COVIDIEN

Operator's Manual

WarmTouch™

Convective Warming System



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1 Introduction

Overview

This manual contains information for operating the Covidien WarmTouch™ Convective Warming System, which consists of the Covidien WarmTouch™ Convective Warming Unit and associated WarmTouch blankets. Before operating the warming system, thoroughly read this *Operator's Manual*. The latest version of this manual is available at:

www.covidien.com

Safety Information

This section lists all safety information associated with the warming unit. Where appropriate in the manual, individual Warnings and Cautions are repeated as reminders. Please familiarize yourself with this safety information before operating the warming unit.

Safety Symbol Definitions

Table 1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.

Warnings

WARNING:
Possible explosion hazard. Do not use the device in the presence of flammable anesthetics or in an oxygen-rich environment.

WARNING:
Possible electric shock hazard. Grounding reliability can be achieved only when the warming unit is connected to a suitable mains outlet with protective earth grounding.

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

WARNING:
Possible burn or infection hazard. Do not allow warming blanket to come in contact with open wounds. All patients' 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:
Thermal injury may occur if the warming unit hose comes into contact with the patient.

WARNING:
Possible fire hazard. Prevent the blanket material from coming into contact with a laser or an electrosurgical active electrode.

WARNING:
Continuously monitor the patient's temperature during treatment with the warming system. Use good clinical judgment in selecting and adjusting temperature settings based on the patient's warming needs and response to treatment.

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

WARNING:
Thermally conductive materials, such as water, gel, and similar substances, can decrease the patient's body temperature when the warming unit is switched off.

WARNING:
Do not use the warming system during magnetic resonance imaging (MRI) scanning.

WARNING:
The use of accessories or cables with the warming system other than those indicated in this manual may result in non-compliance with the specifications listed in *Electromagnetic Compatibility (EMC)* on page 60.

WARNING:
Do not operate the warming system in a stacked configuration with other equipment.

WARNING:
Do not operate the warming system adjacent to other equipment. If such a configuration cannot be avoided, first test the warming system in the intended configuration to verify normal operation.

WARNING:
Use WarmTouch™ blankets only as directed. Carefully follow the *Instructions for Use* provided with the blankets regarding proper handling and positioning.

WARNING:
WarmTouch™ blankets are for single patient use only.

WARNING:
Clean the warming unit after each use, as described in this manual.

WARNING:
If a fault or sudden change in performance occurs in the warming system, discontinue use. Notify your sales/service center. The unit must be serviced by qualified personnel using procedures provided in the *Service Manual*.

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:
No modification of this equipment is allowed.

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:
Only use WarmTouch™ blankets with the WarmTouch warming unit. Do not attempt to use other types of blankets with the warming unit. Similarly, do not attempt to use WarmTouch blankets with other types of warming units.

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

Caution:
The HEPA filter must be replaced every 2,000 hours of operation or 365 days, whichever comes first. Filter replacement must be performed by qualified personnel. Refer to the *Service Manual* for replacement instructions.

Caution:
Operation of the warming system may affect or be affected by other devices in the vicinity due to electromagnetic interference (EMI). If interference occurs, try increasing the distance between devices, repositioning the cabling, or plugging the devices into separate outlet circuit branches. Reference *Electromagnetic Compatibility (EMC)* on page 60 for additional guidance.

Caution:
The USB port on the warming unit is for service use by qualified personnel only. During patient treatment, a USB cable must not be connected to the warming unit.

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.

Labeling Symbols

Table 2 defines the symbols that appear on the warming unit or its shipping label.

Table 2. Symbols on the Warming Unit and Shipping Label

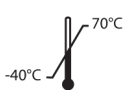
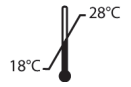
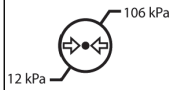
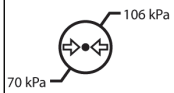
Symbol	Description	Appears On...	
		Warming Unit	Shipping Label
	By prescription only	X	X
	No Free Hosing: Hose nozzle must be connected to a WarmTouch™ blanket or thermal injury may occur.	X	
	Do not use during magnetic resonance imaging (MRI).	X	X
	Degree of protection from electric shock: Protection Class I, Type BF applied part	X	
	Recommendation to consult accompanying documents	X	X
	Requirement to consult accompanying documents	X	X
	Nature of power supply: Alternating Current (AC)	X	
	Potential equalization conductor terminal Used to access the warming unit's electrical ground for electrical safety testing	X	
	Universal Serial Bus (USB) port (For service use by qualified personnel only)	X	
	Keep dry	X	X
	Temperature limitations (shipping/storage): -40°C to +70°C		X

Table 2. Symbols on the Warming Unit and Shipping Label (Continued)

Symbol	Description	Appears On...	
		Warming Unit	Shipping Label
	Temperature limitations (operating): +18°C to +28°C	X	
	Relative humidity limitations (shipping/storage): 10% to 95% (non-condensing)		X
	Relative humidity limitations (operating): 15% to 85% (non-condensing)	X	
	Atmospheric pressure limitations (shipping/storage): 12 kPa to 106 kPa		X
	Atmospheric pressure limitations (operating): 70 kPa to 106 kPa	X	
CE 0123	CE – Conformité Européene authorization mark 0123 – TÜV SÜD Product Service GmbH (notified body) Signifies compliance with Medical Device Directive 93/42/EEC	X	X
C US	CSA – Canadian Standards Association certification mark	X	
EC REP	European Community (EC) authorized representative	X	X
SN	Serial number	X	X
REF	Catalog number	X	X
	Manufacturer	X	X
	Date of manufacture	X	X
	Proper waste disposal for electrical and electronic equipment (WEEE)	X	

Obtaining Technical Assistance

For technical assistance or to order parts and additional manuals, contact Covidien Technical Services or a local Covidien representative.

When contacting Covidien for troubleshooting or service issues, please provide the information described in *Serial Number and System Information* on page 54.

Covidien Technical Services		
Covidien Argentina Aguero 351 Capital Federal - 1171 ABC Argentina Tel: (5411) 4863-5300 Fax: (5411) 4863-4142	**Covidien Asia** Singapore Regional Service Centre 15 Pioneer Hub, #06-04 Singapore 627753 Tel (65) 6578 5288 Fax (65) 6515 5260	**Covidien Australia** 52A Huntingwood Drive Huntingwood, NSW 2148 Australia Tel: (+61) 1800 - 350702 Fax: (+61) 2967 - 18118
Covidien Austria GmbH Campus21 Europaring F09402 Brunn am Gebrige A-2345 Österreich Tel: (+43) 2236 - 3788 39 Fax: (+43) 2236 - 3788 3940	**Covidien Belgie S.A.-N.V.** Generaal De Wittelaan 9/5 Mechelen 2800 België Tel +32 152 981 37 Fax +32 152 167 83	**Covidien Brazil** Av. Das Nações Undias 12995 Andar 23 - Brooklin São Paulo, SP Brasil 04578-000 Tel: (5511) 2187-6200 Fax: (5511) 2187-6380
Covidien Canada 19600 Clark Graham Baie d'Urfe, QC, H9X 3R8 Canada Tel:1-514-695-1220, Ext.4004 Fax: 1-514-695-4965	**Covidien Chile** Camino lo Boza (Ex 8395) Pudehuel Santiago Chile Tel: (562) 739 - 3000 Fax: (562) 783 - 3149	**Covidien China** 2F, Tyco Plaza 99 Tian Zhou Rd Shang Hai 200233 P.R. China Tel: (+86) 4008 1886 86 Fax: (+86) 2154 4511 18
Covidien Colombia Edificio Prados de la Morea Carretera Central Del Norte (Cra 7a) Kilometro 18, Chia-Cundinamarca Bogota, Colombia Tel: (571) 619-5469 Fax: (571) 619-5425	**Covidien Costa Rica** Global Park, Parkway 50 La Auroa de Heredia Costa Rica Tel: (506) 2239 - 5386 Fax: (506) 2239 - 5319	**Covidien ECE** Prosecká 851/64 190 00 Praha 9 Česká republika Tel: +420 239 000 711 Fax: +420 239 000 437

