Rapid Thermal Infusion System

OPERATOR MANUAL

Software Version 3.10

www.ThermaCor1200.com

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

SCD-0098-02 Rev H
ECO # C1149

LIMITED PRODUCT WARRANTY

The ThermaCor® 1200 Rapid Thermal Infusion System is warranted to the original purchaser to be free from defects in material and workmanship for a period of one (1) year from the date of shipment. If the ThermaCor® 1200 Rapid Thermal Infusion System proves to be so defective, the purchaser may return same to Smisson-Cartledge Biomedical, LLC (SCB), or its designated agent, for repair or replacement, if SCB deems appropriate. The foregoing warranty shall not apply if: (i) a product is not used in accordance with its instructions for use or if it is used for a purpose not indicated on the labeling, (ii) any repairs, alterations or other work has been performed by Buyer or anyone other than an authorized SCB representative on a product; or (iii) the alleged defect is a result of abuse, misuse, fluid/blood contamination, improper maintenance, accident or the negligence of any party other than Smisson-Cartledge Biomedical, LLC.

No unauthorized service repairs or modifications on this equipment other than that described in the Operator Manual should be attempted. Any unauthorized repairs will immediately void the remaining time of the warranty.

No agent, employee or representative of SCB has any authority to bind SCB, to any affirmation, representation or warranty concerning its products, and any affirmation / representation, or warranty made by any agent, employee or representative shall not be enforceable by the buyer.

THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) RESPECTING THE THERMACOR® 1200 RAPID THERMAL INFUSION SYSTEM OR ANY OTHER COMPONENT, AND THE LIABILITY AND REMEDY STATED IN THIS LIMITED WARRANTY WILL BE THE SOLE LIABILITY AND REMEDY AVAILABLE TO PURCHASER FOR SAID PRODUCTS, WHETHER IN CONTRACT TORT OR OTHERWISE, AND SMISSON-CARTLEDGE BIOMEDICAL, LLC WILL NOT BE LIABLE TO PURCHASER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR INCIDENT TO THE HANDLING, USE, MAINTENANCE OR SERVICING OR DISPOSITION OF SAME.

TABLE OF CONTENTS

ICON / SYMBOL DEFINITIONS

Symbol	Description
	Caution, Follow Operating Instructions
	Type CF Patient Protection
	Date of Manufacture
	Single Patient Use Only
	Consult Instructions for Use
	Catalog number
	Batch Code
	Sterilized using ethylene oxide
	Manufacturer
	Use-by Date
	Do Not Resterilize
	Do not use if package is damaged

Symbol	Description
	Power On/Off/Standby
	Start
	Stop
	Heat
	Prime
	AC Power
	Battery Charge Level
	Alarm Mute
	Recirculation
	Caution, Hot Surface
	LOAD Cassette
	Cassette LOCKED
	Cassette UNLOCKED
	Alternating Current
	Footswitch

Symbol	Description
	Temperature Limitation
ThermaCor® 1200 Infuser: **IP22**	Protection against objects and protection from vertically drip water.
Footswitch: **IPX8**	Protection against complete, continuous submersion in water.
	Non-pyrogenic fluid path
	RoHS Compliant
	Caution: Federal [USA] law restricts this device to sale by or the order of a physician.
	Lithium Ion Battery
	Authorized representative of the European Community
	Moving Parts
	Serial Number
	Product contains DEHP [**MR-1200 ONLY**]
	Medical Device

EQUIPMENT AND ACCESSORIES

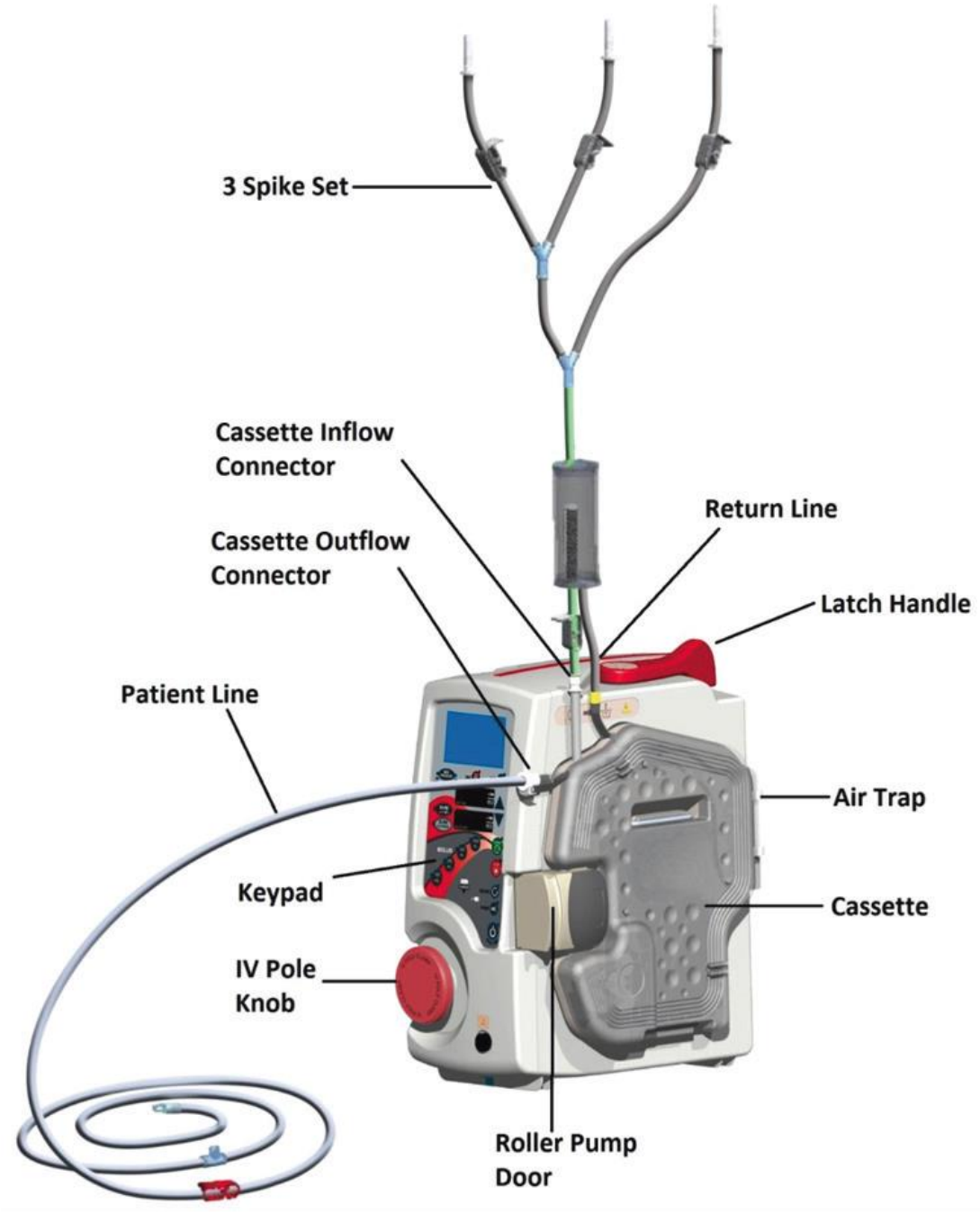
PRODUCTS	DESCRIPTION
ThermaCor® 1200 System	ThermaCor® 1200 Infuser
	Power Cable
	Component Guard
	PTC-1200, Disposable Set (Cassette with Patient Line and 3 Spike Set Inflow Line)
	PNC-1200, Disposable Set (Cassette with Patient Line)
	DNC-1200, Disposable Set (Cassette with Dual Line)
Accessories	On / Off Footswitch
	Rigid Fluid Reservoir
	Rigid Fluid Reservoir Holder
	3 Spike Set
	3 Spike Set Holder
	Dual Outflow Lines
	Patient Lines
	Extension Lines
	Replacement Power Cord (US)
	Replacement Power Cord (European)
	Replacement Power Cord (UK)
	Replacement Power Cord (Australian)
	Replacement Component Guard
	Replacement Silpad
	Drape

NOTE: The use of accessories, transducers, and cables other than those specified by the manufacturer may result in increased Emissions or decreased Immunity of the ThermaCor® 1200 Infuser.

EMC COMPLIANCE

NOTE: The ThermaCor® 1200 Infuser needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. See Appendix A for additional information.

WARNING: The ThermaCor® 1200 Infuser is not permitted for use in an explosive atmosphere.



*The above setup is a schematic only and may not be representative of the setup for each case.

ABBREVIATED QUICK START INSTRUCTIONS

Please read this Operator Manual before using the system. Only medically trained healthcare professional, knowledgeable users, should operate this system.

Please read the remainder of this Operator Manual for complete instructions on installation and use of this system

WARNING: This product contains ferromagnetic materials (e.g. transformers and ferrites) which cannot be used in the presence of high magnetic fields such as that generated by Magnetic Resonance Imaging (MRI) equipment

NOTE: Prior to use of the ThermaCor® 1200 Rapid Thermal Infusion System, the user shall follow appropriate standard operating procedures for anticoagulation prior to administration.

Installing the Disposable Set (Cassette with Tubing Lines) and Priming Instructions

1. Remove the Component Guard if present. Turn on the Infuser 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 Disposable Set's Cassette from packaging using aseptic technique, while retaining sterility of fluid connections.
3. Visually inspect and verify that two (2) pads are in place on the Air Trap. These pads are spaced 3/4" apart.
4. Open the Roller Pump Door and move the Latch Handle all the way to the right to the fully LOCKED (🔒) position and then back to the LOAD (⇩) position.
5. Place the Cassette bottom into the lower metal bar at a 45-degree angle. Push the top of the Cassette toward the Infuser until the top metal bar engages the Cassette.
6. Move the Latch Handle to the fully LOCKED (🔒) position.
7. Insert the Cassette roller pump tubing into the roller pump. **Ensure that the roller pump tubing is fully pushed into the back surface of the roller pump**.

8. Close the Roller Pump Door.
9. Properly drape the top of the Infuser to protect from accidental fluid spills.
10. Unpack the Disposable Set's Tubing Lines using aseptic technique. Connect Inflow, Return, and Outflow Lines. Close pinch clamps on the Inflow Lines. Spike bag(s) and open respective pinch clamps.
11. Press and release PRIME once to run the Auto-Priming cycle. Following Auto-prime, press and release the PRIME button for a 15 second additional prime or hold the PRIME button to continue Manual Priming the Patient Line. Ensure the Patient Line is free of air.
12. Using aseptic technique, make the patient connection without entrapping air. Select the appropriate settings and press START to begin infusing.

NOTES:

- The needleless infusion site on the Patient Line is for low pressure syringe use only while the unit is not pumping. Care should be taken not to infuse air.
- If ERR X: PWR OFF & ON error alarm is generated, check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If the error persists, change the Cassette and power cycle the Infuser. If the error continues, then return the ThermaCor® 1200 Infuser for Service.
- When used for the infusion of blood, the 3 Spike Set filter may show clots or decreased blood flow after an extended period of time. Based on hospital policies and procedures, replace the 3 Spike Set with a new 3 Spike Set at certain intervals.

CAUTION: During Auto-Prime or Manual Prime, the Patient Line from the ThermaCor® 1200 Infuser must be disconnected from the patient. During Auto-Prime and Manual Prime, the Inflow and Outflow air detectors are disabled.

CAUTION: Dispose of medical waste according to hospital policies and local and state regulations. Any used devices shall not be returned to Smisson-Cartledge Biomedical, LLC or Medical Solutions, Inc. unless otherwise directed.

GENERAL DESCRIPTION

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is a portable or pole-mounted device intended for use in the hospital emergency room (ER), operating room (OR), intensive care unit (ICU), and Labor and Delivery (L&D) environments. The system consists of an infusion device and a compatible, single patient use sterile disposable set with supply lines capable of interfacing with intravenous (IV) bags or an optional reservoir. The ThermaCor® 1200 Infuser may be used with a Footswitch (optional accessory) to allow hands-free, user-controlled delivery.

The ThermaCor® 1200 Infuser can deliver flow rates from 10 mL per Hour to 1200 mL per Minute selectable in 10mL/hr in Slow mode and 20mL/min in Rapid mode at normothermic temperatures and is intended for continuous operation. The ThermaCor® 1200 Rapid Thermal Infusion System is driven by a volumetric pump capable of variable-rate continuous infusion up to approximately 100 Liters total volume per Cassette. The system is also capable of delivering discrete bolus infusions. The user can select Bolus Mode to deliver a fixed, predetermined bolus of up to 1 Liter at a default or adjustable rate. When connected to alternating current (AC) power, the ThermaCor® 1200 Infuser can deliver fluids warmed to body temperature under most conditions. The Infuser can also run on battery power (heating capabilities will be disabled) to allow transport of the patient. A lithium-ion battery pack provides the power backup.

CAUTION: Each ThermaCor® Cassette is to be used for a maximum total fluid volume up to 100 Liters or up to a maximum of 24 consecutive hours, whichever occurs first.

Safe use of the Infuser is the responsibility of the medically trained healthcare professional, who should be trained in the operation of medical electrical equipment and should operate the device in accordance with the instructions for use. The Infuser is to be operated with attended use only; the medically trained healthcare professional should never leave the Infuser unattended during infusion. The Infuser is rated CF, though not intended for direct cardiac application other than through a central venous line.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

The ThermaCor® 1200 Infuser can **ONLY** be used with the Smisson-Cartledge Biomedical ThermaCor®1200 Disposable Sets (Cassettes with Tubing Lines) and Accessories. Use of devices other than supplied by Smisson-Cartledge Biomedical, LLC in conjunction with the ThermaCor 1200 Infuser is prohibited. Other such devices may not provide protection and/or adequate use of level sensors, air

detectors, temperature detectors, and pressure sensors. The use of accessories, transducers, and cables other than those specified by the manufacturer may result in increased Emissions or decreased Immunity of the ThermaCor® 1200 Rapid Thermal Infuser.

