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NEBULIZZATORE MESH MESH NEBULIZER NÉBULISEUR MESH NEBULIZADOR MESH

Manuale d'uso - User manual Notice d'utilisation - Manual del usuario

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.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.



Fabbricante/Manufacturer: HONSUN (Nantong) Co., Ltd. No.8, Tongxing Road, Economic & Technical Development Area, Nantong City, Jiangsu, P.R.China Made in P.R.C.

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EC REP



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Thank you for purchasing the 28075 / NB-810B mesh nebulizer. This product is intended for the treatment of respiratory diseases such as asthma, allergies, etc. Working principle: thanks to self-excited oscillation circuit. the ceramic sheets contained in nebulizing head together with the metal mesh are driven successively to oscillate at a high frequency, which makes the liquid flowing through the micromesh of the metal mesh being ejectedand nebulized to form inhalant aerosol.



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SYMBOLS

SYMBOLS	MEANING	
	Manufacturer	
EC REP	Authorized Representative in the European community	
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.	
C € 0123	CE marking in conformity with EC directive 93/42/EEC	
Ĩ	Operating instructions	
†	Type BF Applied Part	
	Keep away from sunlight	
Ť	Keep in a cool, dry place	
	Read instructions carefully	
POWER	Power indicate light	
	Low battery indicate	

SAFETY INFORMATION

Caution:

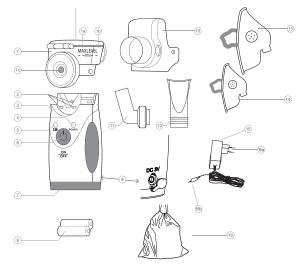
- Never use this device when ambient temperature is over 40°C. For more operating environment requirements, please refer to the section -Specifications.
- Do not shake the nebulizer during operation.
- Avoiding any strong shock on the main unit and its components, e.g., falling on the ground.
- Never dismantle the device or attempt to repair any part or component.
- This device is for human use only.
- · Always use optional accessories as stated in this Instruction Manual only.
- The device and its parts and components and optional accessories shall only be discarded in accordance with the relevant local regulations. Inappropriate disposal may cause environmental pollution.
- Prior to use, make sure the device and its parts and components (e.g. mouthpiece and mask) are correctly assembled as per this Instruction Manual.

Risk of electric shock:

- · Never use the device in case the power cord is wet.
- Never plug in or unplug from the power socket with wet hands.
- Do not immerse the main unit into water or other liquids.
- Protect it against water or other liquid splashes. In case it contacts with any splash, disconnect the power supply and mop up with gauze or other soft adsorbing materials.
- · Never use the device in humid environment such as bathroom.
- When connected to power supply, check the supply voltage at power socket is correct and make sure your plugging in will not cause overload.
- Disconnect it from power supply after the use of this device and never leave an energized device aside.
- · Clean the device only after disconnecting it from power supply.



PARTS AND COMPONENTS



- 1. Nebulizer
- 1a. Cover
- 1b. Lock
- 1c. Nebulizer head (metal mesh)
- 2. Electrode
- 3. Main Unit
- 4. Power LED
- 5. Low battery indicate LED
- 6. ON/OFF Switch
- 7. Battery Cover
- 8. Adapter Plughole

- 9. Battery (2×AA)
- 10. Outer Cover
- 11. Connector
- 12. Mouthpiece
- 13. Adult Mask
- 14. Child Mask
- 15. Adapter (Optional)
- 15a. Power Plug
- 15b. Adapter Connector
- 16. Storage bag



PREPARATION BEFORE USE

1. Power Supply:

Prepare battery or optional power adapter.

1) Use the Battery

Open the battery cover (in the bottom of the main unit) along the direction of arrow as shown in Fig. 1; install two AA batteries into the battery compartment; close the cover.

Note: Please make sure that the polarity is correct.

