

# LMA | PerfectTemp™

PATIENT WARMING SYSTEM

## Instructions for Use



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Issue: PAY2100000c



# Instructions for Use

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Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by state law to use such a device.

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## TABLE OF CONTENTS

Section 1 - Introduction

Section 2 – System Description

Section 3 – Indications, Contraindications, Warnings and Precautions

Section 4 – Installation and Preparation for Use

Section 5 - Operation

Section 6 – Control Panel

Section 7 – Physical Appearance

Section 8 – Cleaning and Maintenance

Section 9 – Service

Section 10 - Troubleshooting

Section 11 - Appendix

Specifications

Certifications

Definition of Symbols

Electromagnetic Compatibility

Section 12 - Warranty

## SECTION 1 – INTRODUCTION

The LMA PerfectTemp™ Patient Warming System is designed to maintain body temperature perioperatively. The pad is on standby prior to the patient's arrival in the OR so that once the patient is positioned on the pad warming begins immediately.

The LMA PerfectTemp™ Patient Warming System consists of: 1) a control unit, 2) surgery table pad(s), and 3) a connection cable. The system is designed for use during surgical procedures to maintain patient normothermia 36°C/96.8°F perioperatively or during diagnostic procedures. Primary sites of usage are hospital and surgery center operating rooms. Other sites include office based surgical practices such as plastic surgery centers.

The pad provides pressure reduction and conductive heating for the patient perioperatively. Heat is provided by a unique X-ray transparent heating element. The heating element warms a layer of pressure reduction foam directly beneath the patient. A fiber optic temperature measurement system accurately measures and manages the interface temperature of the pad cover and patient skin.

A lower layer of foam of a different density, thickness and design supports patients weighing up to 500 lbs. Weight bearing limits are consistent with surgical table manufacturers' recommendations for safety weight limitations.

The combination of pressure reduction and heat is designed to maintain patient normothermia (36°C/96.8°F) and resist capillary occlusion which is a source of surgically acquired decubitus ulcers.

Safety features include: 1) automatic shut off of power to the heating element if a temperature exceeding target temperature is measured by any of the sensors positioned on the upper layer of foam beneath the outer cover. 2) Automatic power off due to improper connection of the cable or of the cable failing due to damage. The user is advised of these events via digital display in the Control Unit and audible alarm systems.

## SECTION 2 – SYSTEM DESCRIPTION

### CONTROL UNIT

The Control Unit mounts to an IV pole or like device with a screw grip clamp on the back mounting plate. The suggested best mounting position is the lower 1/3 of the IV pole for easy viewing and access by the operator. Four non-skid mounting pads are located on the base of the power unit for positioning it on the base or platform of an operating room table.

Unit and power utilization is designed for both US and worldwide use, using external power sources of either 115 VAC or 230 VAC at either 50 or 60 hertz. The unit converts external alternating current to direct current automatically.

The control panel allows the operator to select temperatures between 37°C/98.6°F to 40.5°C/105°F. The control panel has a digital display which shows the temperature measured at the interface of the pad's cover and the patient's skin with +/- .5°C/.9°F accuracy. The control panel provides both visual and audible alarms in an unsafe event. An audible alarm requires the operator to actively mute the alarm during an over temperature event (i.e. a temperature above 42°C/107.7°F).

### PATIENT CABLE

A cable with connectors at each end is required to connect the Control Unit to the Warming Pad. Cable connections are bi-directional, i.e. capable of connecting to either the Warming Pad or Control Unit. Cable length is 12' / 3.67m to allow flexibility in positioning the unit within the surgery table area.

### POWER CORD

A (10' / 3.05m) hospital grade power cord is provided to connect the Control Unit to the wall power source.

### THE WARMING PAD

The Warming Pad is constructed to match operating room table dimensions.

Each pad is designed with a layer of visco-elastic foam designed to provide pressure reduction and reduce the incidence of decubitus ulcers (pressure sores). Within each Warming Pad is a heating element designed for even heating and X-ray translucency to complement the use of an X-ray device during a surgical procedure. Not all pads are heated. Pads with a heating element will be the torso or middle pad. Foot pads, arm board pads and head pads are not heated.

### FIBER OPTIC TEMPERATURE MANAGEMENT SYSTEM (FTMS)

Each Warming Pad contains a fiber optic temperature management system (FTMS) which measures the interface temperature of the patient skin and the pad cover at multiple locations and is X-ray translucent.

