smiths medical

level 1®

Convective Warmer
Chauffage convectif
Konvektives Wärmegerät
Riscaldatore a convezione
Calefactor convectivo
Aquecedor convectivo
Convectieve verwarmer
Konvektionsvärmare
Konvektionsvarmer
Konveksjonsvarmer
Lämpöpuhallin
Θερμοπομπός
Konvekční ohřívač
Konvektívny ohrievač
Konvekciós melegítőkészülék
Ogrzewacz konwekcyjny
Konvektiivne soojendi
Konvektīvā sildītāja
Konvekcinis šildytuvas
Конвекторен нагревател
Dispozitiv de încălzire prin convecţie
Konvekcijski grelnik



- en Operator's Manual
- fr Manuel d'utilisation
- de Bedienungsanleitung
- it Manuale dell'operatore
- es Manual del operador
- pt Manual do operador
- nl Gebruikershandleiding
- sv Bruksanvisning
- da Brugervejledning
- no Operatørhåndbok
- fi Käyttöohjekirja
- el Εγχειρίδιο χειριστή
- cs Uživatelská příručka
- sk Príručka operátora
- hu Kezelői kézikönyv
- pl Podręcznik obsługi
- et Kasutusjuhend
- lv Lietotāja rokasgrāmata
- lt Operatoriaus vadovas
- bg Ръководство за оператора
- ro Manual de operare
- sl Uporabniški priročnik

REF **L1-CW-100V**
REF **L1-CW-120V**
REF **L1-CW-220V**

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Convective Warmer

en Operator's Manual



REF **L1-CW-100V**

REF **L1-CW-120V**

REF **L1-CW-220V**

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Level 1® Convective Warmer Operator's Manual

Part Number: ML-0001-558 Rev. 303 (04/19)

This revision supersedes all previous revisions.

Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company, however, reserves the right to improve the equipment shown. Mention of third-party products is for informational purposes only and constitutes neither an endorsement nor a recommendation. Smiths Medical ASD, Inc. ("Smiths Medical") assumes no responsibility with regard to the performance or use of these products.

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SECTION 1

About this Manual

This Operator's Manual describes the assembly, use, and maintenance of the Level 1® Convective Warmer. This manual is intended for use by individuals trained in the healthcare and biomedical professions.

WARNING: These instructions contain important information for safe use of the product. Read the entire contents of this Operator's Manual, including Warnings and Precautions, before using this product. Failure to properly follow warnings, precautions, and instructions could result in death or serious injury to the patient.

Indications for Use

The Level 1® Convective Warmer is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warmer can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Level 1® Convective Warmer can be used with adult or pediatric patients and is intended for use by healthcare professionals in clinical environments.

Conventions Used in this Manual

This manual uses the following text and text conventions:

Convention	Description
Note	A Note statement alerts the user to important information that requires attention.
WARNING	A Warning statement alerts the user to conditions that may cause death or serious injury to the patient or user.
PRECAUTION	A Precaution statement alerts the user to conditions that may cause malfunction, failure, or damage to the device.

SECTION 2

Description

The Level 1® Convective Warming system consists of a high-flow convective warmer with hose-end temperature control, a convective warming blanket, and accessories.

The convective warmer draws ambient-temperature air through a HEPA air filter. The filtered air is warmed to a selected temperature. The warmed air enters the convective warming blanket through the hose and is distributed through delivery channels. Perforations on the patient side of the air delivery channels in the blanket gently disperse warm air over the patient.

The convective warmer has three outlet temperature settings, which provide flexibility in patient treatment: 37°C, 40°C, and 43°C. These three temperature settings are controlled by thermistors placed at the end of the hose where the hose connects to the convective warming blanket. A fourth temperature setting delivers ambient-temperature air. The temperature at the end of the hose is stable at the set point indicated on the control panel when the selected set point LED stops blinking.

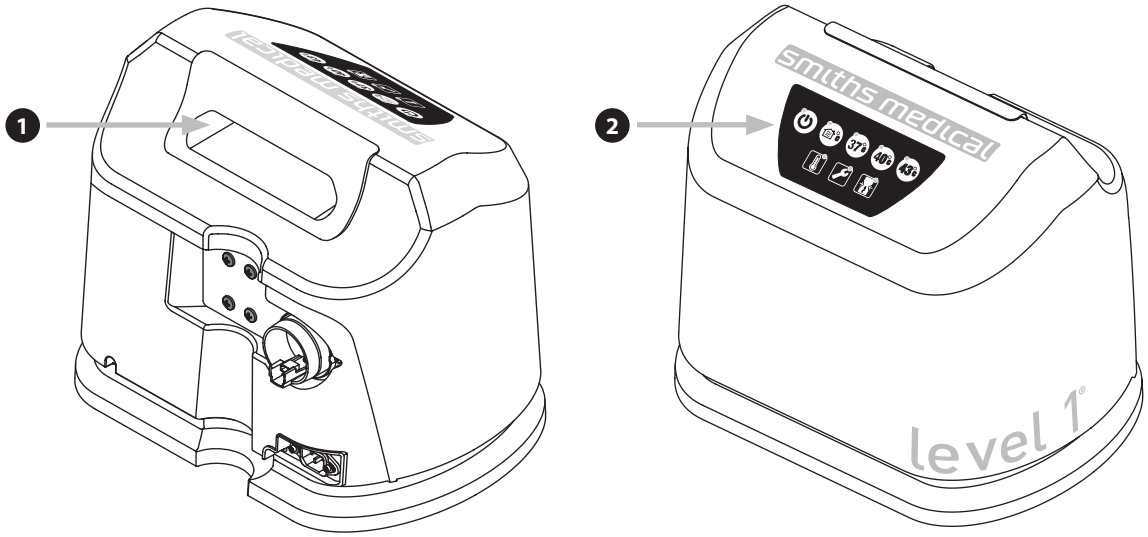
The safety circuit provides an independent means of shutoff which discontinues power to the heater. This prevents patient exposure to excessive temperatures. Over-temperature is monitored and alarms separately for each temperature setting.

See *Appendix A* (page 41) for Product and Accessory information.

