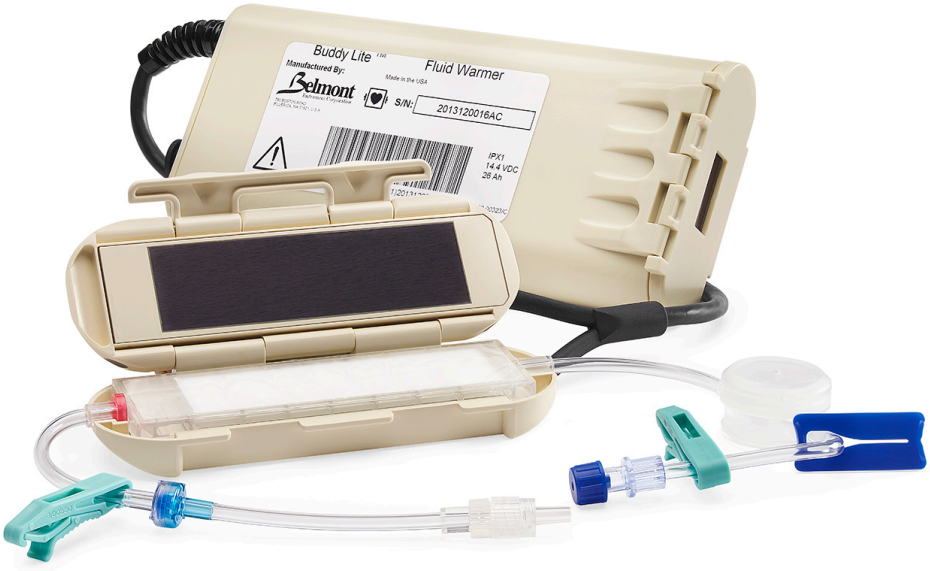
The Belmont® buddy lite™

Blood/Fluid Warmer Operator's Manual

CE 0843



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

702-00091/Rev M

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Chapter

1

System Overview

INTRODUCTION:

The Belmont® buddy lite™ in-line Blood/Fluid warmer is a miniature portable fluid warmer and sensing device that warms intra-venous fluids (including blood products) to physiological temperature at flow rates up to 80 ml/min (4.8 L/hr) for crystalloids at 20°C and up to 50 ml/min (3.0 L/hr) for packed red cells at 10°C. At higher flows, the fluids administered may not heat to normothermia.

The heater, including all control circuitry, is contained in a miniature package, and is powered by a small rechargeable battery. The whole device can be placed close to the patient to minimize line cooling in the infusion line. If the system overheats the fluid or is not heating or sensing temperature properly, the built-in red and blue LEDs will turn on alternately and the alarm sounds to alert the user of the alarm condition.

INDICATIONS FOR USE AND CONTRAINDICATIONS

The Belmont® buddy lite™ Blood/Fluid Warmer is to be used to administer blood, blood products and intravenous solutions. It is intended to be used by healthcare professionals in a clinical environment to prevent hypothermia. The system is not meant for the infusion of granulocyte suspensions.

WARNING

The control system can only be used with the Belmont supplied disposable.

Do not alter the disposable, Heater Unit, or battery pack.

Use only with crystalloid or anticoagulated blood products.

Do not use in the presence of flammable anesthetics.

CAUTION

The system should not be used with pressure infusers. Blood and fluid bags contain air. The set can vent large amounts of air from crystalloid, but with blood only small amounts of air can be vented. The hand squeeze pumps, also known as a ball pump, supplied with some blood sets, may be used to momentarily increase flow, but use caution when doing so.

The system is an efficient blood and fluid warmer designed for use when the flow rate is 80 ml/min or less. It is neither a resuscitation device nor a substitute for a rapid infusion system.

SYSTEM OVERVIEW

The Belmont® buddy lite™ Blood/Fluid Warmer complete system consists of the battery pack, the **Heater Unit**, and the **Disposable Set**.

The system can be placed near the patient at the infusion site. See Figure 1.

The battery contains a built-in battery control circuitry and a built-in 5-segment LCD panel in the status window to provide the battery capacity. When the system detects unsafe conditions, the built-in red and blue LEDs will turn on alternately and the alarm sounds to alert the user of the alarm condition.

The Heater Unit contains the heater plates and temperature monitoring and control system. If it is heating, the green LED will blink with each heating cycle.