## SECTION 3 – INDICATIONS, CONTRAINDICATIONS AND WARNINGS

### INDICATIONS

The LMA PerfectTemp™ Patient Warming System is intended to aid in the maintenance of patient normothermia before, during and after the perioperative experience for pediatric and adult patients. Conductive warming temperatures for the patient are selected by physicians or according to facility hypothermia protocol. Pressure reduction is achieved within the pad design. The pad design can support patients weighing up to 500lbs.

### CONTRAINDICATIONS

Do not use the LMA PerfectTemp™ Patient Warming System during procedures that require patient hypothermia.

### WARNINGS

Use of the LMA PerfectTemp™ Patient Warming System in combination with other conductive or convective heat sources may cause thermal injury.

Thermal injury may occur if heat is applied to ischemic limbs. Place the Control Unit on Standby when an aortic cross clamp or an intra-aortic balloon pump is in use.

The LMA PerfectTemp™ Patient Warming System is designed to operate with specified LMA PerfectTemp™ components only. Connection and use of other products may cause thermal injury or equipment malfunction.

Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.

**EXPLOSION HAZARD:** There is an explosive risk if used with flammable anesthetics.

### PRECAUTIONS

Verify the patient warming system is free from damage before use. Inspect the pad(s) for punctures, holes or other damage that expose inner components. Do not use if damage is observed.

Do not use unless the Control Unit is placed on a hard, flat surface or securely mounted on an IV pole. Otherwise, injury may result.

Monitor the patient's temperature and vital signs according to institutional protocol. Adjust temperature settings or discontinue use if vital sign instability occurs.

Electrical shock hazard. Do not disassemble any component of the LMA PerfectTemp™ patient warming system unless you are a qualified service technician. There are electrically live parts when the Control Unit is connected to a power source, even when the unit is in Standby mode.

Accessory equipment connected to the interfaces must be certified to the respective standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Anyone who connects additional equipment to the ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standard. If in doubt, consult your biomedical department.

Grounding reliability can only be achieved when the power cord is connected to a Hospital Grade power receptacle.

The LMA PerfectTemp™ Patient Warming System meets electromagnetic compatibility requirements of EN 60601-1-2. It will not cause interference to other electronic devices when in operation. Do not subject the system to use in environments with equipment not complying with this standard. Doing so may cause the system to malfunction.

Do not fold or bend the heating pad as damage to the fiber optic temperature system can occur.

Care should be taken with patients having alcohol based skin preparation solutions. Ensure the solution is completely dry prior to use of the Patient Warming System.

## SECTION 4 – INSTALLATION AND PREPARATION FOR USE

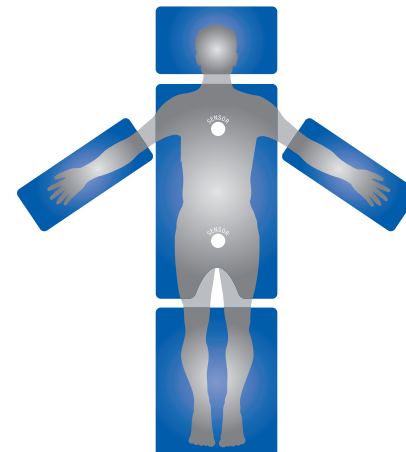
### INITIAL INSTALLATION

1. Unplug the unit from the power source.
2. Insert a flat-headed screwdriver into the slot on the PEM.
3. Insert fuse holder with the appropriate voltage displayed through the window of the PEM.
4. The power cord may need to be changed to mate with the appropriate 230 VAC or 115 VAC socket.

1. Position and align the pad Velcro® strips with the Velcro® adhesive strips on the OR table. In most applications the Warming Pad is placed so the cable connection site is at the head of the table.
  2. A standard hospital sheet should be used to drape the pad(s) during use.
  3. Position the Control Unit on an IV pole or flat surface. Tighten the IV clamp for firm positioning when mounting to an IV pole.
  4. Connect the Control Unit to an AC power source with the provided power cord. Secure the cord with the provided retaining clip.
  5. Connect the Patient Cable to the side of the Control Unit marked “Pad Connection Only” and the other end of the cable to the pad.
  6. Position the rocker power switch on the back of the unit to the ON position.
  7. Press the Power button on the keypad.
  8. The digital display will exhibit an initial message: LMA PerfectTemp™ and default to Standby.
- Note: The system is designed to operate continuously. The system controls power usage and output both when a patient is laying on the pad and when no patient is present.
- When a patient is not on the pad, normal operation is a temperature of 26°/79° with a digital message “Warming”. When a patient is on the pad or insulation material is placed on the pad, the digital display temperature will increase as the thermal interface of the surface rises in temperature. Within 15 to 30 minutes the temperature will reach 37° / 98.6°.

