WarmTouch®
Patient Warming System

Model WT-5300A Patient Warming System

Operator's Manual

To obtain warranty information contact your local Nellcor representative.

Table of Contents

Safety Information

Overview

This manual contains information for using the WarmTouch™ Model WT-5300A patient warming system. Before operating the warming system, thoroughly read the *Operator's Manual*. The latest version of this manual is available on the Internet at:

http://www.nellcor.com/serv/manuals.aspx

Safety Information

This section contains safety information requiring users to exercise appropriate caution while using the warming system.

The WARNING symbol identifies warnings.

Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.

The CAUTION symbol identifies cautions.

Cautions alert the user to exercise care necessary for the safe and effective use of the warming system.

The NOTE symbol identifies notes.

Notes contain important information that may otherwise be overlooked or missed.

Warnings

WARNING

Possible explosion hazard. Do not use this device in the presence of flammable anesthetics.

WARNING

Possible electrical shock hazard. To reduce the risk of electrical shock do not remove the back case. Servicing is only to be done by qualified personnel.

WARNING

Possible electric shock hazard. Grounding reliability can be achieved only when the warming system is connected to a suitable mains outlet.

WARNING

Possible fire hazard. Prevent the blanket material from coming into contact with a laser or an electrosurgical active electrode; rapid combustion could result.

WARNING

Possible burn hazard. Do not apply heat directly to open wounds. All patient's wounds should be covered while using the warming system.

WARNING

Possible patient burns. Use caution and consider discontinuing use on patients during vascular surgery when an artery to an extremity is clamped. Do not apply the warming system to ischemic limbs.

WARNING

Possible patient burns. Use caution and monitor closely if used on patients with severe peripheral vascular disease.

WARNING

If a malfunction occurs in the warming system, discontinue use. Notify your sales/service center of the malfunction. The unit must be serviced by an authorized service technician.

WARNING

No free-hosing. Keep hose nozzle connected to a WarmTouch™ blanket at all times or thermal injury may occur.

WARNING

WarmTouch™ CareDrape™ and CareQuilt™ blankets are for single patient use only.

WARNING

The warming system should not be operated in the presence of electromagnetic fields that are greater than 3 volts/meter. This could cause shutdown of the warming system by the fail-safe function within the equipment.

WARNING

The warming system is not suitable for use during magnetic resonance imaging (MRI) scanning. The warming system may affect the MRI image.

WARNING

Continuously monitor the patient's temperature. Reduce the air temperature or discontinue therapy when normothermia is reached.

WARNING

The patient must be closely monitored for rewarming. Vasodilation and possible hypotension can occur. Use good judgment when selecting a temperature. If unsure of proper setting, consult with the attending physician.

WARNING

The use of accessories and power cables other than those specified may result in increased emission and/or decreased immunity of the warming system.

WARNING

Thermal injury may occur if the warming system hose comes into contact with the patient.

WARNING

Using the warming system on transdermal medication patches may increase the rate of drug delivery, potentially causing harm to the patient.

Cautions

Caution

Federal (U.S.A.) law restricts the use of the warming system to sale by or on the order of a physician.

Caution

The warming system is fitted with an air filter; however, airborne contamination should be considered when using the warming system.

Caution

If the warming system is mounted on the intravenous (IV) pole, it should be installed with the top of the unit's handle less than 76 cm (30 inches) above the floor to prevent the IV pole from tipping over.

Caution

If a malfunction occurs in the warming system, discontinue use. Notify your sales/service center of the malfunction. Service is only to be done by qualified personnel.

Caution

The institution should follow local governing ordinances and recycling instructions regarding disposal or recycling of filter and device components or end of life of the product.

Caution

The HEPA filter **must** be changed every 2,000 hours of operation. Refer to the *Routine Maintenance* section in the *Service Manual f*or replacement procedures requiring a qualified technician.

Caution

Do not spray, pour, or spill any liquid on the warming system, its accessories, connectors, switches, or openings in the case.

Caution

Ensure that the patient is dry or the warming system may be ineffective.

Introduction

Overview

This chapter provides an introduction to the WarmTouch™ Model WT-5300A patient warming system.

Intended Use

The WarmTouch™ Model WT-5300A patient warming system (warming unit and blanket) is intended for prevention and treatment of hypothermia. For example, with the surgical patient, the patient in the preoperative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable in the cold critical care environment.

