GIMA

PROFESSIONAL MEDICAL PRODUCTS

NEBULIZZATORE MESH
MESH NEBULIZER
NÉBULISEUR MESH
MESH-INHALATOR
NEBULIZADOR MESH
MESH-INHALATOR
ΝΕΦΕΛΟΠΟΙΗΤΗΣ ΠΛΕΓΜΑΤΟΣ
NEBULIZATOR CU PLASĂ

Manuale d'uso - User manual - Manuel de l'utilisateur - Gebrauchsanweisung - Guía de Uso - Guia para utilização - Εγχειριδιο χρησης και συντηρησης - Manual de utilizare și întreținere

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto. -* ***ATTENTION:*** *The operators must carefully read and completely understand the present manual before using the product. -* ***AVIS:*** *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit. -* ***ACHTUNG****: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen. -* ***ATENCIÓN:*** *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto. -* ***ATENÇÃO:*** *Os operadores devem ler e entender completamente este manual antes de usar o produto.* ***ΠΡΟΣΟΧΗ:*** *Οι χειριστές πρέπει να διαβάσουν προσεκτικά και να κατανοήσουν πλήρως το παρόν εγχειρίδιο πριν από τη χρήση του προϊόντος -* ***ATENȚIE:*** *Operatorii trebuie să citească cu atenție și să înțeleagă complet prezentul manual înainte de a utiliza produsul*

REF **NE-M01 (GIMA 28066)**

CE 0123

CONTEC MEDICAL SYSTEMS CO., LTD
No.112 Qinhuang West Street,
Economic & Technical Development Zone, Qinhuangdao,
Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Made in China

IP22

EC REP Prolinx GmbH, Brehmstr. 56,
40239, Duesseldorf, Germany

MD

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

-40°C 55°C 500 hPa 1060 hPa 5% 96%

M28066-M-Rev.1-08.24

Statements

- Thanks for purchasing the product.
- To ensure correct usage, please read the User Manual carefully before using this product.
- Please keep the User Manual properly where convenient to read.
- The company takes no responsibilities or provides no free maintenance for any abnormal phenomena or damage due to users not following the User Manual to use, maintain and store.
- The company reserves final explanation right to this manual.

Chapter 1

PRECAUTIONS

Please read the user manual carefully in order to ensure safety use.

Warning

- Prompting the operations with danger or unsafe, if continue operating, it may cause death, server body injury or property lose.

Attention

- Emphasizing important notices, instructions or explanations for better use.

Warnings

- Please follow doctors' advice about medication species, dosage and usage. Otherwise it may cause symptomatic deterioration.
- Please follow the specified operation methods in the user manual, otherwise it may cause operation failure.
- For the first time of using this device or medication cup is unused for a long time, medication cup and mask must be cleaned and disinfected. Otherwise, it may cause bacterial reproductive infection.
- Each user must use the accessory separately, otherwise it may cause cross infection.
- The accessories can be reused, and please clean the accessories after disinfection, otherwise patient may inhale the residual disinfectant, which may cause symptomatic deterioration.
- Used medication can't be reused, please change new medication for every treatment. Otherwise patient may be infected by varieties of bacteria, causing symptomatic deterioration.
- Do not use the device to inhale water, otherwise it may cause symptomatic deterioration.
- Do not use the device at ambient temperature above 40°C. Otherwise it may cause nasal mucosa injury or device failure.
- Do not clean the main body by water or drop it into water or store the device in humid environment. Otherwise it may cause device failure.
- Please do clean the device after use, and dry it immediately after clean. Otherwise patient may be infected by varieties of bacteria.
- Please keep the device out of the reach of children and people with mental illness. Otherwise it may cause danger of swallowing small parts.
- Do not use the device near flammable or explosive gas or anesthetic mixture. Otherwise it may cause personal injury.
- Avoid twining children' dangerous parts(for example neck) by the power cord, or it may cause asphyxia.
- The mask of this equipment is made of PVC material.The material passed the relevant test. After assessment,there is no unacceptable risks.
- This device should not be used where it is difficult to disconnect the power supply device.
- If the storage temperature is lower or higher,please leave the equipment in normal working environment for more than 1 hour. Until it is ready for intended use.
- It is not allowed to modify the equipment or it may cause equipment or it may cause damage to the equipment.

