Belmont Instrument Corporation

buddy™ 2

BELMONT INSTRUMENT CORPORATION

buddy™2 Blood/Fluid Warmer

Operator's Manual

CE 0843

Belmont Instrument Corp.
780 Boston Road
Billerica, MA 01821

EC REP
EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel +31(0) 70 345 8570
Fax +31(0) 70 346 7299

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

702-00211/Rev B

Table of Contents

CHAPTER 1: SYSTEM OVERVIEW

CHAPTER 2: OPERATION

CHAPTER 3: SERVICE AND MAINTENANCE

CHAPTER 4: TECHNICAL SPECIFICATIONS

CHAPTER 5: ORDERING INFORMATION

Chapter 1

System Overview

INTRODUCTION:

The Belmont® buddy™2 in-line Blood/Fluid Warmer combines advanced microprocessor technology with an efficient heating system to provide a safe and simple system for low flow fluid warming in a miniature package. The system warms blood or replacement IV fluid to physiological temperature at flow rates up to 100 ml/min (6 L/hr) for crystalloids at 20 °C and up to 50 ml/min (3 L/hr) for packed red cells at 10 °C. The heating unit is self-contained in a hard shell case that is placed near the infusion site, minimizing IV line cool down and ensuring that fluids are delivered normothermically. The IV pole-mounted power module, supplies power to the Heater Unit, and displays the output temperature and alarm messages which alert the user to abnormal conditions such as low flow, empty set, no heat, and over and under temperature. The audible alarm may be muted, but visual indications of alarm states will always be displayed.

INDICATIONS FOR USE AND CONTRAINDICATIONS

The Belmont® buddy™2 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 Power Module.

Use only with crystalloid or anticoagulated blood product.

Not for infusion of drugs

Do not use in the presence of flammable anesthetic.

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 flow rates below 100 ml/min. It is neither a resuscitation device nor a substitute for a rapid infusion system.

SYSTEM OVERVIEW

The buddy™2 Blood/Fluid Warmer complete system consists of the **Power Module (with AC/DC power supply)**, which is mounted on an IV pole, the **Heater Unit** that is placed near the patient at the infusion site, and the **disposable set**. See Figure 1.

The Power Module incorporates the power supply, display, alarm circuitry, and a magnet for storing the Heater Unit when not in use (Show in Figure 1). The bright alphanumeric display shows the output temperature of the fluid and alerts the user to alarm conditions.

The Heater Unit contains the heater plates and temperature monitoring and control system**.**

Figure 1: The buddy™2 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.

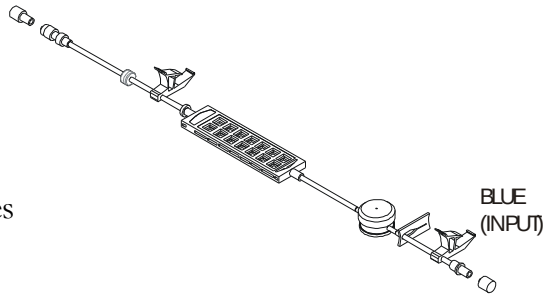


Figure 2: The buddy™ **Disposable set**

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 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 a 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 control and measure the temperature of heater plates that in turn control the temperature of the infusate. The Power Module displays the **infusate** temperature and alerts the user to alarm conditions. An over temperature condition causes the unit to stop heating and issue an audible alarm. The low temperature message (no audible alarm) informs the user that the flow rate is too rapid for the device to maintain the temperature above 31 degrees Centigrade.

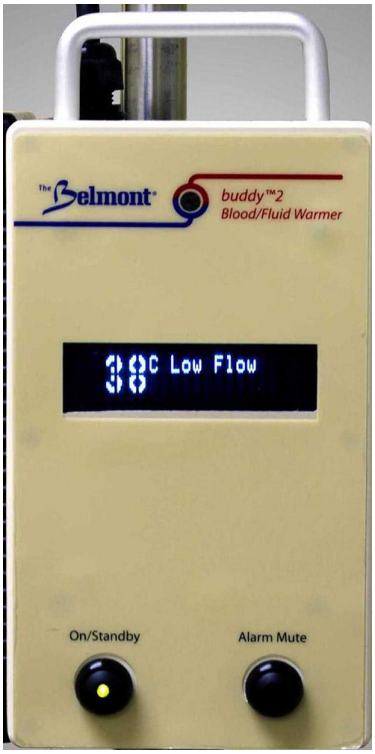
ALARMS AND ALARM MESSAGES:

Under any alarm condition, the system sounds an audible alarm, flashes a red LED, and displays an alarm message on the screen. Certain alarms, such as **Over Temperature, No Heat/Check Connection, Over Current, Probe Fault** and **System Reset** indicate system problems and are always active.

