

Thermogard XP®

Intravascular Temperature Management System

ZOLL®



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Targeted Temperature Management When it matters most

Temperature is one of the four main vital signs

Maintaining target temperature is vital to life. Targeted Temperature Management, which includes fever control, therapeutic hypothermia (TH), and warming, has been shown to improve outcomes, reduce complications, and deliver a beneficial economic impact on society and hospitals.¹⁻⁶

Major medical societies recommend temperature management as the standard of care for many critically ill or surgical patients.

- AANS American Association of Neurological Surgeons
- AHA American Heart Association
- ASA American Society of Anesthesiologists

Thermogard XP® reaches and maintains target temperature within $\pm 0.2^{\circ}\text{C}$ 100% of the time.⁷⁻¹³

Regardless of your target temperature, we can get you there.¹¹ Every time.¹³



How Intravascular Temperature Management works

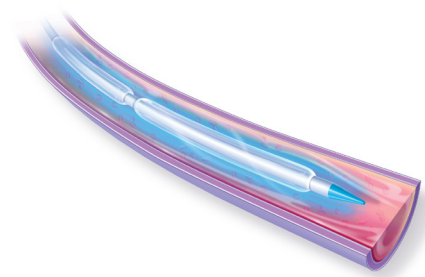
Central to ZOLL's Thermogard XP system is its ability to cool and warm patients from the core. The system consists of the Thermogard XP (TGXP) console and a multi-balloon heat-exchange catheter. Cool or warm saline circulates through the catheter (not infusing into the patient) in a closed loop design, quickly cooling or warming the patient as venous blood passes over the balloons.



A direct line to advanced care

ZOLL's patented catheter doubles as a standard central venous catheter (CVC) as it delivers precise temperature management.

The catheter is placed in the femoral, subclavian, or internal jugular vein. Vein site selection is determined by the cooling/warming application and the unique needs of the patient.

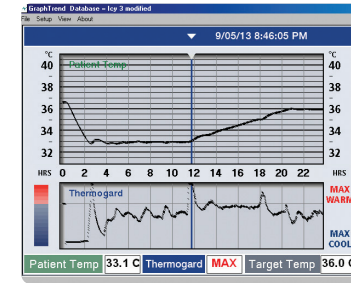


Catheter Name	Quattro®	Icy®	Cool Line®	Solex 7®
Number of Heat-Exchange Balloons	4	3	2	Serpentine
Number of Infusion Lumens	3	3	3	3
Insertion Site	Femoral	Femoral	Subclavian Internal Jugular Femoral	Subclavian Internal Jugular
Outer Diameter (OD) at Insertion Site	9.3 F	9.3 F	9.3 F	9.3 F
Length	45 cm	38 cm	22 cm	20 cm
Dwell Time	4 days	4 days	7 days	7 and 4 days*

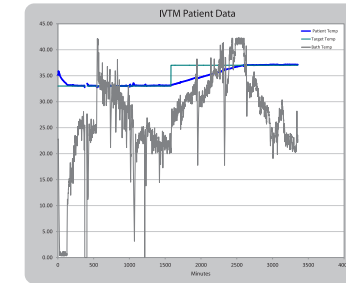
*Solex 7 is cleared for 7-day dwell time for fever control and 4-day dwell time for cardiac and neurosurgery use.

Focus on patient management

Thermogard XP (TGXP) is designed to let you **focus on the patient rather than on device management**. Once the catheter is placed and the target temperature is set, TGXP takes over — reaching and maintaining target temperature rapidly and reliably. TGXP constantly monitors the patient and automatically adjusts to the selected target temperature.



Track patient and system data, then electronically transfer it to the patient's file.

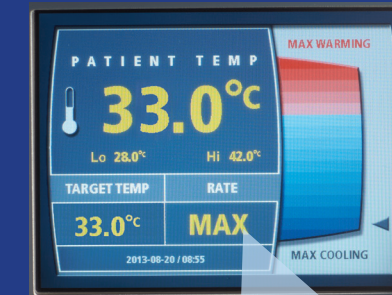


Once treatment is complete, it's easy to view and graph patient data using TempTrend™ software.



