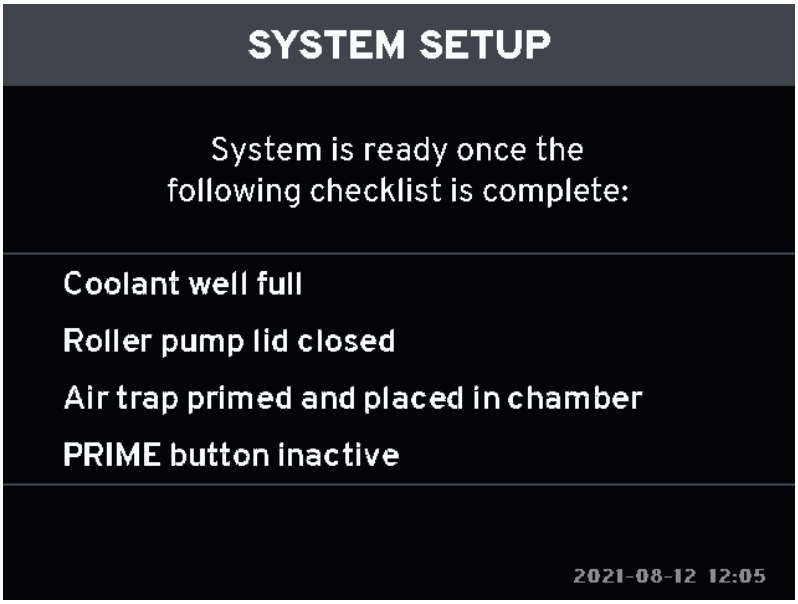


Figure 4.6. System setup checklist screen

Note. Presence of patient temperature probes. The console can enter Standby but not Run without the T1 patient temperature probe connected to the console.

Standby

In Standby, you can select the target temperature, rate, and mode. Patient temperature alarms are active in Standby if the T1 patient temperature probe is connected. From Standby, you can toggle in and out of Run.

You can return to Setup only by powering off the console.

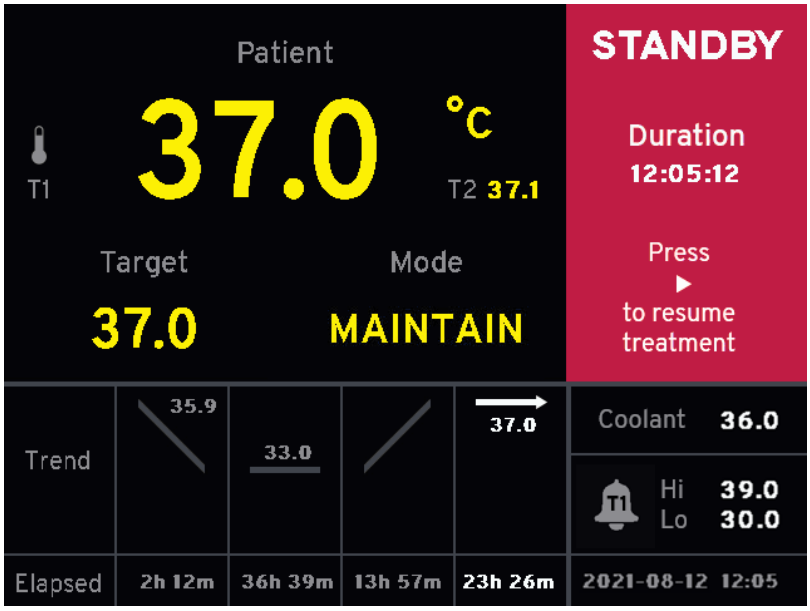


Figure 4.7. Operating screen - Standby

Run

Once you are ready to begin treatment, you can move from Standby to Run. The console becomes fully operational provided that all its sensors indicate that it is ready. Alerts trigger if it is not.

There are three modes in Run: Max Power, Controlled Rate and Fever Control. All three modes are indicated for use with IVTM catheters.

Caution. Mode selection with the Surface Start-Up Kit. The Surface Start-Up Kit is only intended to be used with Fever Control Mode.

Max Power (MAX)

In this mode, the console aims to make the patient's temperature the same as the selected target temperature. The roller pump may stop temporarily when:

- The patient temperature is the same as the target temperature, or
- When you change the target temperature from cooling the patient to warming the patient, or vice versa. The roller pump automatically resumes operating to make the patient's temperature the same as the target temperature.

Controlled Rate

In this mode, the console attempts to move the patient's temperature to the target temperature at the programmed rate of heat exchange (°C /hr). When the patient reaches the target temperature, the console reverts to MAX mode, i.e. it attempts to make the patient's temperature the same as the selected target temperature.

Note. Controlled Rate can be used in both warming and cooling the patient.

Fever Control (FVR)

In this mode, the console starts cooling the patient once the patient temperature is above the target temperature. It does this by keeping the coolant at its coldest permissible temperature and then operating the roller pump whenever the patient's temperature moves above the target temperature.

WARNING. Lo patient temperature alarm limit with Fever Control. The console does not warm the patient when the Fever Control mode is selected. The Lo patient temperature alarm limit ensures that an alarm occurs should the patient stop regulating his/her own body temperature. Such patients cool to room temperature. This can occur when the patient dies or becomes comatose. **Investigate all patient temperature alarms.**

Console Controls

The controls and display screen are illustrated in Figure 2.2 on page 21.

Display Screen

Figure 4.8 shows the screen during Run:

1. The patient temperature, as shown by the primary patient temperature probe (T1) and secondary patient temperature probe (T2)
2. The programmed target temperature
3. The programmed Mode/Controlled Rate value
4. Power expended by the console, as a percentage of its maximum capacity, to warm or cool the patient
5. Trend log
6. Coolant temperature
7. Lo or TrakLo and Hi primary patient temperature (T1) alarm values

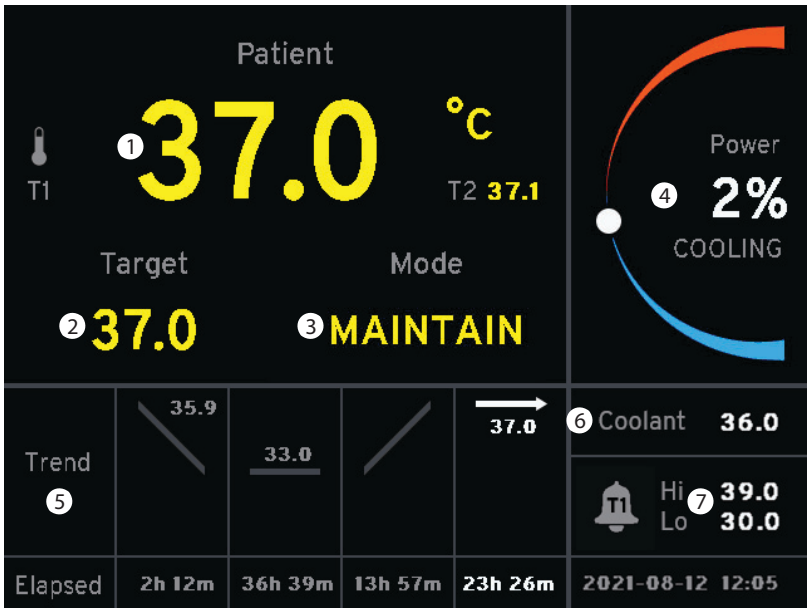


Figure 4.8. Operating screen

Trend Log

The trend log displays a high-level overview of the patient's treatment history. The trend log includes up to four tiles. Each tile represents one treatment segment. The tile farthest to the right is highlighted and shows the

current (active) segment. Tiles to the left show previous segments. Each tile displays time elapsed (in hours and minutes) within the segment.

After initiating warming or cooling of the patient to a new target temperature, a new tile appears, showing a line angled upward or downward. Upon powering on the console, if the initial patient treatment is warming or cooling, then the initial patient temperature is also shown within the tile.

When the patient temperature comes within 0.5°C of the target temperature, a new tile appears, showing a horizontal line and the target temperature. This indicates that the patient temperature is being maintained. The horizontal line remains highlighted as the current (active) segment until a new target temperature is set.

For a graph showing a detailed patient treatment history, see Temperature Trend Graph on page 72.

Changing Target Temperature

1. Press the Target Temp button once.
2. If you are in Run, you are taken to Standby. The target temperature can only be changed in Standby.
3. To change the target temperature, turn the Menu/Enter knob until the desired temperature is displayed. You can choose a temperature from 31°C to 38°C (87.8°F to 100.4°F). When the correct selection is displayed, press the knob once to enter the selection.
4. The target temperature is updated on the display screen.

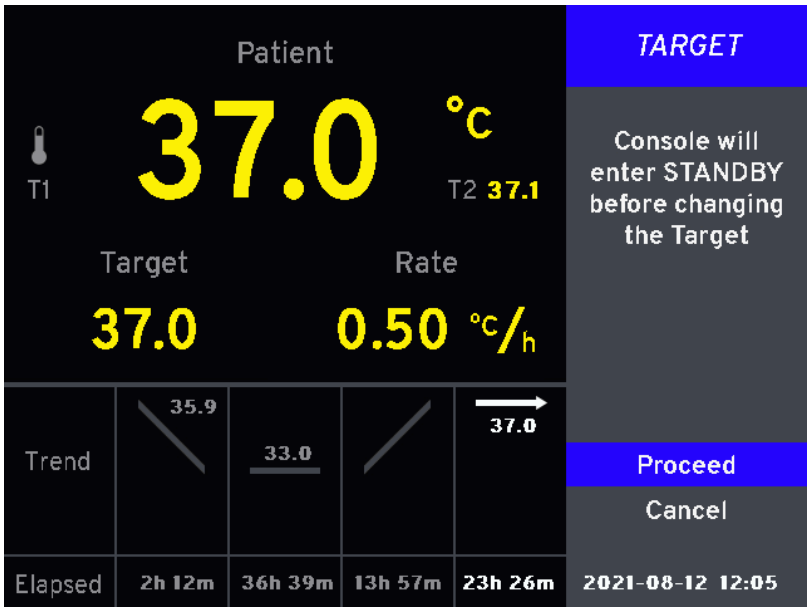


Figure 4.9. Change target temperature in Run

Changing Mode

To select the mode (Run on page 37), use the Mode/Rate button.

1. Press the Mode/Rate button once. If you are in Run, you are taken to Standby. The mode value can only be changed in Standby.

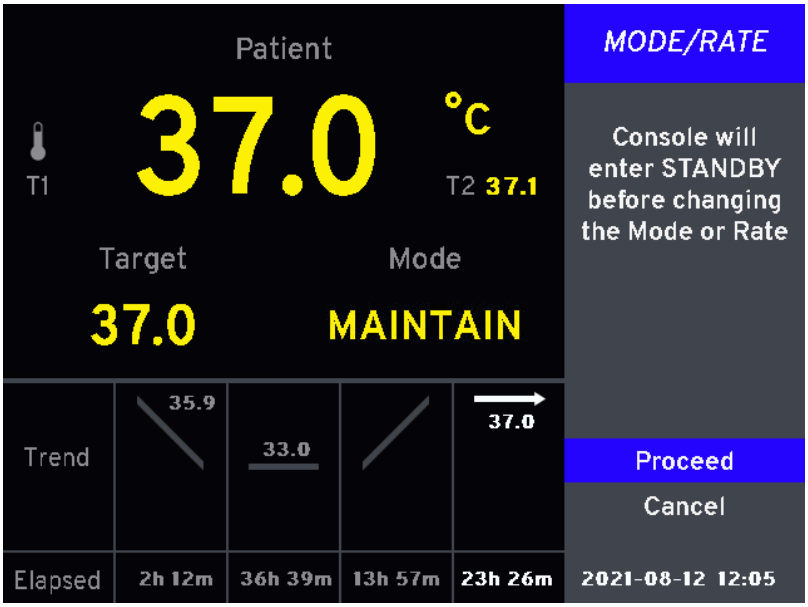


Figure 4.10. Change Mode/Rate in Run

2. Turn the Menu/Enter knob until the desired mode is selected. Press the knob once to enter the selection.

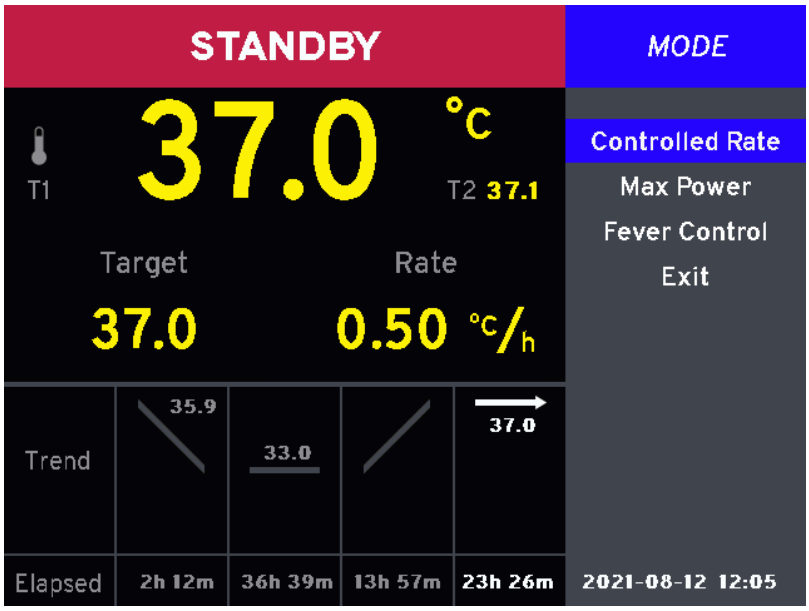


Figure 4.11. Select mode

3. If you select Controlled Rate, a second menu appears. To change the Controlled Rate, turn the Menu/Enter knob. You can choose a rate from 0.10°C/hr to 0.65°C/hr. Press the knob once to enter the selection.

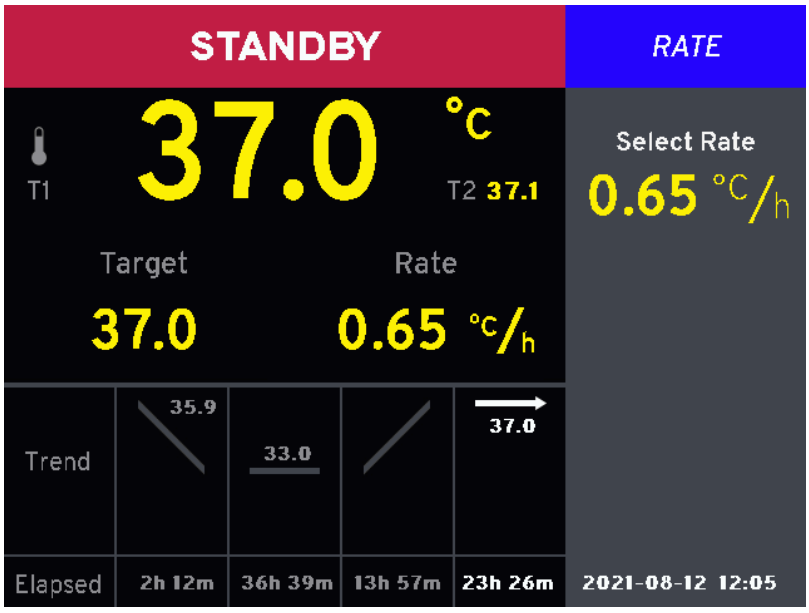


Figure 4.12. Select Controlled Rate

4. If you selected Fever Control mode, you are asked to confirm your selection with the reminder that Fever Control mode only cools and does not warm (Figure 4.13).

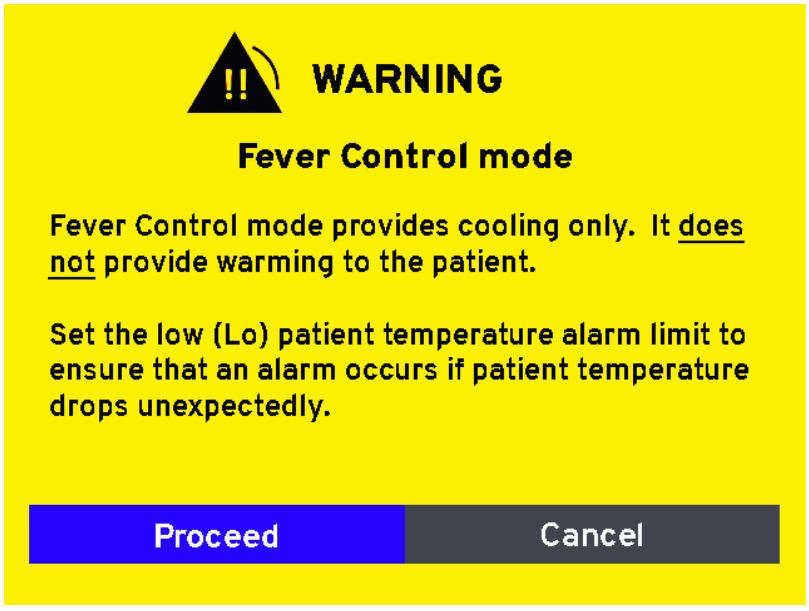


Figure 4.13. Fever Control mode confirmation message

5. The display screen is updated to reflect your selection.

Note. Target temperature in Fever Control mode. The console keeps the coolant cold and starts the roller pump when the patient temperature is greater than the target temperature.

Console Menus

Main Menu

To access the main menu (Figure 4.14), press the Menu/Enter knob. Some settings are accessible only in Standby. Available options are:

View Graphs	Takes you to a display of the patient temperature data log. See “Temperature Trend Data” on page 71.
Settings	Takes you to the Settings Menu (page 43).
Exit	Closes the menu. The coolant temperature replaces the menu.

