

# **Operator's Manual**

# **Fluid Warmer**

ivNow®







MN-38645

REV.05 5/21

**EN** 





## **Manufacturer's Information**

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#### Manufacturer



**Enthermics Medical Systems** 

An ISO 13485:2016 certified company

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Menomonee Falls, WI 53051, USA

#### **Original instructions**

The content in this manual is written in American English.





#### **Authorized Representative:**

MDSS GmbH Schiffgraben 41 30175 Hannover Germany



# FOREWORL

# Thank you for your Purchase!

This warmer has been thoroughly tested and inspected to ensure only the highest quality is provided. We supply the most durable, convenient, efficient and safe warming equipment on the market. All warmers are manufactured and fully inspected in the USA with a commitment to quality.

# **Register Your Warmer**

#### Register

Register your Enthermics appliance online. Registering your appliance ensures prompt service in the event of a warranty claim. You will also receive direct notifications of software updates and additional product information.

Your personal information will not be shared with any other company.

www.enthermics.com/warranty-registration

# **Enthermics 24/7 Emergency Repair Service**

Call

Call 800-558-8744 to reach our 24-hour emergency service call center for immediate access to local authorized service agencies outside standard business hours. The emergency service access is provided exclusively for Enthermics Medical Systems equipment and is available throughout the United States through Enthermics toll free number.

**Availability** 

Emergency service access is available seven days a week, including holidays.



## **FOREWORD**

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Manufacturer's Information	2
Foreword  Thank you for your Purchase!	3
Safety The Meaning of Signal Words	
Labels 1 Label Locations	11 11
Specifications       1         Specification Information	
Installation  How to Unpack the Warmer	
Operation       1         Preparing the Warmer for First Use.       2         How to Turn On and Turn Off the Warmer.       3         How to Operate the Warmer.       4         How to View the Firmware Version       4         How to Change the Temperature Scale.       4         How to Change the Warming Time Limit       4         How to Change the Temperature Set-Point       4	20 21 24 24 25
Maintenance       2         Maintenance Schedule       3         How to Clean the Warmer       3         Warmer Disposal / Decommissioning       3	28
Troubleshooting 2 Error Codes	<b>29</b> 29
Electrical Information	31
Warranty	3 <b>5</b> 35
Declaration of Conformity	37



## **FOREWORD**

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# SAFETY

# The Meaning of Signal Words

This manual contains signal words where needed. These signal words must be obeyed to reduce the risk of death, personal injury, or equipment damage. The meaning of these signal words is explained below.



#### **DANGER**

Danger indicates a hazardous situation which, if not avoided, will result in serious injury or death.



#### **WARNING**

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



#### **CAUTION**

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

NOTICE

Notice indicates a situation which, if not avoided, could result in property damage.



**NOTE:** Note indicates additional information that is important to a concept or procedure.

# **Safety Precautions**

#### Before you begin

Read and understand all instructions in this manual.

#### **Electrical precautions**

Obey these electrical precautions when using the warmer:

- Connect the warmer to a properly grounded outlet. Do not use the warmer if it is not properly grounded. Consult an electrician if there is any doubt that the outlet used is properly grounded.
- Keep the cord away from hot surfaces.
- Do not attempt to service the warmer or its cord and plug, when plugged in.
- Do not operate the warmer if it has a damaged cord or plug.
- Do not immerse the cord or plug in water.
- Do not let the cord hang over the edge of a table or counter.
- Do not use an extension cord.

#### **Usage precautions**

Obey these usage precautions when using the warmer:

- Only use this warmer for its intended use of warming medical solution bags, bottles, and/or blankets. Follow facility and solution manufacturer guidance regarding warming temperature for any item to be placed in the warmer.
- Do not use this warmer for warming blood or blood products.
- Do not cover or block any of the openings of this warmer.
- Do not use this warmer in a wet location.
- Only clean the warmer when the power cord is unplugged.
- Do not use corrosive chemicals when cleaning the warmer.
- Do not use the warmer cavity for storage.
- Do not remove exterior panels from the warmer or attempt repairs. The warmer has no user-serviceable internal components. Only perform routine cleaning and maintenance procedures specifically described in this manual. Inspection and servicing of internal components must only be performed by qualified service personnel.
- Only a qualified Enthermics service representative may make modifications to the warmer. Modifications to the warmer could be hazardous to users and patients.

