GIMA

PROFESSIONAL MEDICAL PRODUCTS

AEROSOL MISTRAL
MISTRAL NEBULIZER
NÉBULISEUR MISTRAL
MISTRAL NEBULIZADOR
INALADOR MISTRAL
MISTRAL INHALATOR

REF **28102**

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Aerosol Mistral is a system for aerosol therapy, with 230V ~ / 50Hz power supply, intended for household use.
The appliance is designed for non-continuous use (Ton: 20 mins / Toff: 40 mins).
The medical device is designed to be easy to transport and use and is indicated for nebulizing bronchodilators and antibiotics. Made of plastic housing with high heat and electrical insulation in accordance with the European safety standards.

GENERAL INSTRUCTIONS

- CAREFULLY READ THE MANUAL BEFORE USE
- FOR DRUG INHALATION ALWAYS FOLLOW MEDICAL ADVICE
- DO NOT DISASSEMBLE THE APPLIANCE. FOR ANY INTERVENTION, CONTACT THE TECHNICAL SERVICE OF THE DISTRIBUTOR AND/OR GIMA's TECHNICAL SERVICE
- REMOVE THE APPLIANCE FROM THE TRANSPORT BAG BEFORE EACH USE

BASIC SAFETY STANDARDS

1. When opening the packaging, check the integrity of the appliance by paying particular attention to the presence of damage to plastic components which may disclose internal live parts of the appliance and to breakage and/or stripping of the power cable. **In this case, do not connect the plug to the socket. Carry out these operations before each use.**
2. Before connecting the appliance, always check that the electrical data indicated on the label and the type of plug used correspond with the data of the power network to which it is intended to be connected.
3. Do not leave the appliance plugged unnecessarily: disconnect the plug from the power network if not used.
4. Comply with the safety standards for electrical appliances. In particular:
   - Use only original accessories and components supplied by Gima S.p.A. in order to ensure utmost efficiency and security of the device.
   - Never immerse the appliance in water.
   - Place the appliance on flat and stable surfaces in order to avoid obstructing the cooling openings located on its sides.
   - Do not use the appliance in environments with the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
   - Do not use the appliance with anesthetic and respiratory equipment.
   - Avoid touching the appliance with wet hands.
   - The use of this appliance by children and/or people with disabilities shall be closely monitored by an adult with full mental capacity.
   - Disconnect the appliance from the power supply if not used.
   - Do not pull the power cable to disconnect the plug. Grab the plug with the fingers to pull it out from the power network.
   - Store and use the appliance in environments protected by atmospheric agents and away from heat sources. After each use, it is recommended to store the device inside its box away from dust and direct sunlight.
   - In general, it is not recommended to use simple or multiple adapters and/or extension cables. If their use is essential, it is necessary to use devices in compliance with the safety standards, paying attention not to exceed the maximum power limits indicated

on the adapters and on the extension cables.

5. For repair works contact only Gima's technical service or a technical center authorized by the manufacturer. The device requires the use of original spare parts. Failure to comply with the above may compromise the safety of the appliance.
6. **This appliance shall be solely intended for the use which was designed for and according to the instructions of this manual. Therefore, it shall be used as aerosol therapy system.** Any other use is improper and therefore hazardous; the manufacturer shall not be deemed responsible for damage caused by an improper use or if the appliance is used in electrical installations that do not comply with the safety regulations in force.
7. The medical device requires specific precautions in terms of electromagnetic compatibility and shall be installed and used according to the instructions provided along with the accompanying documents: the Mistral device shall be installed and used away from portable and mobile RF communication devices (mobile phones, transceivers, etc.) which may affect the appliance.
8. Some components of the appliance are of small size and might be swallowed by children; keep the device out of reach of children.
9. Keep the accessories out of reach of children. Children and dependents shall always use the medical device under the close supervision of an adult with full mental capacity. Keep the ampoule out of reach of children under 36 months as it contains small parts which be may swallowed.
   Do not leave the device unattended in areas accessible to minors and / or people with disabilities.
10. Do not leave the device unattended in areas accessible to minors and / or people with limited mental capacity as they may be strangled with the air hose.
11. The patient can come into contact with the medical device through the nebulizer / masks / mouthpiece and /or nosepiece. These components comply with the requirements of ISO 10993-1, therefore neither allergic reactions nor skin irritation can occur.
12. The product and its parts are biocompatible in accordance with the requirements of EN 60601-1.
13. The device is easy to use. No additional precautions other than the instructions of this manual of use are required.
14. **WARNING**: Do not alter this appliance without the authorization of Gima S.p.A..
    No electrical and / or mechanical part which the device consists of has been designed to be repaired by the user.
    Failure to do so can compromise the safety of the appliance.
15. The use of the medical device in environmental conditions other than those illustrated in this manual may jeopardize the safety and the parameters of the appliance.
16. The materials used for the contact with drugs are thermoplastic polymers with high chemical stability and resistance.
    Such materials have been tested with commonly-used medications (Salbutamol, Beclomethasone Dipropionate, Acetylcysteine, Budesonide, Ambroxol) and no interaction has been reported. Nonetheless, given the variety and the ongoing evolution of the medicines used, potential interactions cannot be ruled out. Therefore, it is recommended to:
    - Use up the drug as quickly as possible after its opening.
    - Always avoid prolonged contact of the drug with the container. Clean the container immediately after its use.
    - In the event of anomalous situations (e.g. softening or cracks) of the container, do not

