USER'S GUIDE

Biothesiometer Plus

Biothesiometer Plus

vers. 1.0

Biothesiometer Plus User's Guide
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CE

Biothesiometer Plus

Assistance :

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CE

Manufacturer: METEDA S.r.l.

Via A. Bosio, 2 int.10

00161 Roma (RM)

Product name: Biothesiometer Plus

Version: 1.0

The license to use may be viewed on installation. It is available on this software and can be accessed by clicking on the "INFO" button.

SYMBOL

LIST OF SYMBOLS

CAUTION – Please read carefully – STRICTLY COMPLY WITH WHAT SPECIFIED HEREAFTER TO PREVENT THE DEVICE FROM MALFUNCTIONING AND/OR AVOID DAMAGING IT, OR HARMING THE PATIENT.

DEVICE SYMBOLS

 aaaa	Manufacturer's name and address, year of production
	This product complies with the provisions of the European Directive 93/42 / CEE on medical devices: Class I
	B application part
	CAUTION! Consult the internal documents
	Operating instructions
	Polarity symbol
	This product complies with the EU Directive 2012/19/EC. The crossed out wheeled-bin symbol on the device or its packaging indicates that at the end of its working life the product should not be treated as general household waste, but taken to one of the recycling centers for electrical and electronic equipment run by local authorities, or returned to the seller upon purchasing a similar device. The user is responsible for delivering the equipment to appropriate collection facilities at the end of its working life. By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential adverse effects on the environment and human health which could otherwise arise due to inappropriate waste handling. For more detailed information on the available waste collection systems, contact your local waste disposal service.
	Direct current
S/N xxxxxxx	Serial Number

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1. INTRODUCTION

Biothesiometer Plus is a portable, hand-held electro-medical device. It is self-calibrated and its vibrating amplitude is preset in micron, regardless of the pressure exerted by the operator on the patient's skin while performing the test. The vibration amplitude may be either set by the operator, or automatically increased/decreased in microns in order to assess the patient's sensitivity to vibration produced by a vibrating tactor.

It is an effective method to look for early signs of neuropathy by assessing the response to vibration of the peripheral nervous fibers responsible for tactile sensitivity.

2. INTENDED USE

Biothesiometer Plus is a system designed to detect sensory deficit and measure the threshold of appreciation of vibration in diabetic patients or in any other cases in which this kind of assessment is required (andrology, gynecology, neurology, occupational medicine)

The system consists in carrying out screening tests which are useful to select the patients for which more complex diagnostic investigations are needed. Biothesiometry must be performed by health care professionals, physicians, nurses and/or skilled technicians in the medical sector, at the premises of diabetology, andrology, gynecology, neurology centers, podology clinics, pharmacies.

The tests provide an effective screening method for studying early dysfunction of the peripheral nervous system in patients suffering from diabetes mellitus or any other peripheral neuropathy.

The device is intended for hospital use at private or public health care centers, pharmacies and/or clinics.

Biothesiometer Plus is intended for use by specially trained health care professionals, physicians, nurses and pharmacists.

3. DISCLAIMER

This document is for health care professionals with a working knowledge of medical procedures and terminology as required for studying and monitoring changes in the peripheral nervous system.

Please read this User's Guide, all the information and the technical sheet that come with the device very carefully before using Biothesiometer Plus.

The use of the device by anyone other than the intended user, or for any purpose or application other than what specified in this User's Guide, or the non-compliance with any of the instructions herein will be considered as IMPROPER USE.

METEDA shall not be held responsible for any incorrect settings.

4. ACCESSORIES AND MATERIALS USED

The device is a compact unit comprising a user's interface with two buttons and a high visibility display.

The Teflon (PTFE) or polyzene tactor on the rear of the device, which is the only part which comes into contact with the patient's skin, vibrates at a frequency of 100Hz for the length of the test, i.e. only few minutes.

The device comes with a micro USB cable battery charger: Input: 100-240 Vac, 50/60 Hz, Output: 5 Vdc, 1000 mA.

Please see the attached technical sheet for any further specifications.

5. INSTRUCTIONS AND PRECAUTIONS FOR PROPER DEVICE OPERATION

Biothesiometer Plus does not cause any electromagnetic interference, nor does it have any adverse effects on the patient or the operator.

Biothesiometer Plus may not be modified or tampered with in any way.

The wearing parts of Biothesiometer Plus require extraordinary maintenance (please see the related paragraph 'Extraordinary maintenance' in this User's Guide).

The routine maintenance and cleaning of the device shall be seen to by the user and carried out by the operator prior to every test session (please see the related paragraph 'Routine maintenance and cleaning').