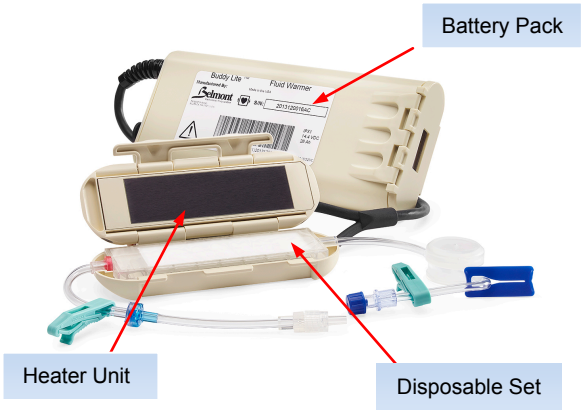


Figure 1: The Belmont® buddy lite™ Complete System

The disposable set has a sterile fluid path, and is **intended for single-use only.** The disposable set has standard luer connectors and can be connected to any standard catheter. It contains two thin films, which contact the heater plates for rapid heating of the fluid, and two internal microporous membranes to vent out-gassed air that is generated during heating, see Figure 2.

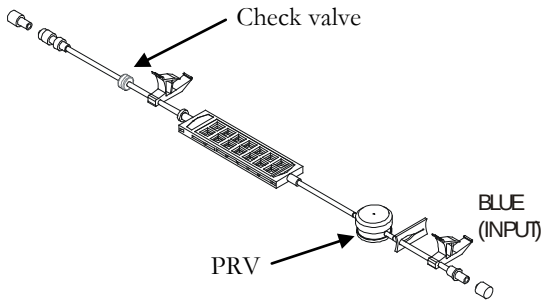


Figure 2: The buddy lite™ **Disposable Set**

The set is color-coded and keyed to ensure proper placement in the Heater Unit, blue at the input from a fluid administration set. Both heater plates are heated during operation. There is a built in valve in the disposable set to prevent air entrainment into the patient and a pressure-regulating valve, PRV, at the input to protect the set and the patient from unintended exposure to high pressure applied to the IV line. This valve will allow increase flow by application of pressure, up to 300 mmHg, but will prevent pressure higher than this from reaching the set or IV line distal to it. There is also a check valve at the output to prevent back flow.

SYSTEM AND TEMPERATURE MONITORING

Blood or replacement fluid is heated as it passes through the disposable that is in contact with the heater plates in the Heater Unit. Thermistors on the heater boards measure the temperature of the heater plates, and a microprocessor, mounted on each of the heater plates, controls the temperature of the infusate. When the Heater Unit functions normally, the green LED on the Heater Unit will blink with each heating cycle. An over temperature condition causes the unit to stop heating, the green LED stops blinking, and an alarm alert will be activated and the blue/red LED will flash alternately.

ALARMS AND ALARM MESSAGES:

Under alarm conditions, an audible alarm is activated and the blue/red LED flashes. Alarm conditions include: **Over Temperature, Probe Fault, Check for Air,** and **No Heat.**

The Battery Housing of the Belmont® buddy lite™ Blood/Fluid Warmer is shown below:

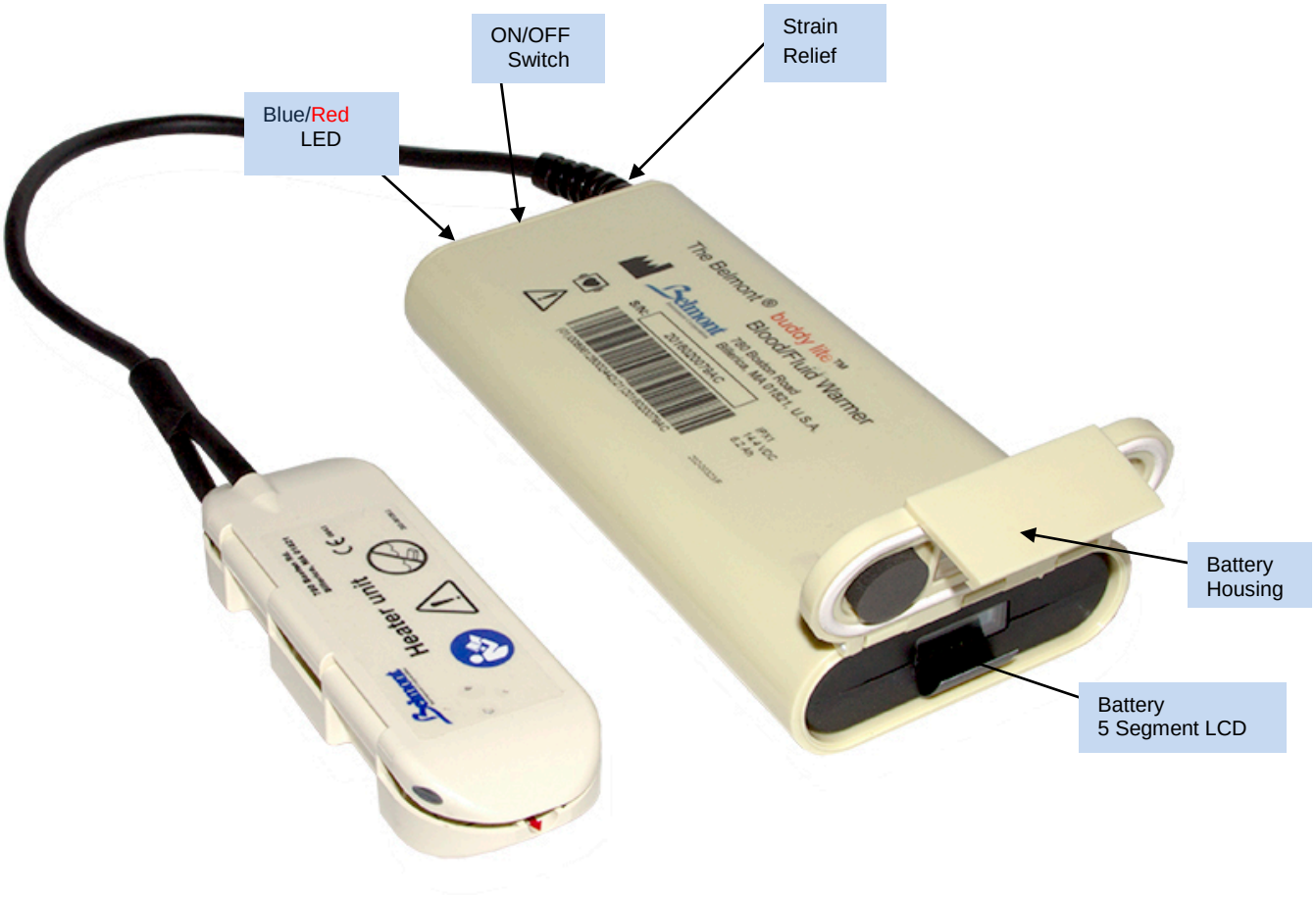


Figure 3: Battery in the Battery Housing

POWER

The battery capacity is displayed via a 5-segment LCD panel on the battery pack. Each LCD segment represents 20% of the full charge capacity. If the battery voltage falls below 9.6 V, the system will shut down due to lack of power.

The **ON/OFF switch** controls power from the battery pack to the Heater Unit.

LED

There is a 2-color LED. The LED is **blue** when the battery power is ON and it flashes **red** when there is an alarm condition.

Chapter

2

Operation of the System

INTRODUCTION

This section reviews the set up and operation of the Belmont® buddy lite™ Blood/Fluid Warmer to ensure safe and effective operation of the system.

CAUTION:

Use of this device requires detailed familiarity with its operating procedures.

Read this manual thoroughly before operating this device.

WARNINGS:

Use only the Belmont supplied disposable. The disposable set is a single-use, sterile, non-pyrogenic fluid path.

Do not change or alter the disposable. Use extreme caution when handling the disposable; do not expose the disposable to sharp objects.

Do not use in the presence of flammable anesthetics.

Do not open the Heater Unit during or after priming.

Do not open the Heater Unit during operation, as this could damage the disposable.

Use only crystalloid to prime the unit. Do not use blood for the initial prime.

Do not attempt to prime unit or subject the disposable to flow outside of the Heater Unit, as the disposable will be damaged.

