Mistral-Air®

Forced Air Warming

User Manual

stryker

Version: INT/R780-PM/4-05/18

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Contents

1 General information

1.1 About this manual

In this manual, you can find important information about how to operate the Mistral-Air® Warming Unit - SYK (MA1200-PM) (hereafter referred to as 'the device').

The manual helps you with the operation and the maintenance of the device, in a safe and responsible manner.

Read this manual carefully. Complete all the procedures. Do the procedures in the given sequence. Always keep the manual near the device.

Please refer to the Mistral-Air® technical manual for maintenance, repair and calibration instructions. The Mistral-Air® technical manual is available for download at the business partner menu of the 37Company website.

1.2 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.

1.3 Contact

Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

E-mail: medicalcustomerservice@stryker.com
Website: www.stryker.com

1.4 FAQ and training

Please refer to our website (*www.the37company.com*) for an up-to-date overview of the frequently asked questions of the Mistral-Air® products: *home / mistral-air | frequently asked questions*.

Warning!

The device may only be operated by trained clinicians and maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.

1.5 Warranty

For the warranty provisions, ask your local Stryker representative.

1.6 Authorization of personnel

Make sure that only authorized personnel use the device.

1.7 Warning, caution and note

Warning!

A "warning" tells you that there is a risk of personal injury or death.

Caution!

A "caution" tells you that:

- there is a risk of damage to the device, and/or
- there is a risk of damage to other equipment.

A "note" gives more information.

1.8 Disclaimer

The manufacturer reserves all rights. No part of this document may be reproduced or published, electronically, mechanically, in print, photographic print, on microfilm or by any other means whatsoever, without the explicit consent of The 37Company.

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless, the manufacturer reserves the right to make alterations and improvements to the device. These may not yet have been described in the instructions. The manufacturer 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 manufacturer.

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

2 Contra-indications, warnings, cautions, notes and symbols

Your device was designed and built with safety in mind. The device 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 the contra-indications, warnings, cautions and notes before using or prescribing the device.

2.1 Contra-indications

- Only apply heat to intact skin and do not apply heat directly to open wounds.
- Do not apply the warming system to ischemic limbs.

1. Use caution and consider discontinuing use on patients during vascular surgery when an artery is clamped to an extremity (i.e. aortic cross-clamping).
2. Use caution and monitor closely if used on patients with severe peripheral vascular disease.

2.2 Warnings

Warning!

- Do not use the device when it is damaged or when the Mistral-Air® Blanket is damaged. Thermal injury may result.
- Do not allow the patient to lie on or contact the hose with the skin when the device is active. Thermal injury may result.
- Do not use the Mistral-Air® Blanket to transfer or move the patient. Injury to the patient may result.
- To prevent tipping when mounting to an IV-pole, mount the device at a height at which the IV-pole is stable. Injury may occur. Before usage, assess the stability by placing the IV-pole on a surface at an angle of 10° from the horizontal plane with brakes activated. The IV-pole may not overbalance, or move. Also passing over a 10 mm threshold may not result in overbalancing. Mass and position of center of gravity are provided in this IFU for theoretical analysis. Stryker cannot provide maximum mounting height prescriptions for different wheel base diameters, numbers of castors (either with brakes or not) and configurations of other equipment mounted to the IV pole.
- Do not use the device without a Mistral-Air® Blanket connected to it (no free hosing). Thermal injury may result.
- Do not use the device and blankets near flammable anesthetics and/or in oxygen-enriched environment, to avoid the risk of explosion or fire.
- Check patient's temperature and skin condition at least every 15 minutes, or according to institutional protocol.
- Do not cover the patient's thorax with our Mistral-Air® Blankets during cardioversion or defibrillation therapy.

- Applying air with a temperature above the normothermic core body temperature range (36 – 37.5°C) incorporates the risk of hyperthermia. Depending on the selected set point, heating time, additional heat sources and insulation, the patient's body core temperature can rise above 37.5°C. Thermal injury may result.
- Pediatric patients of low weight will have a tendency to overheat more rapidly than adults. Failure to monitor core temperature could result in abnormal elevation of body temperature resulting in serious injury or death.
- A physician order is required for setting temperature and for continued use.
- If patient temperature is not responding to treatment or does not reach the desired temperature, notify a physician.
- Warming transdermal medications (patches) can increase drug delivery, resulting in possible harm to the patient.
- Do not use the device with any forced air disposables other than Mistral-Air® Blankets. Thermal injury may result.
- Avoid direct contact between a blanket and a laser. Although the blankets are flame retardant per 16 CFR Part 1610 (Standard for the flammability of clothing textiles) class 1, compliance with ISO 11810:2015 (classification for the laser resistance) is not demonstrated.
- Never fold the blankets during use. This could lead to insufficient treatment.
- Do not obstruct blanket channels by e.g. instruments/tape/clamps. This could lead to insufficient treatment.
- The device is fitted with a HEPA H13 class air filter (EN1822-1:2009, GROUP H). However airborne contamination should be taken into consideration when using the warming system to minimize the risk of infection for the patient.
- Before you clean the device, disconnect the power supply cord to eliminate the risk of electrocution.
- Clean the hose after each use to reduce the risk of infection.
- When replacing the hose, do not touch the temperature sensors. If these sensors are touched in any way, they can be damaged and out of calibration. This could cause burns to the patient. If the temperature sensors are touched or damaged, contact your local Stryker representative.
- Use of accessories, transducers and cables other than those specified or provided by Stryker of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not disassemble the device unless you are a qualified service technician. Injury may occur.
- Before performing corrective maintenance (see *Corrective maintenance* on page 33), disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.
- Mistral-Air® blankets need to be used with the soft blue material towards the patient's skin. When used oppositely the treatment will be ineffective. The blue side provides the air distribution towards the patient.
- When placing the device on a surface, make sure the surface is horizontal, solid and clean. Do not place the device on a carpet because it could block the air inlet and reduce the performance.

- When using bed hooks, only mount the device to a horizontal secured surface. Do not mount the device to a tilting non-secured surface. The device may fall and pull the blanket from the patient.
- Do not place the device above, or in the bed with the patient. Thermal injury may occur.
- Place the device in such a way that the mains plug can be disconnected easily in case of emergency. Operator injury may occur.
- Connect the device to an adequate reliable grounded receptacle. Operator injury may result.
- When mounted to the Mistral-Air® Adjustable Pole, make sure that the hose does not extend beyond the wheelbase of the Mistral-Air® Adjustable Pole so that it is protected by the wheelbase. Otherwise damage to the hose may occur.
- Clean the hose at ambient temperature and make sure the hose is dry before use. Damage to the hose or device may occur.
- When the device has suffered impact, disconnect the power plug and contact your local Stryker representative.

2.3 Cautions

Caution!

- Do not use a sharp object to press the buttons on the control panel.
- The device must be mounted securely, or placed on a stable flat surface before use to prevent the device from falling.
- To ensure stability when mounted to a trolley the device may only be mounted to a Mistral-Air® Adjustable Pole (MA5200-PM).
- Do not immerse the device in liquids. Otherwise, the device can be damaged.
- Stay in viewpoint of the control panel when the device is performing the self-test and selecting the set-point. See *Turning on the device* on page 30.
- In case of an alarm, check for any obstruction of the air flow; ensure that the blanket and the hose are not folded, the inlet is free (not blocked) and no tools/equipment are placed on the blanket. If the device continues to alarm, take the device out of use and contact the hospital service department or the local supplier.
- Do not place the device on a carpet because it could block the air inlet and reduce the performance.