The **Empty Set/Check For Air** alarm may be enabled or disabled from the front panel. If this alarm is disabled, the message is still displayed, and the red LED is lit to alert the Operator.

CONTROL PANEL: DISPLAY AND KEYS

The Power Module of the buddy™2 Blood/Fluid Warmer is shown below:



POWER

The display is illuminated when the unit is plugged into the AC outlet.

The **ON/STANDBY** key controls power from the Power Module to the Heater Unit.

DISPLAY

The display unit shows the infusate temperature.

Under most alarm conditions the temperature display will be replaced by the alarm message. An audible alarm is activated whenever an alarm condition is detected. It can be silenced for 60 seconds by depressing the **ALARM MUTE** key.

DISABLE/ENABLE EMPTY SET/CHECK FOR AIR ALARM

If the ALARM MUTE key is depressed and held for 3 seconds at any time after power up, the **Empty Set/Check For Air** audible alarm will be **disabled** and the red LED will be illuminated. If this alarm condition occurs while the audible alarm is disabled, the red LED will flash and the alarm message will still display, but without the audible tone.

To enable the audible alarm after it has been disabled, depress and hold the ALARM MUTE key for 3 seconds. The red LED lamp within will turn off.

Depressing ALARM MUTE key when the empty set condition occurs can also disable the Empty Set/Check For Air audible alarm. Temperature is displayed on screen indicating that fluid is being heated, the red LED is lit, and the alarm message is displayed.

Chapter

2

Operation of the System

INTRODUCTION

This section reviews the set up and operation of the Belmont® buddy™2 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.

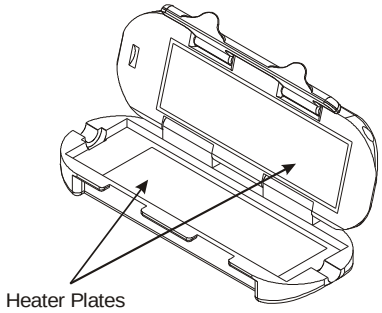
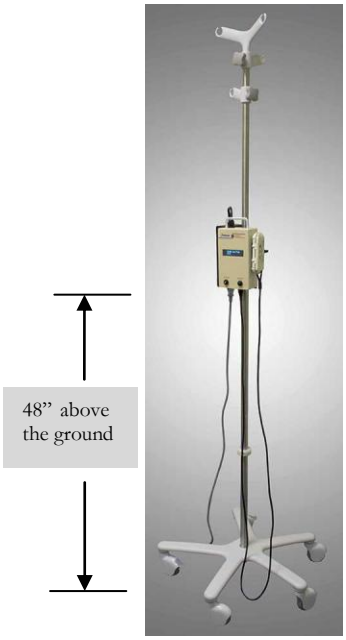
Do not use for administration of drugs, cryo-precipitate, or granulocyte suspensions.

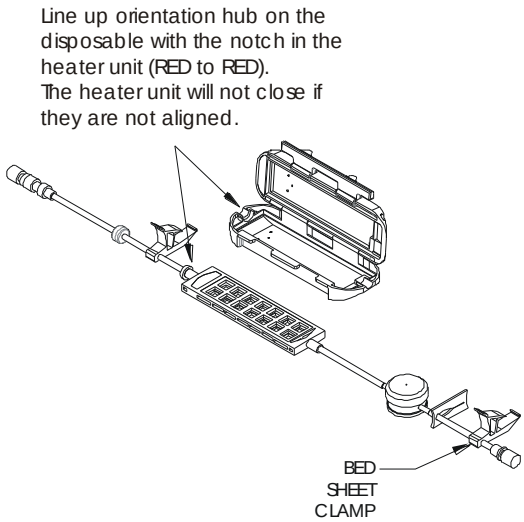
Use only anticoagulated blood products.