introduce any solution and do not inhale. Contact the technical service, specifying the methods of use and the type of drug used.

17. Remember to:
    - use this appliance only with medicines prescribed by your doctor;
    - perform the treatment by using only the accessory instructed by your doctor according to the disease.

⚠ Under certain fault conditions, the packaging temperature can raise and there might be risk of burns if the user comes into contact with such parts. In any event, the temperatures do not exceed the limit of 105°C [221°F] (ref. Interpretation Sheet IEC 60601-1).

⚠ Gima S.p.A. cannot be held liable for accidental or indirect damage resulting from alterations of the device, repairs and/or unauthorized technical interventions, or damage to any of its part due to accident, misuse and/or abuse.

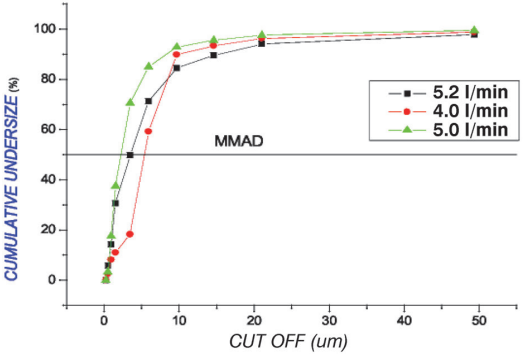
⚠ Any unauthorized intervention on the device, even the slightest one, will immediately invalidate the warranty and does not ensure the compliance with the technical and safety requirements provided by Directive MDD 93/42/EEC (and subsequent amendments) and by the related reference standards.

PRODUCT SPECIFICATIONS

TYPE (Directive 93/42/EEC)	Medical device Class IIa
MODEL	Mistral
POWER SUPPLY	230V~ / 50Hz
ABSORBED POWER	170 VA
FUSE	F 1 x 2A L 250V
MAXIMUM PRESSURE	250 kPa (2.5 Bar)
MAXIMUM FLOW (in the compressor)	14 L/min
OPERATING PRESSURE	110 kPa (1.10 Bar)
OPERATIONAL FLOW	5.0 L/min at 110 kPa
ATOMIZATION	0.35 ml/min (with 4ml solution NaCl 0.9%)
MMAD (measured in accordance with EN 13544-1)	2.44
GSD	2.87
WEIGHT	1.10 Kg
SIZE	130 (L) x 89 (H) x 146 (P) mm
MAXIMUM NOISE LEVEL	60 dB (A)
FUNCTIONING	Ton: 20min / Toff: 40min
MINIMUM NEBULIZER VOLUME LEVEL	2ml
MAXIMUM NEBULIZER VOLUME LEVEL	6ml

OPERATING CONDITIONS	Room temperature: 5 ÷ 35°C Percentage of humidity in the environment: 15 ÷ 93% RH Atmospheric pressure: 700 ÷ 1060 hPa
STORAGE AND TRANSPORT CONDITIONS	Room temperature: -25 ÷ 70°C Percentage of humidity in the environment: 0 ÷ 93% RH Atmospheric pressure: 500 ÷ 1060 hPa

Copy of the EC Declaration of conformity can be requested to Gima S.p.A. - Via Marconi, 1 - 20060 – Gessate, Milan (Italy)



MMAD = Mass Median Aerodynamic Diameter
GSD = Geometric Standard Deviation

NB: The measures and the curves are not valid in the event of medications supplied in high viscosity suspension.