2.4 Notes

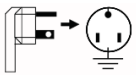
- The heating device does not contain an alarm system with an interruption of power supply/supply mains alarm condition. This means that in case of a power failure, there will be no alarm.
- The device is not equipped with an isolating switch. Temporary interruption of the supply mains will render the device in standby mode and discontinue treatment.

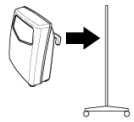
2.5 Device safety symbols

This section contains a list of symbols used for the Mistral-Air® Forced Air Warming Unit.

IP23	Protected against ingress of solid objects larger than 12.5 mm and water falling as a spray at an angle up to 60° from the vertical axis (according to IEC 60429).
Rx Only	Caution: Federal US law restricts this device to sale by or on order of a physician.
	Connect the device to an earthed socket only. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
	No free hosing. **Warning!** 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, or according to institutional protocol.
	**Warning!** Do not use the device distal to arterial cross clamping or with a patient with an ischemic limb.
SN	Serial number
REF	Catalogue / article number
	Manufacturer

	Transport and storage ambient temperature limits
	Transport and storage relative humidity limits
	Transport and storage atmospheric pressure limits
	AC voltage
	Type BF applied parts (according to IEC 60601-1:2005+A1:2012)
	Equipotentiality
	Read the user manual
	Consult the instructions for use
	Caution
	Low priority alarm indication on control equipment

	Medium priority alarm indication on control equipment
	Temporarily audible alarm suppression
	Repair is required
	Upper limit of temperature, overtemperature alarm
	Replace filter
	Air flow at ambient temperature (not heated)
32°C	Air flow setpoint at a temperature of 32°C (heated)
38°C	Air flow setpoint at a temperature of 38°C (heated)
43°C	Air flow setpoint at a temperature of 43°C (heated)
	Prior to use, the user needs to check that the device (including the power cord and the hose) is undamaged. In the event of damage do not use the device.
	Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.
	 **Warning!** Plug the device into an earthed mains socket.

	Before using the device, it should be attached to a pole, Mistral-Air® Adjustable Pole (MA5200-PM), bed rail/end, ISO rail, wall, or placed on a table.

2.6 Blanket safety symbols

This section contains a list of symbols used for the Mistral-Air® Blankets.

	Not for use in magnetic resonance imaging (MRI)
Rx Only	Caution: Federal US law restricts this device to sale by or on order of a physician.
	Do not use the device if the package is damaged.
	Catalogue / article number
	Sterile, method of sterilisation ethylene oxide
	Batch code / lot number
	S = Small, M = Medium, L = Large, XL = Extra large
	Manufacturer

Check patient's temperature and skin condition at least every 15 minutes, or according to institutional protocol.

Warning!

Do not use the device distal to arterial cross clamping or with a patient with an ischemic limb.

Transport and storage ambient temperature limits

Transport and storage relative humidity limits

Transport and storage atmospheric pressure limits

Use-by-date

For single patient use only

Not made with natural rubber latex.

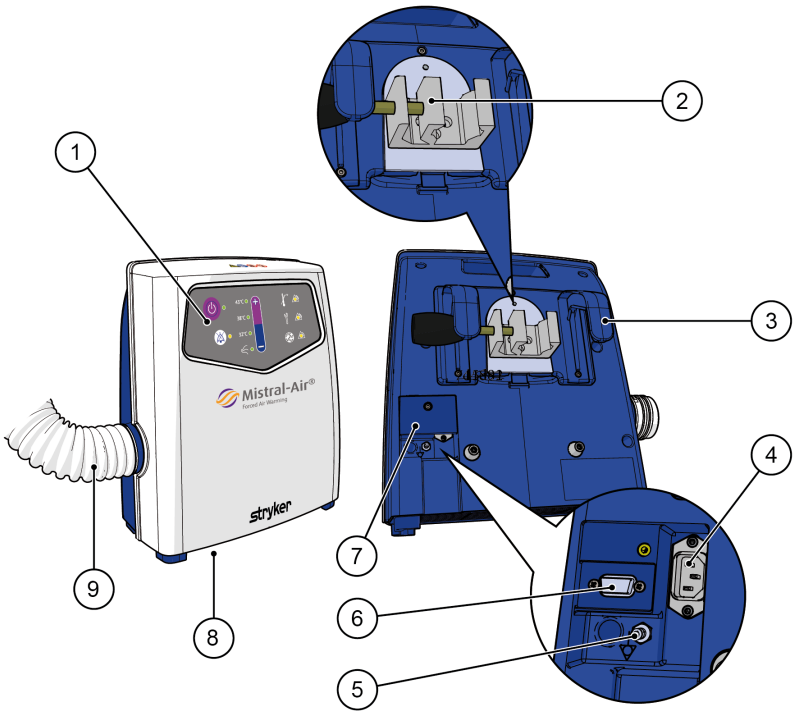
Read the user manual

	Consult the instructions for use
	Caution

3 Description

3.1 Overview of the Mistral-Air® Warming Unit (MA1200-PM)

The device is a Forced Air Warming Unit which consists of a fan, heater, electronics and a filter to propel filtered and heated air to a blanket. The device may only be used with disposable Mistral-Air® blankets that are single use only.



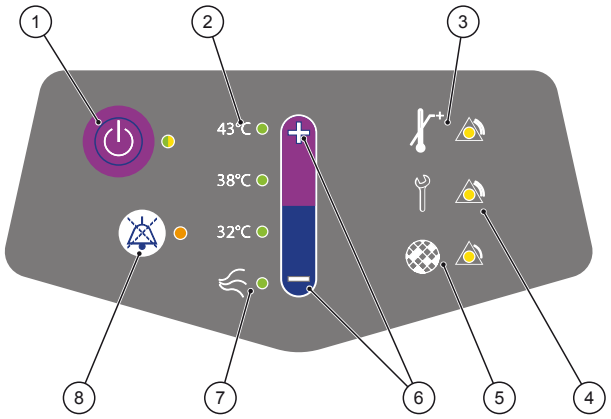
1. Control panel
2. Mounting clamp
3. Mounting options (accessory)
4. Appliance inlet
5. Equipotential pin
6. Data connection
7. Cord anchor
8. Filter (air inlet)
9. Hose

The device can be controlled by using the control panel at the front top of the device. The back of the device is equipped with a universal mounting clamp, a sealed data connector, an appliance inlet and an equipotential pin. It can be expanded with a mounting accessory set as shown in the image above to offer various mounting options, see *Accessories and disposables* on page 20.

For more device specifications, see *Specifications* on page 39.

3.2 Overview of the control panel

The control panel is located at the front top of the device and can be operated by pressure sensitive buttons. The device is easy to use. All settings are visible on the control panel and you can select the preferred temperature by pressing the temperature selection buttons. When an alarm condition is detected, an audible alarm will be activated and an alarm LED will flash yellow.



1. Standby button
2. Temperature selection indicators
3. Overtemperature alarm LED
4. Technical alarm LED
5. Filter replacement indicator LED
6. Temperature selection + and – buttons
7. Fan only/ambient air indicator
8. Temporarily audible alarm suppression button

3.3 Visual and audible warning systems

The device is equipped with visual and audible warning systems to protect against excessive temperatures, to warn for a technical malfunction, and to indicate that filter change is required.