Table 4.2. Main menu

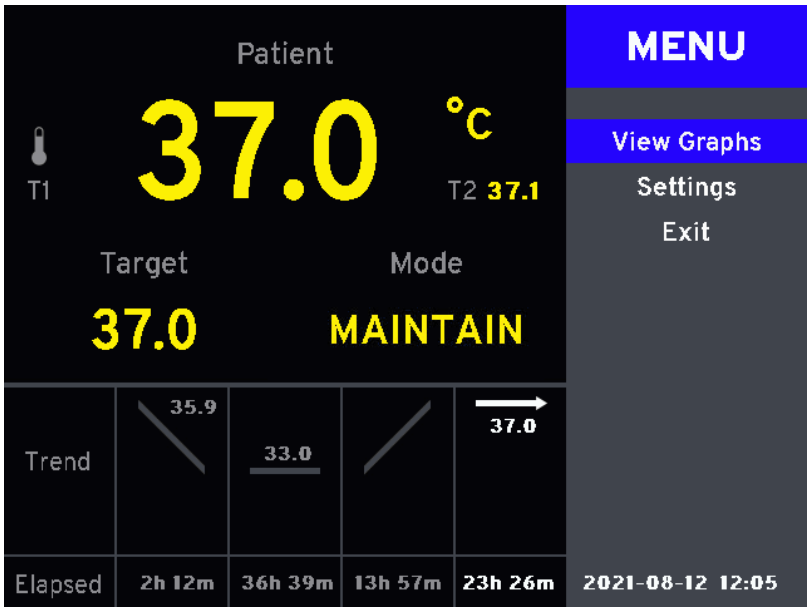


Figure 4.14. Main menu

Settings Menu

The Settings menu (Figure 4.15) allows you to modify the information on the operating display:

Hi/Lo Alarms	Allows you to modify the low (Lo) and high (Hi) patient temperature alarms.
Time and Date	Allows you to modify the console time and date.
°C / °F	Allows you to toggle between displaying temperatures in degrees Celsius or degrees Fahrenheit.
Coolant Preset	Allows you to set the console to either Warming or Cooling the coolant during Standby.
Language	Allows you to select the display language.
Standby Timer	Provides you with a warning alarm after the console has been in Standby for either 15 or 60 minutes. This alarm can be deactivated.
Exit	Closes the menu.

Table 4.3. Settings menu

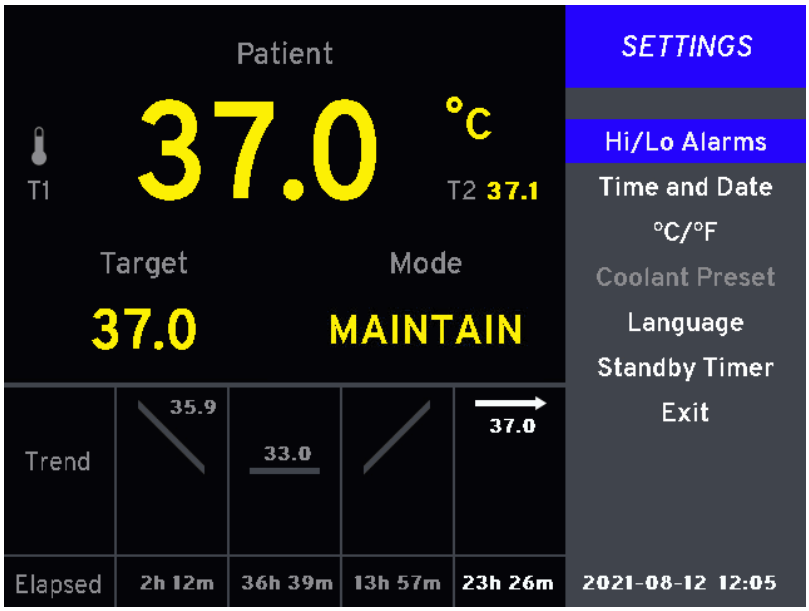


Figure 4.15. Settings menu

Hi/Lo Patient Temperature Alarms

The console features two patient temperature alarms: Hi and Lo. The console triggers an alarm whenever the patient's temperature is higher than the Hi patient temperature alarm value and whenever the patient's temperature is lower than the Lo patient temperature alarm value. The range of values for the Hi and Lo alarms is 28°C – 45°C (82.4°F – 113.0°F).

TrakLo Patient Temperature Alarm

Note. The TrakLo feature is not available in all regions.

If a patient's temperature is lower than the Lo alarm limit [28°C (82.4°F) by default], the Lo alarm is repeatedly triggered until the patient's temperature rises above this limit, which could take hours. The TrakLo feature is designed to avoid alarm fatigue in this situation.

When the TrakLo alarm is activated, it replaces the Lo alarm. The TrakLo alarm limit is displayed (Figure 4.16).

Note. The TrakLo alarm can only be activated if the patient's temperature is lower than the Lo alarm limit.

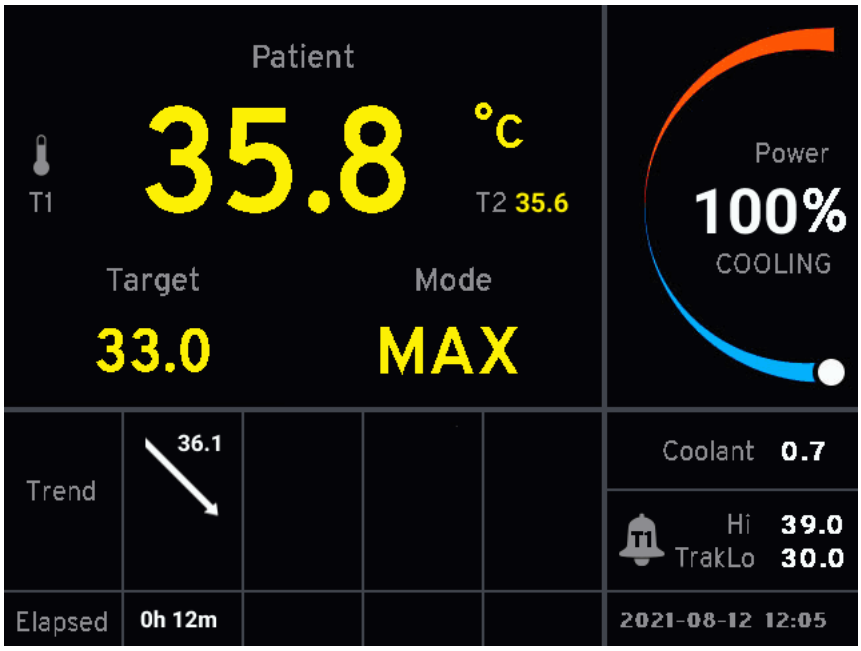


Figure 4.16. TrakLo patient temperature alarm

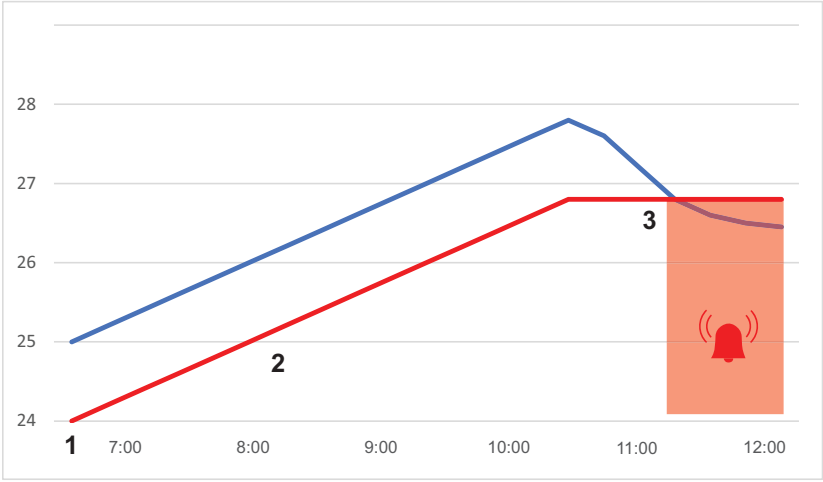


Figure 4.17. TrakLo alarm behavior

	Patient temperature
	TrakLo alarm limit

- The initial TrakLo alarm limit is set at 1°C below the current patient temperature (1 in Figure 4.17). The lowest the TrakLo alarm limit can be set to by the system is 13°C (54.5°F). The TrakLo alarm limit will be automatically set to 13°C only if the initial patient temperature is at or below 14°C (57.2°F).
- As the patient temperature rises, the TrakLo alarm limit also rises to maintain 1°C below the patient temperature (2 in Figure 4.17).

- If the patient temperature drops by more than 1°C, the TrakLo alarm sounds. The TrakLo alarm limit remains the same, at the highest recorded patient temperature since the TrakLo alarm was activated (3 in Figure 4.17).
- When the patient temperature rises back up to above the TrakLo alarm limit, the console turns off the TrakLo alarm sound.
- When the patient's temperature reaches 1°C higher than the previously set Lo alarm limit, the TrakLo alarm deactivates and the Lo alarm reactivates.

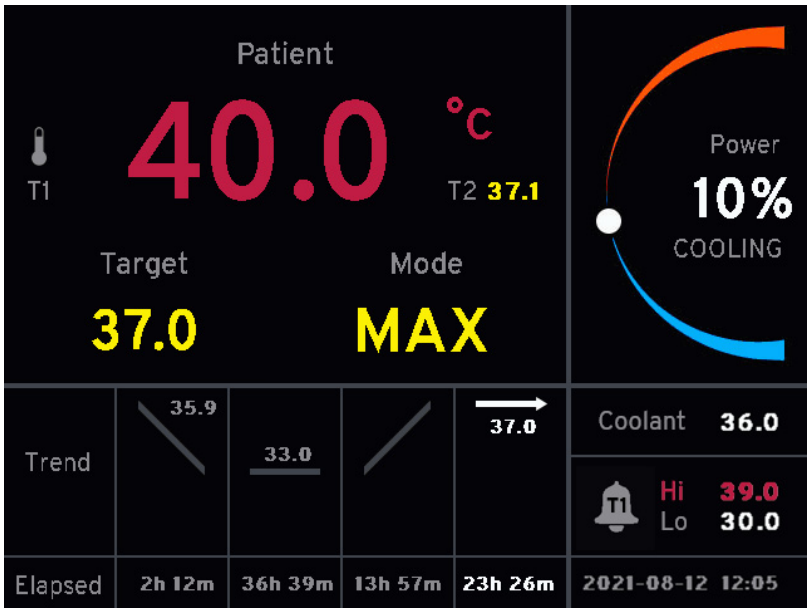


Figure 4.18. Hi patient temperature alarm

The alarms are both visual and audible. The alarms clear when the patient's temperature no longer triggers the alarm.

Press the Mute button to temporarily mute the alarm beep for 2 minutes. The alarm continues after that time unless it has cleared.

The visual alarm displays the patient temperature in flashing red text. The visual alarm does not stop until the alarm has cleared.

WARNING. Setting of patient temperature alarms. The patient temperature alarms are programmable. They cannot be deactivated.

Note. Patient temperature alarms in Standby. If the console is in Standby and the T1 patient temperature probe is connected to the console but not inserted into the patient, a Lo patient temperature alarm can be triggered if the ambient temperature of the exposed probe is below the alarm limit. To avoid the alarm under these conditions, unplug the T1 patient temperature probe from the console until you are ready to connect to the patient. You cannot enter Run without the T1 patient temperature probe connected to the console.

Setting the Alarms

The alarm values can be set in either Standby or Run. To set the patient temperature alarms:

1. Press the Menu/Enter knob. The Main menu appears.
2. Select Settings and press the Menu/Enter knob.
3. Select Hi/Lo Alarms.
4. From the Hi/Lo Alarms menu:
    - To set the Lo alarm value:

a. Select Lo Alarm. The Lo alarm value appears.

Note. If the TrakLo alarm is active, entering the Lo Alarm menu deactivates the TrakLo alarm and reactivates the Lo alarm.

b. Turn the knob until the desired value is displayed and press the knob.

- To set the Hi alarm value:

  a. Select Hi Alarm. The Hi alarm value appears.

  b. Turn the knob until the desired value is displayed and press the knob.

- To set the TrakLo alarm[1]:

  a. Select TrakLo Alarm.

  b. To confirm, select Proceed.

Coolant Preset

The menu allows you to select from either: Cooling, Warming, or No Preset. This selection operates only in Standby and is canceled when the console enters Run.

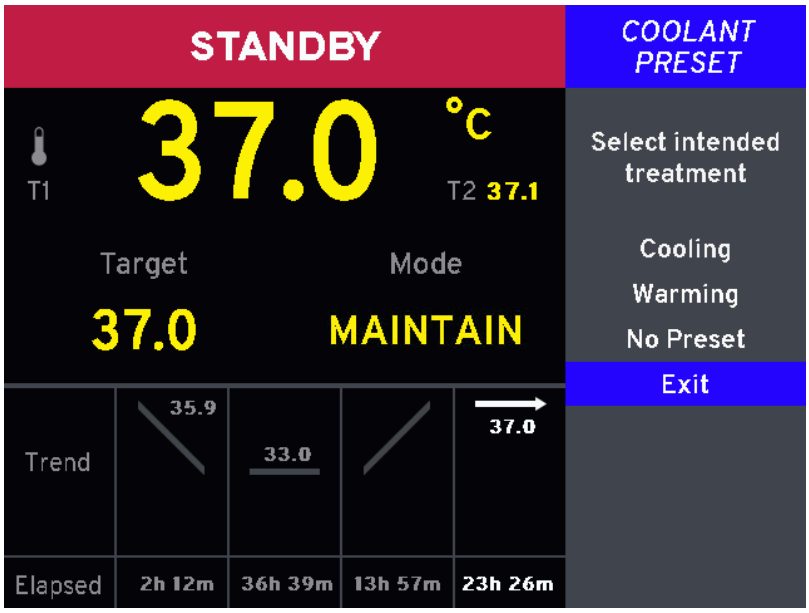


Figure 4.19. Coolant Preset menu

Cooling	The console coolant is cooled to its lowest permitted temperature and maintained at that temperature.
Warming	The console coolant is heated to its highest possible temperature and maintained at that temperature.
No Preset	No Preset maintains the coolant temperature at the time of selection.
Exit	Closes the menu without a change in console status or programming.

Table 4.4. Coolant Preset menu

1. The TrakLo feature is not available in all regions. Available only if the patient's temperature is lower than the Lo alarm limit.

Time and Date

This menu displays the current time and date settings.

The time is divided into two fields: hours (designated HH) and minutes (MM). The console uses 24-hour time (e.g., 3:00 p.m. is 15:00).

The date is divided into three fields: year (designated YYYY) - month (designated MM) - day (designated DD). For example, February 24, 1959 is shown as: 1959-02-24.

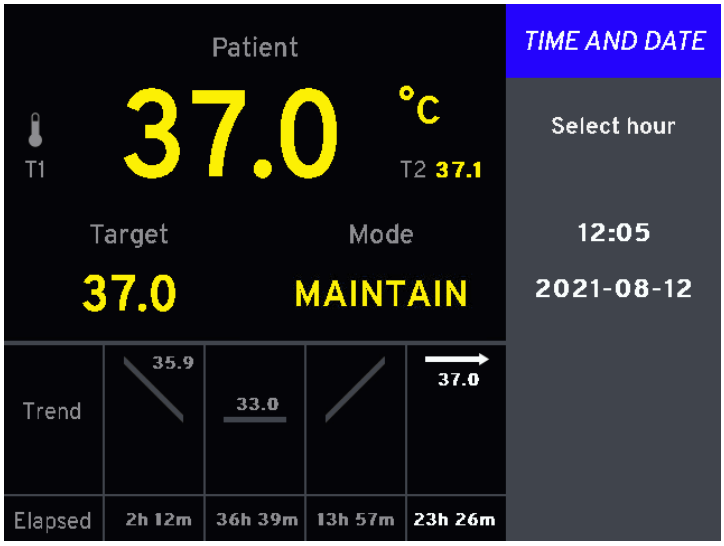


Figure 4.20. Time and Date settings

Time Setting

1. The screen first displays "Select Hour."
2. The numbers displayed in the hour field change as you turn the Menu/Enter knob. When the correct hour is displayed, press the knob once to enter your selection.
3. The screen next displays "Select Minute."
4. Turn the knob until the correct minute is displayed. Press the knob once to enter your selection.

Date Setting

1. The screen displays "Select Day."
2. The numbers displayed in the day field change as you turn the Menu/Enter knob. When the correct day is displayed in the field, press the knob once to enter your selection.
3. The screen next displays "Select Month."
4. Turn the knob until the correct month is displayed. Press the knob once to enter your selection.
5. The screen next displays "Select Year."
6. Turn the knob until the correct year is displayed. Press the knob once to enter your selection.
7. The time and date settings are be updated and the screen displays the Settings menu.

ºC/ºF (Temperature units)

This menu displays the options setting for temperature units. The currently selected setting is highlighted.

- To keep the current selection: Press the Menu/Enter knob once. The current setting does not change and the Settings menu is displayed.

- To change the current setting: Turn the knob to highlight the desired setting. Press the knob once to enter the selection. The setting is changed and the Settings menu is displayed.

