WarmAir®

Operation Manual

For Model 135 Warming Units

GENTHERM

Gentherm Medical, LLC • 12011 Mosteller Road • Cincinnati, Ohio 45241, U.S.A.

www.gentherm.com

Part No. 57128

57128 Rev. S

How to get Technical Help

How to Contact Manufacturer (for Customer Service, Order Placement, or Technical Support):

Gentherm Medical, LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

Telephone 1-800-989-7373
(U.S) 24hr Clinical Support 1-513-460-2038
Med Tech Support 1-888-437-5608
Fax 1-513-772-9119
Website www.gentherm.com
Email medical@gentherm.com

Authorized European Representative:

EC REP CEpartner4U, B.V.
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.CEpartner4U.com

Before You Call for Service...

To help us better serve you, please have the serial number of your WarmAir®135 unit ready when you call for parts or service. The serial number is located on the back plate of the WarmAir®135 unit.

In-Warranty Repair and Parts

WarmAir® 135 units are covered by a one-year warranty. To return defective parts or units, obtain a Returned Materials Authorization (RMA) number from our Medical Technical Service department. A WarmAir® Model 135 shipping carton will be sent to you, if needed. Extended Warranty Available.

Receiving Inspection

After unpacking the WarmAir®135 unit, inspect the system for concealed damage. Retain all packing material and carefully record or photograph any damage. Notify the carrier at once and ask for an inspection (in writing). Failure to do this within 15 days may result in loss of claim. Do not return the equipment to Gentherm Medical. Call our Medical Technical Service department for further instructions.

Important Safety Information

Refer to this manual for instructions and caregiver information. Read and understand all precautionary information before using, prescribing, or servicing the WarmAir®135 unit. See the Operation and Technical Manual for details on how to perform maintenance.

Table of Contents

Illustrations

Symbols


Voltage, Alternating Current


Potential Equalization Connection (Grounding)


Protective Earth (Ground)


Type BF Equipment (per IEC-601-1)
(Patient Applied)


Consult instructions for use and/or manual before operating


Over-Temperature Safety Limit


Under-Temperature Safety Limit


Hour Meter


Power On/Off Indicator


Fan Only Selection


Temperature Selection Switches

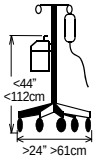

Low setting: 32.2°C


Medium setting: 37.8°C

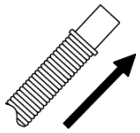

High setting: 43.3°C


Separate collection for electrical and Electronic equipment. Dispose of the WarmAir unit per hospital protocol.


CAUTION! Hose Nozzle MUST be connected to a compatible Forced Air Blanket or thermal injury may occur.



WARNING: To prevent tipping when mounting the Model 135 unit to an IV pole, clamp the unit no higher than 44 inches (112 cm) on an IV pole with a minimum 24 inch (61 cm) diameter base. Failure to heed these restrictions may result in IV pole instability, catheter site trauma, and patient/user injury. Note: For instructions on use of the symbols, refer to the “Operating Instructions” section


Insert Hose

Section 1: Safety Precautions

Gentherm Medical, LLC, reserves the right to make changes to the device, which may not be reflected in this manual.

General Description of the WarmAir® 135

The WarmAir® 135 unit is a small and compact warming unit designed to supply air at temperatures of ambient, 32.2°C, 37.8°C or 43.3°C to a patient-applied air-distribution device. The settings are termed “Fan Only”, “Low”, “Medium” and “High”, respectively.

Indications for Use

The WarmAir® 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient’s temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Contraindications

High temperature settings to be used with close patient observation when treating patients with the following conditions:

- Significant peripheral vascular disease, occlusive or diabetic in nature.
- Low cardiac output.
- Marginal cutaneous perfusion.

Do not apply heat to lower extremities during arterial cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings

- A Licensed Healthcare Practitioner's order is required for setting temperature and use of equipment. At least every 20 minutes, or as directed by a Licensed Healthcare Practitioner, check the patient's temperature and skin condition of areas in contact with the disposable blanket. Pediatric and temperature-sensitive patients should be checked more frequently. **Notify the Licensed Healthcare Practitioner promptly of any change in order to avoid serious injury.**
- Patient temperature depends on ambient temperature and additional sheets or blankets. Reduce or discontinue therapy when therapeutic goal is reached or if vital signs instability occurs. **Thermal injury may result. Notify Licensed Healthcare Practitioner immediately of vital signs instability.**
- Do not use the WarmAir®135 unit distal to arterial cross clamping. **Thermal injury may result.**
- Do not use the WarmAir®135 unit along with High Frequency surgical instruments or endocardial catheters. **Electrical shock, thermal injury or electromagnetic interference may result.**

