

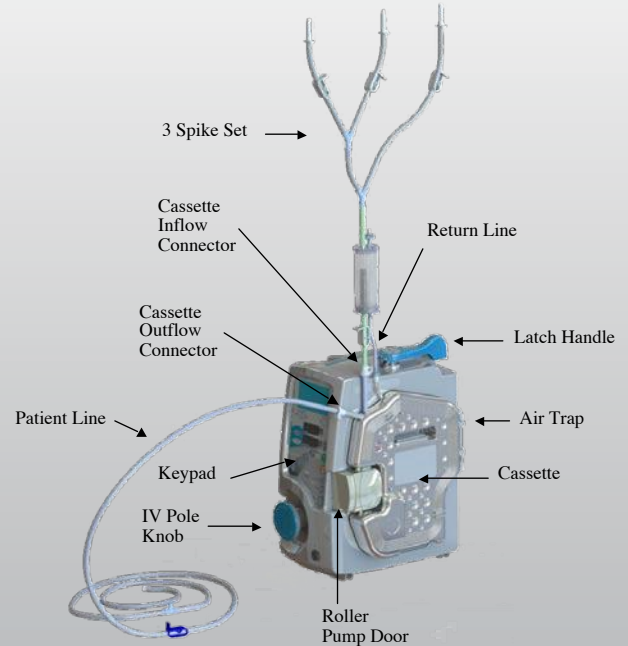
Quick Reference Guide



Customer Service
Toll Free: 1-866-944-9992
Office: 1-478-744-9992

SCD-0081-01, Rev A

ThermaCor is a registered trademark of Smisson-Carlledge Biomedical, LLC.



Please read the Operator Manual before using the system. Only knowledgeable users should operate this device

Quick Start Instructions

1. Turn on the pump by pressing the Power ON button. The Self-Test will then automatically begin and take a few seconds to complete. Following a successful Self-Test, a message will appear stating “NO CASSETTE”.
2. Unpack the Cassette from packaging using aseptic technique, while retaining sterility of fluid connections.
3. Open the Roller Pump Door and place the Latch Handle in the LOAD position.
4. Place the Cassette into the lower metal bar at a 45degree angle, and push the top of the Cassette toward the Pump until the top metal bar engages the Cassette.
5. Insert the Cassette tubing onto the roller pump.
6. Move the Latch Handle to the fully CLOSED position.
7. Ensure that the tubing is fully pushed in the roller pump and close the Roller Pump Door.
8. Connect the Inflow, Return and Outflow lines. Close the pinch clamps on the Inflow spike lines. Spike bag(s) and open respective pinch clamps.
9. Press and release the PRIME button to run the Auto-Priming cycle. Following Auto-Prime, press and release (allows 15sec of additional priming) or press and hold the PRIME button to continue Manual Priming. Inspect that the patient line is free of air bubbles.
10. Using aseptic technique, make the patient connection without entrapping air. Select the appropriate settings and press START to begin infusing.

WARNINGS

The patient outflow line must be completely free of air before fluid is administered.

Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately.

Do not alter or change any part of the cassette. Any changes or alterations to the cassette may endanger the patient or damage the system.

CAUTIONS

STERILE EO



Federal (USA) law restricts this device to sale by or on the order of a physician.

Store the disposable according to manufacturer’s recommendations for temperature and humidity.

See the Operator Manual for complete instructions on installation and use of this system.

Sterile, non-pyrogenic fluid path.

