Încălzirea inteligentă, sigură și confortabilă a pacientului cu ajutorul unității

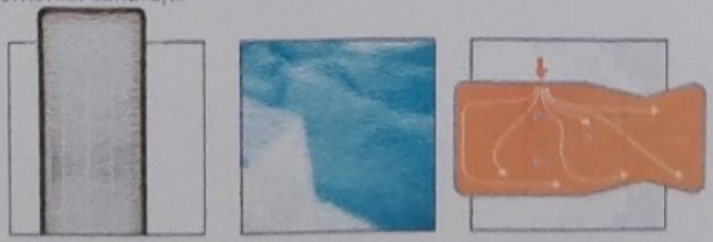
Mistral-Air®

Unitate de încălzire forțată a aerului

Prevenirea hipotermiei perioperatorii involuntare ajută la reducerea infecțiilor chirurgicale, a duratei de ședere în spital, precum și a costurilor aferente fiecărui pacient în parte. Unitatea de încălzire Mistral-Air® Plus este un dispozitiv de încălzire forțată a aerului care permite gestionarea sigură, confortabilă și inteligentă a temperaturii pacientului pentru a obține normotermia. Păturile de încălzire Mistral-Air® sunt adaptabile la majoritatea cazurilor chirurgicale, sunt sigure și confortabile pentru pacient, unitatea fiind un sistem inteligent conceput pentru profesioniștii din domeniul sănătății.

Păturile de încălzire Mistral-Air® sunt proiectate aerodinamic pentru a oferi o distribuție uniformă a căldurii pe întreaga lungime a păturii, prin difuzie controlată. Funcțiile suplimentare, cum ar fi dimensiunea, clapetele de fixare și designul suflantei, asigură o mulare perfectă în jurul corpului pacientului. Aceasta creează un cocon de căldură, rezultând un transfer maxim de căldură către pacient, care ajută la îmbunătățirea rezultatelor prin încălzirea eficientă a acestuia.

515



Siguranță Confort Tehnologie inteligentă

Conform extras Broșură pag. 1

Pături de încălzire Mistral-Air® 515

Portofoliul nostru complet de pături de încălzire îi ajută pe profesioniștii din domeniul sănătății să prevină hipotermia din faza perioperatorie involuntară, îmbunătățind rezultatatele. Portofoliul de pături conține pături Mistral-Air® Premium și pături Mistral-Air® Plus.

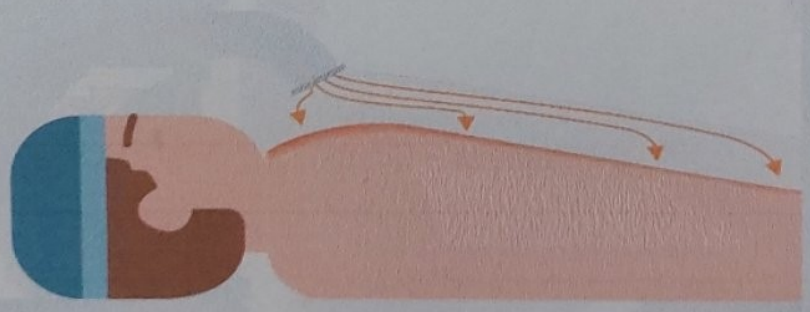
Mistral-Air®
Unitate de încălzire a pacientului

Difuzie controlată

Difuzia controlată a aerului combină **o suflantă cu volum mare** și o pătură **de joasă presiune**. Aerul cald al suflantei cu volum mare este distribuit uniform în pătura de încălzire datorită designului aerodinamic al păturilor de încălzire. Aerul cald este distribuit încet și uniform prin materialul special (permeabil) al păturilor de încălzire Mistral-Air®.

Această tehnologie elimină jeturile de aer individuale, de înaltă presiune, care pot sufla aer către pacienți și pot provoca plutirea păturii. Pătura de unică folosință rămâne în poziție, menținând aerul cald pe pacient.