Notify the Licensed Healthcare Practitioner promptly if any of the following occur:

- If the patient's temperature is not responding properly,
- If the patient's temperature does not reach the prescribed temperature in the prescribed time, or
- If there is a change in the prescribed temperature range. **Failure to inform the Licensed Healthcare Practitioner of the deviation may result in injury to the patient.**

- The warming of transdermal medications (patches) **can increase drug delivery, resulting in possible injury to the patient.**
- Do not use the WarmAir® Model 135 unit with any blanket or warming cover other than Gentherm FilteredFlo® Blankets or the Warming Tube™. **Thermal injury may result.**
- Do not attempt to warm patient without a blanket, i.e. with the hose only. **Thermal injury may result.**
- Unapproved modifications **may cause patient/caregiver injury and/or equipment damage.**
- Do not continue therapy if either the Over-Temperature or Under-Temperature warning light activates or the audible alarm sounds. Do not continue therapy if power cannot be maintained to the unit. **Thermal injury may result.** Turn the unit off and remove from service.
- Do not initiate therapy unless the WarmAir®135 unit is securely mounted or **injury may result.**
- Always unplug the unit before accessing internal components during service. **Failure to unplug the unit could result in electric shock.**
- Do not by-pass ground lug. **Electrical Hazards may result.**
- The use of materials of good thermal conductivity, such as water, gel and similar substances, with the WarmAir®135 unit not switched on, **can decrease the body temperature of a patient.**
- **Thermal injury may occur** if heating therapy is applied to ischemic limbs.
- Do not use the WarmAir®135 unit in the presence of flammable anesthetics. **Risk of explosion may result.**
- The WarmAir®135 unit disposables (FilteredFlo® Blankets, Warming Tube™) are not sterile and are intended for single patient use only. DO NOT sterilize or reprocess these disposables. **Thermal injury and/or cross-contamination may result.**
- Do not allow the hose to contact the patient. **Thermal injury may result.**
- Do not return the WarmAir®135 unit to service without the filter present. **Thermal injury may result.**
- Do not use the WarmAir® 135 unit without the designated filter in place. **Thermal injury or airborne contamination may result.**
- **Electrical shock hazard.** To avoid risk of electrical shock, disconnect power before servicing.
- To avoid the **risk of electric shock**, this equipment must only be connected to a supply mains with protective earth.

Precautions
• CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a Licensed Healthcare Practitioner.
• Read all instructions provided with Gentherm FilteredFlo® Blankets or the Warming Tube™ prior to use.
• The surface of the WarmAir®135 unit and Gentherm FilteredFlo® Blanket or Warming Tube™ should be checked for freedom from mechanical damage prior to each application.
• The WarmAir®135 unit is not intended for use in ambient temperatures above 30°C. Maximum contact surface temperature, during normal operation, is 48°C.
• Do not hipot or dielectric test the WarmAir®135 unit. Only apply the rated voltage to the unit. Subjecting the unit to voltages other than the rated voltage may cause damage to the unit. These tests are done only by Gentherm.
• Power interruption will cause the WarmAir®135 unit to shut down, resulting in no therapy to the patient. Follow instructions listed under the "Operation Fundamentals" section of this manual to resume therapy.
• All temperature settings represent temperatures at the end of the hose outlet, not blanket surface temperature.
• Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC table information provided in this manual.
• Portable and mobile RF communications equipment can affect medical electrical equipment
• Other cables and accessories may affect EMC performance
• Avoid stacking or locating close to other equipment according to the EMC tables.
• If a means is needed in retaining a patient either on or under a Gentherm FilteredFlo® Blanket or the Warming Tube™, the means should not block the fluid pathways of the WarmAir®135 unit.

Read Before Servicing Equipment

Maintenance and service activities will sometimes overlap. In general, maintenance refers to any activity that does not require a certified technician. Maintenance may be performed by healthcare personnel or by other trained persons.

The following actions are considered maintenance:
1. Inspecting, cleaning, and disinfecting the exterior
2. Replacing hoses
3. Cleaning hoses, blankets

Service refers to any activity that requires a Medical Equipment Service Technician, Certified Biomedical Electronics Technician, or a Certified Clinical Engineer.