The ThermaCor® 1200 Disposable Set is a sterile, single patient use assembly of tubing, integrated pump interface components, heat exchanger, filters and reservoirs designed to contain, pump, and heat blood and other IV fluids and deliver them to a patient. The Disposable Set's Cassette can be connected simultaneously to three (3) IV fluid bags to supply the volume required at higher flow rates via a 3 Spike Set or, can be connected to an optional reservoir. The ThermaCor® 1200 Infuser is designed for use with crystalloid, colloid, or blood product, including packed red blood cells [not in additive solutions and stored up to 21 days with anticoagulants], and irrigation fluids. The ThermaCor® 1200 Infuser should not be used for warming of platelets, cryoprecipitates or granulocyte suspension; or for administration of drugs.

Some of the Safety features include:

- An automatic self-test.
- Redundant safety systems (hardware and software).
- Air-in-line sensors.
- Pressure sensors (detects line occlusions, over pressure, and under pressure).
- Thermal sensors (detects over temperatures).
- Low-battery and -Cassette problem detection; a self-test
- Battery backup power with reverse polarity and overcurrent protection.
- Retainer clip to prevent cord from unplugging from the Unit.
- Visual and auditory alarms notify the user when an unsafe condition has been detected and when battery power is nearing depletion.
- The patient is protected against reverse flow while the Disposable Set's Cassette is installed on the Infuser.
- All fluid reservoirs in the Disposable Set's Cassette, except the heat exchanger, are transparent and configured so that they can be easily viewed during use.

INDICATIONS AND CONTRAINDICATIONS

The ThermaCor® 1200 Rapid Thermal Infusion System is indicated for intravenous infusion of liquid products into a patient by regulating the flow under positive pressure generated by the Infuser and, in certain modes, supplying thermal energy to warm the fluid to approximate body temperature.

Indications

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is indicated for use over a full range of flow rates from slow feed to rapid, high flow infusion of: crystalloid, colloid, or blood product, including packed red blood cells [not in additive solutions and stored up to 21 days with anticoagulants], as volume replacement for patients suffering from blood loss due to trauma or surgery; warmed fluid to rewarm patients after surgery or for hypothermia; and warmed fluid for irrigation in urology procedures.

Contraindications

The ThermaCor® 1200 Rapid Thermal Infusion System should not be used in situations requiring a flow rate below 10 mL/hour or above 1200 mL/minute; for warming of platelets, cryoprecipitates or granulocyte suspension; or for administration of drugs. The ThermaCor® 1200 System is contraindicated for use in situations for which rapid infusion is medically contraindicated.

WARNING: Bedside leukocyte reduction filters should never be used when fluid will be forced through the filter.

Please read this Operator Manual before using the system.

Only medically trained healthcare professional users should operate this system.

OPERATING CHARACTERISTICS

WARNING: This equipment is for use by medically trained healthcare professionals only. It is not intended to replace the supervision of infusions. The medically trained healthcare professional should be thoroughly familiar with the features and operation of the ThermaCor® 1200 Rapid Thermal Infusion System and exercise vigilance prior to and during its use.

WARNING: Do not alter or change any part of the ThermaCor® 1200 Rapid Thermal Infusion System. Any changes or alterations to the system may endanger the patient or damage the system.

MODES OF OPERATION

The ThermaCor® 1200 Rapid Thermal Infuser has three powered modes and three operational modes.

Powered Modes

The ThermaCor® 1200 Rapid Thermal Infuser has three (3) powered modes, as follows:

1. **Power Off** – power is connected (AC or battery), but the user has not pressed Power On button for operation. If AC power is connected, the battery will be charging if the battery was low. Pressing Power Off resets all values (volume infused, etc.) and resets the Infuser to default infusion rates for all modes. Electronic memory is not intended to be retained; the memory is reset upon power cycle.

NOTE: The ThermaCor® 1200 Infuser should be Powered Off and then Powered On (called power cycling) between patient uses to reset the ThermaCor® 1200 Infuser prior to beginning the next procedure

2. **AC Power On** – AC power is connected and the user presses Power On for operation.
3. **Battery Power On** – AC power is disconnected, battery is charged, and the unit is running on battery power.

Auto-Prime Cycle

Auto-Prime is initiated after loading of a new Disposable Set/Cassette and is used to automatically purge air from the Cassette via the inflow fluid with a single push of the PRIME button. The Auto-Prime process runs at 1,000 ml/min to fill and to purge air from the Cassette and to fill a portion of the Patient Line. This process runs automatically after a single push of the PRIME button.

The PRIME button may then be pressed and released for an additional 500mL/minute prime for 15sec prior to the first time the START button is pressed. The PRIME button may also be pressed and held at any point when the Infuser is stopped to manually advance fluid. Fluid advances at 500 ml/min and ends when the button is released.

CAUTION: During Auto-Prime or Manual Prime the Patient Line from the ThermaCor® 1200 Infuser must be disconnected from the patient. During Auto-Prime and Manual Prime the Inflow and Outflow air detectors are disabled.

Operational Modes

The ThermaCor® 1200 Rapid Thermal Infuser has three (3) operational modes, as follows:

1. **Slow Infusion (mL/HOUR)** – infuses at a rate of from 10 mL/hour to 1,200 mL/hour, with a Factory Default Rate of 120 mL/hour. The last adjusted set rate becomes the Adjusted Default Rate the next time the Slow Infusion mode is selected (e.g. if the last infusion rate used was 250 mL/hour, this will be the new Adjusted Default Rate the next time Slow is selected). As always, the flow rate can be user selected up or down at any time, in increments of 10mL/hour.
2. **Rapid Infusion (mL/MINUTE)** – infuses at a rate from 20 mL/minute to 1,200 mL/minute, with an initial Factory Default Rate of 500 mL/minute. The last selected Rapid Infusion rate becomes the new Default Rate the next time the Rapid Infusion mode is selected. (e.g. if the last infusion rate used was 1,000 mL/Minute, this will be the new Adjusted Default Rate the next time Rapid is selected). As always, the flow rate can be user selected up or down at any time, in increments of 10mL/min.
3. **Bolus Infusion (mL/MINUTE)** – infuses pre-set boluses of 100, 250, 500 or 1,000 mL of fluid at the Factory Default Flow Rate of 500 mL/minute. The flow rate can be user selected from 20 mL/minute to 1200 mL/minute. The last selected Bolus Infusion rate becomes the new Adjusted Default Bolus Rate the next time the Bolus Infusion mode is selected. (e.g. if the last infusion rate used was 1,000 mL/minute, this will be the new Adjusted Default Rate the next time Bolus is selected). Bolus mode always suspends the active process, which is resumed after delivery of the bolus, except for Recirculation ("Recirc") Mode. Bolus stops if Slow/ Rapid, or Recirc modes are started. When Bolus delivery is complete, the unit returns to the previously set rate and infusion resumes, except if Recirculation Mode was prior to Bolus Mode – in that case the Infuser will stop after Bolus is completed. If an alarm is generated during Bolus mode and infusion is stopped, and the alarm is cleared, then Bolus mode can be resumed by pressing START. At conclusion of the Bolus, the ThermaCor® Infuser will stop infusion since the Bolus was interrupted by an error. To continue infusion, the user has several choices: the user may select a new flow rate or continue with the previously selected flow rate, the user may select a new Bolus, or the user may Recirculate fluid. After choosing a mode, the user must press START to resume operation. If Bolus mode is stopped by the user, the last Adjusted Rate is

displayed, and the user may resume flow to the patient by pressing START or adjusting the rate and press START. To protect the patient, if the device detects an over-infusion or exceeded Bolus delivery, the Infuser is halted, an OVERINFUSD: PWR OFF/ON error alarm occurs and a power cycle is required to continue. No alarms are disabled during Bolus mode.

NOTE:	During regular infusion (e.g. Slow Mode), and a Bolus button is pressed but the START button has not been pressed to confirm, pressing the current mode button (e.g. Slow) will clear the pending Bolus.

4. **Recirculation** – recirculates inflow fluid through the Cassette and back to the inflow fluid source at a flow rate of 300mL/minute for 5 minutes. Recirculation ("Recirc") allows for mixing and pre-heating fluids contained in the reservoir. The Set and Actual LEDs will display "- -", and RECIRC:INFLO TEMP=XXC will display on the Informational Message line. "XX" represents the two (2) digit number for the inflow fluid temperature, as measured during Recirculation. The patient temperature will continue to display, though fluid is not flowing through the Patient Line. When Recirc is active, flow to the patient ceases. Recirculation will end automatically after the 5 minutes unless STOP is pressed sooner, or a different flow mode is activated (e.g. Rapid or Slow) during Recirc. Upon completion of Recirc, the ThermaCor® Infuser stops. The last selected flow rate prior to Recirc mode activation will be flashing on the set LED display and the mode LED will be flashing (e.g. 300mL/hour and the Slow Key will be flashing). Flow to the patient can be resumed by selecting a flow rate and pressing the START button. If Recirc is interrupted by an error, and the alarm is cleared, then the user must press START to resume Recirc (clock resets to 5 minutes). The user may instead choose to resume with a different mode instead of Recirc, by pressing the corresponding mode button, and then pressing START. If Bolus mode precedes Recirc mode, or if Bolus mode is activated during Recirc mode, then the ThermaCor® Infuser will stop following at the completion of those modes. The ThermaCor® Infuser will display the last selected rate prior to the Bolus and Recirc modes. The user will then confirm the flow rate, or select a new flow rate, and press START to resume flow to the patient. Recirc can be activated at any time by pressing the RECIRC button and START.

Flow Rate Toggle

In Slow and Rapid modes, the user may toggle the flow rate as needed between the user selected flow rate and the default flow rate; the default flow rate is 120mL/HOUR in Slow mode and 500mL/MINUTE in Rapid mode. For example, while the Infuser is infusing at 40mL/min (in Rapid mode), the user can press and hold the START button for 1 second, the ThermaCor® Infuser will display 500mL/min, begin infusing at 500mL/min, and the START button will flash. The user may press the START button for 1 second again to toggle back to the user selected flow rate (40mL/min). The ThermaCor® Infuser will begin infusing at that rate and the START button will be continuously lit.

The user may toggle between any user selected flow rate and the default flow rate at any time during Rapid and Slow modes as needed.

Pressure Control

The ThermaCor® Infuser will automatically control the flow rate according to the user selected pressure setting to prevent an overpressure. This Pressure Control feature occurs only during Rapid and Bolus Mode.

While infusing, if the ThermaCor® Infuser detects the pressure rising such that the pressure limit is reached, a "PRESSURE CONTROLLED" informational message will display in the Main Display. The ThermaCor® Infuser will automatically decrease the flow rate such that the maximum pressure is reached according to the user selected pressure setting. For example, the user selected pressure setting is 300mmHg, the Selected Flow Rate is 1,200mL/min, and the catheter size utilized is 22gauge. The Infuser will automatically control the flow rate to maintain the user selected 300mmHg, which may cause the Actual Flow Rate to be less than the Selected Flow Rate.

In Pressure Controlled situations, if the Actual Flow Rate decreases below 20mL/minute in Rapid or Bolus Mode, "---" will display for the Actual Flow Rate and "PT LINE RESTRICTED" will display in the Main Display. Also, in Pressure Controlled situations, if the Actual Flow Rate decreases below 10mL/minute in Rapid or Bolus Mode, "PATIENT LINE BLOCKED" is displayed and operation is halted. If there is a flow restriction and steps are taken to remove it (e.g. change catheter size), such that the ThermaCor® Infuser is no longer in Pressure Controlled mode, the Infuser will automatically change from the Pressure Controlled flow rate to the Selected Flow Rate.

SAFETY SYSTEMS

The ThermaCor 1200® Rapid Thermal Infusion System is designed to provide redundant safety systems to monitor pressure, motor, air, power, interlocks, heat/temperature and timing. The ThermaCor® Infuser

will automatically stop when the following faults are detected; outflow over temperature, outflow pressure or temperature over safe limits, outflow air, inflow over temperature, Bolus over infusion, cassette interlocks that are not appropriately engaged, low power levels, and motor dysfunction. See Alarm Reference Guide.

WARNING: The unit complies with IEC 60601-2-24; other environments are not recommended. Unstable and unpredictable performance may occur if operated in any other RFI environment. Please refer to Product Specifications.

WARNING: This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Infuser or other equipment.

Self-Test

An automatic Self-Test (which takes a few seconds) to ensure proper operation is run each time the ThermaCor® 1200 Infuser powers on. When the Self-Test is running, all display lights are turned on, and the Main Display transitions from a fully lit screen to a display of numeric codes. If the Self-Test is successful, "POST OK" will be displayed in the Main Display for a few seconds, followed by a message reading, "NO CASSETTE" (if a Cassette is not installed). If the Self-Test is not successful, the particular test that failed will be displayed. For example, if memory fails during Self-Test, "ERR 7: PWR OFF & ON" will display. If the Self-Test cannot be resolved by powering off and on, then the medically trained healthcare professional [referred to as "operator" for the remainder of this document] will need to call Customer Service.

The Self-Test performs the following:

- Memory (CRC check is performed on both SRAM and Flash)
- Two Wire Interface (Serial communication to the ADC and Battery)
- Pressure Sensors (Sensors verify that the output is within operating range & resistors are switched to the circuit to verify min and max range)
- LED Check (All LEDs are turned on to allow the user to verify function)
- Main Display (All pixels are turned on to allow user to verify function)
- Audio (Audio enunciator is activated to allow user to verify function)
- Watchdog timer (Watchdog timer function is verified by allowing it to time out)

- Clock Synchronization (Verifies timing between the main CPU and the Infuser clock)

Pressure Sensors

WARNING:	The ThermaCor® 1200 Infuser is designed to stop fluid flow under certain alarm conditions. The ThermaCor® 1200 Infuser is capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge needles and catheters. Periodic patient monitoring must be performed to ensure infusion is proceeding as expected. Flush port(s) per facility protocol at regular intervals while infusing at low flow rates to ensure unobstructed flow.