Convective Warmer Components

REAR VIEW (without clamp) and FRONT VIEW

1. **Handle** – used to lift and move the convective warmer
2. **Control Panel** – contains controls and displays used during operation



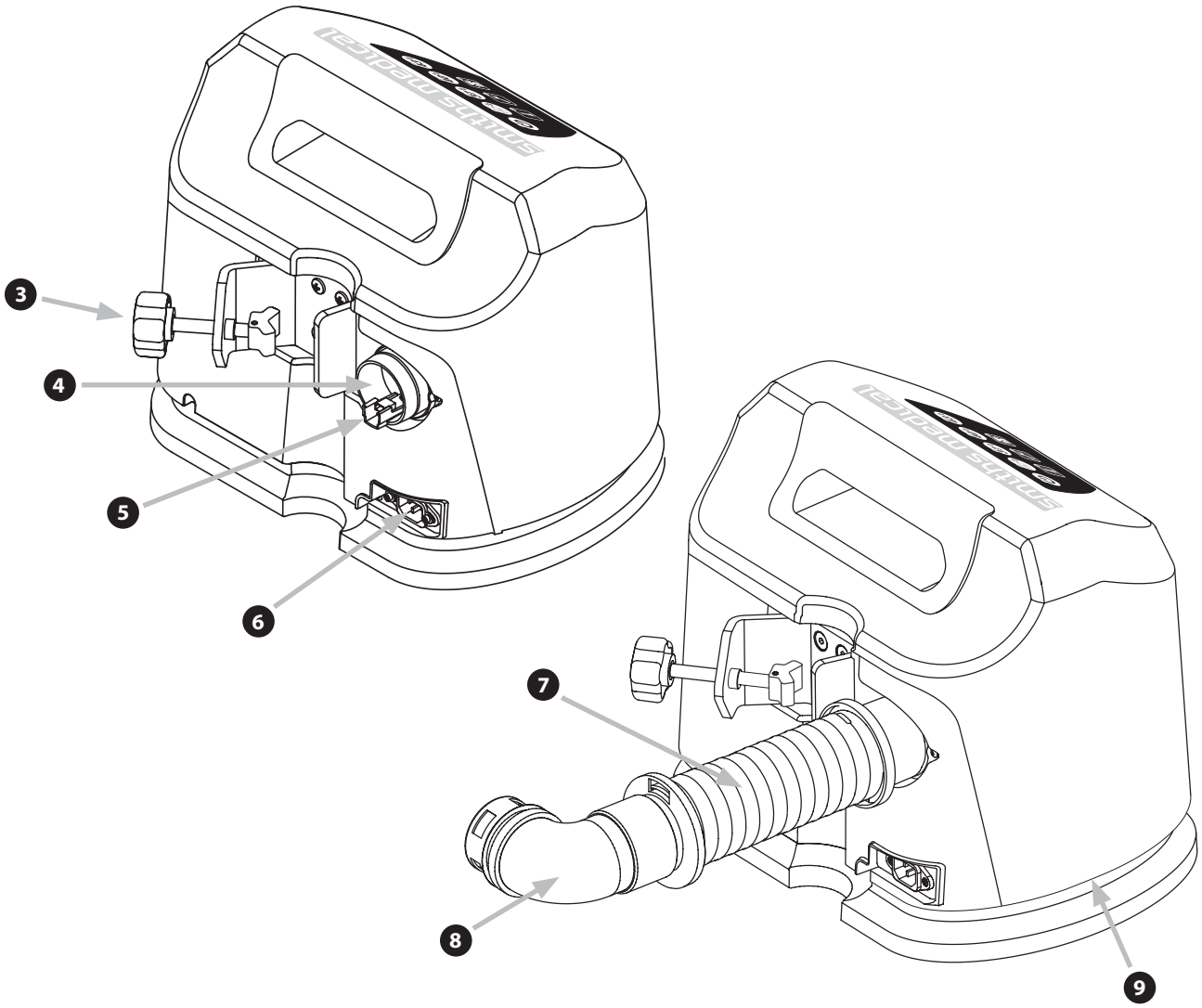
REAR VIEW **FRONT VIEW**

Rear View with clamp

3. **Pole Clamp (Optional)** – mounts the convective warmer on a pole
4. **Air Outlet** – opening where the hose attaches to the convective warmer
5. **Thermistor Receptacle** – connection for the thermistor cable
6. **Power Cord Receptacle** – connector for the power cord (MAINS connect/disconnect)

Rear View with Hose Attached

7. **Hose** – transports air to the convective warming blanket
8. **Hose Nozzle and Elbow** – hose end that attaches to the convective warming blanket
9. **Air Intake** – air enters the convective warmer through the vents located under the top housing



SECTION 3

Important Safety Information

This section covers information for prescribers and guidelines for safe use of the Level 1® Convective Warmer.

Warnings

Death or serious injury may occur to the patient or users if these warnings are not followed:

These instructions contain important information for safe use of the product. Read the entire contents of this Operator's Manual, including Warnings and Cautions (Precautions), before using this product. Failure to properly follow warnings, precautions, and instructions could result in death or serious injury to the patient.

- Thermal injury may occur if convective warming therapy is applied to lower extremities during aortic cross-clamping procedures.
- Thermal injury may occur if convective warming therapy is applied to ischemic limbs.
- To prevent thermal injury, closely observe patient's cutaneous circulation distal to arterial cross-clamping. To prevent thermal injury, do not use the highest temperature setting when treating patients who have poor perfusion.
- Electrocution Hazard. There are no user-serviceable parts inside the enclosure. Only competent personnel knowledgeable in the safety procedures required for servicing live primary MAINS parts shall be allowed to open the enclosure.
- Grounding reliability can only be achieved when the MAINS power cord is connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
- Exposed conductor on the MAINS power cord can cause an electrocution hazard. Remove the device from service if the MAINS power cord has exposed wires.



If mounting to an IV pole using the optional pole mounting clamp, the IV pole must have a minimum of 5 or more legs, a minimum diameter of 1.9 cm (0.75 in) and a minimum base diameter of 56 cm (22 in). Failure to use a proper IV pole may cause tipping that may injure the patient or user.



While in use, do not mount the convective warmer higher than 116 cm (46 in) from the floor on the IV pole. Mounting the convective warmer above 116 cm (46 in) may result in instability of the pole and cause tipping that may injure the patient or user.



The hose must be removed and transported separately or stored within the cart shelf compartment if the convective warmer is being transported while mounted on the cart shelf accessory. Failure to properly transport the warmer could cause tipping that may injure the user or patient.

Warnings *[continued]*

- During use, do not position the convective warmer such that it is difficult to disconnect the power cord from the wall or from the warmer. Thermal injury may occur if the device cannot be powered off easily if needed.
- In compliance with safety standard IEC 80601-2-35, there is a possible risk of electrical shock, burns, or electromagnetic interference with the use of High Frequency surgical instruments or endocardial catheters in the presence of active Heating Devices.
- The convective warmer meets the international electrical interference requirements of EN 60601-1-2. MRI, Portable and mobile RF communications equipment, and other such devices can affect the convective warmer.
- Do not operate the convective warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of explosion exists if the device is operated in a potentially explosive environment.
- To prevent fire hazard and possible damage to the convective warmer, use only fuses specified. Only competent personnel knowledgeable in the safety procedures required for servicing live primary MAINS parts shall be allowed to open the enclosure.
- If so equipped, ensure that the convective warmer IV pole mounting clamp is properly tightened before each use. Failure to securely mount the convective warmer onto the IV pole may cause it to slide down the IV pole, and injure the patient or user.
- Do not perform maintenance while the convective warmer is operating. Risk of thermal injury exists if the device is operating.
- This device can only be used in conjunction with a Smiths Medical convective warming blanket. For the safe operation of this device, the user must follow all warnings, precautions, and instructions provided in the Instructions for Use supplied with the compatible convective warming blanket, in addition to this Operator's Manual.
- Continuously monitor patient's body core temperature, vital signs, and observe cutaneous response at regular intervals to prevent thermal injury. If erythema or instability in vital signs is evident, decrease the temperature setting or discontinue use of convective warming therapy.
- To prevent thermal injury in hypotensive or hypoperfused patients, observe cutaneous response more frequently. Reduce the temperature setting or discontinue use of convective warming therapy if instability in vital signs or erythema occurs.
- If the patient's nose or mouth is positioned against the convective warming blanket or the plastic drape, closely monitor the patient's breathing to prevent suffocation injury.
- Cover all open wounds in contact with the convective warming blanket to prevent airborne contamination.