#### **Operator training**

All personnel using the warmer must have proper operator training. Before using the warmer:

- Read and understand the operating instructions contained in all the documentation delivered with the warmer.
- Know the location and proper use of all controls.
- Keep this manual and all supplied instructions, diagrams, schematics, parts lists, notices, and labels with the warmer if the warmer is sold or moved to another location.



# Operator qualifications

Only trained personnel with the following operator qualifications are permitted to use the warmer:

- Have received proper instruction on how to use the warmer.
- Are familiar with the purpose, limitations, and associated hazards of the warmer.

#### The warmer must not be used by:

People impaired by drugs or alcohol.

#### **Condition of warmer**

#### Only use the warmer when:

- All controls operate correctly.
- The warmer is installed correctly.
- The warmer is clean.
- The warmer labels are legible.

#### Servicing the warmer

- Obey precautions in the manual, on tags, and on labels attached to or shipped with the warmer.
- Only trained personnel are permitted to service or repair the warmer. Repairs that are not performed by a trained technician, or the use of non-factory parts, will void the warranty and relieve all liability.
- Any troubleshooting guides and components views included with this manual are for reference only and are intended for use by qualified and trained service technicians.
- To prevent serious injury, death or property damage, have the warmer inspected and serviced at least every twelve (12) months by a trained technician.
- Contact Enthermics for the authorized service partner in your area.

#### **Incident notice**

Any serious incident that has occurred in relation to the warmer should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



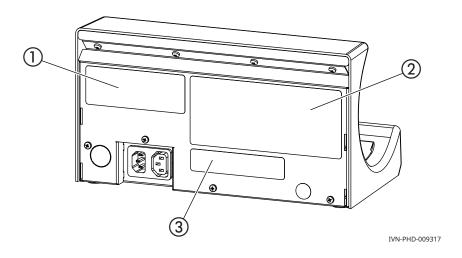
#### **SAFETY**

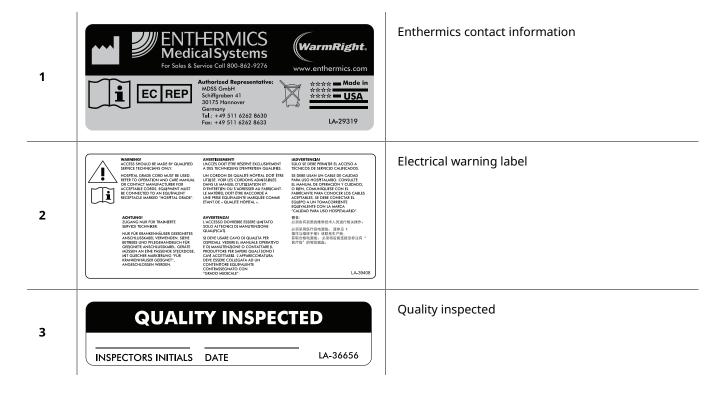
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# LABELS

# **Label Locations**





#### **LABELS**

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# **Specification Information**

Model	ivNow-1	ivNow-2	ivNow-3
Intended use	ntended use Warming injection fluids/iv bags		bags
Weight	Net: 8 lb (3.6 kg) Ship: 11 lb (5.0 kg)	Net: 14 lb (6.4 kg) Ship: 16 lb (7.3 kg)	Net: 20 lb (9.0 kg) Ship: 23 lb (10.4 kg)
Storage cavity capacity	1 bag, 0.5–3 liters	2 bags, 1–6 liters	3 bags, 1.5–9 liters
Temperature 95°F to 104°F (35°C to 40°C range NOTE: Default temperature is 104°F		,	

# Transportation and storage conditions

- Ambient temperature range of -40°F to +159°F (-40°C to +70°C).
- Relative humidity range of 10% to 95%, non-condensing.
- Atmospheric pressure range of 7.25 psi to 15.37 psi (50kPa to 106kPa).

#### **Operating conditions**

- The warmer must acclimate to the room temperature it will be placed in—24 hours is recommended.
- The recommended environmental temperature range is 60°F to 90°F (15°C to 32°C).
- The recommended relative humidity is above 20%, non-condensing.

