

Model: MOBINEB

EN Mesh Nebulizer

TR Mesh Nebülizör Cihazı

FR Nébuliseur à Tamis

ES Nebulizador de Malla

alla ES Manual de instrucciones

Statamante

EN Instruction Manual

TR Kullanım Kılavuzu

FR Mode d'emploi

- ♦ 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 non-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

- Pentamidine drugs and oily drugs, lipid-containing drugs or drugs containing suspended particles are not applicable. It is recommended to use standard nebulization drugs, otherwise it will cause damage to nebulizing sheet.
- Please follow doctors' advice about medication species, dosage and usage. Otherwise it may cause symptomatic deterioration.
- Do not use the device in the circuit of respiratory anesthesia system and ventilator system (life-supporting system), otherwise it may cause incorrect operation.
- Please follow the specified operation methods in the user manual, otherwise it may cause operation failure.
- The accessories of device are designed for single use, do not reuse the accessory, otherwise it may cause cross infection.
- 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.
- Do not use sodium hypochlorite disinfectant to disinfect, to avoid rusting of nebulizing metal mesh.
- Each user must use the accessory separately, otherwise it may cause cross infection.
 Do not use microwave ovens, tableware drivers or hair drivers to dry or disinfect the accessories, to
- avoid damage to the accessories.

 Please do not use water for nebulization, otherwise it may cause worse symptoms.
- If replacing the accessories other than accompanying one, please purchase the accessories with registration certificate, otherwise it may cause allergic reactions and worse symptoms.
- 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 rinse the main unit with water or soak 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 cleaning. 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.
- \blacksquare Possible suffocation danger if power cord wraps on children's neck.
- Do not refit the device without authorization of the manufacturer, otherwise it may not work properly.

Attention

- If the device can't shutdown automatically when medication is exhausted, please immediately press the ON/OFF button to turn it 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.
- Recommended maximum liquid carrying capacity is 10ml, minimum capacity is 2ml.
- When the device is used under its maximum carrying capacity, in normal use, if the medication temperature in the cup is greater than the environmental temperature, the maximum temperature should below 40°C.
- When cleaning medication cup, do not directly place the device under tap water in case water ingresses the device.
- The atomization mask was made of PVC material without plasticizer, according to the provisions in drug instructions, whether PVC accessories can be used should be judged by the clinical medical personnel (use with caution for person who is allergic to PVC material).
- 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 device body 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.
- Commonly used atomized drugs include moistening expectorants, bronchodilators and antibiotics, such as terbutaline sulphate solution for nebulization, ipratropium bromide solution for inhalation. The active ingredient is water-soluble, without strong irritation, non-toxic, and does not cause allergic reactions. The pH is close to neutral, it can adapt to the colloid osmotic pressure of the tissue, and has good atomization effect and stability.
- The face mask is made of plasticizer-free PVC material, clinical medical personal should follow the drug instructions to indicate whether the PVC accessories are available.
- The product can be reused, please disinfect it immediately after use, otherwise it may cause bacteria infection.
- This product should be purchased and used under the guidance of a doctor.
- Do not use suspended or high-concentration medicinal solutions. Please consult your doctor for specific types of nebulization medication, and follow doctor's recommendations to operator.
- Charge the device if low power appears.
- If the device will not be used for a long time, please charge it periodically
- 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 units 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.
- The service life of product is 10 years (consumables are excluded).
- The accessory equipped with the device is sing-use accessory, it is processed by ethylene oxide sterilization. Remember to check the package before use, do not use the accessory if its package is damaged, and contact the supplier.
- We can provide circuit diagram, components list and other information that necessary for maintenance, please contact the supplier.
- Date of manufacture: see the label

Chapter 2 General

2.1 Function and application

The nebulizer can atomize medication into a mist of microscopic droplets, which can be easily inhaled into respiratory system along with breathing, achieving therapeutic effect for respiratory diseases such as acute inflammation of the upper respiratory tract, acute and chronic tracheitis, bronchitis and swelling and pain in throat, etc. The device has two nebulization modes.

Application: inhalation treatment of atomized medication via respiratory system

Contraindications: none.