Manual Availability

The most recent revision of this manual is available on the Internet at:

http://www.nellcor.com/serv/manuals.aspx

Background Information

There are numerous ways of warming your patient, from cotton blankets to water mattresses. Research has shown that low temperatures surrounding the patient are a major factor contributing to hypothermia.[1, 2] The warming system covers the patient with warm air and actively transfers heat across the skin. The result is to achieve normothermia.

---

1 Morris RH, Wilkey BR. "The Effects of the Ambient Temperature on Patient Temperature During Surgery Not Involving Body Cavities." *Anesthesiology* 32:102-107, 1970.

2 Morris RH. "Influence of Ambient Temperature on Patient Temperature During Intra-abdominal Surgery." *Annals of Surgery* 173:230-233, 1971.

In creating this warm customized pocket of air around the hypothermic patient, it is important to note that stagnant air, even if it is warm, does not work as an effective heat transfer medium. Stagnant air acts as an insulator, preventing the boundary layer of molecules next to the skin surface from transferring heat.

Forced air warming causes warmed air molecules to flow over cooler skin surface. It is this active flow of warmed molecules that acts as a heat transfer medium. With the warming system, air is warmed and delivered into a lightweight blanket (CareQuilt™ or CareDrape™ blanket) that rests over or under the patient. The CareQuilt™ and CareDrape™ blankets have many small perforations on the underside that allow air to exit the blanket and surround the patient.

Safety Features

The warming system is designed to give healthcare professionals more control over the patient's core body temperature. There are several safety features of the warming system which make it safe and appropriate for such use.

Customized Warming Therapy

Clinicians select a temperature range setting at the onset of warming therapy to help ensure the appropriate setting is selected for every patient.

Automatic Temperature Stepdown

The warming system provides a 45-minute temperature stepdown feature. When in Boost Mode, blower temperature will automatically drop to the high temperature setting after each 45 minutes of use. The temperature may be reset to Boost Mode by selecting the boost temperature setting on the control panel to start another 45-minute cycle.

Automatic Over Temperature Shutdown

The automatic temperature controller and two back-up systems help ensure the temperature will not reach excessive levels. If necessary, the control system automatically turns off the heater element when the blower outlet temperature rises to between 47°C and 50°C, illuminates the warning light, and sounds an audible alarm. The warming system heater will start producing heat when the

warming system temperature drops to between approximately 34°C and 37°C. A yellow warning light illuminates whenever the control system identifies an over-temperature condition.

Alarms

The WarmTouch control circuit manages and monitors operation of the patient warming system. Should the control circuit encounter a failure condition, it reports failures using both visual and audible alarms. The visual alarm is a yellow warning indicator on the control panel that lights at power on, upon power restoration following power failure, and whenever the control system identifies an alarm condition. The audible alarm sounds intermittently or continuously, depending on the alarm condition. In either case, investigate immediately.

The WarmTouch control circuit recognizes two failure conditions.

1. **Power On/Power Fail Alarm** — This condition causes an intermittent audible alarm and continuous visual alarm. It appears at power on and after power failure, indicating the operator must select the desired temperature. Upon selection of a temperature key, the system cancels the alarm and the blower operates at the desired temperature.
2. **Over-temperature Alarm** — This condition causes a continuous audible alarm and a flashing visual alarm. It appears when reaching the temperature safety limit, and the control system turns off the heater. Once the system air temperature returns to a safe operating temperature of between 34°C and 37°C, the heater will turn back on.

   If the control system determines the heater again exceeds the safety limit, the warming system alarms once more. Take the warming system out of service for repair by a qualified service technician.

   If a power failure occurs while the warming system is in the over-temperature fault condition, and the warming system is still in the over-temperature fault condition when power is restored, continuous audible and visual alarms will activate. In this instance, the over-temperature fault cannot be cleared. Take the warming system out of service for repair by a qualified service technician.

HEPA Filter

Caution

The HEPA filter **must** be changed every 2,000 hours of operation. Refer to the *Routine Maintenance* section in the *Service Manual* for replacement procedures requiring a qualified technician.

The system's High Efficiency Particulate Air Filter is 99.97% efficient at 0.3-micron particle size.

Wheel Locks

The cart is equipped with two wheel locks. The wheel locks prevent the cart from moving while in use. The wheel locks must be released when moving the cart. Press the wheel lock arm down to lock the wheel. Lift the wheel lock arm to release the wheel lock.

Figure 1. Cart Wheel Lock

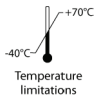
Symbols

The symbols identified are symbols used on the warming system and warming system labeling.