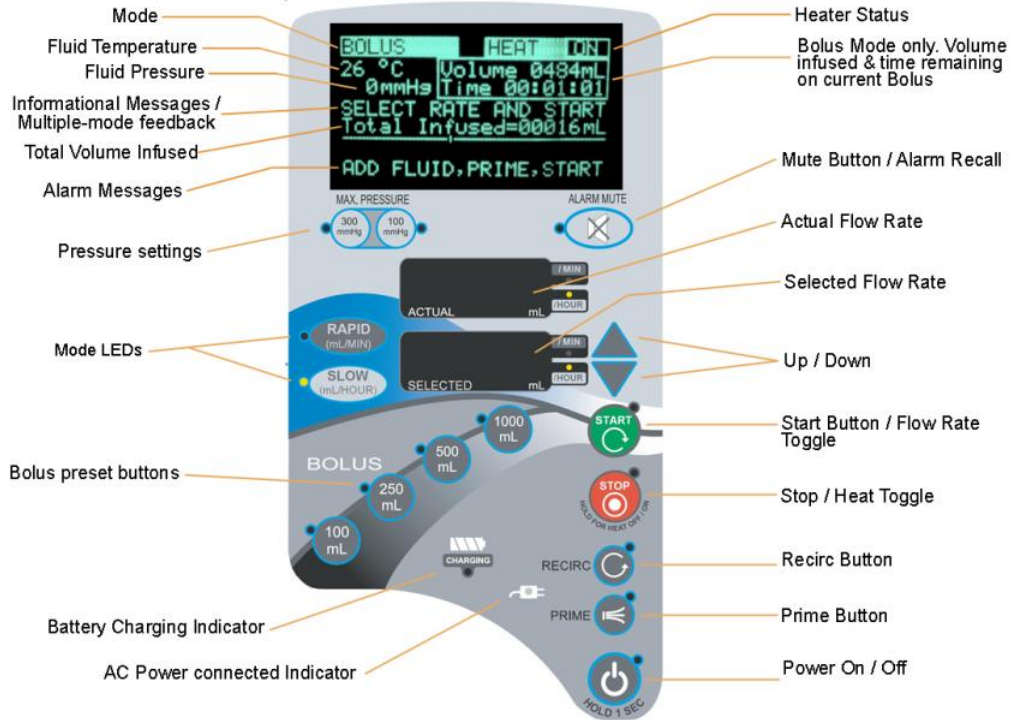
Use aseptic techniques.

DO NOT USE if caps are not in place.

DISPOSE in accordance with local and state regulations regarding medical waste disposal.

THIS PRODUCT IS SINGLE USE ONLY, it cannot be adequately cleaned or sterilized for reuse.

Keypad and Display



Quick Start Instructions

Keypad and Display

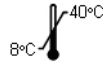
Connecting Large Volume Reservoir

1. If connected, disconnect the 3 Spike Set from the Cassette. Secure the RH-1200 Reservoir Holder to the IV pole above the ThermoCor 1200 Infusion System.
2. Using aseptic technique, unpack the Large Volume Reservoir from packaging while retaining sterility of fluid connections, and place the Reservoir into the Holder.
3. Using aseptic technique, open pouch and connect Reservoir Outflow Tubing Adapter to the Reservoir Outflow Port. Attach the Reservoir Outflow Tubing Quick Connect to the Inflow Line of the Cassette.
4. At the top of the Cassette, unscrew the yellow connector to disconnect the vent bag (if present). Connect the yellow connector to the Return Line of the Reservoir.
5. Close the roller clamp on the Reservoir Outflow Line and fill the Reservoir with appropriate fluids. Follow appropriate standard operating procedures for anticoagulation prior to administration. Open all pinch clamps. Press and release the PRIME button to run the Auto-Priming cycle. Following Auto-Prime, press and release (allows 15sec of additional priming) or press and hold the PRIME button to continue Manual Priming. Inspect that the patient line is free of air bubbles.
6. Using aseptic technique, make the patient connection without entrapping air. Select the appropriate settings and press START to begin infusing.