CLEANING OF THE APPLIANCE

The cleaning of the device shall be carried out with a soft and dry cloth and with non-abrasive detergents. Do not use excessively wet cloths as the contact of liquids with the electrical parts of the appliance may cause malfunctions or may be hazardous.

⚠ **While cleaning the device, make sure that no liquids get inside the appliance and that the power outlet is disconnected.**
Wait for the device to dry off before storing or using it again.

MAINTENANCE

The Mistral device does not have any part that requires maintenance and/or lubrication.
Nonetheless, it is necessary to carry out some checks to verify the function and security of the appliance before each use. Remove the appliance from the box and **always check** that there is no visible damage; particular attention should be given to any cracks in plastics which may leave some electrical components exposed. Check also the integrity of the power cable which might have been damaged during the previous use.
Then connect the cable to the power network and switch it on. Close the compression cap with one finger and check that there are no disturbing noises which may be evidence of malfunction.
Check that the nebulizer has not suffered any breakage during the previous use (it was stored inappropriately or has suffered impacts). The appliance is protected by a protection fuse **(F 2A L 250V)** not accessible from outside. Therefore, contact the technical staff authorized by the manufacturer for its replacement.

Type of defect	Cause	Corrective action
1. Poor atomization.	Clogged ampoule.	Clean and disinfect the ampoule as set out in the manual.
2. Poor atomization.	Clogged ampoule.	If the washing had no positive outcome, replace the ampoule.
3. Lack of atomization.	Nozzle stuck.	Press hard the nozzle (cylindrical immersion tube) placed inside the polycarbonate ampoule bottom with a finger.
4. Slow atomization.	Excessive oily drug.	Dilute the drug with saline.
5. Noisy device.	Prolonged use.	Contact the reseller or Gima's technical service.
6. The Device does not work.	Defective power cable Broken and/or absent power source.	Replace the power cable. Check the power source and voltage.
Defects 1 - 2 - 3 - 4 - 5 - 6	None of the corrective actions has been effective	Contact the reseller or Gima's technical service.

If the appliance still does not nebulize after having checked the above mentioned conditions, it is recommended to contact the reseller or Gima's technical service.

⚠ **BEFORE CARRYING OUT ANY CHECKS IN THE EVENT OF ANOMALIES OR MALFUNCTIONS, CONTACT GIMA'S TECHNICAL SERVICE. THE MANUFACTURER OFFERS NO GUARANTEE FOR THE APPLIANCES WHICH HAVE ASSESSED AS TAMPERED AFTER THE CHECKS CARRIED OUT BY THE TECHNICAL SERVICE.**

CLEANING AND WASHING OF ACCESSORIES

Before each use and / or after the cleaning operations, check the integrity of all accessories supplied with the device. Turn off the device before each cleaning operation and disconnect the power cable from the socket.

PREPARATION

1. Pull out the air hose from the nebulizer leaving it plugged to the air outlet pipe of the device.
2. Rotate the upper part of the nebulizer anticlockwise.
3. Disconnect the internal pisper at the bottom of the nebulizer with finger force.

CLEANING

Clean all the components of the nebulizer (except the air hose) before and after each use by choosing one of the methods described below.

Method 1: Thoroughly clean the components for 5 minutes by using hot drinking tap water (around 40°C – 104°F) and neutral soap.
Method 2: Clean the components (except the air hose) by immersion in a solution of 60% of water and 40% of white vinegar. At the end of the operation, rinse with plenty of hot drinking water (around 40°C – 104°F).

At the end of the cleaning operations, rinse thoroughly by removing excess water and allow to air-dry in a clean spot.

