

It's all about **37°**



Mistral-Air®
Plus warming
unit

mistral-air[®]

User Manual

Mistral-Air[®] Plus Warming Unit

MA1100-EU (220-240V~, 50/60 Hz)

MA1100-US (110-120V~, 60 Hz)

MA1100-JP (100-110V~, 50/60 Hz)

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Foreword

Congratulations on your purchase of the Mistral-Air® Plus Forced Air Warming Unit.

This device was developed with and for users and is built in accordance to the latest safety standards.

We wish you every success in preventing and controlling hypothermia and we are sure that the Mistral-Air® Plus warming unit can help you to do so.

Please read this manual carefully before using the Mistral-Air® Plus warming unit.

The 37Company

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The 37Company reserves the right to make alterations and improvements to the device.

The 37Company cannot be held liable for the final outcome of the patients' treatment.

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These instructions are intended for personnel authorised 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 Contra-indications, Safety Precautions, Symbols and Graphics











Your Mistral-Air® Plus warming unit was designed and built with safety in mind. The unit should provide reliable service and high quality patient care. However, there is no replacement for care providers being attentive to their patients' needs and equipment operation. Read and understand all warnings and precautions before using or prescribing the Mistral-Air® Plus warming unit.













1.1 Contra-indications

	Do not apply heat directly to open wounds.
	Do not apply the warming system to ischemic limbs. a. Use caution and consider discontinuing use on patients during vascular surgery when an artery is clamped to an extremity (i.e. aortic cross-clamping) b. Use caution and monitor closely if used on patients with severe peripheral vascular disease

1.2 Safety Precautions

	Adequate grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked 'hospital grade'.
	Prevent the blanket material from coming into direct contact with a laser or an electrosurgical active electrode, rapid combustion could result.
	Using power cords or spare parts for internal components other than specified by The 37Company may result in increased emission or decreased immunity of the Mistral-Air® Plus warming unit.
	When replacing the hose, do not touch the temperature sensors. If these sensors are touched in any way, the unit must be recalibrated.
	Portable and mobile RF (Radio Frequency) communication equipment, and HF (High Frequency) surgical instruments or endocardial catheters can affect the correct functioning of the Mistral-Air® Plus warming unit.

	The Mistral-Air® Plus warming unit is fitted with an air filter; however airborne contamination shall be taken into consideration when using the warming system.
	In order to prevent the patient from becoming hypothermic due to unanticipated loss of power, connect the unit to the emergency mains power.
	When the unit is switched off, use of good thermal conductivity materials on the patient could decrease the patient temperature.
	The heating device does not contain an alarm system with an interruption of power supply/supply mains alarm condition. This means that in case of a power failure, there will be no alarm.
	The unit is not equipped with an isolating switch. Temporary interruption of the supply mains will render the device in Stand-by Mode.
	<p>The Mistral-Air® Plus warming unit is certified according to IEC 60601-1-2 for electromagnetic interference. However, if electromagnetic interference with nearby devices is experienced, the user is encouraged to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> •Isolate the offending device. •Reorient or relocate the Mistral-Air® Plus warming unit. •Increase the distance between the interfering device and the Mistral-Air® Plus warming unit, use another electrical outlet. •If assistance is required, please contact your local dealer. •The Mistral-Air® plus warming unit shall not be used adjacent to or stacked with other equipment.
	Do not use the Mistral-Air® Plus warming unit with any forced air disposables other than Mistral-Air® blankets. Thermal injury may result.
	Do not place the unit <i>in</i> or on the bed with the patient.
	Monitor patient skin routinely.
	Monitor patient temperature routinely.

	A physician order is required for setting temperature and for continued use.
	Neonates and pediatric patients of low weight will have a tendency to overheat more readily than adults. Failure to monitor core temperature could result in abnormal elevation of body temperature resulting in serious injury or death.
	If patient temperature is not responding or does not reach prescribed temperature in prescribed time notify physician.
	Place the unit in such way that the mains plug could be disconnected easily in case of emergency.
	Warming transdermal medications (patches) can increase drug delivery, resulting in possible harm to the patient
	To remove all power from the Mistral-Air® Plus warming unit, the mains power cord must be removed from the electrical receptacle.
	Stay in viewpoint of the user interface when performing the self-test, and selecting the set-point.
	In case of temperature alarm, check for free airflow. Ensure blanket is not folded and do not place tools/equipment on the blanket which could result in a blocked air flow. Be sure the air inlet is free. If the unit continues to alarm, take the unit out of use and contact the hospital service department or the local supplier.
	Mistral-Air® blankets need to be used with the soft blue material towards the patient's skin and the white or reflective layer away from the patient's skin. The blue side provides the air distribution towards the patient.
	Never fold the blankets during use.
	Do not obstruct blanket channels by e.g. instruments/tape/clamps.
	Do not return the unit from service without the filter present.