Warnings *[continued]*

- Use only one convective warmer and one hose. Use of multiple convective warmers in multiple inlet ports of the same convective warming blanket may cause damage to the blanket and thermal injury to the patient.
- To prevent thermal injury, do not allow any of the patient's body parts to rest on the active hose inlet. Do not allow the hose to contact the patient.
- Use of the device in loud environments may prevent the audio alarm from being heard. Visually monitor patient temperature and device visual indications.
- Do not use a convective warming blanket over transdermal medications (patches) as this may lead to increased drug delivery that may result in patient injury or death.
- To prevent thermal injury to the patient, if Over Temperature alarm sounds and/or Over Temperature alarm indicator illuminates (Amber), restart, select temperature, and determine if the problem persists before placing back in service. If condition persists, remove from service and contact Smiths Medical or your local Smiths Medical distributor.
- The convective warmer must be serviced by competent personnel authorized by Smiths Medical. Failure to service the device correctly may result in thermal injury to the patient.
- To prevent insufficient or excessive heat therapy, the convective warmer should only be used in operating temperatures of 10°C – 40°C.
- The use of materials of good thermal conductivity, such as water, gel and similar substances, with the convective warmer not operating can decrease the temperature of the body of a patient.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- This device can only be used in conjunction with a Smiths Medical convective warming hose and power cord. Failure to use this device with the Smiths Medical hose and power cord could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable and mobile RF communications equipment should be used no closer to any part of the convective warmer, including cables, than the recommended separation distance specified in Section 8, *Specifications*.

Precautions

Malfunction, failure, or damage to the device may occur if these precautions are not followed:

- No modification of this equipment is allowed.
- Hose nozzle MUST be connected to a compatible forced air blanket or thermal injury may occur.
- If the convective warmer does not perform its self-test properly, fails to operate, or stops while running, discontinue use of the convective warmer to prevent thermal injury to the patient. Remove the device from service. Contact Smiths Medical or your local Smiths Medical distributor.
- Do not use strong solvents to clean the hose or exterior surfaces. These solutions may damage labels and other parts.
- Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the convective warmer.
- Do not place the convective warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the convective warmer or into the external connectors.
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

SECTION 4

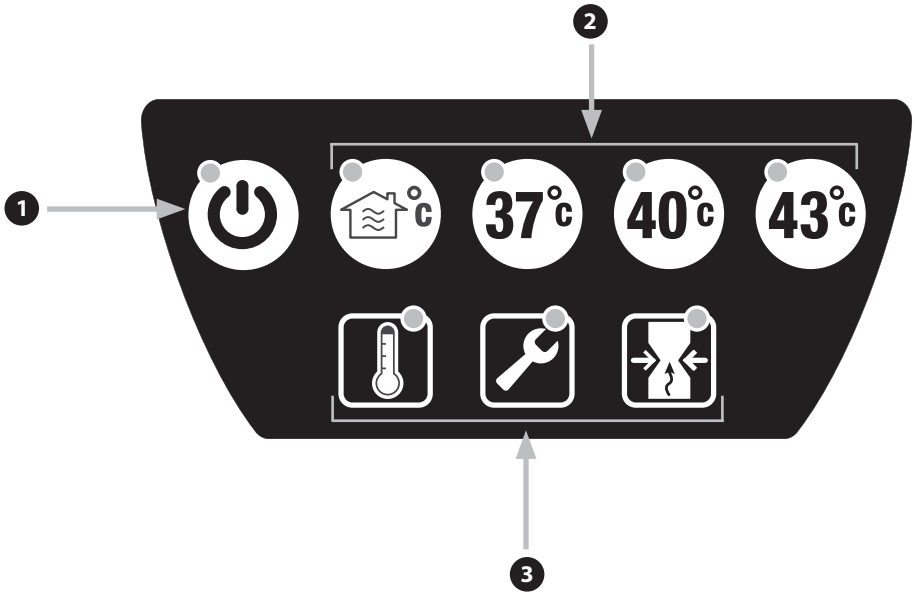
User Interface

Operation of the Level 1® Convective Warmer is monitored and controlled by the control panel (User Interface). This section describes the control panel and the modes of operation.

Control Panel

The Control Panel provides the controls, indicators, and displays used during operation of the convective warmer.

1. **Standby Button**
2. **Temperature Setting Buttons**
3. **Operation Indicators**



Controls, Indicators, and Displays

The following table defines each control, indicator, display and the modes of operation.

Control/Indicator	Definition	Visual Indicator	Audible Beep
	**Standby Button/Indicator** A solid lit LED indicates that the system is powered on but that the heater is OFF and the blower is OFF.	Green LED	None
	**Ambient Air Temperature Setting Button** When selected, the heater is turned OFF and the blower is ON (air flows).	Green LED	None
	**37° C Temperature Setting Button** When selected, the air temperature is set to 37° C at the hose end. A blinking LED indicates that the system has not yet reached the selected temperature.	Green LED	None
	**40° C Temperature Setting Button** When selected, the air temperature is set to 40° C at the hose end. A blinking LED indicates that the system has not yet reached the selected temperature.	Green LED	None
	**43° C Temperature Setting Button** When selected, the air temperature is set to 43° C at the hose end. A blinking LED indicates that the system has not yet reached the selected temperature.	Green LED	None
	**Over Temperature indicator** Blinking or solid lit Indicator LED indicates that the system has detected a temperature that is too high.	Amber LED	Dependent on condition*
	**Maintenance indicator** Blinking or solid lit Indicator LED indicates that an error has occurred which requires maintenance or that routine maintenance is needed.	Amber LED	Dependent on condition*
	**Occlusion indicator** A solid lit Indicator LED indicates that an occlusion in the hose or blanket has been detected.	Amber LED	Dependent on condition*

*See Section 7, *Troubleshooting* for error condition remedies and solutions.

SECTION 5

Initial Setup and Daily Use

Assembly

The Level 1® Convective Warmer must be assembled and tested by authorized Smiths Medical personnel, an authorized distributor of Smiths Medical, or competent personnel prior to placing the convective warmer in service. Read through the instructions completely prior to assembling the convective warmer.

The following steps describe how to assemble and do preliminary set up of the convective warmer.