If the system pressure exceeds the user selected pressure of either 100mmHg or 300mmHg, the ThermaCor® 1200 Infuser automatically reduces the flow rate to remain within the selected pressure limit. Flow rate may be increased by increasing the diameter of the patient access port or by using the Dual Outflow Line. However, if significant abnormalities in pressure are detected, error alarms are generated (see Table 1). Maximum time for an occlusion alarm is one (1) second at any rate or pressure selection and is hardware controlled.

NOTE:	Where an over pressure results in a high pressure alarm (e.g. "PATIENT LINE BLOCKED"), check the pinch clamps and check for occlusions on the Patient Line or Return Line. Press START to resume operation. No excess volume is generated by an over pressure state.

CAUTION:	Whenever uncoupling or removing the Cassette, clamp/close the Inflow Lines, Patient Line and Return Line to prevent uncontrolled free flow.

Pressure Sensor	Pressure Detected	Displayed Message	Alarm Tone	Action
Patient Line Out	Pressure 135% greater than user selected pressure of 100 or 300 mmHg	PATIENT LINE BLOCKED	Three (3) audible tones repeating	Check Patient Line or Return Line for occlusion or restrictions. Open and close Roller 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, (1) power cycle the Infuser, (2) if needed, power cycle and replace the Cassette. If error persists, Call Customer Service.
Patient Line Out	< -100 mmHg during infusion	FLUID SUPPLY BLOCKED	Three (3) audible tones repeating	Check that all clamps are open. If error persists, (1) power cycle the Infuser, (2) if needed, power cycle and replace the Cassette. If error persists, Call Customer Service.
Infuser Outlet	< -100 mmHg, during infusion	FLUID SUPPLY BLOCKED	Three (3) audible tones repeating	Check that all clamps are open. If error persists, (1) power cycle the Infuser, (2) if needed, power cycle and replace the Cassette. If error persists, Call Customer Service.
Infuser Outlet	> 500 mmHg during infusion	PATIENT LINE BLOCKED	Three (3) audible tones repeating	Check for occlusions, open and close Roller Pump Door to relieve pressure and press START. If error persists, (1) power cycle the Infuser, (2) if needed, power cycle and replace the Cassette. If error persists, Call Customer Service.
Infuser Inlet	< -100 mmHg, during infusion	FLUID SUPPLY BLOCKED	Three (3) audible tones repeating	Check Inflow Line for occlusion or restrictions. If error persists, (1) power cycle the Infuser, (2) if needed, power cycle and replace the Cassette. If error persists, Call Customer Service.

Pressure Sensor	Pressure Detected	Displayed Message	Alarm Tone	Action
Infuser Inlet	> 500 mmHg during infusion	HIGH INLET PRESSURE	Two (2) audible tones repeating	Check for occlusions on the Inflow Line. If the problem persists, power cycle the Infuser and replace Cassette. If error persists, call Customer Service.

Table 1. Warnings and Alarms from Pressure Sensor Measurements.

Motor Control

The speed of the motor is controlled to allow a flow rate from 10 mL/hour to 1,200 mL/minute. If the ThermaCor® Infuser stalls for more than 1.5 seconds, an alarm is generated, ERR 11: PWR OFF & ON.

Air Detection / Purging

During operation of the ThermaCor® 1200 Infuser, air detectors monitor working conditions in the Patient Line(s) and Inflow Lines (supply lines). Detection of 50 microliters or more of air in the patient air sensor halts operation and causes an alarm, "AIR IN PATIENT LINE". Detection of continuous air greater than or equal to 25 ml at the input air sensor halts operation and causes an alarm, "ADD FLUID, PRIME, START". When air is detected in the lower portion of the air trap level detector, the Patient Line is momentarily occluded while the Return Line is opened to allow purging of air at 500 ml/min through the Return Line back to the fluid supply. At the completion of purge, the Patient Line is opened, and the Return Line is closed. The ThermaCor® Infuser then automatically resumes fluid flow into the Patient Line. This process is automatically controlled (no user interaction required).

Power

The ThermaCor® 1200 Infuser operates on AC Power. The ThermaCor® Infuser also has internal Battery Backup Power and operates just as it does on AC power, except heating and charging capabilities are disabled. Battery should be charged for 24 hours prior to initial use and recharged bi-monthly if not plugged into AC power and used during this period.

WARNING: Unplugging or disconnecting mains AC Power will not stop the unit due to the internal charged battery. The unit will continue to operate without heat given the supply of the charged battery and device use. The Infuser will sound an alert, ON BATTERY: NO AC PWR will display, and HEAT OFF will flash on the display.

WARNING: Do not attempt to calibrate, repair or replace the battery in the ThermaCor® 1200 Infuser. Call Customer Service for a Return Authorization Number and Authorized Repair Location to send the unit for service and/or calibration. Attempted repair/modification of the device will void the warranty.

WARNING: To avoid the risk of electric shock when connected to the supply mains, the ThermaCor® 1200 Infuser must only be connected to a supply mains with protective earth.

NOTE: The ThermaCor® 1200 Infuser requires a dedicated power circuit. The user shall use the supplied power cord for connection. Make sure there is access to the back of the Infuser to connect the power cord to an available dedicated power circuit.

NOTE: If the alert message "REDUCED AC POWER" is displayed and remains on, this indicates that the power level from the wall power outlet source may not be sufficient and may affect the ThermaCor® Infuser performance.

Messages are provided to indicate when a reduced, or insufficient, wall AC power level has been detected. The battery recharges whenever it is connected to AC power. The typical operating time of the internal battery power source is approximately 2 hours while operating in Slow mode at 250mL/hr, or approximately 30 minutes while operating in Rapid mode at 1,000mL/min. After the Critical Battery Alarm sounds, the Infuser ceases delivery and requires a power cycle. The battery/charging system status is monitored to determine the operational power left in the battery (see Table 2).

Condition Detected	Displayed Message	Alarm Tone	Action
<30 minutes of power remaining in battery at current settings	LOW BATTERY	Two (2) audible tones repeating	Prepare to connect Infuser to AC power source within 25 minutes.
<5 minutes of power remaining in battery at current settings	DEPLETED BATTERY	Two (2) audible tones repeating	Connect Infuser to AC power source. If warning persists, Call Customer Service.
Infusion is Stopped.	CRITICAL BATTERY	Three (3) audible tones repeating	Connect Infuser to AC power source and power cycle the Infuser. If error

At least 3 minutes to power shutdown due to lack of battery power.			persists, Call Customer Service.
Condition Detected	**Displayed Message**	**Alarm Tone**	**Action**
No battery detected	SERVICE BATTERY	Two (2) audible tones repeating	Call Customer Service before operating Infuser.
Battery Charger needs service	SERVICE CHARGER	Two (2) audible tones repeating	Call Customer Service before operating Infuser.

Table 2. Power System Monitoring and Actions.

Once a power warning or error condition is detected, the condition will not be corrected until the Infuser is connected to an AC power source, the battery is charging, and its power level is above the alarm/warning condition.

Interlocks

Interlocks ensure that the Cassette is loaded and locked and positioned appropriately. The ThermaCor® 1200 Infuser will not enable the priming, pumping, or heating unless the interlocks are appropriately engaged. If the Roller Pump Door or the Cassette Latch is opened (in an attempt to remove the Cassette) while the Infuser is running, an alarm is activated.

Heating and Thermal Sensors

The heat exchanger is capable of raising the temperature of compatible fluid media by at least 17°C when fluid is flowing at rates up to 1,000mL/minute as measured at the inlet and outlet of the heat exchanger. Nominal fluid inlet temperature is assumed to be 20°C, and nominal fluid outlet temperature is assumed to be 37±2°C (under similar conditions, rates over 1,000mL/min may result in a temperature rise less than 17°C).

CAUTION: Heating is available only when the Infuser is connected to AC power.

WARNING: Do not add or supply fluids that have been pre-warmed above room temperature. Do not infuse blood or blood products that has been overheated. If an over-temperature failure occurs, follow the procedure below.

A temperature greater than 44.5°C causes an over-temperature failure condition which shuts down the heater, automatically stops the ThermaCor® Infuser from infusing, and displays a “HI TEMP ”X”, PWR

OFF/ON" error message where "X" is 1, 2, 3, 4, 5 or 6 and is defined in Table 3 below. To correct this failure, clamp off Inflow Line(s) and Patient Line(s) then remove the Cassette. Press the Power button to turn the Infuser off, wait 10 seconds and press Power button to turn the Infuser back on and then load a new Cassette. If problem persists, call Customer Service. Temperature cutoffs generating a "HI TEMP "X", PWR OFF/ON" error message are shown in Table 3.

Temperature Sensor	**Cutoff Temperatures**	**Error Message**
Patient Line Out	>44.5°C – Results in system shutdown	HI TEMP 3, PWR OFF/ON
Patient Line Out	>45°C – Results in system shutdown	HI TEMP 4, PWR OFF/ON
Heat Exchanger	>45°C – Results in system shutdown	HI TEMP 1, PWR OFF/ON
Fluid Line In	>45°C – Results in system shutdown	HI TEMP 2, PWR OFF/ON
Heater Platen (non-fluid contacting)	>88°C – Results in system shutdown	HI TEMP 5, PWR OFF/ON
Heater Platen (non-fluid contacting)	>90°C – Results in system shutdown	HI TEMP 6, PWR OFF/ON

Table 3. Temperature Cutoffs at Various Sensors.

FEATURES AND INSTRUCTIONS FOR USE

Console

The console features a Main Display, Buttons and Indicators.

Main Display

Figure 1. Main Display

A Main Display on the front of the ThermaCor® 1200 Infuser shows program status, operator instructions and alarms (see Figure 1). On the upper half of the Main Display (above the solid line), the following are displayed (in whole numbers):

Line 1 – displays the mode (Slow, Rapid, or Bolus) and heater status (e.g. When heat is enabled, HEAT ON is displayed; when heat is disabled, HEAT OFF is displayed).

Line 2 – displays the fluid temperature.

Line 3 – displays the fluid pressure.

Line 4 – displays multiple-mode feedback, indicating that one mode is being set while another is currently running. This line also indicates when the unit is in Recirc mode and displays the inflow temperature. This line also displays user messages that are not alarms.

Line 5 – displays the total fluid infused; this value will be reset only when the Infuser is power cycled.

Line 6 - displays alarm messages, indicating that an alarm has occurred. If more than two alarms or warnings are in effect, messages rotate.

Line 7 - displays alarm messages, indicating that an alarm has occurred. The last generated alarm will display on this line.

Text Box Area (Bolus Mode only) – displays the volume remaining to be infused (VOL) and the time remaining on the current Bolus infusion.

A “Chaser” icon runs across the solid dividing line to indicate the speed of infusion. A fast “Chaser” icon indicates the Infuser is pumping in milliliters/minute. A slow “Chaser” icon indicates the Infuser is pumping in milliliters/hour.

Keypad

The keypad on the front of the ThermaCor® 1200 Infuser (see Figure 2) consists of LEDs, buttons and indicators. Two LEDs indicate the infusion rates (see Figure 2). The SELECTED FLOW RATE LED is displayed in amber, and the ACTUAL FLOW RATE LED is displayed in green.

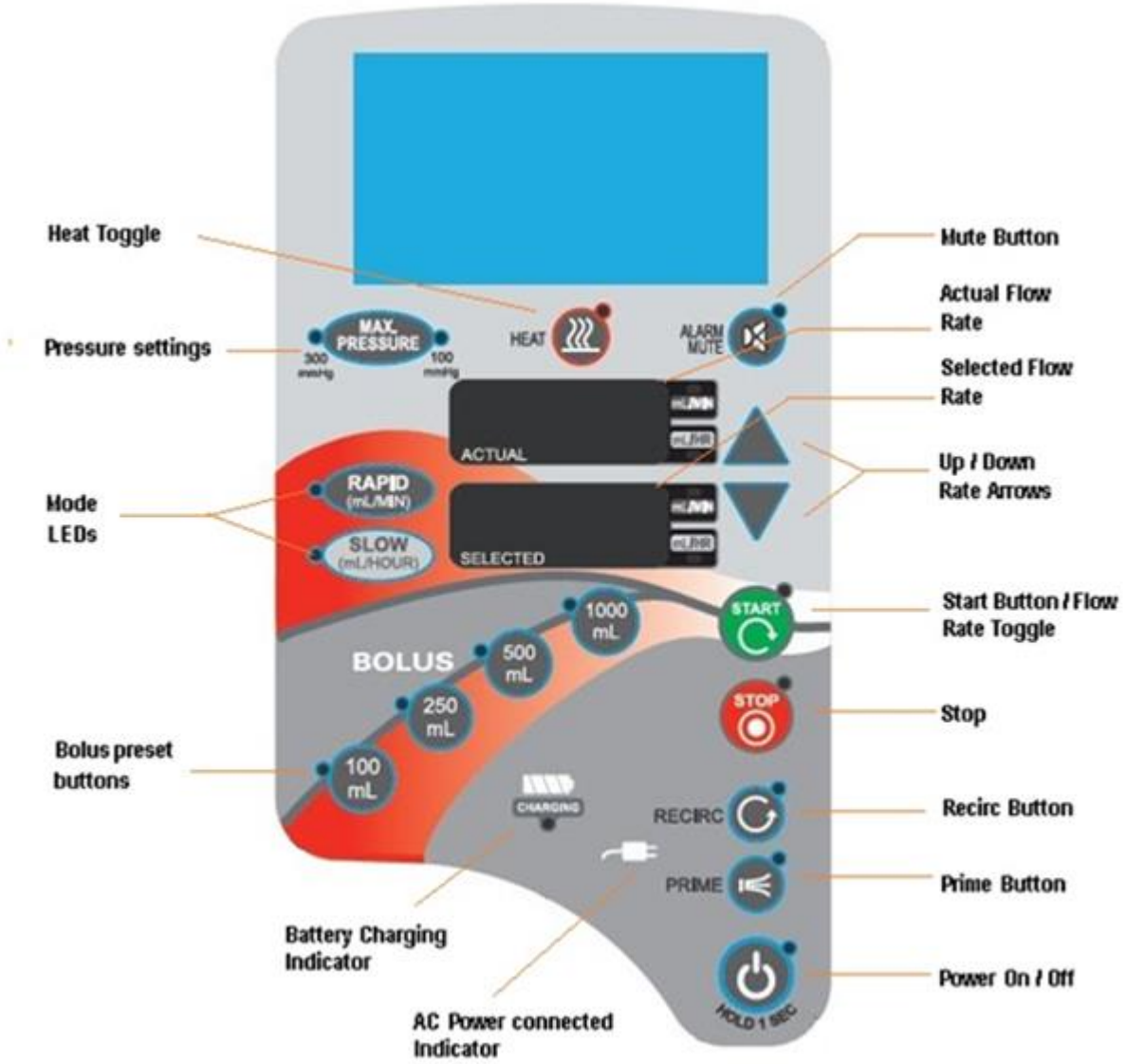


Figure 2. Keypad.