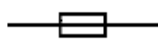













Do not apply the lock screw into the sensor!

1.3 Symbols

This paragraph contains a list of official symbols.

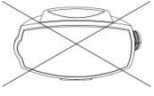







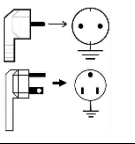

IP21	Protected against solid foreign objects of 12 mm Ø and greater. Protected against vertically falling water drops (according to IEC 60529).
Rx only	Caution: Federal US law restricts this device to sale by or on order of a physician.
	Connect the Mistral-Air® Plus warming unit to an earthed socket only. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
	No free hosing. CAUTION! Hose nozzle MUST be connected to a compatible forced air blanket or thermal injury may occur.
	Check patient's temperature and skin condition at least every 15 minutes.
	Do not apply to patients with ischemic limbs.
	Do not use Mistral-Air® Plus warming unit and blankets near flammable anaesthetics, to avoid the risk of explosion.
SN	Serial number
REF	Catalogue / article number
STERILE EO	Sterile, method of sterilisation ethylene oxide
LOT	Batch code / lot number
	Manufacturer
	Transport and storage ambient temperature range

	Transport and storage relative humidity range
	Transport and storage atmospheric pressure range
	AC voltage
	Electrical shock hazard. Do not disassemble the Mistral-Air® Plus Warming Unit unless you are a qualified service technician. There are electrically live parts within the unit when it is connected to a power supply.
	Type BF applied parts (according to IEC 60601-1)
	Equipotentiality
	Expiry date, year/month
	For single patient use only. Do not re-use.
	Does not contain natural latex components
	Transformer fuses (250V 800 mA Fast Acting)
	Refer to instruction manual/ booklet
	Consult user manual; operating instructions
	Alarm indication on control equipment.
	Urgent alarm indication on control equipment
	Caution

	<p>Not for use in MRI</p>
	<p>Bell, cancel temporary</p>
	<p>Service indicator</p>
	<p>Upper limit of temperature</p>
	<p>Lower limit of temperature</p>
	<p>Non-ionizing electromagnetic radiation</p>

1.4 Mistral-Air® Graphics

This paragraph contains a list of Mistral-Air® graphics.

	<p>Prior to use, the user needs to check that the Mistral-Air® Plus warming unit (including the power cord and the hose) is undamaged. In the event of damage do <u>not</u> use the Mistral-Air® Plus warming unit.</p>
	<p>Do not use the Mistral-Air® blankets when damaged.</p>
	<p>Maintenance and repairs shall be performed by qualified medical instrument technicians only.</p>
	<p>To keep the Mistral-Air® Plus warming unit stable, the wheelbase of the stand must be in a particular ratio to the clamp height. See chapter 7 .</p>
	<p>Do not immerse the Mistral-Air® Plus warming unit in fluid. Clean the appliance with standard cleaning agents. See chapter 11.</p>
	<p>S = Small, M = Medium, L = Large, XL = Extra large</p>
	<p>All steps are followed according to the manufacturer's instructions</p>
	<p>Make sure the power cord is secured by the cord anchor</p>
	<p>Plug the unit into an earthed mains socket</p>
	<p>Before using the Mistral-Air® Plus warming unit, it should be attached to a pole or placed on a table.</p>

2 Indications For Use

The Mistral-Air® Warming System is a forced air warming device and comprises of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.

3 Temperature Management

Hypothermia, an abnormal drop in body temperature, is a threat to human life. Hospital patients in particular run serious risks if their body temperature falls below 36 °C. The risk of hypothermia is particularly high at moments when they are vulnerable, such as pre-, per-, and post-surgical interventions. 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 anaesthetic technique.

