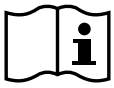
Altrix™ Precision Temperature Management System

REF 8001

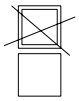
stryker®

Operations Manual

Symbols

	Refer to instruction manual/booklet
	General mandatory action sign
	Consult instructions for use
	General warning
	Caution
	Warning; electricity
REF	Catalogue number / model
SN	Serial number
US Patents	For US Patents see www.stryker.com/patents
	Manufacturer
	Mass of equipment
⎓	Direct current
~	Alternating current
	Product provides terminal for connection of a potential equalization conductor. The potential equalization conductor provides direct connection between the product and potential equalization busbar of the electrical installation.
	Protective earth ground
IPX1	Protection from dripping water from above the device
	Defibrillation proof type BF applied part
	⚠ **CAUTION** Federal law (USA) restricts this device to sale by or on the order of a physician.

Symbols

	**⚠ CAUTION** Always use sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns with this product.
	In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately. Contact your local distributor for disposal information.
 87VL Medical Electrical Equipment	Medical Equipment Classified by Underwriters Laboratories Inc. with Respect to Electric Shock, Fire, Mechanical and Other Specified Hazards Only in Accordance with IEC 60601-1:20 05 (3rd edition), ANSI/AAMI ES60601-1 (2005, 3rd edition), CAN/CSA C22.2 No. 60601-1:20 08, IEC 80601-2-35:2009, CAN/CSA C22.2 NO 80601-2-35:12, ISO 80601-2-56:2009, CAN/CSA C22.2 NO 80601-2-56: 12, IEC 60601-1-8:2007, CAN/CSA C22.2 NO 60601-1-8-08, IEC 60601-1-10:2008, CAN/CSA C22.2 NO 60601-1-1 0-09, IEC 60601-1-6, CAN/CSA-C22.2 No. 60601-1-6:11
	Liquid level indicator
	Fragile, handle with care
	Keep dry
	Do not stack
	This way up

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Warning/Caution/Note Definition

The words **WARNING**, **CAUTION**, and **NOTE** carry special meanings and should be carefully reviewed.

WARNING

Alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

CAUTION

Alerts the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the product or other property. This includes special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

Note: Provides special information to make maintenance easier or important instructions clearer.

Summary of safety precautions

Always read and strictly follow the warnings and cautions listed on this page. Service only by qualified personnel.

WARNING

- Always turn or re-position the patient over the duration of therapy, if possible, to reduce the risk of pressure ulcers. Follow your hospital protocol.
- Always check the integrity of the patients skin and temperature according to hospital protocol when using the **Altrix** system.

CAUTION

- Improper usage of the product can cause injury to the patient or operator. Operate the product only as described in this manual.
- Do not modify the product or any components of the product. Modifying the product can cause unpredictable operation resulting in injury to patient or operator. Modifying the product also voids its warranty.
- Shock Hazard - Improper handling of the power cord may damage the power cord and cause potential shock hazards. If damage has occurred to the power cord, immediately remove the temperature management system from service to avoid the risk of serious injury or death. Contact the appropriate maintenance personnel.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like **Altrix**. Install and place **Altrix** into service according to the EMC information located in the EMC section of this manual. Portable and mobile RF communications equipment can affect the function of **Altrix**.
- Shock Hazard. If the internal electrical components are exposed, because the side panel or cover are compromised, remove the product from use.
- Always make sure that the product reaches room temperature before you setup or operate the product.
- Before first use, disinfect the internal water circuit.
- Do not use **Altrix** located near or stacked with other medical equipment. If it is necessary to locate **Altrix** near other medical equipment, make sure it operates as intended.
- Always apply the wheel locks to prevent unintended movement.
- Always use Stryker accessories. Only IEC 60601-1 equipment shall be hooked to the patient temperature ports. Failure to comply with these instructions may invalidate any or all warranties and may negatively affect the products EMC performance. This also protects the product from cardiac defibrillation.
- Avoid the use of materials of good thermal conductivity, such as water, gel, or similar substances, with the **Altrix** system not powered on. This can decrease the temperature of the body of a patient.
- Do not apply thermal transfer devices to patients with ischemic limbs. This may result in harm to the patient.
- Do not use this product if the patient has a transdermal medication (patch) as this can result in increased drug delivery.
- Always pre-fill the thermal transfer device with sterile distilled water before you apply it to the patient. This is to reduce the risk of pressure ulcers.
- Electric shock. This equipment must only be connected to a supply mains with protective earth.
- Always plug this product directly into a properly grounded hospital-grade or medical-grade wall outlet to achieve grounding reliability.
- Do not use high frequency surgical instruments or endocardial catheters while the **Altrix** system is in use. This is to avoid the risk of electrical shock, burns, or electromagnetic interference.
- Explosion risk. This product is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide other than nasal or mask type.
- Do not place cables, hoses, or power cord in walkways to avoid the risk of trip hazards.
- Avoid reduction in water flow. Do not connect two or more thermal transfer devices in a series on a single port.

⚠ CAUTION (CONTINUED)

- Do not use three or more adult Mul-T-Blanket's at the same time to avoid the risk of water overflow when you power off the controller.
- When you operate the product near ambient temperature limitations of 15.0˚ C (59.0˚ F) or 32.0˚ C (89.6˚ F), you may experience a reduction in product performance.
- Do not place your fingers in between the reservoir and the sides of the controller, to avoid the risk of pinching your fingers.
- Always use sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns with this product.
- Always fill the reservoir with room temperature sterile distilled water to reduce the risk of burn.
- Do not overfill the reservoir to avoid the risk of water spillage and fall.
- Always make sure that there are no water leaks before starting a defibrillation.
- When using the temperature controlled Automatic therapy mode for warming (min, med, or custom), switching to other modes, changing the target patient temperature, or changing the therapy selection may impact the overall benefit of therapy.
- Always monitor the patient for shivering, temperature, signs of intolerance, and skin condition when using this product.
- Always store the power cord, cables, and hoses before you transport the product to reduce the risk of trip hazard.
- Do not store the product with water in the device.
- Always store the product within the specified environmental condition values.
- Always use extra care when you transport the product long distances and on inclines greater than five degrees. Ask for help, if necessary, to avoid the risk of tipping.
- Always use the handle to move the product. Do not attempt to move the product by pulling on cables, hoses, or by any other means.
- Avoid ramps that are steeper than ten degrees to avoid tipping the product.
- Do not hang items on the controller handle to avoid the risk of tipping the product.
- Do not power wash this product.
- Do not use quaternaries that contain glycol ethers as they may damage the reusable accessories.
- Do not disinfect the internal water system with a thermal transfer device attached as this may cause a leak.
- Do not use bleach or any other cleaning or disinfectant agents for internal circuits. This could result in damage to the product. Only use approved disinfectant tablets.
- Always drain the product before disinfecting the internal water circuit. Failure to drain the product may reduce the effectiveness of the disinfection process.
- Always remove the product from use before servicing any components. Contact qualified service personnel for service.

Notes

- Disinfection of the **Altrix** internal water system was validated using *M. mucogenicum*.

This manual assists you with the operation or maintenance of your Stryker product. Read this manual before operating or maintaining this product. Set methods and procedures to educate and train your staff on the safe operation or maintenance of this product.

⚠ CAUTION

- Improper usage of the product can cause injury to the patient or operator. Operate the product only as described in this manual.
- Do not modify the product or any components of the product. Modifying the product can cause unpredictable operation resulting in injury to patient or operator. Modifying the product also voids its warranty.

Notes

- This manual is a permanent part of the product and should remain with the product even if the product is sold.
- Stryker continually seeks advancements in product design and quality. This manual contains the most current product information available at the time of printing. There may be minor discrepancies between your product and this manual. If you have any questions, contact Stryker Customer Service or Technical Support at 1-800-327-0770.

Product description

The Stryker model 8001**Altrix**™ Precision Temperature Management System can supply water to an individual or multiple thermal transfer devices simultaneously with each of these circuits monitored separately. Three operating modes are available to ease patient care: Automatic, Manual, and Monitor. The controller uses the patient temperature probe to provide closed loop feedback for automatic patient temperature management and monitoring. The controller alarms visual and audible indications for when safety parameters are exceeded or it detects system function or performance irregularities. The **Altrix** system is able to provide a patient temperature output reference signal to be connected to a non-specific third party device or system.

The controller regulates water temperatures between 4.0˚ C (39.2˚ F) and 40.0˚ C (104.0˚ F) and circulates the heated or cooled water via hose sets through the thermal transfer devices. A graphical display provides the user an interface for selecting desired water or patient temperature settings, operating modes, help menus, and other key parameters. Visual indicators are displayed to inform the user of system status or when the user must confirm a setting selection. The system's water temperature and flow outputs can be monitored with 400 series compatible devices to optimize system operation.

The **Altrix** system includes the following components:

- controller
- reusable hose sets
- thermal transfer devices (blankets, vests, and leg wraps)
- patient temperature probes
- reusable adapter cables
- reusable patient temperature output cable

Note: The blankets, vests, leg wraps, and patient temperature probes are type BF applied parts.

Indications for use

The **Altrix** system is intended for circulating temperature controlled warm or cold water via patient contact thermal transfer devices for the application of regulating human body temperature in situations where a physician or clinician with prescription privileges determines that temperature therapy is necessary or desirable.

Indications for use for the **Altrix** system include:

- Maintain pre-set body temperature as determined by the physician
- Maintain normal body temperature during surgical procedures

Indications for use (Continued)

- For use in all clinical settings including coronary care units, operating, recovery and emergency departments, burn units, and medical/surgical units
- Adult and pediatric patients
- Monitoring and controlling patient temperature
- Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients

Intended users

- Physicians
- Advanced Practice Registered Nurses
- Nurses

Expected service life

The **Altrix** controller has a five year expected service life under normal use, conditions, and with appropriate periodic maintenance. See the maintenance manual for preventive maintenance and service information.

Contraindications

For core body temperature regulation:

- Raynaud's Phenomenon (primary or secondary)
- Application to lower extremities distal to aortic cross-clamping

Specifications

Model		**8001-000-001**
Electrical Requirements - AC Voltage Input Current and Voltage Ratings		120VAC, 60Hz 12A
Physical dimensions		
Height	42.5 in.	107.9 cm
Width	15.0 in.	38.1 cm
Depth	23.0 in.	58.4 cm
Empty weight	150.0 lb	68.0 kg
Filled weight	160.5 lb	72.8 kg
Reservoir capacity	1.3 gal	5.0 L
Water temperature		
Control setting range	39.2˚ - 104.0˚ F	4.0˚ - 40.0˚ C
Control accuracy	±0.3˚ C (4.0˚ - 40.0˚ C)	
Display measurement accuracy	±0.2˚ C (4.0˚ - 40.0˚ C)	
Display / resolution setting	0.1˚ C	
Default setting	104.0˚ F	40.0˚ C

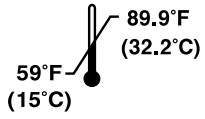
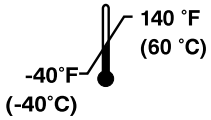
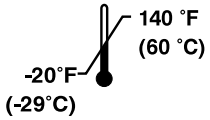
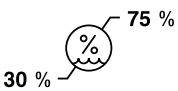
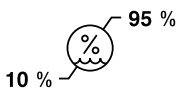
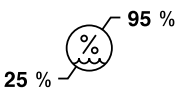
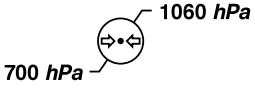
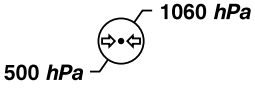
Specifications (Continued)

Patient temperature		
Control setting range	89.6˚ - 100.4˚ F	32.0˚ - 38.0˚ C
Control accuracy	±0.1˚ C (32˚ - 38˚ C)	
Measurement accuracy	±0.3˚ C (25.0˚ - 45.0˚ C)	
	±0.4˚ C (0.0˚ C - 24.9˚ C, 45.1˚ C - 50.0˚ C)	
Display / resolution setting	0.1˚ C	
Display range	32.0˚ - 122.0˚ F	0.0˚ - 50.0˚ C
Default setting	98.6˚ F	37.0˚ C
Controller		
Heater capacity, maximum	500 watts	
Circulating fluid	Sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns with this product	
Battery	9V Lithium	
Alarm tone range	75 - 85 dBA per standard IEC 60601-1-8	
Water flow rate in each hose port	Typical 1.2 lpm	
Refrigerant type	R134a	
Power cord length	14 to 15 feet	4.2 - 4.5 meters
Clinical thermometer	Direct mode	
Equipment Class	Class I	
	Rated for continuous operation	

Note: The controller takes approximately 9 minutes to heat from 23.0±2˚ C (73.4˚ F) to 37.0˚ C (98.6˚ F) when not connected to a patient. Time will vary when connected to a patient.