Buttons

Buttons allow selection of maximum pressure, mode, flow rate (adjusted by the arrow buttons), heat on/off, and bolus volume. An Alarm Mute button allows silencing of audible alarms up to 120 seconds. Some buttons (Power On, HEAT, SLOW, RAPID, BOLUS, START, STOP, RECIRC, MAX PRESSURE, ALARM MUTE, and PRIME) have an LED that is illuminated to indicate status. Some of these buttons blink to indicate that a change is being programmed (i.e. START, BOLUS, RAPID, SLOW, RECIRC). For instance, if a new mode is set while another mode is running, the light on the pending mode button will blink until START or the button for the currently running mode is pressed. The Battery Charging Indicator is lit when AC power is connected, and the battery is charging. It does not change when the Power button is pressed ON or OFF (when the Infuser is connected to AC Power).

NOTES:

- A good button press is followed by a 2 ms tone indicating recognition and acceptance of button press.
- A bad button press is followed by a 5 ms tone to indicate recognition of a button press not applicable in current operating mode.

NOTE: When necessary to make an emergency stop, press the STOP button, then press the POWER button to turn the Infuser off.

Indicators

LED indicators show the status of the ThermaCor® 1200 Infuser and what conditions are selected / operating (see Figure 2) (e.g. Battery Charging, AC Power connected, and which Buttons are active).

BASIC OPERATION / INSTRUCTIONS FOR USE

CAUTION: To operate this device requires extensive knowledge of the ThermaCor® 1200 Rapid Thermal Infuser and its operation. It is necessary to read this entire manual before operating the device.

WARNINGS:

- This product contains ferromagnetic materials (e.g. transformers and ferrites) which cannot be used in the presence of high magnetic fields such as that generated by MRI equipment.
- Do not use the ThermaCor® 1200 System around flammable anesthetics.
- Do not use the ThermaCor® 1200 System with pressure infusers or bag squeezers.
- Do not use the ThermaCor® 1200 System to warm platelets, cryoprecipitates or granulocyte suspensions.
- Do not use the ThermaCor® 1200 System to administer drugs.

NOTE: When used for the infusion of blood, the filter in the 3 Spike Set may show clots or decreased blood flow after an extended period of time. Based on hospital policies and procedures, exchange the 3 Spike Set with a new set at intervals defined in the procedures.

1. Attach the ThermaCor® 1200 Infuser to an appropriately sized heavy duty IV pole with a Base with at least five (5) wheels and no less than 24" diameter and attach the Infuser no higher than thirty-two (32) inches from the bottom of the Infuser to the floor or as recommended by the IV Pole specifications. Turn the pole clamp knob clockwise such that the Infuser is completely secured to the IV pole.

CAUTION: Securely hold the ThermaCor® 1200 Infuser when turning the pole clamp knob counterclockwise to loosen and reposition or to remove the Infuser from the IV pole.

2. Plug the power cord into a dedicated power source, and the AC power indicator will become illuminated.
3. Remove the Component Guard if present. Turn on the Infuser by pressing the Power ON button. The Self-Test will then automatically begin and should take a few seconds. Following a successful Self-Test, a message will appear stating "POST OK" followed by "NO CASSETTE".

CAUTION: Do not obstruct air flow from the fan at the bottom or from the exhaust at the top rear of the device.

4. Unpack the Disposable Set's Cassette from packaging using aseptic technique, while retaining sterility of fluid connections.

5. Visually inspect and verify that two (2) pads are in place on the Air Trap. These pads are spaced 3/4" apart.
6. Open the Roller Pump Door and move the Latch Handle all the way to the right to the fully LOCKED (🔒) position and then back to the LOAD (⇩) position.

CAUTION: Use caution when loading the Cassette on the Infuser as not to pinch fingers between the Cassette and Housing or between the Cassette and the Bail Bar.

7. Place the Cassette bottom into the lower metal bar at a 45-degree angle. Push the top of the Cassette toward the Infuser until the top metal bar engages the Cassette.
8. Move the Latch Handle to the fully LOCKED (🔒) position.
9. Insert the Cassette roller pump tubing into the roller pump. **Ensure that the roller pump tubing is fully pushed into the back surface of the roller pump**.

WARNINGS:

- The Disposable Set (Cassette with Tubing Lines) is for single patient use only and is not for reuse.
- Only Smisson-Cartledge Biomedical ThermaCor® 1200 Disposable Sets (Cassette with Tubing Lines), Reservoirs, and Accessories should be used with the ThermaCor® 1200 System for patient safety. The Disposable Set (Cassette with Tubing Lines), Reservoir, and Accessories should not be modified in any way. Other such devices may not provide protection/adequate use of level sensors, air detectors, temperature detector, and pressure sensors.

10. Close the Roller Pump Door. The roller pump will automatically turn 2 times to center the tubing on the rollers, and the display will read "- -" for the Actual Flow rate, and no flow to the patient occurs.
11. Properly drape the top of the Infuser to protect from accidental fluid spills. An optional drape accessory is available.
12. Using aseptic technique, connect the Disposable Set's 3 Spike Set or Reservoir to the Cassette inflow line connector and Return Line. Connect the Patient Line to the Cassette outflow connector.
13. Disconnect the Patient Line Luer end cap and maintain sterility.

NOTE: The needleless infusion site on the Patient Line is for low pressure syringe use only while the unit is not pumping. Care should be taken not to infuse air emboli.

14. Hang the IV fluid bag(s) above the top of the Infuser.

CAUTIONS:

- When using an IV pole, ensure that the ThermaCor® 1200 Infuser is securely attached to an appropriately sized heavy-duty IV pole with at least five (5) wheels and diameter of twenty-four (24) inches to avoid a tipping hazard.
- When mounting the ThermaCor® 1200 Infuser onto an IV Pole, do not mount higher than thirty-two (32) inches from the floor to the base of the Infuser or as recommended by the IV Pole specifications.
- Hold and support the ThermaCor® 1200 Infuser while unclamping it from the IV pole.
- The IV Pole Clamp Knob should only be used for tightening or loosening the ThermaCor® 1200 Infuser on the Pole.
- User must follow recommended guidelines for the infusate being used to determine when a Disposable Set/Cassette should be replaced. Each Disposable Set/Cassette is limited to a maximum volume of 100 Liters or use up to a maximum of 24 consecutive hours, whichever occurs first.

WARNINGS:

- Only anticoagulated blood products should be used in the ThermaCor® 1200 System.
- Solutions containing calcium should not be mixed with citrated blood products.
- Do not add or supply fluids that have been pre-warmed above room temperature.
- Do not infuse blood or blood products that has been overheated.
- 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.
- Use only high-quality infusate to prevent particulates from clogging the Inflow Line filter. If flow through the Disposable Set's Cassette becomes clogged, replace the Cassette.
- Warming plasma with this device may result in loss of von Willebrand factor activity (vWF:RCo) up to 29% in the infused plasma.

15. Pinch the clamps on all three IV tubes to close them off.
16. Spike the IV fluid bag(s).
17. Open respective pinch clamp(s).

CAUTION: Medically trained healthcare professional [Operator] must ensure that all air is purged from the lines prior to patient use (see following step 16). During Auto-Prime or Manual Prime, the Patient Line must be disconnected from the patient. During Auto-Prime and Manual Prime, the Inflow and Outflow air detectors are disabled.

18. Press and release PRIME to begin Auto-Prime, which fills the system with fluid and purges air out. Auto-Prime should complete within ~60 seconds. After Auto-Prime has completed, press and release the PRIME button to provide an additional 15 seconds of priming or press and hold PRIME to perform additional Manual Priming to continue priming until all the air is purged from the Patient Line.

NOTE: If the Cassette Latch is opened, then after it is closed back to the LOCKED (🔒) position, the system will determine if Auto-Prime or Manual Prime is required.

19. Using aseptic technique, make the patient connection without entrapping air.
20. Select the appropriate pressure.

CAUTION: The ThermaCor® 1200 System can infuse 1,200 mL of fluid/minute. At this rate of infusion, depleting a 500 ml unit of blood will take less than 30 seconds.

CAUTION: Use a pressure of 100 mmHg for patients that may require lower outflow pressures, and 300 mmHg for patients that can allow higher outflow pressures.

NOTE: With Slow Mode selected, the user can select the 100 mmHg maximum pressure setting to cause the ThermaCor® 1200 Infuser to react more rapidly to an obstructed or blocked Patient Line. If the user then chooses to select Rapid Mode, it is recommended to return to the default maximum pressure setting of 300 mmHg unless the user determines otherwise.

21. Select the appropriate Slow or Rapid infusion mode. This will cause default values to be displayed in the RATE LED. If programming the Bolus mode, press the appropriate BOLUS preset button to set the volume to be infused. If selecting Recirc mode, press the RECIRC button and START.
22. Adjust the flow rate, if desired, by pressing the up or down arrow buttons (except for Recirc mode).
23. Press START to initiate operation at the programmed settings.

NOTES:

- If ERR X: PWR OFF/ON error alarm is generated, check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If the error persists, change the Cassette and then power cycle the Infuser. If the error continues, then return the Infuser for Service.
- In Slow, Rapid, and Bolus modes, the last adjusted rate becomes the default rate the next time the Infuser is set in each respective mode, unless the Infuser has been turned off and on.
- The Bolus rate of infusion can be changed while it is completing a cycle, and the last adjust rate will display at the start of a new Bolus delivery.
- Bolus mode is stopped if Rapid, Slow, or Recirc mode is started
- Bolus mode suspends Rapid and Slow mode (e.g., Rapid mode is paused when Bolus mode is activated) and the respective mode automatically resumes following Bolus.

- Bolus mode ends Recirc mode, and Recirc mode will not resume when Bolus mode ends.
- Bolus mode can be paused before completion by pressing the STOP button and resumed by pressing START.
- A paused Bolus may be stopped, and a new Bolus can be selected by pressing a BOLUS button and then pressing START.
- If an alarm is generated during Bolus mode and infusion is stopped, and the alarm is cleared, then Bolus mode can be resumed by pressing START. At conclusion of the Bolus, the Infuser will stop infusion since the Bolus was interrupted. To continue infusion, the user has several choices: the user may select a new flow rate or continue with the previously selected flow rate, or the user may select a new Bolus. The user must then press START to resume operation.
- Turning the Infuser off resets all status values (volume infused, user selected flow rate, etc.) and resets the Infuser to default flow rates.

NOTES:

- Flow rate increases or decreases in 10 mL increments with each key press. Pressing and holding a rate arrow button for 1 second allows more rapid scrolling until you release the arrow button.
- Operator should periodically observe the displayed temperature to ensure it is in an acceptable range.

WARNING: Ensure that tubing remains free of kinks, twists and obstructions that can restrict flow.

24. When finished infusing, press STOP, close all pinch clamps and disconnect the tube from the patient.

NOTE: One action is required for possible free flow: opening the Latch, which will generate an alarm.

CAUTION: Whenever uncoupling or removing the Cassette, clamp the Inflow Line, Return Line and the Patient Line(s) closed to prevent uncontrolled free flow.

25. Turn the power off by pressing the Power On/Standby button.

26. Open the Roller Pump Door and move the Latch to the UNLOCK (🔓) position and lift the Cassette away from the ThermaCor® 1200 Infuser.
27. Discard the Disposable Set's Cassette and associated accessories / tubing, following standard hospital procedures for disposal of biologically hazardous material.
28. Clean the Infuser per the CLEANING AND MAINTENANCE section and Appendix A.
29. Place the Component Guard on the Infuser while the Infuser is not in use.

CAUTION: Dispose of medical waste according to hospital policies and local and state regulations. Any used devices shall not be returned to Smisson-Cartledge Biomedical, LLC or Medical Solutions, Inc. unless otherwise directed.

Recharging the Battery

The battery will automatically recharge when the Infuser is connected to AC power, if battery levels have been depleted. A completely depleted battery can be recharged in 6 hours. Completely or partially exhausted batteries do not interfere with or prevent operation by AC power.

NOTE: The battery will automatically recharge if the Infuser is connected to AC power and the battery level is not full. Battery should be charged for 24 hours prior to initial use and recharged bi-monthly if not plugged into AC power and used during this period.

Disabling the Heater

Press the HEAT button to turn the heater ON and OFF. This can be done at any time, except when operating on Battery power.