Consistent control for targeted temperature management

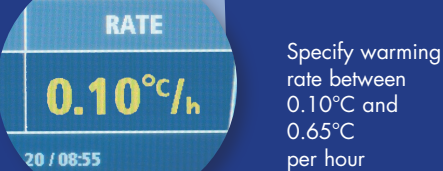
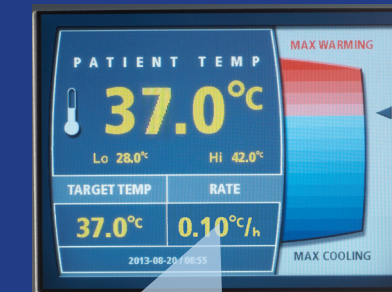
COOLING



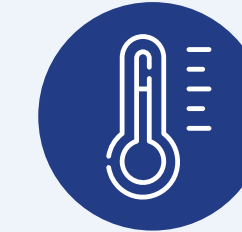
"MAX" Mode: cool patient quickly



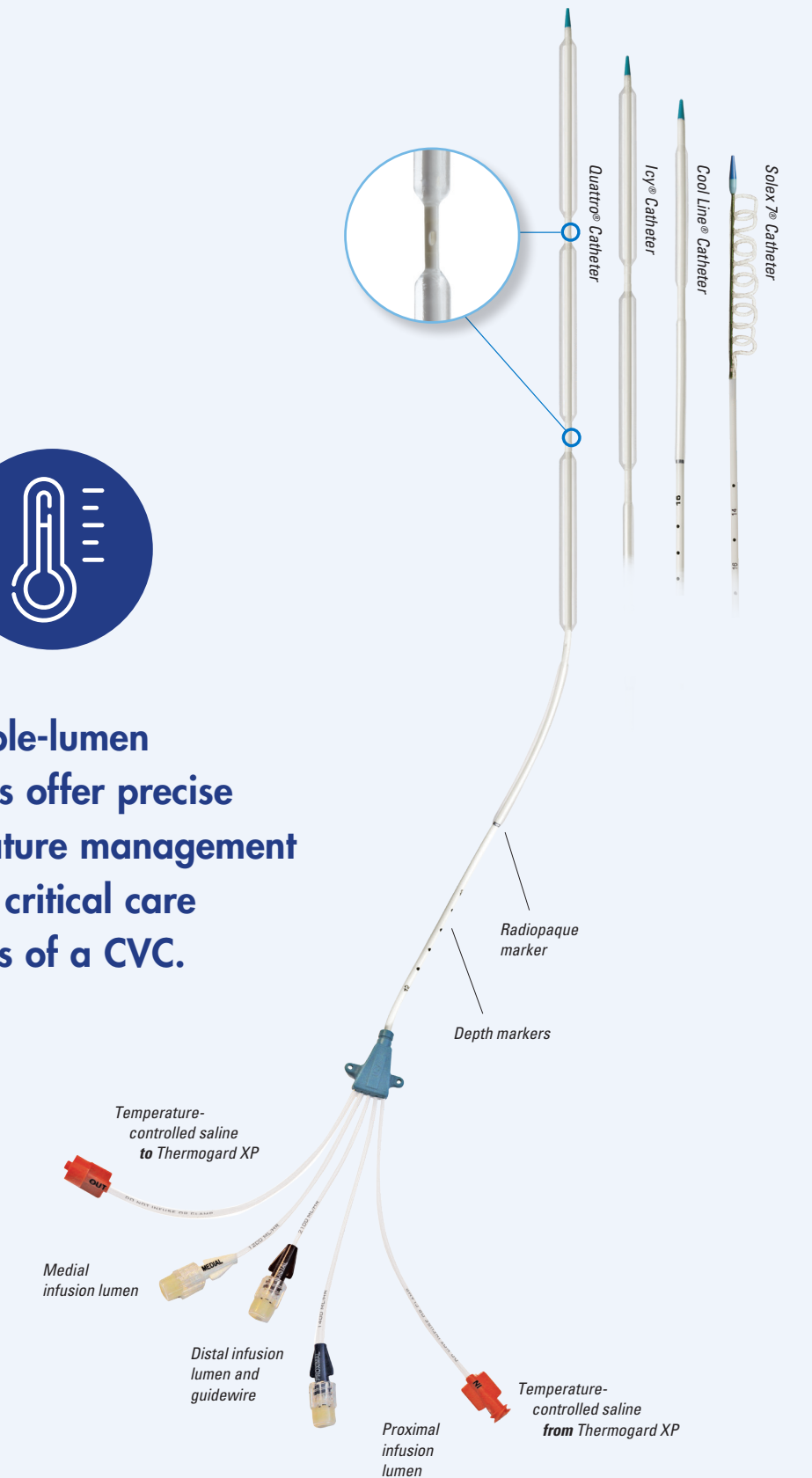
WARMING



Specify warming rate between 0.10°C and 0.65°C per hour



Four triple-lumen catheters offer precise temperature management and the critical care functions of a CVC.



¹ Deye N, et al. Circulation. 2015; 132:182-193.

² 2020 AHA Guidelines.

³ Medicare cost analysis data supplied by Freudman Healthcare Consulting LLC, 2008.

⁴ Kapinos G, et al. Neurology. 2017; 88:1-2.

⁵ Fink K, et al. Anaesthesist. 2008; 57(12):1155-1160.

⁶ Waard MC, et al. Emergency Med Journal. 2014;0:1-6.