Stryker reserves the right to change specifications without notice.

For more information about thermal transfer devices, cables, or probes, see the manufacturer's instructions for use.

Environmental conditions	Operation	Storage	Transporta tion
Ambient temperature			
Relative humidity (non-condensing)			
Atmospheric pressure			Not applicable

Product illustration

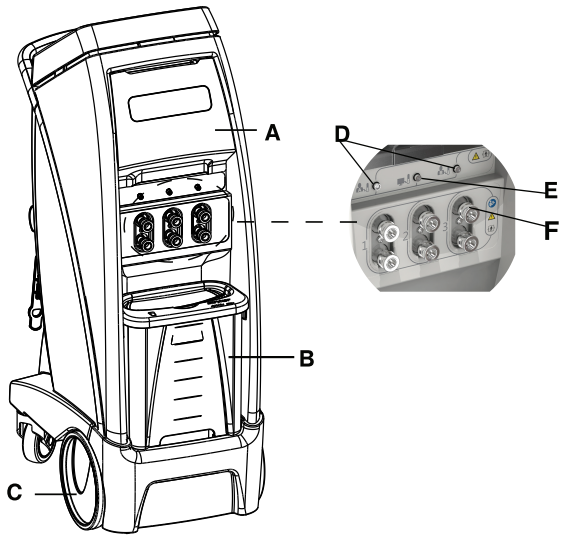


Figure 1: Controller, patient front

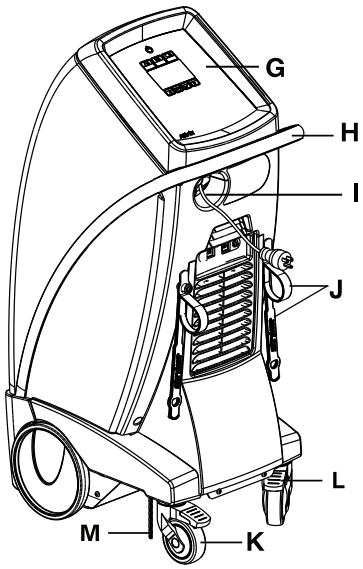


Figure 2: Controller, patient back

A	Storage compartment
B	Removable water reservoir
C	Front wheels
D	Patient probe ports
E	Patient temperature output port
F	Hose connection ports

G	Graphical user interface display
H	Handle
I	Power cord
J	Hose and power cord management straps
K	Swivel casters
L	Wheel locks
M	Ground chain

Product system

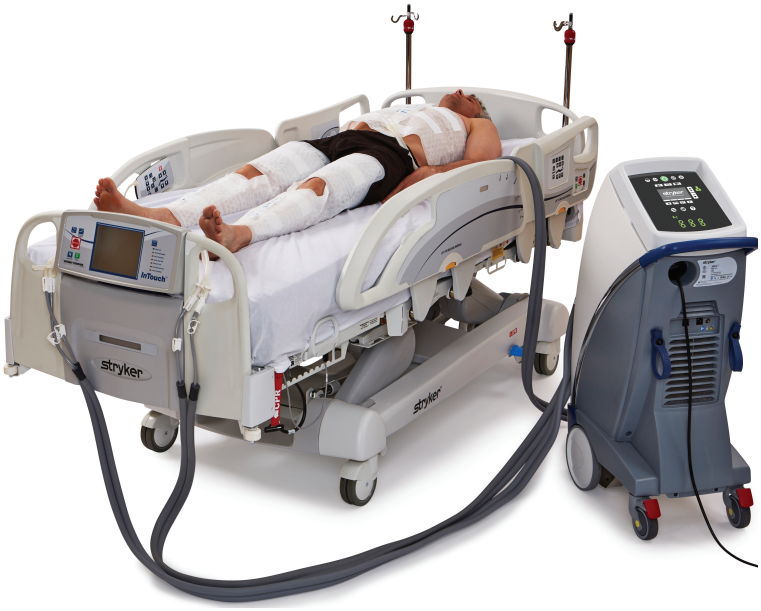


Figure 3: Altrix system - controller with thermal transfer devices

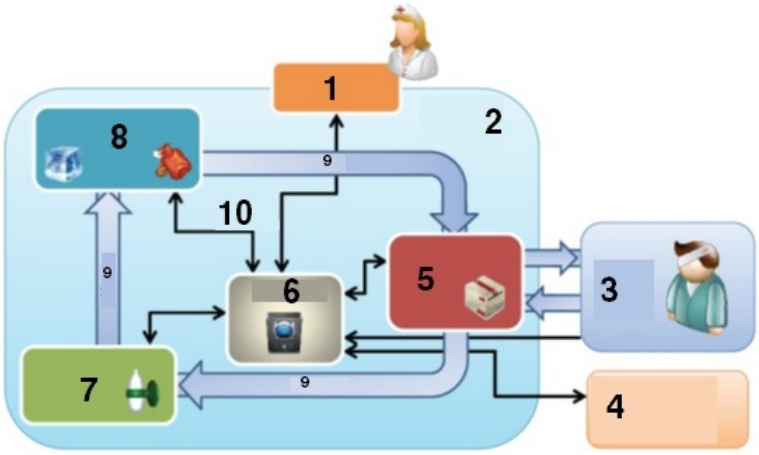
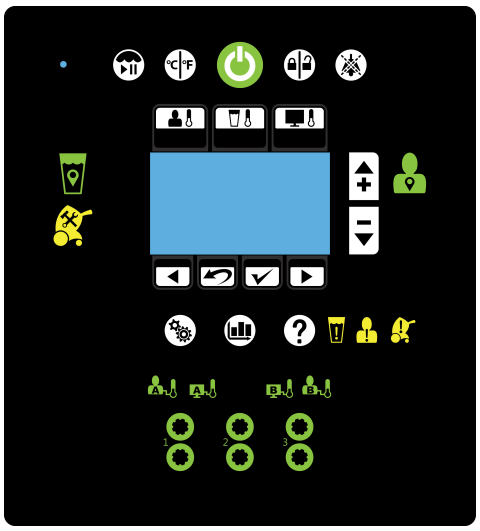


Figure 4: Closed loop system

1	Human machine interface (HMI) system	6	Controls
2	Physical boundary	7	Flow system
3	Patient system	8	Energy transfer system
4	Patient temperature port	9	Water flow
5	Fluid delivery system	10	Signals

Product functions

The graphical user interface shown is for reference only. The image shows where you will see the icons and buttons illuminate when they are active. At no time will you see all of these icons at the same time.



Buttons

The buttons are located on the outside of the graphical user interface. They are visible when available.

Icon	Name	Function
	Stand-by	Press and hold the button for two seconds to stop therapy or power off
	Therapy paused	Press and hold the button for two seconds to pause or resume therapy
	View temperature	Select temperature degree in Celsius or Fahrenheit
	Lock / unlock screen	Press and hold the button for two seconds to lock or unlock the graphical user interface
	Audio paused	Pause or resume the audible indicator when an alarm is active. Silences each alarm for five or ten minutes depending on the alarm condition. This button breathes[1] to indicate that it is in a paused state.
	Automatic therapy mode	Cools or warms the patient to a selected patient target temperature
	Manual therapy mode	Cools or warms the water to a selected water target temperature
	Monitor only mode	Displays the current patient temperature (no therapy)

Product functions (Continued)

Icon	Name	Function
	Increase	Increases the water or patient temperature by 0.1˚ for cooling or warming temperature **Note:** Press and hold the increase button to move the temperature up faster.
	Decrease	Decreases the water or patient temperature by 0.1˚ for cooling or warming temperature **Note:** Press and hold the decrease button to move the temperature down faster.
	Back	Returns to the previous screen or cancel an operation
	Edit settings, Exit, or Cancel	Edit current settings, exit, or cancel
	Confirm selection	Accepts the selected settings
	Next or More	Changes to the next screen, option, or setting
	Page indicators (may also appear vertical)	Indicates that there is more than one page associated with the screen topic for the page that is currently displayed
	Settings	Displays the summary of the current, visual / audible, language, or primary probe settings
	Graph	Graphical display of the selected items such as patient temperature, target temperature, water temperature, and power level
	Help	Displays contextual help screens for therapies, navigation, buttons, and alarm screens. This button breathes to allow the user to view the alarm screen.

Note: If not specified above, make sure that you tap and release the buttons or icons for you selection to register with the system.

Note: The Light sensor (non selectable)  , dims or brightens the LCD based on the amount of light in the room.

Note: [1]Breathe: The brightness of the button or icon will go to a low light and then increase to a bright light. This cycle repeats.

Visual indicators

When the visual indicators are solid green, this indicates that the function is stabilized. The visual indicators breathe to indicate that the controller is at the intermediate target.

Product functions (Continued)

Icon, green	Name
	Water temperature on target, solid green when active, does not breathe
	Patient temperature on target
	Patient probe A port, stabilized
	Patient probe B port, stabilized
	External device, patient probe A
	External device, patient probe B
	Stand-by
	Water flow detected, ports 1, 2, or 3 are active, solid green when active, does not breathe

Graphical user interface icons

Icon	Name
	Cooling therapy
	Warming therapy
	Current therapy duration
	Total duration
	Visual and audible tests
	Target patient or water temperature

Product functions (Continued)

Icon	Name
	Medium: patient temperature increases at a rate of 4.0˚ C in 12 hours (0.33˚ C/ hour).
	Maximum: water temperature approaches water target as fast as possible
	Minimum: patient temperature increases at a rate of 4.0˚ C in 24 hours (0.17˚ C/hour).
	Set Custom: patient temperature increases at a customized temperature and time period the operator selects. The temperature increases 0.05˚ C/hour to 0.5˚ C/hour
	Maximum: water temperature approaches water target as fast as possible
	Medium: water is cooled to target, with a max of 15.0˚ C difference between the patient and the water temperature
	Minimum: water is cooled to target, with a max of 10.0˚ C difference between the patient and the water temperature

Product alarms

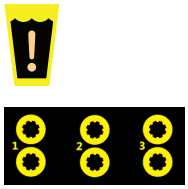
Audible alarms work in conjunction with the display.

Alarm priority and description

Priority alarm	Audible reminder	Icon flashes
Medium	Repetitive burst of three beeps every 25 seconds	When a medium priority alarms, the icon will flash to indicate there is an alarm. It will continue to flash until the alarm is resolved.
Low	Single burst of two beeps	The icon does not flash when there is a low priority alarm.
Audio pause	Button breathes as a reminder	Pausing the alarm will not stop the icon from flashing.