2.2 Features

Power supply: DC 5V or (3.7V rechargeable lithium battery)

Input power: <15 VA

Nebulization rate in level I: > 0.25mL/min

Nebulization rate in level II: ≥ 0.15 mL/min

Noise: ≤50 dB

Quality:0.1kg

Equivalent volume particle diameter distribution: the volume distribution ratio of small atomized particles (diameter $<5~\mu m$) is no less than 60 %

Type of protection against electric shock: Class II equipment, internally powered equipment Degree of protection against electric shock: type BF applied part

Degree of protection against electric snock: type Br application against ingress of liquid: IP22

Note: Please purchase medical power adapter from qualified manufacturer (input: AC 100-240V, 50Hz-60Hz, output: DC 5V, 1.0A).

2.3 Operational environment

Temperature: 5 °C \sim 40 °C

Humidity: 15 %~90 %

Atmospheric pressure: 700 hPa~l060 hPa

Attention: The device is not suitable for use in a strong electromagnetic interference environment, such as medium and high frequency therapeutic equipment, transformers or large electric cabinet, TV transmission tower, other radio frequency transmission equipment, other electrical appliances that may cause interference, etc.

When the transport and storage temperature exceeds the operating temperature range, the device should be placed in a normal temperature environment for more than 4 hours before use.

2.4 Principles Principle of nebulization

The high-frequency vibration of piezoelectric ceramic plate directly leads to the deformation of microplate, making medication in contact with the microplate extruded from it to form a mist spray effect. The mesh nebulizer is applicable for use in hospital, clinic and family.

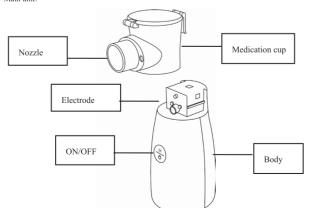
Principle of treatment

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

Structure: The nebulizer consists of a body, a medication cup, mask, power cord and adapter (optional).

Main unit:



Accessories:

4.1 Assembly







Child mask Power cord Adapter (opt

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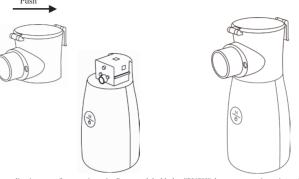
1. Remove all nackages

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

2. Assembly of main unit

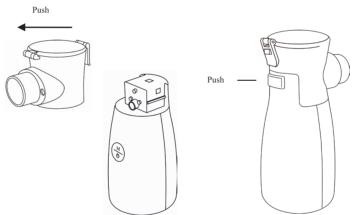
(1) Install medication cup to the main unit by pushing it towards to the main unit

Attention: When installing medication cup to the device body, be sure to install to proper position, and you can hear a click sound. Otherwise it may cause electrode conduction failure, and the device is unable to perform 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.



4.2 Operations for treatment use

Preparations before use:

- Remove medication cup, clean and disinfect it before use.
- 2. Infusion of medication: screw the cup lid following the marked direction to open the lid, load the medication, 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, suspended or volatile liquid medicine, doing so may lead to abnormal atomizing.
- (3) It is recommended not to exceed the maximum capacity of medication cup. If medication cup is fulled with medication, be sure to cover the cup lid to prevent leakage.
 - Close the cup lid.



- 4. Install medication cup to device body.
- 5. Assemble the mask, as shown below:



Attention: if it is necessary to replace a new mask to use again, please repeat the above operation methods to continue using

4.3 Indicator description

The green indicator (fast breathing) flickers.	Operating in level II		
The green indicator (slow breathing) flickers.	Operating in level II		
The blue indicator is always on.	Charging (go out automatically after fully charged)		
The orange indicator is always on.	Low battery (charge immediately)		
The orange indicator flickers 10 times.	No medication and shutdown		

Operation method:

 Startup: press ON/OFF button to turn on the device, 1 second later, the green breathing indicator is light, and the device starts atomizing.

2.Mode switch: the device has two working modes: level I and level II. Level I is the high nebulization rate mode, level II is the low nebulization rate mode. The patient can switch between I/II by short pressing ON/OFF button according to the actual treatment requirements.

3.Inhalation: hold the device in hand, according to different inhalation methods (mask or mouthpiece), inhale the medication mist by breathing slowly and deeply.

4.Shutdown: long press the ON/OFF button, after 1 second, the device stops nebulizing and the

Attention:

There is an air hole on the lid of medication cup, do not cover it to ensure normal atomization.

After pressing the ON/OFF button, the device will have a short startup period (within 1 s), then perform atomizing.

When the medication is used up, it is recommended to slightly tilt the device towards to user (the

side with button is more close to user), so that the remaining solution could contact the nebulizing sheet for atomization.

