SourceMark™ Medical

KoZee°
CONVECTIVE WARMING SYSTEM

Operator's Manual

Model M21507

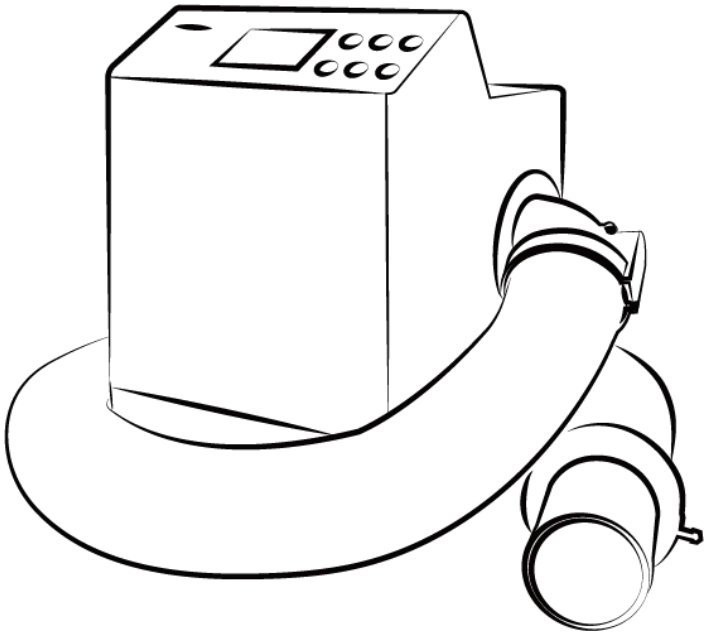

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Table of Content

0. Preface

The KoZee™ Warming Unit was developed for clinical needs and meets the latest safety regulations. It is intended for use by appropriately trained healthcare professionals. Carefully read and understand the entire contents of this Operators Manual, including Warnings and Cautions, before using the product.

SAVE THESE INSTRUCTIONS! READ ALL INSTRUCTIONS!

0.1 About this manual

This manual includes operating instructions and unit specification of the KoZee™ Warming Unit.

SourceMark LLC. reserves the right to make alterations and improvements to the device and this user manual.

SourceMark LLC. cannot be held liable for the final outcome of the patient's treatment.

These instructions are intended for personnel authorized to work with and/or service the medical device mentioned in this manual.

Detailed technical information of this device can be found in the separate technical manual.

1.0 Introduction

1.1 Description of KoZee™ Convective Air Warming System

The KoZee™ Convective Air Warming System consists of the KoZee™ Warming Unit and the KoZee™ Warming Blankets. The KoZee™ Warming Unit, model M21507, draws ambient- temperature air through a 0.2 micron air filter. The filtered air is warmed to a selected temperature. The warmed air enters the KoZee™ Warming Blanket through the hose and is distributed through delivery channels. Perforations on the patient side of the air delivery channels in the warming blanket gently disperse the warmed air over and around the patient.

1.2 Indication for use

The KoZee™ Convective Air Warming System Model M21507 is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

1.3 Temperature Management

Hospital patients in particular encounter serious risks if their body temperature falls below 36°C. The risk of hypothermia gets significantly higher when patients are vulnerable or have underlying conditions. Factors that can contribute to hypothermia include the duration of the surgical intervention, the location of the wound, the amount of blood loss, the surface area of the wound, the environmental temperature, and the anesthetic technique.

1.4 Forced Air Warming

Compared to other thermal conductors, air is a low thermal conductive agent, making it a safe option for patient warming and lowering the risk of thermal injury. Forced air warming is a widely used and clinically accepted intervention for the prevention of hypothermia and/or re-warming of the postoperative surgical patient.

The principle of operation for forced air warming systems is a warming unit that propels warm air via a flexible hose to a blanket draped over the patient. Some blanket designs allow for the patient to be placed on top of the blanket or surrounded by a warming tube.

All of these forced air warming systems are intended to distribute warmed air to the patient in a manner that is safe and effective.

1.5 Symbols Definitions

No free hosing! Do not use the KoZee™ Warming Unit without KoZee™ Warming Blanket connected to it. Thermal injury may result.

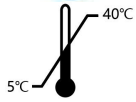
Special recycle, dispose separately

Serial Number

Manufacturer

Date of manufacture

Follow instructions for use



Storage and transportation temperature limitation

Storage and transportation humidity limitation

Caution (Refer to instructions)

Warnings

Alternating current

Type BF applied part (IEC60601-1)

KEEP AWAY FROM SUNLIGHT

KEEP DRY

Electrical hazard! Disconnect the power source before replacing the fuse!

Degree of protection (IEC 60529)

MR Unsafe

1.6 Alertness Symbol Explanation

Warning:

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

Caution:

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

1.7 Contraindications

Do not apply therapy to ischemic limbs.

a. Use with caution and consider discontinuing use on patients during vascular surgery when an artery is clamped to an extremity (i.e., arterial cross clamping) .

b. Use with caution and monitor closely if used on patients with severe peripheral vascular disease.

Do not apply heat directly to open wounds.
All patient wounds should be covered while providing therapy.

1.8 Warnings

The KoZee™ Warming Unit is safe and reliable. It is intended for use by appropriately trained healthcare professionals. Carefully read and understand the following Warnings, before using the product.

	Grounding reliability can ONLY be achieved when the KoZee™ Warming Unit's main power cord is connected to a properly grounded receptacle.
	Do not leave patient without monitoring during prolonged warming therapy sessions. Thermal injury may occur.
	If the over-temperature indicator light illuminates and the alarm sounds, stop using the KoZee™ Warming Unit to prevent the patient from experiencing thermal injury. Unplug the warming unit and contact a qualified service technician.