Prin urmare, nu există întreruperi ale fluxului de aer în mediul înconjurător și niciun efect de răcire creat de aerul care circulă. Nu este nevoie să adăugați lenjerii de bumbac sau alte materiale textile pentru a poziționa păturile de încălzire.

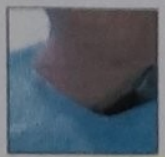


Caracteristici principale:

- Transfer și distribuție optimă a căldurii către pacient
- Fără efect de plutire
- Fără întreruperi ale fluxului de aer în mediul înconjurător
- Nu este nevoie de lenjerie de pat din bumbac

Puncte de deflexie

Tiv



Spațiu pentru pat în formă

Bandă adezivă

Benzi perforate

Conform extras Broșură pag. 2

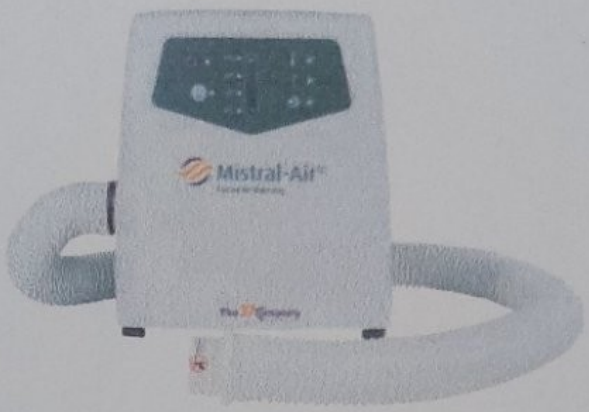
Unitate de încălzire a pacientului, optimizată și sigură

Unitatea de încălzire forțată a aerului Mistral-Air® respectă ultimele cerințe ale pieței. Asigură începerea terapiei în 30 de secunde fiind confortabil de manevrat.

Unitatea de încălzire are o greutate redusă, este ușor de curățat fiind fabricată din materiale rezistente la impact.

Îmbunătățirea rezultatelor prin siguranță și confort, și încălzirea inteligentă a pacientului.

"Soluția de încălzire forțată a aerului Mistral-Air® oferă o calitate superioară gamei de produse dedicate optimizării încălzirii pacientului pe tot parcursul procesului perioperator."



Unitate de încălzire forțată a aerului Mistral-Air®:

- Transfer optimizat al căldurii datorită tehnologiei cu multisenzori și a ventilatorului puternic
- Eliminarea contaminanților din aer cu ajutorul filtrului HEPA
- Ergonomic și flexibil în utilizare datorită designului suplu și ușor


Filtru HEPA


Design suplu

Echipată cu un suport de montare versatil, unitatea de încălzire Mistral-Air® oferă personalului medical siguranță în poziționarea acesteia în toate zonele de îngrijire.

Mai multe opțiuni de montare! Piese de montare Mistral-Air® Nr. articol MA5002

S14

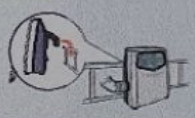
Montare standard
Opțiuni universale de montare


Cărucior sau stativ IV


Șină de pat ISO

Kit de montare extensie:
Extinde numărul de opțiuni


Kit de extensie


Brațe suport pentru pat


Opțiuni montare pe perete

S1 S9

Unitate de încălzire Mistral-Air® | Număr articol MA1200-EU

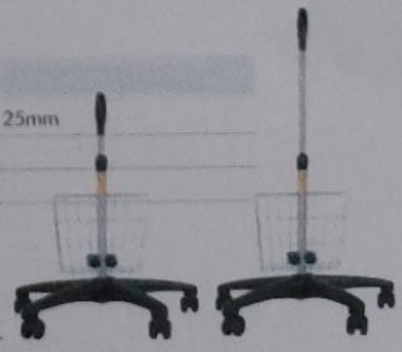
Tensiune, frecvență, curent	220 - 240VAC, 50/60Hz, 3.2A
Puterea medie	600W
Dimensiuni	160mm x 350mm x 400mm (l x w x h)
Greutate	5.2kg
Lungime furtun	1.8m
Lungime cablu de alimentare	4.0m
S2 Temperatură setată	32°C, 38°C, 43°C sau aerul ambiant
S8 Filtrare	Clasă filtru HEPA H13, conform EN 1822-1:2009
Garanție limitată	2 ani
Clasificare IEC 60601-1	Clasa I, Body Floating (BF)
Clasificare IEC 60529	IP23
Clasificare 93/42/EEC	Clasa IIb

