mistral-air®

Technical Manual

Mistral-Air® Warming Unit -SYK

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

Distributed by:

stryker®

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

Disclaimer

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless,
The 37Company is not liable for any consequences arising from the use of the manual.

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.

This document contains proprietary information that may not be disclosed to third parties. This document may not be used without the explicit written consent of The 37Company.

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

Contact Stryker Medical for detailed technical information for this device.

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.

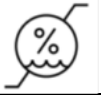
	The Mistral-Air® Plus warming unit is fitted with an air filter; however airborne contamination shall be taken into consideration when using the warming system.
	In order to prevent the patient from becoming hypothermic due to unanticipated loss of power, connect the unit to the emergency mains power.
	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.
	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: •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 *in* 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.

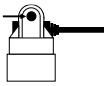
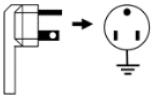
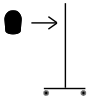
IP21	Protected against solid foreign objects of 12 mm Ø and greater. Protected against vertically falling water drops (according to IEC 60529).
Rx only	Caution: Federal US law restricts this device to sale by or on order of a physician.
	AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) , CAN/CSA-C22.2 No. 60601-1 (2008), IEC80601-2-35, IEC60601-1-8
	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
	Not for use in MRI
	Bell, cancel temporary
	Service indicator
	Upper limit of temperature
	Lower limit of temperature
	Non-ionizing electromagnetic radiation

1.4 Mistral-Air® Graphics

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

	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 not use the Mistral-Air® Plus warming unit.
	Do not use the Mistral-Air® blankets when damaged.
	Maintenance and repairs shall be performed by qualified medical instrument technicians only.
	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 .
	Do not immerse the Mistral-Air® Plus warming unit in fluid. Clean the appliance with standard cleaning agents. See chapter 11.
	S = Small, M = Medium, L = Large, XL = Extra large
	All steps are followed according to the manufacturer's instructions
	Make sure the power cord is secured by the cord anchor
	Plug the unit into an earthed mains socket
	Before using the Mistral-Air® Plus warming unit, it should be attached to a pole or placed on a table.

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 ºC. 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

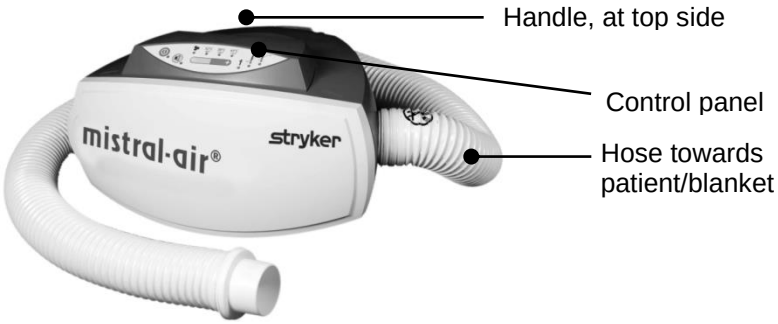
Forced air warming is a widely used and clinically accepted intervention for the prevention of hypothermia and/or re-warming of the postoperative surgical patient. The principle of operation for forced air warming systems is an electrically powered unit consisting of a fan and heating element that propels 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

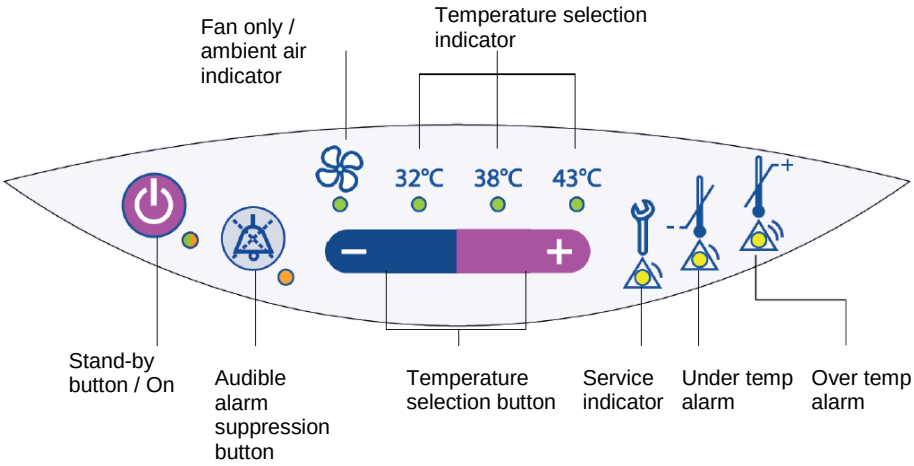


The Mistral-Air® Plus warming unit can be controlled by using the control panel at the front top of the unit. The clamp to fix the Mistral-Air® Plus warming unit to a pole is positioned at the back of the unit.

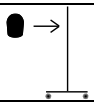
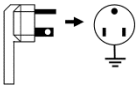
Article Number: MA1100-PM (110-120 V~, 60 Hz)

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

	Before using the Mistral-Air® Plus warming unit, it should be attached to a pole or placed on a table.
	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 not use the Mistral-Air® Plus warming unit.
	Plug the Mistral-Air® Plus warming unit into an earthed socket.
	Place the unit in such way that the mains plug can be disconnected easily in case of emergency.
	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 MA5115A-PM with optional basket MA5120-PM.
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

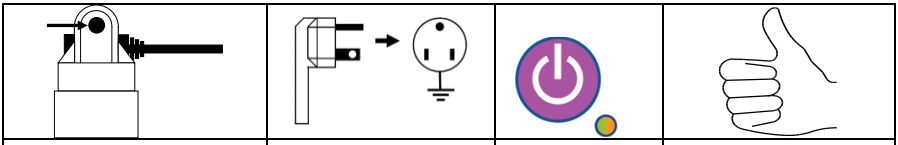
Mistral-Air® Curved Pole incl. Base MA5115A-PM
Mistral-Air® Basket MA5120-PM

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.