	Do not use KoZee™ Warming Unit during transdermal medication. Drug deliveriy rate might be increased and patient injury or death may occur.
	Do not use the power cord, or other spare parts that are not specified by SourceMark. It may increase the electromagnetic emission or decrease immunity.
	When replacing the hose, always disconnect the temperature sensor from the warming unit. Make sure the temperature sensor is properly connected when the new hose is attached, prior to using the device.
	Portable and mobile RF (Radio Frequency) communication equipment, and HF (High Frequency) surgical instruments or endocardial catheters can affect the correct functioning of the KoZee™ Warming Unit.
	Do not place the unit in or on the bed with the patient. Air inlet might be blocked and cause danger to the patient.
	Do not use KoZee™ Warming Unit during MRI imaging. It may affect the MRI image quality.
	KoZee™ Warming Unit is equipped with a HEPA air filter. However, airborne contamination shall be taken into consideration when using the warming system.
	The KoZee™ Warming Unit has been designed to operate safely ONLY with KoZee™ disposable blankets and components. Use of blankets and components from other manufacturers may cause thermal injury. (To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the KoZee™ Warming Unit being used in conjunction with non-KoZee blankets or components.)
	Do not warm patients with the KoZee™ Warming Unit hose alone (without blanket). Thermal injury may result.
	Neonates and pediatric patients of low weight will tend to overheat more easily than adults. Do not leave pediatric patients unattended during therapy.
	To reduce the risk of cross contamination, do not reuse convective warming blanket.

1.9 Cautions

	• Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol. • Monitor the patient's vital signs regularly. • Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.
	Monitor the body temperature of the patient and check the skin condition routinely.
	Do not activate the KoZee™ Warming Unit unless it is safely placed on a hard surface or securely mounted on the rolling stand or using the bed rails hook to hang the KoZee™ Warming Unit to a hospital bed.
	Electrical shock hazard. Do not disassemble the KoZee™ Warming Unit unless you are a qualified service technician. There are electrically live parts in the warming unit when it is connected to a power source, even when the warming unit is in Standby mode.
	KoZee™ Warming Unit is designed to be in compliance with medical electromagnetic compatibility requirements (IEC60601-1-2). If radio frequency interference with other equipment should occur, please follow one or more of the methods below to eliminate the interference: Turn off or isolate the interference source equipment, or Reorient or relocate the KoZee™ Warming Unit, or Connect the KoZee™ Warming Unit to another electrical outlet, or Contact your local dealer if needed. The KoZee™ Warming Unit shall not be used adjacent to or stacked with other equipment.
	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
	To achieve reliablly grounding, the KoZee™ Warming Unit should only be connected to receptacles that are marked with "Hospital Grade".
	KoZee™ Warming Blankets are intended for single patient use ONLY.

	The surface of the KoZee™ Warming Unit should be checked to ensure there is no mechanical damage prior to each application.
	Observe patient body core temperature and cutaneous response under the blanket. Increase the temperature setting if required, using core body temperature as an indicator. Observe cutaneous response; if erythema appears, decrease the temperature setting or discontinue therapy.
	When treating patients who are unconscious or who have peripheral vascular disease (occlusive or diabetic), low cardiac output, or marginal cutaneous perfusion, do not use the 43°C temperature setting, use only the 38°C or 32°C temperature setting.
	Do not place objects onto the convective warming blanket that will obstruct air flow. An item on the blanket can produce localized pressure on the patient's skin, reducing cutaneous blood flow.
	Do not allow the patient to lie on the hose of KoZee™ Warming Unit or allow the hose to directly contact the patient's skin during patient warming. Thermal injury may occur.
	Hose nozzle MUST be connected to KoZee™ Warming Blanket or thermal injury may occur.

1.10 Notice

To avoid KoZee™ Warming Unit damage:

- Do not immerse the KoZee™ Warming Unit or warming unit parts or accessories in any liquid or subject them to any sterilization process.
- Do not use non neutral clean solvent or disinfectant to clean or disinfect the KoZee™ Warming Unit.
- Do not use abrasive cleaners, clean the warming unit's exterior with a soft cloth using clean water or a mild, all-purpose, or non-abrasive cleaner.
- Do not shut down the KoZee™ Warming Unit by pulling out the plug directly.

1.11 Proper Use and Maintenance

SourceMark assumes no responsibility for the reliability, performance, or safety of the KoZee™ Warming Unit if the following events occur:

a. Modifications or repairs are performed by unqualified personnel.
b. The warming unit is used in a manner other than that described in the Operator's or Service Manual.
c. The warming unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.

User should not repair any parts of KoZee™ Warming Unit. If a fault condition occurs, user should not open and repair the warming unit. This may damage the warming unit and void the warranty.
Hospital service department or the local distributor should maintain the device at least once a year. You should know the serial number of your warming unit when you call the hospital service department or your local distributor. The serial number label is located on the bottom or the side of the warming unit.

1.12 Read Before Servicing Equipment

All repair and servicing of the KoZee™ Warming Unit requires the skill of a qualified, medical equipment service technician who is familiar with good practice for medical device repair.

If service does not require the manufacturer's attention, the Service Manual provides the technical information needed to service the warming unit, or SourceMark will provide that information on request.

Perform all repairs and maintenance in accordance with the instructions in the Service Manual.

1.13 Safety Inspection

A safety Inspection should be performed after repairs to the KoZee™ Warming Unit and before returning the warming unit to service.

A safety inspection should include testing the over-temperature detection function as described in the service manual, as well as electrical safety testing of leakage current and ground continuity.

