

USER MANUAL



What the MediCare One Blood Cholesterol Monitoring System is for

- The **MediCare One** Blood Cholesterol Monitoring System is designed for in vitro diagnostic use only (external use only), and is suitable for self-testing. The system is for healthcare professionals and persons with hypercholesterolemia to quantitatively measure cholesterol values in fresh capillary whole blood from a fingerstick. Routinely measuring blood cholesterol is instrumental in hypercholesterolemia care. Simply apply 15 µl drop of blood to the test strip, and the test result is displayed on the screen in 150 seconds. This measurement is based on the determination of electric current caused by the reaction of cholesterol with the reagent on the electrode of the strip.
- The **MediCare One** Blood Cholesterol Monitoring System is suitable for hypercholesterolemia management at home or professional use.
- The **MediCare One** Blood Cholesterol Meter can only be used with **MediCare One** Blood Cholesterol Test Strips. The use of any other test strips may give incorrect results.
- Do not change your medical plan without a doctor's approval.
- The **MediCare One** Blood Cholesterol Monitoring System should not be used for the diagnosis of hypercholesterolemia or to test newborns.
- Before using the products to test your blood cholesterol levels, read this user manual carefully. It includes all the information you need to know in order to get accurate blood cholesterol readings. For customer service, dial: +65-6334-2273.
- Only use the correctly designated strips with your meter.

Important Information

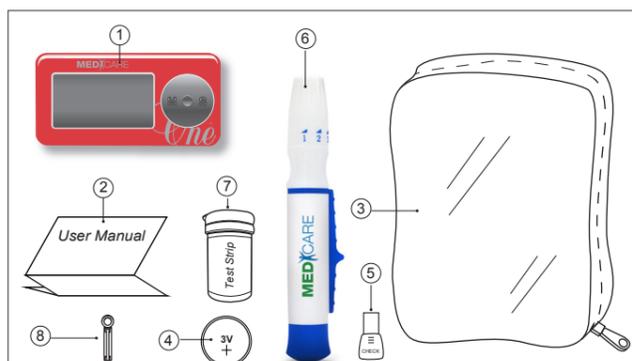
- Results may be inaccurate if blood specimens containing substances at given concentration described below:

Interferon	Cholesterol
Acetaminophen	20 mg/dL (0.5 mmol/L)
Ascorbic acid	10 mg/dL (0.3 mmol/L)
Bilirubin	21.2 mg/dL (0.5 mmol/L)
Dopamine	10 mg/dL (0.3 mmol/L)
L-Dopa	5 mg/dL (0.1 mmol/L)
Uric acid	19.5 mg/dL (0.5 mmol/L)

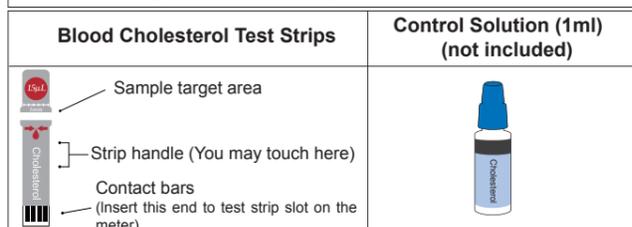
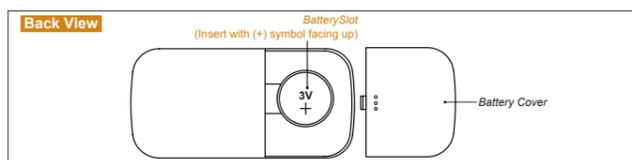
- Grossly lipaemic patient samples, such as those with cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL, have not been tested and are not recommended for testing cholesterol level with the **MediCare One** Blood Cholesterol Monitoring System.
- The monitoring system will not work properly at altitudes greater than 2,400 meters (8,000 feet) above sea level.
- The system is designed for use between 14°C and 40°C (57.2°F and 104°F) and below 20~85% relative humidity. If you use the system outside the proposed conditions, it can give false results.
- Be sure to store the test strips between 4°C and 30°C (40°F and 86°F), away from direct sunlight.
- Be sure to follow your local regulations for proper disposal of used test strips and lancets.
- Do not use this meter in a very dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
- No modification of this equipment is allowed.
- Please follow your local regulations when disposing of meter and components.