## SECTION 5 – OPERATION

1. For best results, turn on the LMA PerfectTemp™ Patient Warming System by pressing the On/Standby button on the control panel at least 30 minutes in advance of use. This will ensure that the heating element has fully warmed up prior to use.
2. Place the patient on the pad in accordance with physician preference and protocol for the type of surgical procedure to be performed. Follow anesthetic and surgical protocol regarding the use of restraints. Reduce / remove layers of linen, patient sliders, gel pads and foam topical surfaces that interfere with transmission of heat to the patient. In the event that an additional layer needs to be between the patient and the pad, arrange the heated pad on the table so that it maintains direct contact with the patient.
3. Be sure that the patient’s body covers at least one of the sensor locations, which are marked by a circle that says “Sensor”. When used with an average or larger sized adult patient in a prone position, the patient’s body will



typically cover both sensors. For very small patients or patients placed in unusual configurations, it may be necessary to ensure that the patient is covering a sensor after placing the patient on the pad.

4. Select the desired maximum temperature by pressing either the **UP** or the **DOWN** arrow until the desired target maximum temperature is displayed. User selectable temperatures are 37°/98.6°, 38°/100.4°, 39°/102.2°, 40°/104° and 40.5°/105°.
- Note:** Temperatures above 41°/106° are unsafe temperatures for patients with circulatory complications. Temperatures above these ranges are prohibited by safety standards and patient care protocols.
5. The digital display will change from **Warming** to **Normal** when above 32°/90°.

**Warming Time** – When the device is active, the LMA PerfectTemp™ Patient Warming System begins warming the patient immediately upon the patient being placed on the pad. Once on the pad, the temperature at the interface between the patient’s skin and the LMA PerfectTemp™ pad will typically reach 37°/98.6° within 15 to 30 minutes.

**Temperature Display** – The temperature display shows the selected target temperature. The temperature at the interface between the patient’s skin and the LMA PerfectTemp-pad can be seen by pressing the Inquiry Button.