Covidien Technical Services (Continued)		
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Covidien Finland Oy Läkkisepäntie 23 00620 Helsinki Finland Te. +35 896 226 84 10 Fax +35 896 226 84 11	**Covidien France SA** Parc d'affaires Technopolis Bat. Sigma, 3 Avenue du Canada LP 851 Les Ulis 91975 Courtaboeuf Cedex France Tel +33 169 821 416 Fax +33 169 821 532	**Covidien Hong Kong** Unit 12 - 16, 18/F BEA Tower Millennium City 5 4187 Kwun Tong Road Kwum Tong, Kowloon, Hong Kong Tel + 852 3157 7299 Fax + 852 2838 0749
Covidien India 10th Floor Building No 9B DLF Cyber City Phase III Gurgaon Haryana - 122002 India Tel + 91 1244 709800 Fax + 91 1244 206850	**Covidien Hungary** 1095 Budapest Mariassy u. 7 Magyarorszag Hungary Tel + 36 1880 7975 Fax + 36 1777 4932	**Covidien Ireland** Block G, Ground Floor, Cherrywood Technology Park, Loughlinstown County Dublin, Ireland Tel +353 1 4381613 Fax 353 1 439 3039
Covidien Israel 5 Shacham St. North Industrial Park Caesarea 38900 Israel Tel +97 246 277 388 Fax+97 266 277 688	**Covidien Italia S.p.A.** Via Rivoltana 2/D 20090 Segrate Italy Tel +39 027 030 81 31 Fax +39 027 031 72 84	**Covidien Japan Inc.** Technical Support Center 83-1, Takashimadaira 1-Chome Itabashi-ku, Tokyo 175-0082 Japan Tel: +81 (0) 3 6859 0120 Fax: +81 (0) 3 6859 0142
Covidien Korea 5F, Hibrand Living Gwan, #215, Yangjae-Dong, Seocho-Gu Seoul, Korea Tel: +822 570 5459 Fax: +822 570 5499	**Covidien Mexico** Insurgentes Sur # 863, Piso 16 Col. Nápoles Del. Benito Juarez Mexico, D.F. 03810 Mexico Tel: (5255) 5804-1524 Fax: (5255) 5536-1326	**Covidien Nederland BV** Hogeweg 105 5301 LL Zaltbommel Nederland Tel +31 41 857 66 00

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Covidien Portugal Lda. Estrada do Outeiro de Polima, Lote 10-1° Abóboda 2785-521 S.Domingos de Rana Portugal Tel +35 121 448 10 36 /30 Fax +35 121 445 1082	**Covidien Puerto Rico** Palmas Industrial Park Road 869 Km 2.0 Bdlg. #1 Cataño, PR 00962 Tel. 787-993-7250 Ext. 7222 & 7221 Fax 787-993-7234	**Covidien Russia** 53 bld. 5 Dubininskaya Street Moscow RUSSIA. 119054 Tel +70 495 933 64 69 Fax +70 495 933 64 68
Covidien Saglik A.S. Maslak Mahallesi Bilim Sokak No: 5, Sun Plaza Kat: 2-3 Sisli, Istanbul 34398 Turkey Tel +90 212 366 20 00 Fax +90 212 276 35 25	**Covidien South Africa** Corporate Park North 379 Roan Crescent Randjespark Midrand, South Africa Tel +27 115 429 500 Fax +27 115 429 624	**Covidien Spain S.L.** Business Park World Trade Center Almeda Park Edificio 7 - 3ª planta Plaça de la Pau s/n Cornellà de Llobregat
Covidien Sverige AB Box 54 171 74 Solna Sweden Tel +46 858 56 05 00 Fax + 46 858 56 05 29	**Covidien Switzerland** Roosstrasse 53 8832 Wollerau Schweiz Tel +41 44786 5050 Fax +41 44786 5010	**Covidien Thailand** 99 Soi Rubia, Sukhumvit 42 Road 13 - 14 Fl., Berli Jucker Building Prakanong, Klongtoey Bangkok 10110, Thailand Tel +662 2073 - 100 Fax +662 657 - 6325
Covidien UK Unit 2, Talisman Business Park London Road, Bicester OX26 6HR, United Kingdom Tel +44(0)1869 328092 Fax +44(0)1869 327585	**Covidien US** 15 Hampshire Street Mansfield, MA 02048 USA Tel 1.800.635.5267 Tel 1.925.463.4635 (toll)	

Related Documents

- **Instructions for Use - Covidien WarmTouch™ Warming Blanket** — This document, provided with WarmTouch warming blankets, contains important information regarding intended use, handling, connection, and positioning of the blanket.
- **Service Manual - Covidien WarmTouch™ Convective Warming Unit** — This document, for use by qualified personnel only, contains instructions for servicing, testing, updating, and maintaining the warming unit. The *Service Manual* also includes schematics, a parts list, and shipping instructions for factory service.

Warranty Information

To obtain warranty information, contact Covidien Technical Services or a local Covidien representative. Reference *Obtaining Technical Assistance* on page 8.

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2 Product Overview

Overview

This chapter provides an introduction to the Covidien WarmTouch™ Convective Warming System, including information about its features, accessories, controls, and requirements for use.

Product Description

The warming system provides a means for treating or preventing hypothermia in adult and pediatric patients in clinical settings. The warming system consists of an electronic blower (warming unit) that delivers heated air through a flexible hose to a lightweight blanket placed on the patient. The blanket distributes the heated air through numerous small perforations that allow the air to reach the targeted areas of the patient's body.

Features

- **Multiple Temperature Settings —** A range of temperature settings allows the clinician to customize and adjust treatment based on the patient's needs.
- **Boost Mode —** For rapid warming, air is generated at 47°C for 45 minutes, after which the temperature automatically drops to the 45°C (High) temperature setting.
- **HEPA Filter —** A High Efficiency Particulate Air (HEPA) filter removes at least 99.97% of particles 0.3 micrometers or larger from the air delivered to the warming blanket. The warming unit monitors the amount of time the filter is in use and indicates when the filter needs to be replaced.
- **Automatic Over- and Under-Temperature Protection —** At any of the heated air settings, if the temperature of the generated air is out of range for a specific amount of time, the heater and fan automatically shut off and an alarm is issued.
- **Optional Cart with Wheel Locks —** An optional transport cart, equipped with wheel locks, is available for the warming unit. The wheel locks reduce cart movement while the system is in use.

Indications for Use

The WarmTouch Convective Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, and for the management of appropriate normothermia.

Contraindications

None known.

Components and Accessories

To order components and accessories, contact Covidien Technical Services or a local Covidien representative. Reference *Obtaining Technical Assistance* on page 8.

Table 3. Warming System Components and Accessories

Item	Description
Covidien WarmTouch™ Convective Warming Unit	Electronic blower that delivers heated air to the warming blanket.
Covidien WarmTouch™ warming blankets	Warming blankets designed for exclusive use with the warming unit. Available for a variety of treatment applications.
HEPA filter	Replaceable air filter for the warming unit.
Power cord	Detachable power cord for the warming unit. Type depends on country of use.
Transport cart (optional)	Optional wheeled cart for mounting the warming unit.

Covidien WarmTouch™ Warming Blankets

The Covidien WarmTouch™ Convective Warming Unit is designed for use with WarmTouch™ blankets only. WarmTouch blankets are designed to attach securely to the warming unit's hose nozzle. The nozzle features guides and a clip to ensure correct orientation.

Do not attempt to use other types of blankets with the warming unit; the performance of the warming system has not been evaluated with other blankets and cannot be predicted.

The warming unit is compatible with all WarmTouch blankets.

Consult the *Instructions for Use* provided with the warming blankets for important information regarding proper handling and application.

Product Views

Front View

Figure 1. Front View



TEM_10110_A

1	Operator's Panel	4	Hose
2	Handle	5	Nozzle Strap with Clip
3	No Free-Hosing Label	6	Nozzle

Rear View

Figure 2. Rear View

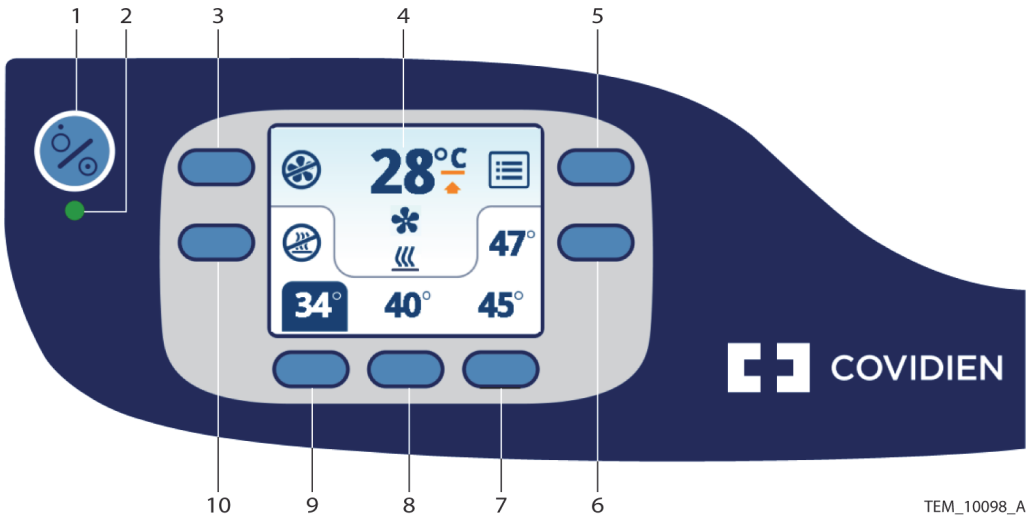


1	No Free-Hosing Label	5	Mounting Channel (x2)
2	Serial Number Label	6	Blower Clamp (x3)
3	Symbols Label	7	Bed Hook
4	USB Port (Under Cover) – For Service Use by Qualified Personnel Only	8	Power Cord

Operator's Panel

The operator's panel includes an **On/Standby** key, a multi-functional keypad, and a display that provides temperature and status information. The display indicates the function of each adjacent key. Key functions change based on operating context, as described in subsequent chapters.