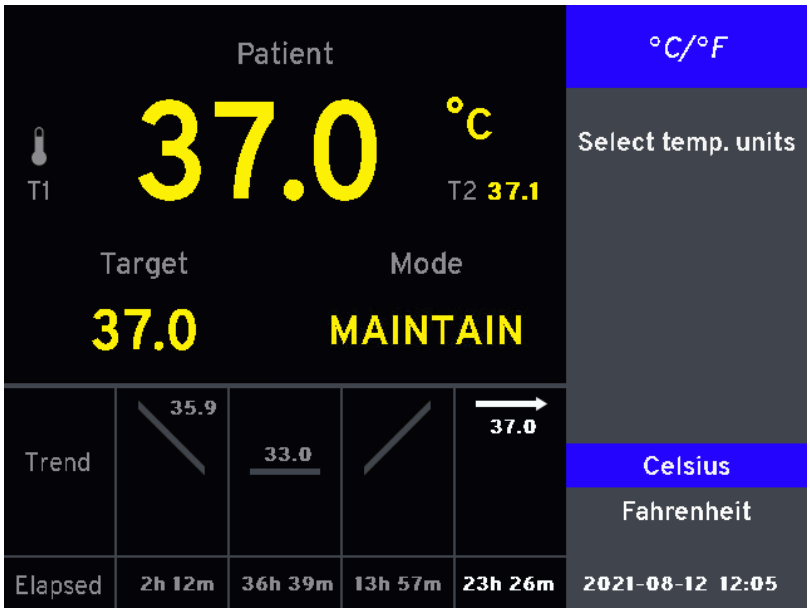


Figure 4.21. Temperature unit settings

Language

This menu displays the language setting. The current language is highlighted.

- To keep the current language: Press the Menu/Enter knob once. The language setting does not change and the Settings menu is displayed.
- To change the language: Turn the knob to highlight the desired language. Press the knob once to enter the selection. The language is changed and the Settings menu is displayed.

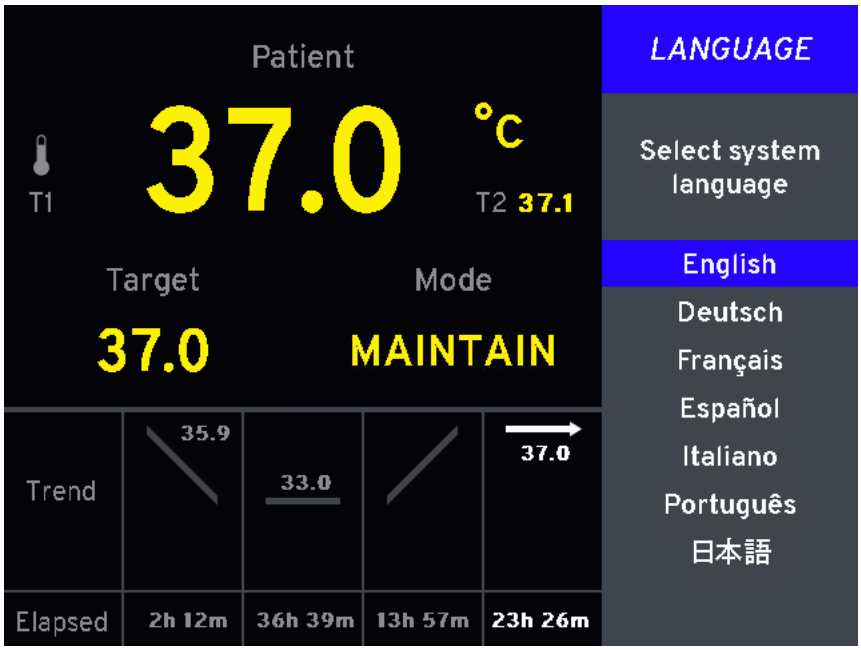


Figure 4.22. Language settings

Standby Timer

The Standby Timer provides an alarm as a reminder when the console has been left in Standby for 15 or 60 minutes. The Standby Timer's selections are: No Alarm, 15 minutes, 60 minutes.

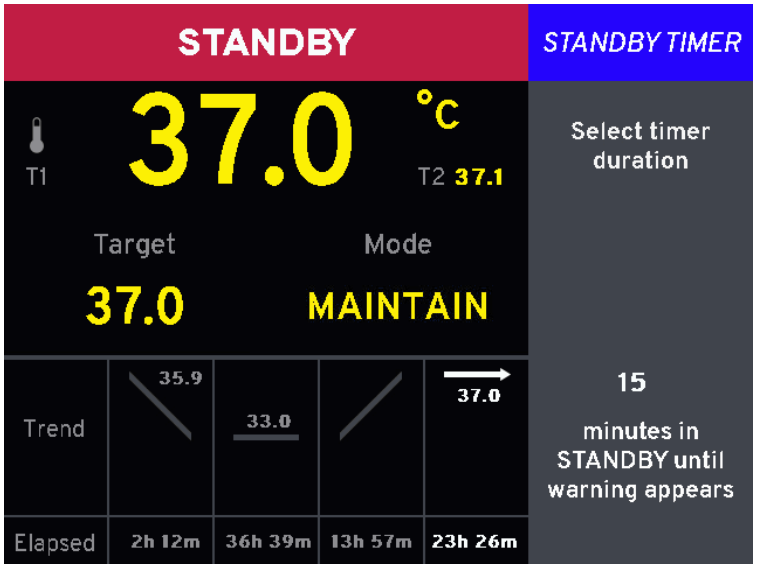


Figure 4.23. Standby Timer menu

If the console has been left in Standby for more than the specified time, an alarm sounds to remind that the console is in Standby. Press the Menu/Enter knob to reset the timer. The Standby Timer function continues until either:

- The console is placed into Run.
- The Standby Timer menu is used to deactivate the Standby Timer.

Press the Mute button to silence the Standby Timer alarm sound for two minutes.

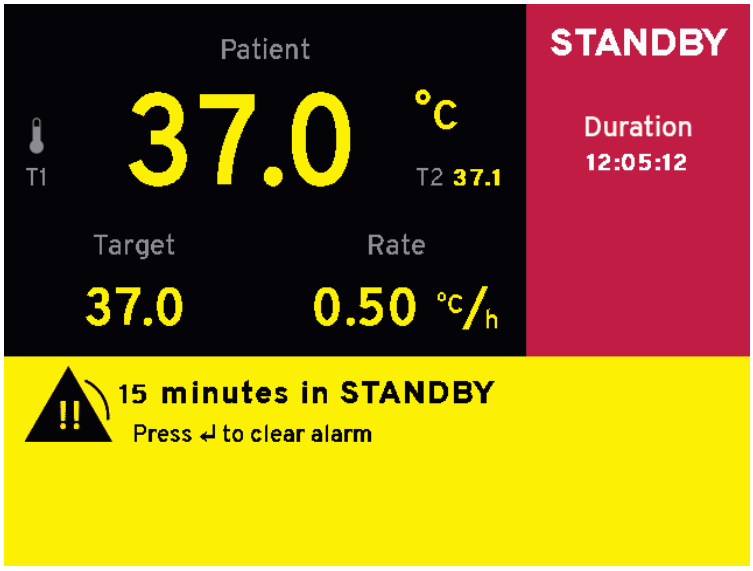


Figure 4.24. Standby timer alarm

T1/T2 Behavior

WARNING. Dislodged Temperature Probe. The console can detect when a patient temperature probe is dislodged suddenly from the patient. However, it is possible for the T1 patient temperature probe to become dislodged from the bladder to rest on the perineum or within the fold of the thighs. In this position, the console may not detect the dislodgement from the patient and will underestimate the patient's core temperature. As a result, the console may inappropriately warm the patient. Failure to use a second temperature probe may result in patient injury.

First Use Warning – No T2 Probe

Each time the console is powered on:

1. The console checks if the T1 and T2 patient temperature probes are present. The console enters Standby without any probes present. The console does not enter Run unless the T1 patient temperature probe is present.
2. When the console is first put into Run, it checks to see which probes are present.
3. If there is no T2 patient temperature probe present, the console asks you to verify that this is intentional. See Figure 4.25.

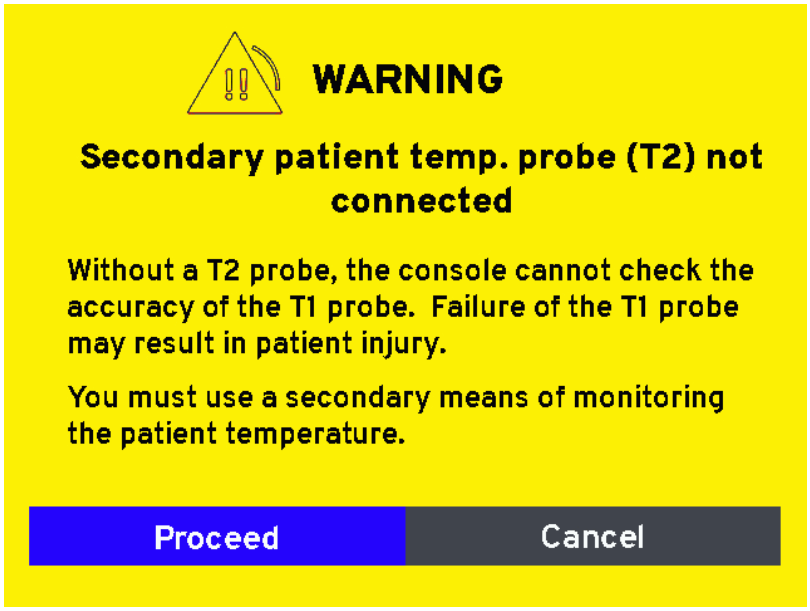


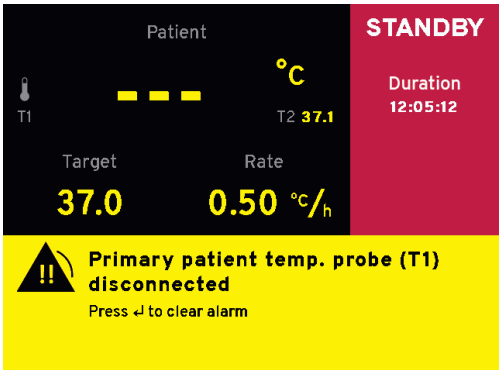
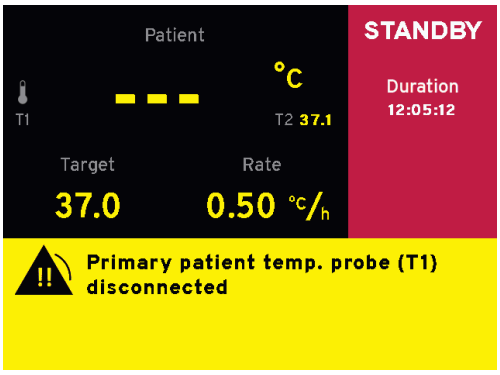
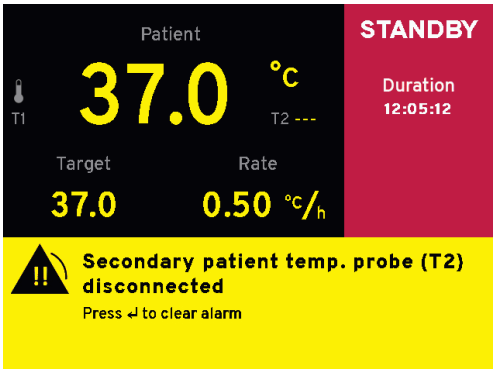
Figure 4.25. Secondary patient temperature probe (T2) not connected warning

T2 Probe Disconnection/Reconnection

If you connect a T2 patient temperature probe at any time during console operation (in Standby or Run), the console assumes that use of the T2 patient temperature probe is desired. If the T2 patient temperature probe is disconnected, the console triggers an alarm – see below.

If you disconnect a T2 patient temperature probe in Standby, the console assumes that this is intentional and does not trigger an alert. When the console is placed into Run without a T2 patient temperature probe present, you see Figure 4.25, "Secondary patient temperature probe (T2) not connected warning," on page 50.

Accidental Disconnection T1/T2 Probe

Disconnection of the T1 patient temperature probe during Run results in an alarm. The console moves to Standby. Press the Menu/Enter knob to mute the alarm. Treatment cannot continue until the T1 patient temperature probe has been replaced. Note that the primary patient temperature is displayed as "---".	
Absence or disconnection of the T1 patient temperature probe during Standby results in an alert (without a persistent alarm beep). The console cannot enter Run until the T1 patient temperature probe has been connected. Note that the primary patient temperature is displayed as "---".	
Disconnection of the T2 patient temperature probe during Run results in an alarm. The console moves to Standby. Press the knob to mute the alarm. If you attempt to return to Run without reconnecting the T2 patient temperature probe, you are asked to verify your intention. Note that the primary patient temperature is displayed correctly if the T1 patient temperature probe remains connected, but the secondary patient temperature (T2) is displayed as "---".	

Alarms & Alerts

Alerts make no sound. The console continues in Run or goes into Standby.

Alarms beep and you must press the Menu/Enter knob to clear the alarm. If an alarm occurs in Run, the console goes into Standby. The exception is if you activate the Prime button during Run – there is no alarm beep.

Alarms and alerts can be cleared by correcting the problem that caused them to occur. For example, a low coolant alert can be cleared by adding coolant to the coolant well of the console. In most cases, the console notifies you to rectify alerts or alarms at power up. See Alarms and Corrective Actions on page 81 and Troubleshooting on page 85. If the alarm persists, call ZOLL for service.

Alerts and alarms are displayed across the lower half of the display screen, with the coolant temperature display obscured, against a yellow background (See Figure 4.26).

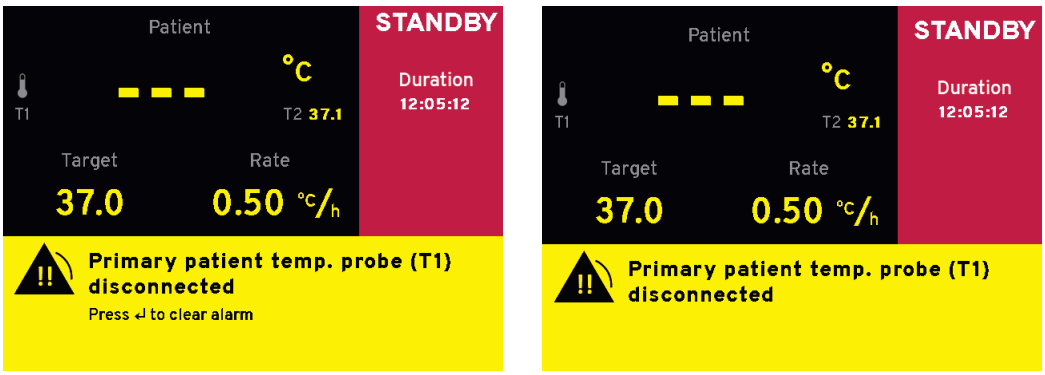


Figure 4.26. T1 patient temperature probe disconnect alarm from Run (left) and alert from Standby (right)

System errors/console malfunctions

A system error/console malfunction is more serious in nature than an alarm and relates to issues that typically require a service call. In most cases a text message, specific to the alarm, identifies the code for the alarm. For example, the screen might announce TCM ID 01 or MID 23 in addition to the text in Figure 4.27.

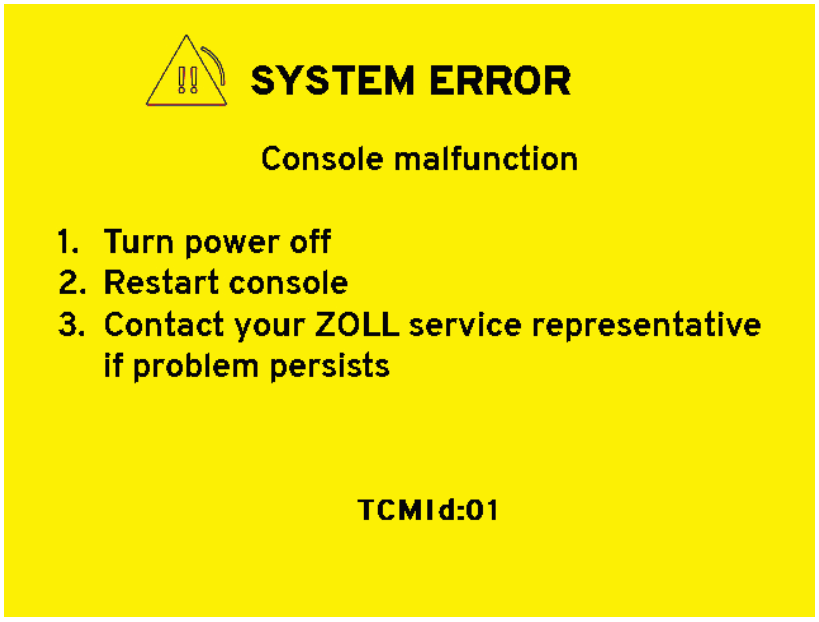


Figure 4.27. System error/console malfunction screen

During an system error/console malfunction, the patient temperature display and the patient temperature alarms are not active.

MID 11 error

The console verifies software integrity at power on. If the integrity check fails, a message with error code MId:11 appears.