⁷ Hoedemaekers CW, et al. Critical Care. 2007;11:R91.

⁸ Diring MN, et al. Critical Care Medicine. 2004;32(2):559-564.

⁹ Sander P, et al. Resuscitation. 2018; 124:14-20.

¹⁰ Bartlett E, et al. Resuscitation. 2019;124:82-85.

¹¹ Horn CM, et al. Journal of Neurointerventional Surgery. 2014 Mar;6(2):91-95.

¹² Knapik P, et al. Kardiologia Polska. 2011;69(11):1157-1163.

¹³ Maekawa T, et al. Therapeutic Hypothermia and Temperature Management Journal. 2020;10(3):179-18.

Speed, precision, and efficiency — when it matters most



Enabling efficiency in your workflow

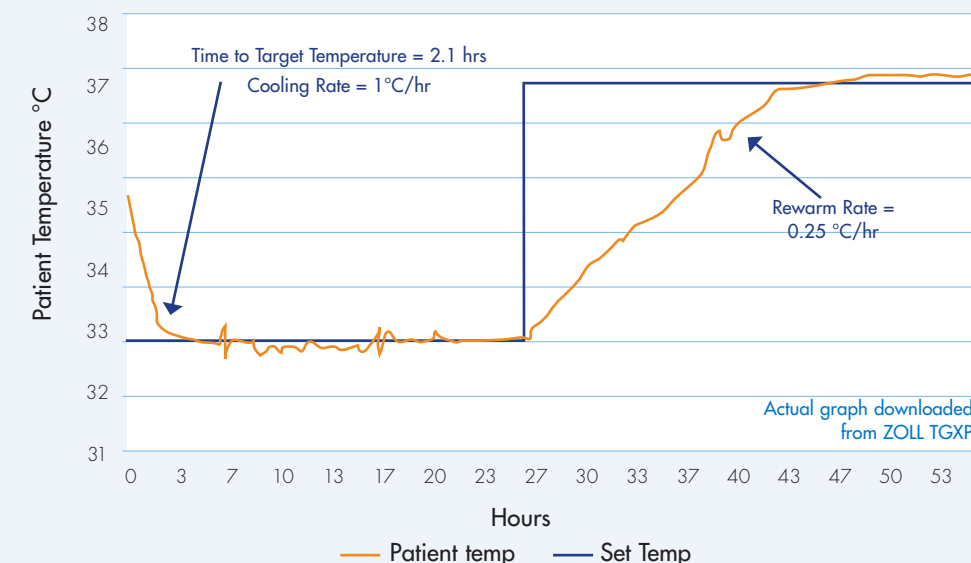
Because it cools and warms from the inside, TGXP offers unhindered patient access. And thanks to intelligent design, it integrates seamlessly into your workflow.