Step 1: Unpack the Convective Warmer

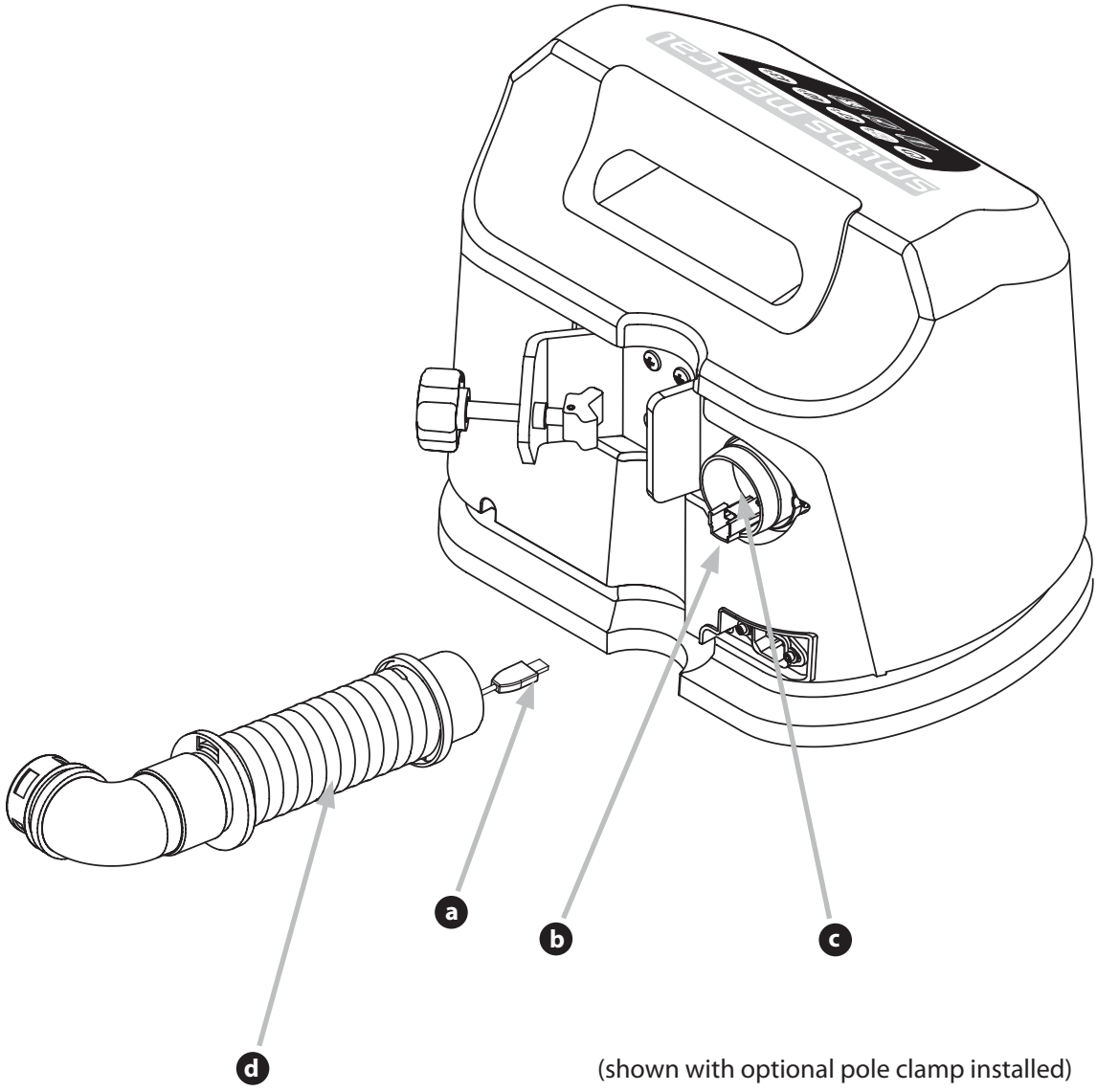
1. Check the contents and verify that all components are present. If any parts are missing or damaged, do not use the convective warmer. Contact Smiths Medical for replacement parts. Refer to the following list of components that are part of the convective warmer:
    - Level 1® Convective Warmer
    - Operator's Manual CD
    - Power Cord
    - Hose
    - Sheet Clip Assembly
    - Cord Wrap

Note: *The Power Cord and Cord Wrap are packaged separately from the Warmer.*

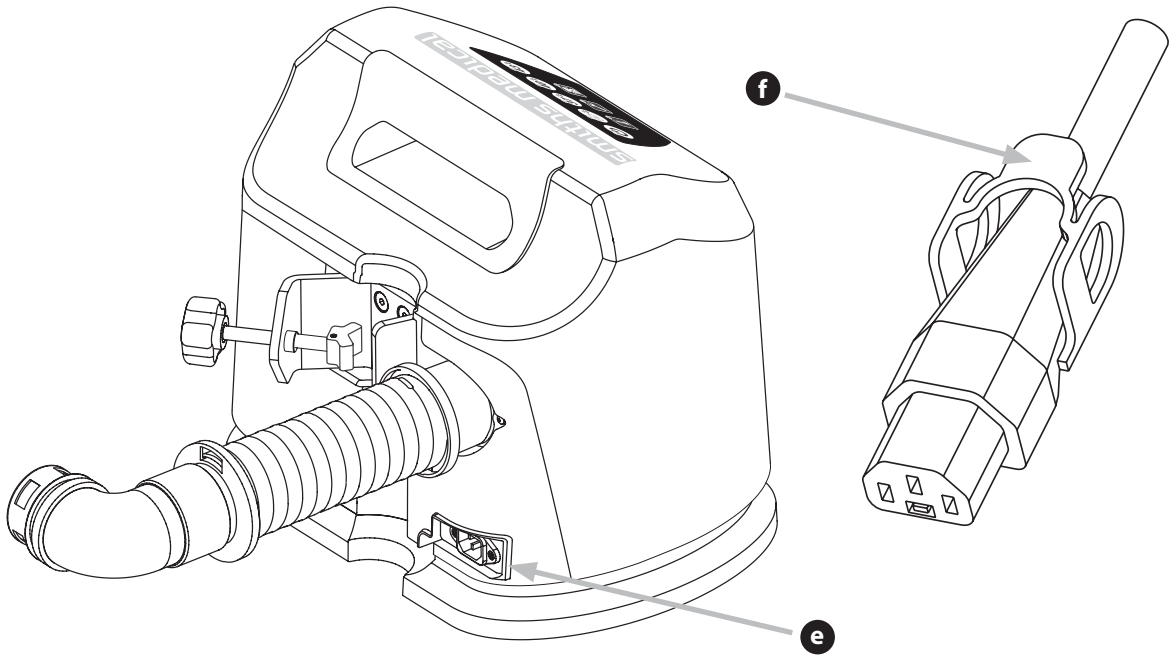
Note: *After unpacking all the contents, please recycle packaging material according to hospital policy for recyclable materials.*

Step 2: Attach the Hose to the Convective Warmer

1. Connect the thermistor cable (**a**) from the hose to the thermistor receptacle (**b**) mounted inside the air outlet (**c**). To connect, align the three prongs in the thermistor with the three holes in the receptacle, then gently push the thermistor inward to secure it in the receptacle.
2. Attach the hose (**d**) to the air outlet. Push the hose firmly into the outlet.