Figure 3. Operator's Panel



1  **On/Standby Key** – Press to place the warming unit in Ready mode or to return to Standby mode. Reference *Beginning Treatment* on page 38 and *Returning to Standby Mode* on page 43.

2 **Status LED** – Indicates the warming unit's operational status. Reference *Overview of Warming Unit Operating Modes* on page 37.

3  **Fan Off Key** – During operation, press to turn off the fan. The heater, if running, shuts off automatically. Reference *Returning to Ready Mode* on page 43.

4 **Temperature/Information Area** – Displays the current air temperature being generated (rounded to the closet 1°C). The following symbols can also appear in this area:

 Dashes instead of a temperature reading indicate that the warming unit is in Ready mode (both heater and fan are off).

 Animated symbol indicates that the fan is on.

 Animated symbol indicates that the heater is on.

 Animated arrow indicates that the temperature is adjusting upward or downward to a new setting. The symbol disappears when the temperature is within 1.5°C of the new setting.

5  **Menu Key** – Press to access screens for viewing filter status and system information. Reference *Monitoring the Filter Status* on page 48 and *Serial Number and System Information* on page 54.

Note: Symbol is shown for reference only. This menu is accessible only when the heater and fan are off (Ready mode).

6 **47°** **47°C (Boost Mode) Key** – Press to generate air at 47°C (116.6°F) for 45 minutes. Reference *Using Boost Mode* on page 42.

7 **45°** **45°C (High) Key** – Press to generate air at 45°C (113°F). Reference *Controlling the Temperature* on page 40.

8 **40°** **40°C (Medium) Key** – Press to generate air at 40°C (104°F). Reference *Controlling the Temperature* on page 40.

9 **34°** **34°C (Low) Key** – Press to generate air at 34°C (93.2°F). Reference *Controlling the Temperature* on page 40.

10  **Heat Off Key** – Press to deliver air at room temperature (unheated). Reference *Controlling the Temperature* on page 40.



Note:
When you press any of the temperature setting keys, the **Heat Off** key, or the **Fan Off** key, the setting is highlighted on the display to indicate the current selection. For example, in the previous figure, 34° is the current selection.



Note:
A soft click tone indicates a successful key press.

Requirements for Use

Clinician Prerequisites

The warming system is intended for use by licensed healthcare practitioners or clinical personnel knowledgeable in its proper operation. Before using the warming system, be sure to familiarize yourself with the information provided in this *Operator's Manual* and in the *Instructions for Use* provided with the warming blankets.

Treatment Environment

WARNING:
Possible explosion hazard. Do not use the device in the presence of flammable anesthetics or in an oxygen-rich environment.

WARNING:
Do not use the warming system during magnetic resonance imaging (MRI) scanning.

WARNING:
Do not operate the warming system in a stacked configuration with other equipment.

WARNING:
Do not operate the warming system adjacent to other equipment. If such a configuration cannot be avoided, first test the warming system in the intended configuration to verify normal operation.

WARNING:
Clean the warming unit after each use, as described in this manual.

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

Caution:
Operation of the warming system may affect or be affected by other devices in the vicinity due to electromagnetic interference (EMI). If interference occurs, try increasing the distance between devices, repositioning the cabling, or plugging the devices into separate outlet circuit branches. Reference *Electromagnetic Compatibility (EMC)* on page 60 for additional guidance.

The warming system is intended for use only in hospitals and hospital-type facilities. Typical locations of use include the operating room, the operative holding area, the post anesthesia care unit (PACU), and other care areas. The warming system is not intended for home use.

Proper operation of the warming system requires the following conditions:

- **Ambient Temperature:** 18°C to 28°C (64.4°F to 82.4°F)
- **Relative Humidity:** 15% to 85% (non-condensing)

Warming Blanket Use

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

WARNING:
Possible fire hazard. Prevent the blanket material from coming into contact with a laser or an electrosurgical active electrode.

WARNING:
Use WarmTouch™ blankets only as directed. Carefully follow the *Instructions for Use* provided with the blankets regarding proper handling and positioning.

WARNING:
WarmTouch™ blankets are for single patient use only.

Caution:
Only use WarmTouch™ blankets with the WarmTouch warming unit. Do not attempt to use other types of blankets with the warming unit. Similarly, do not attempt to use WarmTouch blankets with other types of warming units.

Patient Considerations

WARNING:
Possible burn or infection hazard. Do not allow warming blanket to come in contact with open wounds. All patients' 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:
Thermal injury may occur if the warming unit hose comes into contact with the patient.

WARNING:
Continuously monitor the patient's temperature during treatment with the warming system. Use good clinical judgment in selecting and adjusting temperature settings based on the patient's warming needs and response to treatment.

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

WARNING:
Thermally conductive materials, such as water, gel, and similar substances, can decrease the patient's body temperature when the warming unit is switched off.

3 Installation

Overview

This chapter contains information for installing the Covidien WarmTouch™ Convective Warming Unit.

Safety Reminders

WARNING:
The use of accessories or cables with the warming system other than those indicated in this manual may result in non-compliance with the specifications listed in *Electromagnetic Compatibility (EMC)* on page 60.

WARNING:
No modification of this equipment is allowed.

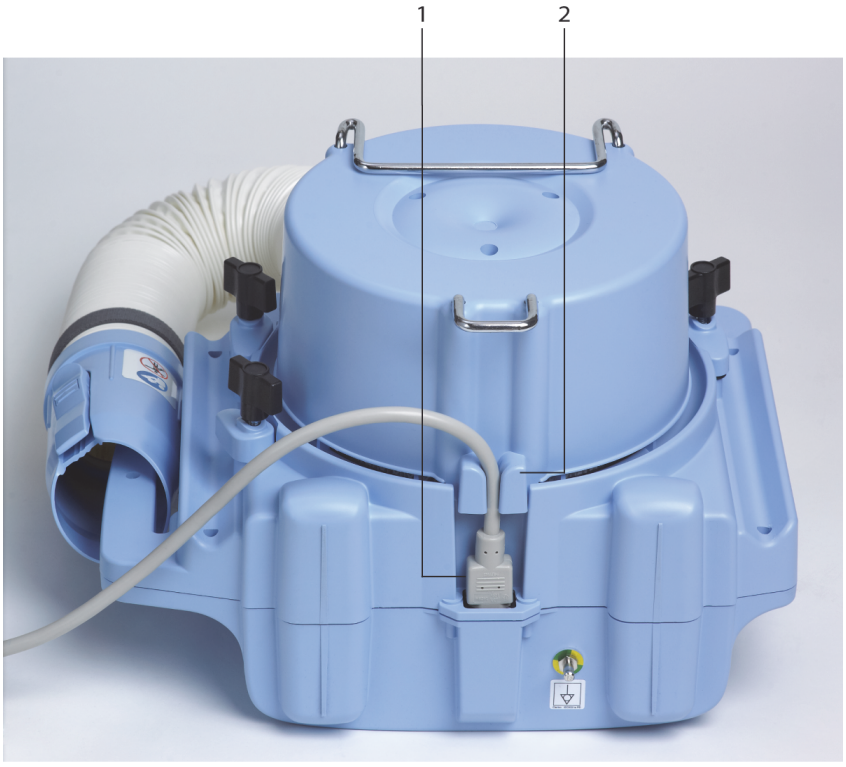
Attaching the Power Cord

The warming unit is shipped with a power cord appropriate to the country of use.

To attach the power cord:

1. Position the warming unit on its front so the bottom of the unit is accessible.
2. Connect the power cord's female connector to the socket in the warming unit, making sure the connector is fully inserted.

