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Технические характеристики на системы управления температурой Thermogard HQ компании ZOLL

Thermogard HQ™

Temperature Management System

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 ZOLL Intravascular Temperature Management (IVTM™) System is comprised of an external heat exchange console (Thermogard HQ™ console) and an IVTM™ intravascular heat-exchange catheter connected via a sterile heat exchanger and tubing circuit (Thermogard HQ™ Start-Up Kit). These components together comprise a patient temperature-regulation apparatus employing feedback control. The catheter and the Start-Up Kit are single-use disposable devices.

This manual provides operating instructions for the console and the Start-Up Kit. Catheter components are referenced where it is necessary to ensure proper use with the system components. Always refer to the catheter's Instructions for Use for additional specific information.

Operating Life

The operating life of the console is five years.

The operating life of the catheters varies by model. Refer to the catheter's Instructions for Use.

The disposable components of the Start-Up Kit are designed for continuous use for a period not to exceed seven days on a single patient. After seven days of use, remove and replace the Start-Up Kit with a new Start-Up Kit.

Caution. The Start-Up Kit is designed for single use only. Do not resterilize or reuse. Do not alter the Start-Up Kit in any way. Failure to adhere to the Start-Up Kit time limit may cause injury to the patient.

Potential risks with reuse of a single use 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
- Device failures

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 system is connected to the temperature-controlled catheter by two small-bore plastic tubes. One tube supplies temperature-controlled sterile saline solution to the catheter, and the other tube returns the saline solution to the console. The sterile saline is pumped through a continuous recirculating loop by a roller pump inside the console. The saline solution acts as an intermediate heat-transfer medium between the patient and the console. Sterile saline is used 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. 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: Saline Flows in a Closed-Loop Circuit".

1. Saline bag
2. Start-Up Kit
3. Catheter
4. Roller pump
5. Out
6. In
7. Temperature control container
8. Air trap
9. Coolant pump
10. Cooling/warming device

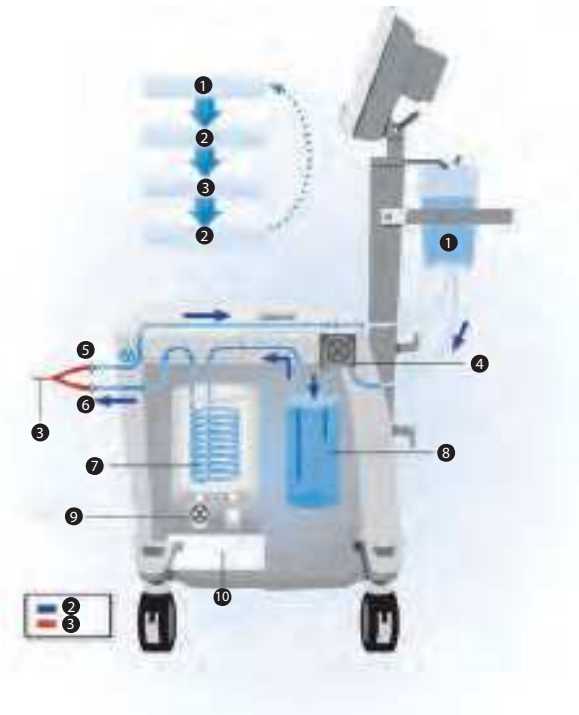


Figure 2.1. Simplified Flow Diagram: Saline Flows in a Closed-Loop Circuit

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 4.51).

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 (IOIO), Patient temperature output (T1 Out)
Alarms	Audible tones and displayed text messages
Displayed temperature range	26°C – 42°C
Displayed temperature accuracy	± 0.2°C
Saline coolant circuit	
Priming volume	200 ml
Heat exchanger	Disposable stainless steel coil
Priming source	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
Coolant circuit 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.	<p>Compatible YSI-400 temperature probes:</p> <ul style="list-style-type: none"> 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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