# Standards for electrical equipment

 Medical equipment listed by Underwriters Laboratories with respect to electrical shock, fire, and mechanical hazards only, in accordance with UL 61010-1 and CAN/CSA C22.2 No. 61010-1.

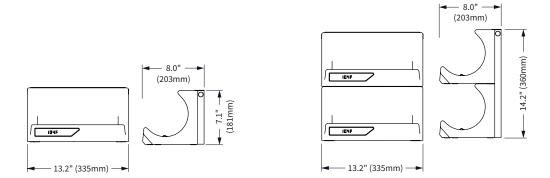


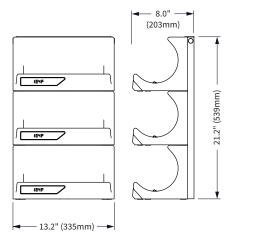
- Grounding reliability can only be achieved when the appliance is connected to an equivalent receptacle marked "Hospital Grade."
- IP-XO ordinary





# **Dimension Drawings**





IVN-DIM-009256

# **How to Unpack the Warmer**

#### Before you begin

**Make sure** you have cutting tools to remove packaging.

#### **Unpack the warmer**

To unpack the warmer, do the following.

Step	Action		
1.	Open the box.		
2.	<b>Remove</b> the warmer from the box with the foam inserts attached to the warmer.		
3.	<b>Remove</b> the foam inserts and paperwork from the warmer.		
NOTE: Examine the warmer for damage. If the warmer has been damaged, do not use the warmer until it has been inspected by an authorized service provider. Contact your carrier or customer service.			

#### Result

The warmer is now unpacked.



# **How to Install and Mount the Warmer**

#### **Background**

ivNow warmers can be installed in a variety of ways. Up to three warmers can be linked together with a jumper cord and connected via a mounting plate. Configurations can be placed on a counter top, mount to a wall or pole.



IVN-TS-009410

#### Requirements

The warmer must not be installed in any area where it may be affected by steam, dripping water, high temperature, or any other severely adverse conditions.

#### **Voltages**

Model	v	Ph	Hz	kW
ivNow-1	120	1	60	0.1
	230	1	50/60	0.1
ivNow-2	120	1	60	0.2
	230	1	50/60	0.2
ivNow-3	120	1	60	0.3
	230	1	50/60	0.3



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# Mounting the warmers

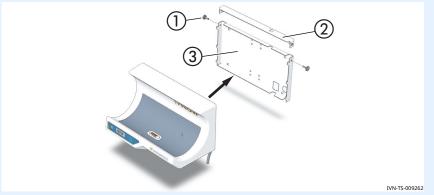
To mount the warmers, do the following.

#### Step Action

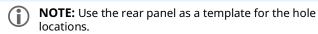
1. **Remove** the two thumb screws ① from the sides of the rear panel. **Remove** the top bracket ② from the rear panel.

**Remove** the rear panel 3 from the assembly.

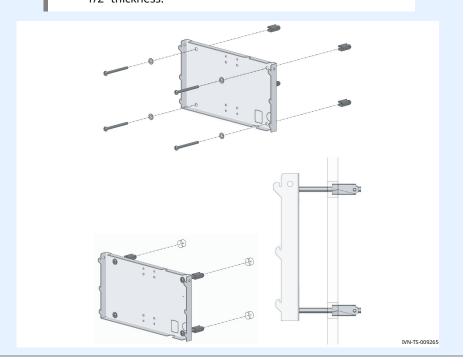
Remove the rear panel (3) from the assembly.



2. **Mount** the rear panel to the wall using 1/4" toggle bolts and washers.



For drywall mounting, the drywall must be a minimum of 1/2" thickness.





Continued from previous page

3. Make sure the toggle anchors are fully tightened.

NN-TS-009268

- 4. **Re-install** the warmer to the rear panel.
- 5. **Re-install** the top bracket to the rear panel.
- 6. **Connect** the plug to the electrical outlet.

Equipotentialbonding terminal (if applicable) For warmers with an equipotential-bonding terminal, an equalization bonding lead must be connected to the equipotential-bonding terminal and the other appliances to provide sufficient protection against potential difference.

Result

The warmer is now installed and ready to be used.

# OPERATION

# **Preparing the Warmer for First Use**

#### Before you begin



WARNING: Electric shock hazard.