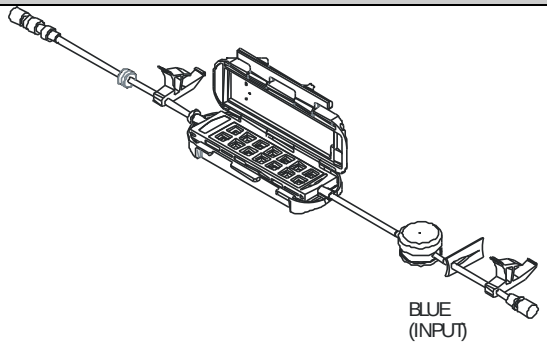
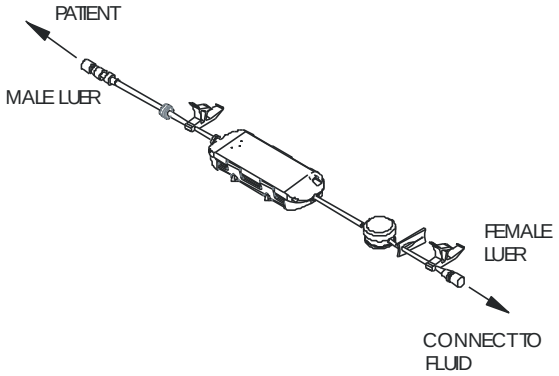
Do not mix lactated Ringer's or other solutions containing calcium with citrated blood products.

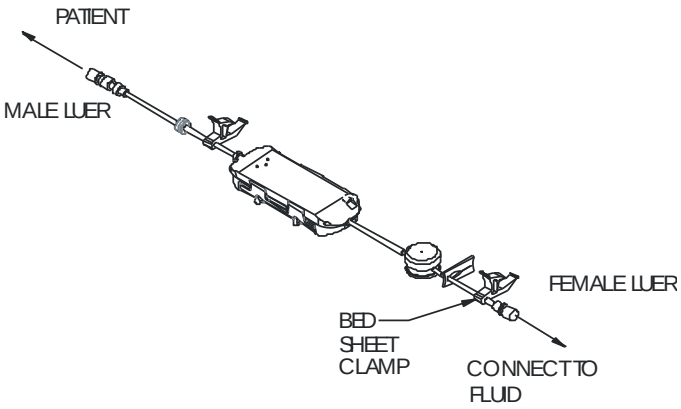
Practice standard hospital policy when handling blood products. Treat blood as if it were infected and clean up all spills immediately.

To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth.

Operating Steps	Detailed Information
Set-up  	Make sure that you have all the necessary supplies. • 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.**
IV Pole Mounting  	Mount the Power Module on the IV Pole at 48" above the ground for the operator to see and access. Open the mounting screw on the rear of the unit by turning it counter clockwise until the IV pole can be placed within the holder. Tighten the mounting screw by turning it in a clockwise direction until the unit is secured on the pole. Plug the Power Module to the wall outlet.

Operating Steps	Detailed Information
Connect Heater Unit to Power Module  	Connect the Heater Unit to the Power Module by aligning the dot on receptacle to the pointed line on the plug. To disconnect, twist the plug toward the arrow to release.
Install the Disposable Set  	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.
Establish Power to the Heater Unit	Depress ON/STANDBY button on the Power Module to supply power to the Heater Unit.

Operating Steps	Detailed Information
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 Heater Unit 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 extension is desired, it should be no longer than 6 inches for optimal thermal transfer. Use of longer extensions will result in some line cooling from heater to patient. • The preferred position is at or below the level of the insertion site.
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 power module display to ensure the unit is sensing flow and the flow is within the normothermic range, as indicated by the infusate temperature reading with no alarm message. • Respond to and correct system alarms.

Operating Steps	Detailed Information
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 ON/STANDBY button on the power module. Unplug from the wall outlet. • Open the heater unit and remove disposable set. • Dispose of disposable set using hospital practices for bio-hazardous materials.

FLOW CHARACTERISTICS

The Belmont® buddy™2 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 100 ml/min for 20ºC 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**. If the set were to become filled with air, the system will activate the EMPTY SET/CHECK FOR AIR alarm to alert the Operator to the problem. The fluid path of the set is only about 7 ml, and therefore, only a few ml of air will trigger the alarm. In addition, there is a pressure-regulating valve, incorporated into the disposable set, prevents potential air entrainment into the system by stopping fluid flow if a partial vacuum condition 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.

OPERATIONAL ALARMS AND TROUBLESHOOTING

The Belmont® buddy™2 Blood/Fluid Warmer detects and displays the following alarm conditions:

Empty Set/Check for Air
Low Flow
Low Temperature
No Heat, Check Connection
Over Current
Over Temperature
Probe Fault
System Reset

The chart below details these alarms, the system response and the recommended user actions.