STERILE/EO



WARNINGS



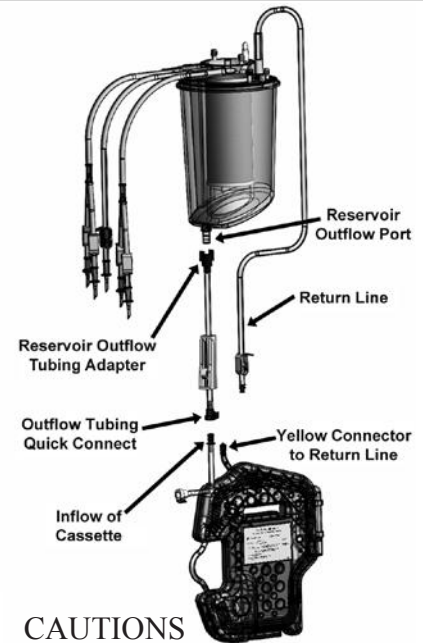
See instructions for use



CAUTIONS

The patient outflow line must be completely free of air before fluid is administered. Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately. Do not alter or change any part of the device. Any changes or alterations to the device may endanger the patient or damage the system.

Sterile, non-pyrogenic fluid path.
DO NOT PRESSURIZE reservoir.
DO NOT USE if caps are not in place.
DISPOSE according to local and state regulations regarding medical waste disposal.



Operational Modes

Slow

- 10ml/hr to 1200ml/hr
- Factory default: 120ml/hr
- Adjustment in increments of 10ml/hr or 50ml/hr

Rapid

- 20ml/min to 1200ml/min
- Factory default: 500ml/min
- Adjustment in increments of 10ml/min or 50ml/min

Bolus

- 20ml/min to 1200ml/min
- Factory default: 500ml/min

Flow Rate Toggle

In Slow and Rapid modes, the user may toggle the flow rate as needed between the selected flow rate and the default flow rate. For example, while the pump is infusing at 40ml/min (in Rapid mode), the user can press and hold the START button for 1 second, the pump will display and begin infusing at 500ml/min and the START button will flash. The user may press the START button again for 1 second to toggle back to the selected flow rate (40ml/min), the pump will begin infusing at that rate and the START button will be continuously lit. The user may toggle between any selected flow rate and the default flow rate at any time during Rapid and Slow modes as needed.

Footswitch

- Connects to ThermaCor 1200 Pump via a connector located on the front of the device in the lower right corner
- Can be connected while powered on
- Performs same function as pressing START and STOP buttons
- The Front Panel can also be used with the Footswitch
- Set the desired flow rate. Start or stop the flow by pressing the Footswitch as needed

Manual Operation

To manually operate the ThermaCor 1200 System without power in an emergency:

1. Turn power off.
2. Open the pump door.
3. Move Latch Handle to Load position.
4. Pull the Cassette outward without removing it.
5. Clamp the Return Line (if using Large Volume Reservoir) and apply pressure to the fluid bags.

Approximate Flow Rates for Catheter Sizes at 300mmHg

French Gauge	Needle Gauge	Whole Blood Single Line (mL / Minute)	Crystalloid Single Line (mL / Minute)
4	18	184	250
5	16	194	380
6	14	555	700
10	10	1200	1200

Connecting Large Volume Reservoir

Operation / Catheter Size Selection

Alarm Reference

Three categories of alarms can be generated in the event of a fault:

- **Error** – Long audible pulses with messages that indicate safety critical events that will cause infusion to be halted. A Critical Error will cause the Pump to stop and requires a power cycle to restart. An Error will cause the Pump to stop and appropriate user action must be taken to clear the alarm and restart infusion.
- **Warning** – Short audible pulses with informational messages that relay to the operator that the system is in a condition that is not safety critical but could become an error if not corrected.
- **Alert** – One single pulse with informational messages that indicates that the ThermoCor 1200 is in a condition that is not safety critical and is not yet a warning.

Note: In the table below, “Power Cycle” refers to pressing the Power button to turn the Pump off, waiting 5 seconds and then pressing the Power button again to turn the Pump back on.