Disconnect the warmer from electric power before cleaning.

#### NOTICE

#### Do not use:

- abrasive cleaning compounds.
- chloride based cleaners.
- commercial or household cleaners containing ammonia.

#### **Procedure**

To prepare the warmer for first use, do the following.

Step	Action	
1.	<b>Make sure</b> that the warmer is disconnected from electric power.	
2.	<b>Wipe</b> the outside of the warmer with a cloth dampened with isopropyl alcohol or 10% bleach solution.	
3. <b>Wipe</b> the interior of the warmer with a damp cloth or approved cleaning agent.		
4.	<b>Dry</b> the warmer with a clean, lint-free cloth.	

#### Result

The warmer is now ready for use.



# How to Turn On and Turn Off the Warmer

Before you begin

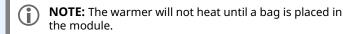
The warmer must be connected to electric power.

Turning on the warmer

To turn on the warmer, do the following.

#### Step Action

1. **Press** the standy button . The screen turns on.



The warmer is now on.

Turning off the warmer

To turn off the warmer, do the following.

2. **Press and hold** the standby button until the screen turns off, then release the button.

The warmer is now off.

# **How to Operate the Warmer**

#### Before you begin

The warmer must be connected to electric power and turned on.



WARNING: Personal injury hazard.

Do not operate the warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment.

WARNING: Electric shock hazard.



If fluid spills inside of the warmer cavity, disconnect the warmer from electric power. Wipe excess fluid from the warmer.

Contact a qualified service technician to remove the module control to remove any remaining liquid. Do any necessary hospital electrical safety checks before continuing operation of the warmer.

**WARNING:** Personal injury hazard.



Verify the fluid temperature prior to using the fluid. Refer to the fluid manufacturer's label for recommended warming procedures.

Do not use any fluids that are warmed above the suggested temperature.

NOTICE

Do not overload the cavity.

Refer to topic *Specification Information* for the storage cavity capacity.



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#### **Procedure**

To operate the warmer, do the following.

#### Step Action

1. **Load** the fluid bag in the warmer. This starts the warming process. Refer to the image below for correct fluid bag placement.



**NOTE:** The warm-up stabilization time will vary depending on the bag temperature and the ambient room temperature.

Correct bag placement





Incorrect bag placement





**Note:** Silver heater plate painted black to increase contrast in photographs

IVN-TS-009262

# During the warming process

2. **Press** the status button



to view the set-point temperature.



**NOTE:** The screen displays the actual bag temperature as the fluid is heated.

3. **Press and hold** the status button at the set-point temperature.



to view how long a fluid bag has been



**NOTE:** The first hour is indicated in minutes and seconds "MM:SS" and subsequent time is indicated in hours and minutes "HH:MM" for the first 24 hours.

After 24 hours, the time is displayed in days and fractions of a day "DD.DD". The timer stops after 60.00 days. The time a bag is held at the set-point temperature will remain in memory until a new bag is loaded in the warmer.

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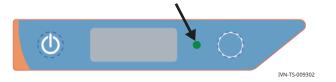
# ivNow status indicators

The warmer displays the following messages depending on the status of the fluid bag.

Status Indicator	Meaning	
4 dashes	Fluid bag is not present.	
Chasing dash	Fluid bag is detected, measuring the initial fluid bag temperature.	
Actual bag temperature flashing on screen	Fluid bag temperature is over the set-point temperature. The actual bag temperature will continue to flash until the temperature falls below the set-point. Do not use the fluid bag until the screens stops flashing.	
Screen displays "dAtE"	Fluid bag heated warming time is in excess of limit. Check with the iv fluid manufacturer for guidance prior to use.	

#### Result

The fluids are now warming. When the fluid bag is within tolerance, the status indicator light will illuminate.





# **How to View the Firmware Version**

**Before you begin** The warmer must be connected to electric power and turned on.

**Procedure** To view the firmware version, do the following.

Step	Action
1.	<b>Press and hold</b> the standby button for 5 seconds, then release the button.
	The current firmware version displays.
2.	<b>Press</b> the standby button to return to the home screen.