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

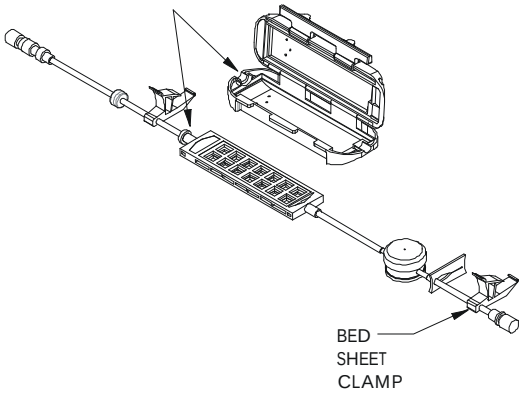
When administering blood products, be sure to use the administration set with a built-in filter.

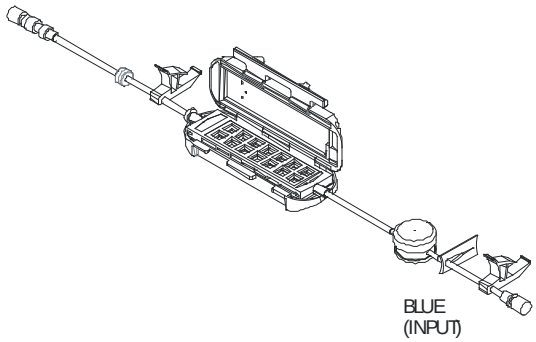
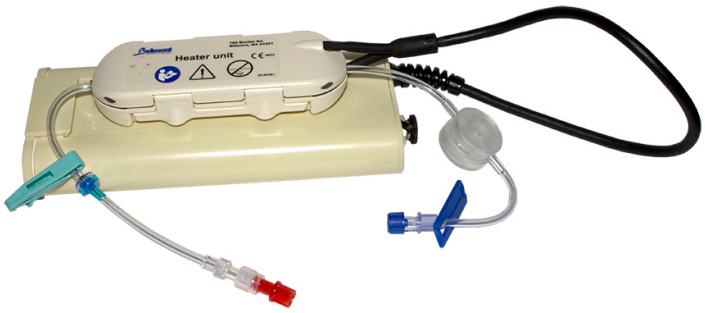
Do not use for administration of cryo-precipitate, or granulocyte suspensions.

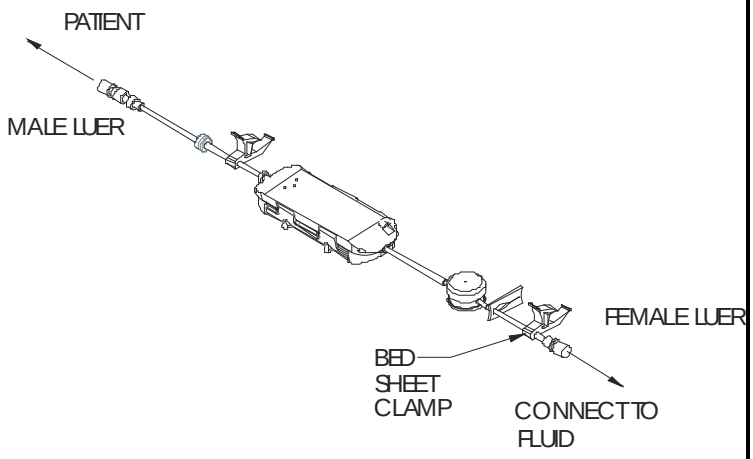
Use only anticoagulated blood products.

Do not mix lactated Ringer's or other solutions containing calcium with citrated blood products.

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

Operating Steps	Detailed Information
Set-up 	Make sure that you have all the necessary supplies. • Make sure that the battery is fully charged, 5-segment shown on the battery LCD. If battery needs to be recharged, see the "Charging Procedure", at the end of this section. • Inspect the Heater Unit to ensure that the heater plates are clean and dry. Wipe off any particles or debris on the plate with a soft cloth. • **There are no adjustments on the Heater Unit.**
Heater Unit can be installed on top of the Battery Housing	The Heater Unit is placed close to the fluid insertion site during operation.
Install the Disposable Set Line up orientation hub on the disposable with the notch in the Heater Unit. (Red to Red) The Heater Unit will not close if they are not aligned.  	• Carefully remove the disposable from its pouch. • Install it into the Heater Unit, being careful to line up the orientation notches on the disposable with the orientation pins on the Heater Unit. Take care not to damage the disposable.