(shown with optional pole clamp installed)



(shown with optional pole clamp installed)

Step 3: Install the Convective Warmer

The convective warmer can be placed on a flat surface, mounted to an IV Pole, or mounted to the Level 1® Convective Warmer cart. See Cart or Pole Clamp Installation and Use Instructions for installing.

Install Power Cord

1. Insert the plug on the power cord into the power cord receptacle (MAINS connection) (**e**) on the rear of the Convective Warmer.
2. Push the power cord lock (**f**) over the plug to secure it in the receptacle. The indicated lock feature is spring-loaded and self-locking. The lock must be intentionally pulled back to release the power cord.

Step 4: Perform Electrical, Functional, and Safety Tests

Perform all applicable electrical, functional, and safety tests as required per institutional procedure.

Electrical safety check must be performed by competent personnel authorized by the institution to perform such testing. These tests include, but are not limited to: leakage current, ground bond test, and hipot.

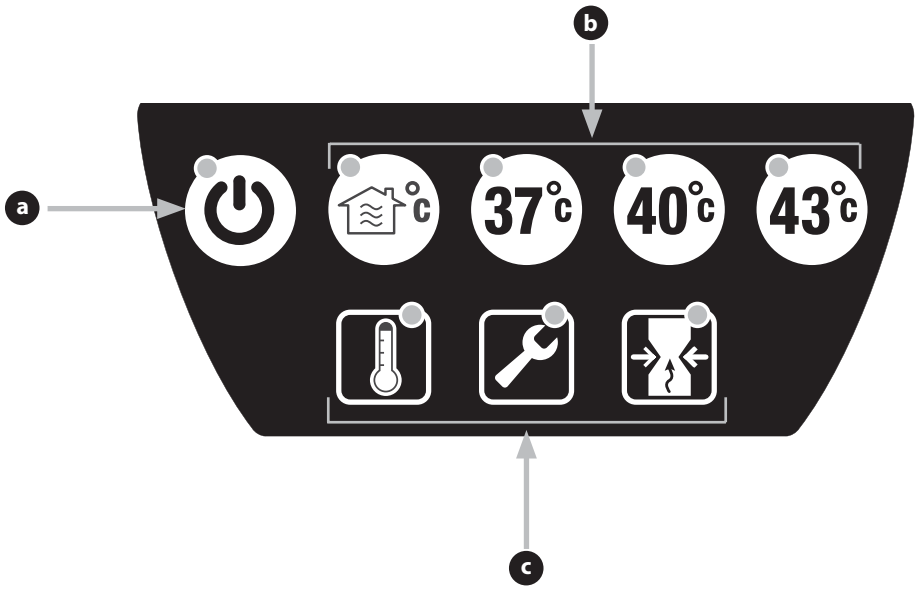
Refer to the *Level 1® Convective Warmer Service Manual* for further information about electrical, functional, and safety testing. Perform all safety checks on a routine basis according to institutional policy.

Daily Use

The Operating Instructions for the Level 1® Convective Warmer are grouped into six steps. Read through each step before performing a procedure.

Step 1: Plug Into Mains Power

1. Plug the power cord into a properly grounded MAINS receptacle to power on the warmer.
2. Verify that the LED indicators for Standby (**a**), Ambient Air, 37° C, 40° C, 43° C (**b**), Over Temperature, Maintenance, and Occlusion (**c**) all light in turn during the automatic selftest. When the self test is complete the Standby LED lights green.
3. Ensure hose connection to back of warmer is firmly seated.
4. Ensure the standby indicator is lit, signifying electrical power is applied.



Step 2: Select the Convective Warming Blanket

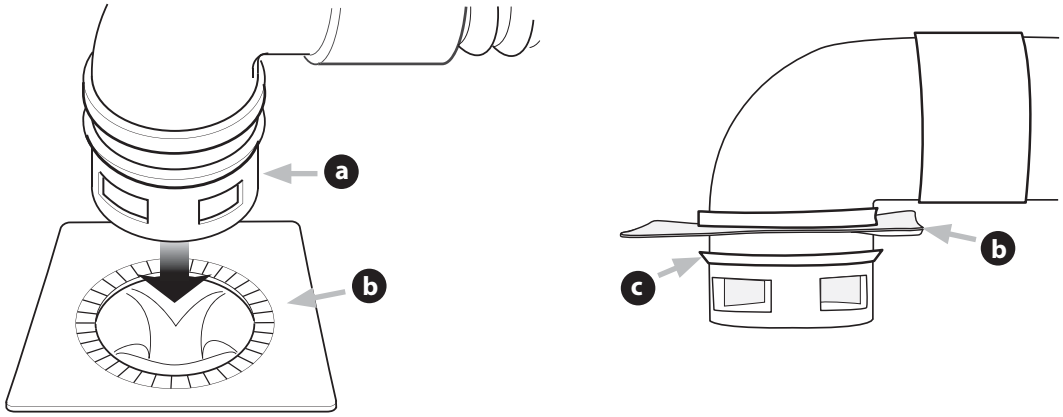
Warning!

Refer to the Warnings and Precautions in the Instructions for Use supplied with each Smiths Medical convective warming blanket.

Determine which convective warming blanket is appropriate for the patient. Contact Smiths Medical or your local Smiths Medical distributor for a list of convective warming blankets available.

Step 3: Attach the Hose to Convective Warming Blanket

1. Insert the hose nozzle (**a**) into the collar ring (**b**).
2. Ensure the hose barb (**c**) snaps into the collar ring (**b**).

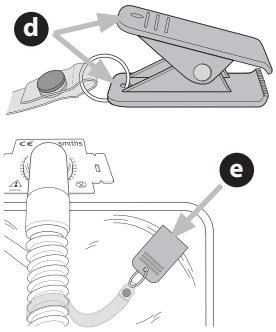


Step 4: Attach the Sheet Clip to the Sheet Under the Patient

Attaching the Sheet Clip

1. Squeeze the handles (**d**) on the sheet clip to open the fastener jaws.
2. Insert the sheet into the open jaws (**e**) and release the handles to lock in place.

Note: *Proper attachment of the sheet clip to the sheet under the patient is essential to the proper function of the sheet clip assembly.*



Step 5: Using the Convective Warmer

1. Press the desired Temperature setting to begin the delivery of therapy. The standby LED indicator will turn off and the selected temperature LED will blink green until the temperature setting is reached. Once the set temperature has been achieved, the temperature LED indicator will be lit green. The temperature setting may be adjusted up or down as required for appropriate therapy by pressing a different temperature setting button.
2. Monitor the patient's temperature and vital signs continuously. Visually examine the heated skin surface at regular intervals. Adjust the temperature setting or discontinue therapy as required.

