User Manual
Piston compressor Nebulizer

Serial number: REFJLN-S0XA
Version: A/3.1
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CE
2862

Read the instructions carefully before using the device

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1 Description and Intended purpose

Dear Client,

First of all, we wish to thank you for choosing our products and congratulate you on your choice of JLN-S0xA series piston compressor nebulizers, which are easy-to-use and extremely reliable. They are a kind of compact medical devices designed to efficiently convert the medication suspension or high concentration medicine solutions into an aerosol of microscopic droplets and deliver them into the bronchus and lungs.

The user manual is suitable for models of JLN-S01A, JLN-S02A, JLN-S03A, JLN-S04A, JLN-S05A, JLN-S06A, which have the same intended purpose and technical specifications, only the shapes of enclosures are different.

1.1 Intended purpose

a) Intended purpose

It is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. The device is for pediatric and adult population, and it should be used under the supervision of a licensed physician and/or a respiratory therapist.

b) Medical condition

- The device should be used under the supervision of a licensed physician and/or a respiratory therapist.
- Child/Adult patient with mild or moderate or severe asthma and COPD, as well as other respiratory infections or diseases, may use the device for drug nebulization.

2 Important safeguards

Note: Please read this instruction manual thoroughly before using the product. The following basic precautions are needed when using an electrical product:

Caution: Failure to read and observe all precautions could result in personal injury or equipment damage.

2.1 Product cautions:

a) Contraindication and side-effect

For the portable piston compressor and its accessory kits, there is not contraindication and side-effects. However, check in the medicine package leaflet for any contraindications for use with common aerosol therapy systems; or ask your physicians for the information about it.

b) To avoid electrical shock:

- Do not connect the power adaptor terminal by using wire or other metallic conductors.
- Do not use the compressor (main unit) or power adaptor while they are wet.
- Keep the unit away from water.
- Do not use or store the device in humid locations, such as a bathroom. Use the device within the operating temperature and humidity.
- Use only the power adaptor provided by Homed for this device. Use of any other power adaptor may damage the device.
- Do not immerse the power adaptor or the unit in liquid.
- Do not use while bathing.
- Do not reach for a unit that has fallen into water - immediately unplug the unit.
- Do not overload power outlets. Plug the power adaptor into the appropriate voltage outlet.

c) Never operate the unit if it has any damaged parts (including power cord), if it has been dropped or

submersed in water. Promptly send it to a service center for examination and repair.

d) The unit should not be used where flammable gas, oxygen or aerosol spray products are being used.

e) Disconnect the unit from the electrical outlet before cleaning, filling and after each use.

2.2 Operating Cautions:

a) Connect this product to an appropriate voltage outlet for your model.

b) Never operate it if this unit has a damaged cord or plug, if it has been dropped, or in any way, into water, if it does not work properly. Return it to a service center for repair.

c) If any abnormality occurs, discontinue use immediately until the unit has been examined and repaired.

d) If you feel anything unusual during use, stop using the device immediately and consult your physician.

e) Do not cover the compressor with a blanket, towel, or any other type of cover during use. This could result in the compressor overheating or malfunctioning.

f) Always unplug the product immediately after use.

g) Never block the air openings of the main unit or place it where the air openings may be obstructed.

h) The compressor is not waterproof. If liquid spills on these parts, immediately unplug the power cord and wipe off the liquid with gauze or other soft absorbent material.

i) Do not use a cellular phone near the device. It may result in an operational failure.

j) Do not use extension cords. Plug the power adapter directly into the electrical outlet.

k) For type, dose, and regime of medication follow the instructions of your licensed physician and/or respiratory therapist.

l) Do not add more than 8ml of medication to the medication cup.

m) Do not use the device if the air tube is bent.

n) Clean and disinfect the nebulizer, air tube, mouthpiece or masks before using them for the first time after purchase.

o) Provide close supervision when this device is used by, on, or near infants, children or compromised individuals.