2.0 Overview and operation

2.1 KoZee™ Warming Unit Illustration

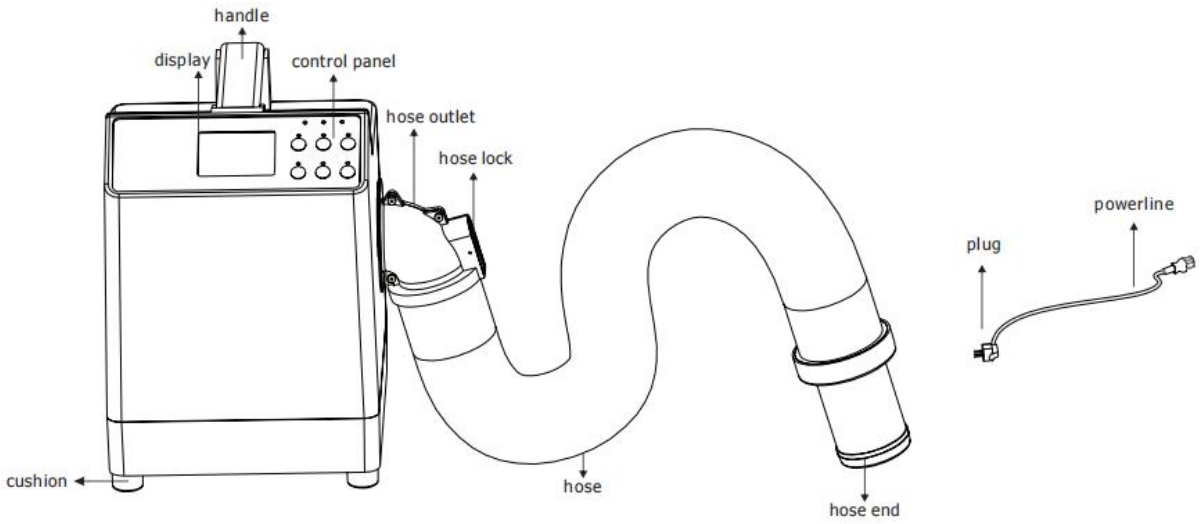


Figure 2.1: Warming Unit Front View

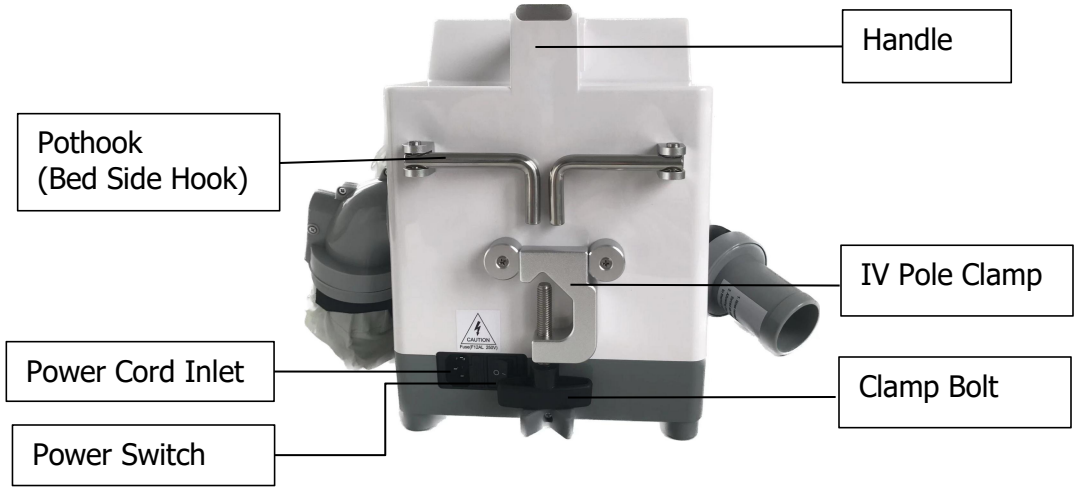


Figure 2.2 : Warming Unit Rear View

Notice: The Power switch on rear will disconnect all power to the warming unit if in off position.

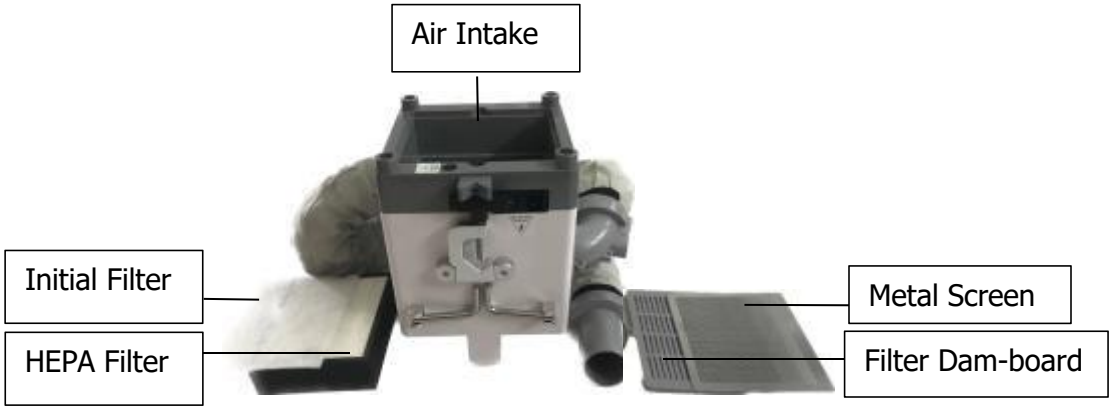


Figure 2.3: Warming Unit Bottom View

2.2 User Interface

The KoZee™ Warming Unit control panel locates on top of the device.

The KoZee™ Warming Unit is very simple to use. All settings can be seen on the control panel and you can press different temperature buttons to select the desired temperature output.

When a system fault occurs, the indicator flashes and an alarm sounds. The fault / error code will be showed on display.