**Result** The firmware version has now been viewed.

# **How to Change the Temperature Scale**

**Before you begin** The warmer must be connected to electric power and turned on.

**Procedure** To change the temperature scale from °F to °C and vice versa, do the following.

Step	Action
1.	<b>Press and hold</b> the standby button for 10 seconds, then release the button.
2.	<b>Press</b> the status button to toggle between the temperature scales.
3.	<b>Press</b> the standby button to accept the change.

**Result** The temperature scale has now been changed.

# **How to Change the Warming Time Limit**

#### Before you begin

The warmer must be connected to electric power and turned on.

#### **Notes**

- Always follow the fluid manufacturer's guidelines for recommendations on best handling and storage practices.
- In the event of power failure, the ivNow internal timer will be reset and become inaccurate. Fluids placed inside of the warmer should be inspected for their expiration date.

#### **Procedure**

To change the warming time limit, do the following.

Step	Action
1.	<b>Press and hold</b> the standby button for 15 seconds, then release the button.
	NOTE: The default warming time limit is 15.
2.	<b>Press</b> the status button to select a date range between 7 and 60 days.
3.	<b>Press</b> the standby button to accept the change.

#### **Result**

The warming time limit has now been changed.



# How to Change the Temperature Set-Point

#### Before you begin

The warmer must be connected to electric power and turned on.



**NOTE:** Always follow the fluid manufacturer's guidelines for recommendations on best handling and storage practices.

#### **Procedure**

To change the temperature set-point, do the following.

# 1. Press and hold the standby button for 20 seconds, then release the button. NOTE: The default temperature set-point is 104°F (40°C). 2. Press the status button to select the temperature set-point. NOTE: The temperature set-point range is 95°F – 104°F (35°C – 40°C). 3. Press the standby button to accept the change.

#### Result

The temperature set-point has now been changed.

## **Maintenance Schedule**



**NOTE:** Do not remove exterior panels from the warmer or attempt repairs. The warmer has no user-serviceable internal components. Only perform routine cleaning and maintenance procedures specifically described in this manual.

**Daily** 

For daily maintenance, do the following.

#### Clean:

any spills with a clean, lint free cloth. See topic *How to Clean the Warmer* for the list of approved cleaners.

Monthly

For monthly maintenance, do the following.

#### Check:

the hardware securing the warmer(s) to the wall, if applicable.

Yearly

For yearly maintenance, do the following.

#### Check:

- the condition of the plug and cord and replace if damaged.
- the controller screen for excessive wear. Make sure the controller screen displays and operates properly.



## **How to Clean the Warmer**

#### Before you begin



**WARNING:** Electric shock hazard.

Disconnect the warmer from electric power before cleaning.

#### NOTICE

#### Do not use:

- abrasive cleaning compounds.
- chloride based cleaners.
- commercial or household cleaners containing ammonia.

# Weekly cleaning procedure

To clean the warmer weekly, do the following.

Step	Action	
1.	<b>Make sure</b> that the warmer is disconnected from electric power.	
2.	<b>Wipe</b> the outside of the warmer with a cloth dampened with isopropyl alcohol or 10% bleach solution.	
3.	<b>Wipe</b> the warmer with a cloth dampened with clean, warm water.	
4.	<b>Dry</b> the warmer with a clean, lint-free cloth.	

#### Result

The warmer is now clean.

# Warmer Disposal / Decommissioning

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste.

### **Error Codes**

#### **Background**

This section is provided for the assistance of qualified and trained service technicians only and is not intended for use by untrained or unauthorized service personnel. Failure to observe this precaution may void the warranty.



**NOTE:** If the warmer is not operating properly, check the following before calling an authorized service agent:

Verify that the power to the warmer is on.

If applicable, ensure the female end of plug is securely seated in the warmer and that the male end of plug is in an appropriate, functioning outlet.

If applicable, make sure the jumper cords between warmers are fully inserted.

#### NOTICE

Do not attempt to repair or service the warmer beyond this point. Contact the manufacturer for the nearest authorized service agent. Repairs made by any other service agent without prior authorization by the manufacturer will void the warranty.