DO NOT BOIL OR AUTOCLAVE THE AIR HOSE AND THE MASKS
DO NOT WASH THE ACCESSORIES IN THE DISH WASHER

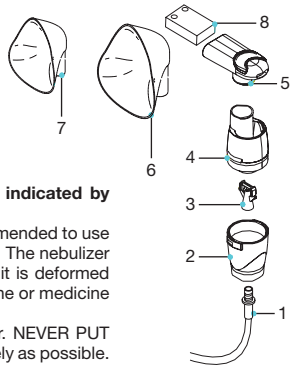
WASHING

Where diseases with risk of infection and microbial contamination are present, the end user shall carry out the washing operations properly. The washing procedure can be performed only if the components have been previously cleaned (see cleaning section).
For the washing procedure, the following operations shall be carried out:
- Fill a container of suitable size to hold every individual component with drinking water and disinfectant (hypochlorite solution easily available in pharmacies) by complying with the proportions indicated on the disinfectant packaging.
- The immersion time in the solution is indicated on the packaging of the hypochlorite solution according to the concentration chosen for the preparation of the solution.
- Rinse with plenty of warm drinking water until removing any trace of solution, dry and store in a dry and dust-free place.
- Dispose the solution used according to the instructions provided by the manufacturer of the disinfectant.

SUPPLIED ACCESSORIES

ACCESSORIES
HI-FLO accessories kit
(HI-FLO ampoule, Adult Mask, Children Mask,
Air hose, Mouthpiece and Nosepiece)
Air filter (+2 spare parts)
Transport bag

1 – Air hose
2 – Ampoule lower part
3 – Nebulizer Nozzle
4 – Ampoule upper part
5 – Mouthpiece
6 – Adult Mask
7 – Children Mask
8 – Nosepiece (non-invasive)



Use only the original accessories intended and indicated by the Manufacturer.
NEBULIZER: For each individual patient, it is recommended to use the nebulizer for 6 months or up to 120 applications. The nebulizer shall be replaced after a long period of inactivity, if it is deformed or broken or if the nozzle is clogged by a dry medicine or medicine in powder form, etc.
Use the Nosepiece only if prescribed by the doctor. NEVER PUT the bifurcations into the nose but place them as closely as possible.

Where diseases with risk of infection and microbial contamination are present, it is recommended to use the accessories and the spray ampoule individually (always seek medical advice).

The device is equipped with a filter which removes any impurities of the air inhaled from the compressor. Check the conditions of the filter on a periodical basis or if the device is no longer efficient. If the filter is too dirty, it shall be replaced.

AIR FILTER REPLACEMENT: The air filter shall be replaced every 25 hours of operation or when it is too dirty. For the replacement, lift the filter from its seat and replace it with a new one. The masks and the air hose shall be replaced when there is evidence of deterioration of their materials.

Expected useful life: More than 1500 operating hours (or 5 years) in accordance with the standard test and operating conditions. Expected shelf life: up to 5 years from the date of manufacture.

INSTRUCTIONS FOR USE

- Check the device before each use in order to detect malfunctions and / or damage due to transport and / or storage.
- When inhaling, the patient must sit upright in a relaxed position at a table and not on an armchair to avoid compressing the airways and thus compromising the effectiveness of the treatment.
- It is recommended not hold the device in the hands during the therapy and/or avoid prolonged contacts with the casing of the appliance.

WARNING: Place the appliance on flat and stable surfaces in order to avoid obstructing the cooling openings located on its sides.

1. Remove the power cable and insert the plug into the socket, making sure that the power network corresponds to the data indicated on the appliance plate. It is recommended to completely unroll the power cable to avoid dangerous overheating. In the event of damage to the power cable, contact Gima's technical service for the replacement.
2. Open the nebulizer by unscrewing the cover anticlockwise.
3. Pour the medicine prescribed by your doctor into the nebulizer.
4. Make sure that the nozzle is properly inserted into the air conduction cone located inside the nebulizer.
5. Close the nebulizer again by screwing the cover clockwise, making sure it is screwed tight.
6. Connect one air pipe end to the air outlet pipe and the other end to the specific outlet at the bottom of the nebulizer.
7. Make sure that the air filter is present.
8. Connect the desired accessory to the nebulizer: children or adult mask, mouthpiece or nosepiece.
9. Set the switch to I and proceed with the atomization.
10. At the end of the atomization, set the switch to O and remove the plug from the socket.
11. Wash the nebulizer and its accessories as specified in the "cleaning" section.
12. Store the accessories into the packaging.

