VEGA TECHNOLOGIES INC.

INSTRUCTION MANUAL

Compressor nebulizer (with disposable accessories)

Model No: CN-02MU

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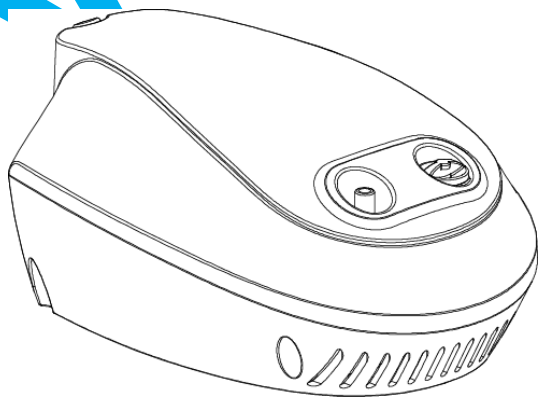


(Read this instruction manual carefully before use)

Contents

1. Introduction

Thank you for purchasing the compressor nebulizer. It is a compact medical device designed to efficiently deliver physician prescribed medication to the bronchial lung passages. With proper care and use, it will provide you with many years of reliable treatment.

This product is developed for the successful treatment of asthma, allergies and other respiratory disorders. It creates a stream of air that travels through clear tube to the nebulizer. When air enters the nebulizer, it will convert the prescribed medication into aerosol mist for easy inhalation.

Your compressor nebulizer should be used under the supervision of a licensed physician and/or a respiratory therapist. We encourage you to thoroughly read this guidebook to learn about the features of this product. Any use of this product other than its intended use should always be avoided.

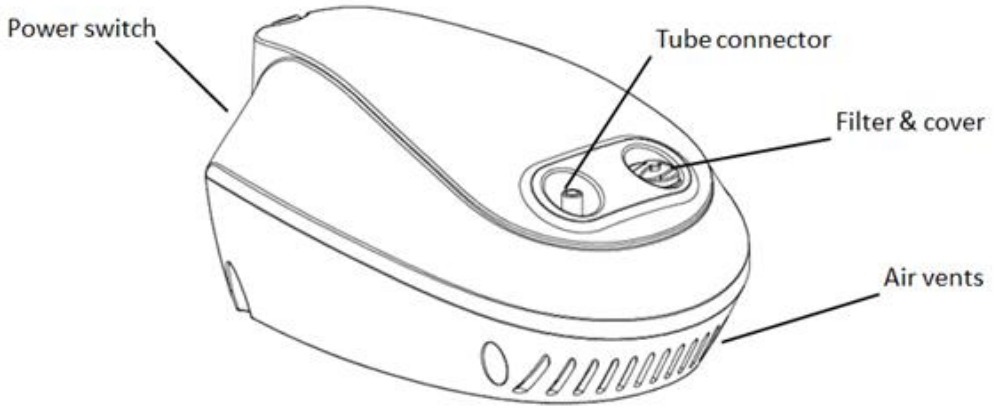
1.1 Intended use \ Intended purpose

The compressor nebulizer is intended to aerosolize physician-prescribed solutions for inhalation that are approved for nebulization. The device may be used for child and adult patients at home and in the hospital, they are not intended for life support nor do they provide any patient monitoring capabilities.

Medical Purpose	The compressor nebulizer is intended to aerosolize physician-prescribed solutions for inhalation that are approved for nebulization.
Intended User	1) Legally certified medical experts, such as doctor, nurse and therapist, or healthcare personnel. 2) The user or patient should also be capable of understanding general machine operation and the content of instruction manual.
Intended patients	This product should not be used on patients, who are unconscious or are not breathing spontaneously.

Intended Environment	This product is intended for use in a medical facility, such as hospital, clinic and doctor office, and in a room of general household.
Precautions for use	Warnings and cautions described in the instruction manual should be observed

1.2 Product identification



1.3 Disposable accessories list

Disposable accessories	**Quantity**	
Nebulizer Bottle	1pc	
Air Tube	1pc	
Mouthpiece	1pc	
Nosepiece	1pc	

Air Filters	5pcs	
Adult Mask	1pc	
Child Mask	1pc	
Infant Mask	1pc	
Connector	1pc	

2. Safety precaution

Read all the information in the instruction manual and any other literature included in the box before using the device.