**Error codes** – In the event of an error a visible

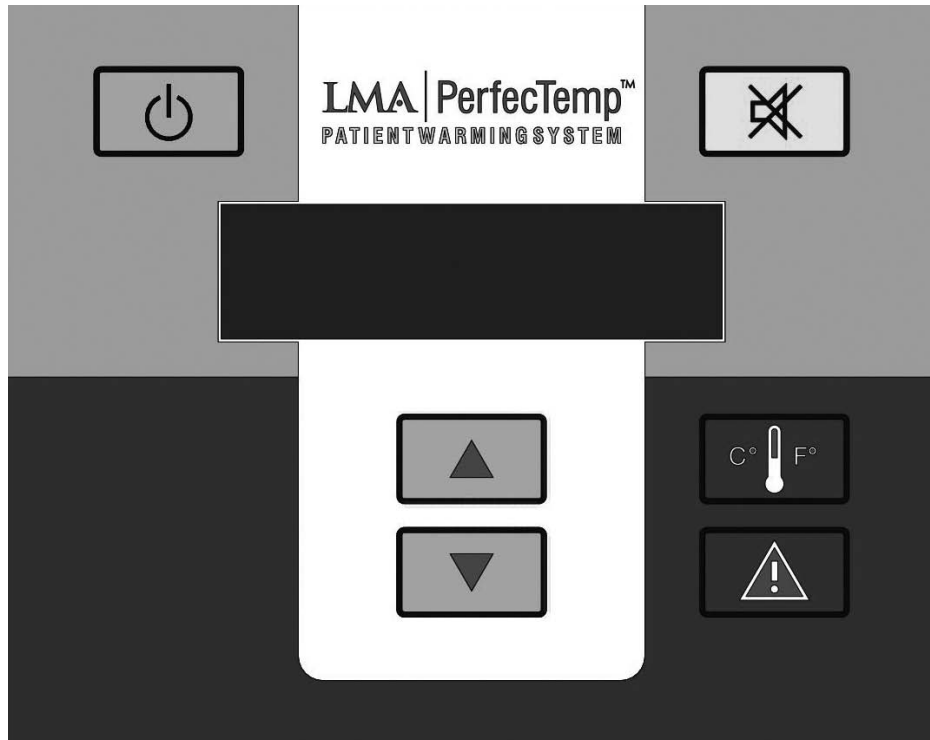
## SECTION 5 – OPERATION

and audible alarm will advise the operator of a failure. Press the Inquiry Button and read the error code message. The most common error code will be cable failure or damage.

**Note:** When the unit is disconnected from the external source and then reconnected the Control Unit defaults to **Standby**. Upon pressing the **ON/Standby** button the unit will always default to the lowest setting and exhibit Fahrenheit temperatures.

**Power** – Always use LMA PerfectTemp™ power cords. The connection cable between the pad and control unit should be in good working order. Cables with cuts, exposed wires or error messages for failed connection should be replaced with the LMA PerfectTemp™ designated cables.

**X-rays** – Buss bars that extend the length of the pad have been designed and positioned on the pad's outer perimeter so as not to interfere with X-ray procedures. These buss bars will be visible on the X-ray. All other aspects of the pad are designed to be X-ray translucent.



## SECTION 6 – CONTROL PANEL

**Standby** in the message window indicates power is on and temperature management is operational. In Standby mode no power is being delivered to the pad for warming.

The **Digital Temperature Display** reports the selected target temperature of the system. Temperatures are reported in either Centigrade or Fahrenheit. The digital display displays SYSTEM NORMAL during normal operation. ERROR is displayed in the event of a malfunction, failure to connect the patient cable correctly, over temperature events or other events that occur during the use of the product. The digital display will offer remedies to ERROR codes.

The **Up/Down arrows** allow the operator to select a desired target temperature for the patient. The highest temperature setting is 40.5°C/105°F. The lowest temperature setting is 37°C/98.6°F. The temperature setting will be shown on the digital display.

The **Inquiry Button** is selected when an ERROR or OVER TEMP message occurs. A message will advise the operator of solutions for ERROR or OVER TEMP. When the Inquiry Button is selected during NORMAL operation the Digital Temperature Display reports the single highest temperature of any sensor reading from multiple temperature sensors in the pad. This single highest temperature is utilized by the unit as the master temperature. Temperatures are reported and measured in tenths of a degree, in either Centigrade or Fahrenheit.

The **F/C selection button** allows selection of either Centigrade or Fahrenheit units of temperature measurement.

An **Over Temp event** will occur when the interface temperature is higher than 42°C/107.7°F. A flashing **Over Temp** message occurs in the digital display and power ceases to the heating element. All safety functions remain active and the unit will not resume heating until the monitoring system records a return to target temperature.

Pressing the **Alarm Mute** button silences alarms during error codes or fault events. An audible alarm occurs after a failure or Over Temp event has been detected. The Alarm Mute will remain active for 10 minutes, and then the alarm will restart if the alarm condition remains.

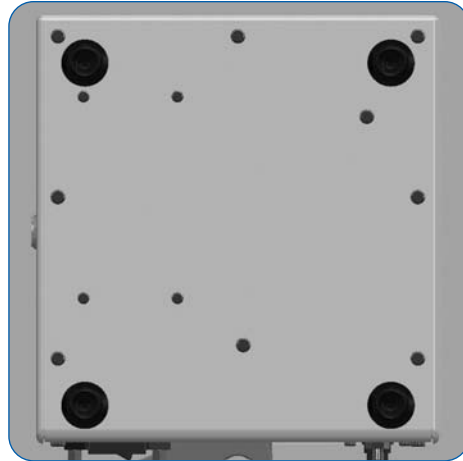
A standard USB **Data Port** is located on the rear of the unit and allows selection of additional features or output of operational information. Each unit comes with system software.

Refer to the software documentation for instructions and features.

## SECTION 7 – PHYSICAL APPEARANCE AND ORIENTATION



**Chassis Left** – Connection port for the patient cable from power unit to pad, multi-pin (6) connector of large diameter for power and data exchange. Labeled **PAD CONNECTION ONLY**.



