

URGENT MEDICAL DEVICE CORRECTION

This is a voluntary Urgent Medical Device Correction intended to update cooler-heater cleaning instructions.

Attention: Chief of Perfusion; Director of Operating Room Services;
Director of Biomedical Services; Materials Management

Affected Products: Sarns™ TCM and TCM II Cooling and Heating Systems;
HX2™ Temperature Management Systems

Reference Number: AA-2018-002-C

Effective Date: March 9, 2018

REASON FOR CORRECTION

As part of on-going discussions with the U.S. Food and Drug Administration (FDA) regarding cooler-heater cleaning guide adequacy, Terumo Cardiovascular Systems (Terumo CVS) has updated its cooler-heater instructions for use (cleaning guides).

Despite the lack of confirmed complaints for infection associated with the use of any Terumo CVS cooler-heater device, Terumo CVS is issuing updates to its cleaning guides for specific products in order to provide customers with the most up-to-date information possible.

POTENTIAL HAZARD

While Terumo CVS has not received any confirmed reports of infection resulting from the use of Terumo cooler-heater devices, it is important to follow cleaning guide recommendations when performing cleaning of cooler-heater devices. For additional information on FDA's recommendations for healthcare facilities, please visit: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm>

AFFECTED PRODUCT

Catalog Number	Product Description	Lot Number or Serial Number Range	Dates of Distribution
15747	Sarns TCM Cooling and Heating Systems	All	May 2, 1985 through June 10, 2015
4415, 4416, 164925, 164935, 164930, 164940	Sarns TCM II Cooling and Heating Systems		
809810	HX2 Temperature Management Systems		

AFFECTED POPULATION

All patients requiring cardiac, vascular or cardiothoracic surgery with the support of Sarns TCM or TCM II Cooling and Heating Systems, or HX2 Temperature Management Systems.

CORRECTION

Updates to the cleaning guides for the products listed in this notice include:

- Clarifying the use of disinfectant wipes when wiping the surfaces of the devices
- Using a 0.22-micron filter
- Performing fill and prime, and draining three times
- Using maintain mode for running the cooling section of the HX2 system
- Meeting the chlorine level
- Using a new 3' tubing for each cleaning process. Then replacing the tubing used between the cooler-heater and heat exchangers after the completion of each cleaning.

Each of these changes aligns with the FDA published recommendations provided to health care providers that use cooler-heater devices.

CUSTOMER INSTRUCTIONS

1. Discard your current Sarns TCM or TCM II Cooling and Heating Systems, or HX2 Temperature Management Systems cleaning guides.
2. Review this notice and the attached updated cleaning guides, and ensure that all users receive notice of the updated cleaning guides.
3. Return the attached Customer Response Form acknowledging receipt of this notice.

QUESTIONS?

We encourage you to contact Terumo CVS with any questions or concerns:

- **Terumo CVS Customer Service:** 1.800.521.2818 Monday – Friday, 8 a.m. – 6 p.m. ET
- **Recall Fax:** 1.734.741.6149

REPORTING

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program:

- **Phone:** 1.800.FDA.1088, **Fax:** 1.800.FDA.0178
- **Web:** www.fda.gov/medwatch/report.htm
MedWatch Online Voluntary Reporting Form (mail to address on form):
www.fda.gov/Safety/MedWatch/HowtoReport

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1 PAGE

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NOTE: ARTWORK COPY MUST ACCOMPANY THIS PRINT.

D	91083	CHANGE FROM REMOVE TO MAY HELP MINIMIZE
C	90829	CLEANING GUIDELINE UPDATES
B	89175	REMOVED REFERENCE TO EPA REGISTRATION NUMBER
SYM.	CHG. NO.	DESCRIPTION
REVISIONS		
TERUMO CARDIOVASCULAR SYSTEMS CORPORATION Ann Arbor, Michigan		
TITLE GUIDE, TCM CLEANING		
PART NUMBER 873694		
SHEET 1 OF 1		DRAWING NUMBER 873950
		REV. D

TERUMO

Sarns™ TCM Cleaning Guide

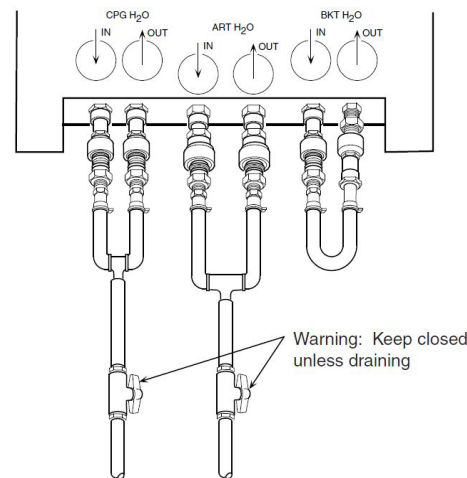
Frequency	Maintenance Procedures	Duration
Before Each Use	Sanitize (Test Chlorine)	5 min
Weekly	Clean and Sanitize	30 min
Every 3 Months	Clean coils	20 min
Every 6 Months	Descale	1 hour
For biofilm	Decontaminate (which descales, cleans, decontaminates and sanitizes)	2-6 hours

Setup Procedure (Detailed Steps Used Throughout Maintenance Procedures)

Whenever “close the circuits”, “fill and prime”, or “drain” are mentioned in the cleaning, descaling or decontamination procedures, follow the steps below.