Step 6: After Use

1. Press the Standby button to place the system in standby.
2. Remove the hose from the convective warming blanket.

Note: *Dispose of the convective warming blankets in a safe manner according to local guidelines for disposal of contaminated medical waste.*

3. Perform routine cleaning after each use. Refer to Section 6, *Cleaning/Maintenance*, for more details.

Step 7: Storage

Store the convective warmer in a cool, dry place away from temperature extremes. Refer to Section 8, *Specifications*, for more details.

SECTION 6

Cleaning/Maintenance

Only competent personnel should perform any routine maintenance and repairs to the Level 1® Convective Warmer.

Clean the Convective Warmer and Hose

Clean the enclosure and hose after every use.

1. Disconnect the MAINS power cord from the electrical receptacle and from the rear of the convective warmer.
2. Visually inspect the convective warmer to ensure there is no visible damage or deterioration of the enclosure such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect. Contact Smiths Medical or your local Smiths Medical distributor.
3. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out excess solution so that the applicator is not dripping. Wipe or scrub the entire surface of the enclosure and control panel. Use a soft brush to clean the power cord if necessary.
4. Rinse a separate soft cloth or sponge in room temperature running potable water. Squeeze out excess water so that the applicator is not dripping. Wipe all of the aforementioned surfaces. Repeat rinsing the cloth or sponge several times with fresh running water during this process to ensure all visible residue is removed.
5. Dry the item with a hand towel or soft cloth.
6. Visually inspect the convective warmer and its components to ensure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary.
7. After thoroughly cleaning the convective warmer, perform disinfection if required.

If it is hospital policy to perform disinfection as part of reprocessing, then follow your institution's guidelines for disinfecting of the surfaces of non-critical medical devices. The list below includes low-level disinfectants that are commonly used in the medical community and high-level disinfectants that are claimed by the manufacturer. The effectiveness of these listed disinfectants should be validated using the hospital procedures.

The following disinfectant agents can be used without causing damage to the enclosure:

- Isopropyl Alcohol / Water mix (70% / 30%).
- Chlorine and Chlorine products
- Cidex®
- Hydrogen Peroxide
- Quaternary Ammonium compounds
- Phenolic Disinfectants

Replace Air Filter

The air filter in the convective warmer should be replaced every 1000 hours of operation. The Maintenance LED indicator will turn ON (solid – not flashing) to signal filter replacement is needed. Competent trained service personnel should be notified for filter replacement.

SECTION 7

Troubleshooting

If the suggested solutions do not correct the problem, discontinue use of the Level 1® Convective Warmer and remove from service. Contact Smiths Medical or your local Smiths Medical distributor.

Problem	Possible Cause/Solution/Operating Conditions
The convective warmer does not start	1. The convective warmer is not plugged in. • Check that the power cord is plugged into the rear of the convective warmer and into a working electrical receptacle. 2. Power cord is defective or cut. • Inspect the power cord and replace if necessary. 3. There is a software fault • Remove the power plug from the Mains and then re-insert the plug.
No heat, but the motor is turned on and air is flowing	1. Ambient air button is selected. • Select desired temperature.
Warmer is running, the selected Temperature Setting Indicator is flashing slowly	1. The warmer is coming up to temperature • Wait for the temperature to be reached.
Warmer is running, the selected Temperature Setting Indicator is flashing slowly and an alarm is sounding	1. The warmer has not come up to temperature in the anticipated time frame • Continue to wait for the temperature to be reached.
No air flow	1. The hose and/or the thermistor cable may not be properly connected. • Check the hose and thermistor cable connections. • Reference Indicator lights for troubleshooting.
Weak air flow	1. Clogged air filter or obstructed air filter intake. • Check the air filter intake for an obstruction and remove. • Check the air filter for clogging or obstructions and replace if necessary. • Reference Indicator lights for troubleshooting.
Air flow is too strong and the convective warmer is noisy	1. Defective air filter or the air filter is not properly installed. • Check the air filter for proper installation. Replace if defective. 2. Blower is not working properly • Remove the power plug from the Mains and then re-insert the plug.
The Occlusion (pinched hose) detector illuminates solid or is flashing, the motor is operating, air is flowing.	1. A blockage in the hose or blanket or an object on the hose or blanket is preventing air from flowing freely through the hose • Check the hose and blanket for anything blocking airflow, such as a pinch or kink. Remove the occlusion and confirm the blanket fills with air and occlusion indicator turns off.

Problem	Possible Cause/Solution/Operating Conditions
The Occlusion (pinched hose) and Standby indicators are lit solid, the Maintenance Indicator is blinking and the heater and motor have stopped operating. The alarm may or may not be sounding	1. The hose and/or the thermistor cable are not properly connected: • Remove the power plug from the Mains, Check the hose and thermistor cable connections, restart, select temperature and determine if problem persists before placing back in service.
Warmer is running, the selected Temperature Setting Indicator is flashing fast, the Maintenance Indicator is on and an alarm is sounding	1. The system is taking much longer than anticipated to warm • Check hose connection • Check that room temperature is not below 15° C (20° C for L1-CW-100V)
Warmer stops, the selected Temperature Setting Indicator is flashing fast, the Maintenance Indicator is on, the Standby Indicator is off and an alarm is sounding	1. The system has detected a temperature below 36° C and there is a possible risk to the patient of hypothermia. • Check hose connection • Check that room temperature is not below 15° C (20° C for L1-CW-100V)
Warmer is running, the selected Temperature Setting Indicator is on solid or is blinking, the Over Temperature Error Indicator is on solid or is blinking, and an alarm may be sounding	1. The temperature at the hose end is above the temperature selected on the control panel. • Continue use and wait for the temperature to reduce.
Warmer stops, the Over Temperature Error Indicator is blinking, the Maintenance Indicator is blinking and an alarm is sounding	1. The warmer has stopped due to the temperature being too high. • Remove the power plug from the Mains, Check the hose and thermistor cable connections, restart, select temperature and determine if problem persists before placing back in service.
The Maintenance Indicator is blinking fast, the Standby Indicator is on solid, audio is sounding, no other LEDs are lit and the system will not operate	1. The over temperature count limit has been exceeded • Contact service or refer to service manual.
The Maintenance Indicator is lit solid but the system still operates normally	1. Service is requested • Contact service or refer to service manual.
All amber indicators (bottom row) are flashing and the warmer will not run	1. The air filter is not properly installed • Remove the power plug from the Mains, verify that the filter is installed, re-insert the power plug

Problem	Possible Cause/Solution/Operating Conditions
All indicators are flashing and the warmer will not run	1. A button was pressed during power up • Remove the power plug from the Mains, verify that no buttons are stuck or pressed, re-insert the power plug and watch for the system to start normally 2. A system fault has occurred • Remove the power plug from the Mains and then re-insert the power plug, watch for the system to start normally
Electromagnetic interference to other devices	This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the instructions, it may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by removing power (unplug power cord) and then reapplying power, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving device. • Increase the separation between the equipment. • Connect the equipment to an outlet on a circuit different from that to which the other device(s) is (are) connected. • Consult the manufacturer or field service technician for help. If placed near monitoring equipment, or other electronic devices, this equipment must be IEC 60601-1-2/EN 60601-1-2 approved or electromagnetic interference may result.
Electromagnetic interference from other devices	Move the convective warmer away from the portable or mobile RF communications equipment per the recommended separation distance specified in Section 8, *Specifications*.