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

8.1 Connection to Power Supply

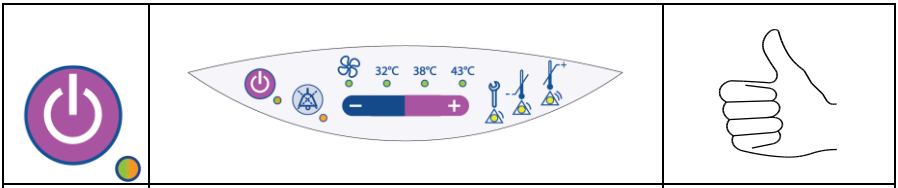


a	b	c	d

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.

	To remove all power from the Mistral-Air® Plus warming unit, the mains power cord must be removed from the electrical receptacle.

8.2 Switching the Unit On



a	b	c

a. Activate the Mistral-Air® Plus warming unit by pressing the Stand-by button. The LED now turns green.
b. 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.
c. After passing the self-test **The Mistral-Air® Plus warming unit will start blowing air at the default temperature setting of 38 ˚C.**

	Stay in viewpoint of the user interface when performing the self-test, and selecting the set-point.

		Do not use the Mistral-Air® Plus warming unit without a Mistral-Air® blanket connected to it. Thermal injury may result.

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

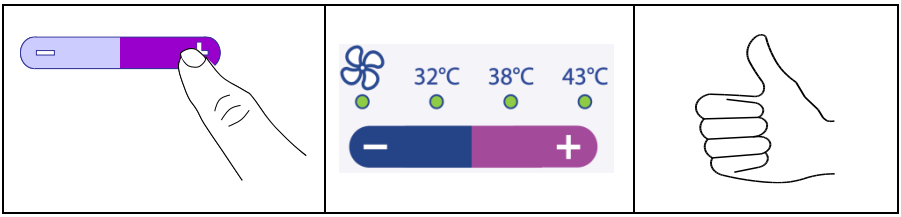
The four settings are:

- Fan only - Ambient air
- 32 ºC (89.6ºF) - Low temperature
- 38 ºC (100.4ºF) - Medium temperature
- 43 ºC (109.4ºF) - High temperature

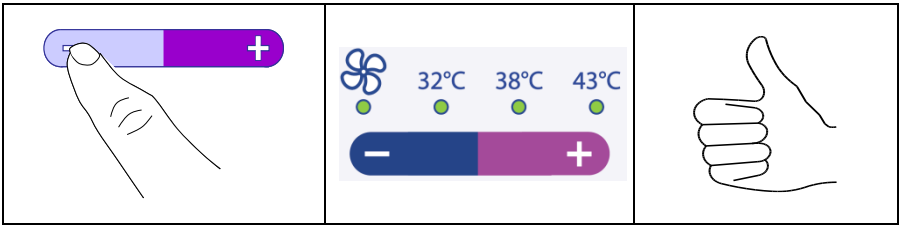
8.4.2 Temperature Selection

The Mistral-Air® Plus warming unit will start up with the default temperature setting of 38 ºC.
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 ºC, 38 ºC or 43 ºC 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:

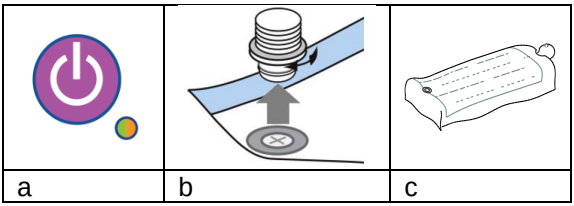


By pressing the “-” of the Temperature Selecting Button, the temperature setting decreases. This is indicated by a green LED:



After selecting the desired temperature, the LED below the Temperature Indicator will flash green. After reaching the set temperature (± 2 ˚C) the green flashing LED will light up permanently.

8.5 Stop Warming



a	b	c

a. Press the Stand-by button
b. Disconnect the hose from the blanket
c. 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.

	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.

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 ºC. 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 ºC.
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: > $T_{primary}$
- Upper limit: ≤ 56.4 ºC

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, take the unit out of service and contact Stryker Medical for technical support.

C. Under Temperature.
This yellow LED indicates an under temperature condition. It is set to activate at 6 ºC 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.

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 13 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.

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 Conditional *(MA02XX-PM series, MA2XXX-PM series and MA05XX-PM 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 Stryker Medical 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 General Description of Hardware

The Mistral-Air® Plus warming unit comprises of plastic enclosure parts, a control panel, an internal heating element, a fan and electrical components. The unit may be mounted to an IV pole.

12.1 Housing

The Mistral-Air® Plus warming unit housing consists of 5 plastics enclosure parts and an internal steel top plate. To disassemble the unit, see paragraph 20.1.

12.2 Top Plate

The Mistral-Air® Plus warming unit top plate frame is made of stainless steel.
The top plate is used to mount the fan blower motor and to create an airtight fan space. A U-shaped, silicone profile is used to support this function.