Attention

- If the device can't shutdown automatically when medication is exhausted, please immediately press the

- "ON/OFF" button to turn off, in order to avoid damage to the nebulizing sheet. Refer to Chapter 6
- Troubleshooting.
- Clean medication cup after each use. Otherwise, the device will not work normally.
- When cleaning medication cup, do not directly place the device under tap water in case water ingresses the device.
- Do not use this product near high-frequency electromagnetic transmitters and other high-frequency
- electronic products.
- Keep the device vertical as much as possible during use.
- Avoid the main unit and medication cup falling or subject to severe impact.
- Do not touch the metal mesh of nebulizing sheet with a cotton swab or other sharp objects. Otherwise, the device may not work.
- This product is subject to the guidance of a doctor. Patient who has sensitive parts with contusion, burns, inflammation, and facial/oral trauma should avoid using. If any discomfort appears during use, please stop using immediately and consult a doctor.
- Do not mix different types of dry batteries.
- Ensure that a guardian is present when used by children.
- Do not store or carry the device with medication in the medication cup.
- Disposal of waste main parts and accessories shall follow the local government regulations.
- The use of this product is different from the laryngeal and nasal mucosa humidification equipment.
- This product can not be used in respiratory anesthesia systems and ventilator systems.
- Please take batteries out if you won't use the device for long time.
- The device service life is 3 years(excluding consumables).
- Please check the packaging carefully before use, stop using it and contact with suppliers if there is obvious damage.
- If necessary, provide circuit diagrams, components lists and necessary information for maintenance, please contact with suppliers.

Chapter 2

GENERAL

2.1 Function and application

Intended use:

The product is intended to aerosolize liquid medications for inhalation by the patient. The device may be used with chidren and adult patients at home, hospital and sub-acute care settings.

Indication:

Atomization treatment.

Patient population:

Adult and child.

Intended users:

Professional medical staff and patient under their guidance.

Contraindications

The product cannot be used with Pentamidine.

2.2 Features

Power supply: DC 5 V or 2 "AA" alkaline batteries
Input power: <3 VA
Nebulization rate: ≥0.25 mL/min
Noise: ≤50 dB
Equivalent volume particle diameter distribution: the occupation of small atomized particles (diameter≤5 μm) is no less than 90 %.
Type of protection against electric shock: Class II
Degree of protection against electric shock: type BF applied part
Degree of protection against ingress of liquid: IP22
Note: please choose the power adapters manufactured by qualified companies(input: AC100-240V, 50Hz

/ 60Hz, output: DC5V, 1A).
The voltage of 2 “AA” alkaline batteries is DC3V.

2.3 Operational environment

Temperature: 5°C ~40°C
Humidity: 15 %~90 %
Atmospheric pressure: 700 hPa~1060 hPa
Attention: This product is not suitable for use in strong electromagnetic interference environments (such as various medium/high frequency therapeutic instruments, transformers, large electrical cabinets, radio and television transmission towers, other radio frequency transmitting equipment, and other electrical appliances or medical equipment may generating interference.).

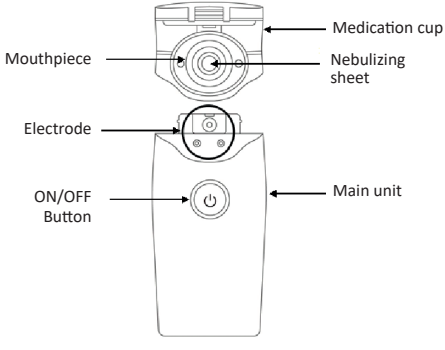
2.4 Principles

Principle of nebulization
The Mesh Nebulizer operates by electrically activating piezoelectric ceramic actuator (PZT) which then transduces the vibration generated to the adjacent supporting plate and polymer mesh bearing numerous apertures. The vibration actively pushes out the liquid medication by physically breaking surface tension of the solution through mesh holes thereby achieving final nebulization. After the patient uses the mask cover his/her nose and mouth, the atomized medication is breathed in the body through his/her inhalation.
Principle of treatment.
Respiratory system is an open system. The atomized medication, after inhalation, can be directly adsorbed on patient’s oral cavity, throat, trachea, bronchus and pulmonary alveoli, etc., through its mucous membrane absorption to achieve the purpose of treatment..

Chapter 3

PRODUCT COMPOSITION

Component description: The nebulizer consists of main unit , medication cup,mask, mouthpiece and the power adapters(optional).
Nebulizer:



Accessories:


Adult mask


Child mask


Power adapters (optional)


Power cord


Mouthpiece

Chapter 4
HOW TO USE
4.1 Assembly

1. Remove all packages

Attention: For the first time of use, please clean and disinfect the device before use.

