ManaFlow 52 Full™

INSTRUCTIONS FOR YOUR NEW MANAFLOW

Adjustable Pressure Vascular Therapy System
(Compressible Limb Sleeve Device)

Power Supply
Input: 100 - 240 Vac, 50 - 60 Hz,
Output: 5 Vdc @ 2 Amp

Customer Service
Toll Free: 888-508-0712
Email: CustomerService@manamed.com
Web: www.manamed.com

Manufactured For:
5240 W Charleston Blvd, Las Vegas NV 89146

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USER MAINTENANCE

Contains no serviceable parts. Contact ManaMed Customer Service at 888-508-0712.

Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut charging cord, cracked plastic housings, torn cuffs, etc). Refer to image of ManaFlow for description of all components.

Do not attempt to connect the wall supply if any damage is noticed.

Avoid subjecting the unit to shocks, such as dropping the pumps.

Do not handle the leg cuffs with any sharp objects. If a bladder is punctured or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available through customer service.

Avoid folding or creasing the bladder during use and transportation of the unit.

Battery is not replaceable; replacement units are available through customer service.

Contact ManaMed to receive replacements instructions for any damaged items.

STORAGE

Store in a dry location between +10°C (50°F) and +40°C (104°F).

Do not expose to heat exceeding 50°C (122°F) for extended periods of time.

Do not store items in direct sunlight.

DISPOSAL

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact ManaMed.

The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the ManaFlow as replacement parts, may result in increased emissions or decreased immunity of the ManaFlow.

Designates Class II medical electrical equipment.

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.

This symbol designates the degree of protection against electrical shock from the wrap as being a type B applied part.

Consult instructions for use.

Rx only CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

WARNING: This device is not protected against water. Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. The rechargeable batteries supplied in this unit are not field replaceable. If you have any issues please contact 888-508-0712. for a replacement unit.

PURPOSE OF DEVICE

The ManaFlow 52 Full is a portable and rechargeable prescriptive device. It is intended to be used in the home or clinical/hospital setting by or under the direction of a medical professional to apply pressure to treat lymphedema and other edematous conditions and to prevent Deep Vein Thrombosis (DVT).

INDICATIONS FOR USE

Prescription Use:

The ManaFlow 52 Full system, part number MFLOW52LEG, is comprised of a gradient compression sleeve and a portable intermittent pump to provide graduated compression in both sustained and intermittent settings for use in both the hospital and outpatient setting. ManaFlow 52 Full can be adjusted by the physician to a pressure within the specified range. It is intended for use in:

- Treatment of lymphedema
- Treatment of chronic venous insufficiency
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Reducing venous leg ulcer healing time
- Reducing edema due to venous stasis
- Enhancing venous return

The device is intended for home, and hospital use.

CONTRAINDICATIONS

The ManaFlow 52 Full must not be used to treat the following conditions:

Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis or an active infection;

On the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg.

Not for use on any neuropathy. Do not use on extremities that are insensitive to pain.

Not for use where increased venous or lymphatic return is undesirable.

TECHNICAL DATA

Specifications:

Dimensions: 16.5cm x 8.3cm x 5.5cm

Weight: Approx. 0.8 kg

SYSTEM OPERATING ENVIRONMENT:

Temperature: +10°C (50°F) to +40°C (104°F)

Humidity: 30%-75%. Keep dry.

Source of Power: DC 5 V or Inner Battery (3.7 volt Li-ion battery)

CAUTION: Charge batteries using only the power source provided by ManaMed.

POWER SUPPLY:

Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 5 V @ 2 Amp)

Use only UL/60601-1 approved power supplies from ManaMed for use in hospital settings.

Output:

Mode of Operation: Continuous

Modes of Operation: ManaFlow 52 Full adjustable pressure – The user has the ability to program each air chamber to a different pressure for patient specific treatment. Pressure can be adjusted from 20 to 80 mmHg per chamber.

TOLERANCES:

Pressure ±10%.

BATTERY CHARGE:

Takes approximately 3 hours (from depleted state).