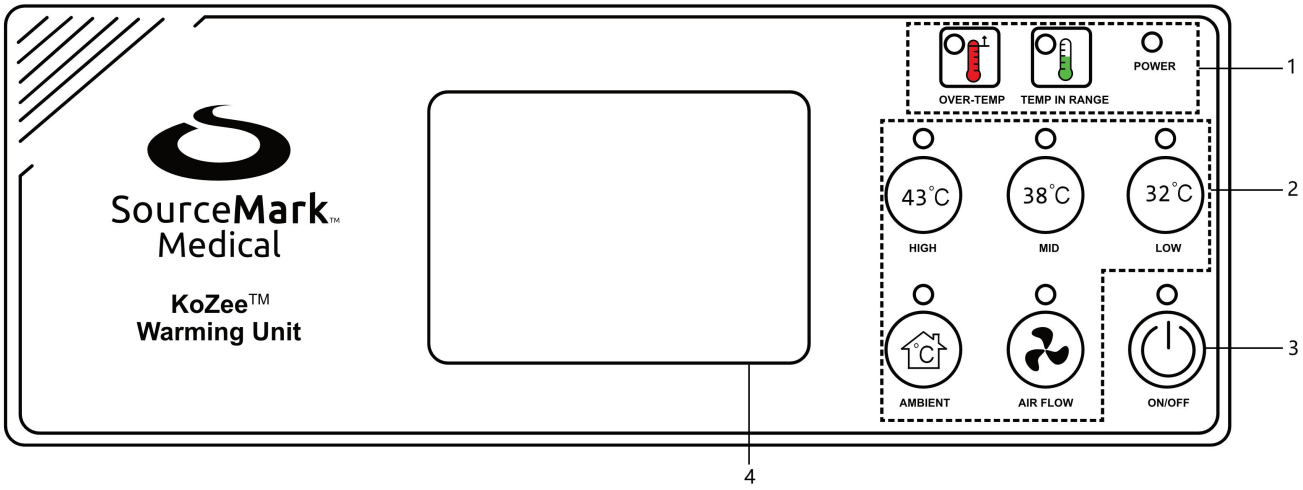


Figure 2.4 Control panel view

1 Operating Indicators

Over temperature alarm indicator.

When illuminated red(flash), it means that the output air temperature exceeds the set range.

Power on indicator

When illuminated steady green, it means the warming unit is power on.

Temperature in range indicator

When illuminated steady green, it means the average contact surface temperature of the blanket has reached the set temperature.

This indicator light does not illuminate in Ambient Temperature Mode.

2 Temperature Selection Buttons

HIGH (43°C) button
When selected, the air temperature is set to 43°C

MID (38°C) button
When selected, the air temperature is set to 38°C

LOW (32°C) button
When selected, the air temperature is set to 32°C

Ambient button
When selected, the air temperature is set to ambient temperature.

Air flow button
When selected, the air flow will be toggled between high and low speed.

Options:
LED on – Low Air Flow Mode.
LED off – High Air Flow Mode.

3 Power ON/OFF Button

Toggles system from operating mode to standby mode, or from standby mode to operating mode.
See the Definitions Section for detailed information about Standby Mode and Operating Mode.

4 Display screen

Displays warning, alarms, and relevant information of the warming unit.

3.0 Instructions for Use

3.1 Preparing to use KoZee™ Warming Unit

a) Please check and verify that all components are present. If any parts are missing or damaged, do not use KoZee™ Warming Unit.
b) KoZee™ Warming Unit should be connected to a properly grounded outlet.
c) Mount the KoZee™ Warming Unit to the rolling stand, IV pole or place KoZee™ Warming Unit on a flat, hard, dry surface, such as a table, before beginning therapy.

3.2 Selecting Proper Blanket

A variety of warming blankets are offered to suit proper application of therapy.
For further details with other blankets, see the warming blanket Instructions for Use (IFU) for the type of warming blanket you are using or contact your dealer.
The warming unit must be connected to its air hose for it to work properly.

3.3 Placing KoZee™ Warming Unit

a) Using a KoZee™ Rolling Stand - Remove the 4 rubber foot pads under the warming unit, and put the KoZee™ Warming Unit on the KoZee™ Rolling Stand.
b) Using an IV Pole - Mount KoZee™ Warming Unit to an IV pole, turn the clamp handle clockwise to tighten the clamp on the IV pole and counterclockwise to release it. To prevent tipping, we recommend clamping the warming unit no higher than 80 cm from the floor on the IV pole. Otherwise, it may result in the IV pole tipping, catheter site trauma, or patient or user injury.
c) Using a table - Please place the KoZee™ Warming Unit on a flat, hard, dry surface, such as table, before beginning therapy. Do not place the KoZee™ Warming Unit on a soft or uneven surface since the air intake may become blocked and cause the warming unit to overheat.
d) Using the bed rail - KoZee™ Warming Unit can also be hung on the edge of a patient bed. The pothook is designed to keep the KoZee™ Warming Unit safely suspended.

3.4 Preparing the patient

a) Place the KoZee™ Warming Blanket on the patient's body with the blue side facing toward the patient. Refer to IFU for additional instructions.

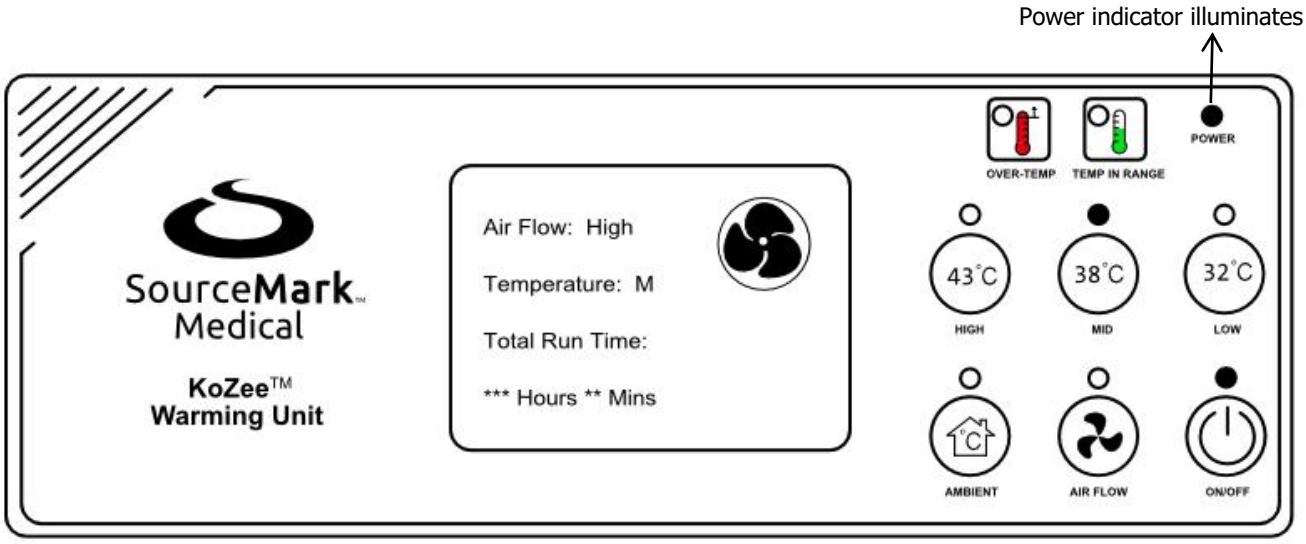
	Do not place the non-perforated side (white side) of the blanket against the patient. Thermal injury may result. Always place the perforated side (blue side) against the patient!