WARNING: The heater is always disabled when the Infuser is operating in the battery mode.

Attaching Optional Disposable Fluid Reservoir

Please see the specific instructions for use for the Reservoir being used. Use of the optional Disposable Fluid Reservoir replaces the Disposable Set's 3 Spike Set. In general, to attach a Reservoir, follow these steps:

1. If attached, disconnect the 3 Spike Set from the Cassette. Secure the Reservoir holder to the IV pole approximately 13 inches above the ThermaCor® 1200 Rapid Thermal Infuser.
2. Using aseptic technique, unpack the Disposable Fluid Reservoir and attach the Reservoir to the Holder.

   Note: One vent port on the Large Rigid Reservoir (MR-1200) will be uncapped to allow low pressure relief and prevent "ADD FLUID, PRESS PRIME" Error Message to display on the Infuser before the Reservoir is empty.

   Note: The Large Rigid Fluid Reservoir (MR-1200) should not be overfilled when the vent cap is open or removed.
3. Adjust the Reservoir Holder to easily attach the Reservoir Outflow Tubing Quick Connect to the Inflow Line of the Cassette without kinking.
4. At the top of the Cassette, connect the yellow connector to the Return Line of the Reservoir. Note: The OFF position of the 3-way stopcock should be pointed towards the bottom of the "T" allowing flow from Cassette to the Return Line.
5. Close the ratchet clamp on the Reservoir Outflow Line and fill the Reservoir with at least 300mL-500mL of appropriate fluids and making certain not to overfill it. Follow appropriate standard operating procedures for anticoagulation prior to administration.
6. Open all pinch clamps (i.e. Reservoir Outflow, Return Line and appropriate Inflow clamps, and Patient Line clamps), except for unused spiked Inflow Lines where no bags are spiked.
7. Press and release the PRIME button to run the Auto-Priming cycle. Following Auto-Prime, press and release PRIME button to continue Manual Priming. Inspect that the Patient Line is free of air bubbles.
8. Using aseptic technique, make the patient connection without entrapping air. Select the appropriate settings and press START to begin infusing. (see the Abbreviated Quick Start Instructions or Basic Operation Steps)

CAUTION:	Do not apply a vacuum to the Reservoir or pressurize it.

NOTE:	When used for the infusion of blood, the filter in the Reservoir may show clots or decreased blood flow after an extended period of time. In addition, the Unit may stop and display the Error Message "FLUID SUPPLY BLOCKED" due to the restriction caused by the clogged filter. Replace the Reservoir with a new set at intervals defined in the hospital procedures and policies.

Manually operating the ThermaCor® 1200 Infuser without power during an Emergency

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

1. Turn power off.
2. Open the Roller Pump Door.
3. Move the Latch Handle to LOAD (⇩) position.
4. Pull the Cassette outward without removing it from the Infuser.
5. Open all Lines and apply pressure to the fluid bags if needed.

WARNING: Emergency manual operation will create a fluid free flow condition. During emergency manual operation, the ThermaCor® 1200 Infuser is not functioning, and extreme care must be taken to ensure patient safety.

Using the Footswitch (Optional Accessory)

The Footswitch allows connection to the ThermaCor® 1200 Infuser via a connector located on the front of the device in the lower right corner. When connected, the Footswitch performs the same function as pressing the START and STOP buttons. To use the Footswitch, set a desired flow rate and start or stop the flow by pressing the Footswitch as needed. Start and Stop functions toggle with Footswitch actuation.

Troubleshooting Tips

It is recommended that the following actions be taken if problems arise during infusion:

- For high pressure: ensure that the access catheter or cannula is appropriately sized for the specific fluid type and flow rate desired (see Table 4).
- For low fluid pressure: ensure that the Inflow fluid lines are not clamped or kinked.
- For high temperature: operation is halted. To correct this failure, clamp off Inflow Lines(s) Return Line and Patient Line(s) and remove the Cassette. Press the Power button to turn the Infuser off, wait 10 seconds, and press the Power button again. Restart with a new Cassette. If problem persists, Call Customer Service.
- For low temperature: ensure AC power is on. Verify that heat is enabled (HEAT ON). Adjust Selected Flow Rate to achieve normothermic flow.
- If air is detected: air in the Inflow Line is self-correcting, assuming fluid is available and there is no obstruction in the fluid path. Air in the Patient Line must be manually primed out. Before doing this, stop the device, disconnect the Patient Line from the patient and direct the open tube into a waste container. Manual Prime can be initiated by pressing and holding the PRIME button.

The ThermaCor® 1200 Infuser will pump fluid out the patient tube for as long as the operator holds the PRIME button.

CAUTION: During Auto-Prime or Manual Prime, the Patient Line from the ThermaCor® 1200 Infuser must be disconnected from the patient. During Auto-Prime and Manual Prime, the Inflow and Patient Line air detectors are disabled.

Flow-Rate / Catheter-Size Considerations

Ensure that the access catheter or cannula is appropriately sized for the specific fluid type and flow rate desired. The tubing from the 3 Spike Set to the inflow connector on the Cassette has an internal lumen of 1/4 inch (inside diameter). The patient tube is 6 feet long and 1/4 inches inside diameter, terminating with a male Luer connector. This tube is appropriate for flow rates up to 1,200 mL/minute.

Catheter size and length as well as fluid viscosity significantly affect infusion flow rate. The maximum actual flow rates (approximate), with user selected pressure of 300 mmHg, for French and Needle gauge catheters are shown in Table 4. The Infuser maintains an approximate 10% flow rate accuracy in Rapid mode and 20% in Slow modes while operated within the specified conditions.

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

Table 4. Approximate Actual Flow Rates for Different Catheter Sizes at 300 mmHg.

The Reservoir bottom should be placed approximately 4 inches above the top of the Infuser and positioned such that its Outflow tubing allows proper flow into the Cassette. Flow rates and volumes are affected if the Reservoir bottom is located below the top of the Infuser, or if the Reservoir bottom is located higher than 4 inches above the top of the Infuser.

NOTES:

- The user may select 100mmHg or 300mmHg as the pressure setting by pressing the MAX PRESSURE button to toggle between 100mmHg or 300mmHg. Under normal operating conditions in Rapid Mode or in Bolus Mode with a flow rate greater than 20mL/min selected, the unit will reduce the flow rate to remain approximately within the pressure selected, and an alert message “PRESSURE CONTROLLED” will display if there is a restriction.

NOTES:

- When operating the Infuser using Slow Mode, the selected pressure of 100mmHg is recommended to trigger a restriction alarm in a shorter time period.
- The catheter size can restrict the maximum achievable flow rate given the user selected pressure. Table 4 describes the approximate flow rate achieved corresponding to the catheter size at the 300mmHg pressure setting. If the intended flow rate is not achieved, check the catheter size against the prescribed flow rate; a larger diameter catheter will achieve a higher flow rate.
- A "PT LINE RESTRICTED" alert message will be displayed when the flow rate is less than 20mL/min in Rapid or Bolus Mode. The displayed Actual Flow Rate will be "- -". This alarm occurs only during Rapid or Bolus Mode.

CLEANING AND MAINTENANCE

The Cassette interface with the Infuser (including silpad, roller pump rollers, and sensors) should be cleaned after every use. The ThermaCor® 1200 Infuser is designed to be easily cleaned and may be wiped with a damp cloth using only mild detergents and water. To disinfect external surfaces, use 10% bleach/distilled water solution. No routine or scheduled calibration, other than normal cleaning and maintenance, is required for operation of the device. See Appendix A.

CAUTION: Power off the ThermaCor® 1200 Infuser and disconnect it from power before cleaning.

CAUTION: Do not clean with alcohol, ketones or other flammable agents. Do not immerse any portion of this equipment in water or other fluids.

WARNING: Do not attempt to calibrate, repair or replace the battery in the ThermaCor® 1200 Infuser. Call Customer Service for a Return Authorization Number and Authorized Repair Location to send the unit for service and/or calibration. Attempted repair/modification of the device will void the warranty.

WARNING: All disposables should be stored in a dry, well-ventilated area that is not exposed to chemical vapors.

NOTE: If battery replacement is required, call Customer Service for a Return Authorization Number before returning the Infuser to the manufacturer for battery replacement.

ThermaCor® 1200 Infuser Alarm Reference Guide

Audible Alarm Types

There are four (4) types of alarms:

- **Error** – Three (3) audible tones repeating approximately every 10 seconds with messages that indicate safety critical events that will cause infusion to be halted.
  Critical Error will cause the Infuser to stop and requires a power cycle to restart.
  Recoverable Error will cause the Infuser to stop and appropriate user action must be taken to clear the alarm and restart infusion.
- **Warning** – Two (2) audible tones repeating approximately every 10 seconds 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 (1) single tone with informational messages that indicates that the ThermaCor® 1200 Infuser is in a condition that is not safety critical and is not yet a warning.
- **Hardware** – Single continuous tone with messages that indicate safety critical events that will cause infusion to be halted or incorrect behavior. This Alarm cannot be muted and is only silenced when Alarm condition is removed.

The two lines below the solid line on the display indicate alarm conditions detected by the ThermaCor® 1200 Infuser.

The following table (Table 5) indicates the conditions leading to alarm messages, the ThermaCor® 1200 Infuser response to the alarm, and operator actions to resolve the alarm.