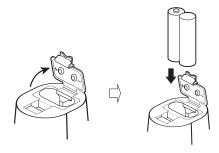


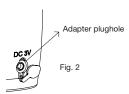
Fig. 1

2) Use the Adapter

 The output port (adapter connector) is connected to the adapter plugholes under the back side of the main unit (see Fig. 2).

2) Connect its input port (Power Plug) to main supply.

Input voltage: AC 220V, 50Hz Output voltage: DC 3V, 1A



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2. Trial Run:

Power on and check whether the Power LED lights up or not. If not, check batteries or replace them if necessary.

If the device still does not work, please refer to the section -

Troubleshooting for solutions.

Nota:

- Remember to clean and sterilize the nebulizer and its parts and components and accessories prior to use for the first time. For details see the section Cleaning and Disinfecting.
- If the device does not be used for a long time, carry out the above described cleaning and disinfecting.
- To avoid cross infection, all users of a same device should each be provided with a set of nebulizer and accessories. The nebulizers and accessories for different users should be stored separately.

ASSEMBLING THE DEVICE

1. Install Nebulizer

Hold the main unit and the nebulizer of the device with your left hand and right hand respectively; gently push the nebulizer along the direction of arrow (see Fig. 3) into the slot; a "Ka" sound indicates it is installed into position.

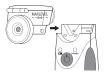


Fig. 3

Note:

- 1) Always keep electrode and nebulizer clean.
- 2) If it is not installed correctly, it may dose not work during nebulizing.
- 3) As consumable, the nebulizer has a service life of 6 months (given that it is used 3 times pay day). You can get additional nebulizers from your supplier or the nearest local distributors.

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2. Install Outer Cover:

As shown in Fig. 4, hold the main unit with your left hand; hold the lower part of the outer cover with your right hand and gently push it inwards along the bottom edge of nebulizer till it buckled to the projected columns at both sides of nebulizing head; press it downwards with your thumb and middle finger successively, a 'ka' sound indicates each installation is completed correctly.



3. Place the assembled device into clean and dry storage bag.

USING THE DEVICE

1. Remove the outer cover:

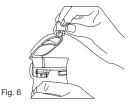
Remove it as per a sequence reverse to installation order (see Fig. 5).



Fig. 5

2. Open the nebulizer:

Hold the main unit with your left hand, pinch the nebulizer lock with the thumb and forefinger of your right hand and snap it upward to open the nebulizer as in Fig. 6.



3. Add the liquid:

pour the liquid drug into drug storage area (near the nebulizing head side) as in Fig. 7.

Note

- The maximum and minimum volume of liquid is 8ml (at MAX LEVEL mark) and 0.5ml respectively
- If it is needed to adjust the temperature of liquid, add hot or cold water into the temperature adjustment storage area.



Drug storage area

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Temperature adjustment storage area

Fig. 7

4. Close Nebulizer:

As shown in Fig. 8, hold the main unit of the device with your left hand and close the nebulizer cover with your right hand, press the lock downwards with the thumb to the point when you hear a "ka" sound which indicates a good closing state.

5. Reinstall the Outer Cover

(see the section - Assembling the Device)



Fig. 8

6. Install mouthpiece or mask:

1) The enclosed parts include a mouthpiece, which is intended for medication through throat.

 Install the mouthpiece: connect the mouthpiece to the outlet of outer cover along the direction of arrow (see Fig. 9).

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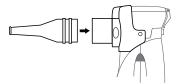


Fig. 9

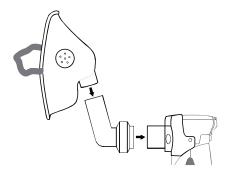
 Use the mouthpiece: bring the mouthpiece into mouth and close lips slightly to facilitate nebulized liquid flowing to the lesion position smoothly (see Fig. 10).



Fig. 10

2) In case of medication through nasal cavity and/or throat, the mask should be used.

 Install the mask: connect the connector and mask successively along the direction of arrow (see Fig. 11).