Table 1. Symbols on the Warming Unit

	Attention symbol, consult accompanying documentation
	Do not direct air from the hose to the patient (free-hosing); use hose only with warming blankets.
	Dangerous voltage
	Protection Class I Protection Type BF
	Date of manufacture
	Visual and audible alert

Table 2. Symbols on the Warming Unit Shipping Label

	Keep away from sunlight
	Keep upright, this side up
	Fragile
	Keep dry
	Relative humidity limitations: 15% to 95%
	Temperature limitations: -40°C to +70°C
SN	Serial Number
REF	Reference Code

Description of the Warming System

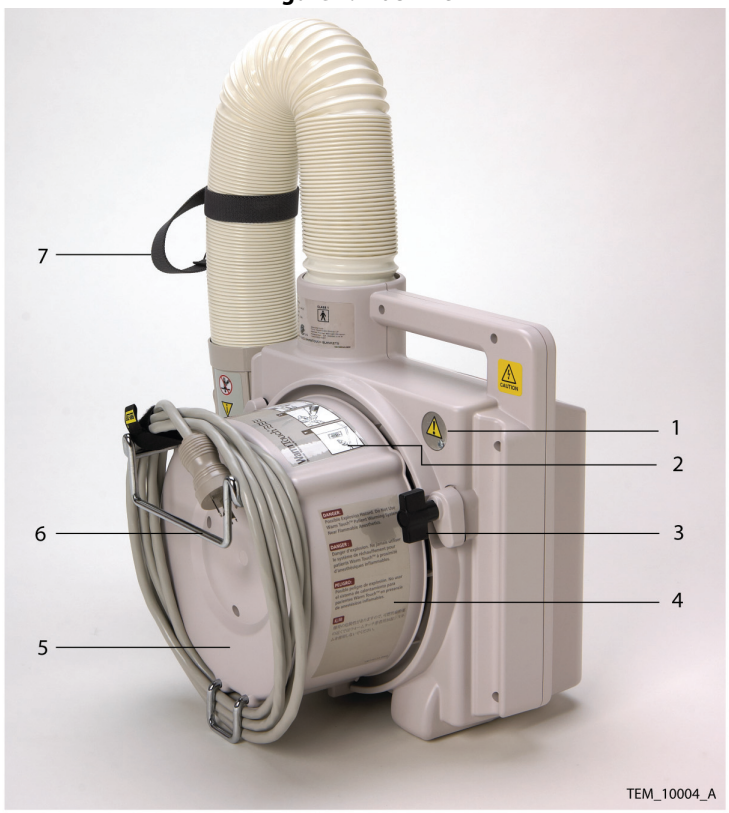
The warming system CareQuilt™ and CareDrape™ blankets are intended for prevention and treatment of hypothermia. For example, use the warming system with the surgical patient, the patient in the preoperative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable in the cold critical care environment.

Figure 2. Front View

1 — Hose
2 — Main Power Switch
3 — Nozzle
4 — Power Cord
5 — Hour Meter
6 — Control Panel

Figure 3. Control Panel Warning Indicator and Temperature Selection Keys

Figure 4. Back View



1 — Over-Temperature Test Port
2 — Instruction Label
3 — Blower Cart Clamp
4 — Warning Label
5 — Filter Cover
6 — Bed Hook Bracket
7 — Nozzle Strap with Clip