The following actions are considered service:
1. Equipment or parts replacement
2. Repairs
3. System testing
4. Replacing hoses, cords, and other accessories

The repair, calibration and servicing of the WarmAir®135 unit must be performed by qualified Medical Equipment Service Technicians, Certified Biomedical Electronics Technicians, or Certified Clinical Engineers familiar with good repair practices for servicing medical devices in accordance with the instructions contained in the Operation and Technical manual. Improper repair can result in patient or user injury and damage to the WarmAir®135 unit. Do not hipot unit. Improper repair may also void the warranty. Reference the Operation & Technical manual for Troubleshooting instructions.

Section 2: Specifications

Physical

Dimensions: 22.2 cm x 22.2 cm x 34.3 cm

Hose Outlet: 1.8m flexible hose

Weight: 6.1 kg

Filtration: 0.2 microns, High Efficiency

Construction: Impact-resistant plastic case with aluminum sub-structure. None of the WarmAir® System components are made with natural rubber latex.

Electrical

WarmAir®135 unit is available in 100V, 110-120V or 220-240V:

100V, 50/60 Hz and 110-120V, 50/60Hz units:
1200 VA
15 Amp Circuit Breaker
15' (4.6m) Power Cord (14/3 SJT with Hospital-Grade plug)

220-240V, 50/60Hz units:
1200 VA
7 Amp Circuit Breaker
15' (4.6m) Harmonized Power Cord (H05VV-F 3x1.5mm^2 cord with CEE 7/7 plug)

220-240V, 50/60Hz units:
1200VA
13 Amp Circuit Breaker
15' (4.6m) British Standard Power Cord (HO5VVF3G1.5mm Molded-on BS1363 fused male plug)

For all units:
Under 300 μA earth leakage current
Ground resistance 0.2Ω or less
Mains Supply Isolation: Two-Pole Mains Switch

Temperature Control System

Control System: Microprocessor and thermistor-based.

Temperature Settings as measured at the hose outlet of the device:

No Heat (ambient temperature)
32.2°C +4.0°C/ -2.0°C
37.8°C +4.0°C/ -2.0°C
43.3°C +4.0°C/ -2.0°C

Operating Environment:
Temperature: 15°C to 30°C (59°F to 86°F)
Relative Humidity: 20% - 60%
Maximum Contact Surface Temperature (during normal operation): 48°C
Time to reach 37°C from 23±2°C: Approximately 3 minutes

Safety System

Maximum Temperature Setting:	43.3°C +4.0°C
Independent Primary Over-Temperature Limit:	52.0°C ± 3.0°C as measured at the hose outlet of the device (i.e. where the hose connects to the blanket). Audible and visible alarms. Heater and blower shutdown. Note: Based on testing, the maximum contact surface temperature of the blanket, when the primary over-temperature limit activates is 45°C ± 3.0°C.
Independent Secondary Over-Temperature Limit:	64°C or less as measured at the hose outlet of the device (i.e. where the hose connects to the blanket). Power shutdown. Note: Based on testing, the maximum contact surface temperature of the blanket, when the secondary over-temperature limit activates is 45°C ± 3.0°C.
Independent Under-Temperature Limit:	29.4°C or less as measured at the hose outlet of the device (i.e. where the hose connects to the blanket). Audible and visible alarms. Heater and blower shutdown. (Heat settings only).
Open/Shorted Sensor Safety:	Audible and visible alarms.

Service Life

The expected service life / lifetime of the WarmAir®135 unit is **seven (7) years** from the date of manufacture provided the product is not subject to misuse, negligence, accident or abuse and under the conditions that the device is properly used as intended, and serviced and maintained according to the Operation / Technical Manual provided with the device.

Approvals

Electrical

CLASSIFIED C UL US
16HV

MODEL 135, MEDICAL ELECTRICAL EQUIPMENT IN ACCORDANCE WITH UL60601-1, IEC60601-1 AND ASTM F2196-02. ALSO CLASSIFIED WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH CSA 22.2 NO. 601.1

EMC COMPATIBILITY TABLES ACCORDING TO IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The WarmAir, Model 135 is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The WarmAir, Model 135 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	The WarmAir, Model 135 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Fluctuations and Flicker emissions testing is not required or 120 or 100 Volt units

Guidance and Manufacturer's Declaration – electromagnetic immunity			
The WarmAir, Model 135 is intended for use in the electromagnetic environment specified below. The customer or the user of the WarmAir, Model 135 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±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%.
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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WarmAir, Model 135 requires continued operation during power mains interruptions, it is recommended that the WarmAir, Model 135 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 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: U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The WarmAir, Model 135 is intended for use in the electromagnetic environment specified below. The customer or the user of the WarmAir, Model 135 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the WarmAir, Model 135, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 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 meters (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 predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measure field strength in the location in which the WarmAir, Model 135 is used exceeds the applicable RF compliance level above, the WarmAir, Model 135 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WarmAir, Model 135.