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• Use the mask:

Keep the mask in slightly contact with or a little away from the patient's face, then pull the elastic belt to the back of the head and secure it appropriately (see Fig. 12).

- 1) In case of medication through nasal cavity, it is recommended to take a long breath through nasal cavity and then exhale through mouth.
- 2) In case of medication through throat, it is recommended to take breath through mouth and then exhale through nasal cavity.
- 3) It is allowed to alternate between both methods said above.



Fig. 12

Note:

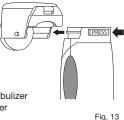
- For the sake of safety, when replacing the mask please select only medical devices that meeting the regulatory requirements for medical devices and made by manufacturers with certificate of registration.
- Use the mouthpiece correctly and avoid nebulized liquid against spraying onto the tongue.
- Never swallow the nebulized liquid and try to let the nebulized liquid stay in the affected part.
- 4) In order for effective nebulizing, the user is required to keep calm, relaxed and sit still. If you want to lay in bed for treatment, it is suggested to put a pillow beneath your back so that you can keep the spine straight. Discomfort posture and unsteady breathing may lead to blockage of the respiratory tract.
- Please posture correctly before startup the device. Take long breathes steadily and slowly so that the nebulized liquid may be inhaled into the respiratory tract deeply.
- 6) Press the ON/OFF switch if you want to stop the nebulizing during treatment; the device will be shut down automatically whenever the liquid is used up.
- When no aeresol comes out you can sheck the nebulizer head lightly after power off.

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- 8) During nebulizing, the maximum permissible tilting angle of the device is 45° (from the vertical line). If the angle is exceeded, the liquid may spill from the metal mesh in nebulizing head.
- 9) If an operating device is tilted to the extent that the liquid is not in contact with the nebulizing head, the device will shutdown after a delay time of 10 seconds (depending on the liquid type).
- 10) When there is not much liquid left, you may tilt the device towards yourself to allow liquid gathers at the nebulizing head side in order to make full use of the residual liquid. During operation be cautious not to shake the device because it may cause device malfunction, such as automatic shutdown
- 7. After completion of treatment, shut it down by pressing the ON/OFF switch; if power adapter is connected, you are also required to unplug it.
- 8. Remove the mouthpiece/mask and the connector in an order reverse to the corresponding installation order.
- 9. Remove the outer cover.
- 10. Remove the nebulizer: hold the main unit with left hand, press the PRESS-key (over the jack for adapter) with your left thumb along the direction of arrow (see Fig. 13); hold both sides of the lower end of nebulizer the right hand to gently pull it out.
- 11. Remove the residual liquid to empty the nebulizer and clean the device. For details please refer to the section - Cleaning and Disinfecting.

Note: You are advised to, after each use, allow the device running with clean water instead of liquid for 1-2 minutes in order to clean the nebulizing head.





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Cleaning

- 1. Remove all accessories (including nebulizer, mask, mouthpiece, connector, outer cover) from the device after each use.
- 2. Open the cover of nebulizer and remove the residual liquid. You are advised to, after each use, allow the device running with clean water instead of liquid for 1-2 minutes in order to clean the nebulizing head. Clean the mask, mouthpiece, connector, outer cover, nebulizer gently (Note that the main unit should not be washed).
- 3. Immediately after completion of cleaning, dry the accessories with medical gauze. Note that the metal mesh in nebulizing head must not be touched strongly any sharp and rough object. Dry the water inlet and outlet of the nebulizing head with medial swab gently.
- If there is dust on the surface of main unit, please wipe it up with wet and dry gauge successively.
- 5. After completion of cleaning, store the device in clean storage bag.