Code	Refers to	Action required
E-10 E-11 E-20 E-21 E-P0 E-P1	Temperature sensor 1 short Temperature sensor 1 open Temperature sensor 2 short Temperature sensor 2 open Plate temperature sensor short Plate temperature sensor open	Press the status button to clear the error code.      If the error persists, contact service.
E-98	Temperature Delta Error	Temperature of the fluid bag sensors 1 and 2 differ by more than 3.3°C (6°F).  1. Remove the fluid bag(s) and allow the warmer to cool down.  2. Verify that the fluid bag sensor is clean and operating correctly.  3. Press the status button to clear the error code.  4. Disconnect, and then reconnect power to the unit.  5. If the error persists, contact service.
E-31	Product over temperature and the warmer has been actively heating	Press the status button to clear the error code.     Remove the fluid bag(s) and allow the warmer to cool down.     Inspect the fluid and discard if necessary.     If the error persists, contact service.



# TROUBLESHOOTING

Code	Refers to	Action required
E-50 E-F0	Analog to digital converter error Flash write error	1. Press the status button to clear the error code.
E-F1	Flash write error Flash write error	2. Remove the fluid bag(s) and allow the warmer to cool down. Inspect the fluid and discard if necessary.
		3. If the error persists, a qualified service technician should replace the lower control assembly. Contact service.
E-F2	Flash value error	1. Press the status button to clear the error code.
		2. This error is acceptable upon initial start-up. The warmer will self-correct.
E-70	Low voltage flag triggered	Measure the outlet voltage. Inspect the voltage rating on the equipment rating tag. Make sure both voltages match.
		2. If the error persists, a qualified service technician should replace the lower control assembly. Contact service.
E-B0 E-B1 E-B2	PCB sensor short PCB sensor open PCB sensor over temperature	Contact service.
E-79	Input voltage high	A qualified service technician should check the input voltage to make sure it is at or below 277VAC.
E-78	Input voltage low	A qualified service technician should check the input voltage to make sure it is at or below 85VAC.
E-179	Input voltage open	Contact service.
E-178	Input voltage short	Contact service.
The warm	ner does not power on	1. Verify that the warmer is plugged into an appropriate outlet.
		2. Measure the outlet voltage. Inspect the voltage rating on the equipment rating tag. Make sure both voltages match.
		3. Allow the warmer to cool down to reset the protective devices.
		4. Inspect the fuses. Replace if blown.
		5. If warmer still does not power on, contact service.
Warmer powers on and off when the fluid bag is loaded		1. Turn off the warmer and disconnect it from electric power.
		2. Contact service.
	eads a temperature without a fluid	1. Inspect the sensor switch.
bag loaded in the warmer		2. If the sensor switch is sticking, clean the sensor switch with a dampened isopropyl alcohol wipe and used compressed air to blow out the area.
		3. If the warmer still displays a temperature, contact service.



#### **Guidance and Manufacturer's Declaration**

The warmer requires special precautions regarding EMC (Electromagnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect medical electrical equipment.

A risk of increased emissions or decreased immunity may result if the power cord is altered or a manufacturer supplied power cord is not used.

The warmer should not be used adjacent to or stacked with other equipment.

The essential performance of the ivNow is to not exceed a warmed fluid temperature of 104°F (40°C).

# Electromagnetic emissions

The warmer is intended for use in the electromagnetic environment specified below.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions; CISPR 11	Group 1	The warmer uses RF energy only for 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 B	The warmer is suitable for use in all establishments, including domestic establishments and those directly connected to
Harmonic emissions; IEC 61000-3-2	Class A	the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/Flicker emissions; IEC 61000-3-3	Complies without conditions	



# **ELECTRICAL INFORMATION**

Continued from previous page

# **Electromagnetic** immunity

The warmer is intended for use in the electromagnetic environment specified below.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	±4 kV contact ±8 kV air	±4 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	±1 kV for power supply lines; ±1 kV for input/output lines	+1 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment. The warmer does not have any input/output lines.
Surge IEC 61000-4-5	±0.5 kV differential mode; ±1 kV common mode	±0.5 kV differential mode; ±1 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% UT for 0.5 cycle 40% UT for 1 cycle 70% UT for 25 cycles <5% UT for 250 sec	<100% UT for 0.5 cycle 100% UT for 1 cycle 70% UT for 25 cycles <100% UT (>95% dip in UT) for 250 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the warmer requires continued operation during power mains interruptions, it is recommended that the warmer be powered from an uninterrupted 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:** UT is the a.c. mains voltage prior to application of the test level.