BATTERY RUN TIME:

5.5 to 6 hours

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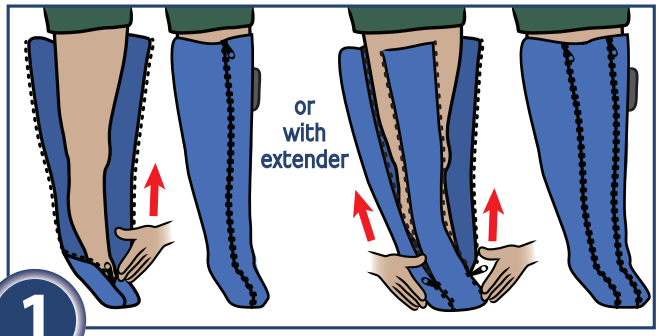
QUICK START GUIDE

ManaFlow 52 Full™

See accompanying documents / User's Manual.

℞ only CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

Charge the device before first use

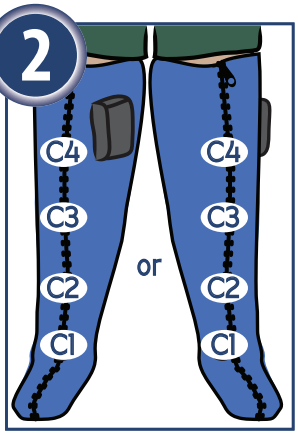


1

INFLATABLE DEVICE APPLICATION

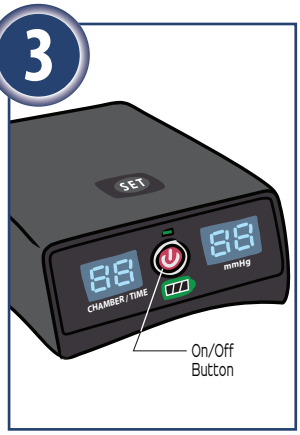
Place the foot in the boot, wrap it to meet in front, and zipper it up to hold it in place. Make sure the wrap is snug, but not too tight. Use the ManaFlow Extender for wider leg application.

2



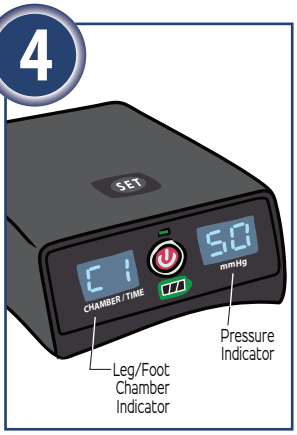
When secured, ManaFlow 52 Full should look like the picture above. C-1 to C-4 indicate Chambers.

3



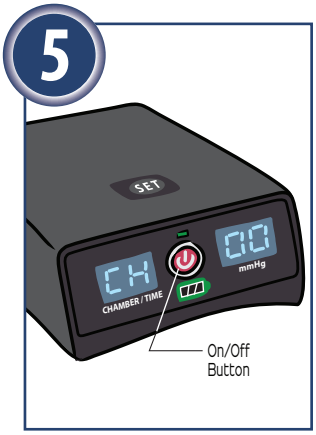
Hold the On/Off button for two seconds to turn device on.

4



Chamber 1 will begin to inflate to 50mmHg. This will be shown in left display with "C 1" and right display will increase to "50".

5



After inflating C1, C2, C3, and C4, the device will indicate "CH". The device will then deflate to "00", and then repeat and cycle Step 4 automatically.

CONTENTS: • One ManaFlow 52 Full Device • Patient Start Guide • Instructions for Use • AC Adapter

The ManaFlow 52 Full is a portable and rechargeable prescriptive device. It is intended to be used in the home or clinical / hospital setting by or under the direction of a medical professional to apply pressure to treat lymphedema and other edematous conditions and to prevent Deep Vein Thrombosis (DVT). The pump will inflate the leg cuff chamber to an adjustable pressure up to 80 mmHg and deflate once the pressure is reached.

INSTRUCTIONS Charge the device before first use

Operation of the ManaFlow 52 Full Device

Hold the On/Off button for 2 seconds to turn on the device, and the four chambers (C1, C2, C3, and C4) of the device will work at the default 50mmHg.

1a. The device will automatically inflate C1 first to 50mmHg (The left display shows C1, indicating Chamber 1; the right display changes from 00 to 50, indicating the air pressure); then inflate C2 to 50mmHg (The left display shows C2, and the right display changes from 00 to 50) ; then inflate C3 to 50mmHg (The left display shows C3, and the right display changes from 00 to 50) ; then inflate C4 to 50mmHg (The left display shows C4, and the right display changes from 00 to 50) . Note: The light indicator is solid during the inflation.