Operating Steps	Detailed Information
	The Heater Unit will not close if the disposable is not installed properly.
	Close and latch the case.
Connect to the Fluid Bag and Administration Set	• Hang a fluid bag and administration set. • Connect the fluid administration set to the disposable luer fitting with the blue slide clamp.
Prime the Disposable Set **WARNING:** **The case must remain closed during and after priming.**	• Open the roller clamps of the administration set and prime the unit making sure there is no air visible in the IV line or patient extension. • Tap the Heater Unit while priming to expel any air bubbles that may collect in the disposable.

Operating Steps	Detailed Information
Establish Power to the Heater Unit	Depress the ON/OFF switch, on the battery housing, to supply power to the Heater Unit. Blue LED turns ON and Red LED flashes once, if the Heater Unit is functioning normally. If not, return for service.
Initiate Infusion  	• Select an appropriate catheter size for the intended flow rate. • Using aseptic technique, make patient connection without entrapping air. • Adjust the roller clamp to the desired flow rate. • **Secure the system in a horizontal position, on a flat surface near the patient** using bed sheet clamp ensuring that there is no strain on the patient line. • If a longer administration set is desired, it should be no longer than 6 inches for optimal thermal transfer. Use of longer set will result in some line cooling from heater to patient. • The preferred position, of the Heater Unit, is at or below the level of the insertion site.

Operating Steps	Detailed Information
Maintain Infusion **There are no adjustments on the Heater Unit.** You may see some condensation around the outer-edge of the Heater Unit after running for an extended period of time. This is normal and will not interfere with the system. If withdrawing fluid from distal end of disposable set via a syringe, do not exceed a rate of withdrawal of 100 ml/min.	• Observe the LED, on the battery housing. The LED is BLUE when the battery power is ON. • The GREEN LED, on the Heater Unit, flashes with each heating cycle. • If there is an alarm, the BLUE and RED LEDs flash alternately, respond to and correct system alarms as needed.
End of Procedure	• Clamp roller clamp on the administration set off. • Clamp the input end of disposable set off using the blue slide clamp. • Turn Heater Unit off by pressing the ON/OFF switch on the battery housing. • Open the Heater Unit and remove disposable set. • Dispose of disposable set using hospital practices for bio-hazardous materials. • Remove the battery by pushing the tab holding the battery, in the housing, up and pull battery tab. • Recharge the battery.

FLOW CHARACTERISTICS

The Belmont® buddy lite™ Blood/Fluid Warmer is designed for gravity flow. The maximum flow rates achievable will be determined by the size of the catheter employed.

The disposable has been designed to withstand up to 300 mmHg infusion pressure, provided the disposable set is within the Heater Unit and latched. The system is designed to maintain normothermic temperature at flow rates specified (50 ml/min for undiluted RBC's at 10°C, and 80 ml/min for 20° C crystalloid). However, at higher flows, the fluids administered may not heat to normothermia. **There are no adjustments for the Heater Unit.**

Pressure Drop:

The disposable and heating unit does not restrict flow. If flow appears to be restricted:

- Check the infusion site to ensure catheter has not infiltrated the surrounding tissue
- Check to make sure line is not crimped or clamped off
- Out-gassed fluids may be causing air build up in the disposable. If air restriction is suspected:
  - Detach the unit from the patient connection
  - Holding the case with the patient connection port upward, tap the case gently while allowing a few seconds of free flow to remove air. Reattach the unit to the patient with a fluid-to-fluid connection.
  - If flow continues to be restricted, replace the disposable set.

Air Venting

As fluid flows through the disposable set, it passes across microporous membranes, which can vent air from the fluid. The air is then released through the side vents of the set. **When infusing crystalloid, the set can vent large amounts of air. With blood or blood products, the set can vent only small amounts of air. CAUTION: When using blood or blood product, the Operator should be vigilant to avoid infusing air especially if using a hand squeeze pump during the infusion**. A pressure-regulating valve, incorporated into the disposable set, prevents abnormally high pressure greater than approximately 300 mmHg from reaching the set or the patient. A second valve built into the set prevents air entrainment by stopping flow if a partial vacuum is present.

During **normal operation** – water vapor, along with out-gassed air from warmed fluid, will be vented and will cause condensation to appear within the side vents after prolonged use. This should **not** be mistaken as a seal failure due to materials or workmanship.

The chart below details alarm conditions, the system response and the recommended user actions.