Items in the Package

1. **MediCare One** Blood Cholesterol Meter
 2. **MediCare One** Blood Cholesterol User's Manual
 3. Pouch
 4. Battery
 5. Check Strip
 6. Medicare Lancing Device
- Not Including:**
7. **MediCare One** Blood Cholesterol Test Strips and Code key
 8. Lancets



Getting to Know the Blood Cholesterol Monitoring System



How to Read the Label on the Test Strip Vial



Setting Up Your Blood Cholesterol Monitoring System

NOTE: Your meter has been factory set to either mg/dL or mmol/L, depending on which of the two units is most commonly used in your country. This setting cannot be changed.

- Installing the Battery

NOTE: Your meter comes with one CR2032 battery (3V).

1. Slide the battery cover off of the meter.
2. Insert the CR2032 battery (3V) into the battery slot.
3. Slide the battery cover back on.

CAUTION:

- Make sure the battery is inserted with the (+) symbol facing up.
- Remove the battery if putting the meter away for storage.

Using the Check Strip to Check the Meter

When to use the check strip:

- You use the **MediCare One** Blood Cholesterol Meter for the first time
- You drop the meter, or think there is something wrong with your results.
- You want to perform a control test.

CAUTION:

When you insert the check strip, the meter will enter control testing mode and display "OK". Control testing results are not saved to memory. To exit this feature, simply insert and remove a strip or wait for the meter to turn off.

1. Insert the check strip into the test strip slot on the meter.
2. If the meter displays "OK", you may proceed with testing. If the meter displays "X", repeat the procedure. If "X" is displayed again, call customer support. Do not test until the meter is working properly.

Control Check with Cholesterol Control Solution

- What a control check is

•By using a control solution that has a measured amount of cholesterol, you can check if your meter and strips are accurate. If your control result falls within the range on the test strip vial, you can be sure that the system is working properly.

- When to run a control check with cholesterol control solution

•You think there is something wrong with the cholesterol measurement you got and you want to check if the meter and test strips are working correctly.

Items You Need

- MediCare One** Blood Cholesterol Meter
- MediCare One** Blood Cholesterol Control Solution (not included)
- MediCare One** Blood Cholesterol Test Strips
- MediCare One** Check Strip

Steps for Running a Cholesterol Control Check

CAUTION:

Always write down the opening date of your control solution vial and test strip vial. Both of them are good for only **two months** after first opening or until the expiration date, whichever comes first.

1. Insert the check strip. When the display shows "OK", press and hold "S" button.
2. After meter beeps, wait for all the segments to show up on the display. Check the display for missing segments. If no missing segments, release "S" button to enter to the control solution mode.
3. Once display shows "C01", remove the check strip and insert a new test strip from the strip vial. Close the vial quickly.
4. Check the code number on display to match the code number on the test vial. If they are not match, remove the strip and wait for your meter to turn off automatically, then refer to the "Steps for Coding Your Meter" section.
5. As the meter displays the blood symbol "▲", hold the control solution bottle upside down, and slowly squeeze the bottle to form a small drop. Discard the first drop of the solution. Squeeze out a second drop, and touch it to the edge of the sample targeting area on the test strip. The test strip draws the control solution into the targeting zone.
6. Immediately after the meter sounds a beep, close the cap of the control solution. The meter then counts down from 150 or less, and then displays your result on the screen and flashes with "C01".
7. Check if the displayed cholesterol value falls within the acceptable range shown on the test strip vial.
8. Remove the test strip from the meter and discard it.

NOTE: Test performed under the control solution mode will not be saved in the memory. Please do not perform your cholesterol test under the control solution mode.

Understanding Your Control Results

You will find the acceptable range of cholesterol control value on the test strip vial label.

If your control result falls within the acceptable range, you can begin your test.

If your control result is not within the acceptable range, consider the following items:

- Are your test strips or control solution expired?
- Have you ever forgotten to close your test strip vials or control solution bottles?
- Did you follow all the instructions correctly?
- Repeat the control test with a new test strip, following the steps exactly.

CAUTION:

If you continue to receive control values that are outside of the acceptable range, discontinue your blood testing and contact customer service or your healthcare provider immediately.

Steps for Coding Your Meter

Whether you are using this monitoring system for the first time, or you have opened a new test strip vial, you will need to code your meter to ensure the accuracy of your results.



1. Find the code number on your strip vial
2. Insert the code card into the strip slot on the meter.
3. Wait for the meter to beep, then press "M" button. Make sure the number on the display matches the code number on the test strip vial you used. Meter displays "OK" indicates the coding complete. The meter then turns off automatically.
4. If the code numbers do not match, please contact your local distributor.