Disinfecting

- Rinse the mask, mouthpiece, connector and outer cover with solution of ammonium chloride diluted to 0.1% for 10 minutes (Not including the MESH HEAD); rinse with water; dry with medical gauze.
- 2. Disinfecting of nebulizing head: gently clean the metal mesh and electrode in nebulizing head with medical swab as dipped with medial alcohol; rinse the nebulizing head with water; dry the surface of nebulizing head with medial swab as soon as possible by patting action.
- Boiling Disinfection for the following accessories: Mouthpiece, connector and outer cover: put them in boiling sterilizer with sufficient water to ensure they can be immerged completely; heating the water to boiling point (for 20 minutes in total); dry them with medial gauze.
- Boiling Disinfection must NOT be used for the following parts: Nebulizer, nebulizing head, main unit, mask, power adapter, storage bag, packaging bag.

STORAGE AND MAINTENANCE

- Make sure no residual liquid in nebulizer.
- Make sure the nebulizer has been cleaned and sterilized thoroughly after each use.
- Store the device and its parts and components and accessories in clean and safe place.
- · Protect the device against direct sunshine and shock.

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- Remember to keep any heating device and open fire far away from the storage place.
- · Protect the device against contact with any corrosive liquid.
- Never dry the device and its parts, components with microwave oven.
- · Never wind any power cord around the main unit.
- Always contact your supplier or the nearest local distributor if repair is necessary.
- The warranty period of this device is one (1) year from the date of purchase.
- Always use or store the device in such environment that the temperature and humidity is in compliance with the requirements as specified in the section – Specifications, otherwise the device could not function well.

Warning:

Before the device is send back to the factory for inspection and repair, never dismantle or attempt to repair it without permission.

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NOTES

- Never touch the metal mesh in the nebulizing head with hands.
- Never use liquids which containing ester, fatty or suspended particles (including diffusion juice of herb); please note that specifications may vary with medication type used; please use doctor-advised standard liquid for nebulizing.
- The liquid for nebulizing should be prepared based on 0.9% saline or whatever advised by your doctor. No tap water or boiled water can be used. The container for preparation of liquid must be boiling-sterilized.
- The duration limit for each use of the device should be not more than 15 minutes or other limits as advised by doctor.
 In consideration that some small-sized parts could be swallowed by infants or children, the device may only be applied to infants or children when sufficient supervision is provided. Children and mental illness patients should use this device under the tutelage of healthy adult.
- Remove the battery if it is predicted that the device will not be used for a certain period.
- Never place the device in water, under waterfall or very humid enclosure.
- Never use it while taking a shower.
 If the device does not work, find the solutions in the section Troubleshooting.
- Please always use private accessories as stated herein.
- Do not use the device where it may be exposed to flammable gas.
- This unit confirms to EMC Standard IEC60601-1-2. However, if it is used together with other medical devices or electrical equipment, they may influence the operations of some of devices. Please follow any instruction in the manuals and use all devices correctly.
- Don't serve and maintain the mask and mouthpiece when in use with patient.

DECLARATION

When technical information for user requirements is not in the scope of confidentiality of the Company, the Company committed to provide information disclosure in accordance with procedure, including circuit diagrams and parts lists, and other related type technology information that does not involve commercial secrets may be disclosed. Access to information channels and procedures, please contact your

dealer or manufacturer.

TROUBLESHOOTING

Please find solutions from the following table first in case of any problem during operation.

NO.	Faults	Symptom/Possible Causes	Solutions	
1	Lower nebulizing rate.	Low battery indicate LED lights up/goes out.	Replace all batteries.	
		Nebulizer is foul.	Clean the nebulizer (please refer to the section – Cleaning and Disinfecting); change nebulizing head if necessary.	
2 Power LED does not light up and the		Battery's polarity has been reversed.	Reinstall batteries correctly.	
	device does not work.	Low battery voltage	Replace all batteries.	
	not work.	Power adapter is not correctly connected to the jack the main unit or the power socket.	Reconnect it to power socket or re-plug it into the jack.	
		Incorrect installation of nebulizer.	Reinstall the nebulizer correctly. Please refer to the section – Assembling the Device.	
3	Power LED lights up but the device	Incorrect installation of nebulizer.	Reinstall the nebulizer correctly.	
	does not work.	Pollution to the nebulizer is serious.	Clean the nebulizer; replace nebulizing head if necessary.	
		The liquid can not be in contact with nebulizing heat.	Slightly tilt the main unit towards yourself to make the liquid gathers at the nebulizing head side.	
		There are bubbles between the liquid and nebulizing head.	Gently shake the liquid.	
		Dirt electric pole of the main unit.	Clean the electrode of the main unit with medical gauze.	