1b. After inflating to 50mmHg, all of the four chambers (C1, C2, C3, and C4) will stay for 10 seconds (The left display changes to show CH, and the right display changes to show 50), and then deflate to zero at the same time (The left display changes to show CH, and the right display changes to show 00). Note: The light indicator is flashing during the deflation.

1c. After staying at the zero pressure for 10 seconds (The left display shows CH, and the right display shows 00), the above steps 1a-1b are repeated.

Calibrating the Set Pressure

2. Press and release the SET button to enter the setting mode of air pressure (Note: Press and release the On/Off button to exit the setting mode).

2a. After entering the setting mode, the left display shows C1 (Chamber 1) and the right display shows a flashing air pressure of 50 (The flashing air pressure in the order of 50, 60, 70, 80, 20, 30, 40, and 50mmHg will show up when the SET button is pressed and released). When the desired pressure shows up, holding the SET button for 2 seconds could finally confirm it. For example, when the flashing "30" is shown on the right display by pressing and releasing the SET button, holding the SET button for 2 seconds could confirm the pressure of 30mmHg for C1;

2b. After the pressure of C1 is set, the left display will automatically change to show C2, and the right display will change to show the flashing 50. Repeat Step 2a to set the pressure for C2;

2c. After the pressure of C2 is set, the left display will automatically change to show C3, and the right display will change to show the flashing 50. Repeat Step 2a to set the pressure for C3;

2d. After the pressure of C3 is set, the left display will automatically change to show C4, and the right display will change to show the flashing 50. Repeat Step 2a to set the pressure for C4;

2e. After the pressure for Chambers C1, C2, C3, and C4 is set, the device will automatically inflate the four chambers one by one: The left and right displays will show the same parameters as Steps 1a-1c (the only difference is the default 50mmHg pressure is replaced by the pressure set at Steps 2a-2d).

3. Hold the On/Off button for 2 seconds to turn off the device.

Note:

a. The light indicator next to the On/Off button will be steady on during the inflation, and flash during the deflation;

b. When the device is off, holding the On/Off button 5 seconds could resume the device back to the use time of 0 hour and the default pressure of 50mmHg for all the four chambers (The left display shows CH and the right display shows 50 for 2 seconds; afterward, Steps 1a-1c will start);

c. The device has the memory capability, recording the last set pressure and the total use time (When the device is on, pressing and releasing the On/Off button could show the total use time, which lasts for 2 seconds on the left display);

d. C1, C2, C3, and C4 represent Chamber 1, 2, 3, and 4, respectively, while CH represent the four chambers;

e. The battery icon keeps flashing during the charging and become steady after the charging;

f. During the charging, the device still could be used.

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WARNINGS AND PRECAUTIONS

WARNINGS

Contact ManaMed™ Customer Service at 888-508-0712 for any questions or to request a replacement.

Do not attempt to repair the device. Do not attempt to open or remove covers.

Do not remove the pump unit from the cuff. Do not attempt to modify or change the device. NEVER attempt any service while the device is in use.

ManaFlow 52 Full is a Medical Electrical Device. The following are precautions specific to Medical Electronic Devices:

- Do not operate in a wet environment.
- Do not immerse in any liquid for any reason. For cleaning and disinfecting instructions refer to "Cleaning and Disinfecting" section.
- Do not place the device in autoclave for any reason.
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- If exposed to temperatures below 10C (50F) allow the device to warm up to room temperature.
- Do not subject the device to extreme shocks, such as dropping the pump.
- Portable and mobile Radio Frequency Communication Equipment can be affected by Medical Electrical Devices.

CAUTIONS

This device is to be sold by or on the order of the physician.

Operation of the device can be done by the patient.

The ManaFlow 52 Full cuffs are designed for single patient use. The device must be ONLY used for its intended use by the patient prescribed. The device must not be transferred to another patient.

Stop using device if swelling, skin irritation or any other unpleasant or painful sensation occurs and consult a Physician.

Loosen cuffs immediately if pulsation or throbbing occurs as the cuffs may be wrapped too tightly.

Patients with diabetes or vascular disease require frequent skin assessment. Consult a Physician.

Patients who use warming devices in combination with cuffs require frequent assessment as skin irritation may occur. Consult a Physician.

Patients positioned in the supine lithotomy position (with or without cuffs) for an extended period of time require special attention to avoid extremity compartment syndrome. Consult a Physician.

USING THE AC ADAPTER / BATTERY CHARGER

IMPORTANT: Charge device before first use.