Probable Alarm Condition	Condition and System Response	Probable Causes	Actions
Check for Air	System detects an empty set condition, flashes the red and blue LEDs alternately, and activates audible alarm. Heater continues to function normally. System automatically resets and continues normal operation when air is cleared from the disposables.	1. Fluid source is empty or air in the fluid path. 2. Line is clamped shut.	1. If appropriate, replace fluid supply. 2. Open clamps.
No Heat	System detects no heat to the heater plates, activates audible alarm, and flashes the red and blue LEDs alternately.	Failure of the microprocessor or temperature sensor.	If failure reoccurs obtain replacement unit and contact service.
Over Temperature	System detects fluid temperature (i) Moderate to High Flow: >42.5°C for 2 min, or ≥ 48°C for 2.5 sec, or (ii) Low Flow: >42°C for 2.5 sec or ≥ 44°C for 1 sec, or (iii) Output Plate Temperature reaches 50.5°C. Stop heating, and flash red and blue LEDs alternately.	1. Repeatedly stopping and restarting during high flow conditions. 2. Failure of the microprocessor or temperature sensor.	1. Clamp line, turn unit off and re-power. 2. If failure reoccurs obtain replacement unit and contact service.
Probe Fault	Internal malfunction, at start-up.	Hardware temperature override circuit not working properly.	Turn unit off and re-power. If not successful, call service.

At these alarms, system stops heating, and flashes the red and blue LEDs alternately. To reset or retry, **press the ON/OFF switch to OFF, and then turn power to ON** to resume operation.

Chapter

3

Service and Maintenance

INTRODUCTION

The Belmont® buddy lite™ Blood/Fluid Warmer has no internal user serviceable parts, and does not require calibration except for the battery fuel gauge. Routine maintenance consists of cleaning and inspecting the Heater Unit, recharge the battery after each use, recalibrate the battery fuel gauge, and testing the system operational. The circuit diagram, component part lists, descriptions, and calibration instructions will be provided to assist service personnel in device repair. The circuit diagram, component part lists, descriptions, and calibration instructions will be provided to assist service personnel in device repair.

CAUTION

The heater plates in the Heater Unit are sealed. Inspect the seals to insure their integrity after each use. If the seal is not intact, do not use. Do not try to open or to service the Heater Unit.

WARNING

Do not submerge the buddy lite™ **system.**

ROUTINE MAINTAINENCE

Turn the ON/OFF switch to OFF.

1. **Clean and/or Disinfect Exterior:**

   A. Battery Housing

   The housing may be wiped down with water or a 10% bleach solution using a soft cloth.

   Note: Avoid the use of acetone or other solvents that may damage the surface.

   B. Heater Unit

   Wiping down the outside surfaces with a soft cloth moistened with water or a 10% bleach solution.

   Note: Avoid the use of acetone or other solvents that may damage the surface.

   Open the Heater Unit and inspect the seal around the heater plates. If the seal is intact, using a soft cloth wipe the heater plates with a 10% bleach solution and dry. If the seal around the heater plates is **not** intact, do not use and return the unit for service or replacement.

   Note: Do not use abrasive cleaners on the Heater Unit or heater plates.

WARNING
Do not submerge the Heater Unit.
Practice standard hospital policy when handling blood products. Treat blood as if it were infected and clean up all spills immediately.

2. **Visual Inspection:**

   Once the unit is cleaned, inspect all wiring and connections for fraying or worn wiring. If noted, do not use; return the unit for service. If the wear is confined to the Heater Unit, replace the heater.

3. Charging the battery:

Material required:

- Charger/Calibrator
- 24V 2.5A DC power supply with universal mains input (90 to 260 VAC)
- Mains cable

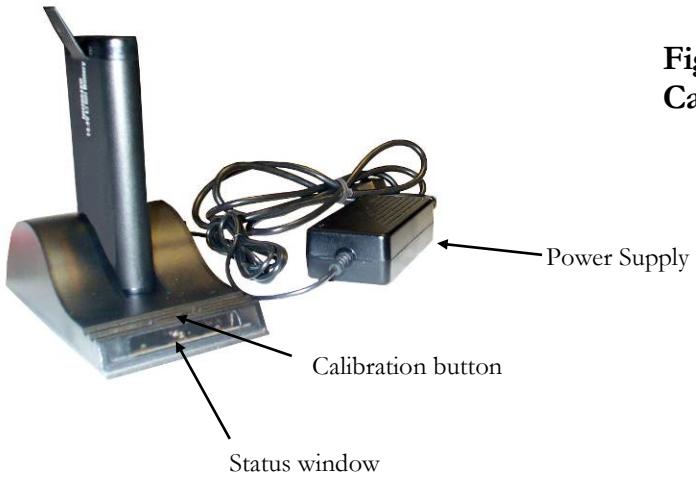


Figure 4: Battery Charger and Calibrator

Procedure:

a. Place the "Charger and Calibrator" on a flat, level surface away from sources of heat and moisture.