Blood Cholesterol Testing

- Items You Need

- MediCare One** Blood Cholesterol Meter
- MediCare One** Blood Cholesterol Test Strips and Code Key
- Puncturer (Lancing Device)
- Lancets
- Log sheet
- Alcohol swab

Preparing the Puncturer (Lancing Device)

NOTE:

To increase blood flow, wash your hands with warm water and let your arm hang down at your side.

CAUTION:

- Blood cholesterol monitoring devices and lancing devices can transmit bloodborne pathogens if shared between users.
- For safety and to prevent cross-contamination, always place the protective cover back on before discarding used lancets.
- To avoid infection, you should:
 - Never share your puncturer with others.
 - Never reuse the lancets.
 - Always use a new sterile lancet each time you perform a test.
 - Always use an alcohol pad to wipe blood off of the puncturer's tip.
- To avoid injury, do not leave a lancet in the puncturer. Always remove used lancets immediately.

5 Depth Adjustable

Lancing Device With Ejector

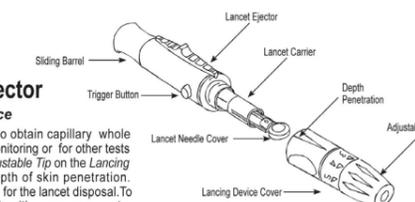
Instructions for the Lancing Device

This Lancing Device With Ejector is used to obtain capillary whole blood samples needed for blood glucose monitoring or for other tests requiring one or two drops of blood. The Adjustable Tip on the Lancing Device allows you to choose the best depth of skin penetration. The ejector is more safe professional system for the lancet disposal. To obtain a drop of blood, first wash your hands with warm, soapy water. Dry your hands thoroughly before using the Lancing Device.

Directions

1. Twist off the Lancing Device Cover.
2. Insert a new Lancet firmly into the Lancet Carrier.
3. Hold the Lancet Needle Cover and gently twist it off of the Lancet.
4. Replace the Lancing Device Cover.
5. The Adjustable Tip offers 5 levels of skin penetration. To select the desired depth, twist the Adjustable Tip in either direction until the numbers line up with the Arrow. To select the best depth:
 - 1-2 for soft or thin skin
 - 3 for average skin
 - 4-5 for thick or calloused skin
6. Hold the Lancing Device Cover in one hand. Using the other hand, slowly pull the Sliding Barrel away from the Lancing Device Cover. You will hear a click, indicating that the Lancet Carrier is locked into position. Release the Sliding Barrel to return it to its original position.

Taking Care of Your Lancing Device With Ejector
Remove the Lancing Device Cover. Wash the Lancing Device Cover in warm, soapy water. Rinse well and allow it to dry thoroughly. Use alcohol or mild soap and water to wipe the remaining outside of the Lancing Device. The Lancing Device can be disinfected using 70% rubbing alcohol. (Hospitals should consult their own infection control protocols.)



7. Position the end of the Adjustable Comfort Tip against the side-tip of the finger. Press the Trigger Button, and then lift the Lancing Device away from the finger after the puncture is complete.
8. Place the Lancing Device aside and wait a few seconds for a blood drop to form. To help form a blood drop, lower the hand to waist level and gently massage the finger from palm to fingertip.
9. To remove the used Lancet from the Lancing Device, first twist off the Lancing Device Cover. While holding the Sliding Barrel, leave the Lancet in the Lancet Carrier and firmly stick the Lancet Needle into the Lancet Needle Cover.
10. Sliding the Lancet Ejector lever in a forward motion and disposing the used lancet in an approved container. Press the Trigger Button to release the Lancet Carrier. Replace the Lancing Device Cover. DO NOT re-use the Lancet. If the Lancing Device is to be used by another person, provide a new Lancing Device Cover and a new Lancet.

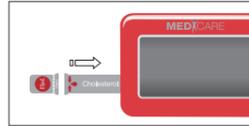
Limited Warranty
The Lancing Device will function effectively for a period of six (6) months from the date of purchase. A malfunctioning device should be returned to your supplier for replacement.

Testing Your Blood Cholesterol Level

CAUTION:

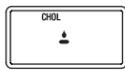
- You can only use **MediCare One** Blood Cholesterol Test Strips on **MediCare One** meter.
- The test strips can be damaged if they are not capped and stored properly.