Figure 4. Power Cord Connection



TEM_10112_A

1 Power Cord Female Connector 2 Routing Bracket

3. Press the power cord into the routing bracket until it is fully seated.
4. Set the warming unit upright. Wrap the power cord around the back of the unit, and secure it with the provided strap. Reference *Figure 5* on page 25.

Figure 5. Power Cord Wrapped and Secured



TEM_10113_A

Installing the Warming Unit

The warming unit can be used as a standalone device, or it can be mounted on an IV pole, bed, or optional transport cart. The following sections provide mounting instructions.

IV Pole Installation

The warming unit can be mounted on an IV pole with a maximum diameter of 3.2 cm (1.25 inches) and a minimum diameter of 1.9 cm (0.75 inches).

To avoid tipping, the warming unit must be mounted on the pole with the handle no higher than 76 cm (30 inches) above the floor.

Tools Required: Measuring tape

To install the warming unit on an IV pole:

1. On the IV pole, mark the maximum mounting height. The warming unit's handle must be no higher than 76 cm (30 inches) above the floor.
2. Ensure that the power cord is secured at the back of the warming unit. Reference *Figure 6* on page 27.
3. Locate the mounting channel with two clamps at the back of the warming unit. Do not use the mounting channel with one clamp. Reference *Figure 6* on page 27.
4. Loosen the knobs on the two clamps and rotate the clamp feet away from the mounting channel.

Figure 6. Rear View



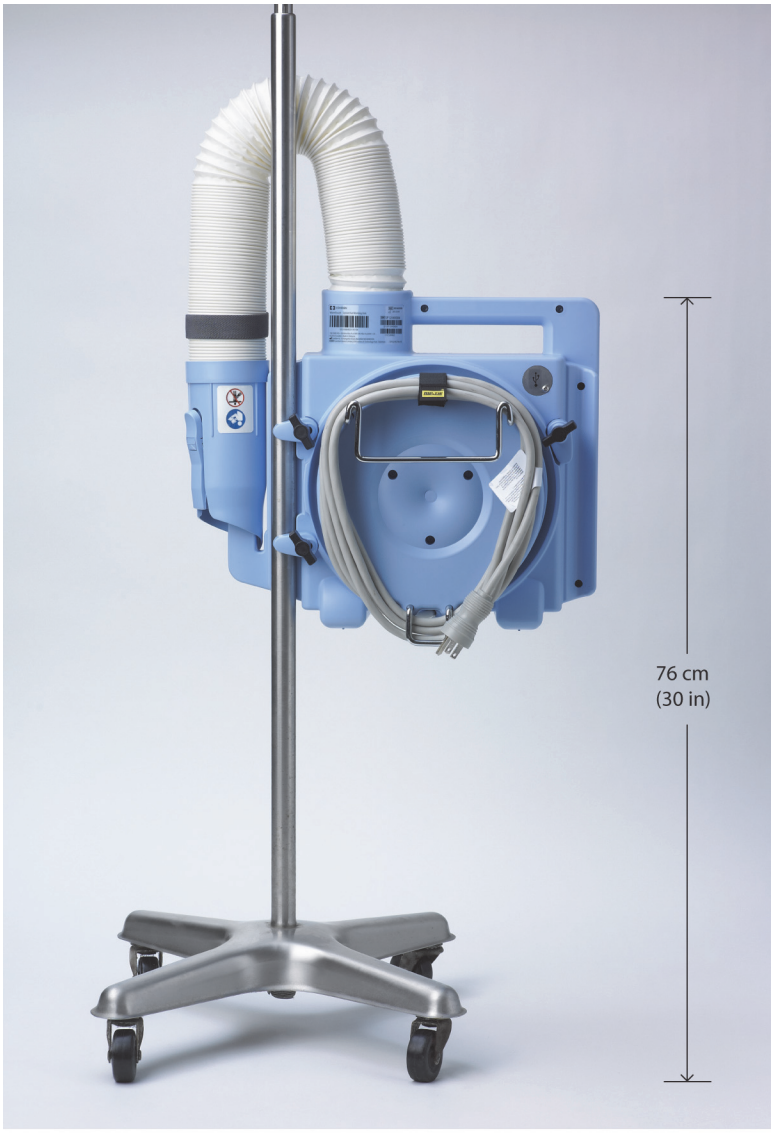
TEM_10114_A

1 Mounting Channel
2 Clamp Foot (x2)
3 Clamp Knob (x2)

5. Bracing the IV pole, position the warming unit against the pole so that the pole is fully seated in the mounting channel. Verify that the handle is not above the maximum height. Reference *Figure 7* on page 28.

6. Rotate the two clamp feet across the IV pole, and tighten the clamp knobs to secure the warming unit. Do not overtighten.

Figure 7. Warming Unit Mounted on IV Pole



TEM_10115_A

Bed Installation

The warming unit can be attached to a bed that has a mounting surface up to 3.6 cm (1.4 inches) wide. Typically, the unit is attached to the bed's head board or foot board.

Tools Required: None

To attach the warming unit to a bed:

1. Locate the bed hook on the back of the warming unit. Reference *Figure 2* on page 17. The hook slides in and out to accommodate different mounting surface widths.

2. Hang the bed hook over the mounting surface to attach the warming unit to the bed.

Figure 8. Bed Installation



TEM_10116_A

Cart Installation

An optional transport cart is available for the warming unit. Contact Covidien Technical Services or a local Covidien representative to purchase the transport cart. Reference *Obtaining Technical Assistance* on page 8.

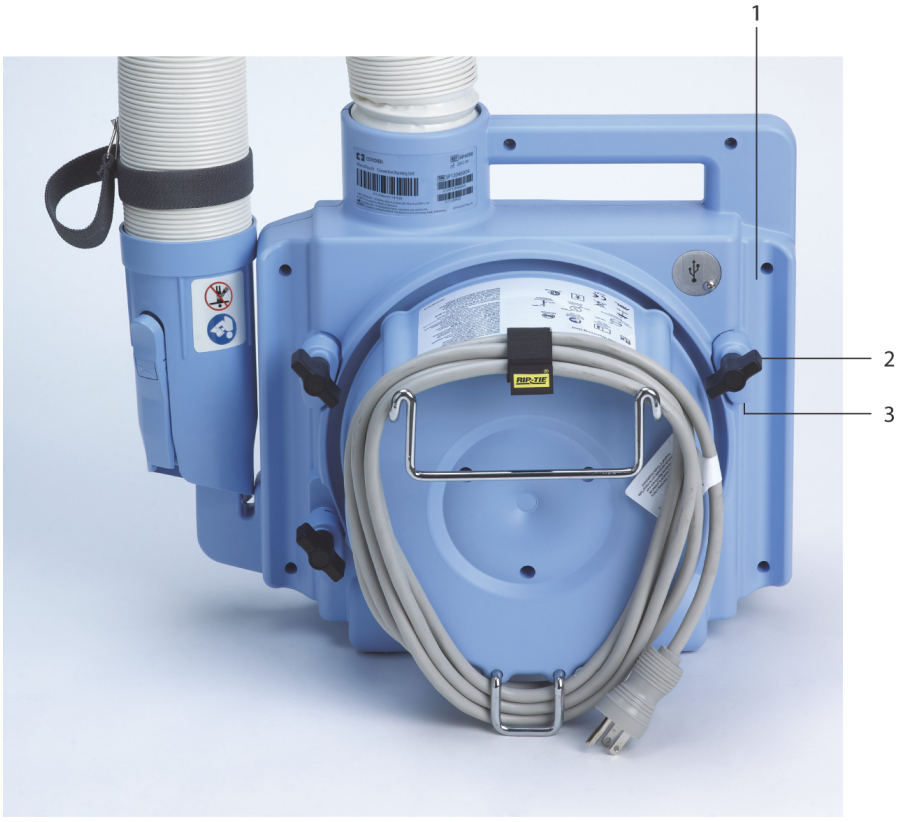
Tools Required: None

To install the warming unit on the cart:

1. Ensure that the power cord is secured at the back of the warming unit. Reference *Figure 9*.

2. Loosen the knobs on the three clamps at the back of the warming unit, and rotate the clamp feet away from the mounting channels.