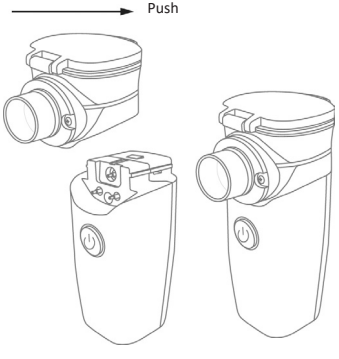
2. Assembly of nebulizer

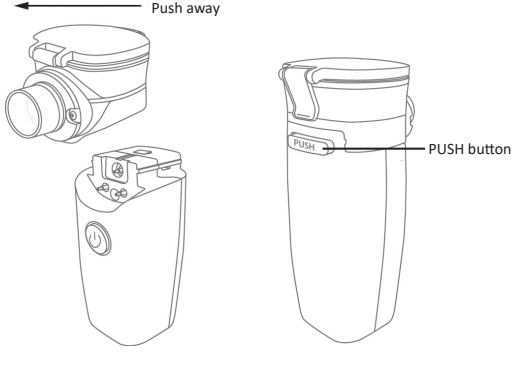
(1) Install medication cup to the main unit by pushing it towards to the main unit.

Attention: When installing medication cup to the main unit, be sure to install it properly until clasp sound is heard. Otherwise it may cause electrode conduction failure, then the device can not atomizing normally.

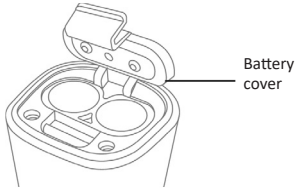
(2) Remove medication cup from main unit. Press and hold the "PUSH" button on main unit, and push medication cup away from the main unit.

Attention: In order to avoid device damage, please press the "PUSH" button first when removing medication cup.

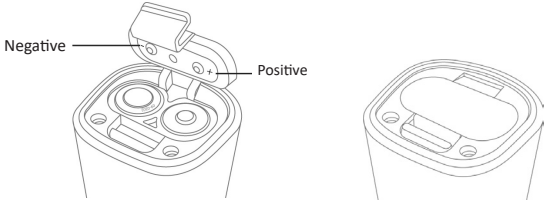




3. Assembly of battery
(1) Open the battery cover.



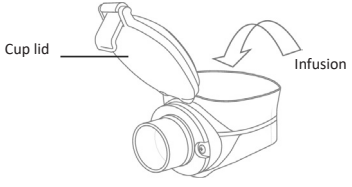
(2) Insert the 2 "AA" alkaline batteries according to the polarity label on battery cover.
Attention: Do not reverse the battery. Insert the battery exactly following the label of “+” “-” on the battery cover.
(3) Close the battery cover.



Battery service life and replacement:
(1) When replacing the battery, make sure there is no medication or water in medication cup. If yes, please remove the medication cup first.
(2) When the orange indicator is light, the device can also work for a while, but it is recommended to replace the new batteries.
(3) Usually two new "AA" alkaline batteries can work continuously 1 hour under normal working situations.
Attention: Please do not mix batteries of different manufacturers or models, otherwise the battery life will be affected.
Remove the batteries if the device won’t be used for long time.

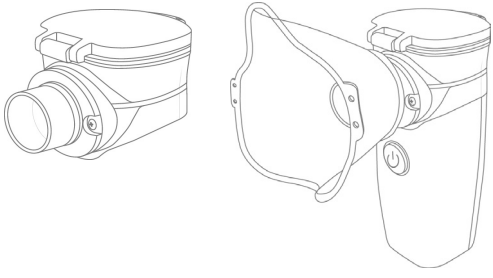
4.2 Operations for treatment use

Preparations before use:
1. Remove medication cup, please clean and disinfect it before use.
2. Infusion of medication: Open the cup lid, decant medication into medication cup. As shown below:



Attention:
(1) Before using any pharmaceutical products or medicines, please consult your doctor to ensure that you are using the product correctly.
(2) Do not use the medication of high concentrations, high viscosity, oily medicines, volatile liquid medicine, doing so may lead to abnormal atomizing.
(3) It is recommended not to exceed the capacity of medication cup. If medication cup is fulled with medication, be sure to cover the cup lid to prevent leakage.Medication in the cup should not be less than 2mL(The maximum capacity for the medication cup is 10mL).

3. Close the cup lid.
4. Install medication cup to main unit.
5. Assemble the mask (mouthpiece), as shown below:



Operation method:
1. Turn on the power: Press “ON/OFF” button for more than 1 second, power indicator (green) lights and device starts atomizing.