p) Make sure the air filter is clean. If the air filter has changed color or has been used on average for more than 30 days, replace it with a new one.

q) Make sure the air tube is correctly connected to the compressor and the nebulizer. Air may leak from the air tube during use if not securely connected.

r) Use only Homed authorized parts and accessories. Parts and accessories not approved for use with the device do not perform the expected specification or it may damage the unit.

s) To avoid the medication residue on the face. After nebulization, be sure to wipe the face after removing the optional masks.

t) Do not use the device where the device may be exposed to flammable gas or vapors.

u) Using a solution, suspension, or emulsion different from that recommended by the manufacturer, in particular, a suspension and/or high-viscosity solution, can alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), aerosol output, and/or aerosol output rate, which can then be different from those disclosed by the manufacturer.

v) The nebulizer and other accessories are designed for single-patient reuse, do not reuse them among different people to avoid cross-contamination.

w) The nebulizing system is not suitable for use in an aesthetic breathing system or a ventilator breathing system.

2.3 Storage Cautions:

a) Do not store the unit under direct sunlight, high temperature or humidity. Store the device within the

storage temperature and humidity.

b) Keep the unit out of reach of small children.

c) Always keep the unit unplugged while not in use.

d) Store the device and the components in a clean and safe place.

e) Do not wrap the power cord around the compressor (main unit).

2.4 Cleaning Cautions:

a) Do not immerse the unit in water. It may damage the unit.

b) Disconnect the unit from the electrical outlet before cleaning.

c) Clean all necessary parts after each use as instructed in this guidebook.

3 Device information and Content information

3.1 Components listing

Your JLN-S0xA series nebulizer comes with the following components:

a) Main Unit and parts

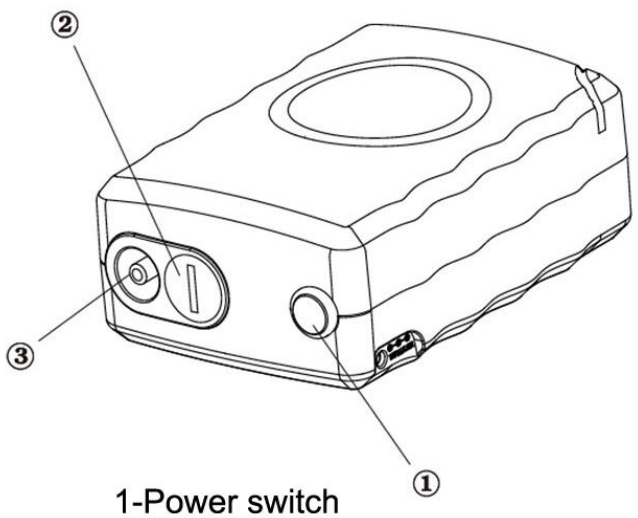
- 1 compressor;
- 1 user Manual
- 5 air Filters
- 1 AC power adaptor

b) Accessories

- 2 nebulizers
- 1 air tube
- 1 adult/big mask
- 1 child/small mask
- 1 mouthpiece

Note: please purchase and use the accessories manufactured by HOMED, which comply with EN ISO 27427 and have CE marking.