WARNING: Use only the charger provided by ManaMed™. The use of the wrong charger can cause excessive heat, damage to the circuit and shorten the life of the battery.

WHEN DEVICE IS OFF: Plug in the power supply adapter to the wall socket using the plug located at the bottom end of the device. The BATTERY icon (located under the Power Button) on the device will keep flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing. Once the battery is fully charged, the BATTERY icon will become solid.

WHEN DEVICE IS ON: The AC adapter can be connected while the device is in use. Whenever the device is ON and the AC adapter/charger is connected and plugged into the wall socket, the BATTERY icon (located under the Power Button) on the device will keep flashing or steady, depending on the state of the charge. When the battery is charging, the BATTERY icon will keep flashing. Once the battery is fully charged, the BATTERY icon will become solid.

ALARMS

E1 – Low Battery: When the device is in use an error code "E1" will become visible. Charge the device for a full 4 hours before resuming use. If the unit continues to alarm, call ManaMed Customer Service at 888-508-0712.

E2 – "Battery Critical" Alarm: The device must be plugged in and charged at this time. You can continue to use the device as long as it is plugged in and charging.

Alarm Reset: To reset an alarm condition after the "operation inhibit" stage is reached, the unit must be turned OFF. If not manually turned OFF within 30 seconds of such an alarm condition occurring, unit automatically turns itself OFF. Once the unit is turned back on the alarm is RESET.

"Low Pressure or Leak" – E1 may also become visible if the pressure limit is not reached within 30 seconds. The cycling will stop and the alarm will sound for 10 seconds (unless unit is powered off). Turn the device OFF, and then back ON. If the device continues to alarm after this step, plug both devices into the wall for a full four hours and resume use after charge. If the device continues to alarm after this step, Call ManaMed™ Customer Service at 888-508-0712. DO NOT ATTEMPT TO FIX THE DEVICE.

Help Video Link - https://www.manamed.com/products/dvt-nmes/ManaFlow

CLEANING AND DISINFECTING

NOTE: Inspect the device and follow the cleaning and disinfecting procedures prior to each use.

WARNING: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting.

WARNING: DO NOT IMMERSE DEVICE IN ANY LIQUID FOR ANY REASON. DO NOT PLACE DEVICE IN AUTOCLAVE.

Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry only.

Clean the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry.

Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.

- Do not remove the pump unit from the cuff.
- Do not place cuffs in dryer or microwave.
- Do not use hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.
- Do not use abrasive cleaners.

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES – RF EMISSIONS CLASS B

The ManaFlow 52 Full is a portable and rechargeable prescriptive device. It inflates the cuff containing air chambers to the pre-determined or adjusted pressure and then deflates to the ambient pressure.

Warning: Don't use 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.

Warning: 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.

Warning: 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.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The ManaFlow 52 Full is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFlow 52 Full should assure that it is used in such an environment.

Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR11	Group 1	The ManaFlow 52 Full 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 CISPR11	Class B	The ManaFlow 52 Full is suitable for use in all establishments, including domestic establishments 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	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The ManaFlow 52 Full is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFlow 52 Full 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	±8kV contact ±15kV air	±8kV contact ±15kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	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 IEC61000-4-11	<5%U_T (>95% dip in U_T) for 0.5 cycle 40%U_T (60% dip in U_T) for 5 cycles 70%U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 seconds	<5%U_T (>95% dip in U_T) for 0.5 cycle 40%U_T (60% dip in U_T) for 5 cycles 70%U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ManaFlow 52 Full requires continued operation during power mains interruptions, it is recommended that the ManaFlow 52 Full be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC61000-4-8	30 A/m at 50 or 60 Hz	30 A/m at 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c mains voltage prior to application of the test level.

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES – RF EMISSIONS CLASS B (continued)

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The ManaFlow 52 Full is intended for use in the electromagnetic environment specified below.
The customer or the user of the ManaFlow 52 Full should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ManaFlow 52 Full, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = .35\sqrt{P}$ 80 MHz to 800 MHz $d = .70\sqrt{P}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic 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:
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

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 the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ManaFlow 52 Full is used exceeds the applicable RF compliance level above, the ManaFlow 52 Full should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ManaFlow 52 Full.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ManaFlow 52 Full

The ManaFlow 52 Full is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ManaFlow 52 Full can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ManaFlow 52 Full 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		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = .35\sqrt{P}$	800 MHz to 2.5 GHz $d = .70\sqrt{P}$
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 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.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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