**Chassis Bottom** – Four (4) grommets located on the bottom to function as non-skid mounting pads for units placed on flat surfaces and not IV pole mounted.



**Chassis Rear** – Position of IV pole mounting clamp. Location of the wall power plug, 60601 approved, 3 prong hospital plug.

Data Port allows operator or biomedical staff to program and/or download data from the controller, set the time, set automatic start-up time, and download temperature history. Staff must install the LMA PerfectTemp™ utility application on a Microsoft Windows computer and connect the computer to the data port using a USB cable. Labeled: **Data Port**

**Fuses**

Pad fuse (1) 2.0A, 250V time delay glass fuse

**Equipotential plug**

Unit serial number identity, manufacturer's contact information

Safety compliance markings

## SECTION 8 – GENERAL MAINTENANCE

### CLEANING

#### Warnings

- Do not expose equipment to steam sterilization. Heat and moisture will damage the components and equipment malfunction will occur.
- Do not immerse equipment in cleaning solutions. Moisture will damage the components and equipment malfunction can occur.

#### Precautions

- Do not use a dripping wet cloth to wipe down the equipment. Moisture may seep into the electrical contacts and damage the components.
- Do not use undiluted alcohol or other solvents to clean the equipment. Solvents may damage the markings or other plastic parts.

#### Method

1. Disconnect from power source before cleaning.
2. Wipe all surfaces with a damp, soft cloth and a mild detergent or anti-microbial solution following facility protocol and standard practice for the cleaning of equipment, pad/mattress in the surgical environment. Comply with manufacturer's guidelines for the dilution of all cleaning agents.

Users should not use cleaning methods different from those recommended by the equipment manufacturer without first checking that the proposed methods will not damage the equipment.

### MAINTENANCE

**Patient Cable and Power cord** – Visually check the patient cable and power cord for damage. Replacement cables and power cords are available. Refer to section 9.

**Calibration** – The patient warming system is factory calibrated and does not require periodic re-calibration after it is put into service.

## SECTION 9 – SERVICE

### READ BEFORE SERVICING THE EQUIPMENT

All repair and servicing of the LMA PerfectTemp™ Patient Warming System requires the skill of a qualified, medical equipment service technician who is familiar with good practice for medical device repair. If service does not require the manufacturer's attention, this manual provides the technical information needed to service the unit, or the manufacturer will provide that information on request. Perform all repairs and maintenance in accordance with the instructions in this manual.

The manufacturer assumes no responsibility for the reliability, performance or safety of the Patient Warming System if the following events occur:

- Modifications or repairs are performed by non-LMA qualified personnel.
- The unit is used in a manner other than described in this manual.
- The unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.

### FAULT CONDITIONS

The LMA PerfectTemp™ Patient Warming System's software recognizes several nonhazardous fault conditions including:

- No Pad Heat
- No Temperature Data

### FUSES

Replace pad fuse with a 2.0A, 250V time delay glass tube, such as Cooper Bussmann MDL-2. Pad fuses can be replaced by unscrewing a fuse holder at the back of the Control Unit.

Replace power entry module fuses with a 2.0A, 250V time delay glass tubes, such as an Interpower 813MSL-2. Power entry module fuses can be replaced by flipping down the fuse cover and removing the fuse holder with a flat-head screw driver.

**Call your local LMA representative to obtain return authorization for any service or repair.**

## SECTION 10 – TROUBLESHOOTING

### THE SYSTEM DISPLAYS “OVER TEMP”

- Is there something between the patient and the warming portion of the pad other than a sheet? The use of additional barriers, such as gel pads, positioning devices or patient transporters between the pad and the patient is not recommended. If possible, remove the additional layer or move it so that it is not directly between the patient and the temperature sensor. If the barrier cannot be removed, press the mute button to quiet the alarm until the temperature is less than 42°C/107.7°F. If the temperature does not decline within 30 minutes, discontinue use.
- Is the patient of bariatric size? Reduce the temperature setting and monitor the temperature display. If the temperature remains above 42°C/107.7°F, discontinue use. Exceeding 500lbs/225 Kg is not recommended.

### THE SYSTEM DOES NOT WARM

- Ensure that the system is turned on (not in standby mode). To verify this check the display for a temperature setting. If a number is displayed then the system is on.
- Is the patient positioned over at least one of the marked sensor locations?
- Is there something between the patient and the warming portion of the pad other than a sheet? The use of additional barriers, such as gel pads or patient transporters, between the pad and the patient is not recommended. If possible, remove the additional layer or move it so that it is on a non-warming portion of the system.
- Adjust the temperature to a higher setting by pressing the ▲ button.