Attention:
If medication cup is not loaded with any medication, the device will automatically shutdown after power indicator lighting about 1s.
After startup, the quantity of medication mist may change at the beginning of device working, which is a normal phenomenon.

2. Inhalation: Hold the device in hand, put on the mask or mouthpiece, slowly inhale the medication mist.

Attention:
(1) The angle of inclination should be within 45° during nebulizing.
(2) During use, please do not strongly shake the device to prevent abnormal use.
(3) Duration of each inhalation should be no more than 20 minutes.
(4) Nebulizing treatment is easy and comfortable, if you have any discomfort during use, please stop the treatment.

3. Turn off the power: When the treatment is over, and medication almost runs out, the nebulizing sheet will generate a high-frequency sound, and then the device automatically turns off. If you need to shut the device down during use, please press the “ON/OFF” button for more than 1 second.

Attention:
At the end of treatment, it is normal that a little medication left in medication cup after automatically shutdown.

Chapter 5
MAINTENANCE, TRANSPORT AND STORAGE

5.1 Clean and disinfection

Clean and disinfect the device after each use. If the device doesn't clean up, the nebulizing will be affected because of drying and coagulation of medication.

1. Remove medication cup, accessory and batteries from the main unit.
2. Open the cup lid and discard residual medication.
3. Add 75% ethanol solution in medication cup, cover the cup lid, then leave for at least 10mins; it is available to gently shake it for better disinfection.
4. Immerse the accessories to be disinfected into a container with ethanol solution, and lid the container. Use 75% ethanol solution soaking for 10mins or longer.
5. Discard the disinfectant in medication cup, take accessories out from the disinfectant; clean the medication cup and accessories with clear-water repeatedly.
6. Fill medication cup with clear-water, assemble it to the main unit, let the device work 10mins in order to clean the nebulizing sheet.
7. After cleaning, use new medical gauze to wipe away the water, and fully dry.
8. Use 75% medicinal alcohol to wipe the surface of main unit, then air-dry or wipe-dry with a clean, soft cloth.
9. After all steps above, store the main unit, medication cup and accessories in a dry, clean place.

Attention:

Do not throw medication cup and accessories into boiling water for disinfection, otherwise the part may be out of shape. Do not put them in a microwave oven for drying.

The parts disinfected with disinfectant must be fully cleaned, or the residual disinfectant may cause symptomatic deterioration.

5.2 Medication cup replacement

The nebulizing sheet is a kind of consumable, In general, the service life of the atomizer is about six months (20 minutes per time, three times a day).

its service life depends on the use, medication, and the degree of cleaning. If no atomizing or little atomizing appears when device working, please replace medication cup in time. (If you need to purchase medication cup, please contact the dealer.)

5.3 Transport and storage

Environment of transport and storage:

Temperature: -40°C ~ +55 ℃

Relative humidity: 5 %~96 %

Atmospheric pressure: 500 hPa ~ 1060 hPa

Requirement of transport and storage:

- No corrosion gas and well-ventilated room.
- Keep the device out of the reach of children.
- Do not store the device in places such as direct sunlight, high temperature, humid, dusty or easy to get to water, etc.
- Avoid the device from slope, vibration or shocked.
- Transportation adopts general transportation means or follows the contract requirements. Avoid violent shock, vibration, rain and snow splash during the process of transportation.

5.4 Pollution-free disposal and recycle

The service life of product is 3 years. If the device exceeds the period of use, it must be discarded. Please contact the manufacturer or distributor for more information.

1) The atomizer out of use can be sent back to the manufacturer or distributor for proper recycling.
2) Used parts can be returned to the manufacturer or distributor for disposal, or in accordance with relevant laws and regulations.