Note: You can pause the audio alarm. The alarm will resume within five to ten minutes or sooner, if not resolved. The alarm will resume depending on when the alarms became active and the number of active alarms.

Product alarms (Continued)

Icon, yellow	Name	Alarm priority and delay	Message	Therapy interrupted	Check
	Water temperature deviation	Medium	Water temperature is ±0.8˚ C (1.4˚ F) outside of target temperature	No	Temporary condition upon startup, addition of thermal transfer device, or addition of water
	No water	Medium, 20 second delay	No water	Yes	Check for leaks Add a minimum of 2 liters of water
	No water flow	Medium, 20 second delay	No flow detected	Yes	Check for leaks and obstructions at connections, hoses, and thermal transfer devices
	Check water flow on any port	Medium, 60 second delay	Reduced flow detected	No	Tap Confirm, if the water port was removed intentionally Check for leaks and obstructions at connections, hoses, and thermal transfer devices

Product alarms (Continued)

Icon, yellow	Name	Alarm priority and delay	Message	Therapy interrupted	Check
	Check patient probe (A or B)	Medium	Abnormal change in patient temperature	Yes	Check probe condition, location, and connections
	Probe or adapter malfunction (A or B)	Medium, 30 second delay	No temperature signal detected.	Yes	Check probe or adapter cable condition, location, and connections
	Adapter cable disconnected (A or B)	Medium, 30 second delay	Adapter cable not detected	Yes	Reinsert the adapter cable. If damaged, replace the adapter cable
	Patient temperature deviation	Medium	Patient temperature is ± 0.5˚ C (0.9˚ F) outside of target temperature (Only will appear after the initial target is reached.)	No	Check patient condition, placement of thermal transfer devices, and all connections
	Normothermia deviation	Low	Patient temperature is outside of 36.0˚ C (96.8˚ F) to 38.0˚ C (100.4˚ F)	No	Check patient condition, placement of thermal transfer devices, and all connections
	Therapy pause	Medium	Therapy is currently paused	Yes	To resume, press and hold the play / pause for 2 seconds
	Battery low	Low	Battery is low	No	Maintenance is recommended. If battery is not replaced, the product may not function on the next startup.
	Patient temperature output (A or B)	Low	Patient temperature output is inaccurate on the external device, or outside supported range	No	Check output adapter cable connection. Tap Confirm to reactivate the output port.

Product alarms (Continued)

Icon, yellow	Name	Alarm priority and delay	Message	Therapy interrupted	Check
	Remove from use (RFU)	Medium	The system has powered off due to a malfunction	Yes	Remove the product from use immediately. Notify the appropriate personnel.
	Power loss	Medium	Not applicable	Yes	Check power cord connection

Notes

- If any of the alarm conditions persist, call maintenance.
- If page indicators appear on the alarm screen, there are multiple active alarms. The highest alarm is displayed. Tap Next or Back to view the active alarms.

Contact information

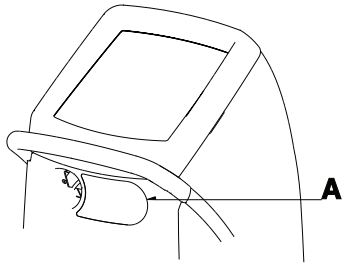
Contact Stryker Customer Service or Technical Support at: 1-800-327-0770.

Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

To view your operations or maintenance manual online, see https://techweb.stryker.com/.

Have the serial number (A) of your Stryker product available when calling Stryker Customer Service or Technical Support. Include the serial number in all written communication.

Serial number location



Date of manufacture

The year of manufacture is the first four digits of the serial number.

Unpack the cartons and check all items. Make sure that the product is free from visual damage before putting into service.

⚠ CAUTION

- Shock Hazard - Improper handling of the power cord may damage the power cord and cause potential shock hazards. If damage has occurred to the power cord, immediately remove the temperature management system from service to avoid the risk of serious injury or death. Contact the appropriate maintenance personnel.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like **Altrix**. Install and place **Altrix** into service according to the EMC information located in the EMC section of this manual. Portable and mobile RF communications equipment can affect the function of **Altrix**.
- Shock Hazard. If the internal electrical components are exposed, because the side panel or cover are compromised, remove the product from use.
- Always make sure that the product reaches room temperature before you setup or operate the product.
- Before first use, disinfect the internal water circuit.

Inspecting

Before you place the product into service, make sure that the controller works.

1. Visually inspect the product for any signs of shipping damage.
2. Plug the product into a properly grounded, hospital grade wall receptacle. Make sure that the power indicator illuminates on the operator control panel.
3. Before first use, .Disinfect the internal water circuit and hoses every 14 days on page 39

Selecting a language

The **Altrix** controller has several language choices. English is the default language.

To select a language when in standby mode:

1. Tap the Settings button, to show the Select Language screen.
   a. Tap Next, if you are in therapy mode.
2. Tap More to view other languages.
3. Select a language. Tap on the Increase or Decrease buttons or tap the language, to highlight a language of your choice.
4. Tap Confirm.

   Note: If you do not touch the screen for three minutes, the LCD will return to the previous menu.

Testing visual and audible alarms

Before placing the product into service, make sure that the visual and audible alarms are functioning.

1. Tap the Settings button.
2. Tap the Back button.
3. Tap the Visual/Audible icon.

Testing visual and audible alarms (Continued)

4. Tap Confirm.

   Notes

   - The system runs through visual tests of the Green Indicators, Yellow Indicators, White Indicators, and Fluid Controller Light tests, and audible alarms.
   - The test will continue until you stop it.

5. To stop the Visual / Audible test, tap the Back button.
6. To exit settings, tap the Exit button.

Placing the product

When placing the product, do not block access to the hospital-grade plug or medical-grade wall outlet.

CAUTION

Do not use **Altrix** located near or stacked with other medical equipment. If it is necessary to locate **Altrix** near other medical equipment, make sure it operates as intended.

Place the **Altrix** controller outside of the patient environment by 1.5 m (4.9 ft) (Figure 5 on page 21).

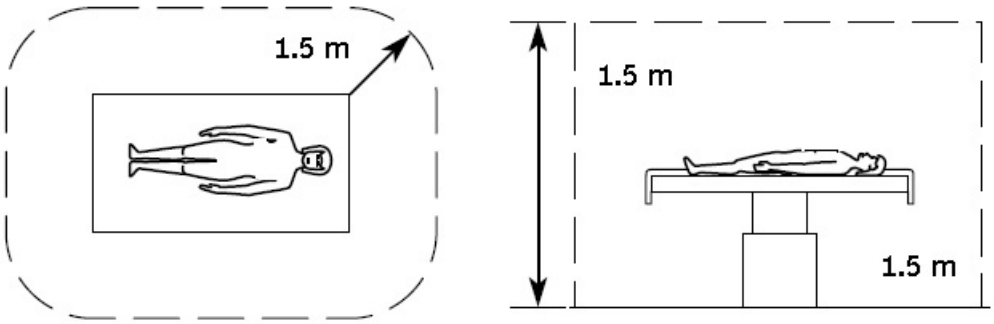


Figure 5: Product placement

Applying or releasing the wheel locks

The wheel locks are to help keep the product in place. The wheel lock prevents the rear caster wheels from rotating but does not prevent the product from sliding on the floor surface.

CAUTION

Always apply the wheel locks to prevent unintended movement.

To apply the wheel locks, push down (A) (Figure 6 on page 21) with your foot.

To release the wheel locks, pull up (A) (Figure 6 on page 21) with your foot.

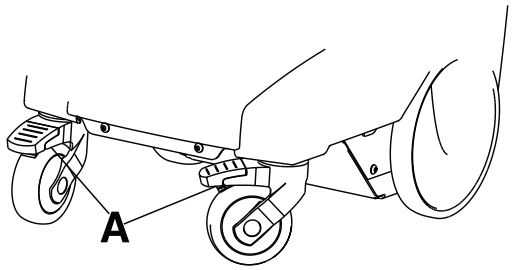


Figure 6: Wheel locks

Selecting and connecting a temperature probe

⚠ CAUTION

- Do not use high frequency surgical instruments or endocardial catheters while the **Altrix** system is in use. This is to avoid the risk of electrical shock, burns, or electromagnetic interference.
- Always use Stryker accessories. Only IEC 60601-1 equipment shall be hooked to the patient temperature ports. Failure to comply with these instructions may invalidate any or all warranties and may negatively affect the products EMC performance. This also protects the product from cardiac defibrillation.

Use only Stryker temperature probes. See Patient temperature probes on page 46.

To connect the temperature probe:

1. Inspect the temperature probe and reusable adapter cable for wear, breakage, or fraying. Replace, if necessary.
2. Align the red dot on the **Reusable Adapter Cable** (B) to the controller (A) with the red dot on the patient probe port A or port B.

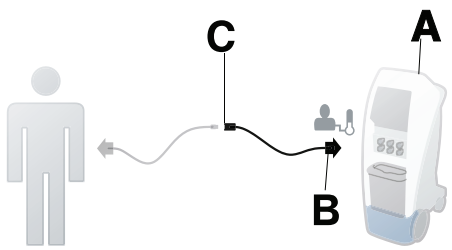


Figure 7: Port selected

3. Connect the plug (C) to the patient temperature probe.
4. Apply the temperature probe to the patient. Follow your hospital protocol and the manufacturer's directions for the selected temperature probe use.
5. Tap Confirm, if applicable.

   Note: Temperature readings may vary between temperature measurement sites.

Connecting the reusable patient temperature output cable

This feature allows the operator to view the temperature on the **Altrix** system and on an external device. Always connect the reusable patient temperature output cable to a 400 series compatible external device for temperature accuracy.

⚠ CAUTION

Always use Stryker accessories. Only IEC 60601-1 equipment shall be hooked to the patient temperature ports. Failure to comply with these instructions may invalidate any or all warranties and may negatively affect the products EMC performance. This also protects the product from cardiac defibrillation.

Connecting the reusable patient temperature output cable (Continued)

To connect the reusable patient temperature output cable:

1. Insert the reusable patient temperature output cable into the patient temperature port (Figure 8 on page 23).

Figure 8: Patient temperature output port

2. Connect the other end of the reusable patient temperature output cable to the external device.

   Note: When **Altrix** is powered, the calibration of the patient temperature output is completed.

   Note: If you need to calibrate the patient temperature output cable, power cycle the product by removing the plug from the wall.

   Note: For the reusable patient temperature output cable to work properly, make sure that you insert a patient temperature probe into port A or port B.

3. Tap Confirm.

Connecting the insulated hoses

To connect the insulated hoses:

1. To connect, push back on the retaining collar of the port on the controller (Figure 9 on page 23).

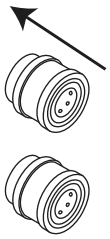


Figure 9: Pull back on the retaining collar

2. Push the hose into an upper or lower port (Figure 10 on page 23) and release the collar until the retaining collar clicks into place (Figure 11 on page 23).

   Note: Connect a set of ports for proper water flow.

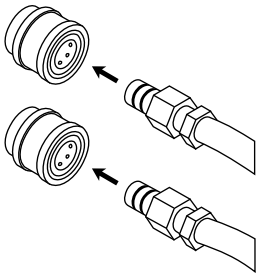


Figure 10: Connect the hoses

Figure 11: Hoses connected

Disconnecting the insulated hoses

To disconnect the insulated hoses:

1. To disconnect, push back on the retaining collar of the port on the controller.
2. Pull the hose to disconnect.

Connecting and disconnecting thermal transfer devices

Read the operations manual for the individual thermal transfer devices for warnings, cautions, and safe operating instructions before use.