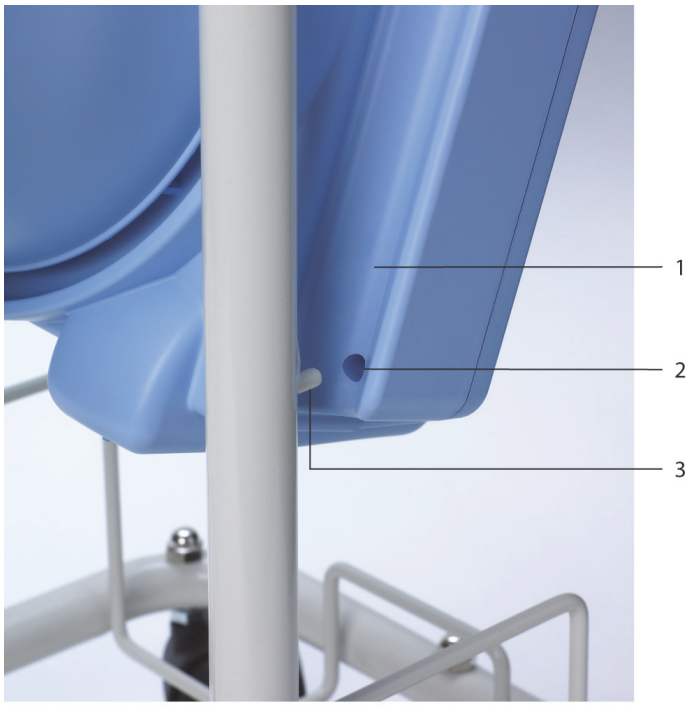
Figure 9. Rear View



1 Mounting Channel (x2)
2 Clamp Knob (x3)
3 Clamp Foot (x3)

3. Locate the mounting pegs on the cart's vertical poles, and locate the holes at the bottom of the warming unit's mounting channels.

Figure 10. Cart Mounting Peg and Warming Unit Mounting Hole



TEM_10118_A

1 Mounting Channel (x2)
2 Mounting Hole (x2)
3 Mounting Peg (x2)

4. Holding the warming unit by the handle and bracing the cart, position the warming unit against the cart so that the mounting holes engage the mounting pegs. The cart poles must be fully seated in the mounting channels.

5. Rotate each of the three clamp feet across the cart poles, and tighten the clamp knobs to secure the warming unit. Do not overtighten.

Figure 11. Warming Unit Mounted on Cart



TEM_10119_A

4 Operation

Overview

This chapter provides instructions for operating the Covidien WarmTouch™ Convective Warming Unit. Use these instructions in conjunction with the *Instructions for Use* provided with WarmTouch™ warming blankets.

Safety Reminders

WARNING:
The use of accessories or cables with the warming system other than those indicated in this manual may result in non-compliance with the specifications listed in *Electromagnetic Compatibility (EMC)* on page 60.

WARNING:
Clean the warming unit after each use, as described in this manual.

WARNING:
If a fault or sudden change in performance occurs in the warming system, discontinue use. Notify your sales/service center. The unit must be serviced by qualified personnel using procedures provided in the *Service Manual*.

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

Caution:
Only use WarmTouch™ blankets with the WarmTouch warming unit. Do not attempt to use other types of blankets with the warming unit. Similarly, do not attempt to use WarmTouch blankets with other types of warming units.

Caution:
The HEPA filter must be replaced every 2,000 hours of operation or 365 days, whichever comes first. Filter replacement must be performed by qualified personnel. Refer to the *Service Manual* for replacement instructions.

Caution:
The USB port on the warming unit is for service use by qualified personnel only. During patient treatment, a USB cable must not be connected to the warming unit.

Positioning the Warming Unit

WARNING:
Do not operate the warming system in a stacked configuration with other equipment.

WARNING:
Do not operate the warming system adjacent to other equipment. If such a configuration cannot be avoided, first test the warming system in the intended configuration to verify normal operation.

As described in *Chapter 3, Installation*, the warming unit may be mounted on a cart, IV pole, or bed. Alternatively, the warming unit can be placed on the floor (under the operating table, for example). Whichever method is used, be sure to consider the following when positioning the warming unit for operation:

- **Power outlet access and power cord position —** Ensure that the power outlet used for the warming unit is easily accessible; disconnection from the outlet is the only way to completely remove power from the warming unit.
- **Air intake clearance —** Ensure that the air intake at the back of the warming unit is not obstructed. Do not cover any part of the warming unit.
- **Front panel access and visibility —** Ensure that the operator can easily access the warming unit's front panel controls and view the display during treatment.
- **Hose position —** Determine where the warming unit hose will be connected to the blanket. Ensure that the hose does not impede access to the patient, warming unit controls, or other equipment. To secure the hose, use the clip attached to the nozzle strap (reference *Figure 1* on page 16).

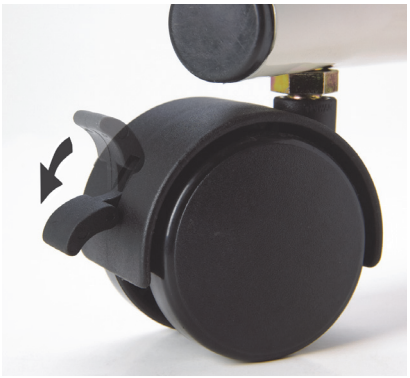
- **Sterility —** When using WarmTouch blankets intended for surgical applications, be aware that the blanket is sterile when used according to its instructions, while the warming unit and hose are not sterile. To maintain a sterile operating field, position the warming unit and hose outside the sterile field. To maintain the blanket's sterility, carefully follow the blanket's *Instructions for Use*.

Prior to operation, check the warming unit, power cord, and safety labels for any damage or deterioration. If service is required, contact Covidien Technical Services or a local Covidien representative. Reference *Obtaining Technical Assistance* on page 8.

Using the Optional Transport Cart

If the warming unit is mounted on the optional cart, engage the two rear wheel locks to reduce cart movement during use. Press the lock arms down to lock the wheels (*Figure 12*). Lift the lock arms up to move the cart.

Figure 12. Cart Wheel Lock



Applying Power

WARNING:
Possible explosion hazard. Do not use the device in the presence of flammable anesthetics or in an oxygen-rich environment.

WARNING:
Possible electric shock hazard. Grounding reliability can be achieved only when the warming unit is connected to a suitable mains outlet with protective earth grounding.

WARNING:
Do not use the warming system during magnetic resonance imaging (MRI) scanning.

Caution:
Operation of the warming system may affect or be affected by other devices in the vicinity due to electromagnetic interference (EMI). If interference occurs, try increasing the distance between devices, repositioning the cabling, or plugging the devices into separate outlet circuit branches. Reference *Electromagnetic Compatibility (EMC)* on page 60 for additional guidance.

To apply power to the warming unit:

1. Ensure that you have followed the guidelines in *Positioning the Warming Unit* on page 34.

2. Plug the warming unit's power cord into a hospital-grade or suitable mains outlet with protective earth grounding.

   The status LED illuminates amber to indicate that the warming unit is in Standby mode. The fan and heater are off, and the display is blank.

Overview of Warming Unit Operating Modes

Standby Mode

- **Status LED:** AMBER
- **Heater:** OFF
- **Fan:** OFF
- **Display:** OFF

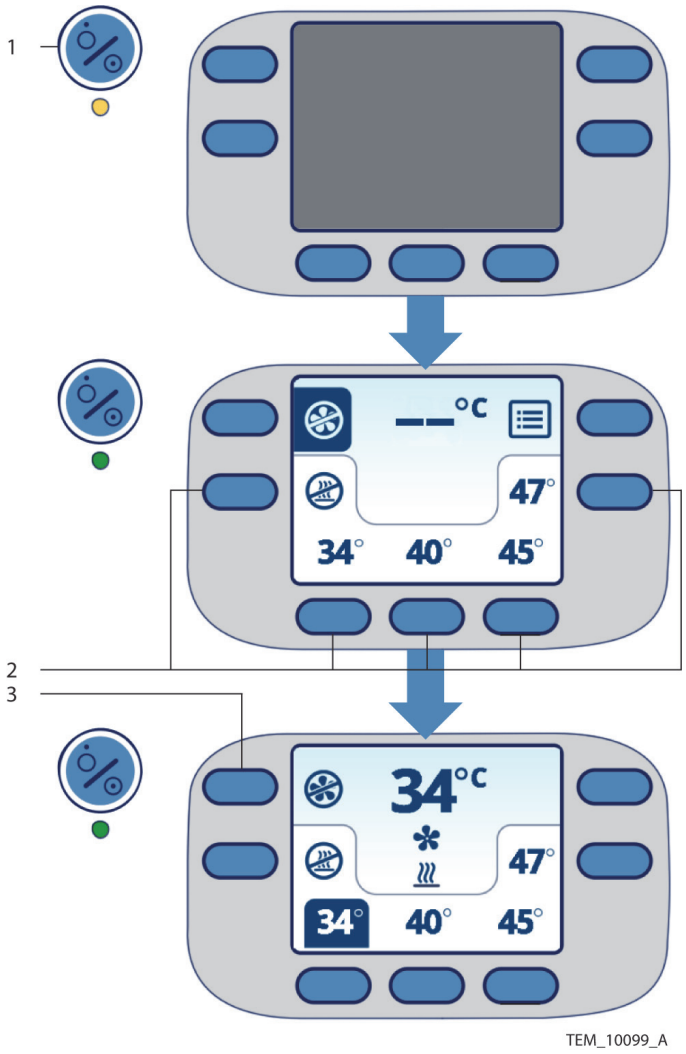
Ready Mode

- **Status LED:** GREEN
- **Heater:** OFF
- **Fan:** OFF
- **Display:** ON

Treatment Mode

- **Status LED:** GREEN
- **Heater:** ON or OFF
- **Fan:** ON
- **Display:** ON

Reference *Operator's Panel* on page 18 for descriptions of the display symbols.



