

Device Description

The Thermogard HQ™ Surface Start-Up Kit is a tubing set that connects the Thermogard HQ™ console to the STx™ Vest or Thermogard™ Vest surface pad. The Thermogard HQ Surface Start-Up Kit is a closed-loop disposable that is composed of a pre-attached water reservoir, an extension tubing, a pump loop, a heat exchange coil and an air trap assembly. All of these items work with the console to supply cool water to the surface pad to regulate patient core temperature.

Indications for Use

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

Intended Purpose

The Thermogard HQ Surface Start-Up Kit intends to lower patient temperature.

Intended User

Intended Users for Thermogard HQ Surface Start-Up Kit include physicians, physician assistants, and nurses.

Clinical Benefits

The primary clinical benefit of the Thermogard HQ Surface Start-Up Kit is to lower body temperature.

Note: Refer to the Thermogard HQ Console Operations Manual and the STx Vest or or Thermogard Vest Instructions for Use for full listing of Indications, Contraindication, Warnings, Cautions, and additional information.

Contraindications

None known.

Warnings

- Read these instructions for use carefully before connecting pads to a patient.
- 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.
- Thermogard HQ Surface Start-Up Kits (non-sterile) are not compatible with intravascular catheter use (sterile).
- The patient's temperature and skin condition must be checked, especially areas in contact with the pad(s), 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 unconscious or incapacitated, persons on prolonged therapy, diabetics, children, persons with sensitive skin areas or poor circulation. Focus attention on all bony prominences.
- When a Thermogard HQ console is used with a Thermogard HQ Surface Start-Up Kit and STx Vest or or Thermogard Vest, the Treatment Mode is set to 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.

Cautions

- U.S. federal law restricts the device to sale on or by the order of a physician.
- Thermogard HQ Surface Start-Up Kits are not sterile and are intended for single patient use. Do not reuse, reprocess or sterilize.
- The cyclical stresses of the roller pump on these items cause fatigue failures. Do not use Thermogard HQ Surface Start-Up Kits beyond the labeled usage time. The products will fail.
- Use care when fitting the pad to the patient. When priming is complete, continue to flow water through the pad before fastening pad to the patient. Once water is fully flowing through the pad, it may be secured to the patient.
- Failure to connect both connectors to the pad may result in overpressure and leaks in the Thermogard HQ Surface Start-Up Kit or surface pad.
- If you notice a depleted reservoir bag or an air trap alarm, do not replace the water prior to identifying the location of the leak and taking the appropriate mitigation. Check for leaks in the Thermogard HQ Surface Start-Up Kit and the STx Vest or or Thermogard Vest surface pad. If a leak is found, replace as necessary. If the vest is replaced, the Thermogard HQ Surface Start-Up Kit reservoir bag may be refilled with additional water as required.

Operating Life

Caution. Thermogard HQ 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 Thermogard HQ Surface Start-Up Kit must be installed in the console. Failure to adhere to this time limit may cause the device to fail.

Setup Instructions

1. Initiate Console

- 1.0 Power on the console
- 1.1 Select "Cooling" for intended treatment
- 1.2 Choose whether new patient
- 1.3 Select Target Temperature
- 1.4 Select "Fever Control" mode

Caution: Always use "Fever Control" mode when using Thermogard Surface treatment.

2. Set Up Tubing

2.0 FILL RESERVOIR BAG

- A. Fill the reservoir bag with water and fasten cap.
- B. Hang the reservoir bag on console hook.

2.1 INSERT COIL

- A. Open coolant well cap.
- B. Place coil in well.
- C. Close cap, passing tubes through slit in cap.

2.2 PLACE AIR TRAP

- A. Place in stand with orange "2" end down. .

2.3 LOAD PUMP TUBE

- A. Open roller pump lid.
- B. Fully insert tubing disc into the slot "3".
- C. Firmly rotate counter-clockwise while feeding tube into the raceway.
- D. Fully seat tube into groove "3".

2.4 CONNECT VEST

- A. Fully connect both fluid connectors to the vest.

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

2.5 PRIME TUBING

- A. Close roller pump lid.
- B. Press and release PRIME button.
- C. Pump will run for 2 minutes. Confirm that the air trap is full of water. .

Caution: If the air trap is not full after 2 min, recheck steps 2.0-2.5.

2.6 INSERT AIR TRAP

- A. Insert air trap into chamber with blue "6" end down.
- B. Close console top cover while ensuring tubing is not pinched.

