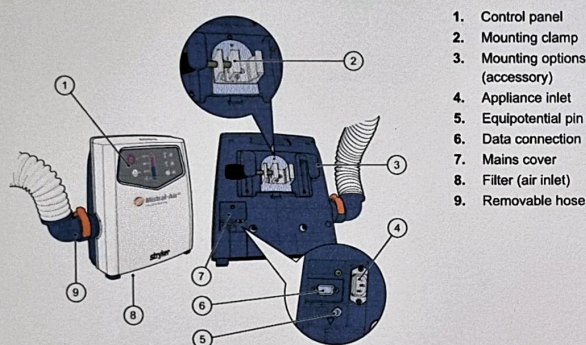
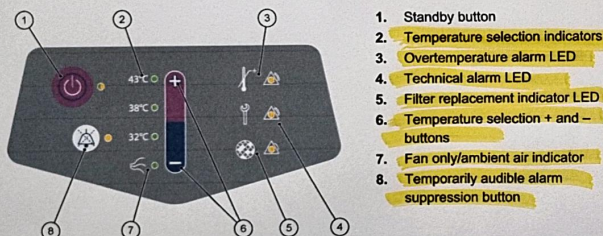


3.2 Overview of the Mistral-Air® Warming Unit (MA1200-QC)



3.3 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.



3.4 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 short beep

3.4.1 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 ($\geq 30\%$) 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 the local supplier.

3.4.2 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.

3.4.3 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.

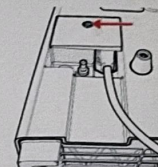
5 Set up

5.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See *Specifications* on page 43.

5.2 Connecting the power supply cord

1. Remove the mains cover using a 4 mm hex key.
2. Attach the C13 plug of the power supply cord.
3. Reattach the mains cover to lock the C13 plug by tightening the 4 mm hex screw with a maximum torque of 1.5 ± 0.2 Nm.



5.3 Attaching the mounting parts

The MA1200 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.



6 Operation

6.1 Safety instructions before operation



Warning!

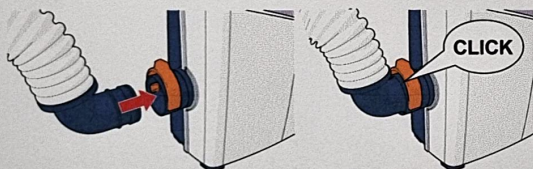
When using the device, first read the warnings in *Warnings* on page 8.

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 Mistral-Air® QC Hose (MA1200-1018 & MA1200-1018XL) to the device

1. Check the QC Hose or QC Hose XL for damage.
2. Hold on to the front-end hose connector (knee part).
3. Place the front-end of the hose into the quick connector.
4. Press the connector firmly into the blower until a "click" is produced.
5. Check to ensure the hose is firmly connected.



The QC Hose can be rotated 360° for optimal range.

6.3 Connecting the power supply



See *Connecting the power supply cord* on page 27 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.

6.4 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.

6.5 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.

6.6 Selecting the temperature

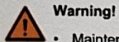
The description of the setpoints corresponds to the average temperature under the blanket. There are four temperature setpoints:

- 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 18.

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.

7 Maintenance



Warning!

- Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from The 37Company.
- 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 The 37Company website.

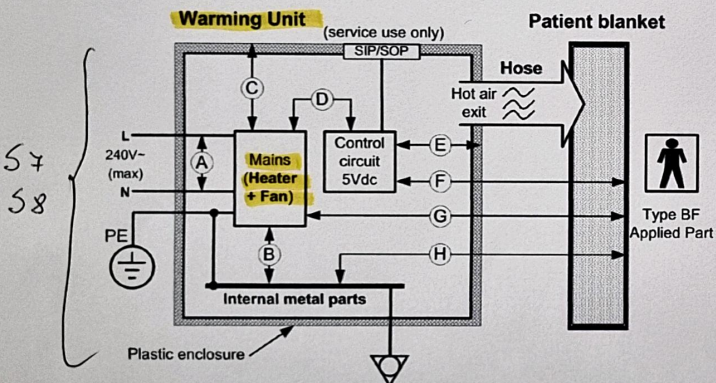


Caution!

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.



9 Specifications

9.1 Specifications of the device

General specifications

Article number	MA1200-EU	MA1200-US
Rated voltage	220-240 V~	100-125 V~
Frequency	50/60 Hz	50/60 Hz
Device sound pressure	48 dBA	51 dBA
Average current	3.2 A	6.1 A
Peak current	9.0 A	10.0 A
Peak power	1000 VA	1000 VA
Average power at 43°C and $t_{amb} 22 \pm 1.5^\circ\text{C}$	750 VA / 600 W	800 VA / 610 W
Fuses	6.3AHF/250V~	10AHF/250V~
Air flow rate at nominal voltages and ambient temperature (1.8 m hose)	Up to 101 [Nm³/h] or 59 [CFM] (depending on orientation of the hose, supply voltage, type and drape of the blanket)	Up to 88 [Nm³/h] or 52 [CFM], (depending on orientation of the hose, supply voltage, type and drape of the blanket)
Air flow rate at nominal voltages and ambient temperature (1.8 m hose), low fan duty cycle	Up to 91 [Nm³/h] or 53 [CFM] (depending on orientation of the hose, supply voltage, type and drape of the blanket)	Up to 79 [Nm³/h] or 47 [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)	
Weight	5.2 kg	
Hose length	1.8 m (3 m hose optional)	
Power supply cord length	4.0 m	
Filtration	HEPA H13 class filter, conform EN 1822-1:2009	
Classification 93/42/EEC	Class IIb	
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	

52 Accuracy of temperature at the $\pm 2.5^{\circ}\text{C}$ (under all validated operating environmental conditions)
end of the hose

53 Setpoint reached after Under 30 seconds

Low temperature limit 10°C

Maximum average contact surface temperature 45.5°C (Compliant with IEC 80601-2-35)

56 High temperature safety limit $< 56^{\circ}\text{C}$ (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 years

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

Relative humidity 30% to 75%

Validated transport and storage specifications

Ambient temperature -20°C to 70°C

Relative humidity 10% to 90% (non-condensing)

Atmospheric pressure 50 kPa to 106 kPa