When using an electrical product, especially when children are present, basic safety precautions should always be followed including the following:

⚠ Warning:

Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

(Usage)

1) For type, dose, and regime of medication, follow the instructions of your doctor or respiratory therapist.
2) Precautions should be taken in the event of changes in the performance of the product or the system.
3) Avoid or minimize potential electromagnetic or other interference between the product and other devices.

4) The long air tube of this product may cause strangulation of the user if use in wrong way.
5) Do not use disposable accessories, detachable parts and materials not described in the instructions for use.
6) Do not use in an oxygen rich environment.
7) Do not interconnect this equipment with other equipment not described in the instructions for use.
8) Warning against servicing and maintenance while the ME EQUIPMENT is in use.
9) No modification of this equipment is allowed.
10) If you feel anything unusual during use stop using the device immediately and consult your doctor.
11) Do not use only water in the nebulizer for inhaling purposes.
12) Do not use this product to treat accidents or in complicated site of accidents, it may cause the secondary accidents or faults.
13) Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
14) Do not use the device while sleeping or sleepy.
15) Do not use in anesthetic or ventilator breathing circuits.
16) Store the device and disposable accessories in a clean location.
17) Do not store the air tube while there is moisture or medication remaining inside it.
18) Do not use the device where it may be exposed to flammable gas.
19) Do not place the device on a soft surface or cover the device with a blanket or towel etc. during use.
20) Make sure that the disposable accessories is clean before use.
21) Always dispose of any remaining medication after use and only use fresh medication each time.
22) Store the parts in a clean location for avoiding infection.

(Risk of electrical shock)

1) Do not use the compressor while they are wet or connect them to a power outlet or other devices with wet hands.
2) Do not spill water, or other liquids on the device. If liquid does spill on these parts, immediately unplug the power cord and wipe off the liquid with soft cloth or other absorbent material.
3) Do not immerse the compressor in water or other liquid.

4) Do not use or store the device in humid locations, such as in a bathroom.
5) Do not operate the device with a damaged power cord or plug.
6) Keep the power cord away from heated surfaces.

⚠ **Caution:**

Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury, or physical damage.

(Usage)

1) Make sure that the air filter is correctly attached.
2) Make sure that the air filter is clean.
3) Do not spill liquid or medication on the compressor.
4) Do not use or store the device while the air tube is creased.
5) Do not leave the device unattended with infants or person who cannot express their consent.
6) When using the device, the main unit may become hot.
7) Do not touch the main unit for other than necessary operation such as turning off the power while nebulizing.
8) Do not reuse the disposable accessories of compressor nebulizer.

(Risk of electrical shock)

1) Always unplug the device from the power outlet to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously after use and before cleaning.
2) Plug the device into the appropriate voltage outlet. Do not overload power outlets or use extension cords.
3) Do not wind the cord of the device around the device.
4) Do not pull the power cord of the device strongly.

General safety precautions:

1) Inspect the device and parts before using them each time, and check that there are not problems. Inparticular, be sure to check the following:

—That the nebulizer bottle and air tube are not damaged.

—That the compressor operates normally.

2) When using this device, there will be some noise and vibration caused by the pump in the compressor. There will also be some noise caused by the emission of compressed air from the nebulizer kit. This is normal and does not indicate a malfunction.
3) Operate the device only as intended. Do not use the device for any other purpose.
4) Make sure that the air tube is securely attached to the compressor and nebulizer bottle, and does not come loose. Twist the air tube plug slightly when inserting it into the air tube connectors to avoid the air tube disconnecting during use.
5) To completely isolate the device from the power source, unplug the plug from the power source.

Save these instructions for future reference.

3. Information for operation

3.1 Functional description

The nebulizer is mainly used for the treatment of various respiratory diseases, such as colds, fever, cough, asthma, sore throat, pharyngitis, rhinitis, bronchitis, pneumoconiosis and other diseases occurring in the trachea, bronchi, alveoli and chest cavity.

Atomizing inhalation is an important and effective treatment method for the treatment of respiratory diseases. The drug solution is atomized into small particles by means of atomizing inhaler, and the drug enters the respiratory tract and lung deposition by means of breathing inhalation, so as to achieve the objective of painless, rapid and effective the treatment. Compared to traditional injections, this treatment gives small doses and effectively reduces side effects.

Note: Drug is normal saline or which has been verified.

3.2 Installation and operation procedure

Note: Prior to every operation, the nebulizer should be thoroughly cleaned.