1. Take one test strip from the vial. Close the vial quickly.



2. Insert the test strip into the test strip slot on the meter.

3. When the screen shows the blood symbol "⬇️", clean your finger with an alcohol swab. Let it dry completely.



4. Place the tip of the puncturer on your fingertip, and then press the trigger on the puncturer.



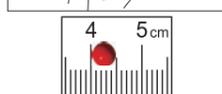
NOTE:

The best puncture site is on the side of fingertip, because it has the best blood supply.

5. Withdraw the puncturer and get a drop of blood. Wipe away the first drop of blood and obtain a second one.



6. Touch the drop of blood to the edge of the test strip target area. The target area absorbs the blood and turns red.



7. The testing reaction starts when the meter sounds a beep. The meter then counts down from 150 or less, shows your result on the screen, and stores your result in its memory automatically.



NOTE:

How much blood should be applied?

Although only a small amount of blood is needed, it is very important that you put enough blood on your test strip so that the entire reaction zone is filled. This ensures that your meter can give accurate and reliable results.

CAUTION:

If you don't apply enough blood, you might need to use a new test strip to do the test again.

8. Record the blood cholesterol level on your log sheet.

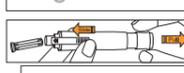
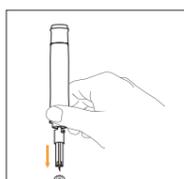
9. Pull the test strip out of the meter. The meter turns off by itself. Unscrew the adjustable tip of the puncturer.

10. Put the protective cover back on the lancet.

11. Pull back the sliding mechanism and slide the lancet ejector forward simultaneously. This ejects the lancet.

12. Discard the used lancet and test strip in an appropriate container with a lid.

13. Screw the adjustable tip back on the puncturer.



CAUTION:

- Be sure to follow your local regulations for proper disposal of used test strips and lancets.

Understanding Your Blood Cholesterol Test Results

The below range is just for reference, and it may not apply to everyone.

Only adapt treatment if you have received the appropriate training from your healthcare provider.

Ranges for blood cholesterol levels:

Desirable	160 - 200 mg/dL (4.1 ~ 5.2 mmol/L)
Borderline High	200 - 239 mg/dL (5.2 ~ 6.1 mmol/L)
High	> 240 mg/dL (> 6.2 mmol/L)

Source: American Heart Association

Consult your doctor for the appropriate range for you.

Using the Meter Memory

The **MediCare One** Blood Cholesterol Meter automatically stores the 200 most recent cholesterol test results. You can review the test results in order from the newest to the oldest. If the memory is full, the oldest result is deleted as the newest result is added. The memory is not affected by replacing/removing the battery.

Reviewing Stored Cholesterol Results

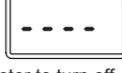
When you review results, the meter displays them from the most recent to oldest.

1. Press "M" to begin. This displays test number and then your most recent test result.



2. Press "M" again to review the second-most recent result. Repeat to review more results.

3. After you review the oldest result, the meter displays "----" and turns off.



4. To exit this feature, press "S" or wait 30 seconds for the meter to turn off.

5. To perform a new test, turn off the meter and follow the steps described in the "testing" section of the manual.

Taking Care of Your Meter

- Do not subject your meter to strong impact or pressures.
- Keep your meter between -10°C and 60°C (14°F and 121°F), and under 95% relative humidity. Do not store the meter in areas such as the kitchen, bathroom, laundry room or car.
- Keep the meter away from water.
- Do not use glass/household-cleaning solutions to clean the meter. Simply use an alcohol pad to wipe the surface of the meter, but do not wipe the test strip slot.
- Do not disassemble the meter.
- If you have any questions, please contact customer service or your healthcare provider.

Replacing the Battery

When the symbol "⚡" is displayed on the screen, replace the battery immediately.

- Slide the battery cover off of the meter.
- Remove the old battery and insert a CR2032 battery (3V) into the battery compartment.
- Slide the battery cover back on and turn on your meter.

Cleaning the Meter

- You can clean your meter with a 70% isopropyl alcohol swab.

CAUTION:

- DO NOT spray any cleaning solution directly onto the meter.
- DO NOT dampen the test strip slot.
- DO NOT immerse the meter in liquid.