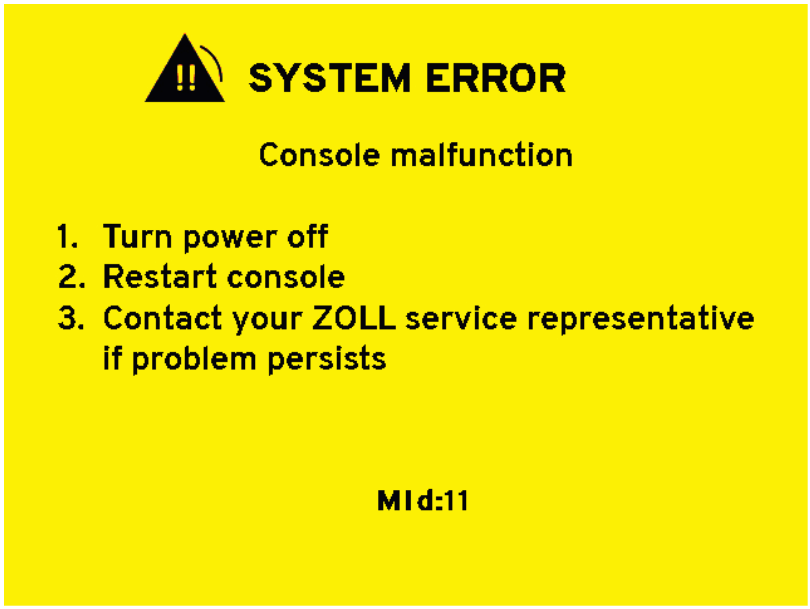


Figure 4.28. System error/console malfunction screen (MID 11)

Required materials

If using the Thermogard HQ system for connection to the surface pad, the following materials are needed:

- A YSI-400 compatible temperature probe e.g. a Foley catheter, rectal or esophageal temperature probe
- The blue patient connection cable to connect the temperature probe to the console
- A surface pad
- A Surface Start Up Kit (non-sterile)
- Access to 2 L of water

If using the Thermogard HQ system with an IVTM catheter, the following materials are needed:

- A YSI-400 compatible temperature probe e.g. a Foley catheter, rectal or esophageal temperature probe
- The blue patient connection cable to connect the temperature probe to the console
- A Start Up Kit for IVTM catheter use (sterile)

  WARNING. Surface Start-Up Kits for surface cooling (non-sterile) are not compatible with IVTM catheter use (sterile).
- An IVTM catheter
- An aseptic work area to support catheter insertion.
- A new 500 mL bag of sterile saline

WARNING. IVTM catheters are inserted via a Seldinger technique similar to a central venous line. See the specific instructions for use included with each catheter to understand its insertion requirements.

Preparing the Console for Treatment

To prepare the console for treatment:

1. Roll the console to a convenient position near the patient's bedside. Plug the power cord into a hospital-grade receptacle.

   Caution. The console left and right side panels contain vents for air flow. Ensure the vents are not covered during operation.

2. Lock a caster by stepping down on the tab above the wheel.
3. At the rear of the console, near the upper left corner is the power switch. Turn the power switch on.

Figure 4.29. Power switch and Power LED

4. The green power LED illuminates and the console emits one long beep followed by a shorter beep.
5. The console performs a self-test. The self-test screen appears. If the self-test detects a problem, an error message is displayed. If this occurs, refer to Alarms and Corrective Actions on page 81 for assistance. At the end of the self-test there are two short beeps.

   Note. The software version shown in Figure 4.30 is shown for reference only; the current product may use a different software version.

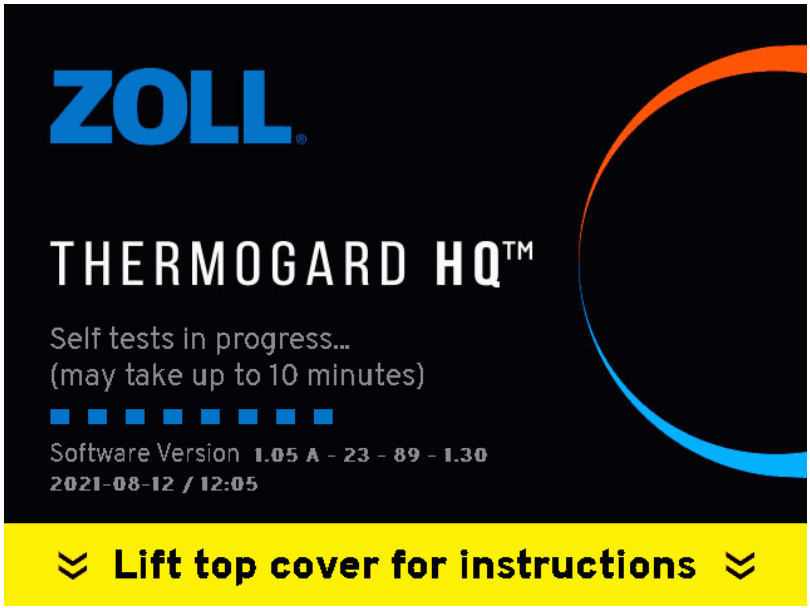


Figure 4.30. Self-Test screen

6. When the self-test is finished, the System Set Up screen displays “Select intended treatment”.

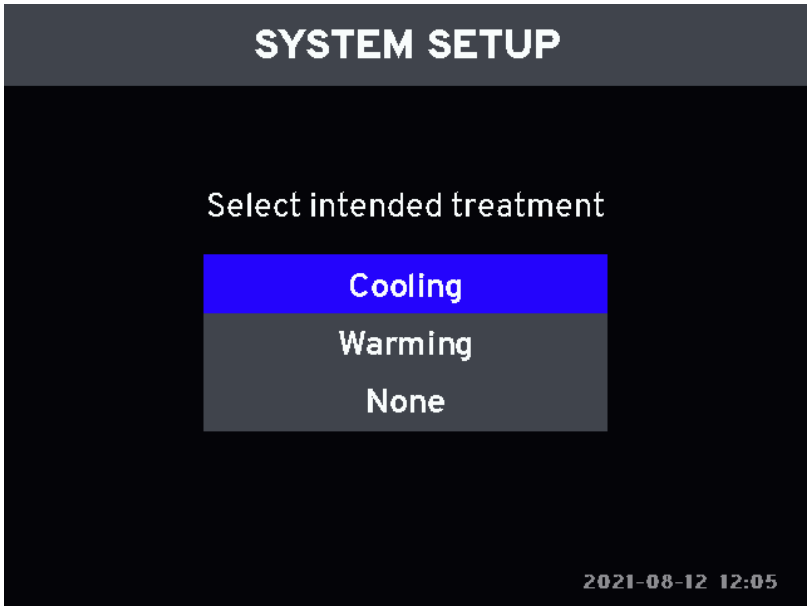


Figure 4.31. Select intended treatment

7. To start cooling or warming the coolant well immediately, choose the desired option and press the Menu/Enter knob (the “knob”) once to enter the selection. If you do not wish to begin cooling or warming the coolant well now, choose None and press the knob once to enter the selection.
8. When asked if this is a new patient, choose Yes or No.The answer is saved to the treatment file. See “Treatment sessions/Log files” on page 76.

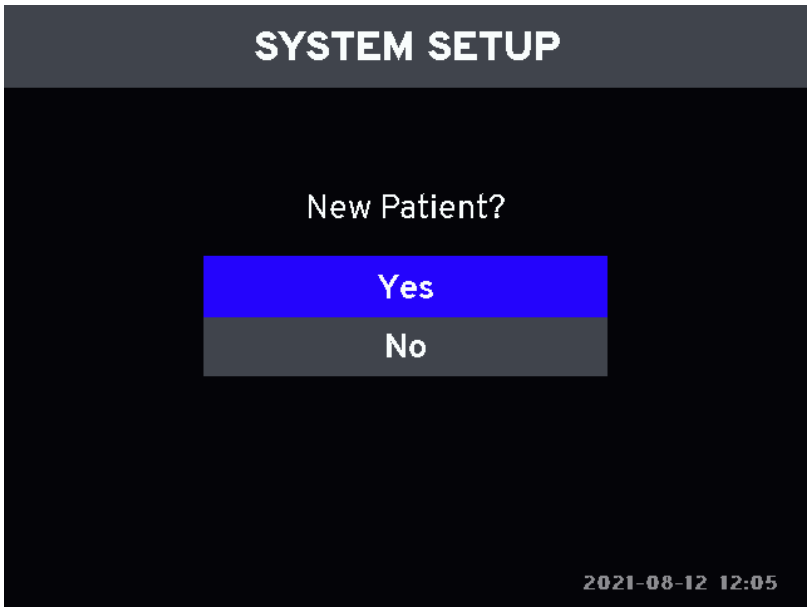


Figure 4.32. New Patient? message

9. The System Set Up screen then displays “Select Target”.

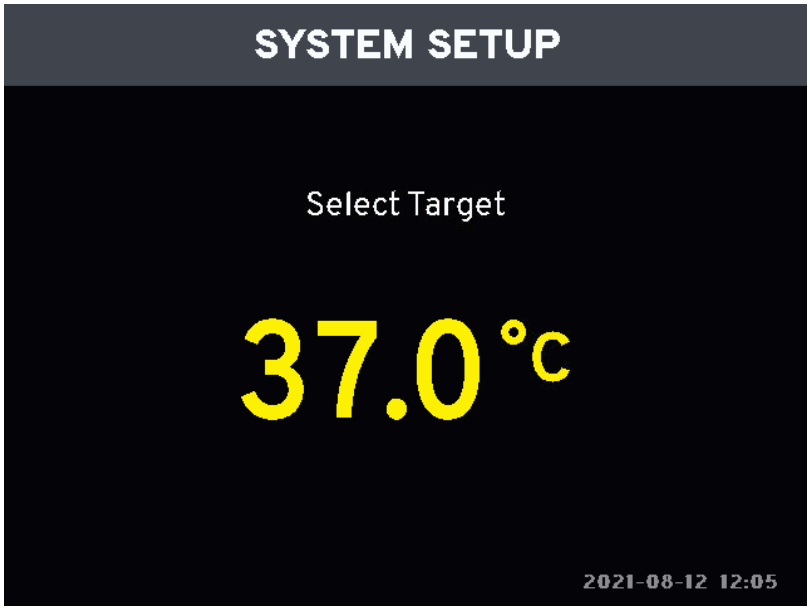


Figure 4.33. Select Target temperature message

10. Turn the knob until the target patient temperature is displayed. Press the knob once to enter the selection.
11. The System Set Up screen displays “Select Mode”. You have three choices: Max Power, Controlled Rate or Fever Control.

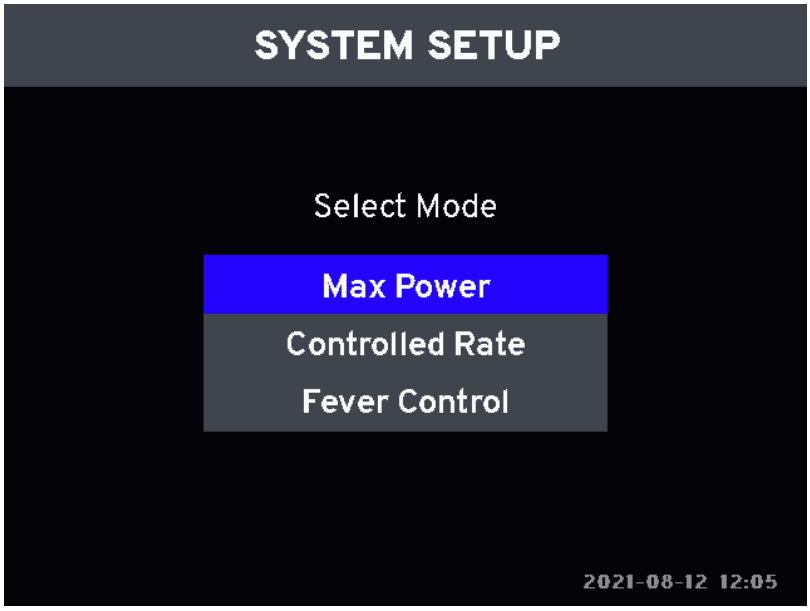


Figure 4.34. Select Treatment mode message

12. Turn the knob to highlight the desired mode. Press the knob once to enter the selection.

Note. Do not select Controlled Rate when using the Cool Line catheter.

Caution. Always use Fever Control mode when using surface pads with the console.

13. If you select the Controlled Rate mode, you are prompted to Select Rate. Use the knob to scroll to the desired rate and then press the knob to select it.

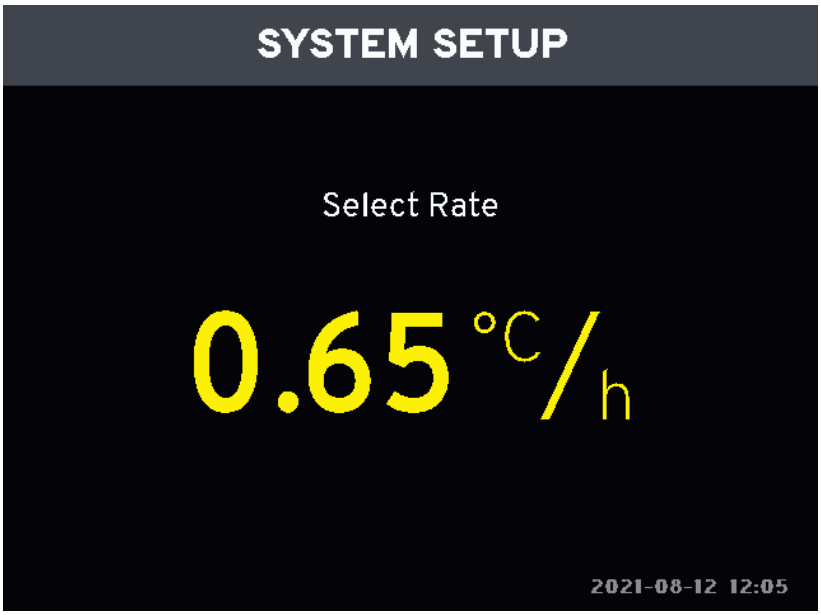


Figure 4.35. Select Rate screen

14. If the console has not yet finished its self tests, the Self-Test screen is displayed (Figure 4.30).
15. Install the Start-Up Kit or Surface Start-Up Kit now. If the console finishes its self test before you complete installing the Start-Up Kit or Surface Start-Up Kit, the System setup checklist screen (Figure 4.36) appears. An unchecked item requires your attention. See Table 4.1, “Setup Sensor Checks,” on page 36.

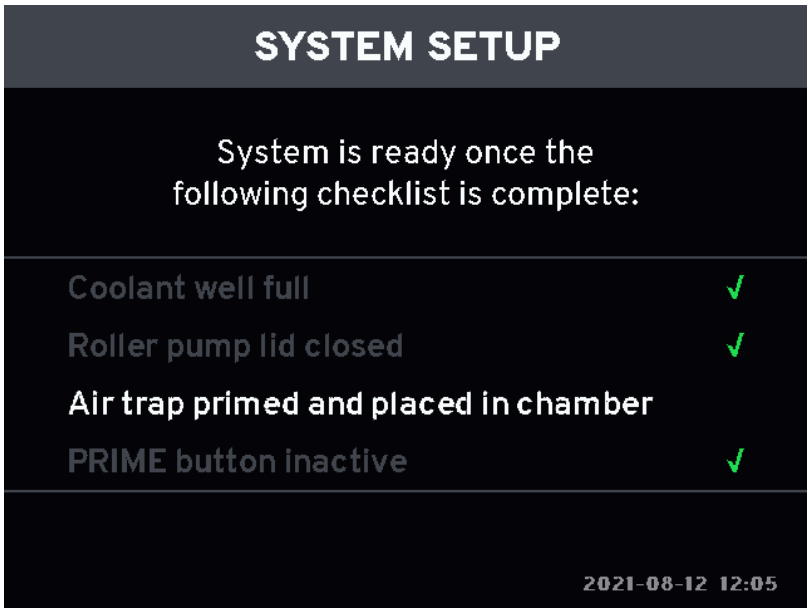


Figure 4.36. System setup checklist screen, Air trap primed and placed in chamber required

Installing the Start-Up Kit or Surface Start-Up Kit

Console Cover

1. Open the console cover.

Figure 4.37. Console cover open

2. An IVTM setup guide is located on the inside of the console cover. Refer to this guide when installing the Start-Up Kit for use with an IVTM catheter. See Figure 2.7 on page 27.

   When using the surface pad with the Surface Start-Up Kit, see the Thermogard HQ Surface Setup Guide (ordered separately, 106942-001).

Coolant well

3. Remove the cap from the coolant well.

Figure 4.38. Coolant well cap

4. Check the level of the coolant. The liquid level should be between the two indicator lines on the wall of the coolant well. If the level is below the bottom indicator line, fill the coolant well with coolant (a ZOLL-approved 50% propylene glycol / 50% deionized water mixture) until the coolant level reaches the MAX line. Add coolant in an area where spills can be managed appropriately.

Figure 4.39. Coolant well liquid level indicator lines

Start-Up Kit or Surface Start-Up Kit

5. Open the Start-Up Kit (Figure 2.6) or Surface Start-Up Kit. For convenience, all items in the Kit are pre-connected.

Prepare the Saline or Reservoir Bag

6. Do one of the following:
   a. If using the Start-Up Kit and an IVTM catheter:

      Hang the 500 mL bag of sterile normal saline on the hook (Figure 4.40).

   b. If using the Surface Start-Up Kit and surface pad:

      Fill the pre-attached reservoir bag with water and fasten the cap. Hang the reservoir bag on the hook (Figure 4.41).

Figure 4.40. 500 mL Saline bag on hook for IVTM catheter use

Figure 4.41. Pre-attached reservoir bag on hook for surface pad use

7. Insert the heat exchange coil into the coolant well.

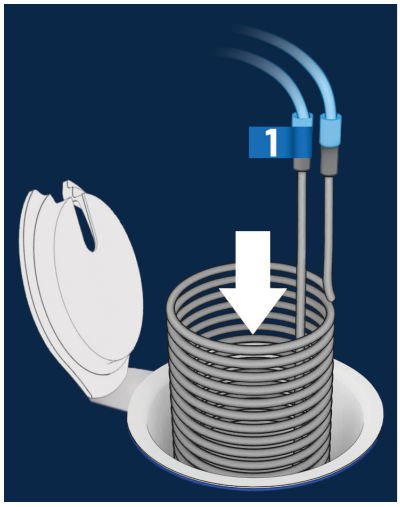


Figure 4.42. Installing the heat exchange coil

8. Close the coolant well cap, passing the tubes through the slit in the cap.
9. Place the air trap into the air trap stand with the orange end down.