⚠ CAUTION

- Avoid the use of materials of good thermal conductivity, such as water, gel, or similar substances, with the **Altrix** system not powered on. This can decrease the temperature of the body of a patient.
- Do not apply thermal transfer devices to patients with ischemic limbs. This may result in harm to the patient.
- Do not use this product if the patient has a transdermal medication (patch) as this can result in increased drug delivery.
- Always use Stryker accessories. Failure to comply with these instructions may invalidate any or all warranties and may negatively affect the products EMC performance. This also protects the product from cardiac defibrillation.
- Do not use three or more adult Mul-T-Blanket products at the same time to avoid the risk of water overflow when the controller is powered off.
- Always pre-fill the thermal transfer device with sterile distilled water before you apply it to the patient. This is to reduce the risk of pressure ulcers.
- Avoid reduction in water flow. Do not connect two or more thermal transfer devices in series on a single port.
- Always clamp the hoses when disconnecting the thermal transfer devices.

To connect or disconnect the **Clik-Tite**® connectors (Figure 12 on page 24) to the insulated hoses.

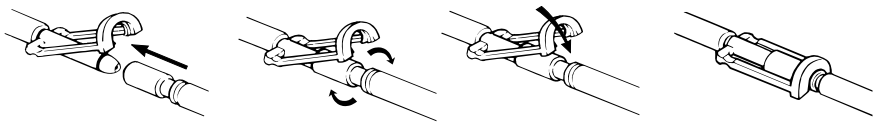


Figure 12: Clik-Tite

To connect or disconnect the Colder style (Figure 13 on page 24) to the insulated hoses.

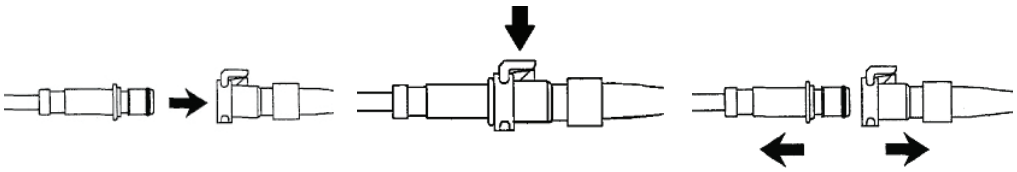


Figure 13: Colder style connectors

To close or open hose clamps (Figure 14 on page 25).

Connecting and disconnecting thermal transfer devices (Continued)

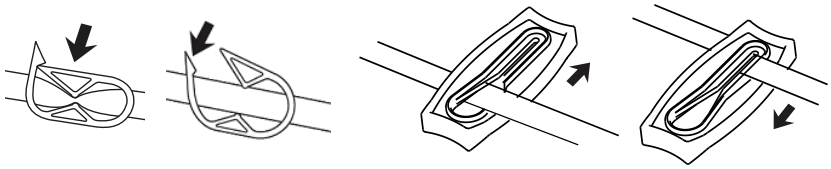


Figure 14: Hose clamps

Note: The term “thermal transfer devices” is used throughout this manual and is interchangeable with blankets and wraps, unless indicated otherwise.

Always clamp the hoses before disconnecting. See Draining the thermal transfer devices on page 33.

Powering on the product

The operator should stand in front of the controller within arm’s reach. This allows the operator to see and respond to the display notifications.

⚠ CAUTION

- Shock Hazard. Improper handling of the power cord may damage the power cord and cause potential shock hazards. If damage has occurred to the power cord, immediately remove the **Altrix** system from service to avoid the risk of serious injury or death. Contact the appropriate maintenance personnel.
- Electric shock. This equipment must only be connected to a supply mains with protective earth.
- Always plug this product directly into a properly grounded hospital-grade or medical-grade wall outlet to achieve grounding reliability.
- Do not use high frequency surgical instruments or endocardial catheters while the **Altrix** system is in use. This is to avoid the risk of electrical shock, burns, or electromagnetic interference.
- Explosion risk. This product is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide other than nasal or mask type.
- Do not place cables, hoses, or power cord in walkways to avoid the risk of trip hazards.
- Avoid reduction in water flow. Do not connect two or more thermal transfer devices in a series on a single port.
- Do not use three or more adult Mul-T-Blanket’s at the same time to avoid the risk of water overflow when you power off the controller.
- When you operate the product near ambient temperature limitations of 15.0˚ C (59.0˚ F) or 32.0˚ C (89.6˚ F), you may experience a reduction in product performance.

To start the product:

1. Plug the power cord into a wall outlet.
2. Tap the Stand-by button to start the product.
3. If you are going into Automatic mode or Monitor mode, see Selecting and setting the primary probe on page 27. If manual mode, got to the next step.
4. See Removing and replacing the reservoir on page 26.
5. See Filling the reservoir with sterile distilled water on page 26.
6. Connect up to three thermal transfer devices (with the exception of adult Mul-T-Blankets) to dedicated adapter hoses and ports.

Powering on the product (Continued)

7. Open the clamps on the connector hose and the thermal transfer devices to provide proper water flow.
8. See Filling a thermal transfer device on page 28.
9. See Selecting a therapy mode on page 28.
10. Make sure that the desired port configuration is maintained and that water is flowing through the thermal transfer devices.

WARNING

Always turn or re-position the patient over the duration of therapy, if possible, to reduce the risk of pressure ulcers. Follow your hospital protocol.

Removing and replacing the reservoir

The removable reservoir enables you to fill or drain the reservoir away from the controller without interrupting therapy. You will need to have the reservoir installed before starting a therapy.

CAUTION

Do not place your fingers in between the reservoir and the sides of the controller, to avoid the risk of pinching your fingers.

To remove the reservoir, pull forward at an angle, and lift out the reservoir (Figure 15 on page 26).

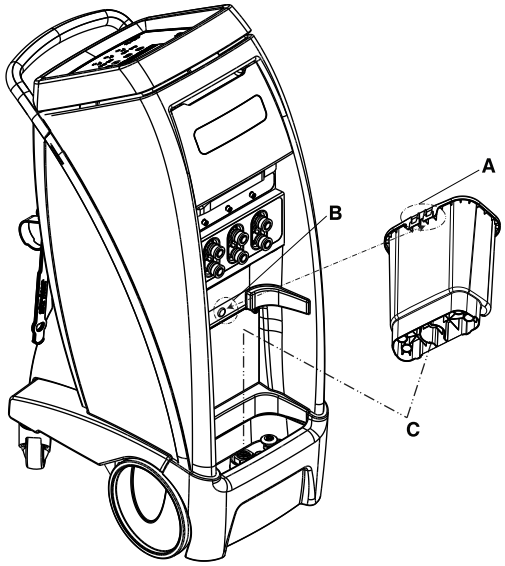


Figure 15: Removable reservoir

1. To replace the reservoir, align the base of the reservoir over the drain (C).
2. Align the notch on the back of the reservoir (A) with the hook on the controller (B) (Figure 15 on page 26)
3. Push the reservoir back into place. Make sure that the reservoir is secure to avoid water leakage.

Filling the reservoir with sterile distilled water

The removable reservoir is translucent for you to see the water levels.

Filling the reservoir with sterile distilled water (Continued)

⚠ CAUTION

- Always use sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns with this product.
- Always fill the reservoir with room temperature sterile distilled water to reduce the risk of burn.
- Do not overfill the reservoir to avoid the risk of water spillage and fall.

To fill the removable reservoir with sterile distilled water:

1. See Removing and replacing the reservoir on page 26.
2. Fill the reservoir with five liters of sterile distilled water. Do not fill past the top fill line to avoid water overflow (Figure 16 on page 27).

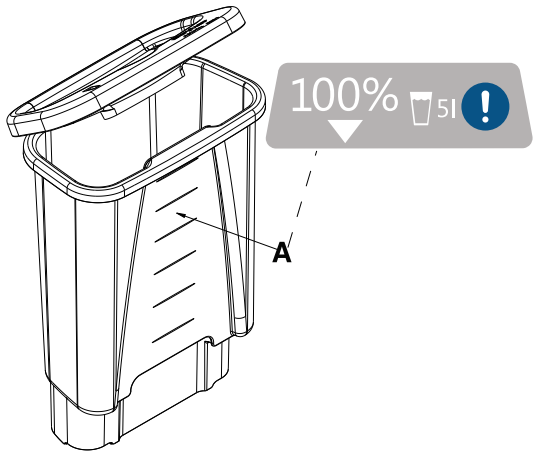


Figure 16: Reservoir fill lines

Selecting and setting the primary probe

A patient probe displays when present, stable, and confirmed. The choice of Probe A or Probe B is highlighted when you insert the cable into port A and port B. If you only insert one cable, the active port displays.

1. Tap the Settings button.
   a. In the standby mode, tap the Back button to display the edit settings screen.
   b. In an active therapy mode, tap the Next button.
2. Tap Select Probe to display the Select Primary Probe (Probe A or Probe B) screen. If both probes are present, the default is probe A.
3. Tap A or B, if applicable.
4. Tap Confirm.

   Notes
   - The message “Probe stabilization in progress... Please wait” is displayed.
   - When you initially select a probe (A or B), detected is checked. When stabilized, the Ready check is displayed.
   - If the probe is not stabilized within three minutes, the message “Probe stabilization error” will appear. Tap the Help button for more detail.
   - You can select help at any time to display help with the current screen or icon descriptions.

Filling a thermal transfer device

CAUTION

Always pre-fill the thermal transfer device with sterile distilled water before you apply it to the patient. This is to reduce the risk of pressure ulcers.

Note: These instructions are to pre-fill the thermal transfer devices only, not therapy. See Switching modes on page 31.

To fill a thermal transfer device:

1. Connect a thermal transfer device following: Connecting and disconnecting thermal transfer devices on page 24.
2. Lay the thermal transfer device on a flat surface. Make sure the thermal transfer device is flat for water flow.
3. Open all of the clamps on the connector hose and thermal transfer device.
4. Make sure that the controller is powered.
5. Tap the Stand-by button.
6. Tap the Manual mode button.
7. Tap Confirm.
8. Select a water temperature that aligns with your target patient temperature.

   Note: Allow the water to flow from the controller into the thermal transfer device until full.
9. Tap Confirm.

Selecting a therapy mode

You can select from one of three therapy modes and tap Confirm:

- Automatic therapy
- Manual therapy
- Monitor non-therapy

For mode descriptions, tap the Help button.

WARNING

Always check the integrity of the patients skin and temperature according to hospital protocol when using the **Altrix** system.

CAUTION

- Explosion risk. This product is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide other than nasal or mask type.
- Always make sure that there are no water leaks before starting a defibrillation.
- When using the temperature controlled Automatic therapy mode for warming (min, med, or custom), switching to other modes, changing the target patient temperature, or changing the therapy selection may impact the overall benefit of therapy.
- Always use Stryker accessories. Failure to comply with these instructions may invalidate any or all warranties and may negatively affect the products EMC performance. This also protects the product from cardiac defibrillation.
- Always monitor the patient for shivering, temperature, signs of intolerance, and skin condition when using this product.
- Always pre-fill the thermal transfer devices with water before applying to the patient.

Starting Automatic therapy mode

In Automatic mode, the therapy cools or warms the patient to a selected patient target temperature. The product in automatic mode continually measures the patient temperature and automatically adjusts the water temperature until the selected patient target temperature is achieved. After the selected patient target temperature is achieved, the product maintains this temperature for the duration of the therapy.