- Reduces nursing workload by 74%¹ — no need to constantly monitor temperature, manage shivering, check pads, etc.
- Doubles as a central venous catheter (CVC) — no other catheter is needed. The TGXP system delivers temperature management and doubles as a triple-lumen catheter.
- Reaches and maintains target temperature within $\pm 0.2^{\circ}\text{C}$ 100% of the time.²⁻⁸
- Results in a lower rate of shivering (4%³ vs. 85%⁹ with surface), which may require less sedation and can be used in awake, non-intubated patients.¹⁰
- Unhindered patient access allows for full-body counter-warming.
- Clinical evidence shows better outcomes: 35% better long-term neurological outcomes than surface cooling.¹
- Can be used with patients who are not candidates for surface (i.e., burn, trauma, fragile skin).
- Effective choice for high BMI patients.¹¹
- Console utilizes 50/50 propylene glycol (which is antibacterial in concentrations >20%) as the heat transfer media.



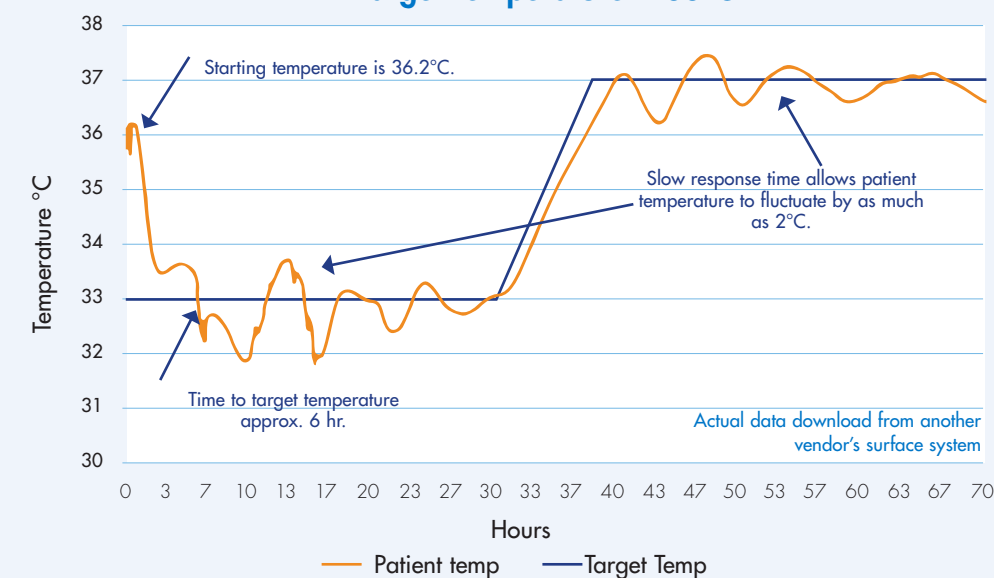
Intravascular Case Study

Target Temperature = 33°C



Surface Case Study

Target Temperature = 33°C



¹ ICEREA Deye N, et al. Circulation. 2015;132:182-193.

² Hoedemaekers CW, et al. Critical Care. 2007;11:R91.

³ Diringier MN, et al. Critical Care Medicine. 2004;32(2):559-564.

⁴ Sonders P, et al. Resuscitation. 2018;124:14-20.