In case of malfunction, or should any extraordinary maintenance be required, please refer to METEDA Technical Assistance service.

As extraordinary maintenance is to be carried out exclusively by the manufacturer, as specified below, no circuit diagrams, list of components, repair instructions or any other information of the kind are included or provided to the final user.

Please do not attempt to use the device while the battery is being charged as Biothesiometer Plus is designed not to work while recharging. Do not use power supply units other than the one provided with the device.

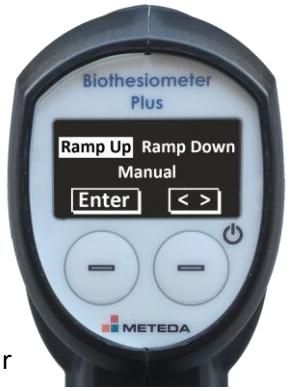
Optimal operating conditions

- Operating temperature 16°C to 40°C
- Operating relative humidity 30 to 70%
- Operating atmospheric pressure from 700 ÷ 1060 hpa
- Maximum operating altitude 2000 mt

Optimal storage and handling conditions

- Storage temperature -20°C to 60°C
- Storage and handling relative humidity 5% to 85% non condensing
- Storage and handling atmospheric pressure from 700 ÷ 1060 hpa
- Maximun altitude 2000 mt

6. HOW TO CARRY OUT THE TEST



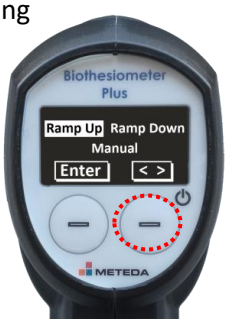
The two buttons on the device will allow you to select/set the available functions as required.

To switch on Biothesiometer Plus keep the button on the right, with the icon beside it, pressed for a few seconds.

Once the device is switched on, you can then use the same button to navigate through the available functions, while pressing the button on the left will confirm your selected options. On the display there is an icon above each button: the navigation icon < > and the confirmation icon Enter

6.1 General instructions for use

Before performing the test the patient has to lie down and you should make sure he/she is as comfortable as possible. It is also very important that the patient is relaxed and informed about what is going to happen, as his/her collaboration is necessary to perform the test as he/she will have to tell you whether any vibration is felt on the tested spot.



To switch on the device hold the button on the right, below the display, pressed for 2 seconds. The display will then show the METEDA logo, the Firmware and Bootloader versions of the device and the battery level.

The navigation button Enter allows you to select one of the three test operating modes shown on the display:

- ***Ramp Up (automatic amplitude increase);***
- ***Ramp Down (automatic amplitude decrease)***
- ***Manual (manual amplitude setting)***

To confirm mode selection, press the **Enter** button.

VIBRATION MEASUREMENT UNITS IN THE DIFFERENT TEST MODES

In Ramp Up and Ramp Down modes the vibration amplitude gradually increases/decreases according to the following criteria:

- Ramp Up: gradual increase from 10 Volts (1 micron) to 32 Volts (10.5 microns)
- Ramp Down: gradual decrease from 32 Volts (10.5 microns) to 10 Volts (1 micron)
- Manual: vibration starts at 10 Volts and may be either increased or decreased by pressing the +/- buttons

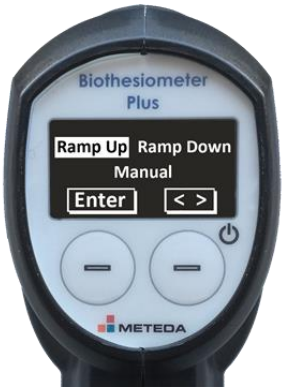
Below is the Volts/Microns table of equivalence applicable to the vibration output in optimal conditions of use of the device. Biothesiometer Plus is calibrated in microns according to the Volt/Micron conversion table, in order to maintain full result compatibility with older Biothesiometer models. The actual equivalence has also been verified by means of an oscilloscope by exerting a suitable pressure on the older Biothesiometer models, using a mechanical system specifically designed for the purpose.

Volts	***Microns***	***Volts***	***Microns***
5	0.25	19	3.7
6	0.36	20	4.0
7	0.50	21	4.5
8	0.66	22	4.9
9	0.82	23	5.4
10	1.0	24	5.9
11	1.2	25	6.4
12	1.4	26	6.9
13	1.7	27	7.5
14	2.0	28	8.0
15	2.2	29	8.6
16	2.6	30	9.2
17	2.9	31	9.9
18	3.3	32	10.5

**Source: Bio-Medical Instrument Company*

6.1.1 Testing

As mentioned above, the test may be carried out in three different testing modes: Ramp Up, Ramp Down and Manual.