SECTION 8

Specifications

System Design Specifications

Compliance	**Standard**
Product Safety	IEC 60601-1 Ed. 3.1
Convective Warming Blanket Flammability	NFPA 702, 16 CFR 1610
EMC	IEC 60601-1-2 Ed. 3.0 and 4.0, FCC 47 CFR Part 15, Class B
Enclosure Protection	IEC 60529 Ed. 2.2, IP Code: IP12
Convective Warmers	IEC 80601-2-35 Ed. 2.0 and 2.1
Drop Test Compliance	IEC 60601-1 Ed. 3.1
Vibration Test Compliance	IEC 60068-2-64 Ed. 2.0
Physical	**Dimensions**
Height, Overall	32 cm
Width, Overall	39 cm
Depth, Overall	28 cm
Weight, Overall	7.2 kg
Weight, Max. Working Load	10.2 kg
Hose, Length	2 m
Power Cord, Length	3 m, 5 m
Maximum Air Flow	48 cfm at 0.4 inches of H_20 backpressure
Filtration System Media	99.97% or greater for 0.2 μm size particles. BFE & VFE efficiency 99.999% tested per ASTM F2101
Tip Test (Cart Mounted)	Meets IEC 60601-1 and EN 60601-1
Shipping Durability	Meets ASTM D4169 - Dist. Cycle 12, Assurance Level I. Vehicle stack height meets Assurance Level II.
Environmental	**Temperature** **Humidity**
Operation	10°C to 40°C 15% to 95% noncondensing
Operation Altitude	-400 to 3000 meters
Transportation & Storage	-40°C to 60°C 15% to 95% noncondensing
Transportation & Storage Pressure	510 mm Hg (67.83 kPa) to 795 mm Hg (105.74 kPa)
Thermal	**Temperature**
Hose End Temperature	Settings: Ambient, 37°C, 40°C and 43°C Distal temperature within ± 1°C of setting
Maximum Contact Surface Temperature	44°C
Hose End Temperature Control The Snuggle Warm® convective warming blankets meet the average and maximum contact surface temperature	IEC: 80601-2-35
Response time to set point (with the lowest back pressure specification of 0.4 inches H_2O)	< 120 seconds at 120 VAC, at 18°C ambient room temperature < 120 seconds at 230 VAC, at 18°C ambient room temperature < 120 seconds at 100 VAC, at 20°C ambient room temperature

Electrical	Type
Supply Power Input:	
100V	100 VAC, 50-60 Hz ± 1 Hz, 12 A maximum
120V	120-127 VAC, 50-60 Hz ± 1 Hz, 12 A maximum
230V	220-240 VAC, 50-60 Hz ± 1 Hz, 7 A maximum
Protection Against Electrical Shock	IEC 60601-1, blanket is a Type BF defibrillation-proof applied part
Mode of Operation	Continuous
Type of Current	AC, 50-60 Hz ± 1 Hz
Fuses	Type GSA, slow blow, 12A, 250 VAC @ 750 A, or 5 mm x 20 mm ceramic, time lag, 12 A, 250 VAC @ 1.5 kA
Ingress Protection Rating	IP12

Alarms

Over Temperature Alarm - Greater than 45°C (Over Temperature Limit), or +1°C of selected temperature (Over Temperature Warning/Error)

Under Temperature Alarm - Less than 36°C (Under Temperature Limit) or -1°C of selected temperature (Under Temperature Warning/Error)

Name	Alarm Description Details	LED Indicator State	Audio Alarm	System State
Over-Temp Initial	Initial over-temp detected. Above Temperature Setting by 1°C for less than 20 seconds.	-Temperature Set LED On -Over Temp LED On	None	On
Over-Temp Warning	Above Temperature Setting by 1°C for more than 20 seconds but less than 30 second. Total Over-Temp Time before the Over-Temp Warning.	-Temperature Set LED On -Over Temp LED Slow Flash	Low	On
Over-Temp Error	Above Temperature Setting by 1°C for more than 30 seconds. Total Over-Temp Time before stopping the warmer, lockout and logging the error.	-Temperature Set LED Off -Over Temp LED Fast Flash -Standby LED On -Maintenance LED Fast Flash	Medium	Off
Over-Temp Limit	Above Temperature Limit of 45°C for more than 5 seconds. Total Over-Temp Limit Time before stopping the warmer, lockout and logging the error.	-Temperature Set LED Off -Over Temp LED Fast Flash -Maintenance LED Fast Flash -Standby LED On	Medium	Off
Under-Temp Initial	Initially Below Temperature Setting for less than 300 seconds.	-Temperature Set LED slow flash while system reaches temperature	None	On
Under-Temp Warning	Below Temperature Setting for more than 300 seconds and less than 600 seconds. Total Under-Temp Time before the Under-Temp Warning.	- Temperature Set LED slow flash	Low	On
Under-Temp Error	Below Temperature Setting by -1°C for more than 600 seconds. Total Under-Temp Time before the Under-Temp Error, Warmer continues to run.	-Temperature Set LED Fast flash -Maintenance LED On	Low	On
Under-Temp Limit	Below Temperature Limit of 36°C for more than 600 seconds. Total Under-Temp Limit Time before stopping the warmer and logging the error.	-Temperature Set LED Fast Flash -Maintenance LED On -Standby On	Medium	Off
Occlusion Initial	Occlusion Detected for less than 30 seconds. Initial Occlusion Detected.	-Temperature Set LED On (or possibly slow Flash) -Occlusion LED On	None	On
Occlusion Warning	Occlusion Detected for more than 30 seconds. Total Occlusion Time before the Occlusion Warning.	-Temperature Set LED On (or possibly slow Flash) -Occlusion LED Slow Flash	Low	On

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The convective warmer uses RF energy only for its internal function. 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	Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Note: Compliance using 100-240V 50/60Hz with AC power cord of 3 m - 5 m, with hose thermistor cable of 2 m

WARNING:

- The use of power cord and hose other than those listed in the electromagnetic emissions declaration may result in increased emissions or decreased immunity of the convective warmer.
- The convective warmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the convective warmer in the configuration in which it is to be used.
- Common portable and mobile consumer electronic devices may cause interference with the convective warmer. Observe the convective warmer to verify normal operation.
- Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines No input/output lines tested	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV for line to line ± 0.5 kV, ±1 kV, ±2 kV for line to ground	± 1 kV line to line ± 2 kV line to ground	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% drop, 0.5 periods, 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, 315^o 100% dip, 250/300 period 30% dip, 25/30 periods	100% drop, 0.5 periods, 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, 315^o 100% dip, 250/300 period 30% dip, 25/30 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Radiofrequency Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.2]\sqrt{P}$
	6 Vrms ISM bands 150 kHz to 80 MHz	6 Vrms 150 kHz to 80 MHz	$d = [0.58]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = [0.35]\sqrt{P}$ 80 MHz to 800 MHz $d = [0.7]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF Proximity Fields	Per 60601-1-2:2014 section 8.10 Table 9.	Per 60601-1-2:2014 section 8.10 Table 9.	$d = [6/E]\sqrt{P}$ *E is the immunity test level in V/m. 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 meters (m). Field strength 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 reflected 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 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 system is used exceeds the applicable RF compliance level above, the 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 system.