Installation

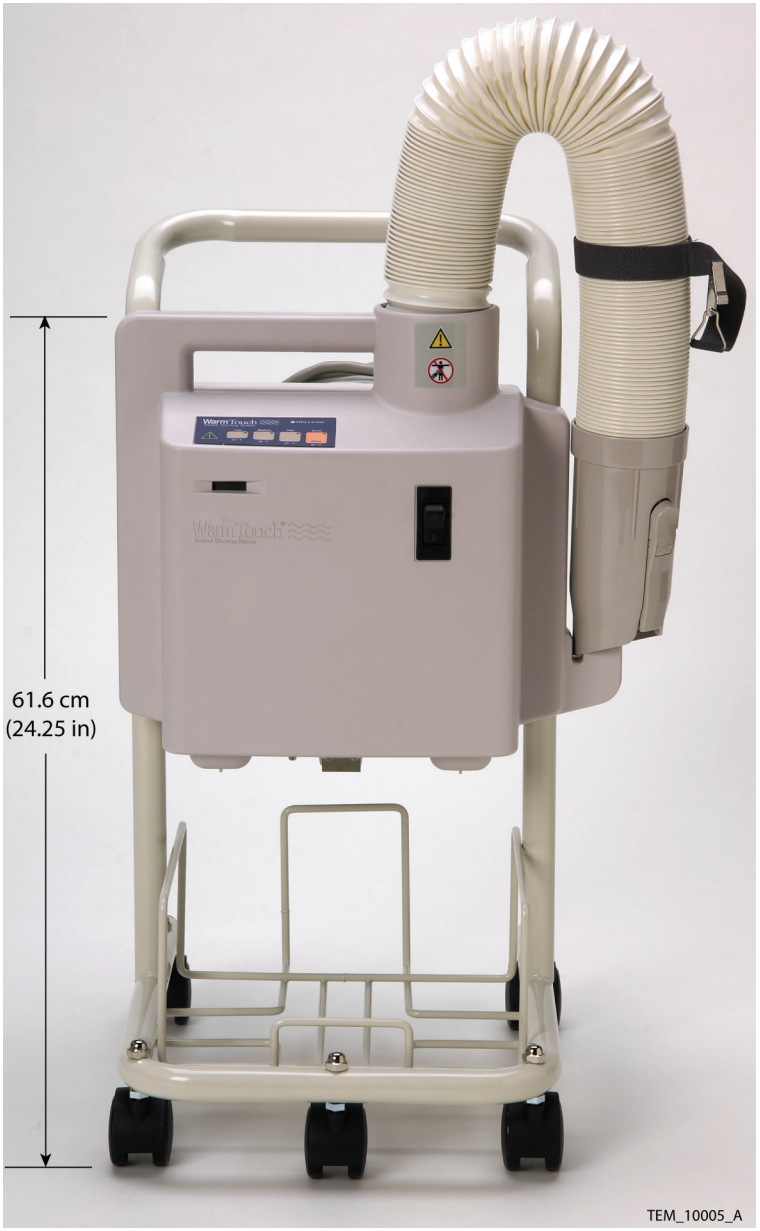
Overview

This chapter contains information for installing the WarmTouch™ Model WT-5300A patient warming system.

Cart Installation

The warming system is shipped installed on the warming system cart. Ensure the three blower cart clamps are tight.

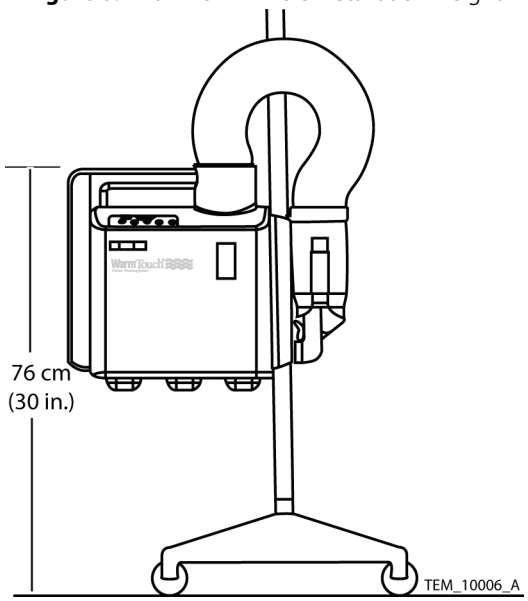
Figure 5. Maximum Mounted Height



IV Pole Installation

The warming system should not be installed on the IV pole with the handle higher than 76 centimeters (30 inches).

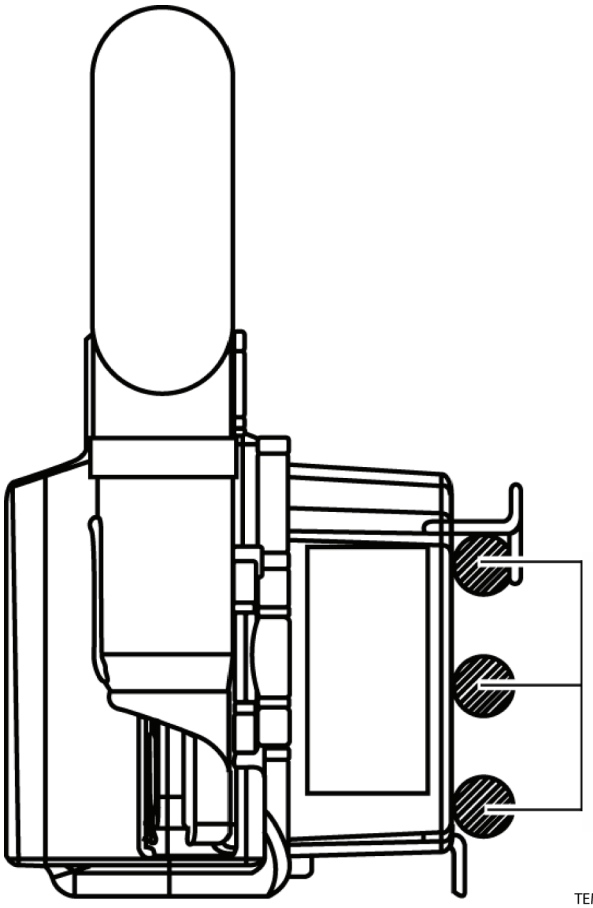
Figure 6. Maximum IV Pole Installation Height