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

Recommended separation distances between portable and mobile RF communications equipment and the WarmAir, Model 135			
The WarmAir, Model 135 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WarmAir, Model 135 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WarmAir, Model 135 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 $d = 1,2\sqrt{P}$	**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
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
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 *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.			

Supplemental certification or EMC information available on request.

European

CE 0344 In compliance with the Medical Device Directive (93/42/EEC)

For Use with Patient-Applied Parts

FilteredFlo® Blankets and Warming Tube™
All Gentherm disposables are:

1. Made from non-woven polypropylene or polyethylene.
2. Manufactured to meet the flammability standards of the Flammable Fabrics Acts and NFPA 99 for Health Care Facilities.
3. Transparent to X-ray and imaging systems.
4. For single-patient use only.
5. Not sterile unless otherwise indicated on product.

Note: Do not sterilize or reprocess Gentherm disposables.

Shipping and Storage Conditions

The WarmAir®135 unit can be transported through normal shipping methods via ground, air, or water when packaged in its original packaging material. During transportation and storage, packaging should not be exposed to conditions that fall out of the ranges below:

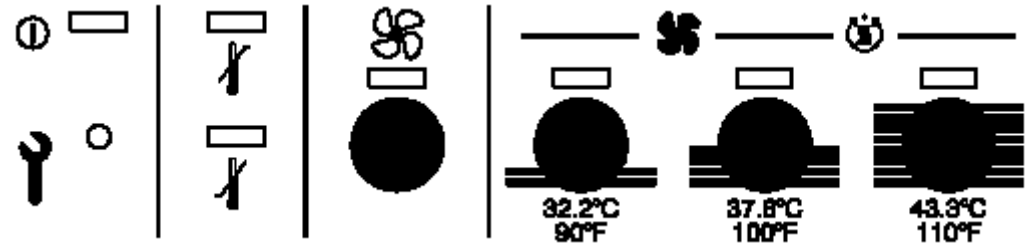
1.1.1 Temperature: -40°C to 50°C (–40°F to 122°F)
1.1.2 Humidity: 5% to 95%

WarmAir accessories and additional technical information is available in the Operation & Technical Manual

Section 3: Operating Instructions

Control Panel and Operation Label

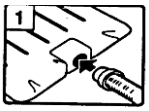
The control panel and operation label for the WarmAir®135 unit are located on the top of the unit.



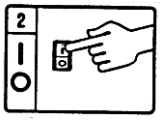
Operation Fundamentals

The lower portion of the control panel gives a brief description of operating the WarmAir® System. Read all instructions and safety precautions included with the FilteredFlo® Blanket or Warming Tube™.

For all WarmAir® Systems

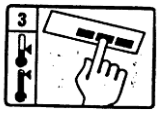


Insert hose. Insert the free end of the flexible hose into the air inlet port of the FilteredFlo® Blanket or Warming Tube™. Make sure the hose is pushed in beyond the raised areas on the fitting.



Power Unit On. Using the rocker switch on the side of the unit, depress the "I" side to activate power to the unit. Depressing the "O" side deactivates power.

The blower and heater will not activate until a temperature setting has been selected.



Select Temperature. Activate the desired temperature setting using the four touch-sensitive buttons, applying the following instructions.

Selecting Temperature and Using the Control Panel

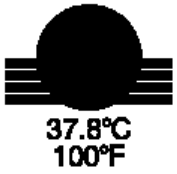
The control panel is located on top of the unit and is composed of four pressure sensitive touch switches, each having a LED display. The external features on the control panel of the WarmAir® unit are described as follows:

Power On/Off Indicator. This LED light will indicate that the unit is on. A temperature selection can now be made. Power is toggled at the rocker switch on the side of the unit.

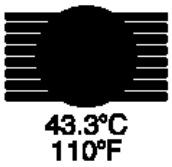
Temperature Selection Switches. Four temperature selection switches on the control panel allow the caregiver to select a temperature setting for the patient.

Fan Only Depressing this switch will activate the unit to draw in ambient room temperature air and deliver it to the patient via the disposable blanket. The heater will not be activated. The temperature delivered to the patient will depend on the current room temperature during operation of the unit. (Air temperature delivered may be up to three degrees higher than the ambient temperature due to heat from the blower motor.) The LED will be activated to indicate that the unit is in the ambient temperature mode.