1) Place your Compressor Nebulizer on a flat and stable surface. Be sure that you can easily reach the controls when you are seated.
2) Open the top cover.

   Important: Prior to initial operation, the nebulizer should be thoroughly cleaned referring to the "Cleaning and Maintenance" in the manual.

3) Gently twist the top cover of the Nebulizer Bottle counter-clockwise to disassemble the Nebulizer Bottle.(Fig.1)
4) Fill the cup base of the Nebulizer Bottle with the medication prescribed by your physician.(Fig.2)
5) Gently twist the top cover clockwise to re-assemble the Nebulizer Bottle. Be sure the two sections fit well.(Fig.3)
6) Attach one end of Air Tube to the cup base of the Nebulizer Bottle.(Fig.4)

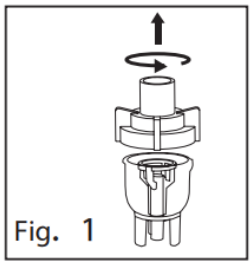


Fig. 1

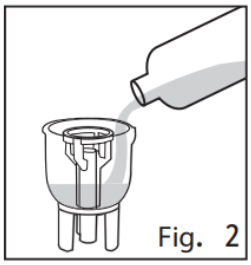


Fig. 2

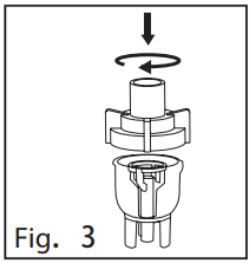


Fig. 3

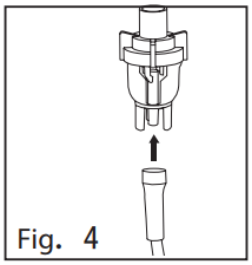


Fig. 4

7) Attach the other end of Air Tube to the tube connector located on the front of the Compressor Nebulizer.
8) Attach one of inhalation device per your choice to the top cover of Nebulizer Bottle, but Infant Mask need to add Connector between mask and Nebulizer Bottle.

   Remark: Inhalation device is Mouthpiece, Nosepiece, Adult Mask, Child Mask, Infant Mask.

9) Plug the power cord into an appropriate electrical outlet. Make sure at this stage, the power switch is at "OFF" status.
10) Press power switch to begin your prescribed treatment.

Important:

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

a. Switch off the unit.
b. Unplug the unit from the electrical outlet.
c. Wait 30 minutes for the motor to cool down before another treatment. Make sure the air vents are not obstructed.

11) When treatment is finished, shut off the unit and unplug it from the electrical outlet.

4. Cleaning and maintenance

Warning:

Please make sure the power cord is not plugged into the power outlet when clean and disinfect the product.

Cleaning:

It is recommended to clean the Compressor Nebulizer after each use unless there are other instructions by your doctor.

Disinfection:

It is recommended to disinfect the Compressor Nebulizer unless there are other instructions by your doctor.

1) Wipe or spray Compressor Nebulizer with 75% medical alcohol after using and cleaning the product.

Cleaning the device:

1) Wet the soft cloth with purified water and wring it out, then clean the surface of the device with the damp cloth.

2) Do not use any powder cleaners or acidic solvents, which may damage the product.
3) The device shall be cleaned at least once a month.

Filter change:

1) Do not use cotton or any other materials. Do not wash or clean the filter. Only use filters supplied by your distributor. And do not operate without a filter.
2) Change the filter before every use due to the Air Filters is disposable.
3) Changing procedure:

   A. Remove the filter cover.
   B. Replace the used filter with a new one.
   C. Put back the filter cover.

5. Troubleshooting information

Check the following if your unit should fail during operation. You can also refer to the pages of this manual for complete instructions.

Problem	Cause	Remedy
When switching it on, it does not work	1) Incorrectly plugged. 2) Electrical energy missing.	1) Check if the unit is properly connected. 2) Verify if there is electrical energy.
The mist does not come out from the jet, nebulizer/aerosol output reduced(low).	1) Not enough medication in the nebulizer bottle. 2) Too much medication. 3) Tubing disconnected. 4) The nebulizer bottle is not creating mist.	1) Add medication. 2) Remove excess medication. 3) Connect the tubing. 4) Replace the nebulizer bottle.

	5) The air filter is clogged.	5) Replace the air filter.