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

Electromagnetic Environmental Recommendations

Recommended separation distances between portable and mobile RF communications equipment and the Level 1® Convective Warmer

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d = [3.5/V1]√P	80 MHz to 800 MHz d = [3.5/E1]√P	800 MHz to 2.5 GHz d = [7/E1]√P
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where power (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: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SECTION 9

Symbols

Symbols	Definitions
	**Catalog Number** Indicates the manufacturer's catalogue number so that the medical device can be identified. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2493
	**Serial Number** Indicates the manufacturer's serial number so that a specific medical device can be identified. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2493
	**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2492
	**Non-sterile** Indicates a medical device that has not been subjected to a sterilization process. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2609
	**Date of Manufacture** Indicates when the medical device was manufactured YYYY-MM-DD. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2497
	**Manufacturer** Indicates the medical device manufacturer. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 3082
	**Quantity** Indicates the number of pieces in package Symbol created by Smiths Medical
	**Not made with natural rubber latex** Large X indicates natural rubber latex (NRL) is not used as a material in the medical product or product container. ISO-15223-1 Symbols - Used with Medical Device Labelling Annex B.2. ISO 7000: None
Rx ONLY	**Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.** CFR 21 801.109
	**Protective Earth ; protective ground** Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode. ISO 7000: 5019
	**Follow Instructions for Use** Refer to the instruction manual/booklet ISO 7010-M002, IEC 60601-1

Symbols	Definitions
EC REP	**Authorized Representative in the European Community** Indicates the Authorized representative in the European Community. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: None
	**No Free Hosing** No Free Hosing. CAUTION! Hose nozzle MUST be connected to a compatible forced air blanket or thermal injury may occur. IEC 80601-2-35
	**Temperature Limitation** Indicates the temperature limits to which the medical device can be safely exposed. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 0632, 0534, 0533. ISO 780
	**Atmospheric Pressure Limitation** Indicates the range of atmospheric pressure to which the medical device can be safely exposed. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2621
	**Humidity Limitation** Indicates the range of humidity to which the medical device can be safely exposed. ISO-15223-1 Symbols - Used with Medical Device Labelling. ISO 7000: 2620
	**Collect separately** Indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved. EN 50419:2006 in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
	**Defibrillation-proof type BF applied part** To identify a defibrillation-proof type BF applied part complying with IEC 60601-1. ISO 7000 / IEC 60417 Graphical symbols for use on equipment. IEC TR 60878
	**Medical electrical equipment with respect to electrical shock, fire, mechanical hazards only in accordance with ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14**

SECTION 10

Limited Warranty

Smiths Medical ASD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the Level 1® Convective Warmer (the "Convective Warmer"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and specifically excludes hoses, warming blankets, roll stands, or any other accessory items or equipment used with the Convective Warmer.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any Convective Warmer (not including accessories) which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the Convective Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases Convective Warmers for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase. The Original Purchaser may have other legal rights which may vary from state to state, province, or country.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, Smiths Medical ASD, Inc., 6000 Nathan Lane, Minneapolis, MN 55442, USA, (800) 258-5361. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE CONVECTIVE WARMER. If authorized, the Convective Warmer must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the Convective Warmer has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the Convective Warmer's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the Convective Warmer or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.
2. To the maximum extent permitted by law, and except as otherwise expressly set forth in this Warranty, Manufacturer makes no warranty or representation and there are no conditions, express or implied, statutory or otherwise, of any kind whatsoever with respect to the Convective Warmer, including but not limited to the merchantability of the Convective Warmer or its fitness for any particular purpose or use, condition, quality, or performance, or workmanship. Nothing contained in the Instructions for Use shall be construed to create an express warranty of any kind whatsoever.
3. The Convective Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Convective Warmer for any particular medical treatment.
4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the Convective Warmer for any particular medical treatment or for any medical complications resulting from the use of the Convective Warmer. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Convective Warmer.

Applies in US: Some states do not allow the exclusion or limitation of incidental or consequential damages, so the limitations or exclusions in this section may not apply.

Applies outside the U.S.: Except as stated above, Manufacturer will not be liable for any loss or damage (including costs) however caused, whether direct or consequential, incurred or suffered by the Original Purchaser or any third party involving the Convective Warmer, but nothing contained herein will or will be considered to exclude or restrict any liability on Manufacturer's part for death or personal injury resulting from negligence.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

SECTION 11

Service

All service must be performed by Smiths Medical, or competent personnel. Service by any other person or organization voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

Non-Warranty Work

Devices received that are no longer under warranty can be returned for repair at a cost. The device will be serviced for a flat fee. Contact Smiths Medical for pricing. Before returning the Level 1® Convective Warmer for service, contact Smiths Medical for a Returned Goods Authorization.

Note: *The convective warmer must be cleaned and disinfected for repair shipment or it will be immediately returned as received.*

Additional Documentation

Upon request Smiths Medical will provide the following documentation:

- Components parts list(s)
- Description of function

Disposal Information

Observe national and local codes or requirements for disposal of contaminated materials and for recycling solid waste materials that may impact the environment.

Service Contacts

Please know the serial number of the convective warmer when you contact the service department. The serial number is located on the rear of the convective warmer. Contact your Smiths Medical Technical Service Department or Smiths Medical distributor at:

USA/Canada

Smiths Medical ASD, Inc.
6000 Nathan Lane
Minneapolis, MN 55442 USA
Tel: 1 800 258 5361 (US/CA)
Tel: + 1 614 210 7300

European Representative

Smiths Medical Czech Republic a. s.
Olomoucká 306, Hranice 1 - Město,
753 01 Hranice, Czech Republic
Tel: +44 (0)1233 722100

www.smiths-medical.com

Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA
Tlf.: 1 800 258 5361 (USA/CA)
Tlf.: +1 614 210 7300

EC REP Europeisk representant:
Smiths Medical Czech Republic a. s.
Olomoucká 306, Hranice 1 - Město,
753 01 Hranice, Czech Republic
Tlf.: +44(0) 1233722100

www.smiths-medical.com

Rx ONLY

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