Close the circuits

- Connect each set of In and Out ports using 3 ft. (1 m) of new tubing; include a ball type valve and drainage line in the cardioplegia and arterial water circuits. Use new 3 ft. (1 m) tubing prior to execution of all cleaning procedures.
- Position the unit near a sink or floor drain.



Fill and Prime

- Use 0.22µm filter on water supply.
- Fill the large tank to maximum level with cold water, fill the small tank with cold water until it begins to overflow into the large tank.
- Turn On and run in Cooldown mode to remove air from the tubing.
- Select Defrost. Turn the Cardioplegia on in Large Tank mode run until all air disappears from the tubing. Turn Cardioplegia off.
- Run in Rewarm mode. If air bubbles appear in the external tubing, immediately change back to Cooldown mode until the air bubbles disappear. Alternate between Cooldown and Rewarm modes until the unit will operate in Rewarm mode without external air bubbles. Return to Standby mode.

Note: The Defrost mode can only be entered through the Standby mode.

Precautions: The system must be properly primed; running the pumps and heaters with the device dry will damage them.

Use only Cage Klenz 100, S-Klenz, and 10% Sodium Hypochlorite solution as cleaning agents, following the manufacturer's directions and safety precautions. * Do not exceed the recommended strength to prevent corrosion damage.

Drain the Unit

- Turn System Power Off and back On to open the internal valves. Open both drain valves to empty tanks.
- Select Standby mode, gravity drain into a floor drain or bucket, OR
Use Cooldown mode; pump the water through the drain hose until only 6 in. (15,2 cm) of water remains in the large tank. Gravity drain the remaining water.
- Close both drain valves.
- Use the tank drain port for all cleaning and rinsing procedures.

Sanitization Procedure (Before Each Use)

Test the total chlorine level using Free Chlorine High Range or equivalent.

Warning: To control bacteria, maintain chlorine level between 3 to 5 ppm.

Precaution: To avoid corrosion, do not allow the chlorine level to exceed 10 ppm.

If chlorine level is below 3-5 ppm:

- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM to circulate water.
- Add up to 5 ml of 10% Sodium Hypochlorite solution to the large tank. Run for 2 minutes.
- Select Rewarm and Small Tank modes; run for 2 minutes.
- Test the chlorine level.

If chlorine level exceeds 10 ppm:

- Drain half the water; replace with 0.22µm filtered water.
- Circulate. Run for 2 minutes in Defrost, with Cardioplegia on in Large to Small Tank mode and 3 RPM. Run for 2 minutes in Rewarm and Small Tank modes.
- Test chlorine level. If still above 10 ppm, repeat water replacement; if below 3-5 ppm, add up to 5 ml the 10% Sodium Hypochlorite solution per above directions.

Warning: Observe proper safety precautions when using Cage Klenz-100. Follow the manufacturer's directions and safety precautions for proper handling.

Cleaning and Sanitizing Procedure (minimum weekly)

Clean with Detergent

- Per Setup, close circuits. Fill and prime if necessary.
- Select Defrost; turn the Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water, add 11 oz. (325,3 ml) of Cage Klenz 100 to large tank. Run for 5 minutes.
- Select Rewarm and Small Tank modes; run for 5 minutes.
- Per Setup, drain. Wipe any debris from the tanks and the tank outlet screens. Screens should be replaced periodically. Do not operate the unit without screens.
- Fill, prime, and drain the system three times using 0.22µm filtered water per the Setup Procedure in these instructions.
- Fill tank and prime.

Add Chlorine per Sanitization Procedure

- Select Defrost; turn the Cardioplegia on with Large to Small Tank mode and 3 RPM.
- Add 5 ml of the 10% Sodium Hypochlorite solution to the large tank. Run for 2 minutes.
- Select Rewarm and Small Tank modes; run for 2 minutes.
- Test and confirm the chlorine level is 3 to 5 ppm. Adjust the chlorine level until within prescribed limits.

Note: This cleaning guideline supersedes the operator's manual, 873949, cleaning instructions.

*Cage Klenz 100 and S-Klenz are products of Steris Corporation, Mentor, Ohio, U.S.A.