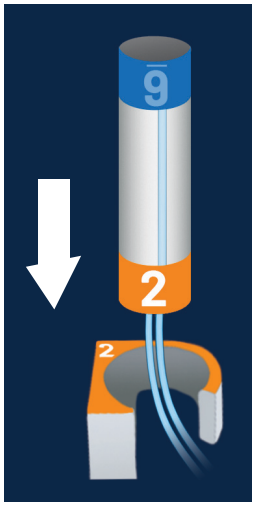


Figure 4.43. Place air trap into air trap stand

Roller Pump

WARNING. Finger injuries. Be careful when inserting the roller pump tubing that you do not catch your fingers in the roller. When the console is operating, do not attempt to circumvent the safety interlocks on the roller pump lid. Do not place fingers or foreign objects into the roller pump raceway when the roller pump is turning. The roller pump has sufficient torque to severely damage a finger.

10. Open the roller pump lid.
11. Fully insert the tubing disc into slot 3 (orange label marked "3").

12. Firmly rotate the pump knob counterclockwise while feeding the tube.

Figure 4.44. Tubing disc

13. Fully seat the tube into groove 3 (blue label marked "3").

Spike the saline bag (IVTM catheter)

14. If using the Start-Up Kit for connection to IVTM catheters: Spike the saline bag. Ensure the spike fully extends into the saline bag.

    Caution. The spike on the Start-Up Kit is relatively long. Be careful not to puncture the side wall of the saline bag when connecting to the Start-Up Kit.

Figure 4.45. Spike saline bag

Connect Surface Pad (Surface Start-Up Kit only)

15. Fully connect both fluid connectors to the surface pad.

    Caution. The tubing must be fully connected to the surface pad (inlet and outlet) before it can be primed.

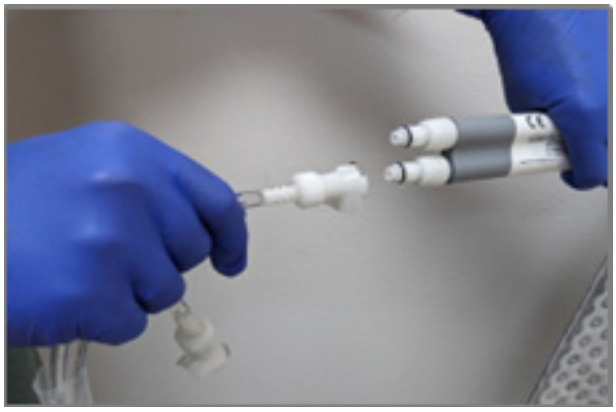


Figure 4.46. Connect tubing to the surface pad

Prime Tubing

16. Close the roller pump lid.
17. Press and release the Prime button.
    - The roller pump runs for 2 minutes.
    - When using the Start-Up Kit for connection to an IVTM catheter, confirm that the Start-Up Kit pinwheel turns and bubbles are cleared.

      Caution. If bubbles continue to circulate after 2 minutes, recheck Step 6 – Step 17.

    - When using the Surface Start-Up Kit:
      - **Caution.** Do not secure the pad to the patient (using the Velcro straps) during priming. Secure the pad at Connecting the Patient to the Console on page 65.
      - When priming completes and the pump stops running, confirm that air trap is full of water. The pinwheel starts to turn approximately 5 minutes after initiating treatment.

        Caution. If the air trap is not full after 2 minutes, recheck Step 6 – Step 17.

Figure 4.47. Prime button and pinwheel

18. Once priming is complete, insert the air trap into the air trap chamber with the blue end down.

Figure 4.48. Insert air trap into air trap chamber

19. Place the tubing to the catheter or surface pad in the two notches at the front of the console. Place the priming line and the fluid return line in the channels leading to the rear of the console.

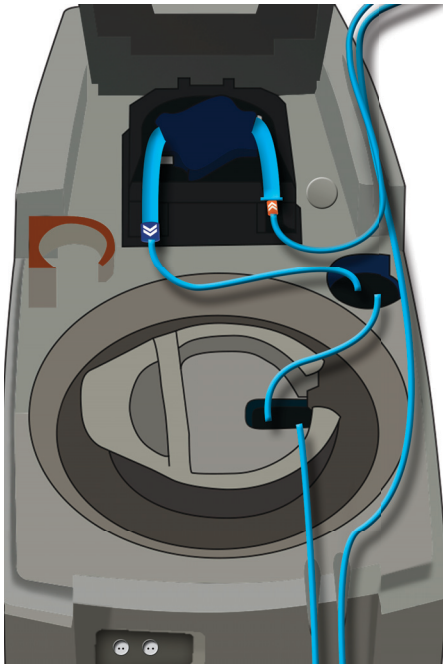


Figure 4.49. Route the tubing out of the console

20. Close the console cover. Ensure the tubing is not pinched by the console cover.

    Caution. Do not sit or place heavy objects on the console cover.

21. If using the Start-Up Kit for connection to an IVTM catheter, lift the 500 mL saline bag off the hook and slip the insulating jacket around the bag. Carefully close the hook-and-loop fasteners at the top and bottom of the jacket. Rehang the bag on the hook.

22. When the self tests are complete and the Start-Up Kit or Surface Start-Up Kit is loaded and primed, the console enters Standby. The console is ready to be connected to the patient.

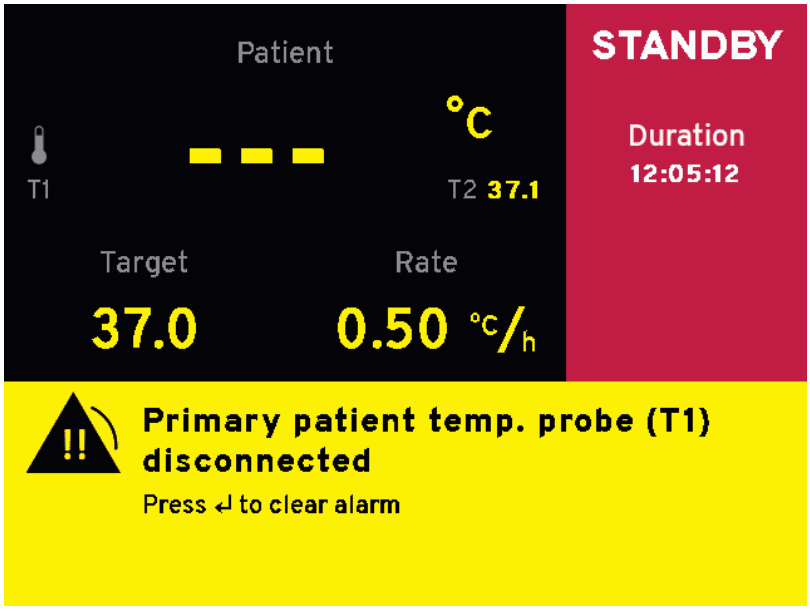


Figure 4.50. Standby screen – T1 patient temperature probe not connected

Connecting the Patient to the Console

WARNING. Verify console function first. Ensure proper functioning of the console and initiate cooling or warming the coolant (if applicable) prior to placing the catheter in or the surface pad on the patient.

When the console has been prepared as directed in the preceding sections, move it to the patient's bedside and connect to the patient as follows:

1. Position the console near the patient's bed. It must be close enough so that the temperature probe cables and the tubing can conveniently reach the patient. Route the cables and tubing safely.

Place Surface Pad

2. Place the surface pad under the patient.

   Caution. Do not secure the Velcro straps at this time. Do not secure the surface pad until Step 14 below.

   Note. The surface pad may be disconnected from the tubing while positioning it under the patient.

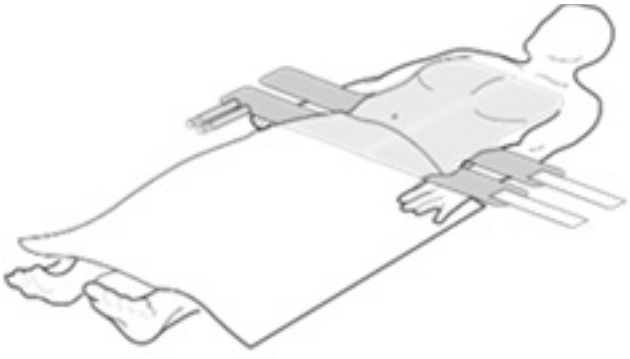


Figure 4.51. Surface pad under the patient

3. Check surface pad connections. Ensure the surface pad is fully connected to the tubing. Both fluid connectors should click when fully engaged.

Figure 4.52. Surface pad connected to tubing

Connect probe

4. If the primary and secondary patient temperature probes have not been placed in the patient, do it now. Refer to the temperature probe Instructions for Use.
5. Connect the blue patient temperature cable to the YSI-400 primary temperature probe (e.g. Foley catheter, rectal or esophageal). Connect the plug at the end of the blue patient temperature cable into the T1 connector on the front of the console.

Figure 4.53. Temperature probe connections

6. If you are using a secondary patient temperature probe, connect the blue patient temperature cable to the YSI-400 secondary temperature probe. Connect the plug at the end of the blue patient temperature cable into the T2 connector on the front of the console. If you are not using a secondary temperature probe, the patient must be monitored by a separate hospital patient temperature monitor.

Catheter placement and connection (for IVTM use)

7. If using the Start-Up Kit and an IVTM catheter, place the catheter in the patient. Refer to the catheter Instructions for Use.

8. If using the Start-Up Kit and an IVTM catheter, the Start-Up Kit tubing to the catheter is supplied with the supply and return connectors connected to each other. Using aseptic technique, disconnect the two connectors.

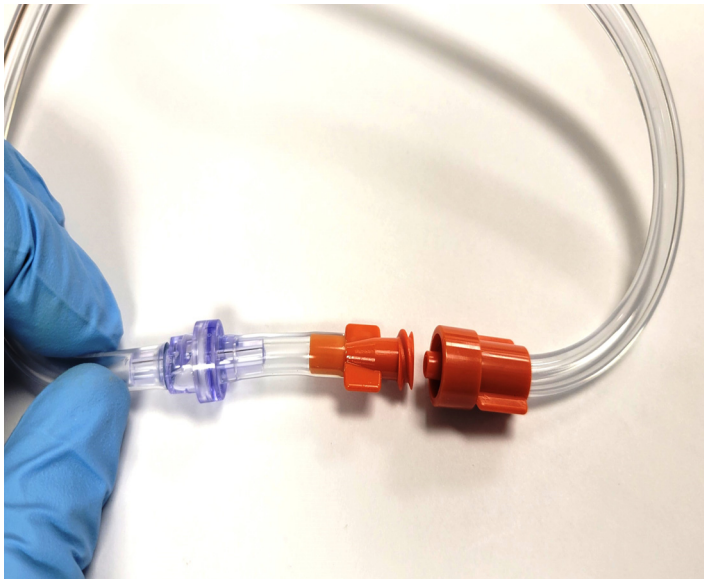


Figure 4.54. Disconnect the connectors using aseptic technique

9. If using the Start-Up Kit and an IVTM catheter, connect the Luer connectors on the Start-Up Kit to the catheter. The gender of the tubing connectors and the catheter connectors ensures that they cannot be connected backwards.

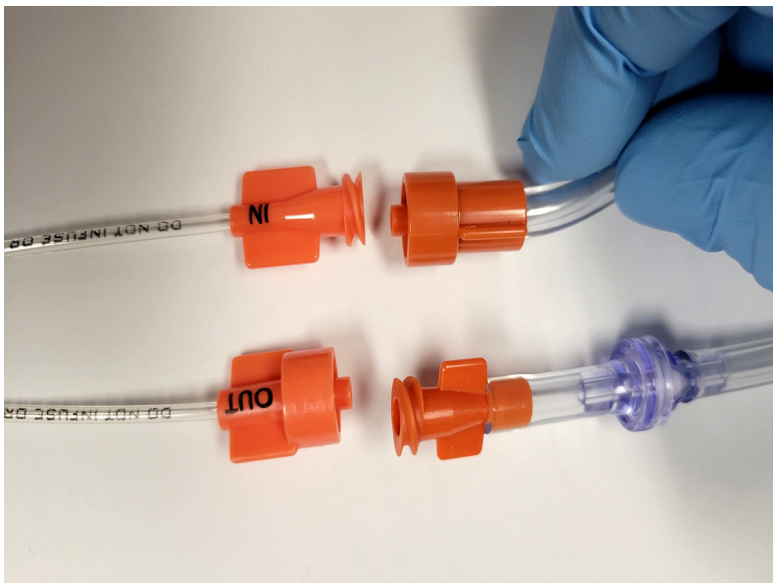


Figure 4.55. Connect the tubing to the catheter

10. Safely route the tubing so that it is not kinked or obstructed and cannot be easily dislodged by a patient's movement.

    The console is now ready to begin treatment.

Start Treatment

11. Press the ▶ II button on the console to start treatment.

Caution. When used with a surface pad, ensure the surface pad is open and the Velcro straps are not secured. The surface pad is not to be secured until Step 13.

Figure 4.56. ▶ II button

12. When used with a surface pad, press the ☰↵ button on the console. Set the Lo patient temperature alarm to 1°C below the target temperature.

    Caution. In Fever Control mode, the console does not warm the patient. Setting the Lo patient temperature alarm ensures that an alarm occurs if the patient's temperature drops.

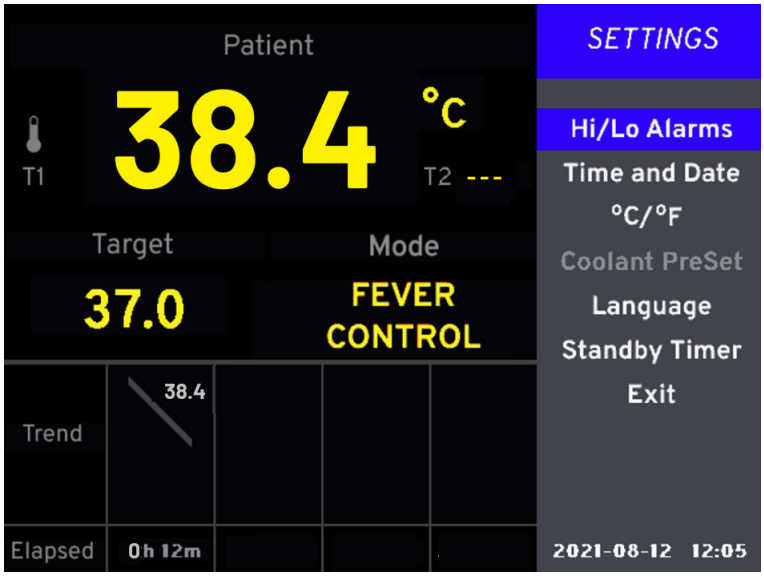


Figure 4.57. Set the Lo patient temperature alarm

13. When used with a surface pad, wait for the surface pad to fill with water. This typically takes 3-5 minutes. A small amount of air in the surface pad is acceptable and dissolves over time.
14. When used with a surface pad, secure the surface pad to the patient by folding the flaps over the abdomen and chest. Secure and adjust to fit the patient using the enclosed stretchable Velcro straps. The surface pad should be snug but not constraining.

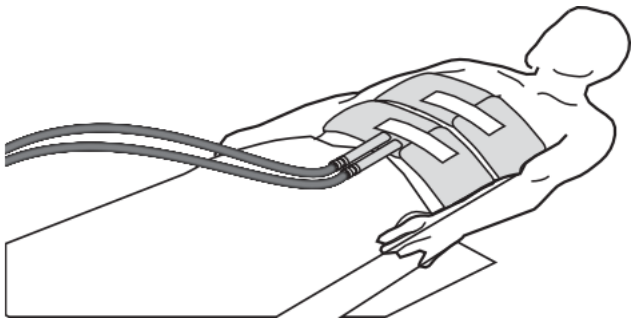


Figure 4.58. Surface pad on patient

15. Once treatment begins, confirm that fluid is flowing through the tubing circuit by observing the rotation of the inline flow indicator (Figure 4.59). With the Surface Start-Up Kit, it may take several minutes for the pinwheel to start spinning. If the flow indicator does not rotate freely during patient treatment, inspect the entire tubing circuit for kinks or other flow restrictions. Tap on the flow indicator to liberate any trapped air bubbles and return them to the fluid bag.

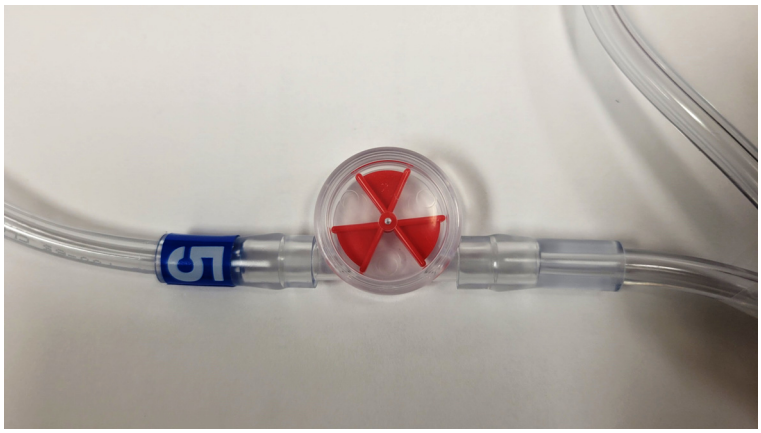


Figure 4.59. Inline flow indicator (pinwheel)

WARNING. Investigate air trap alarms. If an Air Trap Fault alarm occurs, it is likely that there is a leak in the tubing circuit or the catheter or surface pad has failed. Do not keep replenishing saline that is being rapidly depleted–a problem exists that must be immediately remedied. See "Air Entry Into the Tubing Circuit" on page 15.