1 **On/Standby Key** — Press to place the unit in Ready mode and prepare for operation, or press to return to Standby mode when treatment is complete. Reference *Beginning Treatment* on page 38 and *Returning to Standby Mode* on page 43.

2 **Temperature Keys** — Press to place the unit in Treatment mode, delivering air to the blanket. Reference *Controlling the Temperature* on page 40.

3 **Fan Off Key** — Press to return to Ready mode, pausing air delivery during treatment. Reference *Returning to Ready Mode* on page 43.

Beginning Treatment

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

WARNING:
Possible burn or infection hazard. Do not allow warming blanket to come in contact with open wounds. All patients' wounds should be covered while using the warming system.

WARNING:
Thermal injury may occur if the warming unit hose comes into contact with the patient.

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

WARNING:
Thermally conductive materials, such as water, gel, and similar substances, can decrease the patient's body temperature when the warming unit is switched off.

WARNING:
Use WarmTouch™ blankets only as directed. Carefully follow the *Instructions for Use* provided with the blankets regarding proper handling and positioning.

WARNING:
WarmTouch™ blankets are for single patient use only.

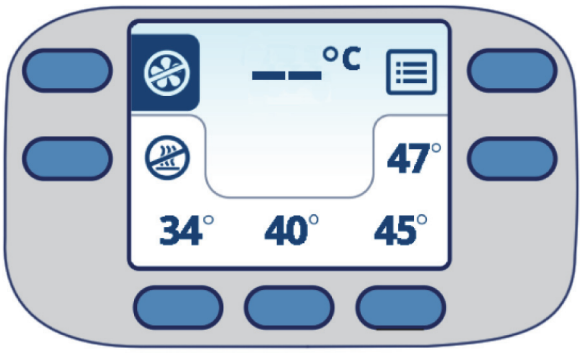
Caution:
Do not spray, pour, or spill any liquid on the warming unit, its accessories, connectors, switches, or openings in the case.

To begin treatment:

1. Press the **On/Standby** key. The unit enters Ready mode:

   - The status LED turns green, and the display turns on.
   - A short tone indicates a successful power-on self-test (POST). If POST is unsuccessful, an alarm screen appears. Reference *If an Alarm Condition Occurs* on page 53.
   - The Main screen appears (*Figure 13*). Note that if the filter needs to be replaced, the Replace Filter screen appears instead of the Main screen (*Figure 14*).

Figure 13. Main Screen at Power-On



TEM_10100_A

Figure 14. Replace Filter Screen at Power-On



TEM_10101_A

2. If you see the Replace Filter screen, take the warming unit out of operation and have the filter replaced by qualified personnel (reference *Filter Replacement* on page 47). It is possible to continue operation; however, failure to replace the filter as recommended can adversely affect device performance. If you choose to

continue operation, press the **OK** key. The Main Screen appears (*Figure 13*). Until the filter is replaced, the Replace Filter screen reappears at each subsequent power-on.

3. Position a WarmTouch warming blanket on the patient, and attach the blanket to the hose, as described in the blanket's *Instructions for Use*. Make sure that the hose is positioned such that it does not twist the blanket inlet.

4. Proceed to *Controlling the Temperature* to select a temperature setting for the patient.

Controlling the Temperature

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

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 fire hazard. Prevent the blanket material from coming into contact with a laser or an electrosurgical active electrode.

WARNING:
Continuously monitor the patient's temperature during treatment with the warming system. Use good clinical judgment in selecting and adjusting temperature settings based on the patient's warming needs and response to treatment.

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

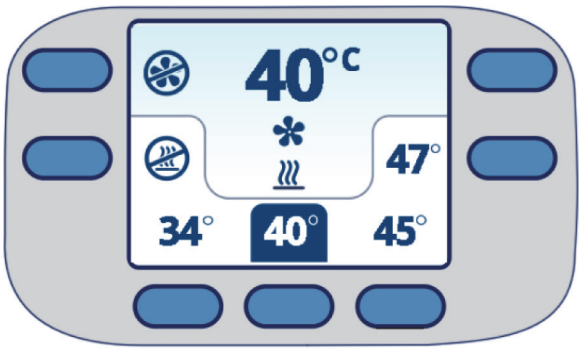
Select an initial setting by pressing one of the temperature keys. Continuously monitor the patient's temperature, and adjust the setting as necessary.

Note that the temperature settings and readings on the display correspond to internal measurements of the air entering the hose. The air temperature entering the blanket is lower and can vary depending on environmental conditions. Use *Table 4* as a guideline for selecting temperature settings.

Table 4. Temperature Settings

Setting	Avg. Temperature Entering Hose	Avg. Temperature Entering Blanket	Typical Use
(Heat Off)	Room temperature	Room temperature	To aid in cooling the patient, if necessary.
34° (Low)	34°C (93°F)	32°C (90°F)	To help prevent or treat hypothermia, or to maintain appropriate normothermia.
40° (Medium)	40°C (104°F)	38°C (100°F)	
45° (High)	45°C (113°F)	42°C (108°F)	
47° (Boost)	47°C (117°F) for 45 minutes	44°C (111°F)	To rapidly warm patients.

Figure 15. Warming System Set to 40°C (Medium)



TEM_10102_A

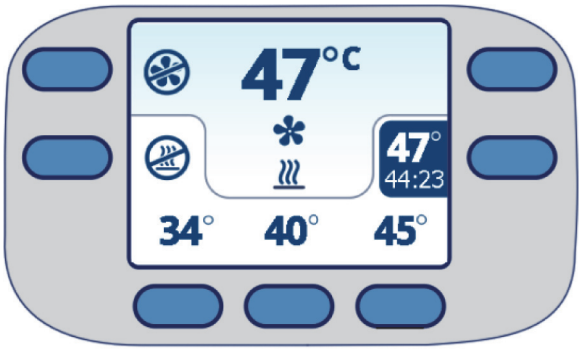
Note that when you change the temperature setting, an amber arrow appears next to the current temperature while it adjusts. When the temperature is within approximately 1.5°C of the new setting, the arrow disappears.

Using Boost Mode

Boost mode allows rapid warming of patients. Air is generated at 47°C (116.6°F) for 45 minutes. After 45 minutes, the setting automatically changes to 45°C (High).

47° To use Boost mode, press the **47°C (Boost Mode)** key. A countdown timer shows the time remaining before the temperature switches to the 45°C (High) setting. Boost mode sessions can be repeated as necessary.

Figure 16. Warming System Set to Boost Mode



TEM_10103_A

Using the Heat Off Setting

If a patient requires cooling, press the **Heat Off** key. Air is delivered to the warming blanket at room temperature (heater off).

Figure 17. Warming System Set to Heat Off



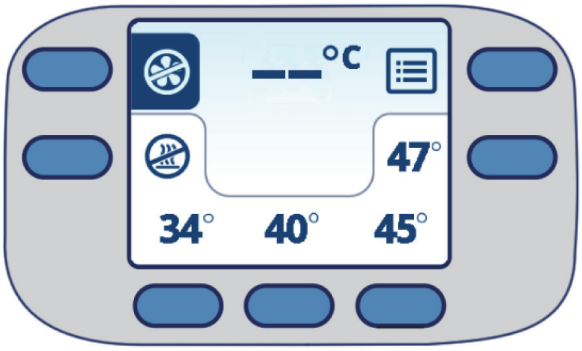
TEM_10108_A

Returning to Ready Mode

During operation, you can switch back to Ready mode (fan and heat off) any time you do not need to apply air to the warming blanket. The display stays on, and the unit remains ready to operate.

To return to Ready mode, press the **Fan Off** key. Note that in Ready mode, the temperature reading shows dashes.

Figure 18. Warming System Set to Ready Mode



TEM_10100_A

Returning to Standby Mode

Use Standby mode when you are finished using the warming system but do not wish to unplug it.