4 Forced Air Warming

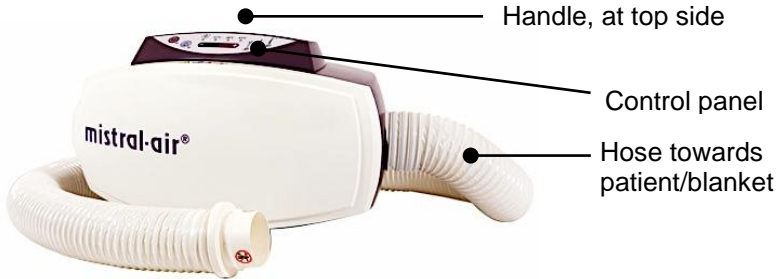
Forced air warming is a widely used and clinically accepted intervention for the prevention of hypothermia and/or re-warming of the postoperative surgical patient. The principle of operation for forced air warming systems is an electrically powered unit consisting of a fan and heating element that propels warmed air via a flexible hose to a blanket draped over the patient. Some configurations 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.

5 Description of Mistral-Air® Plus Warming Unit

The Mistral-Air® Plus warming unit is a system which is intended for use in preventing patients from becoming hypothermic. The Mistral-Air® Plus warming unit shall only be used with disposable Mistral-Air® blankets that are single patient use only.

5.1 The Appliance



The Mistral-Air® Plus warming unit can be controlled by using the control panel at the front top of the unit. The clamp to fix the Mistral-Air® Plus warming unit to a pole is positioned at the back of the unit.

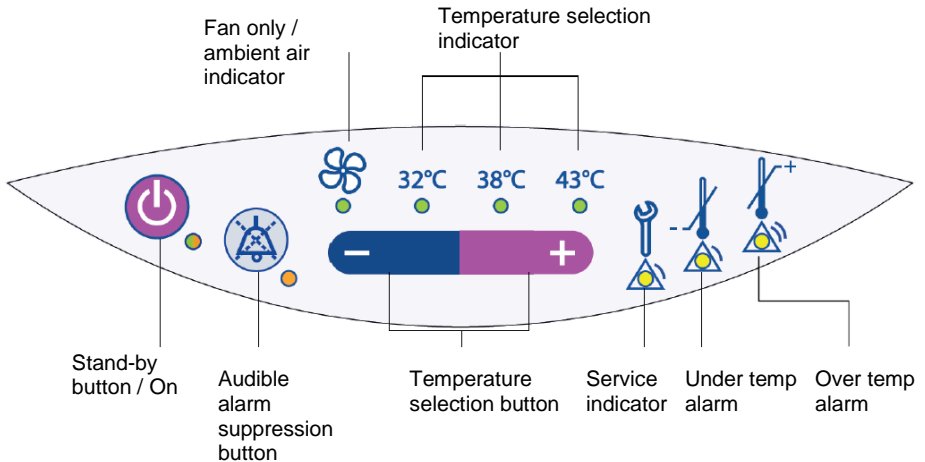
Article number: - MA1100-EU (220-240 V~, 50/60 Hz)
- MA1100-US (110-120 V~, 60 Hz)
- MA1100-JP (100-110 V~, 50/60 Hz)

5.2 The Control Panel

The control panel is located at the front top of the unit and may be operated by pressure sensitive buttons.

The Mistral-Air® Plus warming unit is very easy to use. All settings are visible on the control panel and you can select the preferred temperature by pressing the Temperature Selection button.

In emergencies, an audible alarm will be activated and an LED will flash yellow.



6 Preparing the Mistral-Air® Plus Warming Unit For Use

	<p>Before using the Mistral-Air® Plus warming unit, it should be attached to a pole or placed on a table.</p>
	<p>Prior to use, the user needs to check that the Mistral-Air® Plus warming unit, the power cord and the hose are undamaged. In the event of damage do <u>not</u> use the Mistral-Air® Plus warming unit.</p>
	<p>Plug the Mistral-Air® Plus warming unit into an earthed socket.</p>
	<p>Place the unit in such way that the mains plug can be disconnected easily in case of emergency.</p>



The potential equalization plug at the rear of the device can be connected to the hospital grounding system.

7 Mounting the Mistral-Air® Plus Warming Unit

The Mistral-Air® Plus warming unit must be mounted securely before use. The Mistral-Air® Plus warming unit can be mounted onto the Mistral-Air® curved pole with basket (art. MA5100-C). The unit should be clamped onto the pole at the indentation. Avoid blocking the air inlet (bottom of unit).

It is also possible to place the Mistral-Air® Plus warming unit on a table.