If equipment errors occur, an audible alarm sounds and the relevant LED indicator(s) on the control panel will flash or light up continuously.

There are four different alarms/indicators:

- Technical alarm
- Overtemperature alarm
- Microcontroller watchdog alarm
- Filter replacement indicator

These alarms/indicators are described in the sections below. It is also possible to temporarily suppress the audible alarm.

Alarm/indicator summary

Alarm/indicator	Priority	Behavior
Technical alarm	Medium	Technical alarm LED: Yellow flashing
		Audible alarm: 3 beeps repeated every 6 seconds
Overtemperature alarm	Medium	Technical alarm LED: Yellow flashing
		Overtemperature alarm LED: Yellow flashing
		Audible alarm: 3 beeps repeated every 6 seconds
Microcontroller watchdog alarm	Medium	Technical alarm LED: Yellow continuous
		Overtemperature alarm LED: Yellow flashing
		Audible alarm: continuous beep
Filter replacement indicator	Low	Filter replacement indicator LED: Yellow continuous
		Audible alarm: 1 single beep

3.3.1 Technical alarm

A flashing yellow technical alarm LED indicates that a technical error has occurred and the air temperature cannot be accurately controlled. The visual alarm is accompanied by an audible alarm, which consists of three pulses of 200 ms duration, with 200 ms spacing between each pulse. This pattern is repeated every 6 seconds.

Some possible causes of this alarm:

- The leads to the temperature sensors are damaged, or disconnected.
- The fan is blocked, or damaged and cannot reach its desired speed.
- The heater is damaged and the desired air temperature is not reached.
- A mains power dip (≥ 30%) occurred for more than 1/60 seconds.

If this alarm occurs, the heater and fan are turned off and the device enters standby mode. It is impossible to start the device by pushing the standby button. Control of the device can only be recovered through resetting the device. To do this, disconnect the mains plug and reconnect it.

Caution!

If this alarm occurs, check for anything blocking the air flow path. If the technical alarm continues, take the device out of use and contact the hospital service department or Stryker.

3.3.2 Overtemperature alarm

The overtemperature alarm is triggered with a maximum air temperature of 56°C.

When the overtemperature alarm occurs, the technical and overtemperature LED's flash yellow. These indicate that the air temperature is too high. The visual alarms are accompanied by an audible alarm, which consists of three pulses of 200 ms duration, with 200 ms spacing between each pulse. This pattern is repeated every 6 seconds.

If this alarm occurs, the heater and fan are turned off and the device enters standby mode. It is impossible to start the device by pushing the standby button. Control of the device can only be recovered through resetting the device. To do this, disconnect the mains plug and reconnect it.

Caution!

If this alarm occurs, check for anything blocking the air flow path. Ensure that the blanket is not folded and do not place tools/equipment on the blanket which could result in a blocked air flow. Ensure that the air inlet is free. If the overtemperature alarm continues, take the device out of use and contact the hospital service department or the local supplier.

3.3.3 Microcontroller watchdog alarm

The microcontroller watchdog alarm is visually indicated by a continuous yellow technical alarm LED and a flashing yellow overtemperature LED. The visual alarms are accompanied by a continuous single tone audible alarm.

The microcontroller watchdog alarm indicates a technical malfunction and is triggered when the microcontroller is not functioning properly. If this alarm occurs, the heater and fan are turned off and the device enters standby mode. It is impossible to start the device by pushing the standby button. Control of the device can only be recovered through resetting the device. To do this, disconnect the mains plug and reconnect it.

Caution!

If this alarm occurs, send the device to a certified service department for technical support.

3.3.4 Filter replacement indicator

When the yellow filter replacement LED lights up, the filter needs to be replaced. This LED is activated when the device has been used for more than 2000 hours. When it is activated, it is accompanied by a single beep.

Refer to *Replacing the filter (MA1200-1001-PM)* on page 33 for the filter replacement procedure.

3.3.5 Temporarily audible alarm suppression

The audible alarm may be suppressed for up to 2 minutes by pressing the temporarily audible alarm suppression button.

When the audible alarm is suppressed, the orange LED lights up. After 2 minutes or after pushing the button once again, the audible alarm will automatically be restored.

4 Accessories and disposables

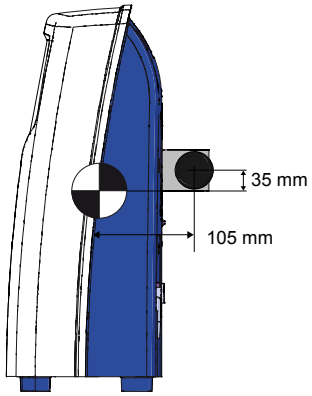
The device can be used with the following accessories and disposables:

- Mistral-Air® Adjustable Pole (MA5200-PM)
- MA1200-PM mounting parts (MA5002-PM)
- Mistral-Air® blankets

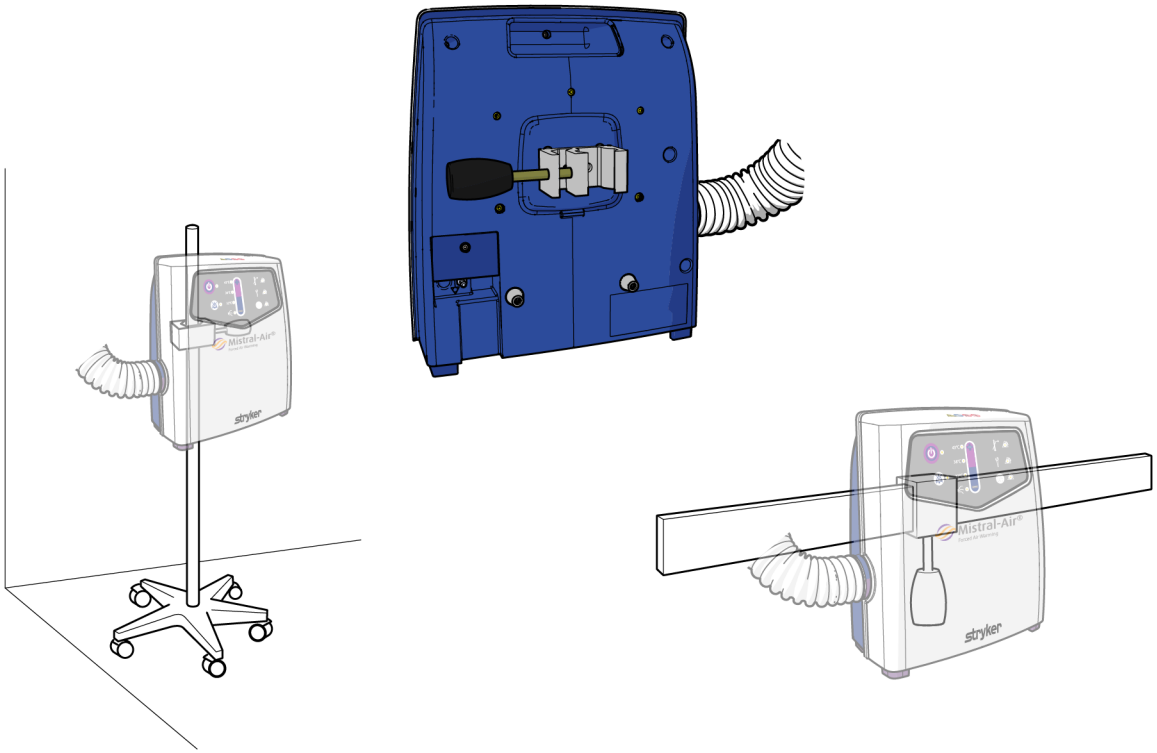
Warning!

