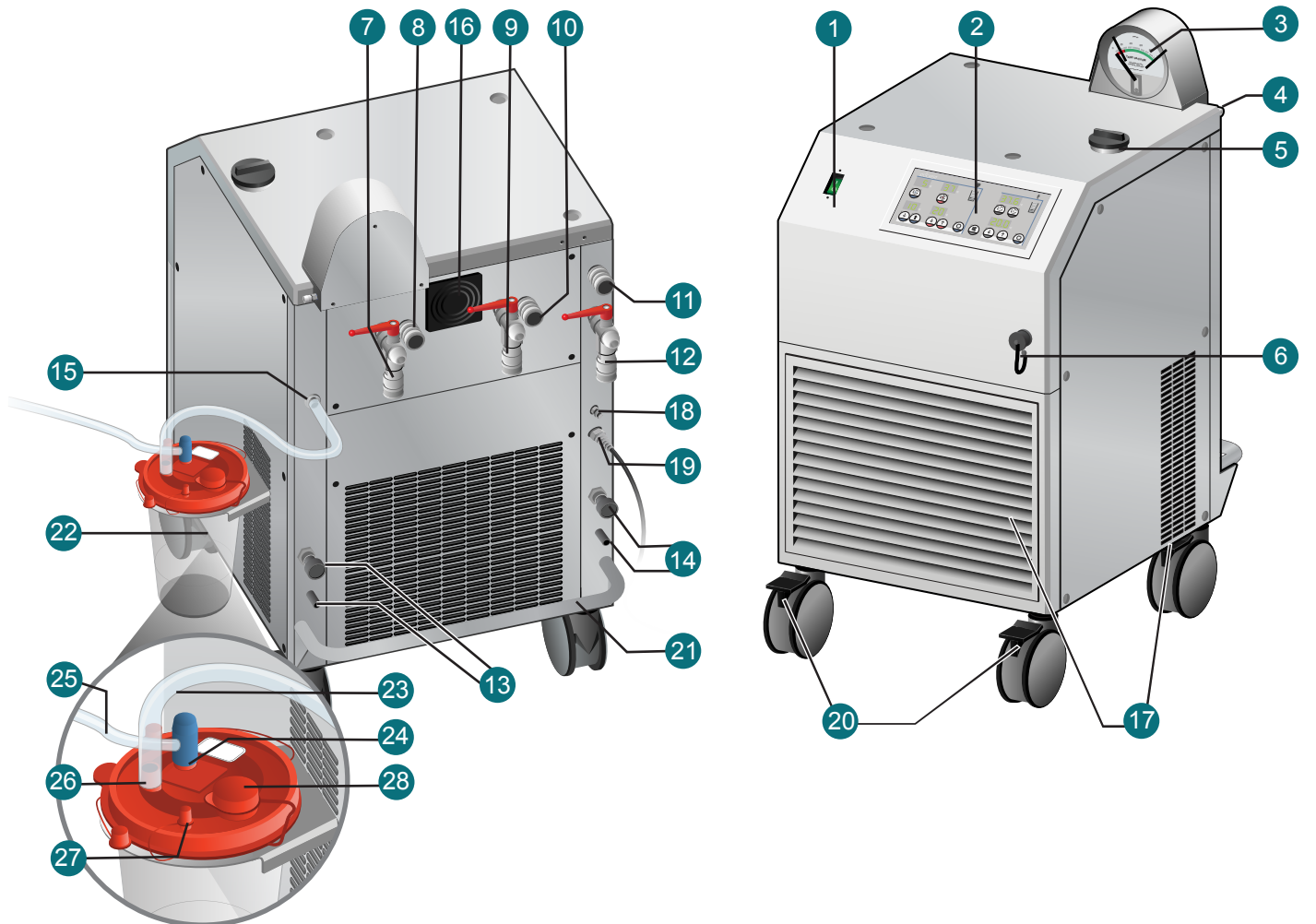


System Description

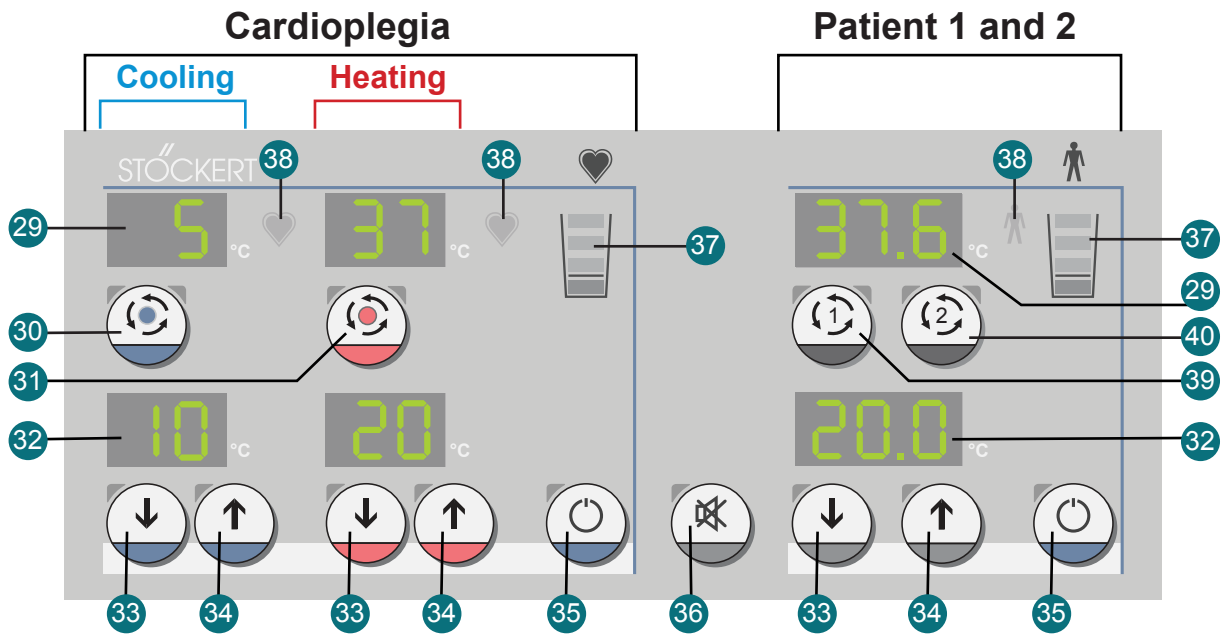
IMPORTANT: Read full IFU for complete details

Heater-cooler



- | | | |
|-----------------------------|-------------------------------------|---------------------------------|
| 1 Main Power Switch | 10 Patient 1 circuit inlet | 19 Power cable |
| 2 Control Panel | 11 Cardioplegia circuit inlet | 20 Castors |
| 3 Vacuum gauge with scale | 12 Cardioplegia circuit outlet | 21 Bumper |
| 4 Vacuum gauge service port | 13 Patient circuits drain valve | 22 Aerosol collection canister |
| 5 Filler neck with cap | 14 Cardioplegia circuit drain valve | 23 Connection line (short line) |
| 6 CAN jack with cover | 15 Overflow outlet | 24 Vacuum port (V) |
| 7 Patient 2 circuit outlet | 16 Fan | 25 Vacuum source line |
| 8 Patient 2 circuit inlet | 17 Ventilation grills | 26 Patient port (P) |
| 9 Patient 1 circuit outlet | 18 Potential equalization point | 27 Tandem port (T) |
| | | 28 Pour spout (S) |