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**Electromagnetic** emissions

The warmer is intended for use in the electromagnetic environment specified below.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.0 GHz 1 V/m		part of the warmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	2.0 GHz to 2.7 GHz		Recommended separation distance
			d = [3.5/3] √P
			d = [3.5/3] √P 80 MHz to 800 MHz
			d = [7/3] √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 <sup>1</sup> , should be less than the compliance level in each frequency range <sup>2</sup> .
			Interference may occur in the vicinity of equipment marked with the following symbol:

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



<sup>1.</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the warmer is used exceeds the applicable RF compliance level above, the warmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the warmer.

<sup>2.</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [VI] V/m.

#### **ELECTRICAL INFORMATION**

Continued from previous page

# Electromagnetic immunity distance

The warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	$d = \left[\frac{3.5}{3}\right] \sqrt{P}$	$d = \left[\frac{3.5}{3}\right] \sqrt{P}$	$d = \begin{bmatrix} \frac{7}{3} \end{bmatrix} \sqrt{P}$	
0.01	0.117	0.117	0.233	
0.1	0.369	0.369	0.738	
1	1.167	1.167	2.333	
10	3.689	3.389	7.379	
100	11.667	11.667	23.333	

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 rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

# WARRANTY

# Warranty

#### Introduction

Enthermics Medical Systems warrants to the original purchaser only, that any original part found to be defective in material or workmanship will be replaced with a new or rebuilt part at Enthermics option, subject to provisions hereinafter stated.

#### **Warranty Period**

The warranty period is as follows:

- For ivNow units shipped to the United States or Canada,
  - The labor warranty remains in effect for one (1) year from installation or fifteen (15 months) from the shipping date, whichever comes first. Enthermics will bear normal labor charges performed during the standard business hours, excluding overtime, holiday rates or any additional fees.
  - □ The original parts warranty remains in effect one (1) year from installation of appliance or fifteen (15) months from the shipping date, whichever comes first.
- For ivNow units shipped outside of the United States or Canada,
  - The original parts warranty is one (1) year from the date of installation of appliance or fifteen (15) months from the shipping date, whichever comes first
- To be valid, a warranty claim must be asserted during the applicable warranty period. This warranty is not transferable.

#### **Exclusions**

This warranty does not apply to:

- Calibration.
- Equipment damage caused by accident, shipping, improper installation or alteration.
- Equipment used under conditions of abuse, misuse, carelessness or abnormal conditions, including but not limited to, equipment subjected to harsh or inappropriate chemicals, including but not limited to, compounds containing chloride or quaternary salts, poor water quality, or equipment with missing or altered serial numbers.
- Any losses or damage resulting from malfunction, including the loss of contents or consequential or incidental damages of any kind.
- Equipment damage caused by use of any cleaning agents other than those recommended by Enthermics, including but not limited to damage due to chlorine or other harmful chemicals.
- Equipment modified in any manner from original model, substitution of parts other than factory authorized parts, unauthorized removal of any parts including legs, or unauthorized addition of any parts.



#### **WARRANTY**

Continued from previous page

■ Collateral or incidental damage as a direct result of servicing equipment built into a wall structure is not covered under warranty. It is the responsibility of the owner to bear all expense related structural repairs including, but not limited to, external electrical connections and wiring, and the removal or replacement of caulk, grout, tile, or wall covering of any kind. A service access panel for built-in equipment installations is strongly recommended.

#### Conclusion

This warranty is exclusive and is in lieu of all other warranties, express or implied, including the implied warranties of merchantability and fitness for a particular purpose. No person except an officer of Enthermics is authorized to modify this warranty or to incur on behalf of Enthermics any other obligation or liability in connection with Enthermics equipment.





DECLARATION OF CONFORMITY
DOCUMENT NO: TF-002
REVISION NO: 12
Page 1 of 3

#### **DECLARATION OF CONFORMITY**

Manufacturer: Enthermics Medical Systems, Inc.