Low Temperature. Depressing this switch will activate the unit to draw in room air, heat the air to 32.2°C +4.0°C/ -2.0°C and deliver it to the patient via the disposable blanket. The LED will be activated to indicate that the unit is in the low temperature mode.



Medium Temperature. Depressing this switch will activate the unit to draw in room air, heat the air to 37.8°C +4.0°C/ -2.0°C and deliver it to the patient via the disposable blanket. The LED will be activated to indicate that the unit is in the medium temperature mode.

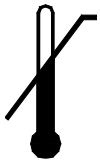


High Temperature. Depressing this switch will activate the unit to draw in room air, heat the air to 43.3°C +4.0°C/-2.0°C and deliver it to the patient via the disposable blanket. The LED will be activated to indicate that the unit is in the high temperature mode. **The high temperature setting is to be used with close patient observation.**

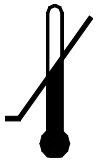
CAUTION!	Do not attempt to warm patient with hose only. Operating the WarmAir®135 unit without a blanket may result in patient injury.

CAUTION!	High temperature setting to be used with close patient observation. Reduce air temperature or discontinue therapy when the therapeutic goal is reached or if vital signs instability occurs.

CAUTION!	High temperature setting to be used with close patient observation when treating patients with the following conditions: a. Significant peripheral vascular disease, occlusive or diabetic in nature. b. Low cardiac output. c. Do not apply to ischemic limbs, e.g., during arterial cross-clamping.



Over-Temperature Safety Limit. This LED indicator light will indicate an over-temperature condition (an audible alarm will also sound). Immediately discontinue use and remove from service if activated.



Under Temperature Safety Limit. This LED indicator light will indicate an under-temperature condition (an audible alarm will also sound). Immeidately discontinue use and remove from service if activated.

Hour Meter. This LED indicator will alert the caregiver that 500 hours of service has transpired and the unit is due for its regular preventative maintenance, including changing the filter.

Mounting the WarmAir® Unit

The WarmAir®135 unit must be mounted securely before it is used. There are three ways to mount the unit:

1. **IV Pole Clamp** The unit may hook onto a secure, vertical IV pole of no less than 2.2 cm and no more than 2.86 cm in diameter.

2. **Mounting Bracket** The unit may hook onto a secure bed rail or footboard up to 3.8 cm thick.

3. **Anti-slip Feet** The unit may be placed on a table or stand near the patient. Do not place the unit in bed with the patient.

WARNING!	To prevent tipping when mounting the Model 135 unit to an IV pole, do not clamp the unit higher than 112 cm on an IV pole with a minimum 61 cm diameter base. When hooking the unit on a rail, make sure the unit cannot tip to a point where it may fall off the rail. When placing the unit on a table or stand near a patient, make sure the unit is not located in an area where it can be knocked off by caregivers or passing traffic. Failure to heed these restrictions may result in IV pole instability, catheter site trauma, and patient or user injury.

Section 4: Preventive Maintenance

Cleaning the Unit

Maintenance and service activities will sometimes overlap. In general, maintenance refers to any activity that does not require a certified technician. Maintenance may be performed by healthcare personnel or by other trained persons. The following actions are considered maintenance:

1. Inspecting, cleaning, and disinfecting the exterior
2. Replacing hoses
3. Cleaning hoses, blankets

Service refers to any activity that requires a Medical Equipment Service Technician, Certified Biomedical Electronics Technician, or a Certified Clinical Engineer. The following actions are considered service:

1. Equipment or parts replacement
2. Repairs
3. System testing
4. Replacing hoses, cords, and other accessories

For cleaning and disinfecting always use conventional hospital-approved, topical equipment cleaners, and disinfectants. Thoroughly wipe down device with a damp cloth to remove any residue from cleaning solutions. Ensure that all inaccessible cracks and crevices on the WarmAir are reached during cleaning.

	**CAUTION!**	Disconnect from power when cleaning the Warming Unit. Allow to air dry thoroughly. Do not use dripping wet cloth or otherwise allow water to seep into electrical areas of the WarmAir®135 unit.

Hour Meter

The WarmAir®135 unit is equipped with a built-in timer that will activate the "Hour Meter" light after 500 hours of use. This is an indication that routine maintenance is required. See Operation & Technical Manual for instructions. Instructions on replacing the WarmAir®135 air filter are also located in the Operation & Technical Manual.

WarmAir®135 unit has approval in accordance with IEC 80601-2-35. These standards are based on contact surface temperature of the blanket being 48°C or less. Temperatures referenced at the hose outlet do not represent contact surface temperatures of the blanket due to temperature loss through the hose and dispersion through the blanket.

Worldwide Order Placement

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