⁵ Bartlett E, et al. Resuscitation. 2019;124:82-85.6

⁶ Horn CM, et al. Journal of Neurointerventional Surgery. 2014 Mar;6(2):91-95.

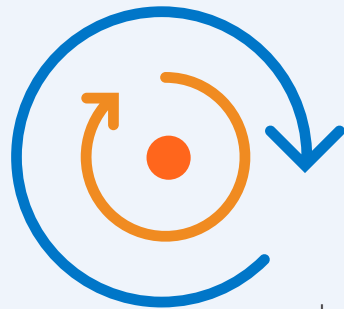
⁷ Knapik P, et al. Kardiologia Polska. 2011;69(11):1157-1163.

⁸ Maekawa T, et al. Therapeutic Hypothermia and Temperature Management Journal. 2020;10(3):179-18.

⁹ Carhuapoma JR, et al. Journal of Neurosurgical Anesthesiology. 2003;15(4):313-318.

¹⁰ Erlinge D et al. Circulation. 2010

¹¹ Ricome S, et al: Ricome et al, Intensive Care Med 2013.



If you are looking to enhance your temperature management program within your hospital, ZOLL offers the resources you need to help ensure the success of your temperature management program within your hospital.

ZOLL's Inside Track Clinical Consultants are ICU-trained, with extensive experience in TTM program development, and are up to date on current research and practices.

Partner with ZOLL's Inside Track Clinical Consultants who can help enhance your temperature management program.



Inside Track Program



Enhance Your Temperature Management Program

Our Inside Track Consultants, all experienced registered nurses in the ICU, CCU, or Cath Lab, can offer guidance in assessing your protocol for quality enhancements best suited for your program. ZOLL has a vast library of temperature management protocols from top medical centers around the world.

- Optimize patient flow
- Patient inclusion/exclusion
- Target temperature selection
- Shivering management



Improving Patient Outcomes Through Data-Driven Results

Seeing is believing. You need to see your results in order to measure performance. Our team of clinical consultants will interpret and review each case with you and your team, either virtually or in person.

- Interpretation
- Data review and follow-up
- Clinician feedback



The Importance of Clinical Support

Our clinical consultants have extensive experience in TTM program enhancement and are up to date on current research and practices. ZOLL also offers a variety of educational opportunities along with superior clinical support for your hospital.

Support includes:

- Device technology
- Patient management
- Current scientific evidence
- Clinical pathophysiology

Performance You Can Count On When It Matters Most

Clinical Parameters	Intravascular	Surface
Reaching Target Temperature	100% reached target temperature ¹	29% of patients did not reach target temperature. ²
Target Temperature Maintained ($\pm 0.2^{\circ}\text{C}$)	Superior: 97% of time in range ³	Poor: 49% of time in range ³
Time to Target Temperature	Rapid: 45 minutes ¹	Slow: 240 minutes ⁴
Target Temperature Overshoot ($<32^{\circ}\text{C}$)	0% ¹	34% ⁴
Time from Event to Start of Cooling	65 minutes ⁵	60 minutes ⁵
Shivering	4% rate of shivering. ⁶ May require less sedation and lower doses of paralytics. ⁷	85% rate of shivering. ⁸ May require higher doses of paralytics. ⁷
Nursing Time	Minimal: Set temperature and device adjusts automatically. Enables more focus on other aspects of patient care. ⁹	Extensive: requires management of temperature overshoot/undershoot, ¹⁰ pads, and shivering
Patient Eligibility		
Patients with spinal injuries	Yes	No ¹¹
Patients with skin issues	Yes	No ¹¹
Patients on multiple vasopressors	Yes	No ¹¹
Conscious patients	Yes	No ¹¹
Patient Access	Unhindered	Limited: at least 40% ¹¹ of the patient is covered with pads and tubing
Adverse Events	Risk of DVT is no greater than a standard CVC ⁶	Potential for skin injuries ¹²⁻¹⁴
Central Venous Catheter (CVC) Requirement	Integrated: CVC integral to ZOLL catheter design	Additional: Separate CVC required ⁹

¹ Maekawa T, et al. Therapeutic Hypothermia and Temperature Management Journal. 2020;10(3): 179-185.