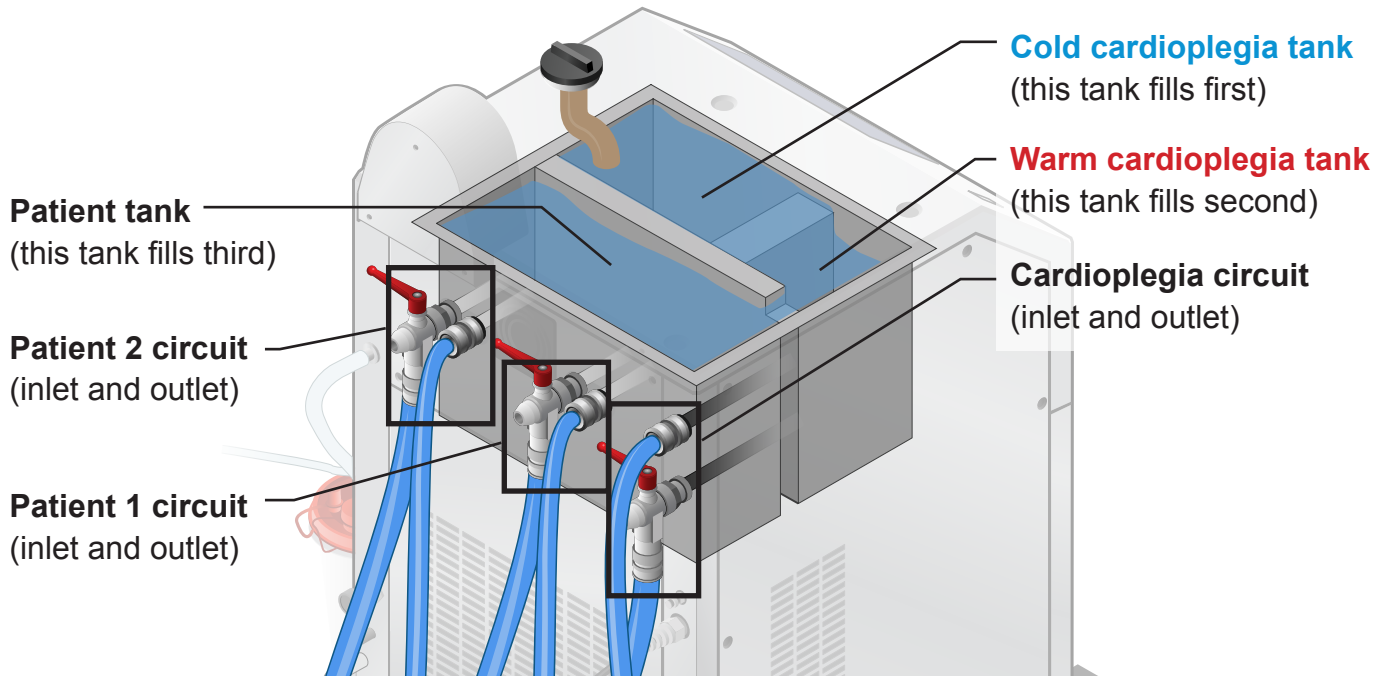
Control Panel



- | | | |
|--|--------------------------|--|
| 29 Actual tank temperature indicator | 33 Set value down button | 37 Water level display |
| 30 Cold cardioplegia circuit Start/Stop button | 34 Set value up button | 38 High temperature indicator Display |
| 31 Warm cardioplegia Start/Stop button | 35 Standby button | 39 Patient 1 circuit Start/Stop button |
| 32 Set temperature indicator | 36 Pause audio button | 40 Patient 2 circuit Start/Stop button |




















Tanks and Circuits

The Patient 1 and 2 circuits draw water from the Patient tank. The Cardioplegia circuit draws water from either the cold or warm cardioplegia tank.



Maintenance Calendar

IMPORTANT: Read full IFU for complete details

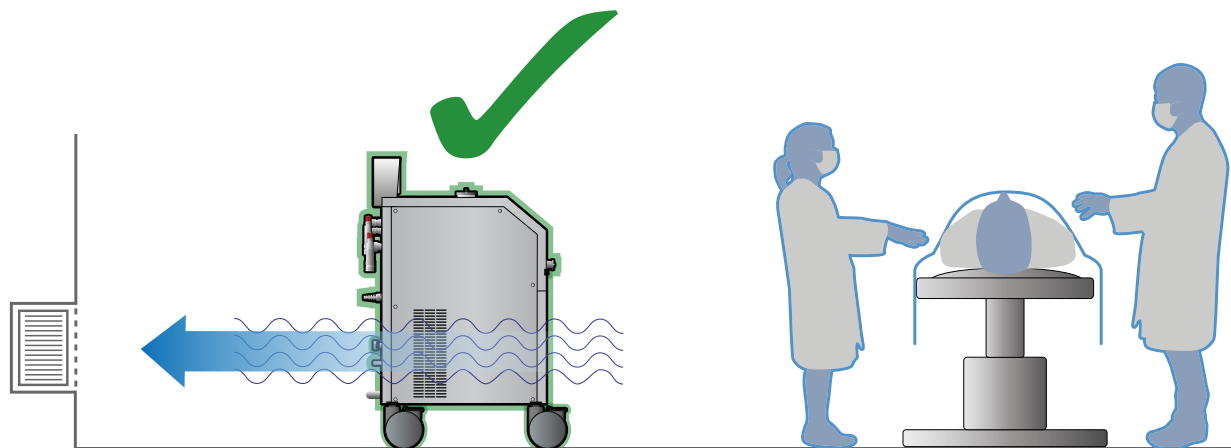
	<p>Clean and disinfect external surfaces, connectors, and fittings</p>	 Chapter 6.3
	<p>Disinfect the water circuits</p>	 Chapter 6.4
	<p>Disinfect connections and fittings</p>	 Chapter 6.3.2 Chapter 6.3.3
	<p>Clean and disinfect external surfaces</p>	 Chapter 6.3.1
	<p>Monitor the hydrogen peroxide concentration</p>	 Chapter 6.5.1
	<p>Replace the aerosol collection set</p>	 Chapter 5.7.2
	<p>Change the water and add hydrogen peroxide</p>	 Chapter 6.6
	<p>Disinfect the water circuits</p>	 Chapter 6.4
	<p>Monitor the water for total bacteria Monitor the water for NTM</p>	 Chapter 6.5.2
	<p>Replace procedural tubing</p>	 Chapter 6.9

Pre-procedure checklist

IMPORTANT: Read full IFU for complete details

Set up and position

- ✓ Machine air exhaust aimed away from the sterile field



! WARNING

Do not position the heater-cooler's and portable vacuum source's (if applicable) exhaust flow toward the operating field. Position the exhaust flow away from the operating field and toward the exhaust vent system.