NOTE: In the following table, "**Power Cycle**" refers to pressing the Power button to turn the Infuser off, waiting 5 seconds and then pressing the Power button again to turn the Infuser back on. Any alarm message accompanied with "PWR OFF/ON" or "PWR OFF & ON" instructs the user to power cycle the Infuser.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
ADD FLUID, PRESS PRIME	Recoverable Error	Three (3) audible tones repeating	Air trap is found empty following Auto-Prime. Auto-Prime has been paused due to a time-out	Operation halted and resumed when corrected	Add fluid, press prime, and continue operation. If paused, check fluid source and press PRIME to reactivate Auto-Prime. If activated again, unlock and relock the Cassette, and power cycle Infuser. If error persists, replace Cassette.
ADD FLUID, PRIME, START	Recoverable Error	Three (3) audible tones repeating	A continuous amount of air has passed through the Inflow Line into the Cassette during infusion. - or - Air purge operation has exceeded 24 seconds.	Operation halted and resumed when corrected	Check that IV Bags or Reservoir is correctly connected and not empty. Check Inflow Lines for blockages and fluid source. Check Return Line for occlusions. Press PRIME to advance fluid. Press START. If error persists, replace Cassette and power cycle Infuser. If error persists, call Customer Service.
ADD FLUID, PRIME, START	Warning	Two (2) audible tones repeating	A continuous amount of air has passed through the Inflow Line during Purge.	Continue operation and Manual Prime if needed until the warning is cleared	Check fluid source and inlet connection. 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. Press START or Manual Prime to infuse fluid. If warning persists, call Customer Service.
AIR IN PATIENT LINE	Recoverable Error	Three (3) audible tones repeating	Air is detected in Patient Line	Operation halted and resumed when corrected	Remove line from patient and press PRIME to remove air.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
ALARM TEST MESSAGE	Warning	Two (2) audible tones repeating	The operator has initiated a test of the Alarm system by holding the mute button	Continue operation	Upon completion of test, resume normal operation.
CASSET FAULTY: REPLACE	Recoverable Error	Three (3) audible tones repeating	Fluid is detected at Patient Line during Auto-Prime	Operation halted and resumed when corrected	Unlock and relock Cassette and power cycle. If error persists, replace Cassette.
CLOSE PUMP DOOR	Recoverable Error	Three (3) audible tones repeating	Roller Pump Door is opened during or after Priming	Operation halted and resumed when corrected	Check that tubing is correctly aligned on roller pump rollers and close Roller Pump Door. If error persists, call Customer Service.
CLOSE PUMP DOOR	Alert	One (1) single tone	Roller Pump Door is opened before priming while a Cassette is attached	Continue operation	Close Roller Pump Door. If alert persists, call Customer Service.
CRITICAL BATTERY	Critical Error	Three (3) audible tones repeating	At least 3 min of battery capacity remaining until Infuser shuts off	Flow rate stops, Operation halted, and requires power cycle	Connect the Infuser to AC power source and power cycle the Infuser. If error persists when connected to AC Power, call Customer Service.
DEPLETED BATTERY	Warning	Two (2) audible tones repeating	Infuser is about to stop due to depleted battery (approx 5 min operation time left)	Continue operation	Connect the Infuser to a dedicated AC power source. If warning persists when connected to AC Power, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
ERR 1: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	There is a problem with the power going to the sensors	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 2: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	There is a problem with the power going to the main display	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 3: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Internal test TW ADC does not complete successfully	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 4: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Valve has detected over current	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 5: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Watchdog timer test does not complete successfully	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 6: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Infuser reports a clock failure	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 7: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	SRAM memory test does not complete successfully	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 8: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	FLASH memory test does not complete successfully	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
ERR 9: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Motor has stopped, motor detected over current	Operation halted and requires power cycle	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 10: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Motor has stopped, motor has an over temperature	Operation halted and requires power cycle	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 11: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Motor has stopped, motor has speed failure	Operation halted and requires power cycle	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 12: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Motor has stopped, motor has direction failure	Operation halted and requires power cycle	Check and clear the tubing of any occlusions or restrictions (e.g. unclamp the line), and power cycle the Infuser. If error persists, change the Cassette and power cycle. If error persists, call Customer Service.
ERR 13: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Infuser reports a mode failure	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
ERR 14: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Software error, a fault in the firmware has occurred, or error when attempting to display a message	Operation halted and requires a power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 15: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Reading from the pressure sensors failed multiple times sequentially	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 16: PWR OFF & ON	Critical Error	Three (3) audible tones repeating	Reading from the temperature sensors failed multiple times sequentially	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
ERR 17: CALL SERVICE	Recoverable Error	Three (3) audible tones repeating	Patient air sensor self-test failed.	Operation halted and resumed when corrected	Unlock and relock Cassette. If error persists, power cycle the Infuser. If error persists, call Customer Service.
ERR 18: CALL SERVICE	Warning	Two (2) audible tones repeating	Inlet air sensor self-test failed	Continue operation	If error persists, unlock and relock Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.
ERR 19: OK TO USE	Warning	Two (2) audible tones repeating	Upper air trap air sensor self-test failed	Continue operation	If error persists, unlock and relock Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.
ERR 20: OK TO USE	Warning	Two (2) audible tones repeating	Lower air trap air sensor self-test failed	Continue operation	If error persists, unlock and relock Cassette. If error persists, restart with a new Cassette. If error persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
FLUID SUPPLY BLOCKED	Recoverable Error	Three (3) audible tones repeating	Occlusion or restriction of Inlet, roller pump inlet. Pressure sensors detect less than -100mmHg.	Operation halted and resumed when corrected	Check Supply Lines or Inflow Lines for occlusion or restrictions. Check that all clamps are open. Change Reservoir or 3 Spike Set if fluid filter is clogged. If error persists, call Customer Service.
HEATING FAULT	Warning	Two (2) audible tones repeating	Heater is not operating correctly	Continue operation	Turn heater off to clear alarm. Cycle heater off and back on. If warning persists, call Customer Service.
HI TEMP 1: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Heat Exchanger temperature > 45˚C	Operation halted and requires a power cycle	Check and clean Infuser heating surface. Power cycle the Infuser and if needed, restart with a new Cassette. If error persists, call Customer Service.
HI TEMP 2: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Inlet temperature > 45˚C	Operation halted and requires a power cycle	Power cycle the Infuser and if needed, restart with a new Cassette and fluid source. If error persists, call Customer Service.
HI TEMP 3: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Patient Line temperature >44.5˚C	Operation halted and requires a power cycle	Power cycle the Infuser and if needed, restart with a new Cassette. If error persists, call Customer Service.
HI TEMP 4: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Patient Line temperature >45˚C	Operation halted and requires a power cycle	Power cycle the Infuser and if needed, restart with a new Cassette. If error persists, call Customer Service.
HI TEMP 5: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Heater Platen temperature > 88˚C	Operation halted and requires a power cycle	Check and clean Infuser heating surface. Power cycle the Infuser. If error persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
HI TEMP 6: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Heater Platen temperature > 90˚C	Operation halted and requires a power cycle	Check and clean Infuser heating surface. Power cycle the Infuser. If error persists, call Customer Service.
HIGH INLET PRESSURE	Warning	Two (2) audible tones repeating	Pressure greater than 500mmHg is detected at the inlet	Continue operation	Check for occlusions on the Inflow Line. If the problem persists, power cycle the Infuser and replace Cassette. If error persists, call Customer Service.
INFUSION AT MAX VOL	Critical Error	Three (3) audible tones repeating	Indicates that the maximum amount that can be infused has been reached	Operation halted and requires power cycle	Power cycle the Infuser and restart with a new Cassette. If error persists, call Customer Service.
INFUSION AT MAX VOL	Warning	Two (2) audible tones repeating	Infusion is about to reach maximum volume of 99,999 mL	Operation continues but will be halted at infusion of 99,999 mL	Power cycle the Infuser, then restart with a new Cassette. If warning persists, call Customer Service.
LO TEMP 1, PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Heat Exchanger sensor detects temperature below 1˚C	Operation halted and requires power cycle	Power cycle the Infuser and resume operation. If error persists, call Customer Service.
LO TEMP 3, PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Patient sensor detects temperature below 1˚C	Operation halted and requires power cycle	Power cycle the Infuser and resume operation. If error persists, call Customer Service.
LO TEMP 5, PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Platen sensor detects temperature below 1˚C	Operation halted and requires power cycle	Power cycle the Infuser and resume operation. If error persists, call Customer Service.
LOW TEMP OUT_SVC SOON	Non-audible notification	Display only.	Heater is not operating correctly	Continue operation	Turn heater off to clear alarm. Cycle heater off and back on. If warning persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
LOW BATTERY	Warning	Two (2) audible tones repeating	The Infuser has ≤ 30 minutes of power available from the battery until fluid flow stops	Continue operation	Prepare to connect the Infuser to a dedicated AC power source within 25 minutes.
MANUALLY PRIMING	Alert	One (1) single tone	Operator has initiated manual prime mode	Continue operation	Upon completion of manual prime, resume normal operation.
NO CASSETTE	Alert	One (1) single tone	Cassette is not detected or unlocked prior to Auto-Prime.	Continue operation	Load Cassette. If Cassette is already engaged, remove and reload. If alert persists, call Customer Service.
NOT LATCHED	Recoverable Error	Three (3) audible tones repeating	Cassette latch is unlocked during Auto-Prime, Prime, or normal operation . Cassette is not detected after Auto-Prime.	Operation halted and resumed when corrected	Lock Cassette Latch. If not corrected, unlock and relock Cassette. If error persists, power cycle the Infuser, remove and reinstall Cassette. If error persists, call Customer Service.
OK TO USE - CALL SRVC	Warning	Two (2) audible tones repeating	Problem communicating with the display	Continue operation	Call Customer Service before operating again.
ON BATTERY: NO AC PWR	Alert	One (1) single tone	AC Power has been disconnected. Infuser is operating on battery	Continue operation	Connect the Infuser to a dedicated AC power source when available.
OVERINFUSD: PWR OFF/ON	Critical Error	Three (3) audible tones repeating	Bolus exceeded desired volume by 20mL or more	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
PATIENT LINE BLOCKED	Recoverable Error	Three (3) audible tones repeating	During Pressure Control if actual flow rate decreases below 10mL/min - or - Restriction of Patient Line pressure > 135% of max pressure setting. - or - Roller pump outlet pressure > 500 mmHg	Operation halted and resumed when corrected	Check for occlusions, check all tubing, open all clamps, open and close Roller Pump Door to relieve pressure. Press Start. If problem persists, increase the size of the patient access port or use the Dual Outflow Line. Power cycle the Infuser and replace Cassette. If error persists, call Customer Service.
POSSIBLE FREE FLOW	Recoverable Error	Three (3) audible tones repeating	The patient and purge valves are open, or the Infuser detects the Cassette not locked during/after operation	Operation halted and resumed when corrected	Unlock and relock the Cassette and resume operation. If error persists, power cycle the Infuser, unlock and relock the Cassette. If error persists, call Customer Service.
PT LINE RESTRICTED	Alert	One (1) single tone	< 20mL/min flow during Rapid or Bolus Mode	Continue operation	Check Patient Line for restrictions or change catheter size.
PUMP PAUSED	Alert	One (1) single tone	Infuser has been paused due to the Roller Pump Door opening, message shows after Roller Pump Door is closed	Continue operation	Press START to resume operation

Main Display Text Message	Audible Alarm Type	Alarm Tone Type	Cause	System Response	Operator Action
PURGING IN PROGRESS	Alert	One (1) single tone	Air purge operation is in progress.	Continue operation	Upon completion of purging, normal operation will proceed.
REDUCED AC POWER	Alert	One (1) single tone	The Infuser is not receiving sufficient power from wall AC power source	Continue operation. Infuser automatically switches to Battery Power	Ensure that Infuser is plugged into a dedicated wall power circuit. Resume operation. If alert persists, call Customer Service.
SERVICE BATTERY	Warning	Two (2) audible tones repeating	Battery not functional	Continue operation	Call Customer Service before starting on a new patient.
SERVICE CHARGER	Warning	Two (2) audible tones repeating	Battery charging is not detected while connected to AC power	Continue operation	Call Customer Service before starting on a new patient.
UNCLAMP RETURN LINE	Recoverable Error	Three (3) audible tones repeating	Pressure > 405mmHg is detected in the Return Line	Operation halted and resumed when corrected	Check the Return Line for restrictions or occlusions and unclamp the Return Line. If error persists, call Customer Service.
UNIT SHUTDOWN 2 MIN	Critical Error	Three (3) audible tones repeating	The Infuser has been continuously on for more than 48 days	Operation halted and requires power cycle	Power cycle the Infuser. If error persists, call Customer Service.
Several potential messages	Hardware	Single continuous tone	Indicates safety critical events that will cause infusion to be halted or incorrect behavior.	Operation halted and resumed when corrected	Power cycle the Infuser. If error persists, call Customer Service.

Table 5. Alarms and Operator Response to Correct

NOTE:	Based on a 1 second maximum response time by the Safety hardware, if the Infuser is running at 1,200 ml/min (20 ml/sec), a maximum volume of 20 ml could be infused before the device is stopped. The 20 ml volume constitutes 1/3 of the volume contained in the 6ft Patient Line.

Silencing an Alarm

To silence an alarm tone, press the MUTE button; this will also stop the alarm from sounding. If more than one alarm condition is currently present, pressing the MUTE button will silence all alarms. Alarms can be silenced 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.

Testing Alarm

Press and hold the MUTE button with moderate pressure for approximately 5 seconds to sound the alarm. The Infuser will display "ALARM TEST MESSAGE" The alarm function can be tested at any time when no alarms are present.

User Messages

User messages or Informational Messages display on the 4th Line (above volume infused), indicating a message to the user. These messages are not alarms and are for informational use only. The operator may continue operation of the Infuser following the appropriate operator action. The following table (Table 6) indicates the messages displayed and the appropriate operator action to take.

Main Display Text Message	Cause	Operator Action
CHECK NO AIR PT LINE	The Cassette is detected as full of fluid but user must inspect Patient Line for air.	Verify there is not air in the Patient Line before making the patient connection. If air is evident, press and hold PRIME to actuate Manual Prime until air is purged and then make the patient connection.

Main Display Text Message	Cause	Operator Action
CONTIN PRIME OR START	The Infuser has been stopped after Auto-prime, manual prime, or air has been detected in the Patient Line or Inflow Line	Verify that the Patient Line does not contain air bubbles. If so, disconnect line from the patient. Press and hold or press and release PRIME to actuate Manual Prime. Verify there is no air in the Patient Line before making the patient connection. Press START to resume operation.
INFUSION PAUSED	Auto-Prime has been paused due to an Error. Lines 6 and 7 of the display will indicate appropriate user action; refer to Table 5 as well.	Press PRIME after correcting cause of the pause to reactivate Auto-Prime. The cause is listed on lines 6 and 7. If error persists, unlock Cassette and check backside for 2 blue pads behind tubing in the 2 holes near the top, and check for 2 grey pads on the back of the air trap. If missing, replace Cassette. Otherwise, relock Cassette and press PRIME to resume operation.
NO CASSETTE	The device is powered on and no Cassette is detected	Latch a Cassette onto the Infuser and close the Roller Pump Door.
PAUSED – PRESS PRIME	Auto-Prime has been paused when the user presses STOP or error occurs during Auto-Prime	Press PRIME to reactivate Auto-Prime.
PRESS START TO RECIRC	RECIRC has been pressed, and START must be pressed to activate Recirc	Press START to activate Recirc
PRESSURE CONTROLLED	The selected flow rate cannot be maintained given the selected pressure.	Check the Patient Line for occlusions or restrictions. If problem persists, increase the size of the patient access port or use the Dual Outflow Line to achieve a higher flow rate.
PRIME PATIENT LINE	Auto-Prime has completed successfully.	Press and release or press and hold PRIME to actuate Manual Prime. Verify there is no air in the Patient Line before making the patient connection.
PRIMING…	The Infuser is in the Auto-Prime state.	None. Continue Operation.
RECIRC:INFLO TEMP=XXC	Recirc Mode has been activated. The inlet temperature displays on line 4.	Continue operation in Recirc Mode.
SELECT RATE AND START	Bolus Mode is selected.	Select the Bolus flow rate and press START.
SELECT RATE AND START	Rapid Mode is selected.	Select the desired flow rate and press START.
SELECT RATE AND START	Slow Mode is selected.	Select the desired flow rate and press START.

Main Display Text Message	Cause	Operator Action
SELECT RATE AND START	The Infuser is stopped.	If following Auto-Prime, press and release or press and hold PRIME to actuate Manual Prime, and then verify there is no air in the Patient Line before making the patient connection. Otherwise, ensure there is no air in the Patient Line, select the desired flow rate, Bolus, Recirc, and press START.
START EXITS RECIRC	The SLOW, RAPID, or BOLUS keys have been pressed. Recirc Mode continues to operate.	Press START to activate the new mode. RECIRC can be pressed again to clear the screen, and RECIRC continues.
UNHOOK PT/PRESS PRIME	The Cassette has been loaded and locked onto the Infuser. The Cassette is detected as empty/dry.	Verify that the Patient Line is not connected to the patient. Press and release PRIME to actuate the Auto-Prime process. Following Auto-Prime, press and release or press and hold PRIME to actuate Manual Prime. Verify there is not air in the Patient Line before making the patient connection.
UNHOOK PT/PRESS PRIME	The Cassette has been attached and detected to be only partially filled and requires priming.	Verify that the Patient Line does not contain air bubbles. If so, disconnect line from the patient. Press and hold PRIME to actuate Manual Prime. Verify there is not air in the Patient Line before making the patient connection. If the air trap is empty or fluid is filled halfway, continue operation. Pressing and holding PRIME for Manual Prime may be necessary.

Table 6. User Messages and Appropriate Operator Response

Customer Service

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

- Contact Name at Location
- Location Name, Address, Phone Number
- Serial number of the ThermaCor® 1200 Rapid Thermal Infuser
  (The serial number of the unit is located on the label on the backside of the ThermaCor® 1200 Infuser)
- Software version of the ThermaCor® 1200 Infuser
  (The software version number appears on the Main Display when the Infuser is powered up)
- Description of problem, any error message(s), and any actions made to resolve problem, key user(s) involved (i.e. surgeon, anesthesiologist, perfusionist)
- Fluids administered
- Lot number(s) appearing on package of item(s): Cassette/Tube Sets/Reservoir/accessories

If Customer Service determines that the ThermaCor® 1200 Infuser 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.