12.3 Heating System

The Mistral-Air® Plus warming unit uses a 1000 Watt coiled electric heating element to heat the air that it delivers to a blanket.

12.4 Blower Motor

After assembly, the flow rate with a blanket attached is approximately 1.4 m^3/min (49 CFM).

12.5 Power Supply & Electronic Hardware

It is fixed at the rear of the Mistral-Air® Plus warming unit.
A Block Diagram of the Mistral-Air® Plus warming unit is shown in paragraph 20.4 “Block Diagram”.

On the printed circuit board two processors are used. Both use software to work. When the unit serial number is known, the original revision number of the software can be identified by The 37Company.

13 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 Stryker Medical.

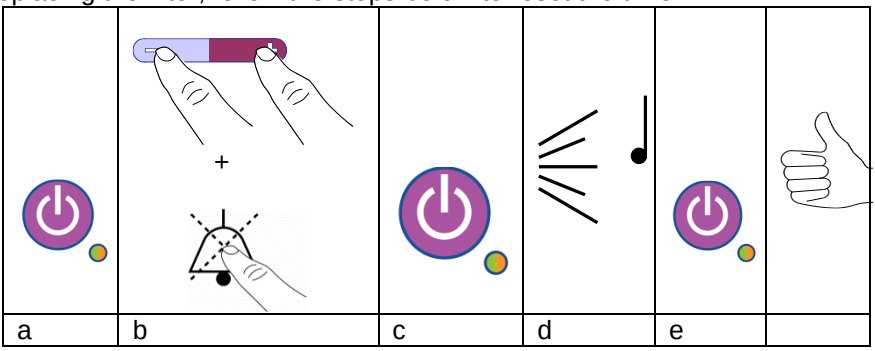
1. For disassembly follow steps 1-2 and 5-7 of paragraph 20.1
2. Insert the new filter with the black seal towards the fan
3. For assembly follow steps 1-2 and 5-7 of paragraph 20.1 in reverse order
4. Reset the Hour Meter (see chapter 14)

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

The filter is the only part, which is allowed to be replaced without the need of a bio medical engineer.

14 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.

15 Repair Procedures

Contact Stryker Medical for spare parts. If you wish to return the unit for examination and repair, please refer to the following section.

	If this equipment is modified, appropriate inspections and testing must be conducted to ensure continued safe use of the equipment.

15.1 Routine Maintenance

Routine Maintenance shall be performed on an annual base. At every service interval, please follow the next steps.

a) Reset the hour meter if filter is replaced — See chapter 14
b) Perform After Service Test Protocols — See chapter 18
c) Clean the unit if needed — See chapter 11

16 Trouble Shooting

Problem	Possible Cause	Action
The unit does not switch on	Unplugged or damaged power cord.	Make sure power cord is plugged in and is undamaged. Replace cord if necessary.
	No power to outlet	Confirm power to outlet.
	Poor or loose wire connections.	Ensure all connectors and terminals are secure.
	Blown fuses at PCB	Replace fuse(s)
Over temperature alarm and warming unit stopped	Poor or loose wire connections.	Verify connections to PCB of the heater, the temperature sensors (2x) and the inductor.
	Faulty heater	Check resistance of the heater connection to the PCB. Cold element resistance should be: MA1100-PM 13.1 Ω ± 10% Replace heater if necessary.

Problem	Possible Cause	Action
	Faulty temperature sensors	Check resistance of the temperature sensors connection to the PCB. Resistance must be 2.4 – 2.6 KΩ Consult Stryker Medical Technical Services.
	Faulty inductor	Replace Inductor
The unit delivers warm air but switches off before reaching the set temperature	Temperature (heater/blower housing) may be out of calibration.	Allow unit to cool from possible over-heat condition. If condition persists, check continuity of each temperature sensor. Consult Stryker Medical Technical Services.
	Faulty PCB	Consult Stryker Medical Technical Services.
	Faulty temperature sensors	Check resistance of the temperature sensors connection to the PCB. Resistance must be 2.4 – 2.6 KΩ Stryker Medical Technical Services.
	Obstructed Filter or Blower fan.	Verify unit has adequate airflow (with new filter and blanket attached: 0,021 – 0,030 m^3/s. Replace filter if necessary and verify that blower fan spins freely.
The unit alarms at too low or too high temperature	Temperature (heater/blower housing) maybe out of calibration.	Adjust the temperature and recalibrate the unit.Consult Stryker Medical Technical Services.
	Faulty temperature sensors	Check resistance of the temperature sensors connection to the PCB. Resistance must be 2 – 3 KΩ (room temperature must be between 18-27 ˚C). Consult Stryker Medical Technical Services.
	Faulty PCB	Confirm unit is being used in ambient temperatures (see paragraph 20.1). Consult Stryker Medical Technical Services.
The unit turns on but does not blow air	Air inlet obstructed or dirty filter	Remove filter and inspect for obstructions. Clean out debris and replace filter if necessary.
	Blower fan is obstructed.	Remove covers and verify that blower fan spins freely.
	Poor or loose wire connections	Ensure all connectors and terminals are secure. Ensure power cord and the base wire harnesses are properly attached to terminal block

Problem	Possible Cause	Action
The unit turns on but temperature settings cannot be selected.	Faulty PCB	Consult Stryker Medical Technical Services.
	Faulty or loose membrane switch (switch contacts or header).	Remove covers and inspect the membrane connection to the control board. Ensure red/white wire is located at the top.
	Faulty control board.	Consult Stryker Medical Technical Services.