Do not place the unit *in* or on the bed with the patient



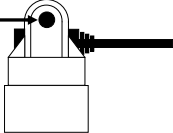
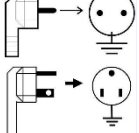


Mistral-Air® curved pole with basket
Art. MA5100-C

8 User Instructions


When using the Mistral-Air® Plus warming unit, please follow the instructions below. In each blanket box an instruction for use is added.

	<p>Check patient's temperature and skin condition at least every 15 minutes.</p>
	<p>Monitor patient skin routinely</p>
	<p>Warming transdermal medications (patches) can increase drug delivery, resulting in possible harm to the patient</p>
	<p>Do not apply to patients with ischemic limbs.</p>

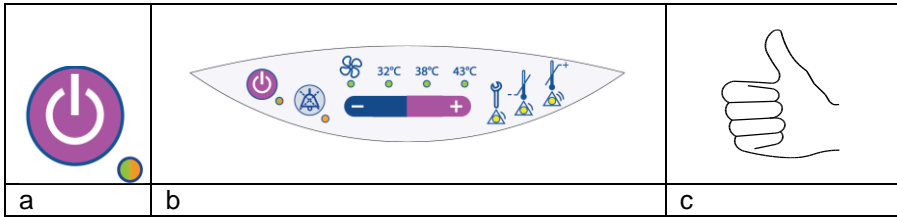
8.1 Connection to Power Supply

			
<p>a</p>	<p>b</p>	<p>c</p>	<p>d</p>

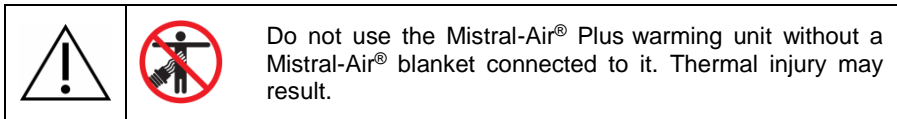
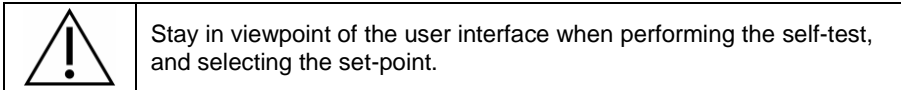
- a. Make sure the power cord is secured by the cord anchor.
- b. Plug the unit into an earthed mains socket.
- c. The unit automatically switches to Stand-by mode, which is indicated by the amber Stand-by LED located on the left side of the control panel.
- d. The Mistral-Air® Plus warming unit is now in Stand-by mode.

	<p>To remove all power from the Mistral-Air® Plus warming unit, the mains power cord must be removed from the electrical receptacle.</p>
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8.2 Switching the Unit On



- Activate the Mistral-Air® Plus warming unit by pressing the Stand-by button. The LED now turns green.
- The Mistral-Air® Plus warming unit will now perform a self-test, which includes a flash of all the LED's and a short audible alarm. When a LED or the audible beep fails, take the unit out of use for repair.
- After passing the self-test **The Mistral-Air® Plus warming unit will start blowing air at the default temperature setting of 38 °C.**



8.3 Connecting the Blanket

Take the selected Mistral-Air® blanket out of the package and follow the instructions on the insert provided with the blanket box.

Place the unit near the hose inlet of the blanket. Insert the end of the flexible hose into the air inlet port of the Mistral-Air® blanket. Make sure the hose is fully pushed in.

8.4 Warming Up With the Mistral-Air® Plus Warming Unit

8.4.1 Temperature Settings

The four settings are:

- Fan only - Ambient air
- 32 °C (89.6°F) - Low temperature
- 38 °C (100.4°F) - Medium temperature
- 43 °C (109.4°F) - High temperature

8.4.2 Temperature Selection

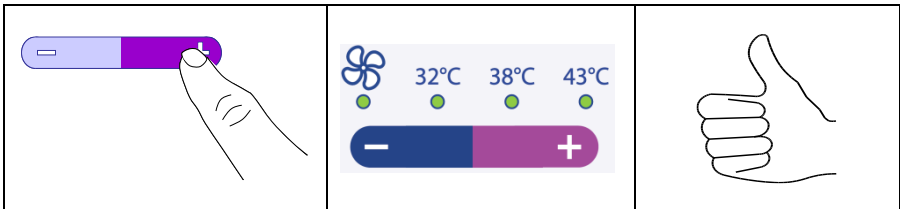
The Mistral-Air® Plus warming unit will start up with the default temperature setting of 38 °C.