3.2 Main Unit and Component



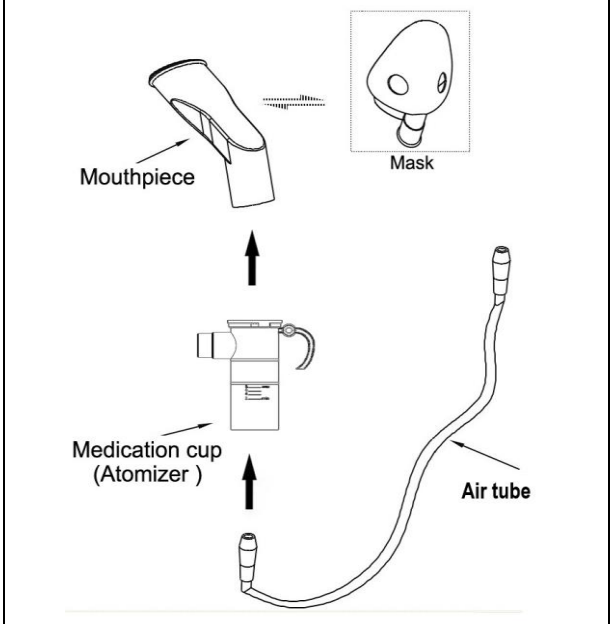


Figure 1-Main Unit	Figure 2-Component (nebulizer parts)

Statement: The parts in table above are required for correct function and that they have to be in compliance with this European Standard.

3.3 Handling

The shipping container has been designed to assure protection of this device, if the device is to be reshipped by common carrier, it should be packed in the same carton.

3.4 Information of power adaptor

Input: a.c. 100-240V 50/60HZ, 1.0A max

Output: d.c. 12V, 1.25A

4 Description of symbols

Symbol	Explanation
	Manufacturer
	Authorised representative in the European Community
	Lot Number
	Serial Number
	Date of Manufacture
	Caution
	Waste Electrical and Electronic Equipment (WEEE)
	The CE conformity marking
	Refer to instruction manual/ booklet
	Type BF applied part
	Class II equipment
	Medical device

5 Operating Instructions

Firstly: Ensure the device and all the accessories are completely clean, please follow instructions below step-by-step:

- Place the device on a level and secure platform (ex. an upright table) with easy access to an electrical

socket.

- Unwind the power supply cord by cutting the plastic tie that holds it folded.
- Take the flexible tubing and attach one end to the device's air outlet and the other end to the bottom of the nebulizer.
- Unscrew the upper section of the nebulizer by turning it anti-clockwise.
- Put the medication to be nebulized into the nebulizer, measuring it according to the scale marked on the side of the nebulizer.
- Replace the upper section of the nebulizer, and secure it by turning it clockwise.
- According to the type of treatment you wish to carry out and the method you choose, attach either the face mask or the mouthpiece to the upper section of the nebulizer.

Secondly: Your device is now ready for use to carry out aerosol therapy treatment.

- Plug your device into a socket.
- Press the switch of the device to position 1.
- Start the treatment and carry on for as long as you can still see the “mist” produced by the nebulisation of the medication performed by the device.

Note: The presence of a small amount (about 0.4 ml or less) of medication in the nebulizer at the end of each treatment is absolutely normal. This amount, called residue volume, cannot be nebulized.

Thirdly: at the end of each treatment:

- Turn off the device by pressing its switch to position 0.
- Unplug the device from the power socket.
- Wind up the power supply cord and place it sideways inside the appropriate panel (exactly as it was before use).
- Detach the face mask (or mouthpiece) from the nebulizer.
- Detach the air tube from both the nebulizer and the device's air outlet.
- Wipe the face mask (or mouthpiece) and the nebulizer clean according to the instructions in the following paragraph.

To ensure maximum efficiency and life-span of your device

While your nebulizer does not need any special care, you should:

- Avoid knocking it or dropping it;
- Store it in a suitable place, away from excessive heat, direct sunlight, damp and dust;
- Clean it with a slightly damp cloth and/or mild detergent (do not use benzine, thinners or similar substances), and dry it carefully and thoroughly;
- Never soak the device in water;
- After each treatment, it is advisable to clean the used accessories in the correct way.
- All you need to do is to dismantle the mask or mouthpiece from the nebulizer and wash it thoroughly in running water. Should you wish to disinfect these accessories, you may use a cold solution as advised by your doctor.

Note: Each time clean/disinfect the nebulizer parts, please reassemble them according to the order in Figure 2.

Note: The compressor motor has a thermal protector which will shut off the unit before the unit is overheated. When the thermal protector shuts the unit off, please:

- Switch off the unit.