- ✓ Castor brakes locked
- ✓ Aerosol collection set installed
- ✓ Vacuum regulator set to full
- ✓ Reading greater than 50Pa on HC3T vacuum gauge

Circuits and water level

- ✓ Procedural tubing secured in circuit connectors
- ✓ Circuit valves opened
- ✓ Circuits primed and water levels adjusted if required
(To adjust the water level, create a mixture with 10 ml of H₂O₂ and 910 ml of filtered tap water and fill the tanks)

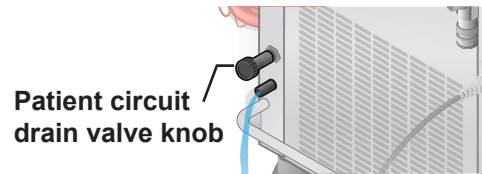
Every
Day

Monitor the hydrogen peroxide

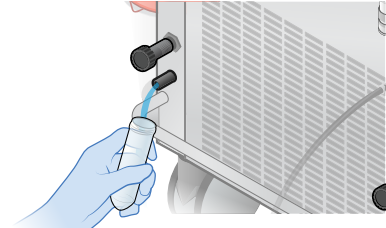
IMPORTANT: Read full IFU for complete details**1**

Check hydrogen peroxide concentration

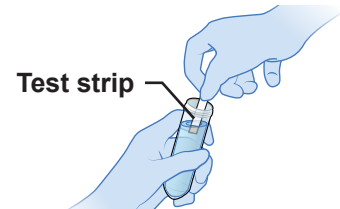
- a) Drain at least **100 ml** of solution from the Patient drain valve and discard.



- b) Drain at least **5 ml** of solution into the sterile sample container.



- c) Immerse the test strip in the sample container according to the test strip instructions.

**2**

Correcting the hydrogen peroxide concentration

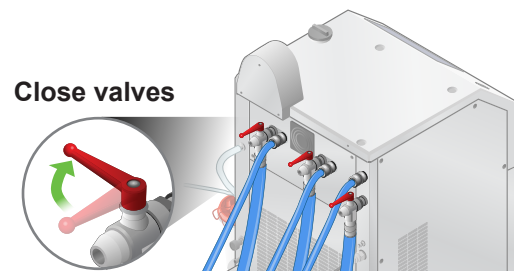
Acceptable concentration: greater than or equal to 100 mg/L H₂O₂

There is no additional action to be taken other than to monitor the concentration daily.

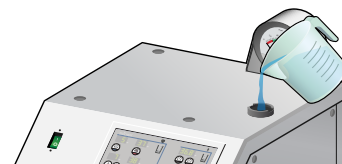
Unacceptable concentration: less than 100 mg/L H₂O₂

Proceed to next steps:

- a) If the procedural tubing is connected: Close the circuit valves, run the circuit pumps, then stop running the circuit pumps once the tubing is drained.



- b) Pour **100 ml** of medical grade 3% hydrogen peroxide into the tank.



- c) Mix tank contents for **5 minutes**.



Change water and add hydrogen peroxide

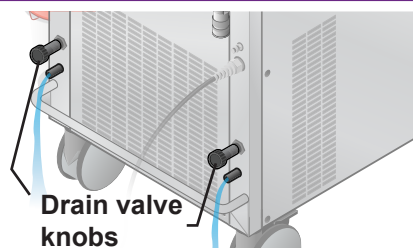
Every
7 days

IMPORTANT: Read full IFU for complete details

1

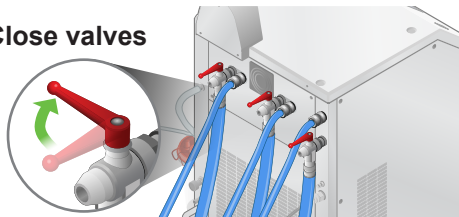
Drain tanks

- Drain the patient and cardioplegia tanks, then close the drain valves.
- Drain and disconnect the procedural tubing (if applicable), and close the red valve levers.



Drain valve knobs

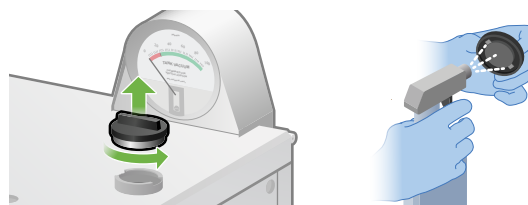
Close valves



2

Disinfect filler neck cap

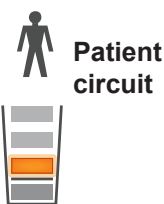
Remove and disinfect the filler neck cap.



3

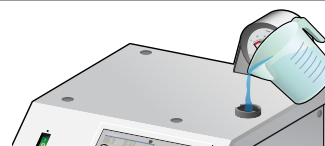
Fill tanks

- Fill the water tanks with filtered tap water to the **orange** segment on the patient circuit water level.



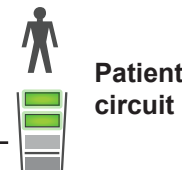
Patient circuit

- Pour **150 ml** of medical grade 3% hydrogen peroxide solution into the tank.



150 ml
3% Hydrogen peroxide

- Continue filling the tanks with filtered tap water until the **second green** segment of the **patient circuit** water level display lights up.