Due to the different characteristics of medication, the device may not shutdown automatically when some medication is used up, so user need to turn off the device manually to protect the nebulizing

If medication cup is not loaded with any medication or other liquid, the device will automatically shutdown. There is a little medication left in medication cup after automatically shutdown, which is a normal phenomenon

Duration of each inhalation should be no more than 20 minutes, if you have any discomfort during use, please turn off the device immediately and consult a doctor in time.

4.4 Use and Charging of lithium battery

indicator goes out, the device turns off.

- Battery working hour:
 (1) The indicator lights up in orange when battery is low, prompting user to charge the device.
- (2) In normal use, the battery can continuously work for 1 hour after fully charged

During use, please hold the device steady and do not shake it strongly.

Charging:
(1) Insert the DC-end of adapter into the power interface on the device.

(2) Plug the adapter into a power socket.

When charging, the indicator lights up in blue, and it goes off automatically after charging is completed.

Attention:

Specification of power adapter: input: AC100-240V 50-60Hz, output: DC5V, 1.0A. Please unplug the power adapter after use, avoid connecting with the power for a long time.

When the device is left unused for a long time, it should be charged every six months, which could greatly extend the battery life. The replacement of battery can not be performed by user, if necessary, please contact local service center or our company.

If you choose to use other adapter, it should meet the requirements in IEC60601-1, and its input is

AC100-240V 50-60Hz, output is DC5V, 1.0A.
Life of lithium battery:

In normal condition, 60 % of the battery capacity should be left after circularly using for 200 times.

Chapter 5 Maintenance, Transport and Storage

5.1 Cleaning and disinfection

Clean and disinfect the device after each use. If the device is not cleaned, the drying and solidification of the medication will cause aging of electrode and nebulizing sheet, which will affect normal atomizing.

- Remove medication cup and accessory from the device body.
- 2. Open the cup lid and discard residual medication.
- 3. Add 75% ethanol solution in medication cup, cover the cup lid, then leave it for at least 10mins; it is available to gently shake it for better disinfection.
 3. 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.

 4. Discard the disinfectant in medication cup, take accessories out from the disinfectant; clean the medication cup and accessories with clear-water repeatedly.
- 5. Fill medication cup with clear-water, assemble it to the device body, let the device work 10mins in order to clean the nebulizing sheet.
- After cleaning, use new medical gauze to wipe away the water, and fully dry.
 Use 75% medicinal alcohol to wipe the surface of device body, then air-dry or wipe-dry with a clean,
- 9. After all steps above, store the device body, medication cup and accessories in a dry, clean place **Attention:**

Please turn off the device when cleaning and disinfecting, do not connect with the power. Please do not maintain the device during normal operating. 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. Generally, the service life of nebulizing sheet is half a year (if it is used 3 times a day, 20 mins each time.). Its service life depends on the use method, 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 °C

Relative humidity: 5 %~96 % Atmospheric pressure: 500 hPa ~ 1060 hPa

Requirement of transport and storage:

- ♦ No corrosion gas and well-ventilated room.
- ♦ When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- \diamondsuit Do not store the device in places such as direct sunlight, high temperature, humid, dusty or easy to get to water, etc.
- ♦ Do not place the device in such places as direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, etc. to avoid affecting its performance.
- 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 10 years. The device exceeding its service life should be scrapped. Please contact the manufacturer or distributor for more information.

- 1) The device 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.

Problems	Reason analysis	Solutions			
The device can't startup.	Low battery.	Please charge the device.			
No atomizing or little atomizing appears when device working.	Medication cup is not well installed. No medication in medication cup Improper medication The nebulizing sheet is	reinstall it. in Trickle medication into medication cup, remendonot exceed its maximum capacity. Consult a doctor if the medication is suitable for device.			
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	Medication cup is not well installed.	Install medication cup once again.			
immediately goes out.	Medication cup is not loaded with any medication	Put the medication into medication cup after consulting your doctor.			
After startup, power indicator lights up, but immediately goes out, or it does not work normally.	Battery is dead.	Please charge the device.			
N. I. V.	Medication may generate bubbles in medication cup	Press ON/OFF button to turn off the device, and clear up the bubbles.			
Nebulizer doesn't automatically shutdown when medication is used up.	Medication may be 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.			
The working hour is too short after the	Battery does not fully charged.	Please charge the device.			
device is charged.	Battery is damaged.	Please contact local customer service.			

If the device still can't work normally after doing all methods above, pleas contact our after-sales service.