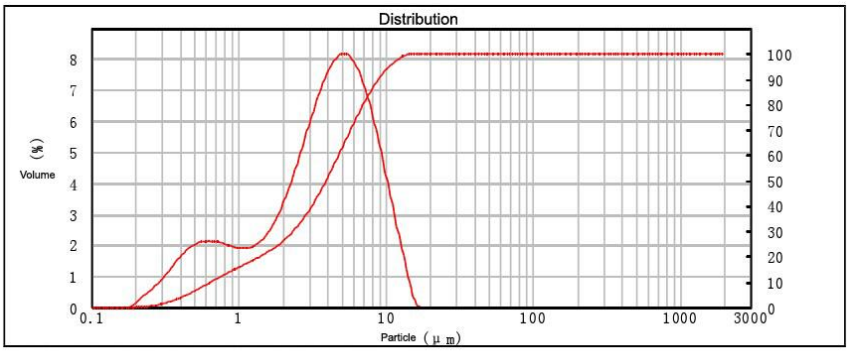
- Unplug the unit from the electrical outlet.
- Wait 30 minutes for the motor to cool down before another treatment. Make sure the air outlet is not obstructed.
- When treatment finishes, shut off the compressor and unplug the adaptor from the electrical outlet.

Statement: Performance information provided by the manufacturer in accordance with this European Standard may not apply to drugs supplied in suspension or high viscosity form. In such cases, information should be sought from the drug supplier or follow your doctor's prescription.

6 Particle distribution diagram

6.1 Particle distribution diagram

The following table is particle distribution diagram, the test particles are respective NaCl.



Particle distribution diagram of NaCl

6.2 Particulate distribution data

Testing solution: Albuterol 0.1% (M/V) concentration in 0.9 % sodium chloride solution.

Testing volumes: 8ml (capacity of the nebulizer)

Item		Adult	Pediatric
Percentage of particulate distribution (%)	>5 μm	38.07%	40.63%
	>2 μm and <5 μm	49.23%	46.73%
	<2 μm	13.03%	12.63%
	<1 μm	3.13%	3.47%
MMAD		4.51μm	4.67μm
GSD		1.87	1.81
Respirable fraction (>0.5 μm and <5 μm) (%)		61.27%	58.57%
Aerosol output		58.06%	57.49%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>72.50%	>72.50%
Residual volume		<0.97ml	<0.97ml

Note: Nebulizer performance is based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric populations.

7 Cleaning and Disinfection

7.1 Main unit

7.1.1 Cleaning the compressor

a) Remove the air tube from the compressor.
b) Clean the casing of the main unit by using a soft cloth moistened with water or a mild detergent.
c) Do not use abrasive cleaners.
d) Dry the casing immediately by using a soft, dry and clean cloth.

7.1.2 Changing the Air Filter

a) Do not use cotton or any other materials. Do not wash or clean the filter. Use only filters supplied by HOMED. And do not operate without a filter.
b) Change the filter every 30 days or when the filter turns gray.
c) Before inserting the new air filter make sure the air filter is clean and free of dust. Do not operate the device without the air filter. Use only the Omron air filter designed for this device.
d) Changing procedure:
   i) Pull the air filter cover to remove from the back side of the compressor.
   ii) Remove the dirty air filter.
   iii) Replace the used filter with a new one.
   iv) Put the air filter cover back on the compressor.

7.2 Accessories

Please follow the cleaning and disinfection instructions of the Accessories (including mouthpiece, mask, air tube, and nebulizer etc.) if they are reusable; It is suggested that the accessories are disinfected after each treatment of the day.

If the accessories are disposable, please handle them by following the local regulations of medical waste after use.