3.5 Connecting the power

a) Securely connect the KoZee™ Warming Unit to a properly grounded power source.

b) Turn on the power switch on the back of the unit. The KoZee™ Warming Unit will perform its STS (Self-Test Sequence). All the indicators and the display will illuminate.

c) After STS (Self-Test Sequence), the warming unit will be operating in standby mode. The default set point is the MID(M) temperature and the light on that temperature selection button will illuminate.



⚠	To completely switch off the electrical power, please press POWER **ON/OFF** switch on the back and disconnect the warming unit from the power source.

3.6 Attaching the hose to the KoZee™ Warming Blanket

a) Take the warming blanket out of its bag.

b) Insert the hose nozzle into the warming blanket's connector port.

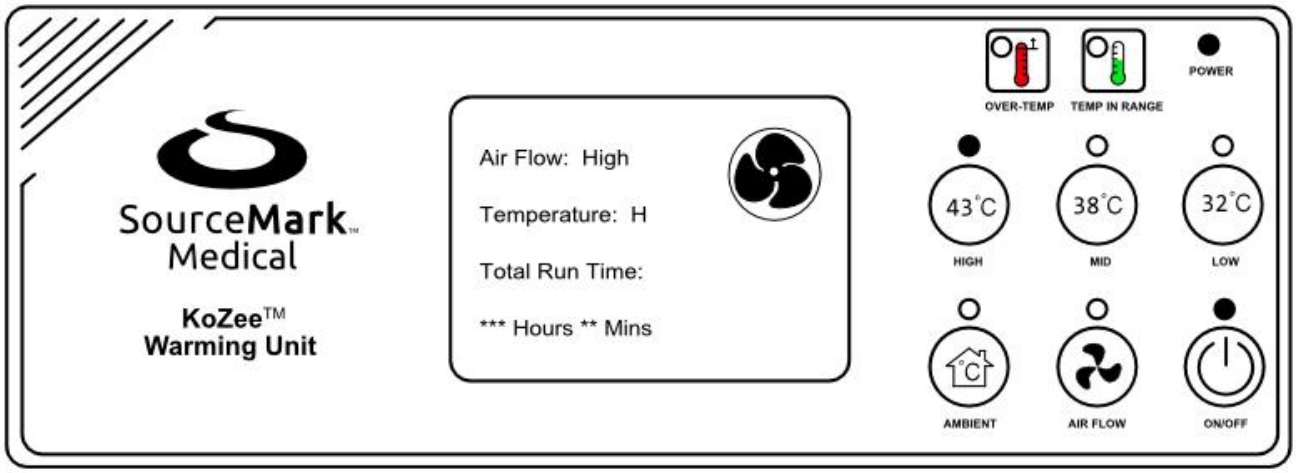
c) Place the hose as to minimize bends.

d) Wrap strap around hose end to ensure a good connection, and that the blanket can be inflated without any blockage.

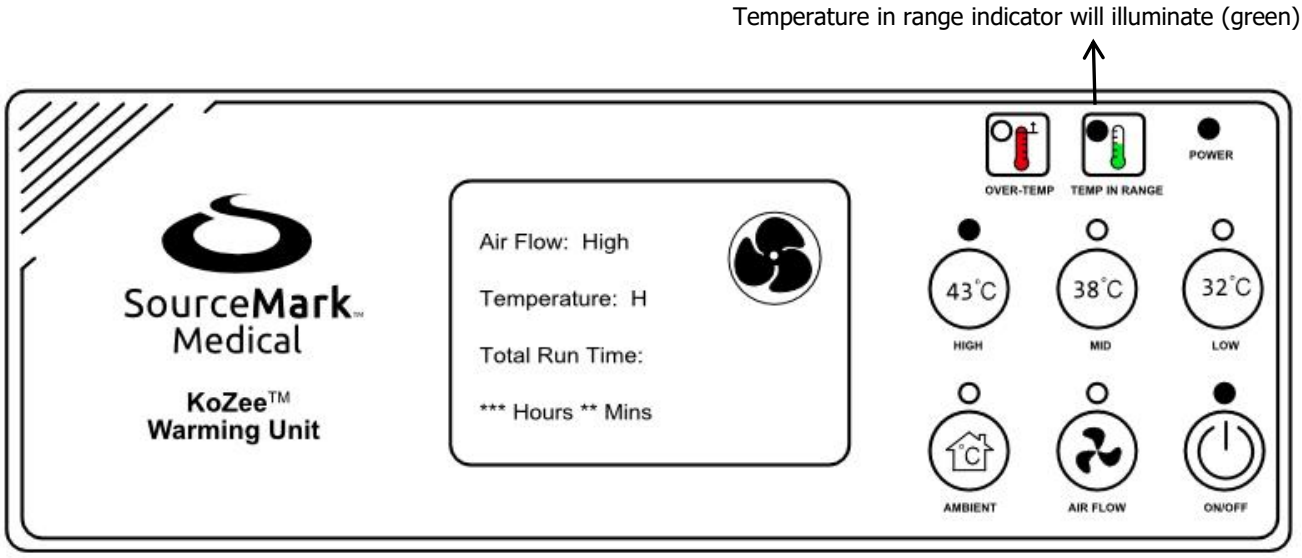
e) Press the ON/OFF button on the panel to start therapy.

3.7 Selecting the Temperature

Select the temperature you wish to operate at and press its button. The LED light above the button will illuminate.



When the average contact surface temperature of the blanket reaches the setting temperature (±2°C), the temperature in range indicator will illuminate (green).



There are four options for temperature:

a) Ambient temperature
   1) Press "Ambient" (room temperature) button.
   2) The KoZee™ Warming Unit will draw in room temperature air and purify the air by means of the air filter.
   3) The blower will create a continuous flow of air to the warming blanket.
   4) The LED light above the button will illuminate.

b) 32°C
   1) Press "32°C" (LOW temperature) button.
   2) The KoZee™ Warming Unit will draw in room temperature air and purify the air by means of

the air filter.