- Do not place the device above, or in the bed with the patient. Thermal injury may occur.
- When placing the device on a surface, make sure the surface is horizontal, solid and clean. Do not place the device on a carpet because it could block the air inlet and reduce the performance.
- When mounted, the device must be mounted securely before use to prevent the device from falling.
- To prevent tipping when mounting to an IV-pole, mount the device at a height at which the IV-pole is stable. Injury may occur. Before usage, assess the stability by placing the IV-pole on a surface at an angle of 10° from the horizontal plane with brakes activated. The IV-pole may not overbalance, or move. Also passing over a 10 mm threshold may not result in overbalancing. Mass and position of center of gravity are provided in this IFU for theoretical analysis. Stryker cannot provide maximum mounting height prescriptions for different wheel base diameters, numbers of castors (either with brakes or not) and configurations of other equipment mounted to the IV pole.

  The image below shows the position of the center of gravity in relation to the center of the pole clamp.



In the standard configuration, the device can be mounted to an IV pole or ISO rail using the universal clamp on the back of the device (see figures below). It is also possible to place the device on a table without reducing the air flow rate.


Mistral-Air®
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Mistral-Air®
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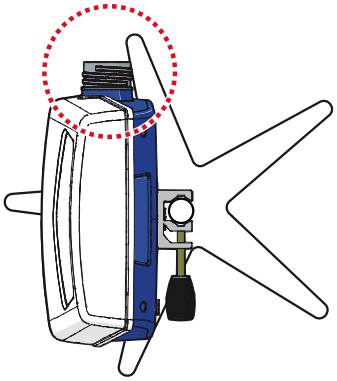
4.1 Mistral-Air® Adjustable Pole (MA5200-PM)

Caution!

- When mounting the device to the Mistral-Air® Adjustable Pole, make sure that the hose is protected by the wheelbase of the trolley. Otherwise, damage to the hose may occur after impact.



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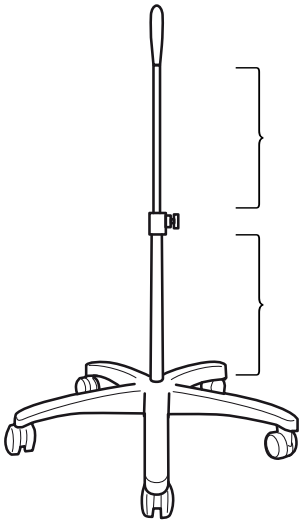
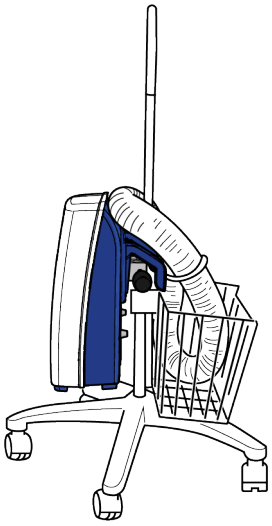


Do not mount the device on the extendable, smaller diameter, part of the trolley's pole. Only mount the device on the non-extendable part of the trolley's pole (the lower part).

Mount the device here.

The device can be mounted onto the Mistral-Air® Adjustable Pole (MA5200-PM):



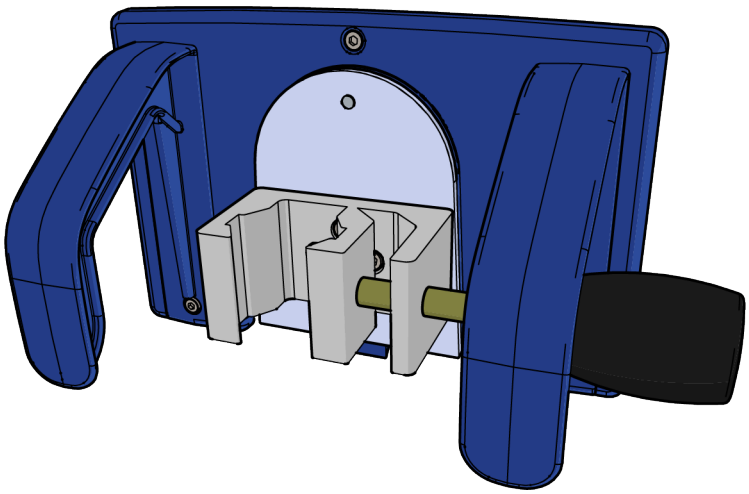
4.2 MA1200-PM mounting parts (MA5002-PM)

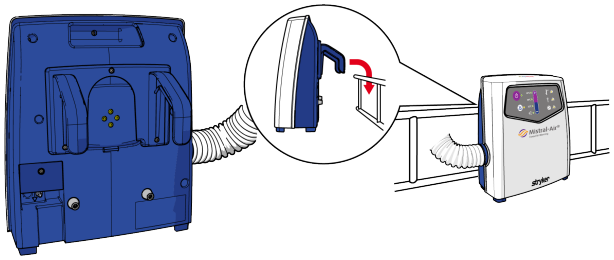
Warning!

- When using bed hooks, only mount the device to a horizontal secured surface. Do not mount the device to a tilting non-secured surface. The device may fall and pull the blanket from the patient.

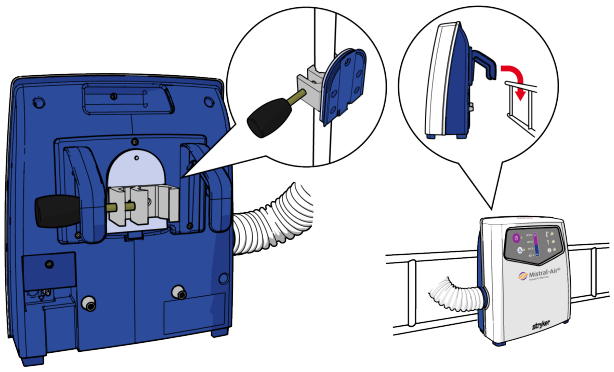
The device has various mounting options using the Mistral-Air® mounting parts – SYK (MA5002-PM).

See *Attaching the mounting parts* on page 26 for more details about attaching the mounting parts.

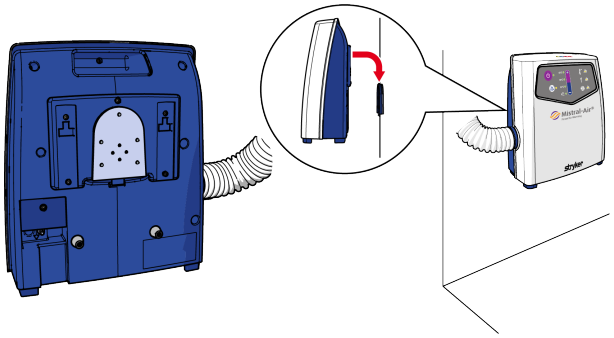




Mounting on a bed rail/end using the bed hooks.



Quick-release mechanism to switch between mounting to bed rail/end and pole.



Mounting on a wall using the Wall mount. Release by using the quick-release mechanism.

4.3 Mistral-Air® blankets

Warning!