S1, S14

Suport reglabil cu coș Mistral-Air® | Număr articol MA5250

Dimensiune suport	685-935mm ± 10mm înălțime, ø 25mm
Dimensiune bază	ø 605mm
Roți	5 - fără latex, cu frâne
Dimensiune coș	195mm x 295mm x 250mm

S1
S14



The 37°Company
part of The Surgical Company

Conform extras Broșură pag. 4

Intraoperator

5 16

MA3350 (Premium) / MA2250 (Plus)
Partea inferioară
1320 x 1330 mm

MA3360 (Premium) / MA2260 (Plus)
Partea superioară
2010 x 760 mm

MA3365 (Premium) / MA2265 (Plus)
Jumătatea superioară
1600 x 760 mm

MA2270 (Plus)
Trunchi
1240 x 760 mm

MA2285
Acces chirurgical/ steril
Partea inferioară
1830 x 1330 mm

MA2290 / MA2280
Acces chirurgical/ steril
2200 x 1330 mm

MA2286
Cardiac / steril
1700 x 1330 mm

MA3330 (Premium) / MA2230 (Plus)
Pediatric
1660 x 1330 mm

PACU

MA3320 (Premium) / MA2220 (Plus)
Adult
2270 x 1330 mm

MA3330 (Premium) / MA2230 (Plus)
Pediatric
1660 x 1330 mm

Sub corp

MA3340 (Premium) / MA2240 (Plus)
Neonatal
1160 x 1330 mm

MA3475 (Premium) / MA2475 (Plus)
Pediatric
1680 x 900 mm

MA3400 (Premium) / MA2400 (Plus)
Complet
2200 x 900 mm

MA3450 (Premium) / MA2450 (Plus)
Jumătate
1680 x 900 mm

Costume

MA1610 - **Premium S**
MA1620 - **Premium M**
MA1630 - **Premium L**
MA1640 - **Premium XL**

... conform extras broşură pag. 5

2 Contraindications, warnings, cautions, notes and symbols

The device was designed and built with safety in mind. However, there is no replacement for care providers being attentive to their patients' needs and equipment operation. Read and understand the contraindications, warnings, cautions and notes before using 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!

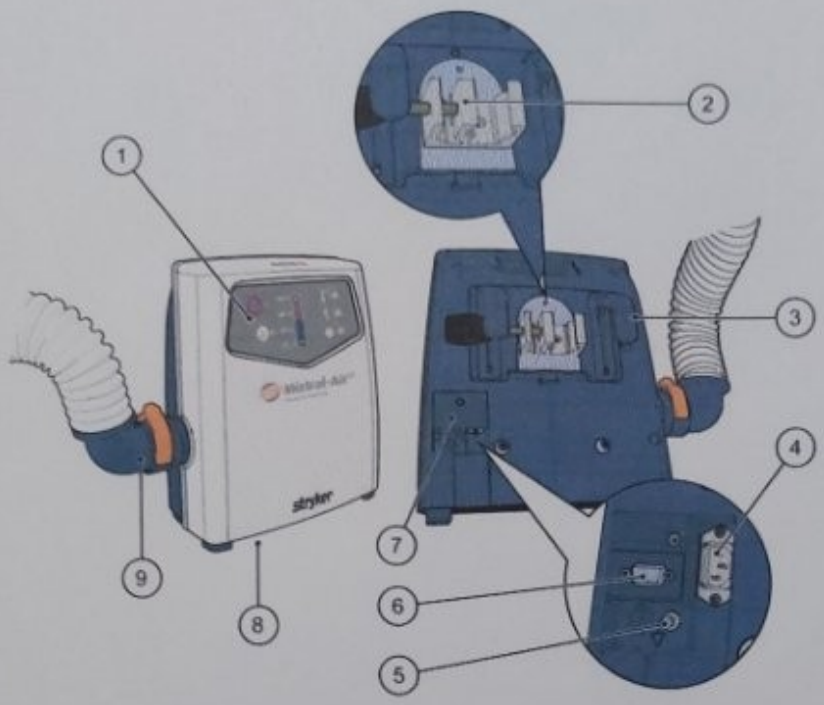
- Do not use the device when it is damaged or when the Mistral-Air® Blanket is damaged. Thermal injury may result.
- Do not allow the patient to lie on or contact the hose with the skin when the device is active. Thermal injury may result.
- Do not use the Mistral-Air® Blanket to transfer or move the 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. The 37Company 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.