Alarm Message	Condition and System Response	Probable Causes	Actions
Empty Set/Check for Air	System detects an empty set condition. Flash LED, display message, and activate audible alarm. Heater continues to function normally. Audible alarm may be disabled in advance by depressing ALARM MUTE for 3 seconds or depressing ALARM MUTE key when condition occurs. Flashing LED and message will occur at alarm condition. 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.	1. If appropriate, replace fluid supply. 2. Open clamps.
Low Flow	System automatically resets and continues normal operation when flow resumes. Display message, **no audible alarm**. Heating continues.	1. Fluid source is empty. 2. Line is clamped 3. Flow is too low to be detected. 4. Disposable has clogged and is restricting flow.	1. If appropriate, replace fluid supply. 2. Open clamps. 3. Increase flow rate until flow is detected. 4. Replace disposable.

Alarm Message	Condition and System Response	Probable Causes	Actions
Low Temperature	System detects fluid temperature below 31EC for 10 sec. Display message, **no audible alarm**. Heating continues.	Flow rate is set too fast.	Slow the flow rate using roller clamp on the administration set.
No Heat Check Connection	System detects that communication is lost between the Heater Unit and power module. Stop heating, flash LED, alarm, and display message. If connection is restored, system will resume normal operation. If not, the system turns power off and displays 'Check Connection, Press ON/STANDBY' message.	1. Cable between the Heater Unit and Power Module is disconnected or loose. 2. Wire is broken.	1. Check and secure connection between power module and Heater Unit. If this fails to rectify the problem obtain a replacement Heater Unit. 2. Replace unit.
****Over Current**	System detects short circuit in heater or heater cable. Stop heating, flash LED, alarm, and display message.	1. Heater circuit board defective. 2. Wire is broken.	1. Unplug power module from wall outlet, and re-power. 2. Call service.
****Over Temperature**	System detects fluid temperature (i) Moderate to High Flow: >42.5EC for 2 min, or ≥ 48EC for 2.5 sec, or (ii) Low Flow: >42EC for 2.5 sec or ≥ 44EC for 1 sec, or (iii) Output Plate Temperature reaches 50.5EC. Stop heating, flash LED, alarm, and display message.	1. Repeatedly stopping and restarting during high flow conditions. 2. Failure of the microprocessor or temperature sensor.	1. Clamp line, turn unit off and unplug power module from wall outlet, and re-power. 2. If failure reoccurs obtain replacement unit and contact service.
****Probe Fault**	Internal malfunction.	Hardware temperature override circuit not working properly.	Unplug power module from wall outlet, and re-power. If not successful, call service.

Alarm Message	Condition and System Response	Probable Causes	Actions
****System Reset**	Internal computer malfunction. Alarm continuously and display message.	Loose watchdog function on the Power Module Processor.	Unplug power module from wall outlet, and re-power. If not successful, call service.

**** At these four (4) alarms, system stops heating, flashes a red LED, alarms, and displays message. Unplug Power Module from wall outlet, and re-plug into the wall outlet. Press ON/STANDBY to apply power to the Heater Unit.**

1. To silence an audible alarm, depress the ALARM MUTE key. If the alarm condition persists, the audible alarm will resume after 60 seconds, except the EMPTY SET/CHECK FOR AIR alarm, which will remain disabled until air disappears and flow resumes for at least 1 minute after which it can again be activated automatically.

2. The EMPTY SET/CHECK FOR AIR audible alarm may be disabled by depressing the ALARM MUTE key for 3 seconds or depress ALARM MUTE key when this condition occurs. The red LED will be lit steadily indicating that the alarm tone has been disabled. If the Empty Set condition occurs during this time, the LED will flash and message will appear on the screen.

   To re-enable the alarm tone, depress and hold ALARM MUTE key for 3 seconds, the red LED will no longer lit indicating that normal operation with alarm tone enabled have been restored.

3. The LOW TEMPERATURE message is not an alarm condition and does not produce an alarm tone. It usually indicates that the flow rate is set too fast; reduce the flow to get rid of the message.

4. To reset the NO HEAT/CHECK CONNECTION alarm after the system turns the power off, press ON/STANDBY button on the Power Module to turn the heater ON to resume operation.

5. The following alarms indicate a probable system fault: OVER CURRENT, OVER TEMPERATURE, PROBE FAULT, and SYSTEM RESET.

   To reset or retry, remove Power Module from the wall outlet then re-connect to the wall outlet. Press ON/STANDBY key to turn the heater on to resume operation.