Main Display Text Message	Cause	Operator Action
ADD FLUID, PRESS PRIME	Air trap is found empty following Auto-Prime.	Add fluid, press prime, and continue operation. If error persists, open/relatch Cassette and power cycle Pump. If error persists, replace Cassette.
ADD FLUID, PRESS PRIME	Auto-Prime has been paused due to a time-out	Check fluid source and press PRIME to reactivate Auto-Prime. If activated again, unlatch and relatch the Cassette. If error persists, replace Cassette and power cycle.
ADD FLUID, PRIME, START	A continuous amount of air has passed through the Inflow line into the Cassette during infusion	Check that IV Bags or Reservoir is correctly connected and not empty. Press PRIME to advance fluid. If error persists, call Customer Service.
ADD FLUID, PRIME, START	Air purge operation has exceeded 24 seconds	Check Inflow Lines for blockage and fluid source. Check Return line for occlusions. Press START. If not corrected, replace Cassette. If error persists, call Customer Service.
ADD FLUID, PRIME, START	A continuous amount of air has passed through the Inflow line during Purge	Check that IV Bags, tubing, or the Reservoir is correctly connected and not empty. Check the Inflow line to ensure that fluid is flowing into the Cassette. If warning persists, call Customer Service.
ADD FLUID, PRIME, START	Air trap is detected empty during Manual Prime and purging.	Check fluid source and inlet connection. Press START or Manual Prime to infuse fluid. If air trap is not empty, open and close Cassette Latch.
AIR IN PATIENT LINE	Air is detected in Patient line	Remove line from patient and press PRIME to remove air.
ALARM TEST MESSAGE	The operator has initiated a test of the Alarm system by holding the mute button	Upon completion of test, resume normal operation.

CASSET FAULTY: REPLACE	Fluid is detected at patient line during Auto-Prime	Relatch Cassette and power cycle. If error persists, replace Cassette.
CLOSE PUMP DOOR	Pump door is opened during or after Priming	Check that tubing is correctly aligned on pump rollers and close pump door. If error persists, call Customer Service.
CLOSE PUMP DOOR	The Pump door is opened before priming while a Cassette is attached	Close pump door. If alert persists, call Customer Service.
CRITICAL BATTERY	At least 3 min of battery capacity remaining	Connect the Pump to AC power source and power cycle the Pump. If error persists when connected to AC Power, call Customer Service.
DEPLETED BATTERY	Indicates that the system is about to be shut down due to low battery (<6 min operation time) while in battery operation	Connect the Pump to a dedicated AC power source. If warning persists when connected to AC Power, call Customer Service.
ERR 1: PWR OFF & ON	There is a problem with the power going to the sensors	Power cycle the Pump. If error persists, call Customer Service.
ERR 2: PWR OFF & ON	There is a problem with the power going to the main display	Power cycle the Pump. If error persists, call Customer Service.
ERR 3: PWR OFF & ON	Internal test TW ADC does not complete successfully	Power cycle the Pump. If error persists, call Customer Service.
ERR 4: PWR OFF & ON	Valve has detected over current	Power cycle the Pump. If error persists, call Customer Service.
ERR 5: PWR OFF & ON	Watchdog timer test does not complete successfully	Power cycle the Pump. If error persists, call Customer Service.
ERR 6: PWR OFF & ON	Pump reports a clock failure	Power cycle the Pump. If error persists, call Customer Service.
ERR 7: PWR OFF & ON	SRAM memory test does not complete successfully	Power cycle the Pump. If error persists, call Customer Service.
ERR 8: PWR OFF & ON	FLASH memory test does not complete successfully	Power cycle the Pump. If error persists, call Customer Service.
ERR 9: PWR OFF & ON	Motor has stopped, motor detected over current	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Pump. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 10: PWR OFF & ON	Motor has stopped, motor has an over temperature	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Pump. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.