² Heard KJ, et al. Resuscitation. 2010;81:9-14.

³ Hoedemaekers CW, et al. Critical Care. 2007;11:R91.

⁴ Glover G, et al. Critical Care (2016) 20:381.

⁵ Tomte O, et al. Critical Care Medicine. 2011;39(3):443-449.

⁶ Dinger MN, et al. Critical Care Medicine. 2004;32(2):559-564.

⁷ Lord A, et al. Neurocritical Care. 2014; 21:200-206.

⁸ Carhuapoma JR, et al. Journal of Neurosurgical Anesthesiology. 2003;15(4):313-318.

⁹ Vaga A, et al. Resuscitation. 2008;76:25-30.

¹⁰ Merchant RM, et al. Critical Care Medicine. 2006;34:S490-S494.

¹¹ Medivance Arctic Sun[®] Energy Transfer Pad™ Instructions for Use.

¹² Varon J, et al. Resuscitation. 2008;78:248-249.

¹³ Wang H, et al. Therapeutic Hypothermia and Temperature Management. 2013;3(3):147-150.

¹⁴ Liu YM, et al. Journal of Burn Care & Research. 2014;35(3):e184-186.

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104455-001, Rev. 01

ZOLL[®]

Thermogard XP Temperature Management System Specifications

ZOLL's Thermogard XP® (TGXP) Temperature Management System provides the power and control you need to rapidly, safely, and effectively manage the core body temperature of critically ill or surgical patients.¹⁻⁴

ZOLL combines precise temperature management with the critical care functions of a standard central venous catheter (CVC). Cool or warm saline circulates through the catheter in a closed loop, quickly cooling or warming the patient as venous blood passes over the balloons, without infusing saline into the patient.

Experience the benefits of the Thermogard XP

- Rapid and precise core body temperature management
- System automatically maintains target temperature within $\pm 0.2^{\circ}\text{C}$
- Easy-to-use
- Multifunction catheters double as a central venous catheter (CVC); adding vital capability to a line that is already being placed.
- Software enables real-time temperature display, storage, and download
- Reduces nursing workload by 74%⁵; no constant monitoring of temperature, managing shivering, checking pads, etc.
- Unhindered patient access



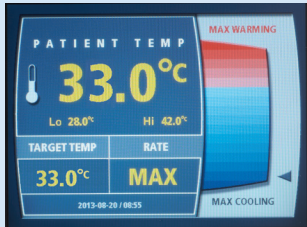
¹ Mayer SA, et al. Critical Care Medicine. 2004;32(12):2508-2515.

² Diringer MN, et al. Critical Care Medicine. 2004;32(2):559-564.

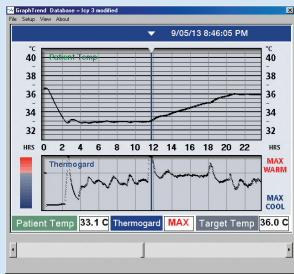
³ Hoedemaekers CW, et al. Critical Care. 2007;11:R91.

⁴ Heard KJ, et al. Resuscitation. 2010;81:9-14.

⁵ ICEREA Deye N, et al. Circulation. 2015;132:182-193.



View current patient and system data on the display or synchronize with your hospital monitor.



Track patient and system data and electronically transfer to the patient's file.



Start-up Kit

Tubing set, including heat exchange coil, air trap, and roller pump tubing.