Chapter

3

Service and Maintenance

INTRODUCTION

The Belmont® buddy™ 2 Blood/Fluid Warmer has no user serviceable parts, and does not require calibration. Routine maintenance consists of cleaning and inspecting the Heater Unit after each use and testing the system operational and routinely test for leakage current to ensure against electrical shock hazard. The circuit diagram, component part lists, descriptions, and calibration instructions will be provided to assist service personnel in device repair.

WARNING:
Test leakage current periodically to insure against electrical shock hazard

CAUTION
Do not open the Power Module. There are no serviceable parts inside the housing. Opening the system will void the warranty.

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.

CAUTION
Check the integrity of the wires between the heater unit and power module. If there is evidence of fraying or damage do not use and return the unit for service.

ROUTINE MAINTAINENCE

Turn heater to STANDBY, unplug the power cord from the wall outlet.

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

   A. Power Module

   The Power Module may be wiped down with water or a 10% bleach solution using a soft cloth. Take particular care not to scratch the display window.

   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 submerse 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 and return the unit for service. If the wear is confined to the Heater Unit, replace the heater. All Heater Units are interchangeable with the Power Module units.

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 supplied on hand:

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

Setup:

1. Mount the Power Module on the IV Pole at a comfortable height for the operator to see and access using the mounting screw at the rear of the unit.
2. Plug the Power Module to the wall outlet.
3. Connect the Heater Unit to the Power Module by aligning the dot on receptacle to the pointed line on the plug.
4. 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 in a horizontal position, 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 ON/STANDBY button on the Power Module to supply power to the Heater Unit. Set the flow rate to approximately 80 ml/min.
2. Observe the Power Module display to ensure the unit is sensing flow and the flow is within the normothermic range, 38 ° ± 2°C, with no alarm message.
3. Briefly stop the flow by closing off the roller clamp. Verify the 'LOW FLOW message.
4. Resume flow and infuse until the fluid bag is empty. Squeeze air in the set and verify that when the disposable is filled with air, the system sounds an audible alarm with 'EMPTY SET/CHECK FOR AIR' message display on screen and the red LED flashes.
5. Turn Heater Unit off by pressing ON/STANDBY button on the Power Module. Unplug from the wall outlet and discard the disposable set.

PERIODIC MAINTENANCE

An electrical safety test should be performed at least once a year by a qualified technician. Prior to performing the electrical safety test, have the following equipment and supplied on hand:

- Electrical Safety Analyzer
- Saline or other crystalloid for testing
- Disposable Set
- Administration set

Set-Up: Plug the buddy™2 Blood/Fluid Warmer into AC outlet on the front of Safety Analyzer.

CAUTION:

Before applying voltage to Safety Analyzer, make sure input line voltage is correct for the VOLTAGE OF UNIT UNDER TEST

1. **Ground Wire leakage Current:** This leakage current is done when there is no equipotential connector on the device under test.

   a. Plug the Safety Analyzer into an appropriate power source. Turn power ON.

   b. Press ON/STANDBY key on the buddy™2 to turn the heater on.

   c. Press the **gnd leakage** key on Safety Analyzer. Do not attach the large red clamp to the device under test.

   d. The **µA**, **gnd leak**, and **open gnd** LEDs will illuminate. Record the leakage current displayed.

   e. All measurements should be < 300 µA (for Domestic unit) and < 500 µA (for 230V unit).

   f. Press ON/STANDBY key on the buddy™2 to turn the heater off.

   g. Turn the Safety Analyzer power off.

2. Patient Leakage Current

a. Install the disposable set.

b. Attach 12 to 16 gauge stainless steel catheter to the end of the disposable set tubing.

c. Install saline solution and the administration set. . Open the roller clamp and adjust for maximum flow.

d. Turn the Safety Analyzer power on.

e. Press ON/STANDBY key on the buddy™2 to turn the heater on.

f. Attach large clamp (red lead) from Safety Analyzer to the catheter.

g. Press the **chassis leak** key on Safety Analyzer.

h. The **μA** LED will illuminate. Record the leakage current displayed for each of the following conditions, with Neutral switch in NORM position.

Polarity	**Ground**	**Tolerance Limit (μA)**
NORM	NORM	<10 μA
REVERSE	NORM	<10 μA
REVERSE	OPEN	<50 μA
NORM	OPEN	<50 μA

i. Turn the Safety Analyzer power off.

j. Press ON/STANDBY key on the buddy™2 to turn the heater off. Close the roller clamp. Remove the disposable set.

k. Remove the buddy™2 from the Safety Analyzer.