Contact

Medical Solutions, Inc.
3901 Centerview Drive, Suite L
Chantilly, Virginia 20151 USA

Smisson-Cartledge Biomedical, LLC
487 Cherry Street
Third Street Tower, Third Floor
Macon, Georgia 31201 USA
www.ThermaCor1200.com

Customer Service: 1-478-744-9992
1-866-944-9992 (US Toll-free)

Contract Manufacturer

Spartronics
22740 Lunn Road
Strongsville, OH 44149

Responsible Company / Legal Manufacturer

Smisson-Cartledge Biomedical, LLC
487 Cherry Street
Third Street Tower, Third Floor
Macon, Georgia 31201 USA

PRODUCT SPECIFICATIONS

Operating Characteristics	
Powered modes	Standby Battery charging AC Power On Battery Power On
Slow Infusion	10 mL/hour to 1,200 mL/hour ±20%
Rapid Infusion	20 mL/minute to 1,200 mL/minute ±10%
Bolus infusion	100, 250, 500 or 1,000 mL of fluid at 500 mL/minute ±10% or User Selected Rate
Recirc Mode	300mL/min for 5 minutes
Bolus Selectable Rate	20mL/minute to 1200 mL/minute at tolerance indicated above
Total infusion amounts	up to 99,999 mL
Selectable infusion pressure	100 or 300 mmHg
Heating capability to compatible fluid media	>30°C rise at 500mL/minute >17°C rise at 1,000 mL/minute
Heater Temperature of blood-contact surfaces Maximum heater temperature (single-fault condition)	 <45°C 45°C
Nominal fluid inlet temperature	20°C
Nominal fluid outlet temperature w/ Heater On	37±2°C at 1,000 mL/minute
Output Temperature	Set to 40±2°C (Displays temperature in 1° increments)
Protection against air infusion	Prevents infusion of air ≥50 µL at max rated flow
Maximum volume per Cassette	100 Liters
Cassette prime volume	≤ 200 mL
Time required for priming	≤ 60 seconds
Audible outputs	
Good Button Press	2-ms tone indicates recognition and acceptance of button press
Bad Button Press	5-ms tone to indicate recognition of button press not applicable in current operating mode
Error Alarm	Three (3) audible tones repeating approximately every 10 seconds with messages that indicate safety critical events that will cause infusion to be halted or incorrect behavior

Warning Alarm	Two (2) audible tones repeating approximately every 10 seconds 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 Alarm	One (1) single tone with informational messages that indicates that the ThermaCor® 1200 is in a condition that is not safety critical and is not yet a Warning
Hardware Alarm	Single continuous tone with messages that indicate safety critical events that will cause infusion to be halted or incorrect behavior. This Alarm cannot be muted and is only silenced when Alarm condition is removed.
Environmental Characteristics	
Operating Temperature Relative humidity Altitude EMC (radiated/immunity) Mechanical noise	5°C to 40°C 20% to 90% 0 to 10,000 feet CISPR11 Group 1 Level B/IEC 1000-3 Level 2 <65 dBA in normal operation @ 1 meter
Storage and Transportation Characteristics	
Infuser	-40°C to 70°C, 10% to 100% condensing Humidity* *Storage condition may affect battery characteristics.
Cassette and Tubing	-40°C to 70°C, 10% to 100% condensing Humidity
Physical Characteristics	
Size	W8.75” x H16.5” x D13”
Weight (without Disposable)	22 lbs
IV pole mount	Accepts IV pole 0.75 to 1.5” in diameter. Heavy Duty IV Pole with a Base with at least five (5) wheels and diameter of twenty-four (24) inches to avoid a tipping hazard. Do not mount higher than thirty-two (32) inches from the floor to the base of the Infuser or as recommended by the IV Pole specifications.
Power Cord	Conductor: 3-14AWG 14 x 30 strand, 9.7mm OD Cord type/temp: SJT/105deg C Power Rating: 1875 Watts 15A @ 125V Hospital Grade plug Or Equivalent
Optional Accessory	
Footswitch	Cord Length: Maximum 2.8m (9.2ft) Conductor: 6-24AWG, 7 x 32 strand 5.8mm OD Cord type/temp: CSA AWM I A/B 80deg C

	Power Rating: 300V
Power Source	
AC Input Voltage	1380 VA Max 100-240 VAC (mains)
Electrical Compliance	 Intertek IEC 60601-2-24, IEC 60601-1, IEC 60601-1-2
Operating Frequency	50/60Hz
Battery backup Type Operating cell capacity Battery Shelf life Battery Recharge time	 Lithium ion battery pack 250 mL/hour for 2 hours or 1,000 mL/minute for 30 minutes* *Storage condition may affect battery characteristics Battery will retain a charge for 3 years from date of manufacture with proper maintenance and charging. Infuser will still function on AC power; battery will require recharging prior to using battery backup. 6 hours
Protection against hazardous output	
Type of Protection Against Electric Shock	Class 1, Internally Powered
Leakage current	Leakage Current: < 100 uA normal conditions (132 VAC @ 60 Hz), < 500 uA, under single fault conditions (264 VAC @ 60 Hz)
Enclosure leakage current	<100 μA (enclosure to any ground) under normal conditions and <500 μA in single-default condition
Patient leakage current	<10μA under normal conditions and <50 μA in single default condition
Tubing length between device and patient	183±5 cm (~ 6ft) for the Patient Line or Dual Outflow Line
Tubing connector at patient end	Locking male Luer or 3/8” tube for barbed fitting

Tubing length between device and fluid bag access	$\geq$ 60±5 cm
Tubing connectors at IV fluid bag connections	Standard IV bag spikes
IP Rating	
First Digit	The first digit of the IP code indicates the degree that persons are protected against contact with moving parts (other than smooth rotating shafts, etc.) and the degree that equipment is protected against solid foreign bodies intruding into an enclosure.
Second Digit	The second digit indicates the degree of protection of the equipment inside the enclosure against the harmful entry of various forms of moisture (e.g. dripping, spraying, submersion, etc.)
Infuser: **IP22**	Protection against fingers or other object not greater than 80mm in length and 12mm in diameter, and protection from vertically dripping water.
Footswitch: **IPX8**	Protection against complete, continuous submersion in water.
Sterilization	
All Disposables	Ethylene oxide, Delivered Sterile for Single Use only
Cleaning	
Cleaning and Maintenance	The Cassette interface with the Infuser (including silpad, roller pump rollers, and sensors) should be cleaned after every use. The silpad should be cleaned gently and allowed to dry completely before the next use. These areas and all external surfaces should be gently cleaned with 10% bleach (0.05% sodium hypochlorite) and distilled water solution or mild detergents and water. Do not clean with alcohol, ketones, or other flammable agents. Do not immerse any portion of this equipment in water or other fluids.
Additional Products	
Minimum Requisite Products	PTC-1200 Disposable Set (Cassette with Patient Line and 3 Spike Set)
Optional Products	DNC-1200 Disposable Set (Cassette with Dual Outflow Line) PNC-1200 Disposable Set (Cassette with Patient Line) Rigid Fluid Reservoir Rigid Fluid Reservoir Holder

Optional Products	3 Spike Sets 3 Spike Set Holder Dual Outflow Lines Patient Lines Extension Lines On / Off Footswitch Replacement Component Guard Replacement Power Cord (US) Replacement Power Cord (European) Replacement Power Cord (UK) Replacement Power Cord (Australian) Replacement Silpad Drape

APPENDIX A

EMC COMPLIANCE

	The ThermaCor® 1200 Infuser has been evaluated with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-2-24, IEC 60601-1, IEC 60601-1-2

NOTE: Portable and mobile RF communications can affect the ThermaCor® 1200 Infuser.

NOTE: The ThermaCor® 1200 Infuser should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ThermaCor® 1200 Infuser should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The ThermaCor® 1200 Infuser is not permitted for use in an explosive atmosphere.

Table 7

Guidance and manufacturer's declaration –electromagnetic emissions		
The ThermaCor® 1200 Infuser is intended for use in the electromagnetic environment specified below. The customer or the user of the ThermaCor® 1200 Infuser should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ThermaCor® 1200 Infuser 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 ThermaCor® 1200 Infuser 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	The ThermaCor® 1200 Infuser 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.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	The ThermaCor® 1200 Infuser 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.

Table 8

Guidance and manufacturer's declaration –electromagnetic immunity			
The ThermaCor® 1200 Infuser is intended for use in the electromagnetic environment specified below. The customer or the user of the ThermaCor® 1200 Infuser 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 20 % (per additional ESD testing).
Electrical 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ThermaCor 1200 requires continued operation during power mains interruptions, it is recommended that the ThermaCor 1200 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A / m	400 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 AC mains voltage prior to application of the test level.			

Table 9

Guidance and manufacturer's declaration –electromagnetic immunity			
The ThermaCor® 1200 Infuser is intended for use in the electromagnetic environment specified below. The customer or the user of the ThermaCor® 1200 Infuser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ThermaCor® 1200 Infuser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=0.35\sqrt{P}$
Radiated RF IEC 61000-4-3 IEC 60601-2-24	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]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.			
[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 ThermaCor® 1200 Infuser is used exceeds the applicable RF compliance level above, the ThermaCor® 1200 Infuser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ThermaCor® 1200 Infuser. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 10

Recommended separation distances between portable and mobile RF communications equipment and the ThermaCor® 1200

The ThermaCor® 1200 Infuser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ThermaCor® 1200 Infuser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ThermaCor® 1200 Infuser 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 (kHz, MHz, GHz) of transmitter in meters (m)**		
	150 kHz to 80 MHz $d=0.35\sqrt{P}$	**80 MHz to 800 MHz** $d=0.35\sqrt{P}$	**800 MHz to 2,5 GHz** $d=0.7\sqrt{P}$
0,01	0.035	0.035	0.07
0,1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.2
100	3.5	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.

Table 11: The graph below shows the flow rate as measured during the first 2 hours of testing. The selected flow rate was 120mL/hr. The test was performed according to the IEC 60601-2-24 Standard.

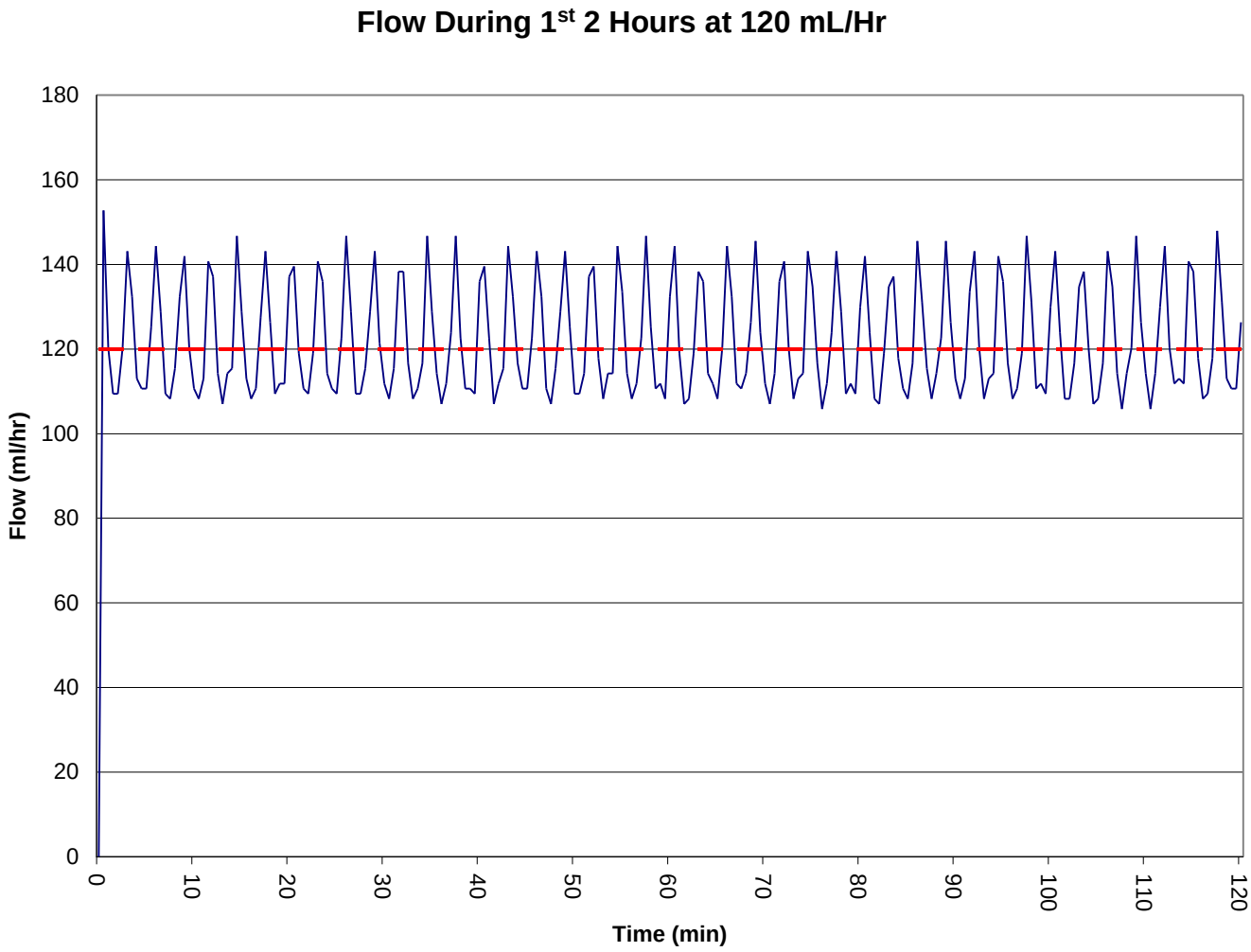


Table 12: The graph below shows the trumpet curve during the first two hours of testing at 600 mL/Hr. This graph shows the average percentage error, maximum percentage error, and minimum percentage error curves. The test was performed according to the IEC 60601-2-24 Standard.