To start Automatic therapy mode:

1. Prepare the thermal transfer devices for therapy.
2. See Filling a thermal transfer device on page 28.
3. Apply the thermal transfer device to the patient.
4. Connect the reusable adapter cable to port A or port B on the product. Make sure that the probe is fully seated.
5. Apply the sensing end of a patient probe to the patient based on your hospital protocol and secure the product to reduce the risk of accidental dislodgment.
6. Connect the patient temperature probe to the reusable adapter cable. See Selecting and connecting a temperature probe on page 22.
7. Tap to Confirm the current patient temperature.
8. Tap the Automatic therapy mode button.
9. Select the target patient temperature.
10. See Setting or editing the cooling rates on page 29 or Setting or editing the warming rates on page 30

    Notes

    - The controller determines **Warming** or **Cooling** therapy based on the selected water target temperature and the current water temperature.
    - Do not place additional heat sources between the patient and thermal transfer device.
    - After the patient target temperature is achieved, patient temperature is controlled within +/-0.3˚ C.
    - If the patient temperature is not within 0.5˚ C of the current target temperature, the yellow patient icon will flash and the patient temperature deviation alarm will sound. This occurs after the initial patient target temperature is achieved.

Setting or editing the cooling rates

Setting cooling rates is for Automatic Mode only.

1. To set the cooling temperature, highlight your choice of cooling rates.

Select a cooling rate	Description
	Maximum: approaches patient target temperature as fast as possible
	Medium: water is cooled to target, with a max of 15.0˚ C difference between the patient and the water temperature
	Minimum: water is cooled to target, with a max of 10.0˚ C difference between the patient and the water temperature

2. Tap Confirm.
3. Tap the Edit button to make changes.

Setting or editing the warming rates

Setting warming rates is for Automatic Mode only.

1. To set the warming temperature, highlight your choice of warming rates.

Select a warming rate	Description
Max	Maximum: approaches patient target temperature as fast as possible
Med	Medium: patient temperature increases at a rate of 4.0˚ C in 12 hours (0.33˚ C/ hour).
Min	Minimum: patient temperature increases at a rate of 4.0˚ C in 24 hours (0.17˚ C/hour).
Set Custom	Set Custom: patient temperature increases at a customized temperature and time period the operator selects. The temperature increases 0.05˚ C/hour to 0.5˚ C/hour.

2. If you select Set Custom, tap the Increase and Decrease buttons to set the rate (Figure 17 on page 30).

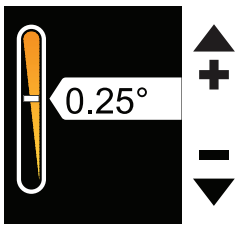


Figure 17: Set custom warming rate

3. Tap Confirm.
4. Tap the Edit button to make changes.

Starting Manual mode

In Manual mode, the therapy will cool or warm the water to a selected water target temperature. The operator must observe the patient's temperature and manually adjust the water temperature to obtain the desired patient temperature.

1. If desired, select and place the sensing end of the patient probe based on hospital protocol. Connect the reusable adapter cable to port A or port B on the product. See Selecting and connecting a temperature probe on page 22.
2. Prepare the thermal transfer devices to be used for therapy.
3. See Filling a thermal transfer device on page 28.
4. Apply the thermal transfer device to the patient.
5. Tap Manual mode. The default water target temperature is 40.0˚ C (104.0˚ F) upon initial entry.
6. Tap Confirm.
7. To select the desired water temperature, tap the Increase or Decrease buttons or hold the button to go faster.
   a. To edit water temperature, tap the Edit button.
8. Tap Confirm.

Starting Manual mode (Continued)

Notes

- The controller determines **Warming** or **Cooling** therapy based on the selected water target temperature and the current water temperature.
- In Manual mode, only the water temperature is controlled.
- A temperature probe is not required when operating in Manual mode.
- After the water target temperature is achieved, water temperature is controlled within +/-0.3˚ C.

Starting Monitor mode

In Monitor mode, no therapy will be delivered, only a display of the current patient temperature.

To start Monitor mode:

1. Connect the reusable adapter cable to port A or port B on the controller. Make sure that the probe is fully seated.
2. Apply the sensing end of patient probe to patient based on hospital protocol. Secure the patient probe to reduce the risk of accidental dislodgment.
3. Tap the Monitor button.
4. Connect the patient temperature probe to the end of the reusable adapter cable. See Selecting and connecting a temperature probe on page 22.

   Note: If the product senses a patient probe temperature below 36.0˚ C (96.8˚ F) or above 38.0˚ C (104˚ F), the normothermia alarm displays and an audible alarm sounds.
5. Tap Confirm. The screen will display the current patient temperature.

Switching modes

Tap Edit and select a different therapy mode.

Pausing and resuming therapy

To pause therapy, press and hold the Pause Therapy button for two seconds. 

To resume therapy, press and hold the Pause Therapy button for two seconds.

Displaying the data storage

The system gathers data at five second intervals and is limited to 90 minutes of storage. The graphical display defaults to show data for all four variables in the Manual and Automatic modes.

Displaying the data storage (Continued)

To display the patient data graph:

1. Tap the Graph icon.

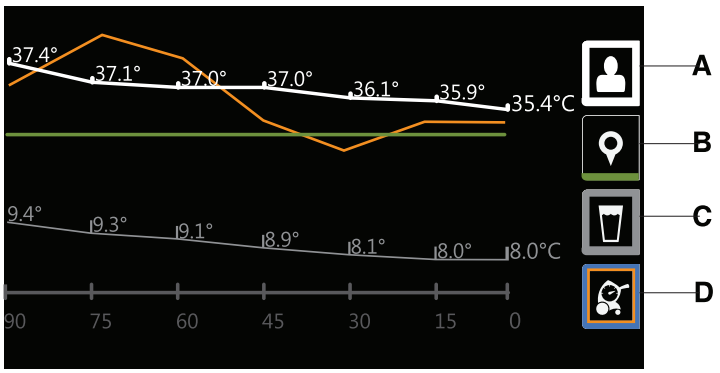


Figure 18: Graphical display

- Primary patient temperature reading from attached probe (A) (Figure 18 on page 32)
- Intermediate target temperature (B)
- Water temperature (C)
- Power level (D)

2. To view data values, hide values, or data lines, tap an icon until the data you desire appears for the selected icon.
3. Tap next to see the current values for each variable.
4. To exit, tap the Graph icon or the Exit button.

Notes

- In monitor mode, only the patient temperature data is displayed (A).
- The graph icon is only available when a therapy is active.
- The patient data remains until the product sleeps or you powered off the product.
- During a power loss the data is lost and not retrievable.

Opening and securing items in the storage compartment

The storage compartment holds a maximum of 3 lb (1.36 kg).

To open the storage compartment door, lift up on the door (Figure 19 on page 33).

The storage compartment secures the following items:

- Two patient probes
- Two reusable adapter cables
- One reusable patient temperature output cable
- Product operations manual

Opening and securing items in the storage compartment (Continued)

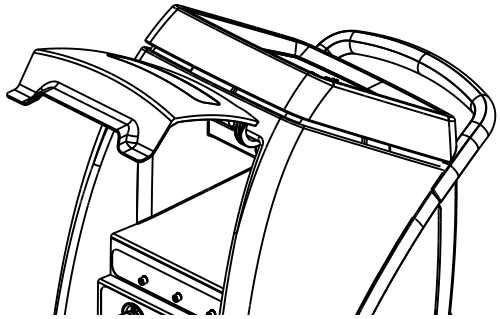


Figure 19: Storage compartment

Notes

- Make sure that the items are securely inside the compartment and not blocking the magnets.
- When closing the storage compartment door, do not place your fingers between the storage compartment door and the sides of the controller.

Stopping therapy or powering off the product

To stop therapy or power off the controller:

1. Press and hold the Stand-by button for two seconds.
2. Unplug the product from the wall outlet.

   Note: If storing the product, see Storing the controller on page 35.

Draining the thermal transfer devices

Read the manufacturer's operations manual for the individual thermal transfer devices (blankets and wraps) for warnings, cautions, and safe operating instructions before use. Make sure that you drain the hoses before you put them in storage.

1. Unplug the product.
2. Remove the thermal transfer device from the patient.
3. Open the clamps on the hoses and thermal transfer devices, if applicable. See Figure 14 on page 25.
4. Raise the thermal transfer devices attached to the hose above the ports on the controller. Gravity helps to drain the water into the controller.
5. Allow most of the water to drain back into the controller. (Approximately 10 minutes).
6. See Connecting and disconnecting thermal transfer devices on page 24.
7. See Disconnecting the insulated hoses on page 24.
8. See Storing the power cord and hoses on page 35.
9. Discard the disposable thermal transfer devices based on your local waste management protocol.

   a. Discard the disposable thermal transfer devices based on your local waste management protocol, if applicable.

Draining water from the reservoir

To drain the water from the reservoir:

1. See Removing and replacing the reservoir on page 26.
2. Dispose of the water per hospital protocol.

Draining water from the reservoir (Continued)

3. Replace the reservoir.

   Note: Make sure that the reservoir is dry before you store the product.

Draining water from the controller and hoses

Make sure that the controller and all components are dry before you store the product. Make sure to drain the hoses before you store them.

1. Place the controller over a floor drain.
2. Remove the reservoir and pull up on the controller drain plug (A) to open the drain (Figure 20 on page 34).

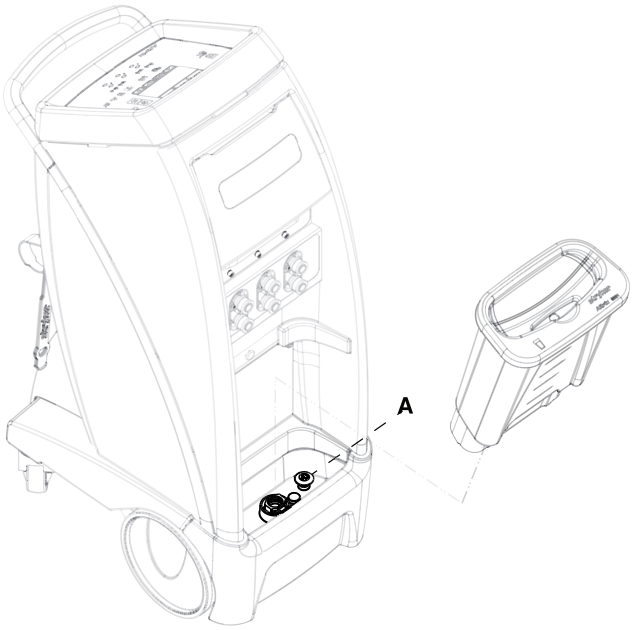


Figure 20: Drain plug

3. Connect a hose to each port.
   a. If you have Colder style connector hoses, attach the service tool adapter hose (8001-999-017).
   b. If you have **Clik-Tite** hoses, make sure that the connectors and clamps are open (Figure 21 on page 34).

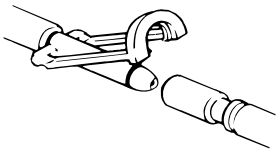


Figure 21: Clik-Tite open

4. Raise all the hoses completely above the connection ports on the controller.
5. Allow the product to drain for a minimum of two minutes.
6. Push down on the drain plug to close the drain.
7. Replace the reservoir.

Storing the power cord and hoses

After you complete therapy or when you transport the product, store the power cord and hoses.

⚠ CAUTION

- Do not hang items on the controller handle to avoid the risk of tipping the product.
- Always store the power cord, cables, and hoses before you transport the product to reduce the risk of trip hazard.

To store the power cord and hoses:

1. Connect the ends of the connector hoses together, if applicable.
2. Coil and fasten the hose with the management straps (Figure 22 on page 35).
3. Unplug the power cord from the wall outlet and store with the management straps (Figure 22 on page 35).