SS

- 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

Conform extras manual de utilizare pag. 8

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

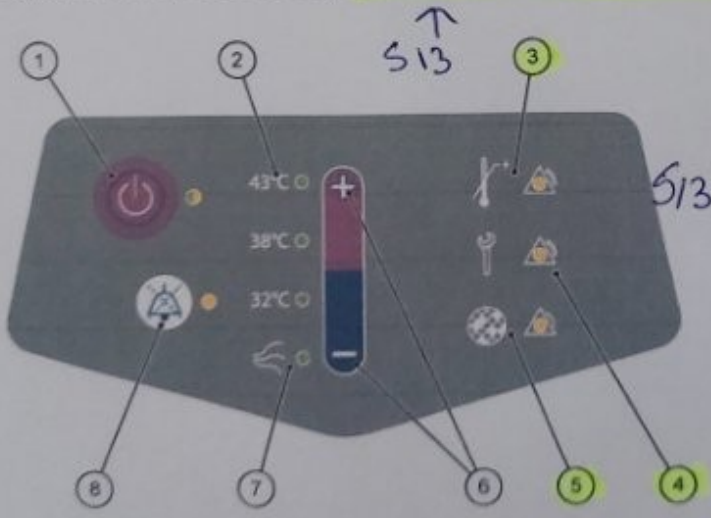


1. Control panel
2. Mounting clamp
3. Mounting options (accessory)
4. Appliance inlet
5. Equipotential pin
6. Data connection
7. Mains cover
8. Filter (air inlet)
9. Removable hose

S12

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.



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

S13 (3–5) S12 (1–8)

Conform extras manual de utilizare pag. 18

- 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 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.

56

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.

55

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.

Conform extras manual de utilizare pag. 20

6 Operation

6.1 Safety instructions before operation

Warning!

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

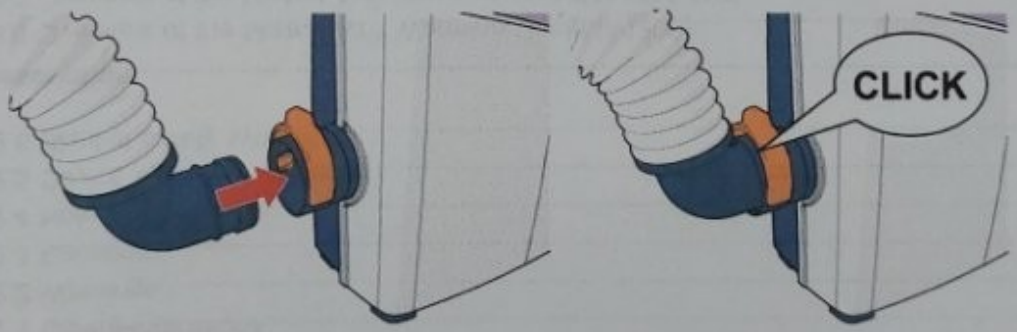
The device is intended to be used only by trained clinicians. Intended patient population: adults and pediatric patients.

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

S10

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.

Conform extras manual de utilizare pag. 31

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.

S11

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.

S3

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.

S2

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.