Manufacturer's Address: W164 N9221 Water Street, Menomonee Falls, WI 53051 USA

Tel: +1 800-862-9276

**EU Representative**: Medical Device Safety Service GmbH (MDSS)

EU Rep's. Address: Schiffgraben 41, 30175 Hannover, Germany

Tel.: +49 511 6262 8630

**Devices**: Multi-purpose warming cabinet, GMDN Code 40516

**Description**: The Enthermics multi-purpose warming cabinets are designed in multiple

configurations. These units typically consist of a cabinet with shelves or baskets,

a heating system, temperature controls, and overheat alarms.

Intended Purpose/Users: Multi-purpose warming cabinets are intended to be used by competent medical

professionals to warm solutions (e.g. irrigation and injection fluids), and/or

blankets.

**Device model schema**: Per the equation: X#Z, (except ivNow & ivNext):

X represents the exterior design and includes any alpha sequence (DC, EC).

# represents the unit capacity code and includes any numeric sequence.

• Z further differentiates models with an alpha-numeric sequence. (L, BL)

**UDI-DI Format:** The top level Global Location Number (GLN) issued by GS1 for Enthermics

Medical Systems is 0851962007008. UDI-DI is displayed as the first number in the UDI barcode on the rating tag of each unit. See Table 1 for the list of device

models, device type and the associated UDI-DI.

The entire UDI displayed on the rating tag consists of the DI, the unit

manufacture date, and the unit serial number.

#### **ENTHERMICS MEDICAL SYSTEMS**

An ISO 13485:2016 certified company

PO Box 443, Menomonee Falls WI 53052-0443 W164 N9221 Water St, Menomonee Falls WI 53051 Phone 262-251-8356 | 800-862-9276 | Fax 262-251-7067

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> > Made in the USA



Continued from previous page



DECLARATION OF CONFORMITY

DOCUMENT NO: TF-002

REVISION NO: 12

Page 2 of 3

#### Table 1: List of Device Models, Device Type, & UDI-DI

Model	Туре	UDI-DI
DC250	Blanket Warmer	00851962007220
DC350	Blanket Warmer	00851962007244
DC400	Blanket Warmer	00851962007251
DC750	Blanket Warmer	00851962007268
EC250	Blanket Warmer	00851962007275
EC350	Blanket Warmer	00851962007282
EC400	Blanket Warmer	00851962007466
EC750	Blanket Warmer	00851962007299
ivNow	Fluid Warmer	00851962007008
ivNext	Fluid Warmer	00851962007435
DC250L	Fluid Warmer	00851962007084
DC400L	Fluid Warmer	00851962007091
EC250L	Fluid Warmer	00851962007237
EC350L	Fluid Warmer	00851962007305
EC400L	Fluid Warmer	00851962007473
EC550BL	Blanket & Fluid Warmer	00851962007497
EC1350BL	Blanket & Fluid Warmer	00851962007428
EC1850BL	Blanket & Fluid Warmer	00851962007312

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Continued from previous page



**Conformity Assessment** 

DECLARATION OF CONFORMITY

DOCUMENT NO: TF-002

REVISION NO: 12

Page 3 of 3

**Quality Management** Certification Body: QMI-SAI Canada Limited (SAI Global)

System Certificate: Certificate Number: CERT-0125669,

Issued: 23, October 2018, Expiry: 27, December 2021

Risk Class: Class I per Annex VIII, Rule 13, Medical Device Regulation (EU) 2017/745

Route:

**Applied Directives**: RoHS Directive of the European Union 2011/65/EU

**Applied Standards**: ISO 13485:2016

EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements EN 61010-2-010:2014 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements

Quality Management System and Assessment of Technical Documentation

for laboratory equipment for the heating of Materials

EN 61326-1:2013 Electrical equipment for measurement, control and laboratory

use - EMC requirements - Part 1: General requirements

The undersigned, representing Enthermics Medical Systems, Inc., hereby declares that the equipment specified above conforms to the Medical Device Regulation (EU) 2017/745 and the Directives and Standards referenced in this Declaration of Conformity.

The Declaration of Conformity is issued at Enthermics Medical Systems, Inc, W164 N9221 Water Street, Menomonee Falls, WI 53051 USA.

The Declaration of Conformity is issued under the sole responsibility of Enthermics Medical Systems, Inc.

Nicole Polley, Quality Assurance Manager

17/03/2021 [date (dd/mm/yyyy)]

Signed at Enthermics Medical Systems, Inc.

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