

# TSC LIFE

## Technical Datasheet

# MISTRAL-AIR®



**Complete Forced Air  
Warming System,  
from Single-use Blankets  
to Warming Unit**

# MISTRAL-AIR® WARMING UNIT

<b>Description</b>	Mistral-Air® Warming Unit. Article numbers MA1200-EU/US & MA1200-QC-EU/US
<b>Indication</b>	The Mistral-Air® Warming System is a forced air warming system and comprises of a warming unit and a variety of blankets and suits.
<b>Intended use</b>	It is intended to raise and maintain patient temperature by means of surface warming.
<b>Composition</b>	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 or suit. The device may only be used with disposable Mistral-Air® blankets and suits that are single use only. The device is available in two models: MA1200 equipped with a fixed hose, and MA1200-QC equipped with a removable hose.
<b>Material</b>	SABIC CYCOLOY™ Resin CX2244ME
<b>Cleaning and disinfecting equipment</b>	Refer to the User Manual section 8.1 Cleaning and 8.2 Disinfection.
<b>Waste disposal</b>	According to hospital protocol (or local regulation) [Disposal Statement].
<b>Packaging</b>	Carton packaging box with label, dimensions 576 x 477 x 294 mm Weight: ± 7.1 kgs (MA1200-EU), ± 7.7 kgs (MA1200-US) gross including: Warming Unit, User Manual, Power Supply Cord and Hose clamp.
<b>Regulatory</b>	MDR 2017/745/ EU Class IIb & FDA classification Class II
<b>Recommended storage conditions</b>	Store the device and accessories according to the transport and storage recommendations according to the User Manual.
<b>Manufacturer</b>	The Surgical Company International B.V. Located in The Netherlands

**Warranty** - Subject to statutory limitations imposed by applicable law, Company warrants that the Units will be free from defects in material and workmanship for a period of two years from the date of shipment ready.

The User Manual Version INT/R778-EN/7-11/24 or newer is the source of this document and therefore, the ultimate technical source.

## General specifications

Article number	MA1200-EU	MA1200-US
<b>Rated voltage</b>	220-240 V~	100-125 V~
<b>Frequency</b>	50/60 Hz	50/60 Hz
<b>Device sound pressure</b>	48 dBA	51 dBA
<b>Average current</b>	3.2 A	6.1 A
<b>Peak current</b>	9.0 A	10.0 A
<b>Peak power</b>	1000 VA	1000 VA
<b>Average power at</b>	<b>43°C and t<sub>amb</sub> 22 +/- 1.5°C</b> 750 VA / 600 W	<b>100.4°F and t<sub>amb</sub> 71.6°F +/- 2.7°F</b> 800 VA / 610 W
<b>Fuses</b>	6.3AHF/250V~	10AHF/250V~
<b>Air flow rate at nominal voltages and ambient temperature (1.8 m / 71 in. hose)</b>	Up to 101 m³/h or 59 CFM (depending on orientation of the hose, supply voltage, type and drape of the blanket)	Up to 88 m³/h or 52 CFM, (depending on orientation of the hose, supply voltage, type and drape of the blanket)
<b>Air flow rate at nominal voltages and ambient temperature (1.8 m / 71 in. hose), low fan duty cycle</b>	Up to 91 m³/h or 53 CFM (depending on orientation of the hose, supply voltage, type and drape of the blanket)	Up to 79 m³/h or 47 CFM, (depending on orientation of the hose, supply voltage, type and drape of the blanket)

Article number	MA1200-EU	MA1200-US
	<b>EMDN</b> 36954 (circulating-air wholebody heating system control unit)	<b>GMDN</b> 36954 (circulating-air wholebody heating system control unit)
<b>Dimensions (l x w x h)</b>	16 cm x 35 cm x 40 cm	6.3 in x 13.78 in x 15.75 in
<b>Weight</b>	5.2 kg	11.46 pounds
<b>Hose length</b>	1.8 m (3 m hose optional)	71 in. (118 in. hose optional)
<b>Power supply cord length</b>	4.0m	157.5 in.
<b>Filtration</b>	HEPA H13 class filter, conform EN 1822-1:2019	
<b>Classification</b>	MDR 2017/745/ EU Class IIb	FDA classification Class II
<b>Classification IEC 60601-1</b>	Class I, Body Floating (BF)	
<b>Overvoltage category according to IEC 60664-1</b>	Category II	
<b>Classification IEC 60529</b>	IP23	
<b>Setpoint temperatures</b>	Ambient air, 32°C, 38°C and 43°C	Ambient air, 89.6°F, 100.4°F and 109.4°F
<b>Accuracy of temperature at the end of the hose</b>	± 2.5 °C (under all validated operating environmental conditions)	± 4.5°F (under all validated operating environmental conditions)
<b>Setpoint reached after</b>	Under 30 seconds	
<b>Low temperature limit</b>	10°C	50°F
<b>Maximum average contact surface temperature</b>	45.5°C (Compliant with IEC 80601-2-35)	113.9°F(Compliant with IEC 80601-2-35)
<b>High temperature safety limit</b>	< 56°C (Compliant with IEC 80601-2-35)	< 132.8°F (Compliant with IEC 80601-2-35)
<b>Auditory alarm signal sound pressure</b>	72 dB(A) measured in a hemisphere with a radius of 1m / 39.4 in. from the geometric center of the device generating auditory alarm signal	
<b>Applicable technical standards</b>	IEC 60601-1:2005+A1:2012+A2:2020, EN IEC 60601-35:2021	
<b>Expected lifetime device</b>	7 years	
<b>Expected lifetime hose</b>	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 EN IEC 60601-2-35.

#### Validated operating environmental specifications

Article number	MA1200-EU	MA1200-US
<b>Ambient temperature</b>	15°C to 30°C	59°F to 86°F
<b>Relative humidity</b>	30% to 75%	

#### Validated transport and storage specifications

Article number	MA1200-EU	MA1200-US
<b>Ambient temperature</b>	-20°C to 70°C	-4°F to 158°F
<b>Relative humidity</b>	10% to 90% (non-condensing)	
<b>Atmospheric pressure</b>	50 kPa to 106 kPa	7.25 psi. to 15.37 psi



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The use of our medical equipment is solely intended for the use of healthcare professionals. Healthcare professionals have the obligation to exercise their own professional clinical judgment when determining the suitability of a specific product for treating an individual patient. TSC Life does not provide medical advice and strongly advises healthcare professionals to undergo training on the usage of any specific product before using it. Healthcare professionals should consistently refer to the package insert, product label, and/or instructions for use, including guidelines for cleaning and sterilization (if applicable), before utilizing any product supplied by TSC Life. The information presented aims to display specific products and the extensive range of offerings from TSC Life. Availability of products may vary across markets due to regulatory and/or medical practices specific to each region. For inquiries regarding the availability of specific TSC Life products in your area, please reach out to your TSC Life representative.

**TSC Life**

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