- Do not use the device with any forced air disposables other than Mistral-Air® Blankets. Thermal injury may result.
- Do not cover the patient's thorax with our Mistral-Air® Blankets during cardioversion or defibrillation therapy.
- Avoid direct contact between a blanket and a laser. Although the blankets are flame retardant per 16 CFR Part 1610 (Standard for the flammability of clothing textiles) class 1, compliance with ISO 11810:2015 (classification for the laser resistance) is not demonstrated.

The Mistral-Air® blanket range consists of the following categories:

- Mistral-Air Blankets Plus - SYK
- Mistral-Air Premium Blankets - SYK
- Mistral-Air Specialty Blankets - SYK
- Mistral-Air Warming Suits - SYK

Please refer to the Blanket manual (INT/R709-WO/x-xx/xx Mistral-Air Blankets) or the website of The 37Company (www.the37company.com) for a description of the individual blankets.

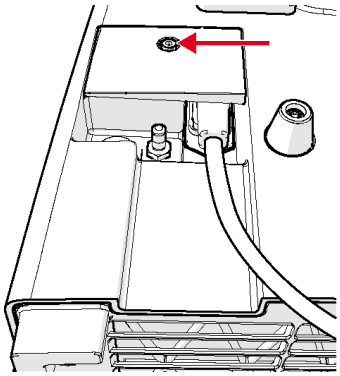
5 Set up

5.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See chapter *Specifications* on page 39.

5.2 Connecting the power supply cord

1. Remove the anchor plate using a 4 mm hex key.
2. Attach the C13 plug of the power supply cord.
3. Reattach the anchor plate to lock the C13 plug by tightening the 4 mm hex screw with a maximum torque of 1.5 ± 0.2 Nm or 13.3 ± 1.3 in-lb.



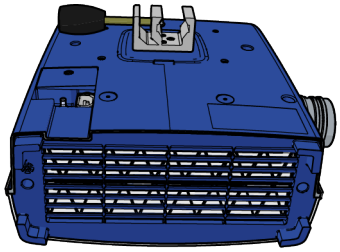
5.3 Attaching the mounting parts

The MA1200-PM mounting parts set consists of the following parts:

- 1x Wall mount
- 1x Cover
- 2x Handle
- 1x Cover plate
- 2x Bed support knobs
- 5x M6 x 6 Button head 4 mm hexagon screw
- 5x M4 x 16 Low Cylindrical head 3 mm hexagon screw
- 2x DELTA PT Torx 20IP screw 40 x 16

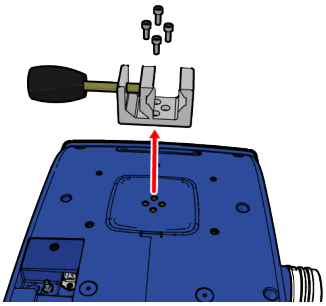
Caution!

Be careful not to scratch the front of the device.

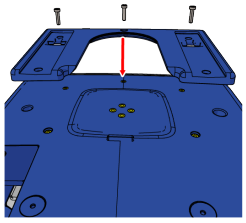


1. Disconnect the device from the mains socket.
2. Place the device face-down on a soft surface.

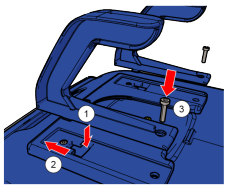
3. Remove the 4 M5 screws of the pole clamp using a 4 mm hexagon key and remove the pole clamp.



4. Attach the Cover at the 3 indicated locations using the first 3 of the 5 M4x16 3 mm hexagon screws with a maximum torque of 1.5 ± 0.2 Nm or 13.3 ± 1.3 in-lb.



If you do not attach the Handles mentioned in the step below, you still need to tighten the last 2 of the 5 M4x16 3 mm hexagon screws.

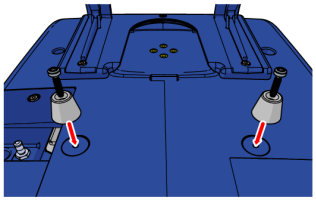


5. Optional: Click the Handles into the sliders of the Cover and tighten them at the 2 indicated locations using the last 2 of the 5 M4x16 3 mm hexagon screws.

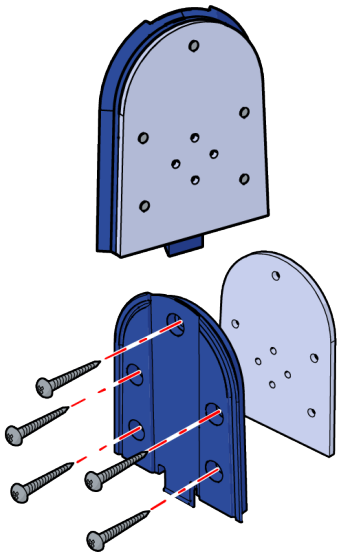
Warning!

If the Handles are attached, always attach the Bed support knobs for stability (see step 6).

6. Optional: Attach the 2 Bed support knobs using the 2 Torx screws. Tighten the screws until the Bed support knobs cannot be rotated anymore.



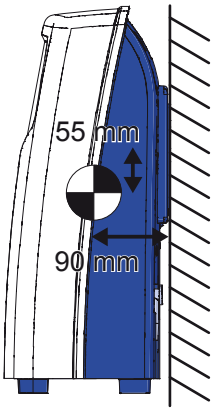
7. Optional: Mount the Wall mount and Cover plate to a wall using wall screws and plugs specifically designed for the used wall material (not supplied). First check the adequacy (of the surface) of the structure to which the wall mount will be attached based on the mass of the device (see *Specifications of the device* on page 39) and the center of gravity shown below.



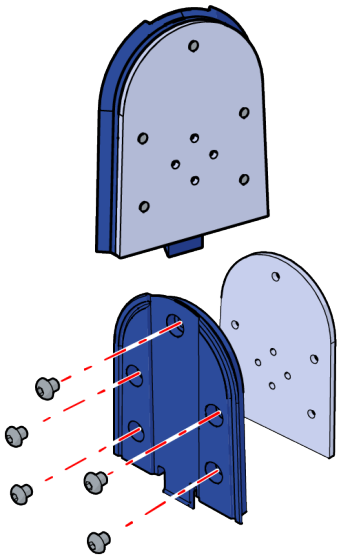
Caution!

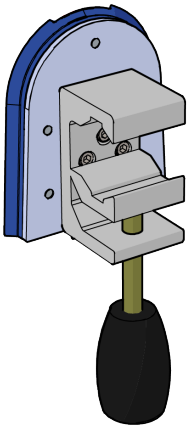
Use screws with a diameter which is small enough (max. M6) not to damage the threads of the Cover plate holes.

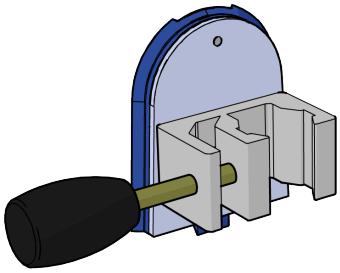
It is advised to account for the readability of the control panel when deciding about the mounting height.



8. Optional: Attach the Cover plate to the Wall mount using the 5 M6x6 4 mm hexagon screws. And attach the pole clamp to the Cover plate using the 4 M5 screws which were removed during step 3 using a 4 mm hexagon key.







6 Operation

6.1 Safety instructions before operation

Warning!

When using the device, first read the warnings in *Warnings* on page 7.