By pressing the “-” temperature selection button twice (2x) (fan is selected and the fan indicator turns green), the Mistral-Air® Plus will activate the unit to draw in room temperature air and deliver it to the patient via the blanket. The heater will not be activated.

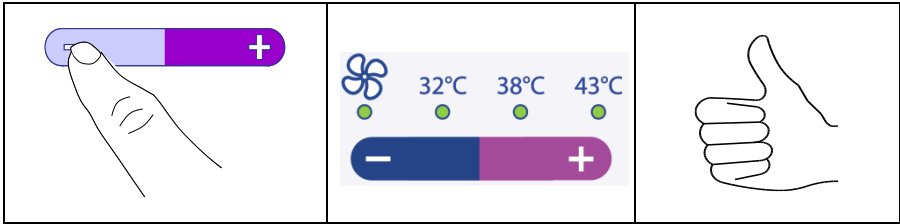
The air temperature to the patient will depend on ambient conditions and possible heat from the blower motor.

By pressing the “+” of the temperature selection button the Mistral-Air® Plus will activate the heater to deliver the set temperature: 32 °C, 38 °C or 43 °C at the end of the hose.

By pressing the “+” of the temperature selecting button, the temperature setting increases. This is indicated by a green LED:

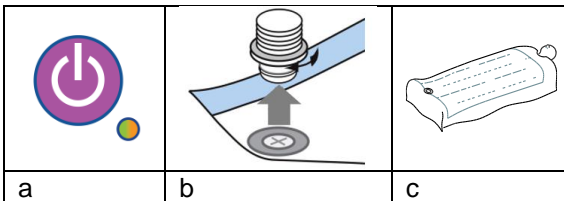


By pressing the “-” of the Temperature Selecting Button, the temperature setting decreases. This is indicated by a green LED:



After selecting the desired temperature, the LED below the Temperature Indicator will flash green. After reaching the set temperature ($\pm 2\text{ }^{\circ}\text{C}$) the green flashing LED will light up permanently.

8.5 Stop Warming



- Press the Stand-by button
- Disconnect the hose from the blanket
- If desired, leave the blanket on/under the patient

9 Safety Systems and Alarms

The Mistral-Air® Plus warming unit is equipped with visual and audible safety systems to protect against over temperature and under temperature conditions as well as to indicate that filter change is required.

	<p>In case of temperature alarm, check for free airflow. Ensure blanket is not folded and do not place tools/equipment on the blanket which could result in a blocked air flow. Be sure the air inlet is free. If the unit continues to alarm, take the unit out of use and contact the hospital service department or the local supplier.</p>
--	--

9.1 General Alarms

If equipment emergencies occur, an audible alarm sounds and the relevant LED(s) on the control panel will turn yellow. These safety systems are described as follows:



A. Primary Over Temperature Alarm

This flashing yellow LED indicates an over temperature condition of ≥ 45.5 °C. The flashing LED will be accompanied by a triple beep with an interval of 12.5 seconds. These alarms will remain activated until the temperature falls below 45.5 °C.

The heater shuts down; the unit tries to control the output temperature to the set point. If this fails three times in a row, the heater and blower will shut down completely.



B. Secondary Over Temperature Alarm

This flashing yellow LED indicates an over temperature condition:

- Lower limit: $> T_{\text{primary}}$
- Upper limit: ≤ 56.4 °C

The flashing LED will be accompanied by a triple beep with an interval of 12.5 seconds. If this occurs, the heater and blower will shut down and control of the unit will not be restored until the unit is powered off by disconnecting the mains plug and the internal temperature sensor has been cooled down.

In case of a secondary over temperature alarm, check for hose blockage.

In case of a repeated secondary over temperature alarm, after resetting the unit, the unit must be sent for technical support to a certified service department.



C. Under Temperature

This yellow LED indicates an under temperature condition. It is set to activate at 6 °C under the set temperature. One single beep is produced

NOTE:

A broken temperature sensor or bad connection to the sensor will result in an over temperature alarm. This applies for two situations:

- A defective sensor of the temperature controlling circuit results in a primary over temperature alarm condition.
- A defective sensor of the safety circuit results in a secondary over temperature alarm condition.