17 Parts Replacement

The replacement procedures contained herein allow trained clinical or biomedical technicians or engineers to repair the Mistral-Air® Plus warming unit. Contact Stryker Medical for replacement parts or when service may be required.

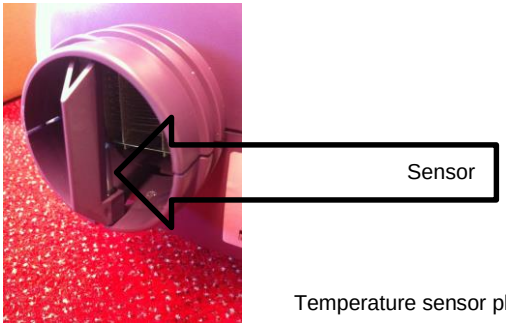
	High risk of accessible electrically live parts when removing the hose!

17.1 Replacing the Hose

a) For disassembly follow steps 1-4 of paragraph 20.1
b) 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. Contact Stryker Medical for calibration service.



Temperature sensor plate

17.2 Replacing the Fuses

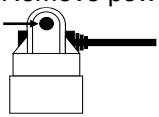
a) For disassembly follow steps 1-11 of paragraph 20.1
Replace fuses; make sure that the replacements fuses have the correct rating refer to “Specifications”.
b) For assembly follow step 1-11 of paragraph 20.1 in reverse order. Follow paragraph 20.2 for placing back the front cover.
c) Execute “After service test protocols” (chapter 18)

17.3 Replacing the Fan

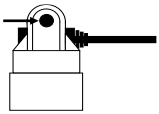
a) For disassembly follow steps 1-18 of paragraph 20.1
b) Replace the fan
c) For assembly follow step 1-18 of paragraph 20.1 in reverse order
d) Execute “After service test protocols” (see chapter 18)

17.4 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:



17.5 Replacing the Temperature Sensors

Due to the technical complexity associated with replacing the sensors, the unit must be returned to Stryker Medical for service according to Stryker Medical instructions.

17.6 Replacing the Heater

Due to the technical complexity associated with replacing the motor or the heater, the unit must be returned to Stryker Medical for service according to Stryker Medical instructions.

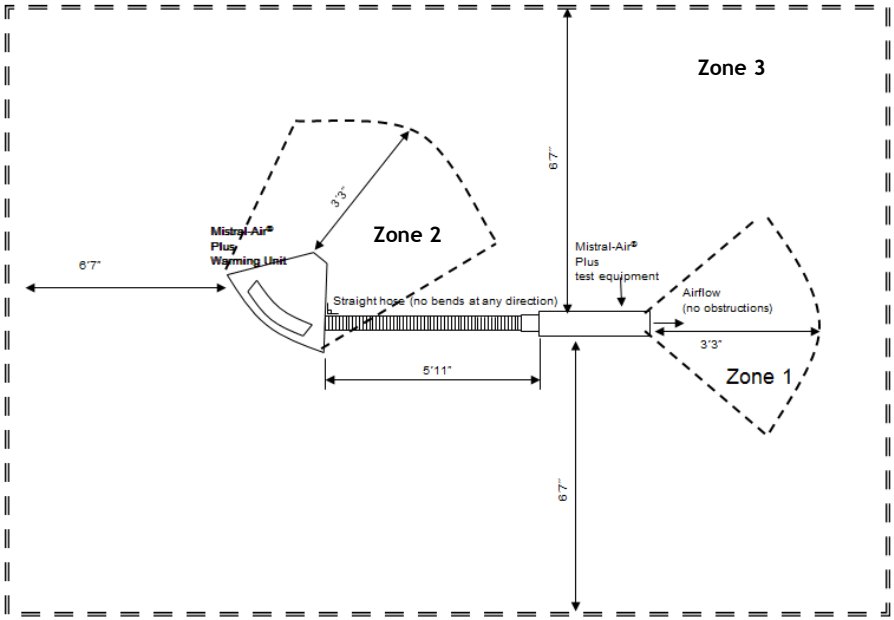
17.7 After Service Test and Preventive Maintenance Protocols

Test conditions:

1 Tests shall be executed at an ambient temperature of 22 ±1.5 ˚C.
2 The unit shall be acclimated to the ambient temperature.
3 Tests shall be executed in a draft free room.
4 No air obstructions within one meter of the air outlet of the Mistral-Air® Plus test equipment (zone 1).
5 Free air inlet, no air obstructions within one meter (zone 2).
6 There shall be no air conditioning or climate control air outlet within 2 metres (zone 3).

Refer to image below “Air Obstruction Zones”.

Record findings at paragraph 18.1.