Alarm Reference

Main Display Text Message	Cause	Operator Action
ERR 11: PWR OFF & ON	Motor has stopped, motor has speed failure	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Pump. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 12: PWR OFF & ON	Motor has stopped, motor has direction failure	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Pump. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 13: PWR OFF & ON	Pump reports a mode failure	Power cycle the Pump. If error persists, call Customer Service.
ERR 14: PWR OFF & ON	Software error, a fault in the firmware has occurred, or error when attempting to display a message	Power cycle the Pump. If error persists, call Customer Service.
ERR 15: PWR OFF & ON	Reading from the pressure sensors failed multiple times sequentially	Power cycle the Pump. If error persists, call Customer Service.
ERR 16: PWR OFF & ON	Reading from the temperature sensors failed multiple times sequentially	Power cycle the Pump. If error persists, call Customer Service.
ERR 17: CALL SERVICE	Air bubble is detected at patient line sensor when pump is stopped	Disconnect patient line from patient. Press and hold PRIME to manually prime the line until all air has escaped. If error persists, call Customer Service.
ERR 18: CALL SERVICE	Air detectors on inlet had a reading check	If error persists, open and relatch Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.
ERR 19: OK TO USE	Air detectors on upper air trap had a reading check	If error persists, open and relatch Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.
ERR 20: OK TO USE	Air detectors on lower air trap had a reading check	If error persists, open and relatch Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.
FLUID SUPPLY BLOCKED	Occlusion or restriction of Inlet. Inlet pressure < -100mmHg	Check Inflow Line for occlusion or restrictions. Change Reservoir or 3 Spike Set if filter is clogged. If error persists, call Customer Service.
FLUID SUPPLY BLOCKED	Pressure < -100mmHg at roller pump outlet pressure sensor	Check that all clamps are open. If problem persists, power cycle the Pump. If error persists, call Customer Service.
HEATING FAULT	Heater is not operating correctly	Turn heater off to clear alarm. Cycle heater off and back on. If warning persists, call Customer Service.
HI TEMP 1: PWR OFF/ON	Heat Exchanger temperature > 45°C	Check and clean Pump heating surface. Restart procedure with new Cassette and power cycle the Pump. If error persists, call Customer Service.
HI TEMP 2: PWR OFF/ON	Inlet temperature ≥ 45°C	Remove and dispose of Cassette and fluid source. Power cycle the Pump and restart with a new Cassette and new fluid source. If error persists, call Customer Service.

HI TEMP 3: PWR OFF/ON	Patient Line temperature $\geq 44.5^{\circ}\text{C}$	Restart procedure with new Cassette and power cycle the Pump. If error persists, call Customer Service.
HI TEMP 4: PWR OFF/ON	Patient Line temperature $\geq 45^{\circ}\text{C}$	Restart procedure with new Cassette and power cycle the Pump. If error persists, call Customer Service.
HI TEMP 5: PWR OFF/ON	Heater Platen temperature $\geq 88^{\circ}\text{C}$	Check and clean Pump heating surface. Power cycle the Pump. If error persists, call Customer Service.
HI TEMP 6: PWR OFF/ON	Heater Platen temperature $\geq 88^{\circ}\text{C}$	Check and clean Pump heating surface. Power cycle the Pump. If error persists, call Customer Service.
HIGH INLET PRESSURE	Pressure greater than 403mmHg is detected at the inlet	Check for occlusions on the inlet line. If the problem persists, power cycle the Pump and replace Cassette. If error persists, call Customer Service.
INFUSION AT MAX VOL	Indicates that the maximum amount that can be infused has been reached	Power cycle the Pump and restart with a new Cassette. If error persists, call Customer Service.
INFUSION AT MAX VOL	Infusion is about to reach maximum volume of 99,999 mL	Power cycle the Pump, then restart with a new Cassette. If warning persists, call Customer Service.
LO TEMP 1, PWR OFF/ON	Heat Exchanger sensor detects temperature below 1°C	Power cycle the Pump and resume operation. If error persists, call Customer Service.
LO TEMP 3, PWR OFF/ON	Patient sensor detects temperature below 1°C	Power cycle the Pump and resume operation. If error persists, call Customer Service.
LO TEMP 5, PWR OFF/ON	Platen sensor detects temperature below 1°C	Power cycle the Pump and resume operation. If error persists, call Customer Service.
LOW BATTERY	The Pump has < 33 minutes of power available from the battery	Prepare to connect the Pump to a dedicated AC power source within 25 minutes.
MANUALLY PRIMING	Operator has initiated manual prime mode	Upon completion of manual prime, resume normal operation.
NO CASSETTE	Cassette not detected	Attach Cassette. If Cassette is already engaged, remove and attach. If alert persists, call Customer Service.
NOT LATCHED	Cassette latch is unlatched during Auto-Prime, Prime, or normal operation	Close Cassette Latch. If not corrected, remove Cassette and reattach. If error persists, power cycle the Pump, remove and reinstall Cassette. If error persists, call Customer Service.
OK TO USE - CALL SRVC	Problem communicating with the display	Call Customer Service before operating again.
ON BATTERY: NO AC PWR	AC Power has been disconnected, pump is operating on battery	Connect the Pump to a dedicated AC power source when available.