Patient Bed Installation

The patient rail connectors will fit on bed rails up to 1.4 inches (3.6 centimeters) wide.

Figure 7. Bed Rail Installation



Using the Warming System

Overview

This chapter provides information on operating the WarmTouch™ Model WT-5300A patient warming system.

Power Supply Cord

Plug the warming system power cord into a hospital grade or suitable mains outlet.

Main Power

WARNING

No free-hosing. Keep hose nozzle connected to a WarmTouch™ blanket at all times or thermal injury may occur.

WARNING

Thermal injury may occur if the warming system hose comes into contact with the patient.

Power is controlled through one main rocker switch located on the front of the warming system. To begin operation, press the Main Power switch to the ON position. The Low temperature light on the control panel illuminates, the warming system begins blowing low temperature air, and the power fail alarm sounds. Press the desired temperature key to cancel the alarm.

Figure 8. Low Temperature Light

Temperature Control

WARNING
The patient must be closely monitored for rewarming. Vasodilation and possible hypotension can occur. Use good judgment when selecting a temperature. If unsure of proper setting, consult with the attending physician.

WARNING
Using the warming system on transdermal medication patches may increase the rate of drug delivery, potentially causing harm to the patient.

The control panel features a warning light indicator and four manually-switched temperature settings. The warning light indicates the control system has identified an alarm condition and an action by the operator is required. Each temperature setting represents the average temperature of air entering the hose.

- Low 32°C (89.6°F)
- Medium 38°C (100.4°F)
- High 43°C (109.4°F)
- Boost 45°C (113°F) for 45 minutes

For patients with severe hypothermia requiring rapid warming, select the Boost temperature setting. To help prevent hypothermia or for treatment of mild hypothermia, select High, Medium or Low temperature settings. The selected temperature light illuminates.

Air Filter

Caution

The HEPA filter **must** be changed every 2,000 hours of operation. Refer to the *Routine Maintenance* section in the WT5300A Service Manual for replacement procedures requiring a qualified technician.

The warming system contains a HEPA filter rated 99.97% efficient at 0.3-micron particle size.

Self-Supporting Air Hose

Air is delivered into the CareQuilt™ or CareDrape™ blankets through a wire-reinforced hose attached to the warming system.

Using WarmTouch™ CareQuilt™ and CareDrape™ Blankets

WarmTouch™ CareQuilt™ and CareDrape™ blankets come in a range of sizes and configurations to fit patient individual sizes, surgical procedures, and comfort needs. Follow the instructions provided with all WarmTouch™ blankets for specific information concerning their recommended use.

Use only WarmTouch™ blankets. The performance of the WarmTouch™ patient warming system has only been evaluated and validated using WarmTouch™ blankets.

Page Left Intentionally Blank

Routine Maintenance

Overview

This chapter describes the steps required to maintain, service, and properly clean the WarmTouch™ Model WT-5300A patient warming system.

Cleaning the Warming System

Caution

Do not spray, pour, or spill any liquid on the warming system, its accessories, connectors, switches, or openings in the case.

For surface cleaning and disinfection of the warming system, follow your institution's procedures or the recommended actions below.

- **Surface cleaning** — Use a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, lightly wiping the surfaces of the warming system.
- **Disinfection** — Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surfaces of the warming system.

Routine Maintenance

Caution

The institution should follow local governing ordinances and recycling instructions regarding disposal or recycling of filter and device components or end of life of the product.

Caution

The HEPA filter **must** be changed every 2,000 hours of operation. Refer to the *Routine Maintenance* section in the *Service Manual* for replacement procedures requiring a qualified technician.