3. Place Vest

3.0 PLACE VEST UNDER PATIENT

Place the vest under the patient. Do not secure the Velcro straps at this time.

Note: The vest may be disconnected from the tubing while positioning it under the patient.

3.1 CHECK VEST CONNECTIONS

Ensure the vest is fully connected to the tubing. Both fluid connectors should click when fully engaged.

3.2 CONNECT PROBE

Connect a core temperature probe to the front of the console.

4. Start Treatment

4.0 PRESS ► ||

Press the ► || button on the console to start treatment.

Caution: Ensure the vest is open and the Velcro straps are not secured.

4.1 SET LO ALARM

Press the ≡ ◀ button on the console, then set the patient Lo alarm to 1°C below the target temperature.

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

4.2 WAIT FOR VEST TO FILL

Wait for vest to fill with water. This typically takes 3 - 5 minutes. A small amount of air in the vest is acceptable and will dissolve in time.

4.3 SECURE VEST TO PATIENT

Fold the vest flaps over the abdomen and chest. Secure and adjust to fit the patient using the enclosed stretchable Velcro straps. The vest should be snug but not constraining.

4.4 CONFIRM FLUID FLOW

Confirm that fluid is flowing through the tubing and pad by observing the rotation of the inline flow indicator (pinwheel). This may take several minutes. Check for kinks and tap on the flow indicator as needed.

Disconnect from Console and Dispose of Used Components

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

To remove used components from the console and dispose of them properly, follow these steps in the indicated order.

1. Place the console in Standby.
 - A) If after discarding the used disposables, they will be replaced and therapy will continue:
 - Leave the console in Standby.
 - Discard the used disposables as indicated in steps 2-12 below.
 - Setup and initiate new treatment according to the respective instructions.
 - B) If treatment has concluded:
 - Turn off the power switch.
 - Discard the used disposables as indicated in steps 2-12 below.
 2. Disconnect the Thermogard HQ Surface Start Up Kit connectors from the vest.
 3. Position a large empty medical waste container or collection bag near the console.
- Caution. Do not disassemble Thermogard HQ Surface Start-Up Kit.** Do not disconnect the tubing connecting the components. They are removed and disposed of as a complete unit.
4. Open the top cover of the console. Open the transparent top cover of the roller pump.
 5. Remove the lid from the coolant well and set it aside in a clean location.
 6. Grasp the pump tubing and gently pull it up and out of the channel while rotating the pump head.
 7. 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.
 8. Pull the air trap up and out of the chamber.
 9. Remove the water reservoir from the hook.
 10. Bundle up the vest and the collection of Thermogard HQ Surface Start Up Kit components, still connected together, and gently deposit them in the medical waste container.
 11. Use a disposable tissue to wipe up any spilled coolant from the top of the coolant well. Place the tissue in the medical waste container.
 12. Replace the insulated lid on the coolant well.

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

Troubleshooting

- If pad surface is not cold after approximately 5 minutes, check for kinks and other restrictions to water flow in the tubing and pad.
- It is normal for some amount of air to release from the pad during the procedure. This air will be captured in the water reservoir.
- Refer to the Thermogard HQ Console Operations Manual and the surface pad Instructions for Use for additional troubleshooting guidance.

Compatibility

- The Thermogard HQ Surface Start Up Kit works in conjunction with the Thermogard HQ Console.
- The Thermogard HQ Surface Start Up Kit connects to the STx Vest or or Thermogard Vest.

Storage

- Store Thermogard HQ Surface Start-Up Kits in a cool, dry environment.

Warranty




















- Refer to the Thermogard HQ Console Operations Manual for information on ZOLL's factory warranty.

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.

ZOLL Thermogard HQ™ Surface Start-Up Kit

Symbols

	Warning/Caution		Consult Instruction for Use
	Do Not Re-use; Single Use		Manufacturer
	Non Sterile		Date of Manufacture
	Lot or Batch Number		Do not use if package is damaged and consult instructions for use
	Catalog Number		Keep Away from Heat/Sunlight
RX ONLY	U.S. Federal law restricts this device to sale by or on the order of a physician		Keep Dry
	Medical Device		Quantity
	Unique Device Identifier		Conformité Européenne
	Authorized representative in the European Community/European Union		Authorized Representative in Switzerland
	Importer		Use by date

Catalog Number	8700-000935-01
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Patent: www.zoll.com/patents



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