In Ramp Up and **Ramp Down** the gradual increasing/decreasing vibration output is automatic. Once the preferred mode has been selected, press the **Start** button on the right. To complete the test with the result of the mean vibration measurements perceived by the patient, press the **Enter** button on the left when the patient feels vibratory sensation. Every time **Enter** is pressed the next ramp will start while the tactor will keep vibrating. Hold the tactor firmly on the patient's skin throughout the 3 sequential assessment steps.

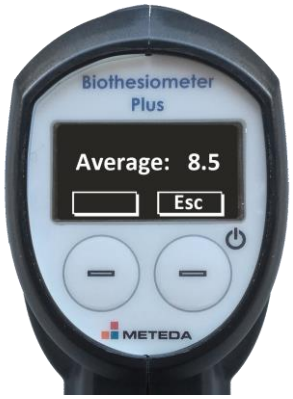
To stop the increasing/decreasing ramp, press the **Stop** button on the right. **Esc** will appear immediately after that on the display. Press the button to exit the test session.

If you do not press the **Esc** button**,** the **Start** button option will appear on the display after a few seconds. Pressing the **Start** button will re-start the ramp from where it was interrupted.

If you wish to start a new ramp from the beginning, press **Enter.**

As the result of each value depends on the patient's timely indication of his/her perception of vibration, a sequence of three repeated measurements will allow you to assess the mean value more accurately.

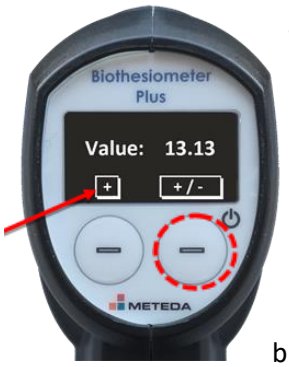
After the third repetition, the mean value obtained will be shown on the display (e.g. Average: 8.5).



To stop vibration or any other ongoing operation and go back to the menu, press the **Stop** button**,** then **Esc**.

In **Manual** mode the health care professional can modify the vibration amplitude by pressing the button on the right, below [+ / -]

In Manual mode you can change from an increasing to a decreasing vibration variation (and vice-versa) by pressing the button on the right, below [+ / -]



'+' indicates that the vibration variation is increasing, **' - '** indicates that it is decreasing.

In Manual mode the test result corresponds to the last value set by the health care professional and felt by the patient.

To stop vibration or any other ongoing operation and go back to the menu, press the button below [+ / -] then **Esc**.

A light pressure on the patient's skin is enough to carry out the test.

Independently of the pressure exerted, a high precision piezoelectric motor and a built-in sensor make it possible for Biothesiometer Plus to emit vibration that is accurately pre-calibrated in microns.

For example, when placed on a particularly hard spot or when the tactor is being pressed hard, the device will use more energy to reach a one micron amplitude. If, on the contrary, the tactor is placed on a softer spot and the pressure exerted on it is correct, the device will use less energy to reach the same amplitude. **This is an innovative feature which makes Biothesiometer Plus completely different from the older devices whose vibration amplitude is based exclusively on the selected voltage. Differently from Biothesiometer Plus, the**

resulting vibration inevitably varies according to the pressure exerted by the operator on the skin, as well as on how hard the tested spot is.

 **CAUTION!** Although hard pressure on the tactor will have no effect on the vibration amplitude, it may affect the response of tactile receptors to vibration.

 **CAUTION!** Hold the tactor in firm contact and minimal pressure on the patient's skin for optimal test performance.

The **stand-by time-out** is an energy saving function of Biothesiometer Plus. If the device is left in stand-by for 5 minutes (no buttons are pressed or the device is not moved), it will switch off automatically.

7. DEVICE MAINTENANCE

7.1 Device Power Charge

Biothesiometer plus comes with rechargeable Lithium-ion batteries Model GSP053759*3P; 3.7V 1250mAh 37.5*59.5mm (ØxH)

- Charge: 0~45℃
- Discharge: 20~60℃
- Extended time storage: -20~25℃

To recharge the device make sure it is switched off, then plug the micro USB cable of the charger (supplied with your Biothesiometer plus) into a standard power outlet.

Do not use in re-charge mode. The device is designed not to work while recharging.

The % battery charge level will be shown on the display both in on and off modes.

CAUTION! Only use the battery charger provided with the unit. Using accessories other than those recommended by the manufacturer may seriously affect the safety of the device.

CAUTION! Any attempt to charge the batteries without strictly complying the instructions of this User's Guide is forbidden and shall be regarded as IMPROPER USE. .