For routine maintenance procedures requiring a qualified technician, including testing and verifying operation of the independent over-temperature safety system and the subsequent over-temperature alarm, refer to the *Routine Maintenance* section of the *Service Manual*.

Page Left Intentionally Blank

Specifications

Overview

This chapter contains physical and operational specifications for the WarmTouch™ Model WT-5300A patient warming system.

Warming System Specifications

Table 3. System Specifications

Warming Blanket Specifications	
Maximum blanket surface temperature	44°C
Blower Specifications	
Dimensions	38 cm x 41 cm x 28 cm (15 inches x 16 inches x 11 inches)
Weight	6.8 kgs (15 lbs.)
Power Requirements	120 volts AC, 50/60 Hz, 10 amp
Automatic Temperature Stepdown (Boost to High Temperature)	After 45 minutes of continuous use blower will step down from the Boost to High setting.
Power Supply Cord	4.26 m (14 feet)
Thermal Protection Threshold	Thermostat (internal): 47°C to 50°C (117°F - 122°F)
Ambient Blower Operating Temperature Range	18°C - 28°C (64.4°F - 82.4°F)
Over Temperature Alarm Level	65 dB at 3 meters
Protection Against Ingress of Fluids	Ordinary
Cart Specifications	
Weight	3.1 kg (6.8 pounds)
Height	67.1 cm (26.4 inches)
Width	32.3 cm (12.7 inches)
Depth	38.6 cm (15.2 inches)

Transport and Shipping in Shipping Container

Table 4. Shipping Container Specifications

Temperature:	-40°C to 70°C (-40°F to 158°F)
Altitude:	-390 m to 6,096 m (-1,280 ft to 20,000 ft)
Barometric Pressure:	1,060 hPa to 500 hPa (375 mmHg to 795 mmHg)
Relative Humidity:	15% to 95% (non-condensing)

Compliance

Table 5. Compliance Standards

Item	Compliant With
Equipment classification	IEC/EN 60601-1 2nd edition CSA C22.2 No. 601.1 M90 UL 60601-1 1st edition IEC 60601-2-35: 1996 EN 60601-2-35: 1997
Type of protection	Class I (on AC power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
Electromagnetic Compatibility	IEC/EN 60601-1-2 3rd edition

Manufacturer's Declaration

WARNING
The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the warming system.

The warming system is suitable for use in the specified electromagnetic environment. The customer and/or user of the warming system should ensure it is used in the prescribed electromagnetic environment.

Electromagnetic Compatibility (EMC)

Electromagnetic Emissions

Table 6. Electromagnetic Emissions Guidelines

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1 Class A	The warming system uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

Electromagnetic Immunity

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 7. Electromagnetic Immunity Guidelines

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC/EN 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 and/or hospital environment.
Surge IEC/EN 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 and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC/EN 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the warming system requires continued operation during power mains interruption, it is recommended that the warming system be powered from an uninterruptible power supply or battery. Note: UT is the AC main's voltage prior to application of the test level.
	40% UT (60% dip in UT) for five cycles	40% UT (60% dip in UT) for five cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (95% dip in UT) for five seconds	<5% UT (95% dip in UT) for five seconds	
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	It may be necessary to position the warming system further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

For transmitters rated at a maximum output power not listed, estimate the separation distance using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

Note:

Portable and mobile RF communications equipment should be used no closer to any part of the warming system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Table 8. Recommended Separation Distances

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
	Frequency of Transmitter		**Equation for Separation Distance**
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz 800 MHz	10 V/m	Distance = $0.35\sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	10 V/m	Distance = $0.7\sqrt{P}$ 800 MHz to 2.5 GHz
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz 80 MHz	3 Vrms	Distance = $1.2\sqrt{P}$ 150 kHz to 800 MHz
Rated Maximum Output Power of Transmitter in Watts	**Separation Distance in Meters**		
0.010	0.120	0.035	0.070
0.100	0.380	0.110	0.220
1.000	1.200	0.350	0.700
10.000	3.800	1.120	2.210
100.000	12.000	3.500	7.000

Page Left Intentionally Blank

Index

Page Left Intentionally Blank

NELLCOR

Tyco Healthcare Group LP
Nellcor Puritan Bennett LLC
4280 Hacienda Drive
Pleasanton, CA 94588 USA
Toll Free: 1.800.635.5267

Manufactured in the U.S.A.
10064187 Rev B 09/2010

tyco Healthcare