The device is intended to be used only by trained clinicians. Intended patient population: adults and pediatric patients.

The clinical areas are: operating room, recovery room, anaesthetic room, intensive care unit, medical/surgical floors and emergency room. Mainly used during the entire perioperative pathway (pre-, per-, and postoperative period).

6.2 Connecting the power supply

See *Connecting the power supply cord* on page 26 if the power supply cord is not yet connected to the device.

1. Plug the device into an earthed mains socket.
2. The device automatically switches to the standby mode, which is indicated by the orange standby LED located on the left side of the control panel.

6.3 Connecting the blanket

1. Take the selected Mistral-Air® blanket out of the package and follow the instructions on the insert provided with the blanket box.
2. Place the unit near the hose inlet of the blanket.
3. Insert the end of the flexible hose into the air inlet port of the Mistral-Air® blanket.
4. Check if the hose is fully pushed in.

6.4 Turning on the device

Caution!

Stay in viewpoint of the control panel when the device is performing the self-test and selecting the set-point.

1. Activate the device by pressing the standby button. The LED turns green.
2. The device will now perform a self-test, which includes a flash of all the LED's and a short beep. When a LED or the audible beep fails, take the device out of use for repair.

3. After the self-test, which lasts several seconds, the device will start blowing air at the default temperature setting of 38°C.

6.5 Selecting the temperature

The description of the setpoints corresponds to the average temperature under the blanket. There are four temperature setpoints:

- Fan only/ambient air: Ambient air temperature. The air temperature to the patient will depend on ambient conditions and possible heat from the fan motor.
- 32°C: Low temperature.
- 38°C: Medium temperature.
- 43°C: High temperature.

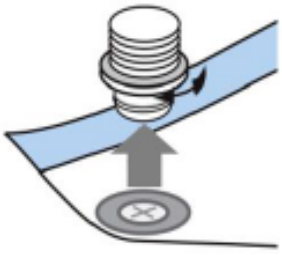
The selected temperature is indicated by one of four green temperature selection indicator LED's, see *Overview of the control panel* on page 16.

1. After the self-test, the device will start blowing air at the default temperature setting of 38°C.
2. Press the – button twice to deactivate the heater. The fan only/ambient air indicator turns green and air at ambient temperature is blown to the patient.
3. Press the + button to activate the heater.
4. Press the + button multiple times to increase the air temperature at the blanket to a setpoint of 38°C, or 43°C.
5. Press the – button to decrease the temperature setpoint.

After selecting the desired temperature, the LED next to the temperature indicator symbol will flash green. After reaching the set temperature (+/- 2°C), the green LED lights up continuously.

6.6 Stopping warming

1. Press the standby button.
2. Disconnect the hose from the blanket.
3. If desired, leave the blanket on/under the patient.



Caution!

To remove all power from the device, the mains power cord must be removed from the electrical receptacle.

7 Maintenance

Warning!

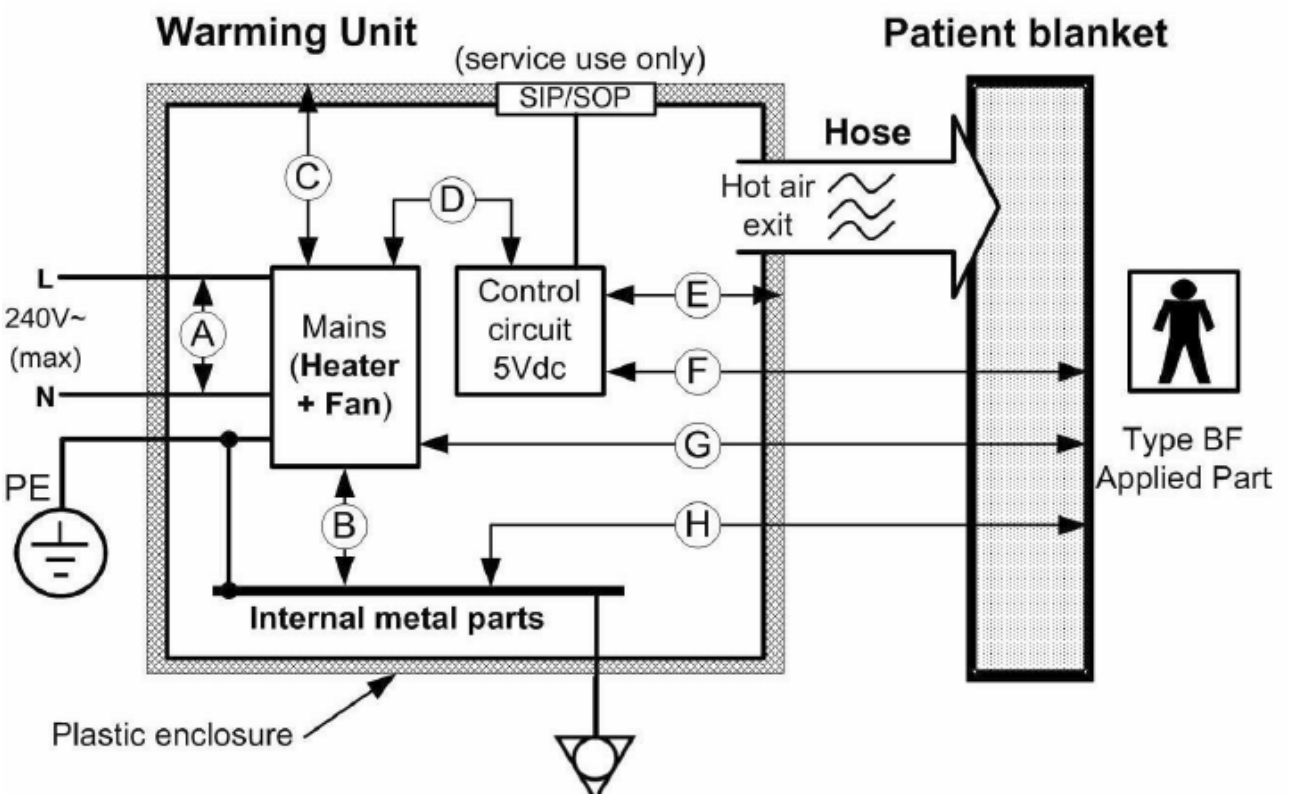
- Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.
- Preventive maintenance needs to be performed on an annual basis. Please refer to the Mistral-Air® technical manual for maintenance, repair and calibration instructions. The Mistral-Air® technical manual is available for download at the business partner menu of the 37Company website.

Caution!

Clinical users may not repair or open the device in the event of a malfunction. This can damage the appliance and will invalidate the warranty.

Have the device serial number ready when you contact the hospital service department or the local supplier for technical support. The serial number is located on the label on the back of the device.

Before performing maintenance, consult the device insulation diagram below.



7.1 Cleaning

Warning!

- Before you clean the device, disconnect the power supply cord to eliminate the risk of electrocution.
- Do not use dripping wet cloths.
- Do not use ketones (MEK, acetone, etc.) or abrasive cleaners.
- Do not use alcohol based cleaners (except isopropyl alcohol and ethanol).
- Do not use acid based cleaners.
- Do not use oxidizing cleaners.
- Do not exceed the concentration specified by the manufacturer; or use premixed solutions.
- Do not use steam sterilization (autoclave) or dry heat to sterilize the device.
- Do not immerse the device in liquids. Otherwise, the device can be damaged.
- Make sure that fluids cannot enter the electrical areas of the device.
- Do not place the device upside down, or on its sides.
- Clean hose at ambient temperature and make sure the hose is dry before use. Damage to the hose may occur.
- Clean the hose at ambient temperature and make sure the hose is dry before use. Damage to the hose or device may occur.