CAUTION! Do not attempt to use the device while it is recharging. The device does not work in charge mode.

IMPORTANT! The maintenance of the rechargable batteries can only be carried out by the manufacturer's technicians. Any attempt to replace the batteries by unauthorized persons may seriously affect the safety of the device.

CAUTION! If the device is left unused for a period of over three months, check the battery charge level before using it again. Should battery replacement be required, please refer to the paragraph "Extraordinary maintenance".

7.2 Routine maintenance and cleaning

Routine maintenance includes all the things you need to do to keep the device in good working condition. To clean the parts that do not come into contact with the patient, make sure the device is unplugged from the power outlet and use a soft, clean cloth with some glass cleaning spray or any mild detergent solution.

CAUTION! Make sure the device has been unplugged from the power outlet before starting routine maintenance, cleaning, technical assistance, transport.

Do not Use volatile detergent solutions or spray detergents directly on the device. A disinfectant is required to clean the tactor.

How often the device needs cleaning obviously depends on frequency/conditions of use.

7.3 Cleaning and disinfection of the applied part

As the tactor is placed against the patient's skin, it is necessary to clean it with a soft cloth moistened with a suitable bactericide, such as hydro-alcoholic quaternary ammonium or similar solutions. Also diluted sodium hypoclorite (diluted bleach) will serve the purpose.

The disinfection of the tactor is required every time a test is completed.

CAUTION! Make sure the device is switched off and unplugged before cleaning or disinfection**.** Do not immerse any part of this device in water or any other fluids. The device is NOT suitable for autoclave, high-temperature or radiation sterilization.

CAUTION! When cleaning the tactor, be very careful not to let any liquid run down inside the unit, as that would damage the device.

7.4 Extraordinary Maintenance

Any operation involving the disassembly of parts of the unit or their removal, replacement and repair is regarded as extraordinary maintenance, which can be carried out only by METEDA's authorized staff.

METEDA shall in no way be held responsible for any such maintenance operations carried out by anyone other than its authorized personnel.

IMPORTANT! In case of malfunction, contact METEDA's Technical Assistance service.

7.5 Calibration

A correct calibration is crucial to the accurate vibration measurement. Biothesiometer Plus is calibrated by the manufacturer.

8. DEVICE DISPOSAL

At the end of its service life Biothesiometer Plus must be disposed of as special waste in accordance with national regulations, as it has built-in batteries.

9. RULES AND DIRECTIVES

Classification: Class I, as provided for in in rule 12 of Annex IX.

The device has been designed in compliance with Directive 93/42/CEE, (and following amendment 2007/47 / CE) and with the regulations listed hereunder:

- UNI CEI EN ISO 13485 - Medical devices – Quality management systems – Requirements for regulatory purposes
- EN 62304 - Medical device software – Software life cycle processes
- UNI CEI EN ISO 14971 – Application of risk management to medical devices
- CEI EN 62366 - "Medical devices– Application of usability engineering to medical devices"
- ISO 15223-1 – Symbols for use in the labelling of medical devices ,labelling requirements, information to provide
- CEI EN 60601-1- Medical Electrical Equipment - General requirements for basic safety and essential performance
- CEI EN 60601-1-6 – Medical Electrical Equipment. Collateral standard: Usability
- CEI EN 60601-1-2 – Medical Electrical Equipment. - General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility

10. EMC INFORMATION– MANUFACTURER'S GUIDE AND DECLARATION

In compliance with CEI EN 60601-1-2 standard, information relevant to various aspects of Electromagnetic compatibility is provided, in particular with reference to the test modes and the environment conditions required for optimal testing.

IMPORTANT! Precautions: this is an electrostatic-sensitive device. If testing is carried out in a very dry environment, on carpeted floors or synthetic mats, if you are wearing synthetic fabric or rubber-soled shoes, you should touch a grounded metal object to discharge any electrostatic build-up from your body, before touching the device

IMPORTANT! Medical devices require some electromagnetic compatibility precautions. It is important to comply with the relevant instructions in this User's Guide on installation and operation.
In particular, make sure there is no electromagnetic interference from radios transmitters, cell phones, or other medical equipment such as electrosurgical instruments, X-ray or MRI equipment.

IMPORTANT! Portable devices, as well as mobile communication devices may affect the performance of this medical electrical device.

CAUTION! This device and its components must not be used near to, or placed on top of, other devices. Should that be unavoidable, make sure the device is actually working correctly in the selected mode.

CAUTION! Using accessories, transducers, connectors and cables other than those indicated by the manufacturer may increase electromagnetic emissions and/or decrease the electromagnetic immunity of the monitoring device. The device comes with cables having the following characteristics: charging device cable (>1 m).