Always use the nebulizer facing upwards in order to prevent any substances and / or the medicine from leaking out of the nebulizer during normal use.
In the event of overfilling, empty the ampoule, clean it and repeat the operation. After having poured the medicine, screw the top again to the bottom and repeat the operations as specified in section "instructions for use".

WARNING: The power cable plug is the separation component from the power network; even though the device has the power on / power off switch, the power plug shall be kept accessible once the appliance is in use in order to allow an additional method of disconnection from the power network.

⚠ **NEVER INHALE IN HORIZONTAL POSITION.**
DO NOT TILT THE NEBULIZER OVER 60°.

ELECTROMAGNETIC INTERFERENCE RISKS AND POTENTIAL CORRECTIVE MEASURES

This section contains information on the device compliance with EN 60601-1-2 (2015). Mistral is a medical device suitable for household use.
Group ranking and CISPR category: group 1, category B

⚠ Avoid using this device close to or overlapped on other appliances because it could not work properly. If such use is necessary and inevitable, special precautions shall be adopted so that the electromedical device works properly in its standard configuration (for instance, by steadily and visually checking the absence of anomalies or malfunctions).

⚠ The use of accessories, transducers and cables other those supplied by the manu-

facturer of the appliance may cause an increase in the electromagnetic emissions and/or a reduction in the electromagnetic immunity of the device, thus causing a malfunction.

⚠ Portable and mobile radio communication devices (mobile phones, transceivers, including peripheral devices like antennas cables and external antennas, etc.) may affect the medical device and should not be used close to (at more than 30cm from any part of the device, including cables), adjacent to or overlapped on the medical device. If such use is necessary and inevitable, special precautions shall be adopted so that the electromedical device works properly in its standard configuration (for instance, by steadily and visually checking the absence of anomalies or malfunctions).

The tables below provide information on the EMC characteristics (Electromagnetic Compatibility) of this electromedical appliance.

Guide and declaration of the manufacturer – Electromagnetic Emissions		
The Mistral aerosol can be used in the following electromagnetic environment. The Customer and/or the user of the Mistral aerosol shall make sure that the appliance is used in such environment.		
Emission test	**Conformity**	**Guide to the electromagnetic environment**
Radiated emissions / Conductions CISPR11	Group 1	The Mistral aerosol uses RF energy only for Internal function. Therefore, its RF emissions are very low and do not cause any interference with other nearby electronic applianc-es.
Radiated emissions / Conductions CISPR11	Class [B]	The Mistral aerosol is designed for use in any environment, including households and those directly connected to the public power distribution grid which supplies power to environments intended for domestic use.
Harmonic currents EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker EN 61000-3-3	Compliant	

Guide and declaration of the manufacturer – Electromagnetic Immunity			
The Mistral aerosol can be used in the following electromagnetic environment. The Customer and/or the user of the Mistral aerosol shall make sure that the appliance is used in such environment.			
Immunity test	**Standard of proof**	**Level of conformity**	**Guide to the electromagnetic environment**
Electrostatic discharge (ESD) EN 61000-4-2	± 8kV contact ± 15kV air	The appliance does not alter its status	Floors should be in wood, cement or ceramics. If floors are covered by synthetic material, the relative humidity should be at least 30%.
Fast transient / burst EN 61000-4-4	± 2kV power supply ± 1kV signal cables	The appliance does not alter its status	The power supply should be that of a typical commercial premise or hospital.