To return to Standby mode during operation, press the **On/Standby** key. The heater and fan shut off, the display goes blank, and the status LED turns amber.

If Power is Interrupted...

If power is interrupted during operation, the warming unit responds as follows, based on the duration of the power loss:

- **Power restored within approximately 15 seconds —** The warming unit powers up, performs a power-on self-test (POST), and resumes operation in the same mode as before the power loss.
- **Power restored after approximately 15 seconds —** The warming unit powers up in Standby mode.

If the warming unit powers back up in Standby mode, press the **On/Standby** key to enter Ready mode, then select a temperature setting to resume treatment.

Powering Off the Warming Unit

To power off the warming unit:

1. Press the **On/Standby** key. The fan and heater (if running at the time) turn off. The display goes blank, and the status LED turns amber.
2. To completely remove power from the warming unit, unplug the unit's power cord from the outlet.

Cleaning the Warming Unit after Operation

WARNING:
Clean the warming unit after each use, as described in this manual.

To reduce the risk of patient or operator infection, clean the warming unit after each use. Reference *Chapter 5, Maintenance* for cleaning instructions.

5 Maintenance

Overview

This chapter describes the cleaning and maintenance requirements for the Covidien WarmTouch™ Convective Warming Unit.

Cleaning the Warming Unit

WARNING:
Clean the warming unit after each use, as described in this manual.

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

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

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

Safety Checks

Physical Inspection

Covidien recommends a visual check of the following items before each use of the warming unit:

- **Equipment —** Inspect the warming unit and power cord for mechanical damage or deterioration.
- **Labels —** Inspect the safety labels for legibility.

Do not use a damaged unit. If service is required, contact Covidien Technical Services or a local Covidien representative. Reference *Obtaining Technical Assistance* on page 8.

Alarm and Temperature Verification

Once a year, qualified personnel must perform tests to verify the alarm system and the heater's output temperatures. Instructions are provided in the *Service Manual*. Covidien recommends performing these tests each time the filter is replaced and any time the unit requires repair.

Electrical Safety Tests

Electrical safety tests must be performed by qualified personnel after specific types of service. Consult the *Service Manual* for requirements and instructions.

Filter Replacement

Caution:
The HEPA filter must be replaced every 2,000 hours of operation or 365 days, whichever comes first. Filter replacement must be performed by qualified personnel. Refer to the *Service Manual* for replacement instructions.

If the filter needs to be replaced, the screen shown in *Figure 19* appears at power-on. Remove the warming unit from operation until the filter can be replaced by qualified personnel. **Failure to replace the filter as recommended can adversely affect device performance.**

Figure 19. Replace Filter Screen



TEM_10101_A

Monitoring the Filter Status

The warming unit monitors filter usage and provides counters that indicate the number of operating hours and days until the filter needs to be replaced. You can anticipate filter replacement by checking the counters on the Filter Information screen.

Note:
The Filter Information screen is only accessible when the warming unit is in Ready mode. It is not accessible while the warming unit is operating.

To view the Filter Information screen:

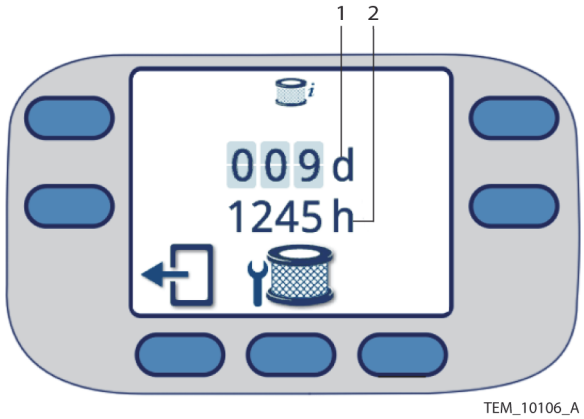
1. If the warming unit is not already powered on, follow the steps in *Applying Power* on page 36.
2. Press the **On/Standby** key to enter Ready mode.
3. Press the **Menu** key on the Main screen. The Menu screen appears.

Figure 20. Menu Screen



4. Press the **Filter Information** key. The Filter Information screen indicates the days and operating hours remaining before the filter needs to be replaced.

Figure 21. Filter Information Screen



1 Filter Days Remaining 2 Filter Hours Remaining

5. To return to the Main screen, press the **Exit** key twice.

Note:
The Menu screen and Filter Information screen shown in the previous figures provide access to service functions used by qualified personnel only. These functions are accessed with the following keys and require input of a key code. If you inadvertently press either of these keys, press the **Exit** key to return to the prior screen.

System Test key **Filter Reset** key

Component Disposal

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.

Instructions for the proper disposal of used warming blankets are provided in the blanket's *Instructions for Use*.

Air filter replacement and disposal must be performed by qualified personnel. Instructions for the proper disposal of used filters are provided in the *Service Manual*.



The warming unit must be disposed of in accordance with WEEE Directive and national laws and regulations. Do not dispose of this product as unsorted municipal waste.

6 Troubleshooting

Overview

This chapter describes how to troubleshoot problems that may occur while using the Covidien WarmTouch™ Convective Warming Unit.

Safety Reminders

WARNING:
If a fault or sudden change in performance occurs in the warming system, discontinue use. Notify your sales/service center. The unit must be serviced by qualified personnel using procedures provided in the *Service Manual*.

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:
No modification of this equipment is allowed.

Caution:
Operation of the warming system may affect or be affected by other devices in the vicinity due to electromagnetic interference (EMI). If interference occurs, try increasing the distance between devices, repositioning the cabling, or plugging the devices into separate outlet circuit branches. Reference *Electromagnetic Compatibility (EMC)* on page 60 for additional guidance.

Problems and Resolutions

Table 5. Warming Unit Problems and Resolutions

Problem	Resolution
Failure to power on	Check the power cord's connection to the warming unit. The connector must be fully seated. Reference *Attaching the Power Cord* on page 24. If the power cord is properly connected, an internal component may have failed. Notify qualified personnel to service the warming unit.
Electromagnetic interference between the warming unit and other devices	Try increasing the distance between devices, repositioning the cabling, or plugging the devices into separate outlet circuit branches. Reference *Electromagnetic Compatibility (EMC)* on page 60 for additional guidance.
Low-priority alarm 	Power the warming unit off and back on to clear the alarm. Reference *If an Alarm Condition Occurs* on page 53 for additional information.
Medium-priority alarm  (flashing)	**Remove the warming unit from operation until it can be repaired by qualified personnel.** Reference *If an Alarm Condition Occurs* on page 53 for additional information.
Filter needs to be replaced 	Remove the warming unit from operation and have the filter replaced by qualified personnel. Reference *Filter Replacement* on page 47. **Failure to replace the filter as recommended can adversely affect device performance.**

If an Alarm Condition Occurs

If an alarm condition or error occurs during operation, the warming unit sounds alarm tones and displays an alarm screen. There are two types of alarms: low-priority and medium-priority.

Figure 22. Low-Priority Alarm (Left) and Medium-Priority Alarm (Right)

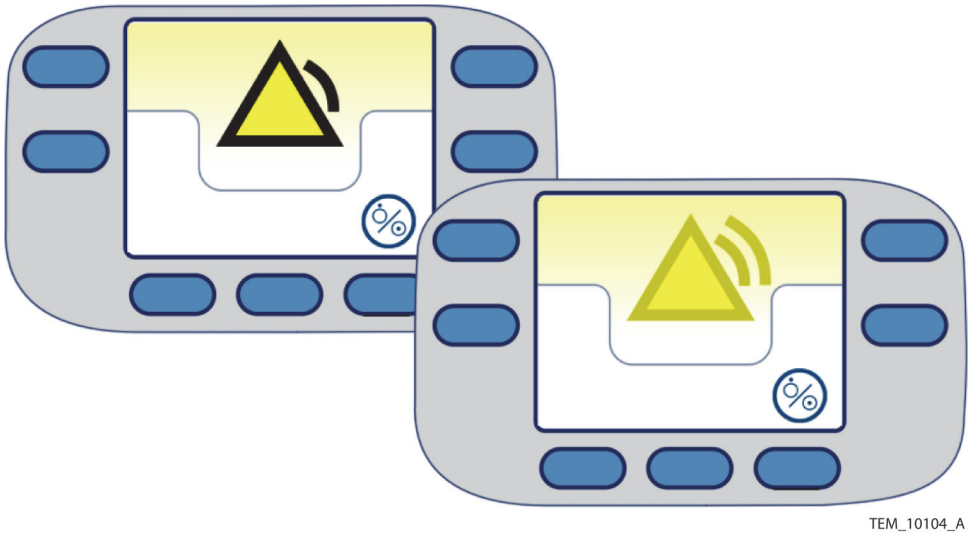


Table 6. Alarm Indicators

Symbol	Tones	Type of Alarm
	Two successive tones repeating	**Low-priority alarm:** A condition that requires operator awareness, but does not pose a risk of harm to the patient. Reference *page 54* for instructions for clearing a low-priority alarm.
 (flashing)	Three successive tones repeating at decreasing intervals	**Medium-priority alarm:** A condition that poses a risk of harm to the patient. **Remove the warming unit from operation until it can be repaired by qualified personnel.**

Note:
If multiple alarms occur at the same time, the unit reports the highest priority alarm.