b. Plug the DC connector from the power supply into the back of the charger.

c. Connect the power supply to the mains AC supply.

d. Place the battery into the battery charger bay ensuring that the 5-way connector is fully seated.

e. The LEDs in the "Charger Status Window" will provide status information and the charger will automatically begin charging the battery.

<u>Charger LED Indication</u>:

Green flashing: Charging
Green solid: Fully charged
Blue flashing: In calibration mode
Blue solid: Calibrated
Red flashing: Need recalibration
Red solid: Error

Recharge Time: It will take approximately 2.5 hours from fully discharged to fully charged.

4. Recalibrate the Battery Fuel Gauge:

If the battery fuel gauge needs to be recalibrated, the red LED indicator, on the battery charger, will flash. The recalibration is used to ensure the reliability of the battery capacity.

Procedure:

a. Place the battery into the battery charger bay ensuring that the 5-way connector is fully seated.

b. Press the "Calibration button".

c. The blue LED will flash to indicate that the battery is undergoing the recalibration cycle.

d. When the blue LED is solid, the battery is fully charged and fully calibrated.

e. Remove battery from the charger bay.

SYSTEM OPERATIONAL CHECKOUT

This system operational checkout including the alarm test should be done periodically. Prior to performing the test, have the following equipment and supplies on hand:

- Saline or other crystalloid for testing
- Disposable Set
- Administration set
- Graduated cylinder and timing device for measuring flow rate

Setup:

1. Make sure the battery is fully charged.
2. Install disposable set. The Heater Unit will not close if the disposable set is not installed properly. Close and latch the case.

Connect to the Fluid bag and Administration Set:

1. Hang a fluid bag and administration set. Connect the fluid administration set to the disposable luer fitting with blue slide clamp. Connect administration set with 14 gauge catheter to the output luer fitting.
2. Open the roller clamps and prime the unit. Tap the Heater Unit while priming to expel any air bubbles that may collect in the disposable.
3. Secure the Heater Unit on the battery housing, making sure that the output of the catheter is at least 5" higher than the Heater Unit to simulate a venous pressure of approximately 10 mmHg.

Operational Test:

1. Depress the ON/OFF switch on the battery housing to turn the battery power to ON. The Blue LED should turn on and the Red LED flashes once. If not, return the Heater Unit for service.
2. Set the flow rate to approximately 80 ml/min.
3. Verify that the GREEN LED, inside the Heater Unit, flashes with each heating cycle.
4. Measure the output temperature at the end of the catheter. It should be 38° ± 2°C, with no alarm message.
5. Turn the Heater Unit off by pressing the ON/OFF switch on the battery housing. Discard the disposable set.

ELECTROMAGNETIC COMPATIBILITY

The Belmont® buddy lite is intended for use in the electromagnetic environment specified below. You should assure that it is used in such environment.

Test	Compliance	Electromagnetic environment - guidance
RF emissions, CISPR 11	Group 1, Class B	The **buddy lite** is a battery operated Blood/Fluid Warmer. RF emission is negligible at any single frequency.
RS103 Radiated E-Field Susceptibility	RS103 of MIL-STD 461F for (Aircraft Internal)	The **buddy lite** was tested and passed in accordance with the radiated susceptibility requirements to RS103 of MIL-STD 461F for Aircraft Internal applications.
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m over the frequency range of 80 MHz to 2.5 GHz	Radiated RF frequency is negligible at any single frequency.
Power Frequency Magnetic Field Immunity IEC 61000-4-8	3 A/m	If interference occurs, it may be necessary to position the buddy lite further from sources of power frequency magnetic field.