Chapter 6
TROUBLESHOOTING

Problems	Reason analysis	Solutions
The device can't startup.	Battery is not well installed.	Check the installation of battery, and reinstall the batteries.
No atomizing or little atomizing appears when device working.	Medication cup is not well installed.	Check the installation of medication cup, and reinstall it.
	No medication in medication cup	Trickle medication into medication cup, remember do not exceed its maximum capacity.
	Improper medication	Consult a doctor if the medication is suitable for the device.
	The nebulizing sheet is dirty	Clean medication cup.
There is water around the nozzle of nebulizer.	Due to temperature differences, the temperature of medication cup surface is relative low, medication mist in contact with the nozzle, then condenses into water droplets.	Remove medication cup, pour the water out.
After startup, power indicator lights about 1s, then immediately goes out.	Medication cup is not well installed.	Install medication cup once again.
	Medication cup is not loaded with any medication	Put the medication into medication cup after consulting your doctor.
After turning on the device, the power indicator lights once, then it is out immediately or the device can not work normally.	The battery had run down.	Replace the batteries immediately.
Nebulizer doesn't automatically shutdown when medication is used up.	Medication may generate bubbles in medication cup	Press "ON/OFF" button to turn off the device, and clear up the bubbles.
	Medication may attached on the nebulizing sheet	Press "ON/OFF" button to turn off the device, and clean medication cup.
	The electrodes contacting with the medication cup may be dirty	Press "ON/OFF" button to turn off the device, and clean the electrodes.
If the device still can't work normally after doing all methods above, pleas contact our after-sales service.		

Chapter 7
MEANING OF SYMBOLS

	Keep in a cool, dry place		Stand-by	REF	Product code
	Keep away from sunlight		Temperature limit	LOT	Lot number
	Fragile, handle with care		Date of manufacture	SN	Serial number

	Follow instructions for use	CE	Medical Device compliant with Directive 93/42/EEC		Caution: read instructions (warnings) carefully
IP22	Covering Protection rate		Type BF applied part		Manufacturer
	WEEE disposal		Class II applied	EC REP	Authorized representative in the European community
	Atmospheric pressure limit	%	Humidity limit		This side up
	Temperature limit	MD	Medical Device		Disposable device, do not re-use
	Consult instructions for use.	STERILE	Sterile	STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged.				Indoor use
N	Stacking layer limit is N N subject to actual conditions				Imported by

Chapter 8

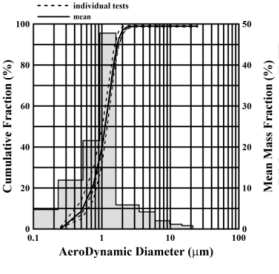
PACKING LIST

1. Main unit 1pc
2. User manual 1pc
3. Medication cup 1pc
4. Accessories 1set (adult mask, child mask)

Appendix I

Curve chart of equivalent volume particle diameter distribution:

the median particle diameter (D 0.50) is1~4 μm.error shall be within ±25 %.



Appendix II

ELECTROMAGNETIC COMPATIBILITY (EMC)

Warning

- **Don't 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.

- **Use of the NE-M01 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, NE-M01 and the other equipment should be observed to verify that they are operating normall.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of NE-M01 could result in increased electromagnetic emissions or decreased electromagnetic immunity of NE-M01 and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NE-M01, including cables specified by the manufacturer. Otherwise, degradation of the performance of NE-M01 could result.**

Note:

NE-M01 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

The basic performance:Nebulization rate: ≥0.25 mL/min.

When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.

Other devices may affect this device even though they meet the requirements of CISPR.

The following cable types must be used to ensure that they comply with interference radiation and immunity standards:

Name	**Cable length(m)**
Power cord	1,0

Table 1

Guidance and Declaration - Electromagnetic Emissions	
Emissions test	**Compliance**
Radiated RF EMISSIONS CISPR 11	**Group 1**
Radiated RF EMISSIONS CISPR 11	**Class A**
Harmonic distortion IEC 61000-3-2	**Class A**
Voltage fluctuations and flicker IEC 61000-3-3	**Complies**

Table 1

Guidance and Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV, line(s) to line(s)	± 0,5 kV, ± 1 kV, line(s) to line(s)
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % UT; 0,5 .cycle .At0°,45°,90°,135°,180°, 225°,270°and315°. 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles ;Single phase:at 0°. 0 % UT ; 250/300 cycle	0 % UT; 0,5 .cycle .At0°,45°,90°,135°,180 °,225°,270°and315°. 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles ;Single phase:at 0°. 0 % UT ; 250/300 cycl
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Conduced RF IEC61000-4-6	3 V 0,15MHz - 80 MHz 6 V in ISM bands between 0,15MHz to 80 MHz 80%AM at 1kHz	3 V 0,15MHz - 80 MHz 6 V in ISM bands between 0,15MHz to 80 MHz 80%AM at 1kHz
Radiated RF IEC61000-4-3	10V/m 80 MHz-2,7GHz 80%AM at 1kHz	10V/m 80 MHz-2,7GHz 80%AM at 1kHz
NOTE UT is the a.c.mains voltage prior to application of the test level		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC60601-1-2 Test level (V/m)	Compliance level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	27	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	870					
	930					
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28	28
	1845					
	1970					
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9
	5500					
	5785					

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