Symbol IP22 The degree of waterproof and dustproof is IP22. Class II equipment Type BF applied part Keep dry Fragile, handle with care

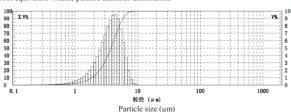
<u>††</u>	This way up
96% 5%	Humidity limitation: 5 % \sim 96 %
-#55°C	Temperature limitation: -40 °C∼+55 °C
1060hPa	Atmospheric limitation: 500 hPa ~ 1060 hPa
<u>M</u>	ON/OFF button and Nebulization rate switch button
(3)	Refer to instruction manual/booklet Note: On ME equipment "follow instructions for use"
SN	Serial number
***	Manufacturer
8	Do not re-use.
[]i	Consult instructions for use.
STERILE	Sterilized using ethylene oxide
STERILE	Sterile
REF	Catalogue number
®	Do not use if package is damaged.
	Date of manufacture
\subseteq	Use-by date
LOT	Batch code
EC REP	Authorized representative in the European Community
	Indoor use
Z	WEEE (2012/19/EU)
N N	Stacking layer limit is N N subject to actual conditions

Chapter 8 Packing List

- 1. Device body 1pc
- 2. User manual 1pc
- 3. Medication cup 1pc
- 4. Accessories 1set (adult mask, child mask)
- 5. Power cord 1pc

Appendix I

Curve chart of equivalent volume particle diameter distribution:



Median particle size (D 0.50): 3.7μm, error: within ±25 %.

Appendix II EMC Guidance and Manufacturer Declaration

Varning:

- 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 equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment 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 MOBINEB, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

...

- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may affect this device even though they meet the requirements of CISPR.
- 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.
- When an input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- The basic performance: the equipment works normally and ensures the accuracy of the equipment.
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.

The device compliance with the emission and immunity requirement specified in YY0505-2012. The functions of the device may be affected by electromagnetic interference exceeding the level specified in IEC 60601-1-2.

Guidance and Declaration - Electromagnetic Emissions

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

the user of the MOBINEB sh	ould assure that it	is used in such an environment				
Emissions test	Compliance	Electromagnetic environment - guidance				
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	The MOBINEB uses RF energy only for its inte function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electr				
Conducted and radiated RF EMISSIONS CISPR 11	Class A	equipment. The MOBINEB is suitable for use in all establishments				
Harmonic distortion IEC 61000-3-2	Class A	other than domestic and those directly connected to the public low-voltage power supply network that supplies				
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	buildings used for domestic purposes.				

Table 2

Guidance and Declaration - Electromagnetic Immunity

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

romagnetic environment - guidance	
Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %	
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

Note: UT is the AC mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity

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

Immunity Test IEC 60601 Compliance level	Electromagnetic environment - guidance
Conduced RF IEC61000-4-6	Portable and mobile RF communications equipment should be used no closer to any part of the MOBINEB, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance $d=[3.5/V1]\sqrt{P} 150k \text{ to } 80 \text{ MHz}$ $d=[3.5/E1]\sqrt{P} 800 \text{ MHz} \text{ to } 800 \text{ MHz}$ $d=[7/E1]\sqrt{P} 800 \text{ MHz} \text{ to } 2.7\text{GHz}$ Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: $((\bullet))$

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 MOBINEB is used exceeds the applicable RF compliance level above, the MOBINEB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MOBINEB.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 3

Recommended separation distances between portable and mobile RF communications equipment and the MOBINEB

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

Rated maximum	Separation distance according to frequency of transmitter			
output power of transmitter W	$\frac{m}{150 \text{ kHz to } 80 \text{ MHz}}$ $d=[3.5/V1]\sqrt{P}$	80MHz to 800MHz $d=[3.5/E1]\sqrt{P}$	800MHz to 2.7GHz d=[7/E1] \sqrt{P}	
0,01	0.12	0.04	0.07	
0,1	0.38	0.11	0.22	
1	1.2	0.35	0.70	
10	3.8	1.1	2.2	
100	12	3.5	7	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity

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

ncy (MHz) 385 Radiate d RF	Freque ncy	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNIT TEST LEVEL (V/m)
	385	380 -390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 -390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
IEC610 00-4-3	710	704 –	LTE Band 13,	Pulse modulation b) 217 Hz	0,2	0,3	9
(Test	745	787					
specific ations	780			217112			
for	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
ENCLO SURE PORT IMMU NITY to RF wireless communication s equipm ent)	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	2	0,3	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	2	0,3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5500						
	5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

 As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

TURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

 $E = \frac{6}{4}\sqrt{P}$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.



ind Contec Medical Systems Co., Ltd.
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