Chapter

4

Technical Specifications

DIMENSIONS	
Size	Battery Housing: 3.33" x 7.26" x 1.36" (W x L x H) Battery: 3.1" x 5.9" x 0.89" Heater Unit: 1.5" x 5.2" x 0.87"
Weight	Battery Housing : 4.4 oz Battery: 0.97 lbs Heater Unit: 3.5 oz
POWER	
Battery Nominal Voltage	14.4 VDC
Electrical Compliance	EN 60601-1, UL60601-1, CAN/CSA C22.2-No. 601.1-M90
ENVIRONMENTAL	
Operating Temperature	10° to 35°C
Relative Humidity	10% to 80% RH
Pressure	49 to 103 kPa
Storage Temperature	-10° C to 40°C
Shock and Vibration	ISTA Pre-shipment Test Procedure, Test procedure 1, 1996
Electromagnetic Compatibility	EN 60601-1-2

OPERATING PARAMETERS	
Flow Rate	Input temperature 20°C: Max 80 ml/min Input temperature 10°C: Max 50 ml/min
Output Temperature:	38° ± 2°C
Prime Volume	4 ml without tubing, 7.5 ml with valves and tubing at the input and output
OPERATING PANEL	
Control Keys **(On Battery Housing)**	**On/off** Switch – Turn battery ON/OFF
LED **(On Battery Housing)**	BLUE: Solid – Battery power is ON RED: Flashing once at start-up – Heater Unit is working RED: Flashing alternate with BLUE flashing - Alarm
LED **(On Heater Unit)**	GREEN: Flashing with each heating cycle.
SAFETY AND MONTORING	
Infusate Temperature	Heater power shut off if fluid temperature exceeds specified limits
Independent Safety Circuit	Shut off the heater if temperature exceeds a limiting value
Alarm Condition	CHECK FOR AIR NO HEAT OVER TEMPERATURE PROBE FAULT
DISPOSABLE SET	
Disposable Set	Sterile, Non-Pyrogenic Fluid Path, Single-Patient Use Only
Sterilization Method	Ethylene Oxide
Sterility Assurance Level	Greater than or equal to 10^{-6}

CLASSIFICATION	
Type of Protection Against Electrical Shock	Class II
Degree of Protection Against Electric Shock	CF defibrillator-proof
Degree of Protection Against Harmful Ingress of Water	IPX1, Drip proof
Degree of Safety in Presence of Flammable Anesthetics	Not suitable
Mode of Operation	Continuous
Medical Equipment UL 60601-1 CAN/CSA-C22.2 No. 601.1 ANSI/AAMI/ES60601-1 (2005) CAN/CSA-C22.2 No. 60601.1 (2008)	Medical – General Medical Equipment As to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA-C22.2 No. 601.1, ANSI/AAMI/ES60601-1 (2005, 3rd ed.), CAN/CSA- C22.2 No. 60601-1 (2008).
Medical Device Directive: Council Directive 93/42/EEC	Hardware: Class IIb
	Disposable Set: Class IIa

SYMBOLS AND DEFINITIONS	
Symbol	**Description**
CE 0843	Compliance to Medical Device Directive 93/42/EEC
 or 	Attention, consult accompanying documents/refer to manual
	Defibrillator-proof type CF equipment
IPX1	Protected against dripping water
SN	Serial Number
	Do not immerse into water or any other liquid
	Manufactured by
EC REP	Authorized European Representative

Chapter

5

Ordering Information

The Belmont® buddy lite™ Blood/Fluid Warmer System, European	P/N 905-00016
The Belmont® buddy lite™ Blood/Fluid Warmer System, N. America	P/N 905-00017
The Belmont® buddy lite™ Blood/Fluid Warmer System, UK	P/N 905-00018
The Belmont® buddy lite™ Blood/Fluid Warmer System, Switzerland	P/N 905-00019
The Belmont® buddy lite™ Blood/Fluid Warmer System, Netherlands	P/N 905-00029

(Battery Housing and Heater Unit plus accessory)

Disposable set	P/N 905-00010
Battery Pack	P/N 101-00029
Battery Charger, N. America	P/N 111-00026
Battery Charger, European	P/N 111-00027
Battery Charger, UK	P/N 111-00028
Power Cable/ Switzerland	P/N 118-00119

To order parts for,

The Belmont® buddy lite™ Blood/Fluid Warmer System

call or write to the following:

Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821, USA

866-663-0212 US/Canada
978-663-0212 Worldwide
www.belmontinstrument.com