9.2 Other Safety Features

D. Audible Alarm Suppression



The audible alarm may be suppressed for a short period by pressing the Audible Alarm Suppression button. Audible alarm suppression is indicated by a solid amber led. After the interval of 2 or 3 minutes, or after pushing the button once again, the audible alarm will automatically be activated again.

Unit type	50 Hz	60 Hz
MA1100-EU	3 min.	2 min.
MA1100-US	-	2 min.
MA1100-JP	3 min.	3 min.



E. Service Indicator

When the yellow LED under the wrench turns on, accompanied by a single beep, the Mistral-Air® Plus warming unit has been used for ≥ 2000 hours. This service indicator means that the filter must be replaced. Reference Chapter 12 for filter replacement instructions.

Alarm type	Alarm priorities
Service indicator	Low priority
Under temperature alarm	Low Priority
Over temperature alarm (primary and secondary)	Medium priority





9.3 The Blankets

	Do not use the Mistral-Air® Plus warming unit with any forced air disposables other than Mistral-Air® blankets. Thermal injury may result.
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The Mistral-Air® Warming System is a forced air warming device and is comprised of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.

All Mistral-Air® blankets do not contain latex components and are:

- Made from non-woven polypropylene and polyethylene
- Manufactured to meet flammability standards
- MR (Magnetic Resonance) Conditional (*MA02XX series, MA2XXX series and MA05XX series only*)
- Non-conductive (electrical and thermal).
- Non-sterile, except for several dedicated blankets (ask your distributor)
- Blanket box including an instruction insert in the main world languages
- Single-patient use only
- Made from lightweight, soft materials that have been approved for skin contact

	Mistral-Air® blankets need to be used with the soft blue material towards the patient's skin and the white or reflective layer away from the patient's skin. The blue side provides the air distribution towards the patient.
	Never fold the blankets during use.
	Thermal injury may occur if heat is applied to ischemic limbs.
	Do not obstruct blanket channels by e.g. instruments/tape/clamps.

10 Maintenance

It is recommended that Routine Maintenance be performed on an annual basis for The Mistral-Air® Plus warming unit. Routine Maintenance or other service shall only be performed by trained clinical or biomedical technicians or engineers. Clinical users shall not repair or open the Mistral-Air® Plus warming unit in the event of a malfunction. This can damage the appliance

and will invalidate the warranty. When the service indicator is activated, the filter must be replaced.

Have the Mistral-Air® Plus warming unit serial number ready when you contact the hospital service department or the local supplier for technical support. The serial number is located on the side of the unit.

11 Storage and Cleaning

Store the Mistral-Air® Plus warming unit and its accessories in a cool and dry place when not in use.


Disconnect from power when cleaning the Mistral-Air® Plus warming unit. Do not use dripping wet cloths and do not allow water to seep into electrical areas of the Mistral-Air® Plus warming unit.


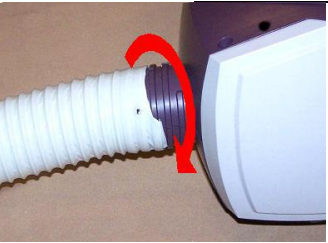
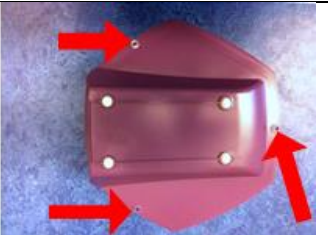
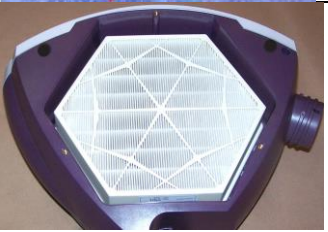
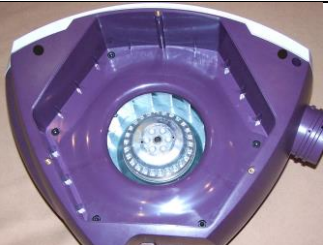
Clean the unit by wiping the outer surface (including the hose) with a soft cloth lightly dampened with a solution of water and mild detergent or a non-staining hospital disinfectant.

Wipe all excess detergent or disinfectant from the unit and allow to air dry. Do not use alcohol or acid based cleaners on the control panel.