3) The air will be heated by the heater and the blower will create a continuous flow of air to the warming blanket.
4) The LED light above the button will illuminate
5) The Temp In Range LED light indicates the average contact surface temperature of the blanket has reached the LOW temperature setting.

c) 38°C

1) Press "38°C" (MIDDLE temperature) button.
2) The KoZee™ Warming Unit will draw in room temperature air and purify the air by means of the air filter.
3) The air will be heated by the heater and the blower will create a continuous flow of air to the Warming Blanke.
4) The LED light above the button will illuminate.
5) The Temp In Range LED light indicates the average contact surface temperature of the blanket has reached the MID temperature setting.

d) 43°C

1) Press "43°C" (HIGH temperature) button.
2) The KoZee™ Warming Unit will draw in room temperature air and purify the air by means of the air filter.
3) The air will be heated by the heater and the blower will create a continuous flow of air to the warming blanket.
4) The LED light above the button will illuminate.
5) The Temp In Range LED light indicates the average contact surface temperature of the blanket has reached the HIGH temperature setting.

3.8 Switching to Operating Mode

a) Press **ON / OFF** button on the panel to switch the warming unit into Operating Mode.
b) The warming unit enters operating mode and blows warm air, and then the actual exhaust temperature will increase gradually.
c) The temperature selection switch can be pressed anytime when the KoZee™ Warming Unit is in operating model to change the temperature set point.

	Do not warm patient without the warming blanket. Thermal injury may occur.

3.9 Adjusting the blower speed

The blower speed can be toggled between High and Low speed by pressing the **Air Flow** button.

3.10 Monitoring in the process of treatment

a) Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating, and/or who are without a sense of feeling, every 15 minutes or according to institutional protocol.
b) Monitor the patient's vital signs regularly. Monitor and record the patient's temperature.

3.11 Discontinue Warming Therapy

a) Press the power ON / OFF button on the panel. The warming unit will automatically turn off the heater and blower. Then the warming unit switches into standby mode.
b) Detach the hose from the warming blanket.
c) Remove the warming blanket from the patient's body.
d) Unplug the KoZee™ Warming Unit to disconnect it from the power source.

4.0 Safety system and alarms

4.1 Faults and Alarms

Fault Alarm Conditions Table

Fault #	LCD display	Alarm Sounds	Device status	Remark
E01	SENSOR 1 ERROR Or SENSOR 2 ERROR	High Pitched Sound	1) LCD shows which Sensor is causing the error. 2) Heater stops working and fan stops working. 3) Alarm prompts. 4) Any operation is invalid.	Alarm sounds until the error is resolved.
E02	BLOWER ERROR	High Pitched Soundl	1) LCD shows Blower error. 2) Fan stopped. 3) Alarm prompts.	Alarm sounds until the error is resolved
E03	OVER TEMP ERROR	High Pitched Sound	1) LCD shows over temperature. 2) OVER-TEMP indicator light flashing. 3) Alarm prompts. 4) Heater stops working, fan stops working.	Alarm sounds until the error is resolved
E04	POWER_OFF ERROR	High Pitched Sound	1) Device is not functioning. 2) Alarm prompts.	Alarm sounds until the error is resolved

Note:
a) Alarming levels
There is only one alarm level: high priority alarm (Indicated with High Pitched Sound.)
b) The warming unit has 2 sensors
1) Sensor1: Temperature Sensor in the hose outlet. (Inside of the hose nozzle)
2) Sensor2: Temperature Sensor in the air outlet. (At the elbow of the hose)
After the STS (Self-Test Sequence), while the exhaust air temperature is higher than 56°C typical, or the sensor2 temperature is higher than 63°C typical, the over temperature alarm rings.