To clean the surface of the device:

1. Use a soft cloth lightly dampened with a solution of hand warm water with a mild detergent solution or use one of the following disinfectants:
   - isopropyl alcohol (isopropanol) based cleaners ≤ 90%
   - ethyl alcohol (ethanol) based cleaners ≤ 90%
2. Use a moist cloth to remove excessive detergent or disinfectant.
3. Wipe the surface (including the hose).
4. Let the device air dry.

7.2 Corrective maintenance

Warning!

Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from Stryker.

7.2.1 Replacing the filter (MA1200-1001-PM)

The accumulation of dust in the air filter will reduce the efficiency of the device. The filter must be replaced when the Filter Replacement indicator is activated, or when indicated by visual inspection. Only use parts provided by Stryker or your local distributor.

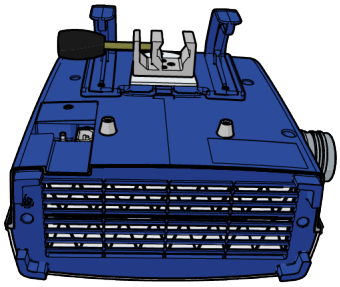
Warning!

- Do not return the device from service without the filter present.
- Before performing a repair, disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.

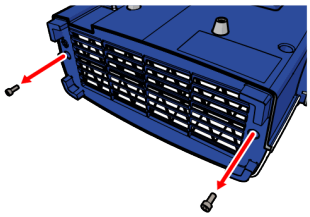
Caution!

Be careful not to scratch the front of the device.

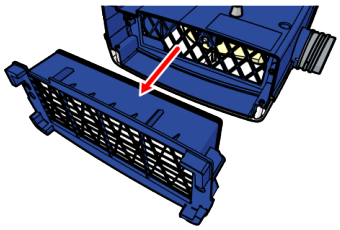
1. Place the device face-down on a soft surface.
2. Disconnect the device from the mains socket.



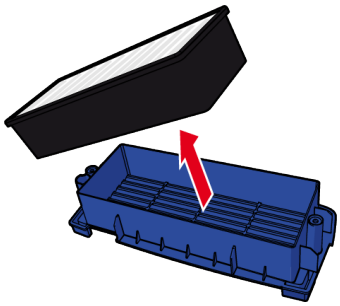
3. Remove the two screws of the filter cap with a 4 mm hex key.



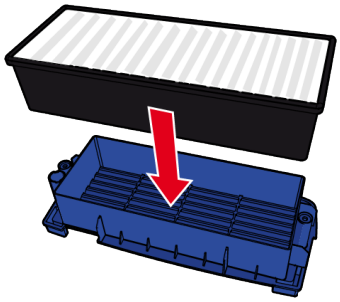
4. Remove the filter cap.



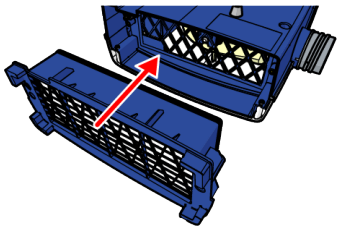
5. Remove the filter.



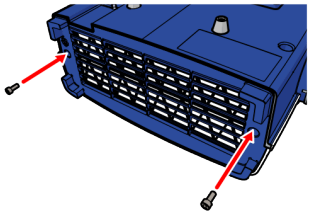
6. Place the replacement filter in the filter cap with the rubber seal facing up.



7. Place back the filter cap.



8. Place back the screws and tighten them with a maximum torque of 2.1 ± 0.2 Nm or 18.6 ± 1.9 in-lb.
9. Connect the power plug to the wall socket and leave the device in standby mode.
10. Press and hold the -, + and the alarm suppression buttons simultaneously.
11. While holding down the three buttons, press the standby button.



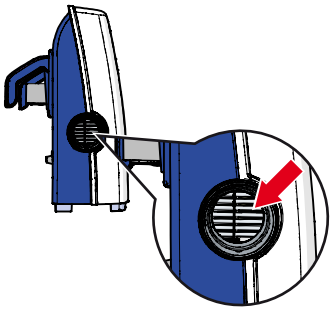
You will hear a beep and the device returns to standby mode, indicating that the Filter timer has been reset.

12. Dispose the replaced filter according to hospital protocol.

7.2.2 Replacing the hose (MA1100-1018-PM & MA1100-1018XL-PM)

Warning!

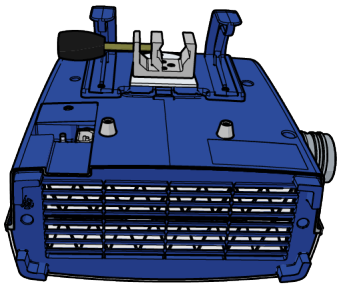
- When replacing the hose, do not touch the temperature sensors. If these sensors are touched in any way, they can be damaged and out of calibration. This could cause burns to the patient. If the temperature sensors are touched or damaged, contact your local Stryker representative.
- Before performing corrective maintenance (see *Corrective maintenance* on page 33), disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.



Changing the 1.8 m or 5.9 ft long hose for a 3 m or 9.8 ft long hose reduces the temperature of the air transferred to the patient with at least 1.9 °C.

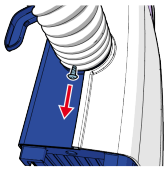
Caution!

Be careful not to scratch the front of the device.

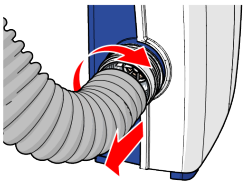


1. Disconnect the device from the mains socket.
2. Place the device face-down on a soft surface.

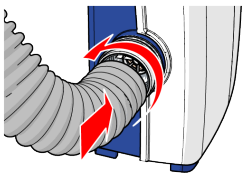
3. Unscrew the screw that fixes the hose.



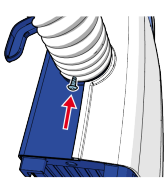
4. Unscrew the hose by rotating it clockwise.



5. Attach a new hose by rotating the hose anti-clockwise.



6. Pierce the hose with a sharp object at the location where the screw must be attached. Apply and tighten the screw that fixes the hose.
7. Dispose the replaced hose according to hospital protocol.



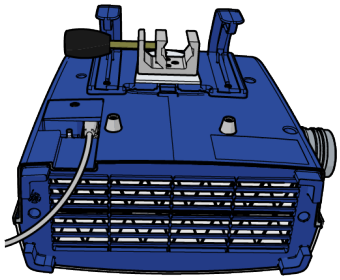
7.2.3 Replacing the power cord

Warning!

- Use of accessories, transducers and cables other than those specified or provided by Stryker of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Before performing corrective maintenance (see *Corrective maintenance* on page 33), disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the device when it is connected to a power supply.

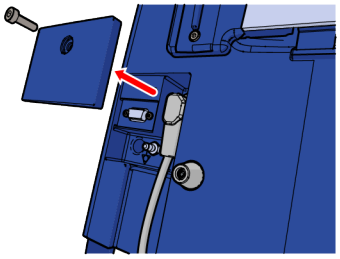
Caution!