12 Replacing the Filter

The accumulation of dust in the air filter will reduce the efficiency of the Mistral-Air® Plus warming unit. The filter shall be replaced as alerted by the service indicator or when indicated by visual inspection. Only use parts provided by The 37Company or your local dealer.

Step	Description	Image
1	Disconnect the unit from the power outlet	n.a.
2	Place the unit upside down (be careful not to scratch the top cover)	

3	Remove hose screw	
4	Twist off hose clockwise	
5	Remove screws (3x) of filter screen	
6	Remove filter screen	
7	Remove filter	

1. For disassembly follow steps 1-2 and 5-7 this paragraph
2. Insert the new filter with the black seal towards the fan
3. For assembly follow steps 1-2 and 5-7 in reverse order

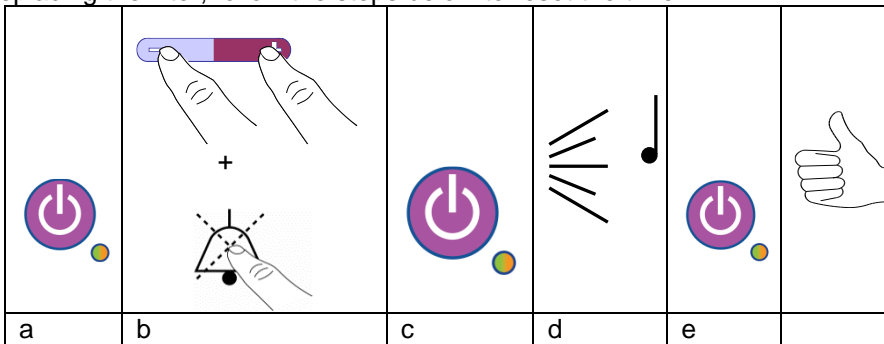
4. Reset the Hour Meter (see chapter 13)



Do not return the unit from service without the filter present.

13 Reset the Hour Meter

The Mistral-Air® Plus warming unit is equipped with a built-in timer (hour meter) that will activate the “service indicator” after ≥ 2000 hours of use. This is an indication that replacement of the filter, is required. After replacing the filter, follow the steps below to reset the timer.



- a) Switch unit in Stand-by mode.
- b) Press and hold the “-”, “+” buttons and the Audible Alarm Suppression button simultaneously.
- c) While holding down the buttons, press the Stand-by button.
- d) Now an audible alarm is produced and the unit returns to Stand-by mode.
- e) The hour meter has been reset successfully.

14 Replacing the Hose

For disassembly follow steps 1-4 of chapter 12. Apply the new hose by twisting it firmly **counter clockwise** into place and apply the lock screw to secure the hose.



Do not apply the lock screw into the sensor!

Note: When replacing the hose, do not touch the temperature sensor (see image). If these sensors are touched in any way, the unit must be recalibrated.

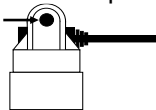


Sensor

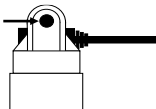
Temperature sensor plate

15 Replacing the Power Cord

- a) Unplug the unit
- b) Remove power cord from back of unit by unlocking the cord anchor:




- c) Insert the new power cord and press it firmly into place.
- d) Lock cord anchor:



16 Parts Replacement

The replacement procedures contained herein allow trained clinical or biomedical technicians or engineers to repair the Mistral-Air® Plus warming unit. Be sure to contact your local dealer or The 37Company for all your replacement part needs before servicing the unit. Service is available for this Mistral-Air® Plus warming unit: contact your local dealer or The 37Company.

	High risk of accessible electrically live parts when removing the hose!
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17 Spare Parts and Order List