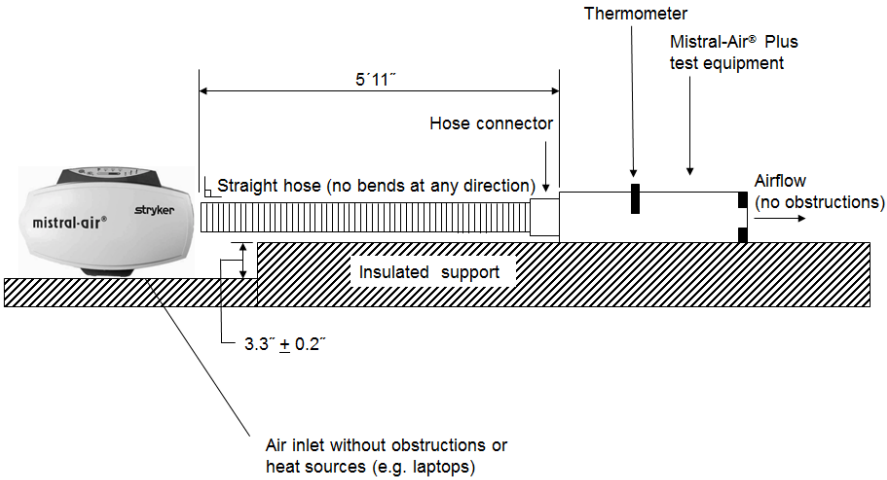
Zone 1 + 2: No air obstructions or heat sources

Zone 3: No airconditioning units

Image: Air Obstruction Zones

17.8 Test set-up Mistral-Air® Plus Warming Unit

All tests shall be executed by using the Mistral-Air® test equipment (MA2100-B-PM). The test tube is representing a MA0220-PM / MA2220-PM Adult blanket.



The Mistral-Air® Test Equipment has an own thermometer (check calibration due date).

17.9 Control Board Test

1 Switch unit from Stand-by mode to on.
2 Check that all LED'S blink once and the audible alarm sounds once.
3 Check that after this self-check procedure the blower is in the 38 ˚C heating mode, indicated by the blinking 38 ˚C LED at the control panel.
4 Select the following different settings: FAN ONLY, 32, 38 and 43 ˚C using the control board buttons (5 seconds per temperature set point). Check that the buttons react within 0.5 seconds.

Record findings at paragraph 18.2.

17.10 Set Point Temperature Test

1 Switch unit from Stand-by mode in active mode.
2 Select 43 ˚C and wait for at least 3 minutes for the temperature to stabilize. After the set point is reached the 43 ˚C LED stops flashing and turns solid green.
3 Check that no low temperature alarm or primary over temperature alarm is enabled (alarm LED and buzzer) due to possible temperature overshoots.
4 Measure the temperature in the test tube (must be between 40.5 and 45.5˚C).
5 Repeat steps 2, 3 and 4 for 38 ˚C and 32 ˚C (35.5 – 40.5 respectively 29.5 - 34.5 ˚C in test tube).

Record findings at paragraph 18.3.

17.11 Alarm Tests

Low temperature alarm test
Switch unit in Stand-by mode.
1 Press and hold the audible alarm button and press the Stand-by button once.
2 The ventilator now starts and the set point 32 °C and service indicator LED starts blinking.
3 Press the audible alarm suppression button to confirm. The heater starts to control the temperature till the 43 ˚C set point is reached. Both the 43 ˚C and the Service Indicator LED's are blinking. Then heating is stopped.
4 After 20 seconds: check if the low temperature alarm is also visually and audibly enabled. The tube temperature must be lower than 37.5 ˚C.
5 Exit this test mode by switching the blower OFF by pressing the stand-by button.

Record findings at paragraph 18.4.

Primary over temperature test
Switch unit in Stand-by mode.
1 Press and hold the audible alarm button and press the Stand-by button once.
2 The ventilator now starts and the set point 32 °C and service indicator LED starts blinking.
3 Scroll via the "-" or "+" buttons to 38 ˚C.

4 Press the audible alarm suppression button to confirm. The heater will control the temperature till the primary over temperature set point is reached. Both the 43 ˚C and the Service Indicator LED's are blinking.
5 Check if the primary over temperature alarm is also visually and audibly enabled (blinking over temperature LED).
6 Check if the primary temperature alarm is enabled ≥ 45.5 ˚C.
7 Then, heating is stopped automatically till the temperature has dropped to the under temperature alarm value, followed by a second and third heating/cooling cycle. Check if the heater and ventilator switches OFF after the third cycle.

Note: The secondary over temperature alarm shall not be enabled!

Record findings at paragraph 18.4.

Secondary over temperature test

Switch the unit in Stand-by mode.

1 Press and hold the audible alarm button and press the Stand-by button once.
2 The ventilator starts and you are able to select between the set points 32, 38 and 43 ˚C.
3 Scroll via the "-" or "+" buttons to 43 ˚C.
4 Press the audible alarm suppression button to confirm. The heater will control the temperature till the primary over temperature set point is reached; the primary alarm will be enabled and the unit will keep on heating.
5 Check if the secondary over temperature alarm is enabled between:
   - Lower limit: > $T_{primary}$
   - Upper limit: ≤ 56.4 ˚C (triple beep, over temperature LED on).
6 The ventilator and heater are switched off by the alarm circuit.
7 After the test: press at the ON/Stand-by button. Check if the audible alarm is disabled. Switch the power on by pressing the Stand-by button to check if the alarm is still on (triple beep).
8 Switch the power OFF by disconnecting the mains plug.
9 Switch the power ON to check restarting without an alarm.

Record findings at paragraph 18.4.

17.12 Electrical Safety Test

Execute an electrical safety test conform IEC 60601-1, for a class I, BF device.

Record findings at paragraph 18.5.