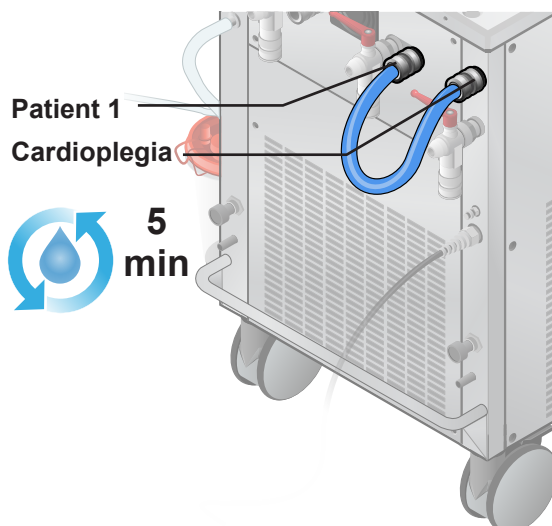


Patient circuit

4

Mix tanks

- Connect short-circuit tubing between the Cardioplegia circuit inlet and the Patient 1 circuit inlet.
- Run the **cold cardioplegia** circuit for **5 minutes**.
- Disconnect the short circuit between the cardioplegia circuit inlet and the patient circuit inlet.



Patient 1
Cardioplegia

5 min

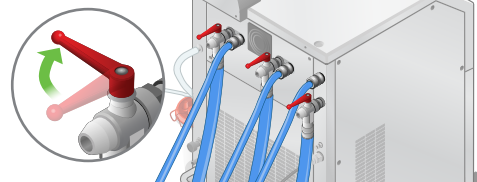
Disinfect the water circuits

IMPORTANT: Read full IFU for complete detailsEvery
14 days**1**

Drain tanks

- a) If the procedural tubing is connected: close the circuit valves, run the circuit pumps until the tubing is drained. Then stop the circuit pumps and disconnect all procedural tubing.

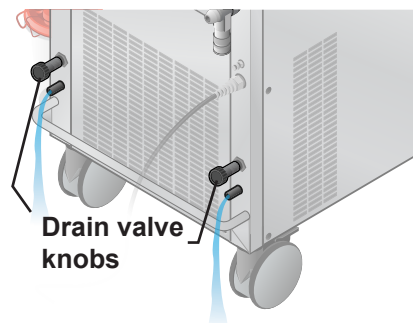
Close valves



- b) If you are monitoring the water for bacteria or NTM today, take water samples before draining the system.

- c) Fully drain the patient and cardioplegia tanks.

- d) Twist both drain valve knobs clockwise until drain valves are fully closed.

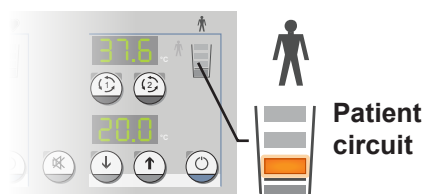
**2**

Fill tanks and add disinfectant

- a) Remove and disinfect the filler neck cap.



- b) Fill the water tanks with filtered tap water until the **orange** segment on the patient circuit water level display lights up.



- c) Add one disinfectant to the tank contents using the appropriate amount:

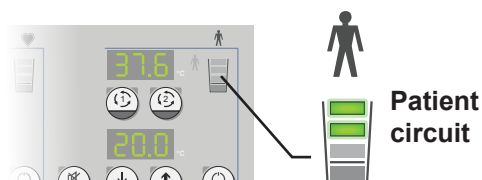
! WARNING

- **Use only one disinfectant.** The use of both products will potentially result in a dangerous chemical reaction.
- Use of a higher volume of disinfectant might damage the heater-cooler.

Option 1: 450 ml of Minncare Cold Sterilant or Puristeril 340 or Peresal
OR

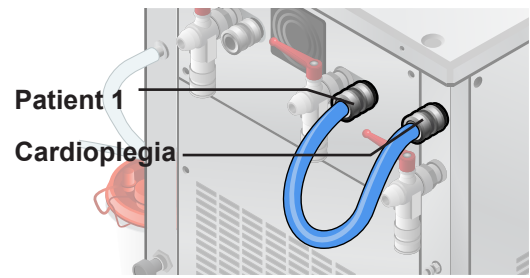
Option 2: 180 ml of Clorox® Germicidal Bleach (8.25%)

- d) Continue filling the tanks with filtered tap water until the **second green segment** of the **patient circuit** water level display lights up.

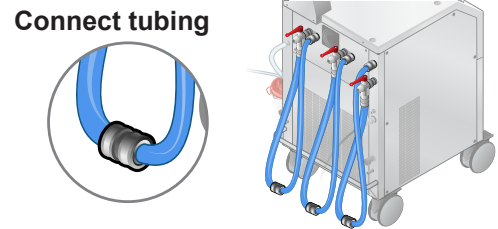


3 Run disinfectant through system

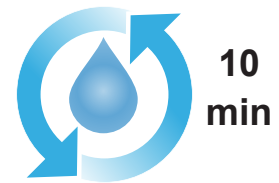
- a) Connect **short-circuit tubing** between the cardioplegia circuit inlet and the Patient 1 circuit inlet.
- b) Run the **cold cardioplegia** circuit for **5 minutes**.