Time From Last Power Down

If the console detects that it is less than 3 minutes since the last time it was powered off, it dispenses with some of its self tests depending on the state of the cooling engine at the time of power off. The idea is that, with such a short time, it is likely that the power off was either unintentional (you tripped over the power cord) or an intentioned brief adjustment that required the console to be powered off (you moved the console to a new position).

The console gives you the option to use the last programmed settings. If you elect to do this, you may still use the menu to change console settings in Standby.

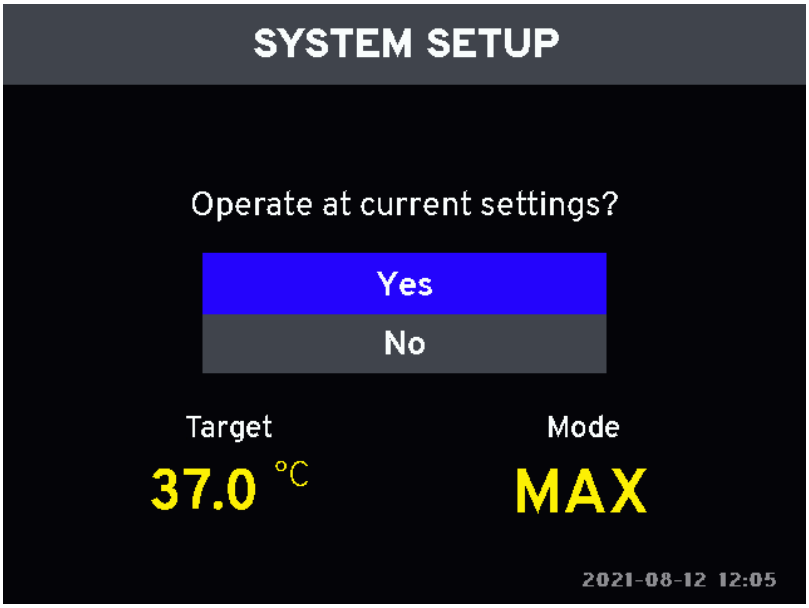


Figure 4.60. Operate at Current Settings

If it has been less than 3 minutes since the last power off, when you power on the console, Figure 4.60, "Operate at Current Settings," on page 70 is displayed.

1. If you select Yes and press the knob, you proceed directly to Standby once the console self tests have completed.
2. If you select No and press the knob, you are presented with screens that allow you to select operating parameters for the console prior to entering Standby.

   If the console detects that it is more than 3 minutes since the last time it was powered off, it conducts all self tests. You are not offered the option of operating the console at the current settings.

New Patient – No Power Down

Change the Start-Up Kit or Surface Start-Up Kit

The console does not have to be powered down to start a new case. A new catheter or surface pad, patient temperature probe. and Start-Up Kit or Surface Start-Up Kit are required for each patient – see Disposal of Used Components on page 71. To immediately start a new case without powering down:

1. Place the console in Standby.
2. Verify the console settings.
3. Use the Settings menu to select Cooling or Warming the coolant, or None to keep the previous setting.
4. Connect the new patient.
5. Place the console in Run when desired.

Disposal of Used Components

Single-use device – do not reuse. ZOLL IVTM catheters, surface pads, Start-Up Kits, and Surface Start-Up Kits are single-use devices and may not be reprocessed or reused. The cyclical stresses of the roller pump on these items cause fatigue failures. **Do not use catheters, surface pads, Start-Up Kits, or Surface Start-Up Kits beyond the labeled usage time. The products will fail.**

Caution. Avoid contact with used components. Handle used components as medical waste.

For disposal instructions for surface pads and Surface Start-Up Kits, see the Surface Start-Up Kit Instructions for Use.

IVTM catheters and Start- Up Kit disposal

To remove used components from the console and dispose of them properly:

1. Ensure that the patient has been disconnected from the console and that the power is off.
2. If using the console with an IVTM catheter, cross connect the loose ends of the Start-Up Kit when you disconnect it from the catheter. This reduces the amount of fluid that has to be cleaned up later.
3. Position a large empty medical waste container or collection bag near the console.

   Caution. Do not disassemble the Start-Up Kit. Do not disconnect the tubing connecting the components. They are removed and disposed of as a complete unit. To avoid injury, do not disconnect the saline bag.
4. Open the console cover. Open the roller pump lid.
5. Remove the cap from the coolant well.
6. Remove the insulating jacket from the saline bag and set it aside.
7. Lift the handle on the roller pump.
8. Grasp the roller pump tubing and gently pull it up and out of the channel while rotating the pump head.
9. Pull the tubing out of the pump head. Press the handle down onto the rollers until it locks into place and close the roller pump lid.
10. Loosely coil the disconnected ends of the catheter tubing.
11. Lift the heat exchange coil out of the coolant well. Hold the coil above the coolant well to allow coolant to drip back into the well.
12. Pull the air trap up and out of the chamber.
13. Unhook the saline bag from the hook.
14. Bundle up the collection of components, still connected together, and gently deposit them in the medical waste container. Take care to avoid contact with the saline bag spike.
15. Use a tissue to wipe up any spilled coolant from the top of the coolant well. Place the tissue in the medical waste container.
16. Replace the insulated cap on the coolant well. Replace the insulating jacket on the hook.

Removal and disposal of the used components is complete. The console may now be stored or moved to its next treatment location.

Temperature Trend Data

Overview

During operation, the console continuously collects and stores temperature trend data, storing a record each minute. This data is stored in memory and can be downloaded to a USB drive for later analysis or plotting.

At any time during operation, the complete record of temperature trend data can be displayed as a graph on the screen. This section explains how to display temperature trend data and provides details about the format and structure of the downloaded data.

Displaying the Temperature Trend Graph

To display the temperature trend graph:

1. Press the Menu/Enter knob once. The screen displays the menu (Figure 4.14). The View Graphs selection is highlighted.
2. Press the knob once. The screen displays the temperature trend graph.

Temperature Trend Graph

Temperature trend data can be displayed as an interactive graph on the screen. The display is a time-series of patient temperature (from the primary temperature probe) and console activity, plotted in two graphs. The patient temperature graph plots temperature vertically and time horizontally. The console activity graph plots cooling/warming activity vertically and uses the same time scale horizontally. An example of the patient temperature trend display is shown below.

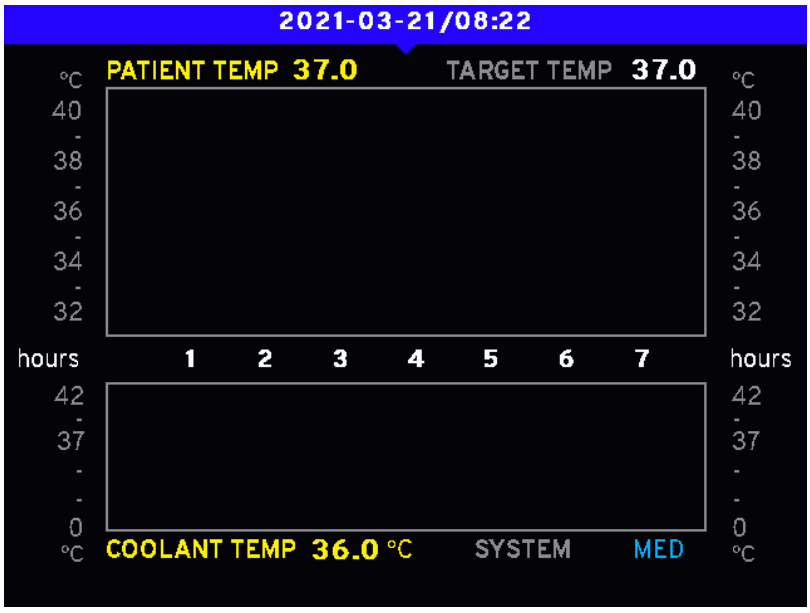


Figure 4.61. Temperature trend display

Patient Temperature

The patient temperature graph (labeled "Patient Temp") is scaled for any temperature between 31°C and 41°C (87.8°F– 105.8°F). The time scale can be set to one of four intervals (see Setting the Time Scale on page 73). Figure 4.61 shows the vertical temperature displayed in degrees Celsius, and the horizontal time scale displayed for a 4-hour interval.

System Activity

The System activity graph (labeled "System") is scaled for any console activity, from maximum cooling to maximum warming. The horizontal time scale is the same as that set for the Patient Temperature graph. The vertical scale uses a colored activity indicator:

- The red zone indicates coolant temperatures between 36°C and 42°C.
- The neutral point (between red and blue) indicates coolant temperature of 36°C and also indicates when the pump is not operating.
- The blue zone indicates coolant temperatures between 0°C and 36°C.

Cursor

The cursor is a fixed vertical line that runs through the center of both graphs. When the temperature trend graph is displayed, turn the Menu/Enter knob to scroll the display screen to the left or right. As data scrolls under the cursor, the top of the display screen shows the time and date of the data under the cursor.

Turn the knob clockwise to scroll to the right. As you scroll to the right, the time and date display shows later data. Scroll right to the end to display the most current data.

Turn the knob counterclockwise to scroll to the left. As you scroll to the left, the time and date display shows earlier data. Scroll left to the beginning to display the data collected when treatment began.

Status Bar

Across the bottom of the display screen is a status bar which displays the patient's temperature, the status of the console, and the target temperature for the data point under the cursor.

The patient's temperature and target temperature are displayed using the current temperature unit setting (Celsius or Fahrenheit).

The status field uses colors to display one of nine status messages that are described in the following table.

Status Message	Message Color	Explanation
STBY	Black	The console was in Standby (pump off).
MAX	Red	The console was warming.
MED	Red	
LOW	Red	
0	Black	The console was neither warming nor cooling.
LOW	Blue	The console was cooling.
MED	Blue	
MAX	Blue	
OFF	Black	The console was turned off.

Table 4.5. Status bar messages

Setting the Time Scale

The time scale displayed by the temperature trend graph can be set to any of four intervals: 4 hours, 12 hours, 24 hours, or 72 hours. To set the time scale, follow these steps:

1. Display the temperature trend graph.

2. Press the Menu/Enter knob once. The screen displays a pop-up menu with the Set Time Scale choice highlighted.

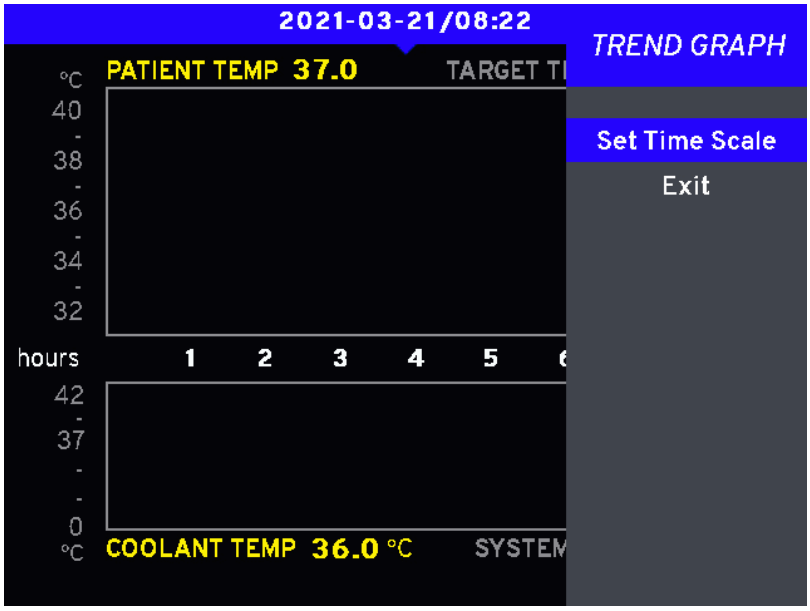


Figure 4.62. Set Time Scale

3. Press the knob once. The screen displays the Select interval message followed by four interval choices. The most recent choice is highlighted.

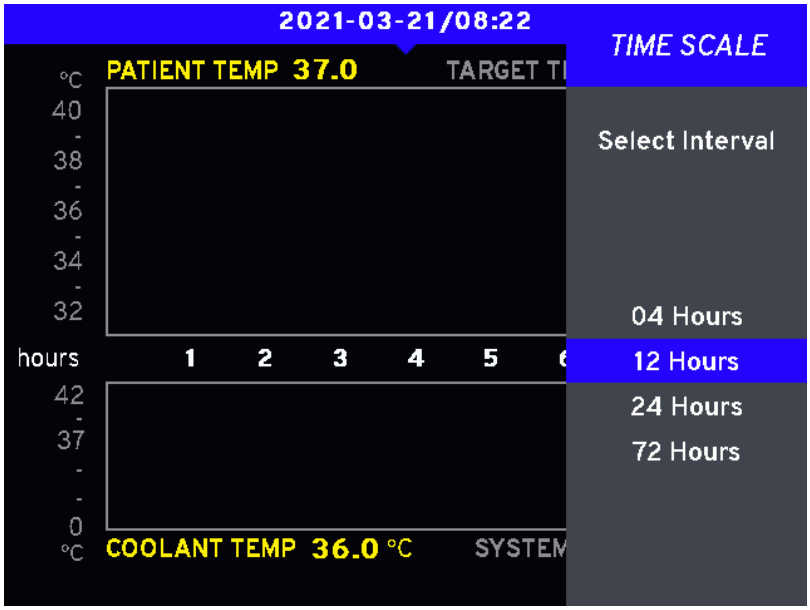


Figure 4.63. Select Interval

4. Turn the knob to highlight your desired selection. Press the knob once.
5. The screen displays the pop-up menu again. Turn the knob to highlight the Cancel/Exit selection.
6. Press the knob once. The menu disappears and the temperature trend graph is displayed using the interval you selected.

Mechanical Components

Console Cover

When access to the tubing or coolant well of the console is required, lift the console cover to a fully upright position.

Figure 4.64. Console cover fully open

Display Head Tilt

To modify the tilt of the display head, or to lock the display head in place, use the clamp/lever located at the swivel point. Turn the clamp/lever clockwise to tighten or counterclockwise to loosen. The position of the clamp/lever may be changed, without adjusting the tightness, by pulling the clamp/lever towards you.

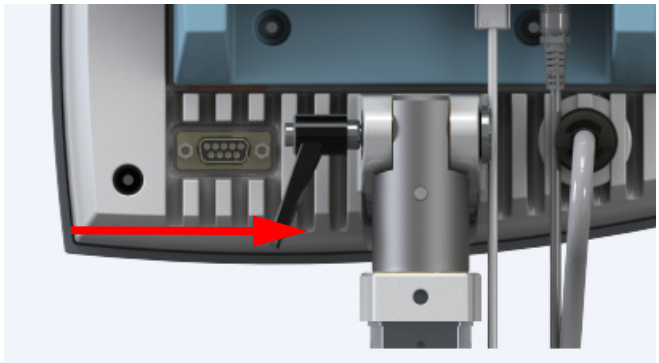


Figure 4.65. Display head clamp/lever

Casters

There are two different types of casters (wheels) on the console.

1. The front casters have a longer latch to engage the lock.
2. The rear casters have a shorter latch to engage the lock.

Figure 4.66 shows the location of the casters.

1. Front casters
2. Rear casters

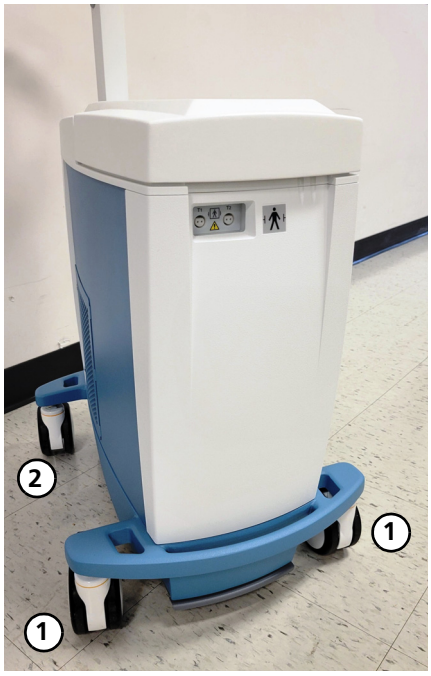


Figure 4.66. Casters on the console

Treatment sessions/Log files

The console can hold up to 20 log files. Each file contains one treatment session. When the maximum number of log files is reached, the oldest file is deleted.

Note. The console automatically stops recording after10 days of continuous use.

Connectivity

The console can transmit patient temperature and other treatment information to a hospital monitor or EMR data hub. It can also copy log files to a USB drive or upload them to a ZOLL cloud server via Wi-Fi if Wi-Fi is enabled.

Note. The console does not store or transmit any patient-dentifiable information.

Figure 4.67 shows the connections that can be made between the console and other equipment.