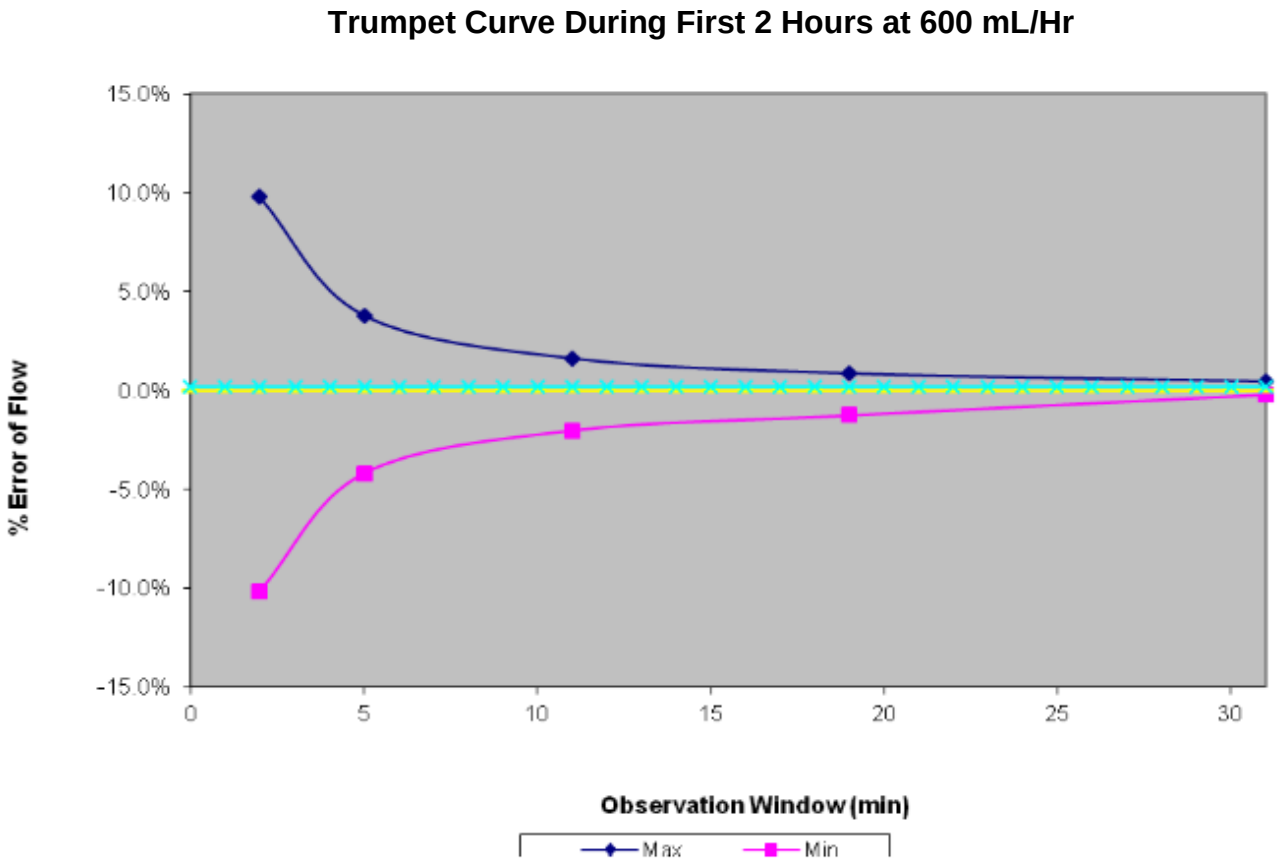
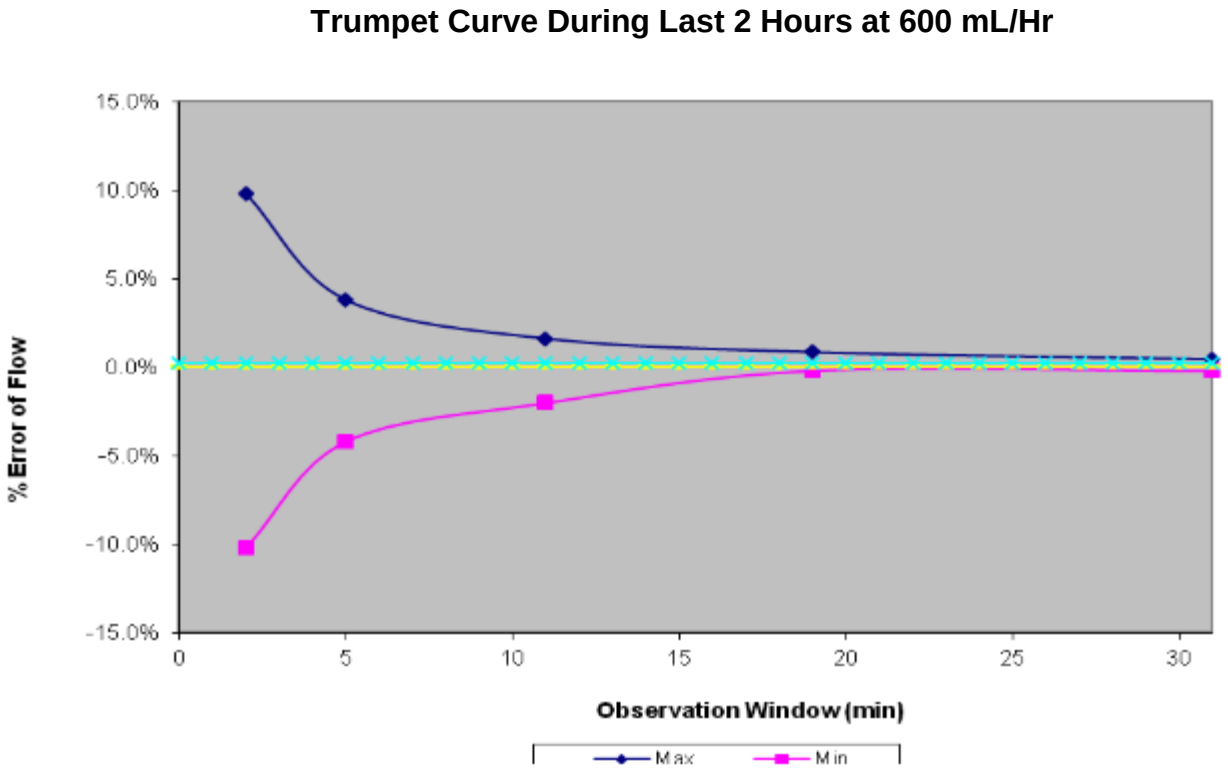


Table 13: The graph below shows the trumpet curve during the last two hours of testing at 600 mL/Hr. This graph shows the average percentage error, maximum percentage error, and minimum percentage error curves. The test was performed according to the IEC 60601-2-24 Standard.



Cleaning and Maintenance Procedures and Schedule

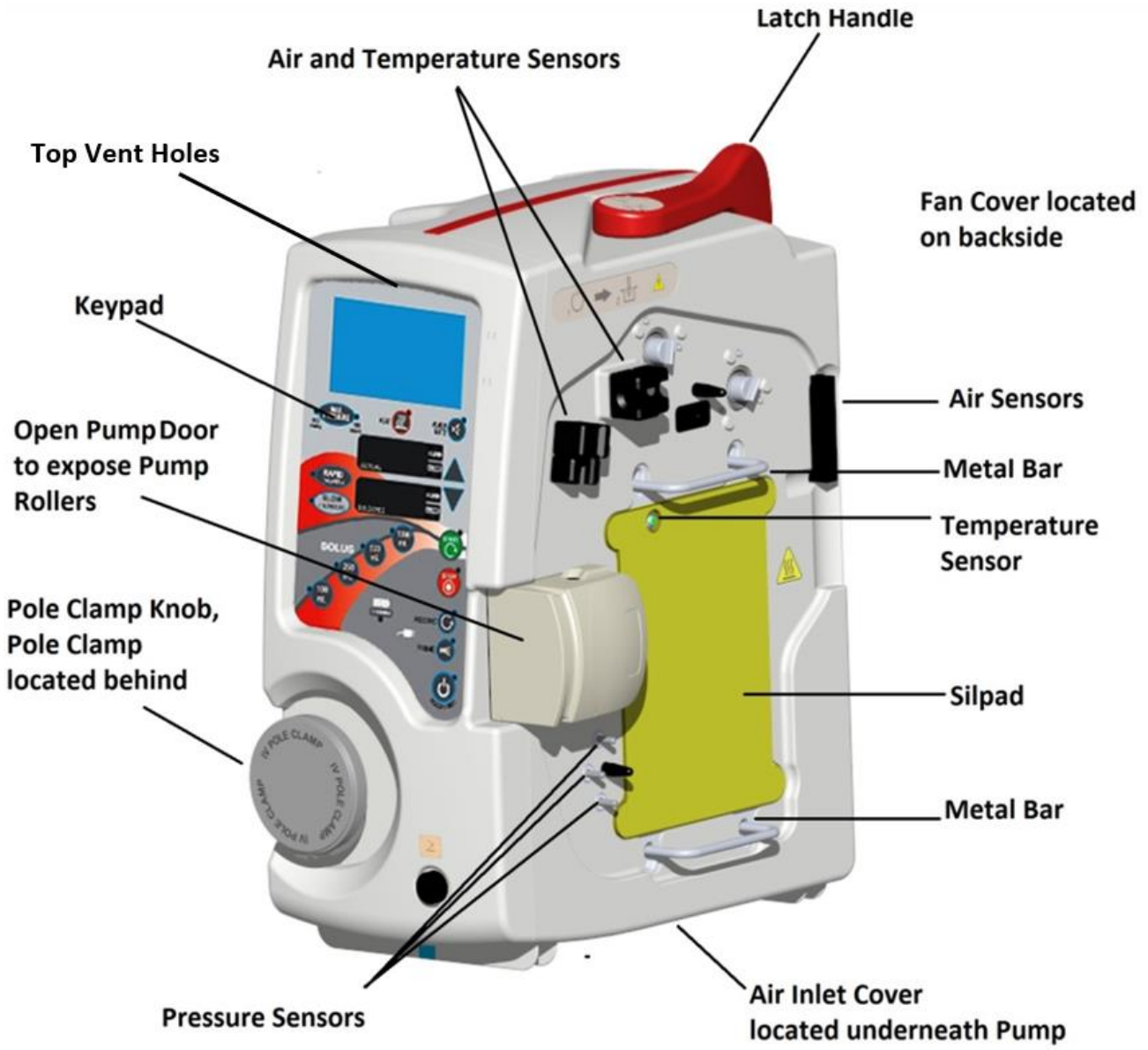


Figure 3: Schematic for Cleaning and Maintenance

CAUTION:	Do not clean with alcohol, ketones or other flammable agents. Do not immerse any portion of this equipment in water or other fluids.

NOTE:	Cleaning and Maintenance shall be performed by a medically trained healthcare professional or Biomedical Equipment Technician (BMET).

CLEANING:

1. Turn the Infuser off and disconnect from AC power before cleaning. If attached, disconnect Footswitch (optional accessory) 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 gently wipe all surfaces of the Cassette-Infuser interface, including the sensors, silpad, roller pump door, and roller pump rollers indicated in Figure 3. Extreme care should be taken not to damage these components. Allow the silpad to dry completely before the next use.
4. Clean and wipe the Keypad surface. Do not allow fluid in top vent holes.
5. Clean and wipe all exterior surfaces contacted by fluids during use.
6. Clean and wipe 3 Spike Set Holder and/or Large Reservoir Holder (optional accessories).
7. Clean and wipe the Footswitch (optional accessory) surface and cord.
8. Allow surfaces to dry before next use.
9. Place the CG-1200 Component Guard on the Infuser while the Infuser is not in use.

MAINTENANCE:

1. Turn the Infuser off and disconnect from AC power before performing maintenance.
2. Inspect the Power Cord for any damage. If power cord shows damage, discontinue use and please contact Customer Service.
3. Inspect the Footswitch (optional accessory) for any damage. If Footswitch shows damage, discontinue use and 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. If the ThermaCor® 1200 Infuser is to remain attached to the IV Pole, ensure that the Pole Clamp Knob is securely tightened.
5. Inspect and clean the 3 Spike Set Holder and/or Large Reservoir Holder (optional accessories). Inspect for damage. If Holder is damaged and unable to perform intended function, please contact Customer Service.
6. 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, remove the air inlet cover using a Phillips

screwdriver and remove the metal mesh filter. Using compressed air from a can or facility air, blow the mesh filter clean and reinstall the filter in the unit. Replace the air inlet cover.

7. 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.
8. Place the CG-1200 Component Guard on the Infuser while the Infuser is not in use.

Table 14. Time intervals for Cleaning and Maintenance

Cleaning / Maintenance Step	**Perform before or after each use**	**Perform monthly**	**Perform bi-monthly**
Cassette - Infuser interface surfaces	√		
Keypad surface	√		
Exterior surfaces	√		
3 Spike Set Holder / Large Reservoir Holder	√		
Power Cord	√		
Footswitch (optional accessory)	√		
Pole Clamp		√	
Air Inlet Cover and Filter		√	
Fan Cover		√	
Battery Charging			√

Authorized Rep/ CE Mark

European Representative:

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE

2797

Patent Information

www.SCB-IP.net