18 After Service Test and Preventive Maintenance Form

Hospital	
Location	
Serial Number	
Date	
Test Engineer	
Signature	

18.1 Test Conditions Check

Ambient temperature (˚C)	˚C	20.5 – 23.5˚C
Draft free room	Pass ☐	Fail ☐
No air outlet obstructions	Pass ☐	Fail ☐
Free air inlet	Pass ☐	Fail ☐
No air conditioner / climate control	Pass ☐	Fail ☐
Pass ☐ Fail ☐ Comment …		

18.2 Control Board Test

LED’s blinking	Pass ☐	Fail ☐
Audible alarm	Pass ☐	Fail ☐
Switch on at set point 38 ˚C	Pass ☐	Fail ☐
Button check	Pass ☐	Fail ☐

18.3 Set Point Temperature Check

Selected set point temperature (˚C)	Temperature	Range (˚C)
43	˚C	40.5 – 45.5
38	˚C	35.5 – 40.5
32	˚C	29.5 – 34.5
Pass ☐ Fail ☐ Comment …		

18.4 Alarm Tests

Selected alarm	Temperature	Range (˚C)
Low temperature	˚C	< 37.5
Primary over temperature	˚C	≥ 45.5
Secondary over temperature	˚C	Lower limit: > $T_{primary}$ Upper limit: ≤ 56.4 °C
Alarm suppression button		Pass ☐

18.5 Electrical Safety

During the electrical safety test, maximum values of continuous leakage and patient auxiliary currents shall be measured, according the following table:

	Type Body Floating (BF)			
	Maximum values [μA]		Measured [μA]	
Current	Normal Condition (NC)	Single Fault Condition (SFC)		
Earth leakage current general	500	1000		Pass ☐ Fail ☐
Cabinet leakage	100	500		Pass ☐ Fail ☐

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 powered from an

	(>95 % dip in U_T) for 5 sec	(>95 % dip in U_T) for 5 sec	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.			
			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
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d

			is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured filed 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, filed strengths should be less than 3 V/m

19.2 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emissions		
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.		
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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
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

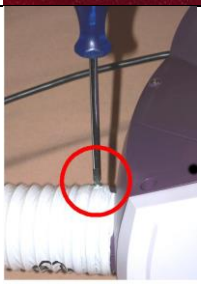
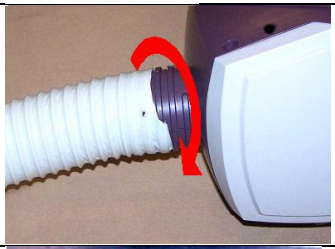
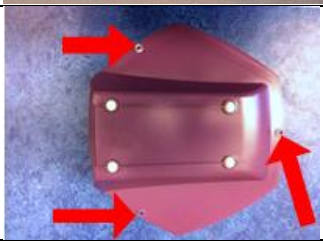
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

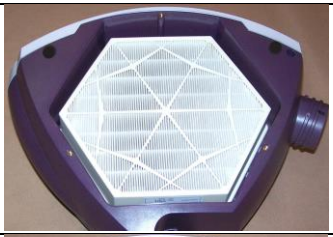
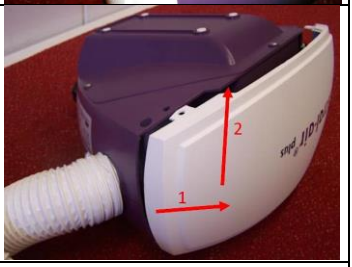
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

20 Illustrations

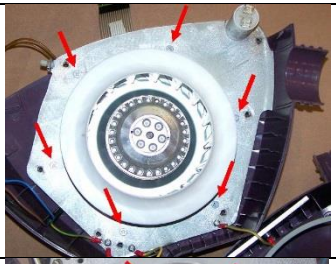
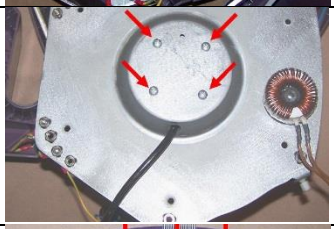
20.1 Disassembly of the Mistral-Air® Plus warming unit

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	
8	Remove screws (6x) of bottom housing	
9	Remove both front cover pins by using a Phillips screwdriver. Prevent the screw sleeve from rotating by pressing with your finger or a knife.	
10	Take out the screw sleeve and remove the front cover in the directions as indicated below by (1) and (2)	
11	Place the unit upright	**n.a**

12	Remove screw from PCB	
13	Disconnect the wiring of the user interface (keyboard)	See paragraph 20.3
14	Disconnect the wiring of the inductor	See paragraph 20.3
15	Disconnect the wiring of the start capacitor Disconnect the wiring of the fan.	See paragraph 20.3
16	Lift upper housing and place beside the unit	

For maintenance to the fan and user interface please follow the next few steps.

17	Remove screws (6x) of spiral casing cover	
18	Remove screws (4x) to release fan. During re-assembly, apply droplets of Loctite to secure screws into rubber struts	
19	Remove screws (7x) to access user interface	

20.2 Assembly of the Mistral-Air® Plus warming unit

Follow the disassembly steps of paragraph 20.1 in reverse order.