Surge EN 61000-4-5	± 0.5kV e± 1kV differential mode	The appliance does not alter its status	The power supply should be that of a typical commercial premise or hospital.
Voltage dips, short outages and voltage variations EN 61000-4-11	5% U_T (>95% dip in U_T) per 0.5 cycle 40% U_T (60% dip in U_T) per 5 cycles 70% U_T (30% dip in U_T) per 25 cycles <5% U_T (>95% dip in U_T) per 5 s	--	The power supply should be that of a typical commercial premise or hospital. If the user of the Mistral aerosol requires the appliance to work continuously, it is recommended to use it with an uninterruptible power supply.
Network frequency magnetic field EN 61000-4-8	30 A/m	The appliance does not alter its status	The power supply should be that of a typical commercial premise or hospital.
Note: U_T is the value of the supply voltage			

Guide and declaration of the manufacturer – Electromagnetic Immunity			
The Mistral aerosol can be used in the following electromagnetic environment. The Customer and/or the user of the Mistral aerosol shall make sure that the appliance is used in such environment.			
Immunity test	**Level set out by EN 60601-1-2**	**Level of conformity**	**Electromagnetic Environment - Guide**
Conducted immunities EN 61000-4-6	3Vrms 150kHz to 80MHz (for non-life-supporting appliances)	V_1 = 3 V rms	Portable and mobile RF communication devices should be used no closer than the separation distance from any part of the Mistral device, including cables, calculated from the equation applicable to the frequency of the transmitter.
Radiated immunity EN 61000-4-3	10 V/m 80MHz to 2.7GHz (for non-life-equipment appliances)	E_1 = 10 V / m	**Recommended separation distances** $d = [3.5 / V_1] \sqrt{P}$ $d = [12 / E_1] \sqrt{P}$ 80MHz to 800MHz $d = [23 / E_1] \sqrt{P}$ 800MHz to 2,7GHz P is the maximum rated output power of the transmitter in Watt (W) according to the manufacturer of the transmitter and d is the recommended separation distance calculated in meters (m). The field strengths from fixed RF transmitters, as established in an electromagnetic survey of the site[a], could be less than the level of conformity of each frequency range[b].

			It is possible to check the interference close to the appliances labelled with the following symbol: 

Note 1: At 80 MHz and 800 MHz the highest frequency range applies.
Note 2: These guidelines could not apply to all conditions. The electromagnetic propagation is affected by the absorption and reflection of premises, objects and individuals.

a. The field strengths for fixed transmitters like base stations of radiotelephones (mobiles and cordless) and terrestrial mobile radio networks, amateur radio appliances, AM and FM radio transmitters and TV transmitters cannot be theoretically and accurately predicted. In order to determine an electromagnetic environment caused by fixed RF transmitters, an electromagnetic survey of the site should be taken into account. If the field strength measured in the place where the Mistral appliance is used exceeds the applicable level of conformity hereinabove, the normal operation of the appliance should be kept under watch. If abnormal performances are noted, additional measures could be necessary, such as a different direction or positioning of the appliance.
b. The field strength on a frequency range between 150 kHz and 80 MHz should be less than 10 V/m.

Recommended separation distances between portable and mobile radio communication appliances and the monitor

The Mistral aerosol is designed to operate in an electromagnetic environment in which the RF radiated interferences are kept under control. The customer or the user of the Mistral appliance can contribute to prevent electromagnetic interferences by ensuring a minimum distance between portable and mobile RF communication devices (transmitters) and the Mistral appliance as recommended below, according to the maximum rated output power of the radio communication devices.

Maximum rated output power of the transmitter W	**Separation distance at transmitter frequency m**		
	150KHz to 80MHz $d = [3.5 / V_1] \sqrt{P}$	80MHz to 800MHz $d = [12 / E_1] \sqrt{P}$	800MHz to 2,7GHz $d = [23 / E_1] \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

The recommended separation distance d in meters (m) for transmitters with maximum rated output power not specified above can be calculated from the equation applicable to the frequency of the transmitter, in which P is the maximum rated output power of the transmitter in Watt (W) according to the manufacturer of the transmitter.
Note 1: At 80 MHz and 800 MHz the separation distance for the highest frequency range applies.
Note 2: These guidelines could not apply to all conditions. The electromagnetic propagation is affected by the absorption and reflection of premises, objects and individuals.

SYMBOLS

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
REF	Product code	LOT	Lot number
CE	Medical Device complies with Directive 93/42/EEC	SN	Serial number
	WEEE disposal		Type BF applied part
	Class II applied		Temperature limit
	Humidity limit		Atmospheric pressure limit

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.