Part Number	Description
Parts available for local repair	
MA1100-1001	Filter (box of 20)
MA1100-1002A	Upperhousing + pins
MA1100-1004A	Front cover + pins <i>For units with serial > 130715001</i>
MA1100-1004R	Front cover replacement Kit (box of 15) <i>For units with serial < 130715001</i>
MA1100-1006	Filterscreen
MA1100-1007 EU	Fan EU
MA1100-1009 EU	Fuse EU (pack of 10)
MA1100-1012	Pole cent.plate
MA1100-1014	Bracket
MA1100-1015	Mains entrance
MA1100-1016	Spiralcasing cover
MA1100-1017	Coil
MA1100-1018	Hose
MA1100-1019	u-shape profile
MA1100-1020 EU	Capacitor EU
MA1100-1021	PE connector
MA1100-1022	IV pole knob
MA1100-1024	Screw/assy set
MA1100-1025	Wiring set
MA1100-1026D	Handle with keyboard + pins
MA1100-1027A	Packaging
MA1100-1028	Cord Anchor
MA1100-1031	Mistral-Air Front Cover Pin (10 pcs)
MA5001	Hoseclamp (box of 20)
R295-EN	User Manual printed ¹
R298-EN	Technical Manual printed ¹
MA0100-PC-XX ²	Standard power cord (<i>customized by country</i>)
Spare parts NOT for local repair	
MA1100-1003A	Bottom housing + pins (<i>provide serial number</i>)
MA1100-1008 EU	Heater
MA1100-1010	Plus Outletplate
MA1100-1011 EU	Print circuit board
MA1100-1013	Temp. Sensor
MA1100-1030	Sensor Plate

1 = Free of charge download at www.the37company.com distributor menu

2 = available types EU, CH, GB, DK, IT, AU, SA

18 Specifications

Article number	MA1100-EU	MA1100-US	MA1100-JP
Voltage	220-240 V~	110-120 V~	100-110 V~
Frequency	50/60 Hz	60 Hz	50/60 Hz
Current	3 A	6 A	8 A
Peak current	4.3 A	8.7 A	13.5 A
Peak power	950 W	925 W	1010 W
Average power	525 W	550 W	630 W
Fuses	6.3AT/250 V~	10AT/125V~/25 0V~	12.5AT/125V~/25 0V~
GMDN-code and term	P 36954 (Heating pad control unit, air) 47681 (Air heating/cooling pas, single use, non-sterile) 47682 (Air heating/cooling pas, single use, sterile)		
Dimensions	27.6 cm x 38.5 cm x 23.9 cm (l x w x h)		
Weight	+ 6.0 kg		
Hose length	1.8 m		
Power cord length	4.0 m		
Filtration	HEPA, 0.3 µm, 99.99%, H13 conform EN 1822-1		
Current leakage	< 50 µA		
Classification 93/42/EEC	Class IIb		
Classification IEC 60601-1	Class I, Body Floating (BF)		
Classification IEC 60529	IP21		
Protective earth impedance	≤ 0.1 Ω		
Set point temperature	32 °C, 38 °C, 43 °C + ambient temperature		
Accuracy of temperature	± 2.5 °C		
Set point reached after	Maximum 2 minutes		
Low temperature limit	6 °C below set point		
Maximum contact surface temperature:	45.5 °C		
Primary high temperature Limit	≥ 45.5 °C		
Secondary high temperature Limit	Lower limit: > T _{primary} Upper limit: ≤ 56.4 °C		
Auditory alarm signal sound pressure	54 dBA		
Environmental conditions			
Ambient temperature	10 °C to 40 °C		
Relative humidity	30 % to 75 %		
Atmospheric pressure	70 kPa to 106 kPa		


Transport and storage conditions	
Ambient temperature	- 40 °C to 70 °C
Relative humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa

19 Electromagnetic Compatibility

19.1 Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The Mistral-Air® Plus warming unit is intended for use in an electromagnetic environment specified below. The customer or the user of the Mistral-Air® Plus warming unit should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guidance
Electromagnetic 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 ±1kV for input/output lines	±2 kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mistral-Air® plus warming unit requires continued operations during power mains interruptions, it is recommended that the Mistral-Air® plus warming unit be

	(>95 % dip in U_T) for 5 sec	(>95 % dip in U_T) for 5 sec	powered from an uninterruptible power supply or a backup battery system.
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.			
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should not be used any closer to any part of the Mistral-Air® plus warming unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 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

			<p>transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

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

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

19.2 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emissions		
<p>The Mistral-Air® Plus warming unit is intended for use in an electromagnetic environment specified below. The customer or the user of the Mistral-Air® plus warming unit should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Mistral-Air® Plus 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 B	The Mistral-Air® Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

19.3 Recommended Separations Distances

Recommended separation distances between portable and mobile RF communications equipment and the Mistral-Air® Plus warming unit

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

	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
Rated maximum output power of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

20 **Warranty**

For the general The 37Company warranty statement please visit our website www.the37company.com. Contact information is located on the last page of this manual.

Partner in Patient Temperature Management

The 37Company is a leading European company in the field of hypothermia and offers a complete range of innovative solutions for patient temperature management.

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