Note: If the suggested remedy does not solve the problem, do not try to repair the device-no parts of the unit are user serviceable. Please contact an authorized distributor.

6. Service information

Under this warranty, VEGA' s obligation shall be limited to any such units which prove, by VEGA' s inspection, to be defective within two years from the original purchase date. This warranty does not extend to non-durable components which are subject to normal wear and need periodic replacement.

Any abuse, operation other than the intended use of this product as outlined in the manual, negligence, accident, or repairs by someone other than a VEGA' s Authorized Service Professional, shall immediately void this warranty.

ME EQUIPMENT that is intended for use by a LAY OPERATOR shall indicate that the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or the MANUFACTURER'S representative:

– for assistance, if needed, in setting up, using or maintaining the ME EQUIPMENT or ME SYSTEM; or

– to report unexpected operation or events.

VEGA will not accept damages or charges for labor, parts, or expenses incurred in making field repairs.

The foregoing warranty is exclusive and in lieu of all other expressed warranties. Implied warranties, if any, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, shall not extend beyond the duration of the express warranty provided herein. In no event shall VEGA or its subsidiaries by liable for loss of use or profit or other collateral, special or consequential damages.


VEGA

7. Technical specifications

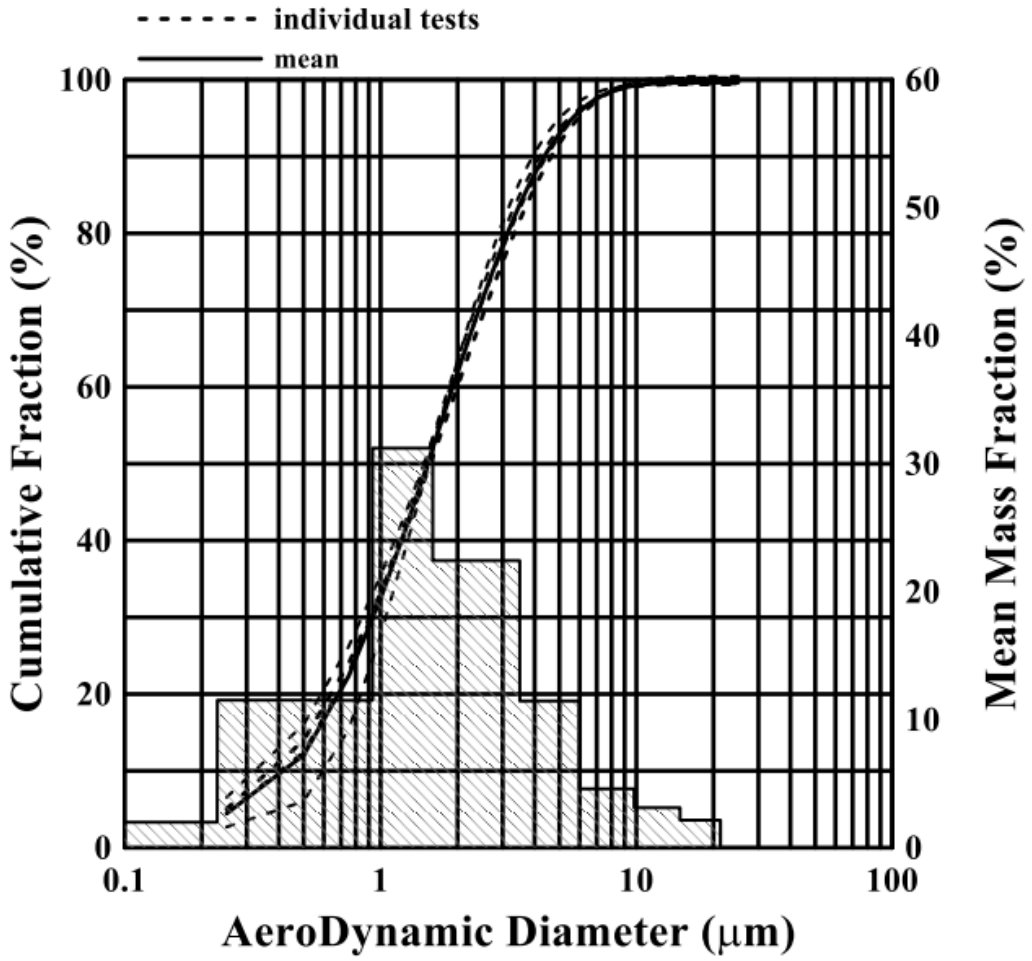
7.1 Specifications table

Product name	Compressor Nebulizer
Model	CN-02MU
Applied part	Type BF Mouthpiece Adult/child mask
Power (main unit)	230V/50Hz
Mode of operation	Non-continuous (30 Min. on / 30 Min. off)
The typical operation time	30 min.
Power consumption	180 VA Max
Type of nebulizer	Compressor nebulizer
Recommended fill volume	2 to 5ml(Max. 6ml)
Air flow	5.0 to 8.0 Lpm
Nebulization rate	≧0.20 ml/min. (0.9% salt water solution)
Operating pressure	8.0 to 13.0 Psi (0.06 to 0.09Mpa)
Maximum pressure	≧ 25 Psi (≧ 0.17 Mpa)
MMAD	5 μm
Noise level	Less than 60 dB (1m away)
Dimension (L X W X H)	188 x 145 x 88 mm
Weight	1.2 kgs
IP degree	IP21
Life time	≧ 2 years for homecare usage (or 1,000 hours)
Disposable accessories shelf-life	1 year
Operating environment	Temperature: 5 to 40˚C (41˚F to 104˚F) Humidity: 15% to 90% RH Atmospheric pressure: 700 to 1,060hPa
Storage environment	Temperature: -25˚C to 70˚C (-13˚F to 158˚F) Humidity: 0% to 90 % RH Atmospheric pressure: 700 to 1,060hPa

7.2 Specification table of disposable accessories

No.	Item	Specification	Model
1.	Nebulizer Bottle	PP	CNK-M03
2.	Mouthpiece	PP	CNK-M06
3.	Air Filter	PU	CNK-S03
4.	Nosepiece	PP, translucent	CUK-M04
5.	Child Mask	PVC, transparent, with mask strap	CUK-M02
6.	Adult Mask	PVC, transparent, with mask strap	CUK-M01
7.	Air Tube	PVC, 150cm	CNK-S01
8.	Connector	PP	CUK-S01
9.	Infant Mask	PVC, blue, PMS284C, with mask strap	CNK-M14

7.3 The particle size distribution curve



8. Symbols

8.1. Symbols and description