Alarm Reference

Main Display Text Message	Cause	Operator Action
OVERINFUSD: PWR OFF/ON	Bolus exceeded desired volume by 20mL or more	Power cycle the Pump. If error persists, call Customer Service.
PATIENT LINE BLOCKED	Pressure greater than maximum pressure is detected from the pressure sensors	Check for occlusions, open and close Pump Door to relieve pressure. If problem persists, increase the size of the patient access port or power cycle the Pump and replace Cassette. If error persists, call Customer Service.
PATIENT LINE BLOCKED	Occlusion, or flow rate is $\leq 10\text{mL}/\text{min}$ in Rapid Mode with 300mmHg pressure setting selected, or restriction of patient line pressure $\geq 135\%$ of max pressure setting	Check patient line for occlusion or restrictions. Open and close Pump Door to relieve pressure and press START. If problem persists, increase the size of the patient access port. Use the Dual Outflow Line. If error persists, call Customer Service.
POSSIBLE FREE FLOW	The patient and purge valves are open, or the pump detects the Cassette not latched during/after operation	Close and relatch the Cassette and resume operation. If error persists, power cycle the Pump and relatch the Cassette. If error persists, call Customer Service.
PT LINE RESTRICTED	$<20\text{mL}/\text{min}$ flow during Rapid Mode	Check patient line for restrictions or change catheter size.
PUMP PAUSED	Pump has been paused due to the pump door opening, message shows after pump door is closed	Press START to resume operation
PURGING IN PROGRESS	Air purge operation is in progress.	Upon completion of purging, normal operation will proceed.
SERVICE BATTERY	Battery not functional or Battery charger needs service	Call Customer Service before starting on a new patient.
SERVICE CHARGER	Battery charging is not detected while connected to AC power	Call Customer Service before starting on a new patient.
UNCLAMP RETURN LINE	Pressure $\geq 405\text{mmHg}$ is detected in the Return line	Check the Return line for restrictions or occlusions and unclamp the Return line. If error persists, call Customer Service.
UNIT SHUTDOWN 2 MIN	The Pump has been continuously on for more than 48 days	Power cycle the Pump. If error persists, call Customer Service.

The Alarm Mute button allows silencing of audible alarms for 120 seconds. If the problem has not been corrected within that time, the alarm will begin sounding again. A new alarm condition detected during the mute period will cancel mute and the new alarm will sound.

Pressing and Holding the MUTE button for approximately 5 seconds will sound an alarm. The pump will display “ALARM TEST MESSAGE.”

The alarm function can be tested at any time when no alarms are present.

When operating the Pump using Slow Mode, the selected pressure of 100mmHg is recommended to trigger a restriction alarm in a shorter time period.