8 Technical specifications

AC power adaptor	a.c. 100-240V 50/60Hz; d.c. 12V, 1.25A
Flow	≥6L/min
Medication Capacity	2-8ml
Particle Size	0.5-6 μM
Working pressure	50 kPa -150 kPa
Water protection	IPX0
Aerosol output rate	≧0.15ml/min
Noise	≤60dB
Working Environment	10℃-40℃; 15%-90%RH; 700 hPa -1060hPa
Storage & transport environment	-25℃-55℃; 10%-95%RH (non-condensing); 500 hPa -1060hPa
Standard requirements	Comply with EN 60601-1-2, EN60601-1 and EN60601-1-11
Weight and Size	

Model	Weight / Size	Model	Weight / Size
JLN-S01A	1.0Kg /136mm*96mm*57.5mm	JLN-S04A	1.0Kg /136mm*96mm*57.5mm
JLN-S02A	1.0Kg /136mm*96mm*57.5mm	JLN-S05A	1.0Kg /136mm*96mm*57.5mm
JLN-S03A	1.0Kg /136mm*96mm*57.5mm	JLN-S06A	1.0Kg /136mm*96mm*57.5mm

9 EMC information

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and the device can be affected by portable and mobile RF communications equipment.

EMC Warning:

1) The portable (ultrasonic) nebulizer is intended to be used in the hospital and family setting except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

2) Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.

3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.

4) Caution: Use of this equipment 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.

5) Use of accessories other than those specified or provided by the manufacturer of this the nebulizer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

6) Do not expose the device to RFID systems.

Essential performance of the compressor nebulizer:

Model Number	JLN-S01A
Power on/off	Normally turn on and turn off
Flow	≥6L/min

Table 9.1 Electromagnetic emissions

JLN-S0xA series piston compressor nebulizers are intended for use in the electromagnetic environment specified below; The customer or the user should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	JLN-S0xA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies
Harmonic emissions	Complies	

IEC 61000-3-2		buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 9.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
JLN-S0xA is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8V Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0% UT; 1 cycle 0 degree 70% UT (30% dip in UT) for 25 cycle single phase at 0 degree 0% UT; 250 cycle	0% UT; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0% UT; 1 cycle 0 degree 70% UT (30% dip in UT) for 25 cycle single phase at 0 degree 0% UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the JLN-2305AS be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity

JLN-S0xA is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 VRMS 150kHz to 80MHz 6Vrms in ISM bands between 150kHz to 80MHz 80%AM at 1kHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of JLN-S0xA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz 80%AM at 1kHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, 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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which JLN-S0xA is used exceeds the applicable RF compliance level above, JLN-S0xA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating JLN-S0xA

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 9.4 Electromagnetic Immunity

JLN-S0xA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and JLN-S0xA as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

10 Troubleshooting

Problem	Probable cause	Solution
Excessive noise with the device	No filter	Reload a filter
The device doer not operate	Power off	Power on
	Not clean the cup last time	Clean the cup
	Tube bends	Unbend the tube
	Filter blocks	Replace a new filter
	No medication liquid	Add the appropriate medication liquid into the cup
	Inhalation top or baffle does not screw well	Screw it well
Excessive water drops attached inside the tubing wall	Too much medication liquid loaded	Remove some liquid by tool, until the liquid line down to the 8ml scale mark.

11 Warranty and Validity

Validity of Main Unit: 5 years

Validity of Nebulizer parts: single use

The legal provisions in this respect apply. The warranty is limited to detective material and workmanship. Cables are not covered by the warranty, damage through misuse or modification is not covered. The warranty is only valid if the product has neither been opened nor subjected to violence or willful damage and it is return with the original receipt. Contact your dealer if you have any complaints. For further information contact the customers service (TeL: +86 0755 29821671/29821673/29821675, E-mail: sales-oe@systems.citizen.co.jp). In the event of warranty claims being deemed to be justified, the customer concerned will be supplied with a replacement product. The customer is only entitled to receive a comparable replacement product.

Notice to User and/or patient:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Caution: Instructions for a correct disposal of the product

Disposal requirement: Comply with WEEE directive, it must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

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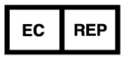

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