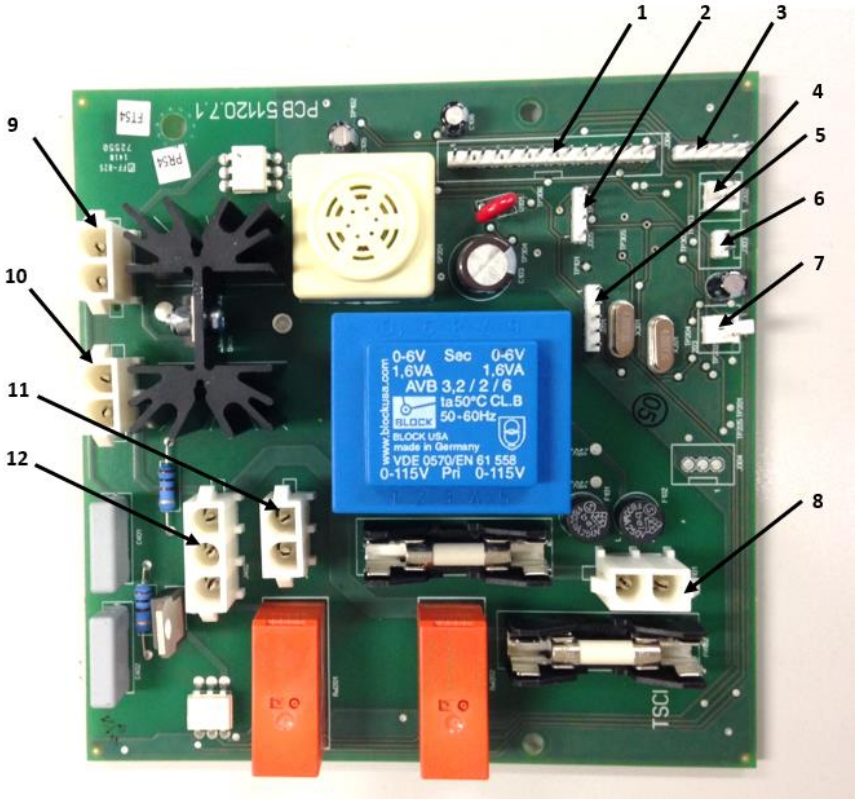
When placing back the front cover, below steps must be followed.

20	Remove silicone residues. Use a knife if needed. Clean edges of front cover with alcohol (defatting).	n.a.
21	Add silicone on top, left, and right side of front cover (indicted by the red lines)	
22	First place the front cover in the upper housing and then the bottom housing (from right to left (1, 2, 3 and then 4).	 
23	Secure the front cover with new front cover pins to be inserted through the bottom housing openings and gently hit it with a hammer.	

24		
25	Remove any surplus of silicone with an alcohol swab.	n.a

After assembling, a functional check, temperature safety check, and electrical safety check must be performed according to the Technical Manual Mistral-Air® Plus.

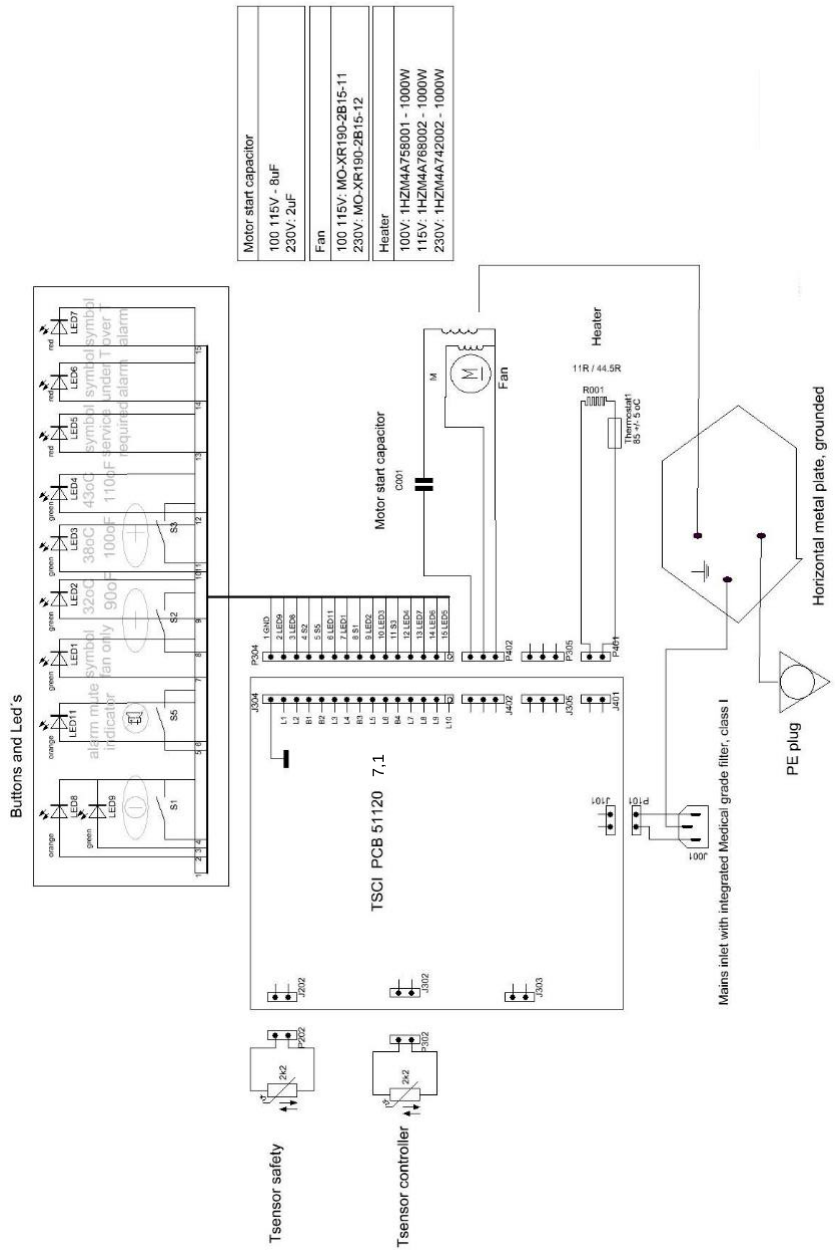
20.3 The Power Controller Board (PCB)