- c) Connect procedural tubing between circuits using a suitable short-circuit adapter (part number 73-300-160). **NOTE:** If needed, bridge any unused circuits with short-circuit tubing.

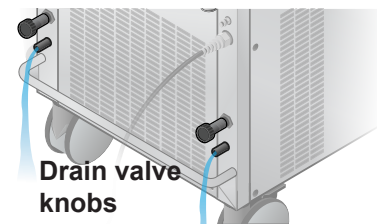


- d) Run the disinfectant through the system:
 - Open venting valves
 - Run the **Patient 1, Patient 2, and warm cardioplegia** circuit for **10 minutes**.
 - Close the venting valves before stopping the circuit pumps to drain tubing.

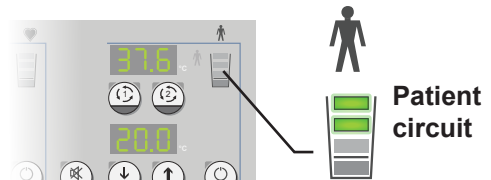


4 Drain, refill, rinse TWO (2) times

- a) Drain the patient and cardioplegia tanks, then twist both drain valve knobs clockwise until drain valves are fully closed.



- b) Using filtered tap water, fill the water tanks until the **second green segment** of the patient circuit water level display lights up.



- c) Rinse tanks and tubing:
 - Open the venting valves
 - Run the **Patient 1, Patient 2, and Warm cardioplegia** circuit for **3 minutes**.
 - Close the venting valves before stopping the circuit pumps to drain tubing.



- d) **Repeat steps a) through d)** so that the system is rinsed **two (2) times**.

5 Final steps

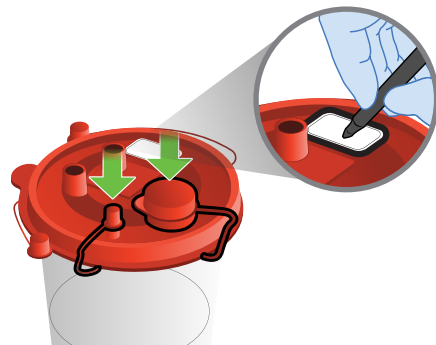
- a) Replace the aerosol collection set (including tubing).
- b) Fill the water tanks per the water change procedure, as required.
- c) If you are monitoring the water for bacteria or NTM today, take water samples after disinfecting and filling the system.

Aerosol collection set

After
7 days**IMPORTANT:** Read full IFU for complete details**1**

Installation procedure

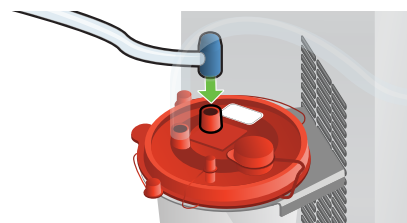
- a) Place lid on canister
- b) Place caps on Tandem port (T) and Pour spout (S)
- c) Write installation date on label



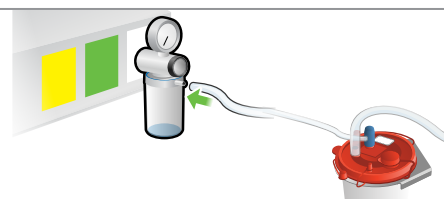
- d) Connect Patient port (P) to the HC3T Overflow using the short tube.



- e) Connect Vacuum port (V) to the vacuum regulator using the long tube (90° connector on Port V).

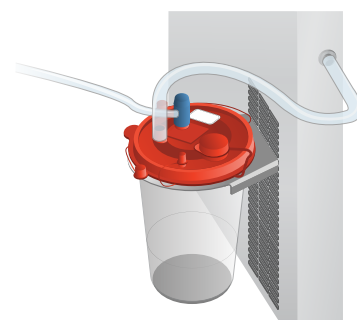


- f) Connect the long tube's other end to the external vacuum source.