Figure 22: Management straps

Storing the controller

Storage is equal to or greater than 7 days without use.

⚠ CAUTION

- Do not store the product with water in the device.
- Always store the product within the specified environmental condition values.

To store the controller:

1. See Disinfect the internal water circuit and hoses every 14 days on page 39.
2. See Draining the thermal transfer devices on page 33.
3. See Cleaning the external surfaces on page 37.
4. See Disinfecting external surfaces on page 38.

   Notes

   - Always bring the controller to room temperature after high or low temperature storage.
   - Always store the controller with the reservoir in place.

Transporting the product

Make sure to follow these procedures for transporting the product to avoid the risk of possible injury or equipment damage.

⚠ CAUTION

- Always use extra care when you transport the product long distances and on inclines greater than five degrees. Ask for help, if necessary, to avoid the risk of tipping.
- Always use the handle to move the product. Do not attempt to move the product by pulling on cables, hoses, or by any other means.
- Avoid ramps that are steeper than ten degrees to avoid tipping the product.
- Do not hang items on the controller handle to avoid the risk of tipping the product.
- Always store the power cord, cables, and hoses before you transport the product to reduce the risk of trip hazard.

1. Make sure that the pathway is clear.
2. Unplug the product from the hospital-grade or medical-grade wall outlet. See Storing the power cord and hoses on page 35.
3. Make sure to place the product with the ports facing the front (Figure 23 on page 36).

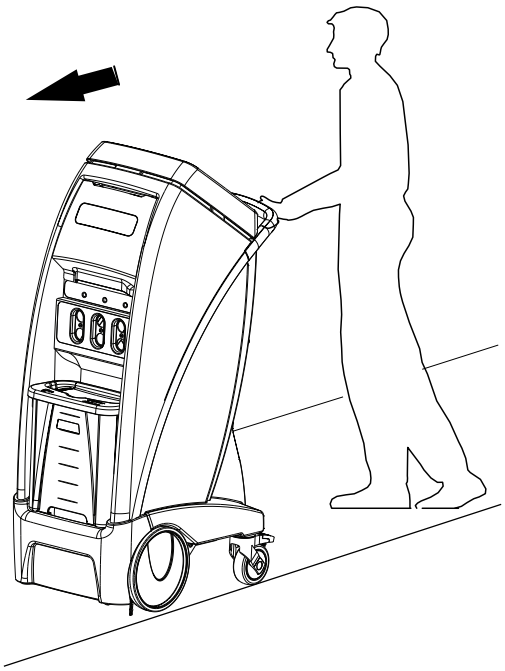


Figure 23: Transport position

4. Use the handle to push the product.
5. Limit movement to a slow careful walk.
6. Use two or more operators to move the system on inclines or long distances.

   Notes

   - Wheel chair ramps are usually less than five degrees.
   - The system weighs 150 lb (68.0 kg) when dry. Weight also depends on other items in the storage compartment.

Cleaning the external surfaces

Clean the external surfaces of the controller and system components before each use. System components may be subject to contamination during use from contact with soiled hands of the user, airborne pathogens, and unexpected or accidental events. Make sure you remove all visible soils.

⚠ CAUTION

Do not power wash this product.

Tools Required:

- Mild soap
- Soft, lint free cloth (2 or more)

Validated mild soap:

- Enzol® Enzymatic Instrument Cleaner by Johnson & Johnson

To clean the external surfaces of the controller and system components:

See Product illustration on page 10 for clarification of product component names and locations.

1. Unplug the power cord from the wall outlet.
2. Apply wheel locks.
3. Undo power cord and hose straps.
4. Unravel and lay out hoses, cables, and power cord.
5. Disconnect the hoses. Push back on the retaining collar of the port on the controller. Pull the hose to disconnect.
6. Disconnect the patient temperature probe cable from the port.
7. Remove the reservoir. Pull forward at an angle, and lift out the reservoir.
8. If necessary, empty the water from the reservoir. Dispose of the water per your hospital protocol.
9. Prepare a mild soap and water solution as described by the manufacture.
10. Wipe the inside and outside of the reservoir and reservoir lid, with a soft, lint free cloth moistened with soap and water solution.
11. Wipe the hoses and patient temperature probe cables, with a soft, lint free cloth moistened with soap and water solution.
12. Wipe the controller surfaces while the reservoir is removed with a soft, lint free cloth moistened with soap and water solution. Also wipe the following system components:
    - Hose connectors
    - Power cord
    - Hose and power cord management straps
    - Storage compartment door
    - Inside storage compartment
    - Graphical user interface display
    - Handle
13. Wipe the controller, reservoir and reservoir lid surfaces, and system components with a clean, dry cloth to remove any excess liquid.
14. Replace the reservoir.
15. Allow the external surfaces of the controller and components to dry thoroughly.

Disinfecting external surfaces

Disinfect the external surfaces of the controller and system components before each use. System components may be subject to contamination during use from contact with soiled hands of the user, airborne pathogens, and unexpected or accidental events. Follow your hospital protocols for disinfecting the product. Make sure to follow the manufacturer's instructions for the disinfectants.

⚠ CAUTION

Do not use quaternaries that contain glycol ethers as they may damage the reusable accessories.

Note: If the product is visibly soiled, clean the surface before disinfecting.

Tools Required:

- Personal protection equipment (PPE) as recommended by the disinfectant manufacturer's instructions
- Soft, lint free cloth (2 or more)
- Disinfectant
- 2 gallons (7.6 L) of sterile distilled water

Recommended disinfectants for the external surface of the controller and system components:

- Quaternary cleaners (active ingredient - ammonium chloride)
- Phenolic cleaners (active ingredient - o-phenylphenol)
- Chlorinated bleach solution ((1 part bleach solution (5.25% sodium hypochlorite) to 100 parts of water which equals 520 ppm available chlorine (40 ml of a 5.25% bleach solution per 4000 ml water))

Validated disinfectants for the external surface of the controller and system components:

- Sodium hypochlorite based - Clorox® Healthcare Bleach Germicidal Cleaner (EPA registration number 56392-7)

To disinfect the external surfaces of the controller and system components:

See Product illustration on page 10 for clarification of product component names and locations.

1. Use PPE as recommended by the disinfectant manufacturer's instructions.
2. Unplug the power cord from the wall outlet.
3. Apply the wheel locks.
4. Unfasten the power cord and hose straps.
5. Unravel and lay out hoses, cables, and power cord.
6. Disconnect the hoses. Push back on the retaining collar of the port on the controller. Pull the hose to disconnect.
7. Disconnect the patient temperature probe cable.
8. Remove the reservoir. Pull forward at an angle, and lift out the reservoir.
9. If necessary, empty the water from the reservoir. Dispose of the water per your hospital protocol.
10. Prepare disinfectant solution as described by the manufacture.
11. Apply disinfectant solution to the inside and outside of the reservoir and reservoir lid, with a soft, lint free cloth moistened with disinfectant. Reapply disinfectant to cloth as needed.
12. Apply disinfectant solution to the hoses and patient temperature probe cables, with a soft, lint free cloth moistened with disinfectant. Reapply disinfectant to cloth as needed.
13. Apply disinfectant solution to the controller surfaces while the reservoir is removed with a soft, lint free cloth moistened with disinfectant. Reapply disinfectant to the cloth as needed. Also wipe the following system components:
    - Hose connectors
    - Power cord
    - Hose and power cord management straps
    - Storage compartment door
    - Inside storage compartment

Disinfecting external surfaces (Continued)

- Graphical user interface display
- Handle

14. Follow specified contact time in accordance with the disinfectants manufacturer's instructions for use.
15. To rinse, wipe the hoses and patient temperature probe cables, with a soft, lint free cloth moistened with sterile distilled water.
16. To rinse, wipe the controller, reservoir and reservoir lid surfaces, and system components with a lint free cloth moistened with sterile distilled water.
17. To dry, wipe the controller, reservoir, reservoir lid surfaces, and system components with a clean, dry cloth to remove any excess liquid.
18. Replace the reservoir.
19. Allow the external surfaces of the controller and components to dry thoroughly.
20. Store the power cord, cables, and hoses.

Disinfect the internal water circuit and hoses every 14 days

Use the **BruClean TbC** disinfectant tablets by **BruClean TbC** (EPA registration number 71847-2-106) before first use, at least every 14 days, and before storage. **BruClean TbC** has been validated for internal water circuit disinfection. Make sure that you follow the disinfectant manufacturer's guidelines to avoid the risk of injury. Failure to follow the disinfectant's instructions may void your warranty.

⚠ CAUTION

- Always use sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns with this product.
- Do not disinfect the internal water system with a thermal transfer device attached as this may cause a leak.
- Do not use bleach or any other cleaning or disinfectant agents for internal circuits. This could result in damage to the product. Only use approved disinfectant tablets.
- Always drain the product before disinfecting the internal water circuit. Failure to drain the product may reduce the effectiveness of the disinfection process.

Note: Disinfection of the **Altrix** internal water system was validated using *M. mucogenicum*.

Tools Required:

- 2 gallons (7.6 L) of sterile distilled water or water that has been passed through a filter less than or equal to 0.22 microns
- Personal protection equipment (PPE) as recommended by the disinfectant manufacturer's instructions
- Soft, lint free cloth (2 or more)
- 2 **BruClean TbC** 13.1 g tablets (Active ingredient NaDCC solution ppm = 1874 mg/L)
  Note: BruClean TbC is a blend of 48% sodium dichloroisocyanturate and Adipic Acid with a 5% sodium dodecyl benzene sulphonate surfactant.
- Service tool adapter hose (8001-999-017) for **Colder** style connector hoses
- Floor drain

See Product illustration on page 10 for clarification of product component names and locations.

Draining the internal water circuit and hoses for disinfection

1. Unplug the power cord from the wall outlet.
2. Place the controller over a floor drain.

Draining the internal water circuit and hoses for disinfection (Continued)

Note: For best results, the floor drain should be within reach of a wall outlet to power on the controller.

3. To drain the controller, pull up on the controller drain plug (A) to open the drain (Figure 24 on page 40). Leave the drain open.

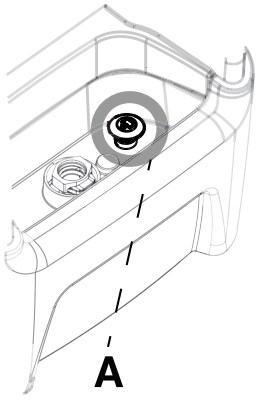


Figure 24: Drain plug

4. Connect a hose to each port (Figure 25 on page 40).

Figure 25: Hoses connected

5. Close the connector ends of all three hoses:

   a. If you have **Colder** style connector hoses, attach the service tool adapter hose (8001-999-017) (Figure 26 on page 40). Complete this for all three hoses.