Legend:

1. Keyboard connector
2. RS232 connector
3. Programmer connector main controller processor
4. Temperature sensor main controller
5. Programmer connector safety processor
6. Not connected (used for production testing)
7. Temperature sensor safety controller connector
8. Mains connector
9. Heater connector
10. Inductor connector
11. Start capacitor connector
12. Fan connector

20.4 Block Diagram



21 Spare Parts and Order List

Part Number	Description
Parts available for local repair	
MA1100-1001-PM	Filter - SYK
MA1100-1002A-PM	Upperhousing + pins - SYK
MA1100-1004A-PM	Front cover + pins - SYK *For units with serial > 130715001*
MA1100-1004R-PM	Front cover replacement Kit- SYK *For units with serial <130715001*
MA1100-1006-PM	Filterscreen - SYK
MA1100-1007-PM	Fan US - SYK
MA1100-1009-PM	Fuse US - SYK
MA1100-1012-PM	Pole cent.plate - SYK
MA1100-1014-PM	Bracket - SYK
MA1100-1015-PM	Mains entrance - SYK
MA1100-1016-PM	Spiralcasing cover - SYK
MA1100-1017-PM	Coil - SYK
MA1100-1018-PM	Hose - SYK
MA1100-1019-PM	u-shape profile - SYK
MA1100-1020-PM	Capacitor US - SYK
MA1100-1021-PM	PE connector - SYK
MA1100-1022-PM	IV pole knob - SYK
MA1100-1024-PM	Screw/assy set - SYK
MA1100-1025-PM	Wiring set - SYK
MA1100-1026D-PM	Handle with keyboard + pins - SYK
MA1100-1027A-PM	Packaging - SYK
MA1100-1028-PM	Cord Anchor - SYK
MA1100-1031-PM	Front Cover Pin - SYK
MA5001-PM	Hoseclamp - SYK
R295-EN-PM	User Manual printed - SYK[1]
R298-EN-PM	Technical Manual printed - SYK[1]
MA0115-PC-US-PM	Standard power cord US Type - SYK
Spare parts NOT for local repair, only for authorized calibration center	
MA1100-1003-PM	Bottom housing - SYK *(provide serial number)*
MA1100-1008-PM	Heater - SYK
MA1100-1010-PM	Outletplate - SYK
MA1100-1011-PM	Print circuit board - SYK
MA1100-1013-PM	Temp. Sensor - SYK
MA1100-1023-PM	Printed typelabel - SYK *(provide serial number)*
MA1100-1030-PM	Sensor Plate - SYK

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

22 Warranty

Please contact Stryker Medical Customer Service or your Stryker Medical Sales Representative for warranty related questions. Contact information is located on the last page of this manual.

23 Specifications

Article number	MA1100-PM
Voltage	110-120V~
Frequency	60 Hz
Current	6 A
Peak current	8.7 A
Peak power	925 W
Average power	550 W
Fuses	10AT/125V~/250V~
GMDN-code and term	P 36954 (Heating pad control unit, air) 47681 (Air heating/cooling pad, single-use, non-sterile) 47682 (Air heating/cooling pad, single-use, sterile)
Dimensions	$10^{7}/_{8}$ inch x $15^{1}/_{4}$ inch x $9^{3}/_{8}$ inch (l x w x h)
Weight	+/- 13 lbs
Hose length	6 ft
Power cord length	13 ft
Filtration	HEPA, 0.3 µm, 99.99%, H13 conform EN 1822
Current leakage	< 50 µA
Classification IEC 60601-1	Class I, Body Floating (BF)
Classification IEC 60529	IP21
Protective earth impedance	≤ 0.1 Ω
Set point temperature	32 ºC, 38 ºC or 43 ºC & ambient temperature
Accuracy of temperature	± 2.5 ºC
Set point reached after	Maximum 2 minutes
Low temperature limit	6 ºC below set point
Maximum contact surface temperature:	45.5 °C
Primary high temperature Limit	≥ 45.5 ºC
Secondary high temperature Limit	Lower limit: > $T_{primary}$ Upper limit: ≤ 56.4 ºC
Auditory alarm signal sound pressure	54 dBA
Expected product life time	7 year (Mistral-Air® Warming Unit)
Environmental conditions	
Ambient temperature	10 ºC to 40 ºC
Relative humidity	30 % to 75 %
Atmospheric pressure	70 kPa to 106 kPa
Transport and storage conditions	
Ambient temperature	- 40 ºC to 70 ºC
Relative humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa

Tools needed for repair:
Phillips PH2 screwdriver
Pozidriv PZD2 screwdriver
Allen key HOP2.5 (2.5mm)
Torx key T20
Wrench 10 (Metric)
Pincers (to cut cable ties)
Disposable syringes 60 cc, to apply silicone glue
A hot-melt gun

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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The 37Company is member of The Surgical Company Group

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AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008), IEC 80601-2-35, IEC 60601-1-8
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