Be careful not to scratch the front of the device.

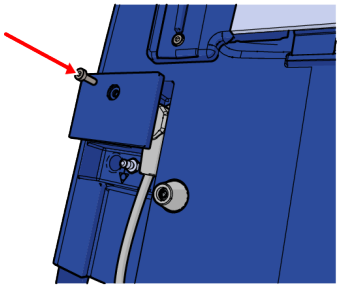


1. Disconnect the device from the mains socket.
2. Place the device face-down on a soft surface.

3. Remove the anchor plate using a 4 mm hex key.



4. Unplug the C13 plug from the device.
5. Insert a new Stryker power supply cord and press it firmly into place.
6. Reattach the anchor plate to lock the C13 plug by tightening the 4 mm hex screw with a maximum torque of 1.5 ± 0.2 Nm or 13.3 ± 1.3 in-lb.
7. Perform an IEC 60601-1 electrical safety test.
8. Dispose the replaced power cord according to hospital protocol.



8 Troubleshooting

Problem	Possible Cause	Action
The device 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 PCA	Send the device to a certified service department for technical support.
The technical alarm is activated and the warming device stopped working.	Obstructed air flow path	If this alarm occurs, check for anything blocking the air flow path (e.g. blocked inlet, blocked hose end, or kink in the hose). Remove the obstruction(s), unplug the device from mains power, reconnect it and verify the alarm is gone. Press standby to activate the device again. In case of a recurring alarm, send the device to a certified service department for technical support.
	Poor or loose wire connections, or damaged heater or electronics	
	Large mains power dip (≥ 30%) for more than 1/60 of a second	
The microcontroller watchdog alarm is activated.	Malfunctioning electronics	Send the device to a certified service department for technical support.
The device does not deliver enough air.	Obstructed air flow path	Check for anything blocking the air flow path and remove the obstacles.
	Clogged air filter	Send the device to the technical department to replace the filter with new filter supplied by Stryker.
Other technical problems.	Unidentified cause	Send the device to a certified service department for technical support.

9 Specifications

9.1 Specifications of the device

General specifications

Article number	**MA1200-PM**
Rated voltage	100-125 V~
Frequency	50/60 Hz
Device sound pressure	51 dBA
Average current	6.1 A
Peak current	10.0 A
Peak power	1000 VA
Average power at 43°C and t_{amb} 22 +/- 1.5°C Average power at 109°F and t_{amb} 72 +/- 2.7°F	800 VA / 610 W
Fuses	10AHF/250V~
Air flow rate at nominal voltages and ambient temperature (1.8 m hose) Air flow rate at nominal voltages and ambient temperature (5.9 ft hose)	71 - 88 Nm³/h (depending on orientation of the hose, supply voltage, type and drape of the blanket) 42 - 52 CFM (depending on orientation of the hose, supply voltage, type and drape of the blanket)
GMDN code	36954 (circulating-air whole-body heating system control unit)
Dimensions	16 cm x 35 cm x 40 cm (l x w x h) 6.3 in x 14 in x 16 in (l x w x h)
Weight	5.2 kg 11.5 lb
Hose length	1.8 m (3 m hose optional) 5.9 ft (9.8 ft hose optional)
Power supply cord length	4.0 m 13 ft
Filtration	HEPA H13 class filter, conform EN 1822-1:2009
Classification IEC 60601-1	Class I, Body Floating (BF)
Overvoltage category according to IEC 60664-1	Category II
Classification IEC 60529	IP23

Setpoint temperature	Ambient air, 32°C, 38°C, 43°C Ambient air, 90°F, 100°F, 109°F
Accuracy of temperature at the end of the hose	± 2.5 °C / 4.5 °F (under all validated operating environmental conditions)
Setpoint reached after	Under 30 seconds
Low temperature limit	10°C 50°F
Maximum average contact surface temperature	45.5°C (Compliant with IEC 80601-2-35) 114°F (Compliant with IEC 80601-2-35)
High temperature safety limit	< 56°C (Compliant with IEC 80601-2-35) < 133°F (Compliant with IEC 80601-2-35)
Auditory alarm signal sound pressure	80 dBA
Applicable technical standards	IEC 60601-1:2005+A1:2012, IEC 80601-2-35:2016
Expected lifetime device	7 year
Expected lifetime hose	1 year

The essential performance of the Mistral-Air Warming System is: when supplying air to the patient “the Maximum CONTACT SURFACE TEMPERATURE” must be below the safe temperature limits according to IEC 80601-2-35: 2009 + C1:2012 +C2:2015, Clause 201.11.1.2.1.102.

Validated operating environmental specifications

Ambient temperature	15°C to 30°C 59°F to 86°F
Relative humidity	30% to 75%

Validated transport and storage specifications

Ambient temperature	-20°C to 70°C -4°F to 158°F
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa 7.3 psi to 15.4 psi

10 Electromagnetic compatibility

Warning!

- Use of accessories, transducers and cables other than those specified or provided by Stryker of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

- The Emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the device.
- It is possible that a technical alarm is triggered at a 30% dip. Degradation does not affect ESSENTIAL PERFORMANCE and BASIC SAFETY and is therefore compliant. Refer to *Troubleshooting* on page 38 and *Specifications of the device* on page 39 for a solution.
- This device complies with IEC 60601-1-2:2014 for electromagnetic compatibility. However, if electromagnetic interference with nearby devices is experienced, the user is encouraged to take one or more of the following measures:
  - Isolate the offending device.
  - Reorient or relocate this device.
  - Increase the distance between the interfering device and this device.
  - Use another mains socket.

  If electromagnetic incompatibility is still experienced, please contact your distributor.

10.1 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC60601 test level
Electromagnetic discharge (ESD) EN-IEC 61000-4-2 (2009)	± 8 kV contact
	± 15 kV air

Immunity test	IEC60601 test level
Electrical fast transient (EFT) / burst EN-IEC 61000-4-4 (2012)	± 2 kV
Surge EN-IEC61000-4-5 (2014)	± 1 kV L-N
	± 2 kV L-PE / N-PE
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11 (2004)	0% U_T for 0.5 cycle
	0% U_T for 1 cycle
	70% U_T for 25/30 cycles
	0% U_T for 250/300 sec
Power frequency (50/60 Hz) magnetic field IEC EN-IEC 61000-4-8 (2010)	30 A/m
Conducted RF EN-IEC 61000-4-6 (2014)	3 Vrms + 6 Vrms (ISM + Amateur)
Radiated RF EN-IEC 61000-4-3 (2006) + A1 (2008) + A2 (2010)	3 V/m
Proximity fields from RF wireless communications equipment EN-IEC 61000-4-3 (2006) + A1 (2008) + A2 (2010)	9-28 V/m
Electrical transient conduction along supply lines ISO 7637-2 (2004)	Not applicable (system not intended for use in vehicles)

10.2 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance
RF emissions CISPR 11 (2015)	Group 1
RF emissions CISPR 11 (2015)	Class A

Emissions test	Compliance
Harmonic emissions IEC 61000-3-2 (2018)	Not applicable (the device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes)
Voltage fluctuations/flicker emissions IEC 61000-3-3 (2017)	

10.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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**	**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.

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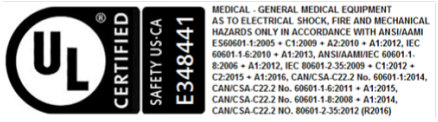

applicable to model MA1200-PM only