If faults still exist after take measures as listed above, contact your supplier or your nearest local distributor.



WARRANTY OBLIGATIONS

1. Warranty for this mesh nebulizer is 12 months since the date of purchase.

2. The warranty obligations are prescribed by warranty card for buyer.

WARNING:

- Do not modify this equipment without authorization of the manufacturer.
- All major maintains on the device must be performed by an authorized service center or distributor.No use-serviceable parts inside, before servicing to authorized representative or manufacturer!

CLASSIFICATION

- Equipment not suitable for use in the presence of flammable mixtures.
- Type BF applied part. Recognized the mask or mouthpiece as applied part.
- Internally powered equipment (without adapter), Class II equipment (with adapter).

SPECIFICATIONS

Name of Product	Mesh Nebulizer	
Model	NB-810B	
Power Supply	2×AA batteries or Adapter (AC-DC 3V1A)	
Rated Power	2W	
Ultrasonic Frequency	Approximately 140kHz	
Safety level	Type BF, Class II	
Nebulizing Rate	≥0.2ml/min	
Max./Min. Liquid Volume	8ml/0.5ml	
MMAD	Approximately 5µm	
Low Battery Indicate	2.2V ± 0.2V	
Nebulizing Head Life	180 hours	
Battery Life	90 minutes supplied by two	
	AA Alkaline Battery	
Automatic Shutdown	Automatic shutdown without liquid	
Operating Temperature and	+10°C~+40°C, ≤ 85% R.H	
humidity Air pressure	700hPa to 1060hPa	
Storage Temperature and	-10°C~+40°C, ≤ 85% R.H	
humidity Air pressure	500hPa to 1060hPa	
Pollution degree	Degrees 2	
Voltage Category	Category II	
Altitudes	≤2000M	
Accessories	Outer cover, Connector, Adult mask, Child mask,	
	Mouthpiece, Instruction manual, Gift box, Warranty card, 2×AA batteries, Adapter (optional).	

Technical specifications may be subject to variations without prior notice.

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity

The 28075 / NB-810B is intended for use in the electromagnetic environment specified below. The customer or the user of the 28075 / NB-810B 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors 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	± 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 line(s) to line(s)	± 1 kV line(s) to line(s)	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	<5% UT (>5% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>5% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 25 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 28075 / NB-810B requires continued operation during power mains interruptions, it is recommended that the 28075 / NB-810B be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity

The 28075 / NB-810B is intended for use in the electromagnetic environment specified below. The customer or the user of the 28075 / NB-810B should assure that it is used in such an environment.

IMMUNITY test	IEC 60601test level	Compliance level	Electromagnetic environment - guidance	
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the 28075 / NB-810B, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right] \sqrt{P}$ 800 MHz to 2,5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter, as determined by an electromagnetic site survey. ⁴ should be less than the compliance level in each frequency range. ⁵ Interference may occur in the vicinity of equipment marked with ((•))	

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 the 28075 / NB-810B is used exceeds the applicable RF compliance level above, the 28075 / NB-810B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 28075 / NB-810B. Do Voer the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the 28075 / NB-810B

The 28075 / NB-810B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 28075 / NB-810B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 28075 / NB-810B as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m			
output power of transmitter W	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$	
0,01	0,117	0,117	0,233	
0,1	0,369	0,369	0,738	
1	1,167	1,167	2,333	
10	3,689	3,689	7,379	
100	11,667	11,667	23,333	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.

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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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national leaislation and reaulations.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial

The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.