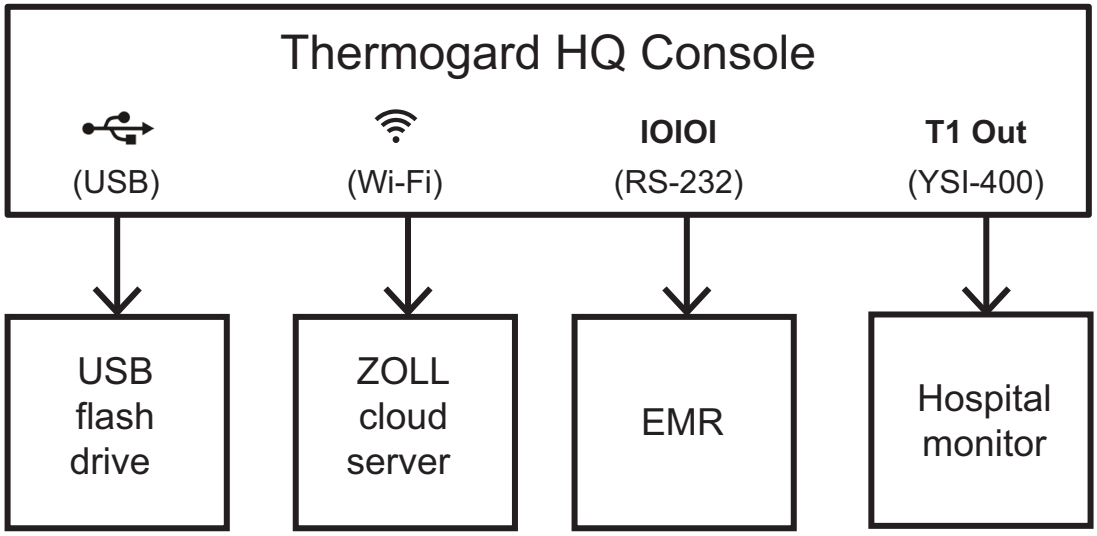


Figure 4.67. Console connections

Connection	Type	Function
USB	Outgoing	The USB type A port is used to copy treatment log files to a USB drive. **USB drive requirements.** The USB drive must be formatted to the FAT32 file system and have equal to or less than 32 GB capacity.
Wi-Fi	Outgoing	The console can upload treatment log files to the ZOLL cloud server over Wi-Fi for review using ZOLL online tools. This feature is disabled in the factory. To enable this feature, contact your ZOLL service representative.
IOIOI RS-232	Outgoing	The IOIOI port streams treatment data to an external, compatible EMR data hub over RS-232. To connect the console to your EMR data hub, contact your EMR data hub vendor.
T1 Out YSI-400	Outgoing	The T1 Out port outputs the patient temperature using a YSI-400 compatible signal. It can be connected to a hospital monitor with YSI-400 compatible input port for an additional patient temperature display.

Table 4.6. Console connections

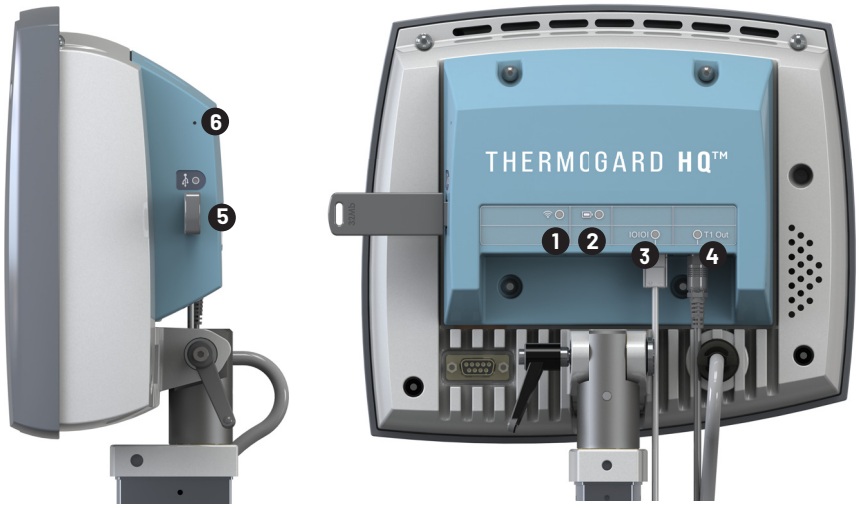


Figure 4.68. Console connections

The console provides:

1. Wi-Fi configuration.
   - Off: Wi-Fi is disabled (factory default).
   - On: Wi-Fi is enabled.

     Note. To enable Wi-Fi, contact your ZOLL service representative.
2. Wi-Fi battery. Used only to power the console for Wi-Fi uploads after the console is powered off. It does not power any other console functionality.
   - Green: Wi-Fi battery is charged.
   - Red: Wi-Fi battery is charging.
3. EMR (Electronic Medical Record) output (RJ-45 port, labeled IOIOI)
   - Off: Disabled
   - Green: Enabled (factory default)
   - Red: The EMR output is malfunctioning. Contact your ZOLL service representative.
4. Patient temperature output (T1 Out port to connect to a hospital monitor). See “Connection Cable Part Numbers” on page 80.

   WARNING. Using the Patient temperature output to view the patient’s temperature on a hospital monitor is not a replacement for the T2 Temperature probe on the console. It simply simulates the T1 Temperature probe. Use of the Patient temperature output does not obviate the need for a second patient temperature monitoring method. Failure to use a second patient temperature monitoring method can result in injury to the patient in the event of a T1 Temperature Probe failure.

   - Off: Disabled
   - Green: Enabled (factory default)
   - Red: The Patient temperature output is malfunctioning. Contact your ZOLL service representative.
5. USB type A port See “Downloading files via USB” on page 79.
6. Delete button. Press and hold the pinhole-protected Delete button for at least 3 seconds to delete all treatment data stored on the console, for example, before sending a console for service.

Wi-Fi troubleshooting

Wi-Fi performance can depend on a variety of conditions, such as the location of the Wi-Fi access point, the location of the console, and distances from nearby RF-emitting equipment. If the console is having trouble making and maintaining Wi-Fi connection, it may fail to transfer log files. Try these remedies to improve the Wi-Fi connection:

- Reorient the console
- Move the console closer to the Wi-Fi access point
- Keep the console away from RF-emitting equipment

Downloading files via USB

To download files from the console, insert a USB drive into the USB port.

- The console automatically copies Treatment sessions/Log files (page 76) onto the USB drive.
- During download, the USB LED flashes green.
    - The typical download process takes approximately 1-2 minutes but can take up to 5 minutes when the internal storage is close to being full.
- When the download is complete, the USB LED shows a solid green light.
- The USB LED is red when a USB drive is inserted and there are issues with the file transfer. See “USB Troubleshooting” on page 79.
- Files are not deleted after a successful download. Files are deleted when the maximum capacity is reached or when the Delete button is pushed.

USB Troubleshooting

These issues could include:

- Ensure the USB drive meets requirements. See “USB drive requirements” on page 77.
- Ensure that the USB drive has a minimum of 30 MB free space available. To check, insert the USB drive into a Windows PC, right-click the USB drive, and select Properties.
- Ensure the USB drive is functioning by copying a file from a Windows PC.
- Try a different USB drive, preferably from a name-brand manufacturer.

Connection Cable Part Numbers

The following connection cables are provided to allow you to connect the console to your hospital monitor. If your hospital monitor has another type of connector or you do not know which connector to use, contact ZOLL Customer Service.

Part Number	Connects to
500628-001	Monitors using a 3.5mm phone jack (Bard®)
500629-001	Monitors using a 2.5mm phone jack (Terumo®)
500630-001	Monitors using a 2-pin Molex type connector with socket contacts (Mallinckrodt® or Smiths Medical®)
500631-001	Monitors using a 2-pin Molex type connector with pin contacts (Rüsch®)
500632-001	Monitors using an RCA type Phono plug (GE®, WelchAllyn® or Mallinckrodt®)

Table 4.7. Connection Cable Part Numbers

5. Alarms and Corrective Actions

Overview

This chapter lists alarm messages that may appear on the console display during operation. If an alarm occurs, refer to the following table for information about the cause and corrective action. In some cases, you must take corrective action and then restart the console.

WARNING. When treating a patient with the system, appropriately qualified medical staff must routinely and closely monitor the patient. Audible and visual alarm signals generated by the console require you to remain in close proximity to the patient throughout the procedure.

Note. Alarm priorities. In accordance with the IEC 60601-1-8:2006 safety standard, the console alarms have been categorized as High, Medium, and Low priority. High priority alarms are physiological, determined when the patient's temperature exceeds programmed values. They are indicated by red flashing text on the display and require prompt attention from the operator to prevent irreversible injury or death. Medium and low priority alarms are console-related. Medium priority alarms are indicated by a yellow banner and require attention to prevent reversible injury or discomfort to the patient. Low priority alarms are displayed with a yellow banner and delay the treatment of the patient until they are addressed.

Alarms and Corrective Actions

Alarm messages are grouped according to their priority.

Alarm Message	Cause	Corrective Action
Hi PATIENT TEMPERATURE ALARM	The patient's temperature is above the programmed Hi patient temperature alarm value.	The console alarm resets when the patient's temperature falls below the programmed Hi patient temperature alarm value.
Lo PATIENT TEMPERATURE ALARM	The patient's temperature is below the programmed Lo patient temperature alarm value.	The console alarm resets when the patient's temperature rises above the programmed Lo patient temperature alarm value.

Table 5.1. High priority Alarm Messages, Causes, and Corrective Actions

Alarm Message	Cause	Corrective Action
AIR TRAP FAULT[1]	Air has been detected in the air trap, or the air trap is full of fluid but the fluid level detector indicates a fault.	See Air Entry Into the Tubing Circuit on page 15. If the problem persists, discontinue use and contact your ZOLL service representative.
	The air trap is full of fluid but the fluid level detector indicates a fault.	1. Completely dry the outside of the air trap with a towel to remove any condensation. 2. Wipe clean the inner surface of the air trap chamber before reinserting the air trap. 3. Verify that the air trap is seated firmly at the bottom of the air trap chamber. 4. If the problem persists, discontinue use and contact your ZOLL service representative.
COOLANT EMPTY[1]	The coolant well is empty.	Fill with coolant (ZOLL-approved 50% propylene glycol / 50% deionized water mixture) until liquid level reaches the MAX line.
COOLANT LOW	The coolant level is low.	
PRIMARY PATIENT TEMPERATURE PROBE DISCONNECTED[1]	The primary patient temperature probe is disconnected.	Verify the position of the primary patient temperature probe. Ensure that primary patient temperature probe is plugged into the T1 connector, or if an interconnect cable is used, the primary patient temperature probe is plugged into the cable and the cable is plugged into the T1 connector.
PRIMARY TEMPERATURE PROBE DISLODGED[1]	Temperature output from the primary patient temperature probe changed by –0.2°C or more within 10 seconds.	Replace the primary patient temperature probe in the patient.
ROLLER PUMP LID OPEN[1]	The roller pump lid is open.	Close the roller pump lid.
PUMP FAILURE[1]	The roller pump has failed.	Inspect the roller pump. Clear any obvious faults and restart. If the problem persists, discontinue use and contact your ZOLL service representative.
SECONDARY TEMPERATURE PROBE DISCONNECTED[1]	The secondary patient temperature probe is disconnected.	Verify the position of the secondary patient temperature probe. Ensure that secondary patient temperature probe is plugged into the T1 connector, or if an interconnect cable is used, the secondary patient temperature probe is plugged into the cable and the cable is plugged into the T1 connector.

Table 5.2. Medium priority Alarm Messages, Causes, and Corrective Actions

SECONDARY TEMPERATURE PROBE DISLODGED[1]	Temperature output from the secondary patient temperature probe changed by –0.2°C or more within 10 seconds.	Verify the position of the secondary patient temperature probe.
TEMPERATURE PROBES DO NOT AGREE[1]	Temperature outputs from the primary and secondary patient temperature probes differ by more than 2°C.	Determine the cause of the discrepancy and correct it. One or both temperature probes may need to be replaced.
SYSTEM MALFUNCTION[1]	May be caused by a variety of failures.	Discontinue use and contact your ZOLL service representative.

Table 5.2. Medium priority Alarm Messages, Causes, and Corrective Actions (continued)

1. Stops operation of the console.

Alarm Message	Cause	Corrective Action
DOWNLOAD ERROR. PLEASE CHECK EXTERNAL COMPUTER	Data download has failed or there is no computer connected to the console.	Check the connection between the computer and the console and select Try again. If problem persists, select Cancel and contact ZOLL technical support.
PATIENT DATA LOG FULL. PLEASE DOWNLOAD NOW	The console is full. Only two hours of space remain.	Download data. See Downloading files via USB on page 79. If data is not downloaded, it will be overwritten.

Table 5.3. Low priority Alarm Messages, Causes, and Corrective Actions

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6. Troubleshooting

Overview

Caution. Qualified medical personnel must read and understand these instructions before performing troubleshooting on the console.

This chapter provides information about performing troubleshooting and service for the console. A table of symptoms, probable causes, and recommended corrective actions has been provided to assist troubleshooting by qualified users.

Some test and repair tasks must be performed only by ZOLL-trained service personnel. If you encounter a problem that is not listed in this chapter, do not attempt to make repairs or adjustments–contact your ZOLL service representative for assistance.

Warranty and Service on page 95 provides information about how to obtain assistance or service from a ZOLL representative.

Symptoms and Remedies

Consult the following table for help with troubleshooting the console. If the problem you are experiencing is not listed in the table, contact your ZOLL ExpertCare service representative for assistance.

Symptom	Probable Cause	Corrective Action
The red LED on the control panel is illuminated and an alarm sounds.	Console or control failure.	Discontinue use and contact ZOLL.
The red LED on the control panel is blinking and an alarm beeps repeatedly.	Electrical power was momentarily interrupted.	Turn off the power and wait 30 seconds. Turn on the console and restart. If the problem persists, discontinue use and contact ZOLL.
Console does not start.	No electrical power.	Verify that the console is plugged into a working circuit of correct capacity. Ensure that the power cord is securely plugged into the power inlet connection of the console.

Table 6.1. Symptoms, Probable Causes, and Corrective Actions

The patient does not cool. The activity monitor indicates 100% cooling power and the patient's temperature is increasing.	The patient may be febrile.	The fever has overcome the cooling capability of the system. Use additional patient cooling methods as needed until the patient's temperature is stabilized.
	The temperature controller setting is incorrect.	Verify the target temperature, and that the cooling rate option is not used.
	The fluid flow is obstructed–indicated by no rotation of the flow indicator (pinwheel).	Inspect the entire length of tubing, from the heat exchange device (catheter or surface pad), to the console and back to the patient. Clear all restrictions. Check the flow indicator (pinwheel) to confirm flow. If using surface pad, manually adjust the pad to assess for water flow restrictions.
	If using an IVTM catheter, the catheter is improperly positioned or is not connected.	Place and position the catheter as directed by the catheter Instructions for Use. Connect the saline circuit tubing to the catheter and prime the saline circuit.
The patient does not cool. The activity monitor indicates 100% cooling power and the patient's temperature is increasing.	The heat exchange coil is not in the coolant well.	Place the heat exchange coil into the coolant well.
	The console is not operating within specifications.	Contact your ZOLL ExpertCare service representative.
The patient does not cool. The activity monitor does not indicate 100% cooling power and the patient's temperature is increasing after 45 minutes of sustained activity.	The console is not operating within specifications.	Download the TempTrend data file. If the coolant temperature is above 42°C, contact your ZOLL service representative.
The patient's temperature is more than 0.5°C below the set point.	The patient's resistance to hypothermia has diminished.	Monitor the patient's temperature. If the patient's temperature drops more than one degree below the target temperature, ensure that the console is operating normally. If the coolant temperature is at or below the patient's temperature, the activity monitor should indicate warming and the pump should be off. Use warming blankets to stabilize the patient's temperature.
	Console malfunction.	See above for correct console function. Use conventional methods to rewarm the patient and discontinue use of the console.
The patient does not stop cooling. The activity monitor indicates 100% cooling power when the target temperature has been reached.	A cooling or temperature controller fault has occurred.	If the activity monitor indicates 100% cooling power and the patient's temperature is one degree below the target temperature, discontinue treatment and contact ZOLL.
The patient is warming (when set for cooling).	A cooling or temperature controller fault has occurred.	If the target temperature is below the patient's temperature, and the activity monitor does not indicate cooling activity, discontinue treatment and contact ZOLL.

Table 6.1. Symptoms, Probable Causes, and Corrective Actions (continued)

The patient does not warm. The activity monitor indicates 100% cooling power and the patient's temperature continues to decline.	The warming capacity of the catheter has reached its upper limit.	Use warming blankets to supplement catheter performance until the patient's temperature has been stabilized.
The patient is warming too fast (when set for warming).	The warming rate is incorrect.	Reset the target temperature to maintain or cool the patient's temperature. Verify the warming rate setting.

Table 6.1. Symptoms, Probable Causes, and Corrective Actions (continued)

Events Requiring Technical Assistance

Caution. The console has multiple internal alarm states - see Alarms and Corrective Actions on page 81.

You can clear some alarms, such as filling the coolant well with coolant to rectify the coolant level alarm.

There are others that may be alleviated, in some cases, by power cycling the console (i.e. turning it off and then back on).

If neither user action nor power cycling the console clears the alarm – **Do not use the console.** Call a ZOLL service representative for any alarm that does not clear.

Immediately discontinue using the console and seek advice from your ZOLL service representative if any of the following events occur:

- The console repeatedly trips an outlet equipped with a ground fault circuit interrupter (GFCI).
- The protective fuse repeatedly blows.
- Fluid is observed leaking from the console.
- The console emits an unusual odor when operating.
- The console produces loud or unusual noises when operating.
- The display screen, Menu/Enter knob, or control buttons fail to operate as expected.
- The console has been exposed to fire, flood, or hazardous substances.
- The console has suffered potential damage due to improper storage, rough handling, or being dropped.

7. Maintenance

Overview

Maintain the console to ensure safe operation and a long service life. This chapter describes scheduled and unscheduled maintenance tasks.

Scheduled maintenance tasks must be performed at least as frequently as recommended in this chapter. If your console is subject to very long periods of continuous use, you may be required to perform these tasks more frequently than the schedule recommends.

The frequency of performing unscheduled maintenance tasks depends upon the manner in which you use the console. Most of these tasks are performed when an inspection indicates that they are necessary, or after a problem is discovered.

Failure to perform the maintenance tasks listed in this chapter may cause degraded performance of the console or may reduce the operating life of its parts.

To ensure safe operation of the console, preventive maintenance and service, including a comprehensive technical inspection and electrical safety test, is required annually. Contact your local sales representative for information on preventive maintenance pricing and complete service packages available in your region.

WARNING. Never perform any maintenance tasks while the console is in use with a patient.