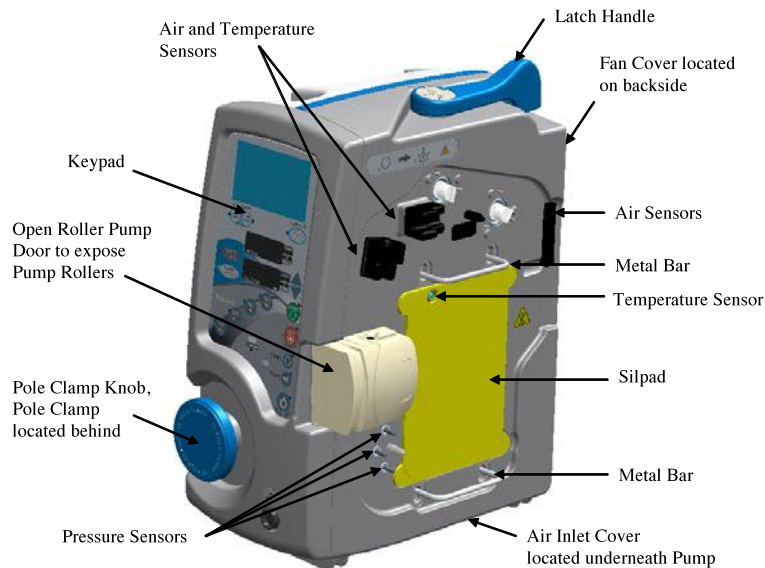
Cleaning

1. Turn the Pump off and disconnect from AC power before cleaning. If attached, disconnect Footswitch as well.
2. Use a cleaning solution [10% bleach (0.05% sodium hypochlorite) and distilled water solution or mild detergents and water] and a damp cloth.
3. Clean and wipe all surfaces of the Disposable Cassette-Pump interface, including the sensors, silpad, pump door, and pump rollers indicated in the figure to the right. Extreme care should be taken not to damage these components.
4. Clean and wipe the Keypad surface.
5. Clean and wipe all exterior surfaces contacted by fluids during use. Ensure all components are thoroughly dried before next use.
6. Clean and wipe the Footswitch surface and cord.
7. Allow surfaces to dry before next use.
8. Place the CG-1200 Component Guard on the Pump while not in use.

Maintenance

1. Turn the Pump off and disconnect from AC power before performing maintenance.
2. Inspect the Power Cord for any damage. If power cord shows damage, please contact Customer Service.
3. Inspect the Footswitch for any damage. If Footswitch shows damage, please contact Customer Service.
4. Inspect and clean the Pole Clamp. Inspect for damage. If Pole Clamp is damaged and unable to perform intended function, please contact Customer Service.
5. Inspect and clean Air Inlet Cover. Use a cleaning solution [10% bleach (0.05% sodium hypochlorite) and distilled water solution or mild detergents and water] and a damp cloth. If the mesh filter does not allow air flow, please call Customer Service for replacement.
6. Inspect and clean Fan Cover. Use a cleaning solution [10% bleach (0.05% sodium hypochlorite) and distilled water solution or mild detergents and water] and a damp cloth.
7. Place the CG-1200 Component Guard on the Pump while not in use.

Note: Do not immerse any components



Cleaning / Maintenance Step	Perform Before or After Each Use	Perform Monthly
Disposable Cassette - Pump interface surfaces	✓	
Keypad surface	✓	
Exterior surfaces	✓	
Power Cord	✓	
Footswitch	✓	
Pole Clamp		✓
Air Inlet Cover		✓
Fan Cover		✓

Contacting Customer Service



Customer Service can be reached at 1-866-944-9992 or 1-478-744-9992. Before calling, please have the following ready:

- Contact Name
- Location Name, Address, Phone Number
- Serial number of the ThermaCor 1200
(The serial number of the unit is located on the label on the backside of the ThermaCor 1200 Pump)
- Software version of the ThermaCor 1200
(The software version number appears on the Main Display when the Pump is powered up)
- Description of problem and any error message(s)
- Fluids administered
- Lot number appearing on package of item

If Customer Service determines that the ThermaCor 1200 needs to be returned for service or repair, they will issue a Return Material Authorization (RMA) number and directions for return shipping the device for service.

Protected by US Patent Nos.: 7,563,248; 7,713,236; 7,896,834 and related global patents and applications.



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