<table>
<tr><th colspan="3">MANUFACTURER'S GUIDE AND DECLARATION –ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">To ensure its correct functioning, Biothesiometer Plus should be used in certain environmental conditions, as specified below. The user should always make sure the following requirements are met:</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Biothesiometer Plus uses RF energy only for its internal functioning, which produces extremely low RF emissions and causes no interference with other electronic devices placed close to it.</td></tr>
<tr><td>Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Biothesiometer Plus is suitable for use at premises with a low voltage mains power outlet (household power supply)</td></tr>
<tr><td>Outflow of high frequency harmonics
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker
IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

The table shows all the possible emission related issues which may cause disturbance to or interference with other electronic devices.

MANUFACTURER'S GUIDE AND DECLARATION – ELECTROMAGNETIC IMMUNITY			
To ensure its correct functioning, Biothesiometer Plus should be used in certain electromagnetic conditions, as specified below. The user should always make sure the following requirements are met:			
Test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic Environment**
Electrostatic discharges IEC 61000-4-2	Contact discharges ±6kV	Contact discharges ±6kV	Wooden flooring or ceramic tiles. If the flooring is in synthetic material, there should be a relative humidity of at least 30 %.
	Air discharges ±8kV	Air discharges ±8kV	
Transient/rapid pulse sequence 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
	+- 1 kV for input/output lines	+- 1 kV per le linee di ingresso/uscita	
Voltage surges IEC 61000-4-5	phase-phase ±1kV	phase-phase ±1kV	Mains power quality should be that of a typical commercial or hospital environment
	phase(s)-ground ±2kV	phase(s)-ground ±2kV	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	V_{RES} <5% V_{NOM} 0,5 cycles	V_{RES} <5% V_{NOM} per 0,5 cicli	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 Biothesiometer Plus be powered from the uninterruptable powersupply or battery.
	V_{RES} =40% V_{NOM} 5 cycles	V_{RES} =40% V_{NOM} 5 cycles	
	V_{RES} =70% V_{NOM} 25 cycles	V_{RES} =70% V_{NOM} 25 cycles	
	V_{RES} <5% V_{NOM} 5s	V_{RES} <5% V_{NOM} 5s	
Power frequency magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels typical of a commercial or hospital environment
NOTE: 230 Vac is the CA mains voltage prior to the application of the test level			

The table refers to the various immunity tests performed and contains specification of test type and levels as well as some important notes and advice for the user. 'Electromagnetic immunity' means the ability of a device or component(s) or separate technical unit(s) to operate without degradation of performance in the presence of electromagnetic disturbances transmitted through cable or over the air.

MANUFACTURER'S **GUIDE AND DECLARATION – ELECTROMAGNETIC IMMUNITY**

Biothesiometer Plus is designed for use in suitable environmental conditions, as indicated hereunder. Please make sure such conditions are provided before using this device.

Test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment**
			Portable and mobile RF communications equipment should be used no closer to any part of Biothesiometer Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
RF Condotta IEC 61000-4-6	3 Veff 150kHz to 80 MHz	3 Veff	$d = 1.2\sqrt{P}$
			$d = 1.2\sqrt{P}$ 80 MHZ to 800 MHz
RF Irradiata IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHZ to 2.5 GHz
			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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic on-site survey, a. should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 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 RF transmitters, such as radio-based electronic communications systems (cell/cordless phones) and other terrestrial technical systems, two-way radios, amateur radio receivers and transmitters, AM FM radio transmitters, TV transmitters, cannot be accurately predicted. 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 being used exceeds the applicable RF compliance level above, Biothesiometer plus should be observed to verify normal operation. Should any anomalies be detected, additional measures may be required, e.g. change its orientation or position.

[b] The field strength in the 150 kHz to 80 MHz frequency range should be less than 3 V/m

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE/MOBILE RF COMMUNICATIONS EQUIPMENT AND Biothesiometer Plus

Biothesiometer Plus is designed to work as intended in an environment in which RF emission disturbances are controlled. The customer/user can contribute to prevent electromagnetic interference by ensuring the minimum separation distance (as recommended below) between Biothesiometer Plus and mobile/portable RF communications equipment and systems, according to the maximum output power.

Rated maximum output power of the transmitter (W)	**Transmitter frequency separation distance (m)**		
	da 150 kHz a 80 MHz $d = 1.2\sqrt{P}$	**da 80 MHz a 800 MHz** $d = 1.2\sqrt{P}$	**da 800 MHz a 2.5 GHz** $d = 2.3\sqrt{P}$
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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 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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