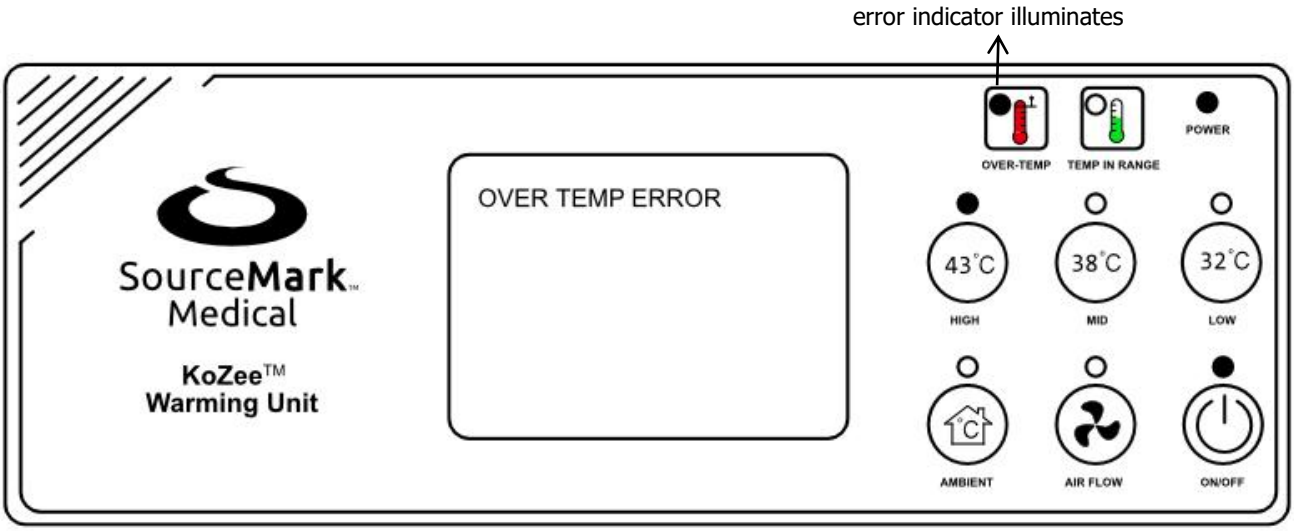
4.2 Trouble shooting

Fault Alarm Troubleshooting Table

Fault #	Possible Cause	Solution
E01	One or both of the temperature sensors are electrically disconnected, or there is a fault condition with a sensor.	1) Power off the KoZee™ Warming Unit and wait for 5 minutes. 2) Check if the hose is connected firmly to the device, then restart the warming unit. 3) If the display shows the same fault code, contact a qualified service technician for solutions.
E02	Blower does not run, or there is a fault condition.	1) Power off the KoZee™ Warming Unit and wait for 5 minutes. 2) Restart the warming unit. 3) If the display shows the same fault code, contact a qualified service technician for solutions.
E03	Over Temperature. Temperature detected at Sensor1 or Sensor2 is out of range.	1) Discontinue all temperature management therapy immediately, stop and discard the disposable warming blanket. 2) The alarm sounds and indicator light flashes , fan stops working. Press ON/OFF to eliminate the alarm and enter the standby mode. 3) Check if the hose is blocked, verify the hose is unobstructed. 4) If the display shows the same fault code, contact a qualified service technician for solutions.
E04	Loss of power	1) Turn off the power swith on the KoZee™ Warming Unit and wait for 5minutes. 2) Restart the warming unit by turning on the power swith, press any button to eliminate the alarm. 3) If the same fault appeared, contact a qualified service technician for solutions.

4.3 Over Temperature Alarm Conditions

If OVER TEMP ERROR fault occurs, an alarm sounds, and the OVER-TEMP error indicator illuminates as shown below:



If the air temperature at the hose elbow is higher than 63°C, or the air temperature at the hose nozzle is higher than 56°C, the red over temperature error indicator illuminates, and the alarm sounds within 6 seconds. At the same time, the display flashes and shows "OVER TEMP ERROR". The warming unit automatically turns off the heater and blower.

If over temperature error occurs:

a. Stop all temperature management therapy immediately;
b. Power off the KoZee™ Warming Unit;
c. Check hose for blockage. Minimize the number of bends in hose for maximum air flow;
d. If the same fault appears, contact a qualified service tachnician;
e. If you wish to continue therapy, replace the warming unit.

4.4 Other Alarms Conditions

When a system fault occurs, an alarm will sound, and the display will show a fault. The fault will be stored in the memory. The heater and blower will turn off.

If a fault condition occurs:

a. Unplug the power cord and wait for 5minutes.
b. Reconnect the KoZee™ Warming Unit to a grounded power source. The warming unit should reset the normal sequence.
c. Reselect the temperature setting.
d. If the KoZee™ Warming Unit does not return to normal operation, please contact a qualified service technician.

4.5 Maintenance Alert:

When the KoZee™ Warming Unit has run over 500 hours, the warming unit will then switch into standby mode, and the display will show "FILTER ERROR Please replace Filter". The air filter must be replaced.

When KoZee™ Warming Unit runs over 500 hours, the warming unit will switch into Standby mode,

and the display will show "FILTER ERROR Please replace Filter". The Initial Filter and HEPA Filter should be replaced. After the Initial Filter and HEPA Filter are replaced, reboot the warming unit in normal sequence, then press the ON/OFF button for 30 seconds to reset the filter timer.
The routine maintenance of replacing the air filters is needed once a year, regardless of the warming unit running time is more than 500 hours or not.

If the blower is in operating mode and reaches 500 hours of use, the blower will not go into standby mode until the user exits operating mode.

5.0 Storage and Cleaning

5.1 Proper Use and Maintenance

SourceMark assumes no responsibility for the reliability, performance, or safety of the KoZee™ Warming Unit if the following events occur:

a. Modifications or repairs are performed by unqualified personnel.
b. The warming unit is used in a manner other than that described in the Operator's or Service Manual.
c. The warming unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.
d. For maintenance, please refer to the Service Manual.

Hospital service department or the local distributor should perform maintenance of the warming unit at least once a year. You will need to know the serial number of your warming unit when you call the hospital service department or your local distributor. The serial number label is located on the bottom or the side of the warming unit.

	All repairs, calibration, and servicing of the KoZee™ Warming Unit require the skill of a qualified, medical equipment service technician who is familiar with good practices for medical device repair.

5.2 Storage

The KoZee™ Warming Unit and its accessories must be stored with temperature range 5°C to 40°C and relative humidity range 20% to 80%.

5.3 Cleaning and disinfection Method

	Do not immerse the warming unit or hose while cleaning. Moisture will damage the components, and thermal injury may result.

	Do not use an excessively wet cloth to clean the warming unit. Moisture may seep into the electrical contacts and damage the components.
	Do not use solvents to clean the warming unit. Solvents may damage the label and other plastic parts.

a. Disconnect the warming unit from the power source before cleaning.
b. Wipe the warming unit and the outside of the hose with a damp, soft cloth and a mild detergent or antimicrobial spray.
c. Dry and wipe the warming unit and the outside of the hose with a separate soft cloth.
d. Finish the cleaning with a mild disinfection solution, avoid moisture (see warnings!).

6.0 Specifications and product parameters

6.1Physical Characteristics

Dimensions	11.6 inch High x 8.7 inch Deep x 8.7 inch Wide (29.5 cm High x 22 cm Deep x 22 cm Wide)
Weight	5.4 kg
Relative noise level	≤58 dB(A)
Hose	Flexible, 72 inches long (180 cm)
Filtration system	High efficiency HEPA 0.2 µm air filter
Recommended filter change	Every 12 months or 500 hours of use

6.2 Temperature Characteristics

Recommended operating environment	Temperature: 15 °C to 25 °C
Temperature control	Electronic control
Heat generated	950 W (average)
Blanket surface temperature	HIGH: 43 ±2°C MID: 38 ±2°C LOW: 32 ±2°C

6.3 Safety System

Thermostat	Independent electronic circuit; thermal cutoff shuts the heater OFF to ensure hose end air remains within temperature setting ±2°C or below 56°C; the device features dual temperature sensors.
Alarm system	Over-temperature (out of temperature setting ±2°C or higher than 56°C): red Over-temp indicator light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn OFF, control panel becomes unresponsive.
Fault	Fault information will display on the LCD, alarm sounds.
Over current protection	Dual input fused lines.