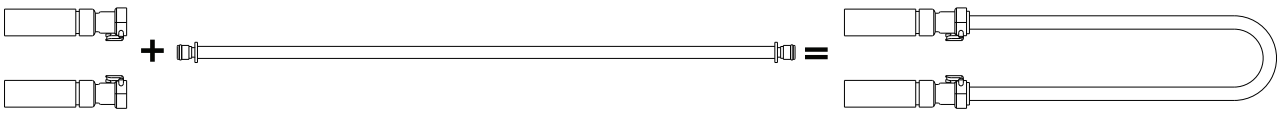


Figure 26: Colder style connector hose connected to a tool adapter hose

   b. If you have **Clik-Tite** hoses, make sure that the connector ends are connected and closed (A), and clamps are open (B). Complete this for all three hoses. Figure 27 on page 41

Draining the internal water circuit and hoses for disinfection (Continued)

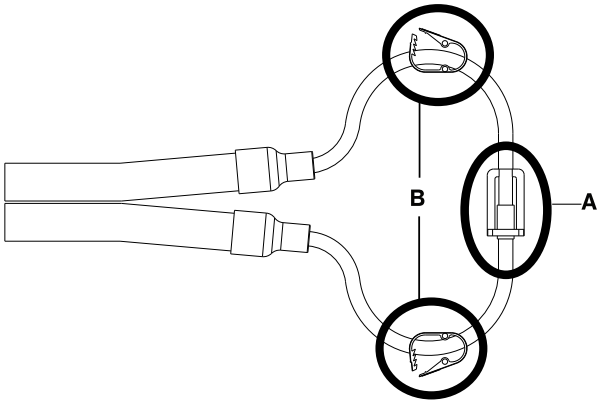


Figure 27: Clik-Tite hose ends are closed and clamps are open

6. To fully drain the hoses, raise all the hoses (Figure 28 on page 41) above the connection ports on the controller.

   Note: For best performance, hang the hoses to keep them raised. Do not lower the hoses until you have completed the disinfection and rinsing process.

Figure 28: Raise the hoses

7. Allow the controller and hoses to drain for a minimum of two minutes.
8. Push down on the drain plug to close the drain.

Disinfecting the internal water circuit and hoses

1. Use personal protection equipment as recommended by the **BruClean TbC** disinfectant manufacturer's instructions for use.
2. Put 2 **BruClean TbC** tablets into the reservoir.
3. Using appropriate measuring equipment, fill the empty reservoir with 1 gallon (3.8 L) of sterile-distilled water.

   Note: Always allow the disinfectant tablets to completely dissolve before starting the 20 minute disinfection cycle.
4. Place the reservoir into the controller.

Disinfecting the internal water circuit and hoses (Continued)

5. Disconnect the bottom hose from the bottom right port (Figure 29 on page 42).

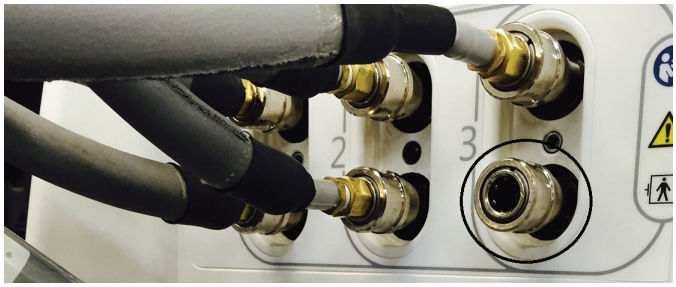


Figure 29: Disconnected hose

6. Connect the bottom hose end to the hydraulic connector in the lid of the reservoir (Figure 30 on page 42).

Figure 30: Bottom hose end in the lid of the reservoir

7. Plug the power cord into a wall outlet.
8. Press and hold the Stand-by button.
9. Tap the Manual mode icon.
10. Tap Confirm.
11. Set the water target temperature to 25.0˚ C (77.0˚ F).
12. Tap Confirm.
13. Run the controller for 20 minutes. 00:20:00
14. After 20 minutes, turn the controller off by pressing and holding the Stand-by button for two seconds.
15. Unplug the power cord from the wall outlet.
16. Place the controller over a floor drain.
17. Remove the reservoir. Pull forward at an angle, and lift out the reservoir.
18. Remove the bottom hose end from the hydraulic connector adapter in the reservoir lid by pushing down on the collar.
19. Empty water from the reservoir, dispose of the water per hospital protocol.

Disinfecting the internal water circuit and hoses (Continued)

Note: Do not rinse the reservoir.

20. Pull up on the controller drain plug (Figure 31 on page 43) to open the drain.

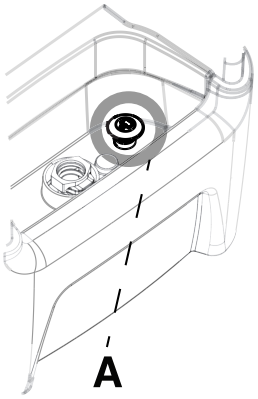


Figure 31: Drain plug

21. Make sure that all 3 hoses remain raised above the connection ports for draining.
22. Allow the controller and hoses to drain for a minimum of two minutes.
23. Push down on the controller drain plug to close the drain.
24. When the controller and hoses are drained, continue to Rinsing the internal water circuit and hoses on page 43.

Rinsing the internal water circuit and hoses

1. Using appropriate measuring equipment, fill the empty reservoir with 1 gallons (3.8 L) of sterile-distilled water.
2. Place the reservoir into the controller.
3. Connect the bottom hose end to the hydraulic connector in the lid of the reservoir.

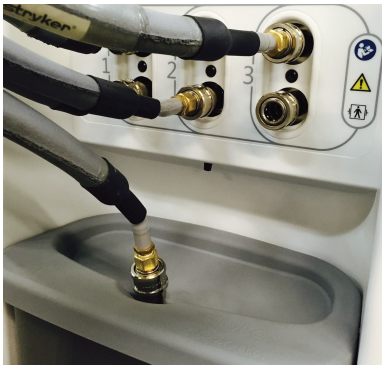


Figure 32: Bottom hose end in the lid of the reservoir

4. Plug the power cord into a wall outlet.
5. Press and hold the  Stand-by button.
6. Tap the Manual mode icon. 

Rinsing the internal water circuit and hoses (Continued)

7. Tap Confirm. 
8. Select the water target temperature of 25.0˚ C (77.0˚ F).
9. Tap Confirm. 
10. Allow the controller to run for 5 minutes. 

    Note: The timer will run on the main display, follow the current therapy duration timer.

11. After 5 minutes, turn the controller off by pressing and holding the Stand-by button for two seconds. 
12. Unplug the power cord from the wall outlet.
13. Place the controller over a floor drain.
14. Remove the reservoir. Pull forward at an angle, and lift out the reservoir.
15. Remove the bottom hose end from the hydraulic connector adapter in the reservoir lid by pushing down on the collar.
16. Empty water from the reservoir, dispose of the water per hospital protocol.
17. Pull up on the controller drain plug to open the drain.
18. Make sure that all 3 hoses remain raised above the connection ports for draining.
19. Allow the controller and hoses to drain for a minimum of two minutes.
20. Push down on the controller drain plug to close the drain.
21. Wipe the inside and outside of the reservoir and reservoir lid, with a dry, soft, lint free cloth.
22. Place the reservoir into the controller.
23. Disconnect and store the service tool adapter hoses from all three of the hoses. (If applicable, when used with colder style hoses.)
24. Store the power cord, cables, and hoses.

Thermal transfer devices

These accessories are currently available for purchase. Not all accessories are available for all regions. Call Stryker Customer Service at 1-800-327-0770 for availability and pricing. For more information, see the thermal transfer device instructions for use.

Thermal transfer device	Connector type	Part number	Size	
Rapr-Round, small / medium vest chest	**Clik-Tite**	8001-061 -530	32 in. to 46 in.	81 cm to 117 cm
Rapr-Round, large vest chest	**Clik-Tite**	8001-061 -535	46 in. to 54 in.	117 cm to 137 cm
Rapr-Round, leg wrap, one size for the left or right leg - thigh circumference	**Clik-Tite**	8001-061 -540	20.5 in. to 28.5 in.	52 cm to 72 cm
Mul-T-Blanket, adult	Colder	8001-061 -610	25 in. x 64 in.	64 cm x 163 cm
Mul-T-Blanket, pediatric	Colder	8001-061 -612	22 in. x 33 in.	56 cm x 84 cm
Rapr-Round, small / medium vest chest	Colder	8001-061 -630	32 in. to 46 in.	81 cm to 117 cm
Rapr-Round, large vest chest	Colder	8001-061 -635	46 in. to 54 in.	117 cm to 137 cm
Rapr-Round, leg wrap, one size for the left or right leg - thigh circumference	Colder	8001-061 -640	20.5 in. to 28.5 in.	52 cm to 72 cm
Mul-T-Blanket, adult	**Clik-Tite**	8001-061 -810	25 in. x 64 in.	64 cm x 163 cm
Mul-T-Blanket, pediatric	**Clik-Tite**	8001-061 -812	22 in. x 33 in.	56 x 84 cm

Thermal transfer device kits

Kit part number	Contents	Quantity	Type of Connector
8001-061-550	8001-061-530	1	**Clik-Tite**
	8001-061-540	2	
8001-061-560	8001-061-535	1	
	8001-061-540	2	
8001-061-650	8001-061-630	1	Colder
	8001-061-640	2	
8001-061-660	8001-061-635	1	
	8001-061-640	2	

Patient temperature probes

Patient temperature probes	Part Number	Measurement Specialties, Inc. (MEAS) for Canada only
Adhesive skin temperature sensing probe	8001-063-401	4499
9FR General purpose temperature sensing probe	8001-063-409	4491
12FR General purpose temperature sensing probe	8001-063-412	4492
14FR Foley catheter temperature sensing probe	8001-063-414	4464
16FR Foley catheter temperature sensing probe	8001-063-416	4466

Cables

Description	Part Number
Reusable adapter cable	8001-064-110
Reusable patient temperature output cable	8001-064-120

Hoses

Description	Part Number
Insulated **Clik-Tite** Hose	8001-064-035
Insulated **Colder Connector** Hose	8001-064-135

Problem	Possible cause	Action	Remove from use
Controller will not turn on	Power cord is not plugged into a properly grounded hospital grade wall outlet	Insert the plug fully into the properly grounded hospital grade wall outlet	If the product does not turn on after trying a different outlet
	Damaged power cord or plug	Visually make sure that the power cord is not damaged	If damaged, RFU
Controller user interface blackout	Power outage	If the Stand-by button is solid green, visually inspect the LCD for damage	If damaged, RFU
Product alarming, user interface blackout	Power outage	If the Stand-by button is yellow and flashing, visually inspect the LCD for damage	If damaged, RFU
Temperature probe	Not responding, does not connect, temperature outside of range	Replace temperature probe Check connections	If damaged, RFU
Controller will not heat	Reservoir is empty	Fill reservoir, tap Confirm that water has been added, restart	If filling the reservoir does not resolve
Controller will not cool	Reservoir is empty	Fill reservoir, tap Confirm that water has been added, restart	If filling the reservoir does not resolve
Thermal transfer device not filling with water or ports not detecting flow	Locking ring on Clik-Tite connector is not snapped into place	Check the **Clik-Tite** connection Replace the cable or thermal transfer device Thermal transfer device may be to high, lower the bed level Thermal transfer device may be folded, lay flat to make sure the water flows	Not applicable
	Quick disconnect not seated properly	Secure the thermal transfer device connection to the controller Replace the cable or thermal transfer device	Not applicable
Water level alarm	Water level too low	Fill reservoir	Not applicable

Problem	Possible cause	Action	Remove from use
Patient temperature	Out of range	Check the placement of the probe	Not applicable
Patient temperature output (PTO)	External device output displays high value >45˚ C when input is out of range (As a result of one of the following: patient probe disconnected, controller in standby / sleep mode, patient temperature outside the range of 25˚ - 45˚C).	To resume calibration: • Disconnect the external device from the reusable adapter cable • Tap the Help button to display the alarm screens • Find the “Temperature Output Alarm” screen • Tap Confirm to restart calibration • Wait until the “Monitor” is solid • Connect the external device to the reusable adapter cable	Not applicable

Preventive maintenance

At a minimum, make sure that all items listed during annual preventive maintenance for all Stryker Medical products. Preventive maintenance is to be completed by a qualified service technician.