### THE SYSTEM DISPLAYS “NO TEMP DATA”

- Disconnect the patient cable from the pad and the controller. Count to 5 and reconnect the cable, ensuring that a proper connection has been made.

## SECTION 11 – APPENDIX

### SPECIFICATIONS

PHYSICAL	
Dimension of Control Unit	7.5"/19cm W x 8"/20.3cm L x 11.5"/29.2cm H slanting (30°) to 7.5" / 19cm H
Weight of Control Unit	8.8lbs/ 4 kg
Dimensions and weight of Warming pads	See website for product details
Control unit mounting	Can be clamped to an IV pole or placed onto a hard, flat surface

TEMPERATURE CHARACTERISTICS	
Operating Environment (non-condensing)	Temperature: 55°/12.7° – 80°/26.7° Relative Humidity: 5 – 95%
Transport/Storage (non-condensing)	Temperature: -18°/-28° – 120°/49° Relative Humidity: 5 – 95%
Operating Temperatures	98.6°/37° – 104.9°/40.5°
























SAFETY SYSTEM	
Alarm system	Over temperature: Display flashes over-temperature, alarm sounds, heating element shuts down Fault: Display flashes fault, alarm sounds
Over current protection	Fused lines

ELECTRICAL CHARACTERISTICS	
Classification	Class I Equipment
Protection against electrical shock	Type BF applied part
Mode of Operation	Continuous Operation
Input Voltage	115~240 VAC, 50~60 Hz
Output Voltage	48 VDC
Power Cord	10' / 3.05m 18/3 SJT, 10 Amp
Fuses	2.0 A, 250V
Diagnostics	Fault code trouble shooting

Conforms with IEC 60601-1, UL 60601-1, CAN/CSA 22.2 No. 601, EN 60601-2-35, IEC 60601-1-2

### Definition of Symbols

The following symbols may appear on the product's labeling or exterior packaging:

-  Read instructions before use
-  Latex Free
-  Keep dry
-  Store in this position, keep upright
-  Product code
-  Lot number
-  Serial Number
-  Alternating current. This symbol indicates that the equipment requires alternating current input.
-  On / Standby. This symbol indicates that the power line switch is in STANDBY.
-  On (used on isolation switch)
-  Off (used on isolation switch)
-  Equipotential plug (ground)
-  Fuse
-  Nonexplosion proof
-  Dangerous voltage
-  Type BF equipment (applied part)
-  Storage Temperature Range is -18° to 120°
-  Transport Temperature Range is -28° to 49°
-  Relative Humidity Range (non-condensing) is 5% to 95%
-  Keep out of direct sunlight
-  CE Mark
-  Date of manufacture
-  IPX2 Protected against vertically-falling water drops when ENCLOSURE tilted upto 15°

## SECTION 11 – APPENDIX

### ELECTROMAGNETIC COMPATIBILITY

#### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The LMA PerfectTemp™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal functions. 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 system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Current Harmonics IEC 61000-3-2	Class A	
Voltage Fluctuation IEC 61000-3-3	Complies	

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### ELECTROMAGNETIC COMPATIBILITY (CONTINUED)

#### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The LMA PerfectTemp™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure 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	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.  At ± 6kV, contact discharge causes the control unit to power down. Operator action is required to put the control unit back into running mode.
Electrical fast transient/burst IEC 61000-4-4	± 1kV for power supply lines ± 0.5kV for input/output lines	± 1kV for power supply lines ± 0.5kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode ± 2kV 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	100% dip in $U_T$ for 10ms 60% dip in $U_T$ for 100ms 30% dip in $U_T$ for 500ms >95% dip in $U_T$ for 5S	100% dip in $U_T$ for 10ms 60% dip in $U_T$ for 100ms 30% dip in $U_T$ for 500ms >95% dip in $U_T$ for 5S	Mains power quality should be that of a typical commercial or hospital environment. At >95% dip in $U_T$ , interrupt causes the control unit to power down. Operator action is required to put the control unit back into running mode.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3A/m	3A/m	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	

NOTE:  $U_T$  is the a.c. mains voltage prior to application of the test level.