To clear a low-priority alarm:

1. Power off the warming unit by pressing the key indicated on the alarm screen.
2. Press the **On/Standby** key to power on the warming unit.

If the alarm does not clear, remove the warming unit from operation until it can be repaired by qualified personnel.

Serial Number and System Information

If you need to contact Covidien Technical Services for assistance, please provide the warming unit's serial number and, if possible, the software version number and any error messages displayed.

Serial Number

The serial number is located on the back of the warming unit.

Figure 23. Serial Number Label on Back of Warming Unit



TEM_10120_A

System Information

The software version number and recent error messages can be obtained from the warming unit's System Information screen.

Note:
The System Information screen is only accessible when the warming unit is in Ready mode. It is not accessible while the warming unit is operating.

To access the System Information screen:

1. If the warming unit is not already powered on, follow the steps in *Applying Power* on page 36.
2. Press the **On/Standby** key to enter Ready mode.
3. Press the **Menu** key. The Menu screen appears.

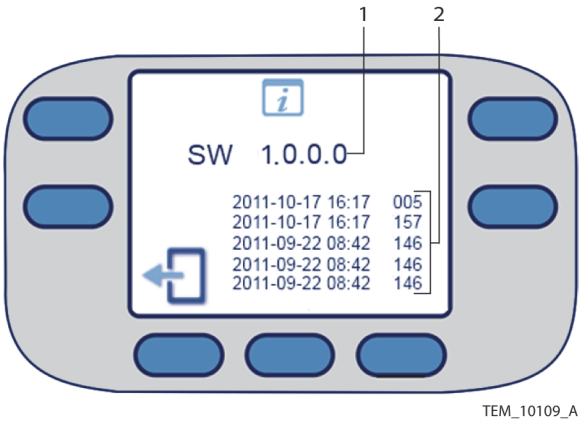
Figure 24. Menu Screen



4. Press the **System Information** key. The System Information Screen shows the software version and the most recent error messages, if any.

Note:
Time stamps associated with error messages do not necessarily reflect local time. The warming unit is set to GMT at manufacture.

Figure 25. System Information Screen



1 Software Version 2 Error Messages (Up to Six)

5. To return to the Main screen, press the **Exit** key twice.

Note:
The warming unit maintains a log of errors and events to assist qualified personnel in troubleshooting. Log entries are maintained through power cycles. Instructions for accessing the log are provided in the *Service Manual*.

7 Product Specifications

Overview

This chapter provides physical and operational specifications for the Covidien WarmTouch™ Convective Warming Unit.

Physical Characteristics

Warming Unit

Weight with Power Cord	5.2 kg (11.5 pounds)
Dimensions - hose fully collapsed, nozzle in storage position on unit	60 cm x 43 cm x 30 cm (24 inches x 17 inches x 12 inches)
Power Cord Length	4.3 m (14 feet)

Transport Cart (Optional)

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)

Electrical Requirements

Power Requirements	100 to 240 V AC Max. current at 100 V = 8 A Max. current at 240 V = 5 A
Input Frequency	50/60 Hz ±1 Hz
Fuse (x2)	Littlefuse (mfr.) 0218010; 250 V, 10 A

Environmental Specifications

Operating

Temperature	18°C to 28°C (64.4°F to 82.4°F)
Relative Humidity	15% to 85% (non-condensing)

Shipping and Storage

Temperature	-40°C to 70°C (-40°F to 158°F)
Relative Humidity	10% to 95% (non-condensing)
Atmospheric Pressure	12 kPa to 106 kPa (90 mmHg to 795 mmHg)



Note:
Before operating the warming unit after it has been shipped or stored, allow the unit to acclimate to the operating environment for at least 60 minutes.

Performance Specifications

Maximum Contact Surface Temperature	44.1°C (111.4°F)
Average Time for Contact Surface Temperature to Rise from 23°C ±2°C to 37°C	6 minutes
Average Time for Temperature of Air Exiting the Hose to Rise from 23°C ±2°C to 37°C	< 1 minute
Accuracy of Displayed Temperature	±1.0°C (air entering hose)
Automatic Temperature Stepdown (Boost to High Temperature)	After 45 minutes of continuous use, blower will step down from the Boost to High setting.
Thermal Protection Threshold	Thermostat (internal): 49°C to 55°C (120°F to 131°F)
Average Alarm Level	56 dB @ 1 meter

Product Compliance

Equipment Classification	IEC 60601-1:2005, EN 60601-1:2006 ANSI/AAMI ES60601-1:2005 CAN/CSA C22.2 No 60601-1:08 IEC 80601-2-35:2009 EN 80601-2-35:2010
Protection Type	Class I
Degree of Protection	Type BF - Applied part
Mode of Operation	Continuous
Electromagnetic Compatibility	IEC/EN 60601-1-2:2007, Class A Emissions, Non Life-Support Equipment. IEC/EN 80601-2-35; Hazard Free to 10 V/m.
Protection Against Ingress of Fluids	Ordinary

Electromagnetic Compatibility (EMC)

Manufacturer's Declaration

The warming system is suitable for prescription use only in the specified electromagnetic environments. Use the warming system in accordance with the electromagnetic environments described in the following sections.

Electromagnetic Emissions

Table 7. Electromagnetic Emissions Guidelines

Guidance and Manufacturer's Declaration—Electromagnetic Emissions (IEC/EN 60601-1-2:2007, Table 1)		
The warming system is intended for use in the electromagnetic environment specified below. The customer or the user of the warming system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emission CISPR 11	Group 1, Class A	This is a class A product per IEC CISPR 11 and is not intended to be used in a residential environment. If used in a domestic environment, this equipment may not offer adequate protection to radio-frequency communication services. The user may be required to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC/EN 61000-3-2	Class A	The warming 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.
Voltage fluctuation/ flicker emissions IEC/EN 61000-3-3	Complies	

Caution:
The warming system is not intended for use in residential environments and may not provide adequate protection to radio communication services in such environments.

Electromagnetic Immunity

Table 8. Electromagnetic Immunity Guidelines

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 2)			
The warming system is intended for use in the electromagnetic environment specified below. The customer or the user of the warming system should assure that it is used in such an environment.			
Immunity Test	**IEC/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	Floors 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 line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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.
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 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 5 seconds	<5% UT (>95% dip in UT) for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC main's voltage prior to application of the test level.			

Table 9. Recommended Separation Distance Calculations

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 4)			
The warming system is intended for use in the electromagnetic environment specified below. The customer or the user of the warming system should assure that it is used in such an environment.			
Immunity Test	**IEC/EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the warming unit, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz 80 MHz	3 Vrms 150 kHz 80 MHz	Recommended Separation Distances $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m 80 MHz 800 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	3 V/m 800 MHz 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the warming system is used exceeds the applicable RF compliance level above, the warming system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the warming system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 10. Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Warming System (IEC/EN 60601-1-2:2007, Table 6)

The warming system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the warming system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the warming system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power (*P*) of Transmitter in Watts	**Separation Distance in Meters**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, estimate the separation distance (*d*) 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 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Ground Integrity Test

Without power cord: ≤ 100 m Ω

With power cord: ≤ 200 m Ω

Earth Leakage Current Test

Table 11. Earth Leakage Current Test

AC Polarity	Line Cord	Neutral Cord	Leakage Current
Normal	Closed	Closed	300 µA
Reversed	Closed	Closed	300 µA
Normal	Open	Closed	1000 µA
Normal	Closed	Open	1000 µA

Enclosure Leakage Current Test

Table 12. Enclosure Leakage Current Test

AC Line Cord	Neutral Line Cord	Power Line Ground Cable	AAMI / ANSI Standard ES1
Normal	Closed	Closed	100 µA
Normal	Closed	Open	500 µA
Normal	Open	Closed	500 µA
Reversed	Closed	Closed	100 µA
Reversed	Open	Closed	500 µA
Reversed	Closed	Open	500 µA

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