CE 0123

AZURE SYTEMS

Mesh Nebulizer / NE-M03

by Contec Medical Systems Co., Ltd.

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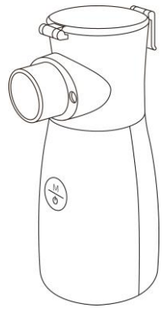

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Statements

- 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 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 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 dryers or hair dryers 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℃. 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.**
- **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℃.
- 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 by multiple people, 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 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

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 5V or (3.7V rechargeable lithium battery)

Input power: <15 VA

Nebulization rate in level I: ≥ 0.25mL/min

Nebulization rate in level II: ≥ 0.15mL/min

Noise: ≤50 dB

Quality:0.1kg

Equivalent volume particle diameter distribution: the volume distribution ratio of small atomized particles (diameter＜5 μm) 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 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 ℃～40 ℃

Humidity: 15 %～90 %

Atmospheric pressure: 700 hPa～1060 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 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.

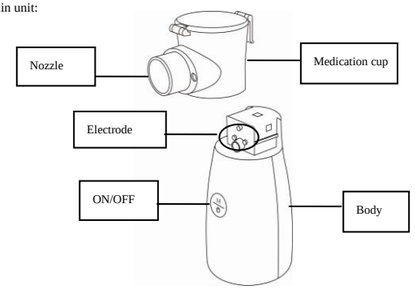
Principle of treatment.

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

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

Main unit:



Accessories:

Adult mask Child mask Adapter (optional) Power cord

Chapter 4 How to use

4.1 Assembly

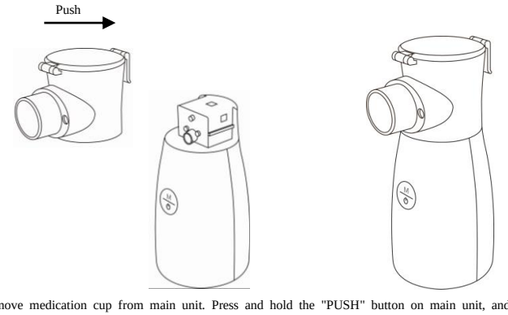
1. Remove all packages

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

2. Assembly of main unit

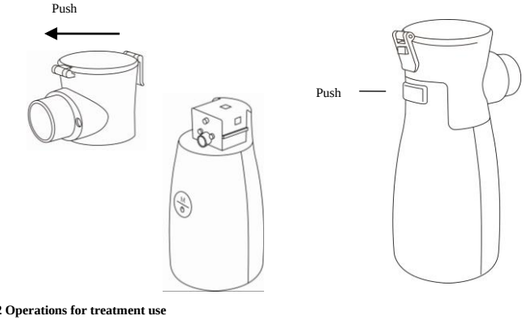
(1) Install medication cup to the main unit by pushing it towards to the main unit.

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.

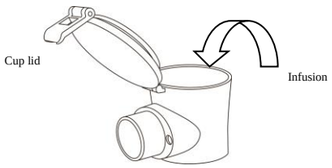


4.2 Operations for treatment use

Preparations before use:

1. 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.

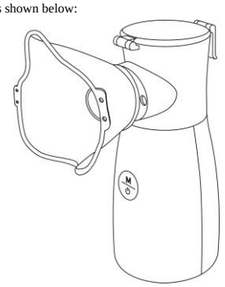
(2) Do not use the medication of high concentrations, high viscosity, oily medicines, volatile liquid medicine, doing so may lead to abnormal atomizing.

(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.

3. 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 I
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:

1. 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 indicator goes out, the device turns off.

Attention:

①There is an air hole on the lid of medication cup, do not cover it to ensure normal atomization.

②During use, please hold the device steady and do not shake it strongly.

③After pressing the ON/OFF button, the device will have a short startup period (within 1 s), then perform atomizing.

④When 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.

⑤Due 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 sheet from damage.

⑥If 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.

⑦Duration 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

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.

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.

1. 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.
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 device body, 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 device body, then air-dry or wipe-dry with a clean, soft cloth.
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.

Do not use purified water or distilled water for atomisation.

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 ℃~+55 ℃

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.

✧ 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.

Chapter 6 Troubleshooting

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.	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 startup, power indicator lights up, but immediately goes out, or it does not work normally.	Battery is dead.	Please charge the device.
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 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 device is charged.	Battery does not fully charged.	Please charge the device.
	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.		

Chapter 7 Symbols

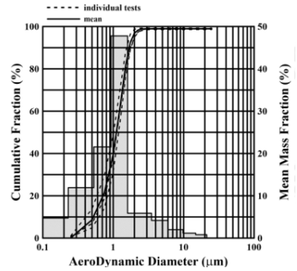
Symbol	Meaning
IP22	The degree of waterproof and dustproof is IP22.
	Class II equipment
	Type BF applied part
	Keep dry
	Fragile, handle with care
	This way up
	Humidity limitation: 5 %~96 %
	Temperature limitation: -40 ℃~+55 ℃
	Atmospheric limitation: 500 hPa ~ 1060 hPa
	ON/OFF button and Nebulization rate switch button
	Refer to instruction manual/booklet Note: On ME equipment "follow instructions for use"
SN	Serial number
CE 0123	REGULATION(EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
	Manufacturer
	Do not re-use.
	Consult instructions for use.
STERILE EO	Sterilized using ethylene oxide
STERILE	Sterile
REF	Catalogue number
	Do not use if package is damaged.
	Date of manufacture
	Use-by date
LOT	Batch code
EC REP	Authorized representative in the European Community
	Indoor use
	WEEE (2012/19/EU)
N	Stacking layer limit is N N subject to actual conditions
MD	Medical device

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:



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-M03 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, NE-M03 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-M03 could result in increased electromagnetic emissions or decreased electromagnetic immunity of NE-M03 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-M03, including cables specified by the manufacturer. Otherwise, degradation of the performance of NE-M03 could result.**

Note:

NE-M03 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 2

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						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC60601-1-2 Test level (V/m)	Compliance level (V/m)
	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
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	1720 1845 1970	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
	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 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9