**2**

In-procedure use

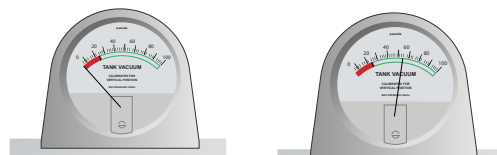
- a) Verify connections
 - Patient port (P) to heater-cooler
 - Vacuum port (V) to the vacuum source
 - All other ports are capped



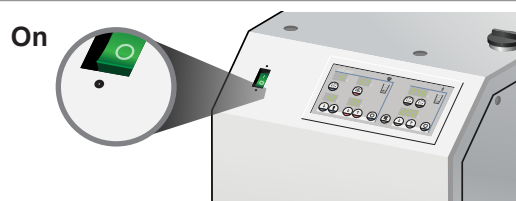
- b) Verify vacuum regulator is set to zero or off

- c) Check zero point on HC3T vacuum gauge

- d) Set vacuum regulator to **maximum**



- e) Verify vacuum gauge reads **> 50Pa**

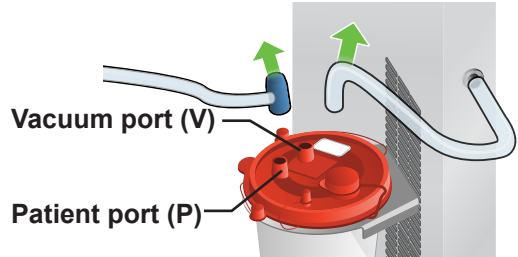
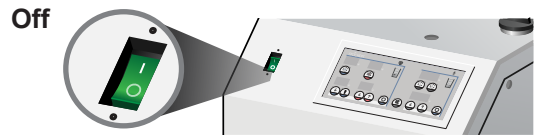


- f) Turn on heater-cooler

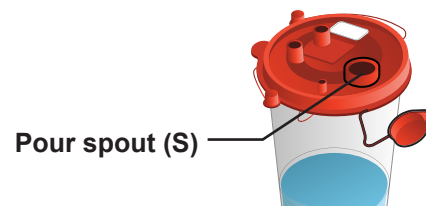
3

Emptying (if less than 7 days use)

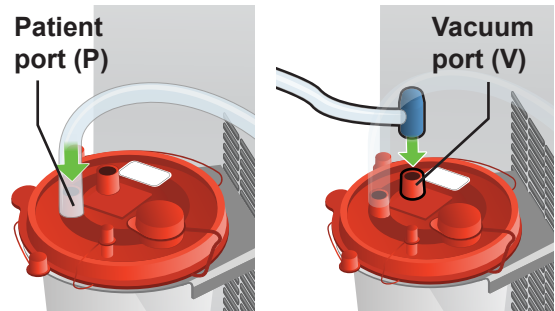
- a) Turn off heater-cooler (as required).
- b) Set vacuum regulator to off (or turn off portable source).
- c) Disconnect tubes from Patient port (P) and Vacuum port (V).



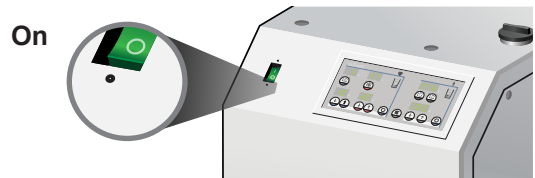
- d) Lift canister from holder.
- e) Uncap Pour spout (S) and pour contents of canister into appropriate drain.



- f) Recap Pour spout (S), and place canister back into holder.
- g) Reconnect Patient port (P) to heater-cooler and Vacuum port (V) to the vacuum regulator.



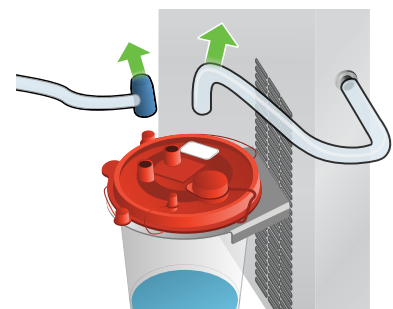
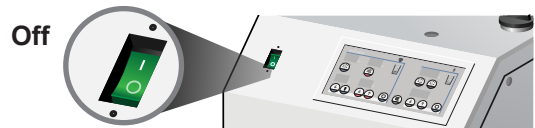
- h) Set vacuum regulator to maximum
- i) Turn on heater-cooler (as required)



4

Disposal (after 7 days)

- a) Turn off heater-cooler (as required)
- b) Set vacuum regulator to off (or turn off portable source)
- c) Disconnect tubes from Patient port (P) and Vacuum port (V), and from HC3T and vacuum source.
- d) Remove collection canister from holder, and discard all aerosol collection set components according to hospital policy.



Monitor for bacteria and NTM

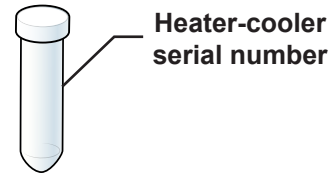
IMPORTANT: Read full IFU for complete details



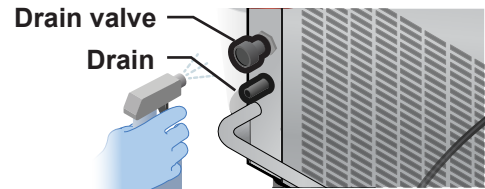
1

Preparation

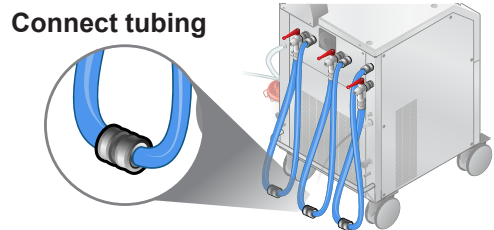
- a) Gather required sample containers
 - 2 x 50 ml for total bacteria
 - 4 x 50 ml or 2 x 100 ml for NTM