Conform ex-tras manual de utilizare pag. 32

7 Maintenance

Warning!

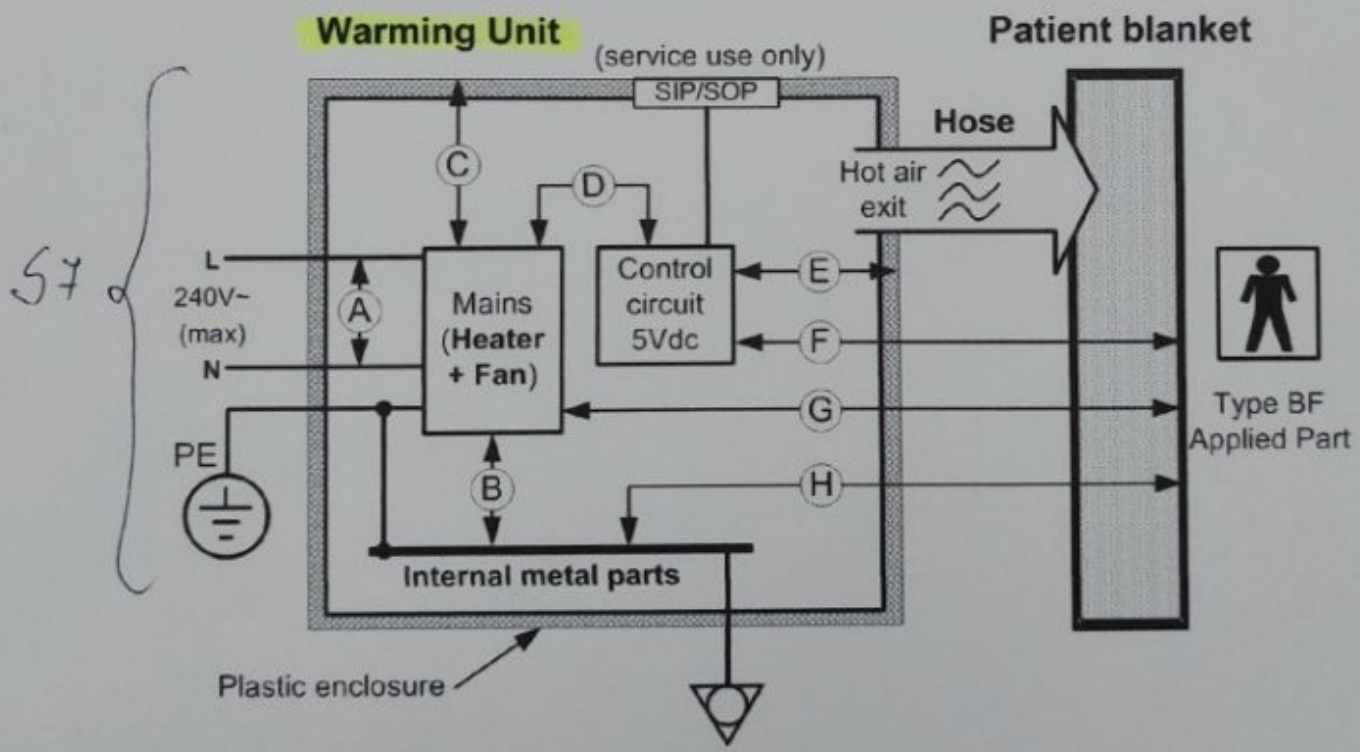
- Maintenance may only be performed by trained biomedical technicians or engineers. Both user groups must be trained by certified trainers from The 37Company.
- Preventive maintenance needs to be performed on an annual basis. Please refer to the Mistral-Air® technical manual for maintenance, repair and 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.



Conform extras manual de utilizare pag. 34

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 +/- 1.5°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	

54

Conform extras manual de utilizare pag 43

Accuracy of temperature at the end of the hose	± 2.5 °C (under all validated operating environmental conditions)
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)
High temperature safety limit	< 56°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

S3

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

Conform extras manual de utilizare pag. 44