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
978-421-9655
800-804-4356

Dimensions

Height: 45 in (114 cm)
Width: 17 in (43 cm)
Depth: 30 in (76 cm)
Weight: 115 lbs (52 kg)

Electrical Configuration:

100-120 VAC, 50/60 Hz, 5A
220-240 VAC, 50/60 Hz, 2.25A
Voltage: 115 V, 230 V
Fuse Protection:
T6.3A (slow blow) 5 x 20 mm

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 0 m head (0 ft)
Temperature Range:
0°C – 42°C
Refrigerant: HFC 134a

Controller and Display

Screen Display:
6.4 in. (16.25 cm) LCD
color VGA
Controls:
Push buttons and knob
Temperature Input:
Thermistor, YSI-400 series
Articulation:
180° swivel, 45° tilt
Data Interface:
Serial RS-232C, 9-pin
sub-D connector
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 and alarm system
Coolant Circuit Operating Life:
Replace disposable components
after seven (7) days of continuous use

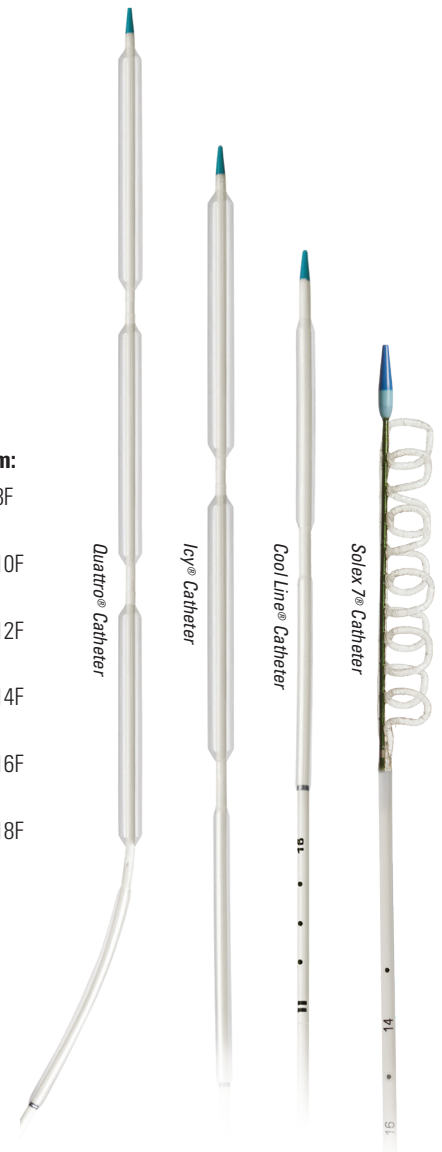
Equipment Classifications

**Type of Protection Against
Moisture:** Ordinary
**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
**YSI-400 temperature probes
verified to work with the system:**
Mallinckrodt Medical Foley Probe 8F
(200818-001)
Mallinckrodt Medical Foley Probe 10F
(200818-002)
Mallinckrodt Medical Foley Probe 12F
(200818-003)
Mallinckrodt Medical Foley Probe 14F
(200818-004)
Mallinckrodt Medical Foley Probe 16F
(200818-005)
Mallinckrodt Medical Foley Probe 18F
(200818-006)
Mallinckrodt Medical GP/Rectal
Probe 9F (200820-001)
Smith Medical Foley Probe 10 FR
(600244-001)
Smith Medical Foley Probe 12 FR
(600224-002)

Smith Medical Foley Probe 14 FR
(600224-003)
Smith Medical Foley Probe 16 FR
(600224-004)
Smith Medical Foley Probe 18 FR
(600224-005)
Smith Medical GP/Rectal Probe 9 FR
(600225-001)
Smith Medical GP/Rectal Probe 12 FR
(600225-002)
YSI-400 Temperature probes verified
to work with the system and Rüsçh
Patient Interconnection Cable –
Rüsçh P/N 179516
Rüsçh Sensor Temperature Foley
Catheters (CH 8, 10, 12, 14, 16, 18)
– Rüsçh P/N 179360
Rüsçh Temperature Supracath (CH 10,
12, 14) – Rüsçh P/N 179370



Specifications subject to change without notice.

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