*Use any EPA registered 10% Sodium Hypochlorite sanitization solution.

Clean the Exterior

- Use disinfecting wipes to clean the exterior surfaces of the TCM. Keep liquids out of displays; away from probe jacks, and switches.
- Use disinfecting wipes to clean all surfaces above the waterline of the tank, both sides of the tank covers, and all external water connections.
- Allow the cleaning agent to remain in contact with surfaces per the cleaning agent manufacturer's instructions.
- Use a soft brush or vacuum to remove lint from lint filter.
- Clean writing spaces with a soft eraser. Do not use any abrasive material.

Make New Ice or Store Unit

- To make new ice, turn Ice Maker to On. The Ice Making LED will light but all other LEDs will be off.
- To store the unit, turn System Power Off, disconnect unit from wall power, drain unit; wipe tanks dry and put the tank covers in place.

Clean the Coils (every 3 months)

Precaution: Remove any lint from the refrigeration coils to prevent damaging the ice maker. Take care when cleaning the refrigeration coils as the coils have sharp edges.

- Disconnect unit from wall power supply. Remove the rear panel and left rear panel (corner away from the small tank).
- Use a soft brush and vacuum to remove lint from the coils.
- Replace the panels. Connect unit to wall power.

Descaling Procedure (every 6 months)

Descal more frequently in areas with a high mineral content in the water supply.

Warnings: Observe proper safety precautions when using S-Klenz as this is a phosphoric acid detergent.

Do not mix S-Klenz (acid descaler) with the 10% Sodium Hypochlorite solution (chlorine sanitizer) as exothermic reaction will occur, creating harmful chlorine gas.

Descale

- Test for chlorine. Remove chlorine prior to descaling; drain, fill and prime per Setup.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water, slowly add 11 oz. (325,3 ml) of S-Klenz to large tank; run for 15 minutes.
- Select Rewarm and Small Tank modes; run 15 minutes.

Rinse and Drain

- Drain the system.
- Fill, prime, and drain the system three times using 0.22µm filtered water per the Setup Procedure in these instructions.
- Fill tank and prime.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM. Run for 2 minutes.
- Select Rewarm and Small Tank modes; run 2 minutes.
- Drain the rinse water. Wipe debris from tanks and tank outlet screens. Fill with 0.22µm filtered water and prime.
- Perform complete Cleaning and Sanitizing Procedure.

Decontamination Procedure (when needed)

Decontaminate whenever biofilm is evident, which may be noticeable by a discoloration or cloudiness in the external fluid lines.

Prepare

- Descale Rinse and Drain according to the Descaling Procedure.
- Wipe any debris from the tanks and the tank outlet screens.

May Help Minimize Biofilm

- Add 20-30 lbs. (9,1-13,6 kg) of ice to the large tank (or make a full block of ice); add ice to small tank.
- Fill tanks and prime.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water, slowly add 11 oz. (325,3 ml) of the 10% Sodium Hypochlorite solution to the large tank. Run for at least 1 hour, adding ice if necessary to keep water below 20°C.
- Select Rewarm and Small Tank modes. Run for at least 1 hour.

Note: If biofilm is still visible, continue alternating between Defrost and Rewarm, running for 1/2 hour at each setting. Keep below 20°C when in Defrost. Do not add more sanitizer. As much as four hours additional time may be required to remove excessive biofilm.

Rinse

- Drain the system.
- Fill, prime, and drain the system three times using 0.22µm filtered water per the Setup Procedure in these instructions.
- Fill tank and prime.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM. Run for 2 minutes.
- Select Rewarm and Small Tank modes. Run for 2 minutes.
- Test the chlorine level. Sanitize per Sanitization Procedure. Replace all external water lines once the unit is drained.
- Make new ice or store the unit.
- Wipe any debris from the tanks and the tank outlet screens.

Obtain supplies from:

Steris Corporation

Product Name	Part Number
Cage Klenz 100	1K1005 5 Gallon Pail
S-Klenz	1J8108 4X4 Liters/case
1 Ounce Hand Pump	T611Q0

Industrial Test System

Product Name	Part Number
Free Chlorine High Range	480022

Pall Medical

Product Name	Part Number
In-Line Disposable Water Filter ≤ 0.22µm filter	AQINA or AQIN for other countries or equivalent

Clorox Healthcare®

Product Name	Part Number
Clorox Healthcare® Germicidal Wipes	30577 or equivalent

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
6200 Jackson Road Ann Arbor, Michigan 48103-9300
(734) 663-4145 (800) 521-2818

EC REP TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

TERUMO AUSTRALIA PTY LTD
Macquarie Park NSW 2113 Australia

TERUMO CORPORATION
Tokyo 151-0072, Japan

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