Inspect all of the following items:

_____ Power cord and plug for fraying
_____ Condition of covers and push handle for damage
_____ Hose ports are operational
_____ Ground chain attached
_____ LCD is not cracked
_____ Wheels for smooth operation
_____ Rear caster wheels for free swivel action
_____ Both rear wheels lock securely when the brake is applied
_____ Front and rear wheels are not loose or wobbly
_____ Battery backup functional
_____ Alarm system - visual and audible
_____ LCD functional
_____ Touch screen functional
_____ Water temperature and flow verification
_____ Probe resistance
_____ Clear RFU codes
_____ Ground impedance not more than 100mΩ (millohms)
_____ Current leakage not more than 300 (microamps)
_____ Verify the integrity of all clamps and clamped joints located in the air elimination circuit.

Replace the following on an annual basis:

_____ Replace the 9 volt battery
_____ Replace the condenser inlet filter
_____ Replace the Air eliminator hose

Product Serial Number:
Completed by:
Date:

Cleaning tools

Description	Part Number
BruClean TbC 13.1g tablet, 52 count	8001-999-224
Service tool adapter hose	8001-999-017

The alarm rank establishes the order of presentation of the alarm on-screen message. The D in the table indicates the alarm is deactivated during that mode. Maintenance and RFU modes are always in the deactivated mode and are not listed in the table.

This product maintains the individual alarm status for all alarms as defined below.

- Alarm condition present
- Visual indicator state
- Audible indicator state
- Current timer for audio pause activation
- Alarm rank per therapy mode

Alarm	Stand-by	Auto	Auto Paused	Manual	Manual Paused	Monitor
Remove from use	0	0	0	0	0	0
Power loss	D	1	1	1	1	1
Check patient probe	D	7	7	11	11	4
Patient probe malfunction	D	6	6	10	10	3
Probe disconnected	D	5	5	9	9	2
Patient temperature deviation	D	9	9	D	D	D
Water temperature deviation	D	D	D	7	D	D
Check water flow (all ports)	D	11	D	6	D	D
No water flow alarm (all ports)	D	4	D	4	D	D
No water	D	2	D	2	D	D
Therapy paused timed out	D	D	3	D	3	D
Normothermia deviation	D	D	D	D	D	5
Power backup level	1	19	19	14	14	6
Patient output deviation	D	22	22	17	17	7

Notes

- If more than one alarm is active at the same time, the product maintains the active state for the individual alarm including the audio pause timer. The screen alarms are displayed with the highest level alarm first with a page toggle to allow the operator to scroll to the subsequent alarms.
- The Paused in Auto Paused and Manual Paused refer to the Therapy Pause state.

Check patient probe alarm

This alarm notifies the operator that data provided by the probe is not normal or appears removed.

Notes

- The product only activates the Check Patient Probe Alarm when met during an Active Therapy. Otherwise, the alarm is disabled.

Alarm generation:

Primary patient temperature changes by more than 1.0˚ C within two minutes.

Note: The product will deactivate the heat exchange and keep the pump activated as requested by the Active Therapy.

Patient probe malfunction alarm

This alarm notifies the operator that the probe is not providing information to the product during an active therapy.

Alarm generation:

When the primary patient probe is in a shorted, opened condition, or out of range for more than 30 seconds, the product will display the Patient Probe Malfunction Alarm.

Note: The product will deactivate the heat exchange and keep the pump activated as requested by the Active Therapy.

Patient probe disconnect alarm

This alarm notifies the operator that the probe is not providing information to the product during an active therapy.

Alarm generation:

When the adapter cable for the primary probe is removed and the reading of the Primary Patient probe is out of range for more than 30 seconds, the product displays the Patient Probe Disconnected alarm.

Patient temperature deviation medium alarm

This alarm notifies the operator that the patient is not responding as expected in the active therapy.

Alarm generation:

The product will display the Patient Temperature Deviation Medium Alarm, if after the initial achievement of the current patient temperature target, the actual primary patient temperature becomes 0.5˚ C or more above, or below the Current Target Temperature.

Patient temperature output deviation alarm

This alarm notifies the operator that the patient temperature output is out of range or their is a calibration error.

Alarm generation:

The product will display the Patient Temperature Output Deviation Alarm, if the calibration has failed, or the patient temperature output is out of range.

Normothermia deviation alarm

This alarm notifies the operator of that the Primary Patient Temperature is out of range.

Alarm generation:

If the actual Primary Patient Temperature is lower or equal to 35.9˚ C or higher or equal to 38.1˚ C, the controller will display the Patient Normothermia Deviation alarm.

Water temperature deviation alarm group

This alarm notifies the operator that the water is not responding as expected to the therapy. The product is at full power, with the current mode and the temperature selection. The water temperature cannot remain within a range of ±0.8º C of the selected Water Target Temperature.

Water temperature deviation alarm group (Continued)

Alarm generation:

1. If the actual water temperature is 0.8˚ C or more above or below the Final Target Temperature, the product will display the Water Temperature Deviation Alarm.
2. When the product is entering the Manual mode or you change Target Temperature, the product will pause the audible component of the Water Temperature Deviation Alarm for four hours. The four hour pause automatically cancels after the Water Temperature becomes equal to the Final Target Temperature.

Check water flow alarm

This alarm notifies the operator of the quality of the flow in each individual water circuit.

Alarm generation:

- When in Manual or Automatic Mode and several ports are in use for the therapy.
- You have selected an outlet port and the flow is lower than 0.8 l /min for a period of 60 seconds or more. The product will display a Check Water Flow Alarm for the given port.

Notes

- The alarm displays if the flow is not at an optimal level on each port. This alarm will ask the operator to confirm which ports are currently in use.
- The addition of a port does not need the operator to confirm the addition.
- The removal of a port requires the operator to confirm.
- The Check Water Flow Alarm for the given outlet port stops, if the operator confirms removal.
- When none of 3 ports has a flow higher than or equal to 0.6l / min, the product deactivates the heater exchange and generates a no flow alarm. Otherwise the heater exchange will remain active as indicated by the current mode.

Power backup level alarm

This alarm notifies to the operator an indicator of the status of the Backup Power Level.

Notes

- The indicator will remain active until a qualified technician replaces the battery.
- There is no reduction in the usability of the product. The product remains functional and a visual alarm is displays.
- The product will disable the Backup Power Level Alarm in Sleep Mode. Otherwise, the alarm is enabled.

Alarm generation:

The product will display Backup Power Level Alarm when the battery level backup power is less than 100 minutes of alarms. Once activated, the Backup Power Level Alarm will remain active until you power off the product.

Therapy paused time out alarm

This alarm converts a therapy pause into an alarm if the duration of the pause is too long.

Alarm generation:

When paused for five minutes, the product will display the Therapy Paused Time Out Alarm. After you resume the current therapy, the Therapy Paused Time Out Alarm is deactivated.

Remove from use mode

The Remove From Use (RFU) is a safety mode to limit operations. A fault condition prevents the product from normal functions and requires service. The controller will stop the Active Therapy and communicate to the operator that the controller is going into RFU mode.

⚠ CAUTION

Always remove the product from use before servicing any components. Contact qualified service personnel for service.

Depending on the remove from use (RFU) condition, text may or may not be displayed. For example, if there is a power loss.

- Water temperature probes are out of the allowed range
- Program and data checksum error
- High thermal cutout test failed
- Backup power product replacement required
- Low or over safety temperature
- Pump over current
- Compressor power fault
- Heater power fault
- Refrigerant control valve fault
- Main DC power lost
- CAN heart beat lost
- Dual safety temperature sensors do not match readings
- Dual safety temperature sensors are out of the allowed range
- Hardware watchdog heartbeat failure

Guidance and manufacturer's declaration - electromagnetic emissions		
The **Altrix** system is intended for use in the electromagnetic environment specified below. The customer or the user of **Altrix** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment**
RF Emissions CISPR 11	Group 1	The **Altrix** system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The **Altrix** system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A 220-240V/50Hz 220V/60Hz Does not apply to 100V 50/60Hz or 120V/60Hz	
Voltage Fluctuations Flicker Emissions IEC 61000-3-3	Complies 220-240V/50Hz only	

Recommended separations distances between portable and mobile RF communications equipment and the Altrix system			
The **Altrix** system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of **Altrix** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Altrix** system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz **D=(1.2) (√*P*)**	**80 MHz to 800 MHz** **D=(0.35) (√*P*)**	**800 MHz to 2.5 GHz** **D=(0.70) (√*P*)**
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The **Altrix** system is suitable for use in the electromagnetic environment specified below. The customer or the user of **Altrix** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, voltage variations and short interruptions on power supply input lines IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Main power quality should be that of a typical commercial or hospital environment. If the user of the **Altrix** system requires continued operation during power main interruptions, it is recommended that the device be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage before applications of the test level.			

(Continued)

Guidance and manufacturer's declaration - electromagnetic immunity			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Altrix** system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance D=(0.35) ($\sqrt{P}$) 80 MHz to 800 MHz D=(0.70) ($\sqrt{P}$) 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(Continued)

Guidance and manufacturer's declaration - electromagnetic immunity
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Altrix** system is used exceeds the applicable RF compliance level above, the **Altrix** system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Altrix** system.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths are less than 3 V/m.

Warranty

Stryker Medical, a division of Stryker Corporation, warrants to the original purchaser the Stryker Model 8001 **Altrix**, to be free from defects in material and workmanship for a period of one years after date of delivery. Stryker's obligation under this warranty is expressly limited to supplying replacement parts and labor for, or replacing at its option, any product which is, in the sole discretion of Stryker, found to be defective. If requested by Stryker, product or parts for which a warranty claim is made shall be returned prepaid to the factory. Any improper use or any alteration or repair by others in such a manner as in Stryker's judgment affects the product materially and adversely, shall void this warranty. Any repair of Stryker products using parts not provided or authorized by Stryker shall void this warranty. No employee or representative of Stryker is authorized to change this warranty in any way.

Stryker Medical temperature management products have a five year expected service life under normal use, conditions, and with appropriate periodic maintenance as described in the maintenance manual for each device.

The above noted warranty periods apply only to the original purchaser of the **Altrix** and begin on the date of delivery to such original purchaser.

Warranty exclusion and damage limitations

The express warranty set forth herein is the only warranty applicable to the product. **Any and all other warranties, whether express or implied, including any implied warranty of merchantability or fitness for a particular purpose are expressly excluded by Stryker.** In no event shall Stryker be liable for incidental or consequential damages.

To obtain parts and service

Stryker products are supported by a nationwide network of dedicated Stryker Field Service Representatives. These representatives are factory trained, available locally, and carry a substantial spare parts inventory to minimize repair time. Simply call your local representative or call Stryker Customer Service at 1-800-327-0770.

Return authorization

Product cannot be returned without prior approval from the Stryker Customer Service Department. An authorization number will be provided which must be printed on the returned product. Stryker reserves the right to charge shipping and restocking fees on returned product. Special, modified, or discontinued products are not subject to return.

Damaged product

ICC Regulations require that claims for damaged product must be made within fifteen (15) days of receipt of the product. Do not accept damaged shipments unless such damage is noted on the delivery receipt at the time of receipt. Upon prompt notification, Stryker will file a freight claim with the appropriate carrier for damages incurred. Claims will be limited in amount to the actual replacement cost. In the event that this information is not received by Stryker within the fifteen (15) day period following the delivery of the product, or the damage was not noted on the delivery receipt at the time of receipt, the customer will be responsible for payment of the original invoice in full within thirty (30) days of receipt. Claims for any incomplete shipments must be made within thirty (30) days of invoice.

International warranty clause

This warranty reflects U.S. domestic policy. Warranty outside the U.S. may vary by country. Contact your local Stryker Medical representative for additional information.

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