ELECTROMAGNETIC COMPATIBILITY

The Belmont® buddy™2 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 **buddy2** may emit electromagnetic energy so that nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/ flicker emissions IEC 61000-3-3		
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 1 GHz	Radiated RF frequency is negligible at any single frequency.
Electric Fast Transient Burst Immunity IEC 61000-4-4	± 2kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Fast Surge Immunity IEC 61000-4-5	± 2kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
RF Common Mode Immunity IEC 61000-4-6	3 Vrms	If interference occurs, it may be necessary to position the **buddy2** further from sources of power frequency magnetic field.
Power Frequency Magnetic Field Immunity IEC 61000-4-8	3 A/m	If interference occurs, it may be necessary to position the **buddy2** further from sources of power frequency magnetic field.
Voltage Dip and Interrupt Immunity IEC 61000-4-11	> 95% dip for 0.5 cycle > 60% dip for 5 cycles > 30% dip for 25 cycles > 95% dip for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the power main interrupts, the system automatically switches to battery mode.

Chapter

4

Technical Specifications

DIMENSIONS	
Size (W x H x D)	Power Module: 4.33" x 7.48" x 2.39" AC/DC Supply: 4.25" x 8.42" x 1.85" Heater Unit: 5.1" x 0.89" x 1.7"
Weight	Power Module: 1.00 lbs AC/DC Supply: 2.65 lbs Heater Unit: 3.5 oz
POWER	
AC Input Voltage, Universal	100 V~ to 240 V~
Operating Frequency	47 to 63Hz
Maximum Power	210 VA
Ground Wire Leakage Current	<300 μA (For Domestic Unit < 500 μA (For 240 V~ Unit)
Patient Leakage Current (Open Ground)	< 50 μA
Electrical Compliance	EN 60601-1, UL60601-1, CAN/CSA C22.2-NO. 601.1-M90
Power Cord	3/18 AWG, type SJT, 3-wire grounded with hospital grade plug

ENVIRONMENTAL	
Operating Temperature	10° to 35°C
Relative Humidity	10% to 90% 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 100 ml/min Input temperature 10°C: Max 50 ml/min
Output Temperature: Input temperature 20°C: Input temperature 10°C:	100 ml/min ≥ flow ≥ 80 ml/min, 38E ∀ 2EC flow < 80 ml/min, 39E ∀ 2EC 39E ∀ 2EC
Prime Volume	4 ml without tubing, 7.5 ml with valves and tubing at the input and output
OPERATING PANEL (On Power Module)	
Control Keys	**On/Standby** Switch – Turn heater ON/OFF **Alarm Mute** – Mute an audible alarm. Hold for 2-3 seconds to disable/enable EMPTY SET/CHECK FOR AIR alarm
Display Area	2 line alphanumeric display; 0.75in x 2.75in • Infusate Temperature (°C) during normal operation • Alarm and Status Message

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
ALARMS/ALERTS	
System Status (Alert, no audible alarm)	LOW FLOW LOW TEMPERATURE
Operator Setting, User Correctable (Alarm and display message)	EMPTY SET/CHECK FOR AIR NO HEAT, CHECK CONNECTION CHECK CONNECTION, PRESS ON/STANDBY
System Failures (Alarm and display message)	OVER CURRENT OVER TEMPERATURE PROBE FAULT SYSTEM RESET
DISPOSABLE SET	
Disposable Set	Sterile, Non-Pyrogenic Fluid Path, Single-Patient Use Only, Not made with natural rubber latex
Sterilization Method	Ethylene Oxide
Sterility Assurance Level	Greater than or equal to 10^{-6}

CLASSIFICATION	
Type of Protection Against Electrical Shock	Class I
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 CLASSIFIED C UL US 49WB  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 and 2011/65/EU
	Alternating current
 or 	Attention, consult accompanying documents/refer to manual
	Defibrillator-proof type CF equipment
IPX1	Protected against dripping water
SN	Serial Number
	Class I equipment: the protection against electric shock is provided by a combination of basic insulation and the use of the EARTH connection
	Do not immerse into water or any other liquid
	Manufactured by
EC REP	Authorized European Representative

Chapter 5

Ordering Information

To order buddy System and the Disposable Set call or write the following:

Belmont Instrument Corporation
780 Boston Road
Billerica, MA 10821, USA

T: (866) 663-0212 US/Canada
T: (978) 663-0212 Worldwide
F: (978) 663.0212
Email: sales@belmontinstrument.com

REF: 905-00037 buddy™2 System, 100-240 VAC, English
REF: 905-00010 buddy Family Disposable Set