- b) Disinfect patient drain valve

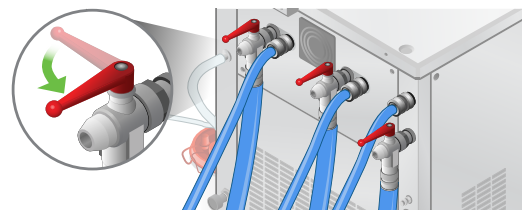


- c) Connect procedural tubing between circuits using a suitable short-circuit adapter (part number 73-300-160)



i **IMPORTANT:** Do not connect tubing to any circuits not used during procedures.

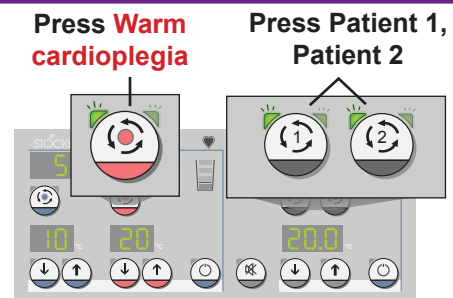
- d) Open red valves for circuits with tubing connected.



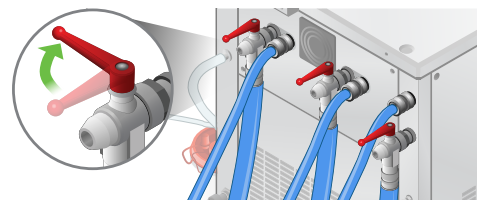
2

Run Circuits

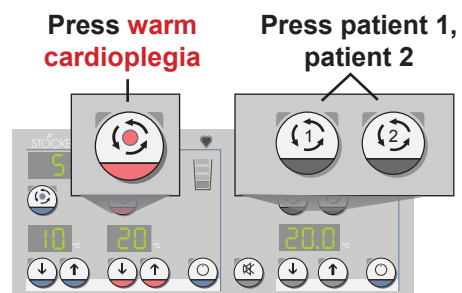
- a) Press the Start/Stop buttons for **Warm cardioplegia**, **Patient 1**, and **Patient 2** circuits.



- b) Run the circuits for **5 minutes**, then close the venting valves and drain the tubing.



- c) Stop the circuit pumps.

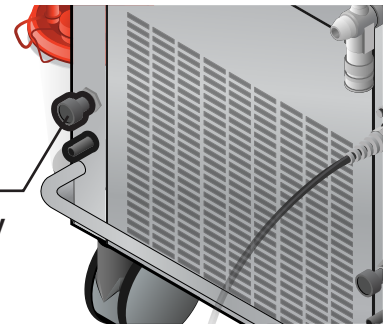


3

Collection

a) Check the patient drain valve and make sure the disinfectant is dry.

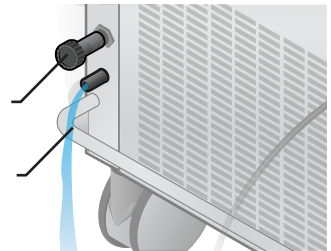
Make sure valve is dry



b) Fully open patient drain valve

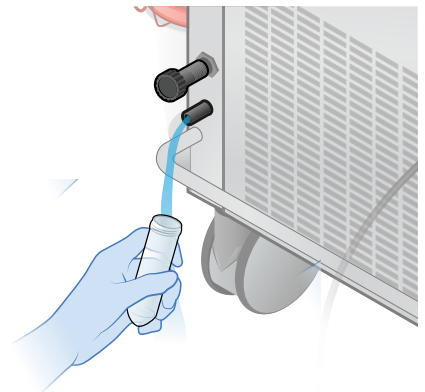
c) Drain for at least 5 seconds and discard

Patient drain valve knob
Drain for 5 seconds

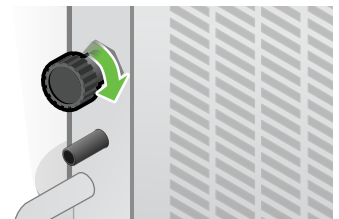


d) Collect samples:

- Total Bacteria: **50 ml** of water in one sample container
- NTM: **100 ml** of water in one or two sample containers



e) Close the drain valve.



f) Disinfect heater-cooler, then **repeat steps 1 to 3** of this quick reference guide to collect a second set of samples.



Disinfect heater-cooler, then repeat steps:

- 1
- 2
- 3

g) Interpret results according to the IFU Chapter 6.5.2, step 4.



Interpret results, Chapter 6.5.2, Step 4