	Refer to instruction manual/booklet		Manufacturer
LOT	Batch code		Date of manufacture
SN	Serial number		Caution

	Type BF applied part		Temperature limitation
	Keep away from sunlight		Protection class II
	Humidity limitation	IP21	Ingress protection
	Direct current		Keep away from rain
	"ON"/"OFF" (push-push)		Alternating current
CE 0123	This device complies with the requirements of Regulation (EU) 745/2017	QTY	Quantity
	This way up	EC REP	Authorized representative
	Fragile; handle with care		Atmospheric pressure limitation
	The symbol indicating separate collection for EEE	MD	Medical Device

9.Disposal

⚠ **Danger of infection!**

The device and disposable accessories may come into contact with infectious material and be contaminated during their lifetime. For this reason, the device and its disposable accessories should be decontaminated before disposal or transportation.

Dispose of the device properly at the end of its service life. According to the European Directives 2012/19/EU (WEEE) and 2011/65/EU (RoHS) the device may

not be disposed of with unsorted domestic waste. Look for a careful separation of materials. Consider the country-specific laws and regulations that apply to the disposal of the device. The proper disposal of the device prevents environmental and human damage.

Outside the EU, the appropriate national regulations for disposal must be observed.

10. Information about Electromagnetic Compatibility

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC). The device needs to be installed and put into service according to the EMC information provided in this chapter.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the device as recommended below.

⚠Warning:
The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Table 1

Guidance and manufacturer’ s declaration –electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby

		electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer’ s declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 ±1 kV for input/output lines	Not applicable	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) ± 2 kV line(s) to earth	Not applicable	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 (>95 % 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 (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from a continuous power supply or a battery.
Power frequency	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

(50/60 Hz) magnetic field IEC 61000-4-8			environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer’ s declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated	3Vrms 150kHz to 80MHz 3V/m	Not applicable 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2$\sqrt{P}$ d = 1.2$\sqrt{P}$ 80MHz to 800MHz d = 2.3$\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,

RF IEC 61000-4-3	80MHz to 2.5GHz		should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Table 4

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

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, 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.

11. Contact information

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