Specifications

- **MediCare One** Blood Cholesterol Monitoring System

ET-1004	Cholesterol
Measuring Range	100 ~ 400 mg/dL (2.6 ~ 10.4 mmol/L)
Calibration	Plasma equivalent
Test Time	150 seconds
Memory Capacity	200 test results
Operating Condition Temperature Humidity	14~ 40°C(57.2 ~ 103°F) 20~85% R.H
Meter Storage Conditions (Transportation Conditions) Temperature Humidity	Meter: -10 ~ 60°C (14 ~ 121°F) ≤ 95% R.H Strips: 4~30°C (39.2~86°F) ≤ 95% R.H
Sample Volume	≥ 15 µl
Resolution	1 mg/dL (0.1 mmol/L)
Sample Type	Finger capillary whole blood
Hematocrit Range	30 ~ 55%
Shelf life of strips	18 months (60 days after first opening)
Power Supply	One CR2032 battery, with 3V operation
Meter Dimension (mm)	H x W x D / 83 x 42 x 12
Display	LCD Display (37 x 17 mm)
Weight	Approx. 25 grams not including battery Approx. 26 grams including battery
Life of Battery	Approx. 1000 tests
Technology Used	Electrode-based biosensor
Repeatability	The MediCare One Blood Cholesterol Monitoring System can be used repetitively. If the meter remains idle for approx. 3 min., it shuts down automatically.

Product Liability

Bioptik Technology, Inc. is not responsible for any accidents or worsening illness resulting from buyers' or users' improper use of the device without the instructions of professionals (e.g. medical personnel). Consumers may not request compensation in this regard.

Please read this manual thoroughly before using this monitoring system.

Troubleshooting Guide

SYMBOL	WHAT IT MEANS	ACTION
	The battery power is low.	Replace the battery soon.
	"LO" flashes 5 times before the meter turns off automatically. The battery is dead.	Replace the battery.
	The ambient temperature is too low to perform a test.	Repeat the test in a warmer place, about 14°C~40°C (57.2°F~104°F). You may need to wait as long as 20 minutes for the meter to warm up before testing again.
	The ambient temperature is too high to perform a test.	Repeat the test in a cooler place, about 14°C~40°C (57.2°F~104°F). You may need to wait as long as 20 minutes for the meter to cool down before testing again.
	Your cholesterol level is higher than 400 mg/dL (10.4 µmol/L).	Re-check your cholesterol level. If "HI" is displayed again, call your healthcare provider immediately.
	Your cholesterol level is lower than 100 mg/dL (2.6 µmol/L).	Re-check your cholesterol level. If "LO" is displayed again, call your healthcare professional immediately.
	Wrong type of strip inserted or the meter hasn't been coded yet.	Make sure to code the meter and insert strip which is compatible with The MediCare One Blood Cholesterol Meter.
	Code key malfunction	Repeat the test. If the symbol is displayed again, contact customer service.
	The operating procedure is not correct. The test strip has been used, or the meter is not performing correctly.	Repeat the test with a new test strip. If the symbol is displayed again, contact customer service.

Warranty Information

Thank you for choosing the **MediCare One Blood Cholesterol Monitoring System**. *Bioptik Technology, Inc.* is honored to present this new product to you.

Our customers are entitled to free repair and replacement of parts. However, damage resulting from improper use or accidents is excluded: strong impact or pressures, moisture intrusion, unauthorized repair, disassembly, and natural disasters. If you have problems with the product, please contact the local distributor or agent for further information. For EU customer service, dial: +49-6894-581020.

Labeling and Information

Item	Description	Item	Description
	Do not reuse		Consult instructions for use
	Temperature limitation		Keep away from sunlight
	Manufacturer		Use by
	Caution, consult accompanying documents		Authorized representative in the European Community
	Batch code		Catalogue number
	Serial number		Control
	In vitro diagnostic medical device		Sterilized using irradiation
	Keep dry		Date of manufacture

Guidance and manufacturer's declaration – electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissionsCISPR 11	Group I	This 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 emissionsCISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments.

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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 environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ 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 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 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.

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

Recommended separation distances between portable and mobile RF communications equipment and this device			
This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this 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		
	150 kHz to 80 MHz $d = 1,2$	80 MHz to 800 MHz $d = 1,2$	800 MHz to 2,5 GHz $d = 2,3$
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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

*The Meter has been safety and EMC tested and approved according to the requirement of EN 61010-1/EN 61010-2-101/EN 60601-1-2/EN 61326-1/EN 61326-2-6

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