6.4 Electrical Characteristics

Heating element	950W Resistive PTC heater
Leakage current	Meets IEC 60601-1 requirements

Blower motor	Operating speed: approximately 3500 rpm
Airflow	Low: 30 CFM ~ 35 CFM High: 36.5 CFM ~ 45 CFM
Power consumption	PEAK: 1700 W AVERAGE: 950 W
Device ratings	110-120 VAC; 60 Hz; 14 A
Power cord	5 m, 3 Cond, 13 A (110 V)
Fuses	F12AL250V 6x30mm; F12AL250V 5x20mm
Classification	Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment, Continuous operation Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Device Directive as a Class II device (US FDA)

7.0 Definitions

KoZee Trademark of SourceMark LLC.

STS Self-Test Sequence

PTC Positive Thermal Coefficient Ceramic Heater

Sensor 1 Temperature Sensor in the hose outlet. (Inside of the hose nozzle)

Sensor 2 Temperature Sensor in the air outlet. (At the elbow of the hose)

Standby mode When entering Standby mode, the following events occur:

- PTC heater and the fan turn off.
- Alarm and fault detection functions remain active.

The warming unit can be switched into standby mode in one of the 2 ways:

1) At power on with the power switch on the back panel;
2) If the warming unit is operating at one of the 4 operating temperatures, to switch the Warming Unit into Standby mode, press the **ON/OFF** button.

Operating Mode The warming unit can be switched into operating mode by pressing the **ON/OFF** button on the front control panel.

When entering operating mode, the following events occur:

- Unit will control the temperature as selected by the illuminated Temperature Selection Button.
- Except in Ambient Temperature Mode, PTC heater will be activated.
- Running mode timer will be activated.
- **TEMP in RANGE** indicator light illuminates when the average contact surfact temperature at the blanket is within $\pm$2.0°C of the selected setting; this indicator light does not illuminate in Ambient Temperature Mode.

8.0 Warranty

The warranty will not apply to the products that are not made or authorized by the SourceMark LLC.

The warranty is only valid when the KoZee™ Warming Unit and KoZee™ Warming Blanket are used together.

Relevant parts should be properly packed and returned to the local suppliers for repairs.

9.0 Technical Support and Customer Service

SourceMark LLC.
302 Innovation Drive, Suite 410 Franklin, TN 37067
Customer Service: 866-528-7001 customersevice@sourcemarkusa.com

a. Technical Support and Service

You will need to know the serial number of your KoZee™ Warming Unit when you call us. The serial number label is located on the back or side of the KoZee™ Warming Unit.

b. In-Warranty Repair and Exchange

Call or email customer service if your KoZee™ Warming Unit requires factory service. A customer service representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your KoZee™ Warming Unit. Your customer service representative will also send a shipping carton to you at no charge if needed. Call your local supplier or sales representative to inquire about borrowing a KoZee™ Warming Unit while we service your unit. For more detailed instructions on returning units for service, please contact your local distributor.

Appendix 1

EMC COMPATIBILITY TABLES ACCORDING TO IEC 60601-1-2

<table>
<tr><th colspan="3">Guidance And Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">KoZee™ Warming Unit, Model M21507 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.</td></tr>
<tr><th>Emissions tests</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>KoZee™ Warming Unit, Model M21507 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">KoZee™ Warming Unit, Model M21507 is suitable for use all establishments, including domestic establishments and those
directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">NOTE 1: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows:
Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.</td></tr>
</table>

Guidance And Manufacturer's Declaration – Electromagnetic Immunity			
The KoZee™ Warming Unit, Model M21507 is intended for use in the electromagnetic environment specified below. The customer or the user of the KoZee™ Warming Unit, Model M21507 should assure that it is used in such an environment.			
Immunity test	Basic EMC standard	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact: ±8kV Air: ±15kV	Contact: ±8kV Air: ±15kV
Electrical fast transient/burst	IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency
Surge	IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode
Voltage dips	IEC 61000-4-11	0%UT; 1cycle and 70%UT; 30cycles Single phase: at 0°	0%UT; 1cycle and 70%UT; 30cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0%UT; 300cycles	0%UT; 300cycles
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50/60Hz	30A/m 60Hz
Conducted RF	IEC 61000-4-6	3 Vrms 6 V in ISM bands 0.15MHz~80MHz 80%AM at 1kHz	3 Vrms 6 V in ISM bands 0.15MHz~80MHz
Radiated RF	IEC 61000-4-3	10V/m 80MHz~2.7GHz 80%AM at 1kHz	10V/m 80MHz~2.7GHz
Proximity fields from wireless communications equipment	IEC 60601-1-2 Table 9	Ref. to Table 9 in Standards 380MHz~5.8GHz	Ref. to Table 9 in Standards 380MHz~5.8GHz
NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2: 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. NOTE 3: If the measure field strength in the location in which the KoZee™ Warming Unit, Model M21507 is used exceeds the applicable RF(such as CT&RFID) compliance level above, the KoZee™ Warming Unit, Model M21507 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KoZee™ Warming Unit, Model M21507.			

Guidance And Manufacturer's Declaration – Electromagnetic Immunity

The KoZee™ Warming Unit, Model M21507 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KoZee™ Warming Unit, Model M21507 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KoZee™ Warming Unit, Model M21507 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 $d = 1,0\sqrt{P}$	80 MHz to 2.7 GHz $d = 0,6\sqrt{P}$	2.7 GHz to 5,8 GHz $d = 0,67\sqrt{P}$
0,01	0,10	0,06	0,07
0,1	0,32	0,19	0,21
1	1,00	0,60	0,67
10	3,16	1,90	2,12
100	10,00	6,00	6,70

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where 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 structure, objects, and people

Manufactured for SourceMark LLC. by Jiangmen Dacheng Medical Equipment Co., Ltd.
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文件名称：SourceMark升温机（M21507）操作手册　颜色：封面单面四色印刷，内页四色印刷

规格尺寸：210x293mm　材质：封面230g皮纹纸（白色），内页100g双胶，胶装

物料编号：10.06.0735　版本：V1.00

公司名称：江门大诚医疗器械有限公司

修订记录：

V1.00，初版发布；

编制：罗敏霞	审核：钟明	批准：邹太奇
日期：2023.08.08	日期：2023.08.08	日期：2023.08.08

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