WARNING. No user-serviceable parts inside the console. Only ZOLL-authorized personnel may service and repair the console.

Safety Precautions

Required personal protective equipment (PPE)

- Safety glasses
- Latex or neoprene gloves

Required tools and materials

- Phillips screwdriver
- Screwdriver
- Inspection lamp or flashlight
- Vacuum cleaner with crevice tool

Scheduled Maintenance

Item	Frequency	Maintenance Task
Coolant well	Before each use	If necessary, inspect and refill with coolant (ZOLL-approved 50% propylene glycol / 50% deionized water mixture) until liquid level reaches the MAX line.

Table 7.1: Scheduled Maintenance

Condensate pan	After each use	Inspect the condensate pan and empty if necessary (see Clean Console and Condensate Pan on page 91).
Refrigeration condenser filter	Every 6 months	Inspect the filter and replace if necessary (refer to Inspect/Replace Condenser Filter on page 90).
Roller pump	Monthly	Clean rollers and tubing path with cloth moistened with water. Clean rollers and apply light lubricating oil if rollers have been in contact with saline solution.
	Annually	Verify the pump roller gap.
Coolant	Annually	Drain and refill with new coolant.
Power cord	Annually	Inspect for wear or damage.
Temperature accuracy	Annually	Perform a temperature accuracy test (refer to Temperature Accuracy Test on page 91).

Table 7.1: Scheduled Maintenance (continued)

Note. Infection control. 50% propylene glycol coolant has been evaluated for antimicrobial effectiveness and determined not to promote growth of gram negative rods, gram positive cocci, or yeast microbes. 50% propylene glycol was found to be comparable to 70% isopropyl alcohol.

Unscheduled Maintenance

The following table lists unscheduled maintenance tasks for the console. These tasks should be performed when indicated.

Item	Criteria	Maintenance Task
Console	When deterioration is evident	Inspect mechanical and electrical components for wear and loose or deteriorated parts. Verify continuity of the electrical ground connection.
Console	When soiled	Clean the exterior of the console (refer to Clean Console and Condensate Pan on page 91).
Coolant	If contaminated	Drain coolant, clean the coolant well, and refill with new coolant (refer to Table 7.1, "Scheduled Maintenance," on page 89 and Drain coolant on page 92).
	If particulate matter is observed in the coolant	

Table 7.2: Unscheduled Maintenance

Inspect/Replace Condenser Filter

Required Tools and Materials

- Phillips screwdriver
- Inspection lamp
- Vacuum cleaner with a crevice tool

Procedure

To inspect and replace the condenser filter:

1. Turn off the console and unplug the power cord.

2. Use a screwdriver to unscrew the screws securing the access door. Remove the access door from the panel.
3. Remove and inspect the filter. Replace it if it is clogged with dust.
4. Use the inspection lamp to inspect the area in and around the condenser. Look for accumulations of dust and debris.
5. If necessary, use the vacuum cleaner's crevice tool to remove dust from the condenser. Gently pass the crevice tool over all exposed surfaces of the condenser only. Take care not to bend any of the cooling fins of the condenser. Never use cleaning fluids or water on the condenser.
6. When finished, replace the access door and reattach the screws.
7. Inspection and cleaning are complete. The console may be returned to clinical use.

Temperature Accuracy Test

Required Tools and Materials

- Calibrated temperature source (e.g., Fogg System Co. model TP-400 or equivalent)

Procedure

To perform a temperature accuracy test:

1. Set the calibrated temperature source to exactly 37° C and plug it into the T1 connector.
2. Start the console and proceed to the Standby screen.
3. Observe the patient temperature displayed on the screen. It should indicate 37° C ± 0.2° C.
4. If the displayed temperature is above or below the indicated range, contact your ZOLL service representative.
5. If the displayed temperature was within the indicated range, the test is complete.

Clean Console and Condensate Pan

Required Tools and Materials

- Soft, lint-free cloth
- Solution of mild detergent and water

Procedure

To clean the console:

1. Turn off the console and unplug the power cord.
2. Clean the exterior of the console using a soft cloth dampened with a mild detergent and water mixture. Never use solvents or abrasive cleaners on the console. Avoid vigorous scrubbing, especially on the front surface of the display.

   Note. Console disinfection. To disinfect the console, use a product that includes at least 55% isopropyl alcohol or other approved non-corrosive hospital-grade disinfectant (where regionally available, ZOLL recommends PDI® Super SANI-CLOTH® germicidal disposable wipes, EPA Reg. No: 9480-4). ZOLL highly recommends testing the disinfectant on a small area on the outer surface of the console prior to wiping all surfaces of the console. Follow directions provided by the manufacturer of the disinfectant. The hospital determines the effectiveness of the disinfectant.
3. Wipe down the outside surfaces with a water-dampened cloth to remove remaining spots or residue.

4. Slide out and remove the condensate collection pan from under the front of the console (see Figure 7.1).

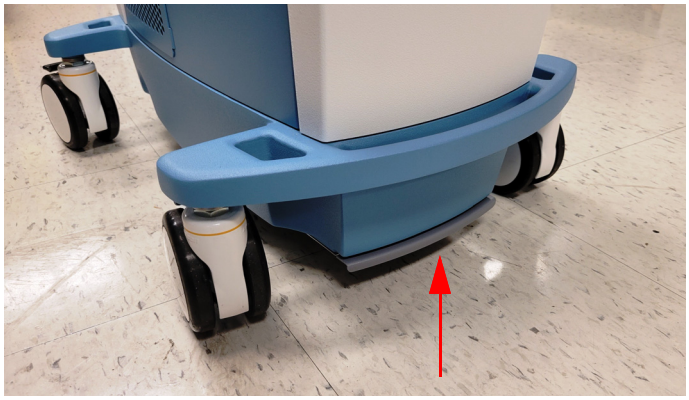

Figure 7.1. Condensate pan

5. The pan may be washed in hot soapy water. Never use solvents or abrasive cleaners on the pan. Dry the pan when finished and reinstall it in the console.

Note. Do not operate the console without a condensate collection pan properly installed. Failure to do so may allow water to accumulate on the floor under the console.

Drain coolant

Drain and clean the coolant well if the coolant is contaminated, or to prepare the console for shipment.

Required Tools and Materials

- Drain line and connector assembly (supplied with the console)
- 2-liter waste container

Drain the coolant in an area where spills can be managed appropriately.

Procedure

To drain the coolant well.

1. Unplug the console.
2. Remove the cap on the coolant well and set it aside on a clean surface.
3. Visually inspect the coolant well for discolorations or foreign matter.

4. Remove the front panel of the console by pulling the panel straight away from the front of the machine (no tools are required to remove the panel). Near the bottom left corner of the console is a drain hose held by a clamp and the drain coupler.

Figure 7.2. Drain hose and drain coupler

5. Place the open end of the drain hose into a suitable container or position it above a floor sink or drain.
6. Push the connector on the drain hose into the drain coupler on the coolant well (refer to Figure 7.3).

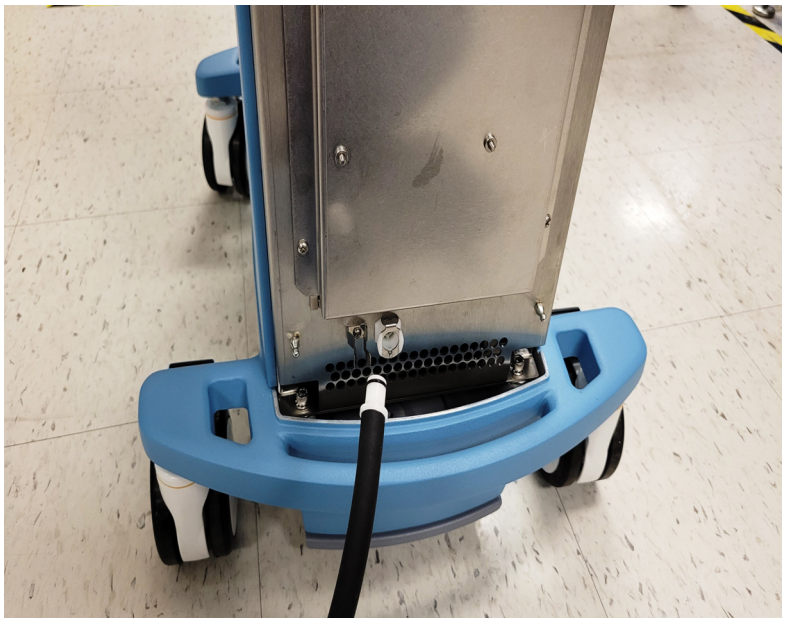

Figure 7.3. Push hose into drain coupler

7. When the connector is firmly seated in the coupler, coolant automatically flows through the line.
8. Wait until the coolant flow has stopped. Disconnect the drain line by pressing down on the metal tab on the coupler. Gently pull out the drain hose.
9. Dispose of the used coolant.
10. Wipe the coolant well dry. Visually inspect the drained coolant well for discolorations or foreign matter.

11. Thoroughly wipe the coolant well with at least 55% isopropyl alcohol or other non-corrosive hospital-grade disinfectant.
12. Rinse the coolant well with coolant. Do not rinse with saline.
13. Reconnect the drain hose as described in Step 5-Step 7 and drain the liquid used for cleaning. Dispose of the liquid.
14. Rinse the coolant well with coolant. See Table 7.1, "Scheduled Maintenance," on page 89.
15. When cleaning is complete, you may leave the coolant well empty (to prepare it for shipment), or refill it with coolant. Refer to Table 7.1, "Scheduled Maintenance," on page 89 and Preparing the Console for Treatment on page 54 for details.
16. Replace the cap on the coolant well.
17. Replace the drain hose in the clamp. Replace the front panel on the console.

Spillage

Both saline and coolant are corrosive and electrically conductive. Although the console is designed and tested to be in compliance with the spillage protection requirements of IEC 60601-1, it is important to clean up spillage quickly:

- To ensure a safe work environment. Spillage, especially of coolant, can result in a very slippery floor.
- To minimize the risk of corrosion or damage to the console.

Spillage is most likely under the following conditions:

- During setup of the Start-Up Kit. Spillage of saline in this case should be cleaned up as with the handling of any infusion fluid.
- During filling or emptying of the coolant well. The coolant may be safely wiped with paper towel and the towel disposed of in the trash. Propylene-glycol: Water mix is slippery on sealed floors.
- In the event of an air trap alarm. With any air trap alarm, investigate to see if there is spillage into the raceway. Remove the rotor and blot dry the raceway and motor shaft.

8. Warranty and Service

ZOLL Factory Warranty

ZOLL Medical Corporation (ZOLL) warrants to the Customer that from the date of shipment from ZOLL's manufacturing facility, the console shall be free from defects in material and workmanship under normal use for the period of one (1) year after the purchase date or the date the console is first placed in service, whichever date occurs later, not to exceed two (2) years from date of manufacturing, when the console has been properly operated, maintained, and used for its intended purpose.

During the factory warranty period, if the console requires repair, ZOLL at its sole discretion shall repair or replace the defective parts without charge to the purchaser. ZOLL reserves the right to make any necessary repair at the facilities of the purchaser, ZOLL's manufacturing facility, or at any ZOLL-authorized repair center. The warranty covers all parts, labor, and shipping costs for the repair of the console. Replacement parts may be new or remanufactured parts. Parts replaced under warranty become the property of ZOLL. If ZOLL's inspection detects no defects in material or workmanship, ZOLL's regular service charges shall apply. Replacement parts are covered during the remainder of the warranty period.

ZOLL warrants to the Customer that disposable products (including catheters, surface pads, Start Up Kits, Surface Start-Up Kits, guidewires, etc.) will be free from defects in material and workmanship during the shelf life stated on the packaging or for a period of six (6) months from date of shipment, whichever comes first. During this period, the disposable shall be returned to ZOLL for assessment to confirm the defect. ZOLL, at its sole discretion, may replace the disposable found by ZOLL to be defective without charge to the purchaser. A product that is not returned to ZOLL does not qualify for replacement.

This warranty does not cover items subject to normal wear and burnout during use, including but not limited to bearings, fuses, cables, and batteries. The warranty does not apply to software included as part of the console (including software embodied in read-only memory, known as firmware).

ZOLL shall not be responsible for any console or disposable defect, the failure to perform any specified function, or any other non-conformance caused by or attributable to: misuse, abuse, neglect or accident, failure to perform the required maintenance described in the Operation manual; any modification by the Customer, unless such modification is made with the prior written approval of ZOLL; any repair made by anyone other than ZOLL or its expressly authorized representative; use with any associated or complementary equipment, accessory or software not supplied by ZOLL; exposure to conditions beyond the environmental, power or operating constraints specified by ZOLL; or installation or application not specified by ZOLL's instructions.

This warranty does not include preventative or scheduled maintenance. This warranty shall be void if any labels or other identifying marks permanently affixed to the console or disposable when shipped by ZOLL are removed, altered, defaced or obliterated.

THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ZOLL shall have no liability whatsoever for any improper use or improper repair of the console.

Technical Support and Resources

ZOLL provides field- and factory-based technical support for its products. Our service hotline can answer questions, provide guidance, and schedule service for your console.

Upon request, ZOLL can provide circuit diagrams, parts lists, and service documentation to authorized users.

Obtaining Service from ZOLL

To obtain service from ZOLL Circulation, Inc., contact your local sales representative. For 24 hour technical support, call: +1-877-225-7487.

Packing and Shipping Instructions

Contact your local sales representative before returning items to ZOLL. Items must be packed carefully to avoid damage during shipment.

Disposal of the Console

Do not dispose of the console as unsorted municipal waste.

Dispose of the console in accordance with local regulations and in an environmentally safe manner. Use the disposal process that has been specified for your hospital or medical practice.

The functional life of the console is best extended if you properly maintain the console. See "Maintenance" on page 89. Do not attempt to service the cooling engine yourself as this may release R134a refrigerant into the atmosphere.

The console contains:

- A CCFL bulb
- Refrigerant R134a, a green house gas

Serious Incident Reporting

If a serious incident related to the device occurs, immediately report the incident to a healthcare professional.

For healthcare professionals, immediately report any serious incident to the applicable competent authority and ZOLL.

9. Specifications

Physical	
Dimensions	Height: 45 in. (114 cm) Width:17 in. (43 cm) Depth: 30 in. (76 cm)
Weight	107 lb. (49 kg)
Electrical	
Configuration	100-120 VAC, 50/60 Hz, 5 A
Fuse protection	See product label
Configuration	220-240 VAC, 50/60 Hz, 2.25 A
Fuse protection	See product label
Environmental	
Operating temperatures	10°C – 27°C (50°F – 81°F)
Operating humidity	30% to 75% noncondensing
Atmospheric pressure	70 kPa to 106 kPa
Chiller and Heater	
Reservoir volume	2.0 liters (0.5 gal.)
Pump capacity	7 lpm at pump head
Temperature range	0° C – 42° C
Coolant	ZOLL-approved 50% propylene glycol / 50% deionized water mixture
Refrigerant	RFC 134a
Controls and display screen	
Display screen	6.4 in. (16.25 cm) LCD color VGA
Controls	Pushbuttons and knob
Temperature input	Thermistor, YSI-400 series
Articulation	180° swivel, 45° tilt
Data interface	USB, Wi-Fi, EMR output (IOIOI), Patient temperature out-put (T1 Out)
Alarms	Audible tones and displayed text messages
Displayed temperature range	26°C – 42°C
Displayed temperature accuracy	± 0.2°C
Start-Up Kit saline circuit for connection to IVTM Catheters	
Priming volume	200 ml
Heat exchanger	Disposable stainless steel coil
Priming source	500 mL Sterile saline solution (hospital-provided)

Patient connection	Directional Luer connections on 72 in. (183 cm) lines
Pump tubing	Roller pump compatible with directional fittings
Sterility	Gamma sterilized
Saline alarm	Reservoir level detection & alarm system
Operating life	Replace disposable components after seven (7) days of continuous use.
Surface Start-Up Kit water circuits	
Priming volume	1200 mL
Heat exchanger	Disposable stainless steel coil
Priming source	Pre-attached reservoir bag (filled with 2 L hospital-provided water)
Patient connection	Quick disconnect with integral shut-off valve on 90 in (230 cm) lines.
Pump tubing	Roller pump compatible with directional fittings.
Sterility	Non-sterile
Fluid alarm	Reservoir level detection and alarm system
Operating life	Replace disposable components after seven (7) days of continuous use.
Equipment classifications	
Type of protection against moisture	IPX0
Type of protection against electric shock	Type BF for temperature inputs Type B for catheter connections
Protection class	1
Mode of operation	Continuous
Approved Patient Temperature Probes	
Temperature probe standard	YSI-400

Compatible YSI-400 Temperature probes: Use with ZOLL temperature probe cables.	Compatible YSI-400 temperature probes: C.R. Bard Foley Catheter, BARDEX, 8F C.R. Bard Foley Catheter, BARDEX, 12F C.R. Bard Foley Catheter, LUBRI-SIL, 14F C.R. Bard Foley Catheter, LUBRI-SIL, 16F C.R. Bard Foley Catheter, LUBRI-SIL, 18F Covidien Foley Catheter with Temperature Sensor, 8F Covidien Foley Catheter with Temperature Sensor, 10F Covidien Foley Catheter with Temperature Sensor, 12F Covidien Foley Catheter with Temperature Sensor, 14F Covidien Foley Catheter with Temperature Sensor, 16F Covidien Foley Catheter with Temperature Sensor, 18F Covidien General Purpose Probe, 9F Smiths Medical Foley Probe 10F Smiths Medical Foley Probe 12F Smiths Medical Foley Probe 14F Smiths Medical Foley Probe 16F Smiths Medical Foley Probe 18F Smiths Medical G/P Rectal Probe 9F Smiths Medical G/P Rectal Probe 12F

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