Pulse Oximeter

USER MANUAL

1. General Description

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

2. Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a fingertip. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

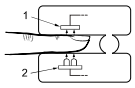


Diagram of Operation Principle

1. Red and Infrared-ray Detector
2. Red and Infrared-ray Light Source

3. Precautions for Use

1. Carefully read the manual before use
2. Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the pulse oximeter in an MRI or CT environment.
5. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the pulse oximeter in an explosive atmosphere.
7. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
8. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
9. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
10. This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
11. Do not disassemble, repair or modify the equipment without authority.
12. It may be unsafe to:
    -use accessories, detachable parts and materials not described in the instructions for use;
    -interconnect this equipment with other equipment not described in the instructions for use;
    -disassemble, repair or modify the equipment.
13. Stop using and contact local service center if one of the following cases occurs:
    -Any of the problems in the Possible Problems and solutions cannot be solved.
    -The oximeter cannot be powered on in any case and not the reasons of battery.
    -There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.
14. The materials that contact with the user's skin have passed the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
15. The 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.
16. When the signal is not stable, the reading may be inaccurate. Please do not refer to the measurement.
17. The material of the device contains no nature latex.
18. The pulse oximeter equipment is calibrated to display functional oxygen saturation.
19. Portable and mobile RF communications equipment can affect medical electrical equipment. The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
20. 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.
21. The waveform is normalized.
22. Aging infrared-ray detector or insufficient battery level may affect the equipment performance. Please follow the instructions in the manual to maintain the device.
23. Please contact the manufacturer for any question about usage or maintenance.
24. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist the user's appropriately trained personnel to repair those parts of the equipment designated by the manufacturer to be repairable.

4. Inaccurate Measurements may be Caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive user movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The user is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

5. Product Features

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Color screen displays SpO_2, PR, RR, PI, Pulse bar, and waveform.
4. 4 display modes.
5. Level 1-10 adjustable brightness.
6. Smart BLE 5.0 for data transmission
7. 2pcs AAA-size alkaline batteries; real-time battery status indication.
8. Weak or unstable signal prompt.
9. The device will automatically shut off without operation in 8 seconds after "Finger out" displays.
10. Compatible with iOS or Android App.

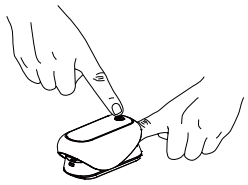
6. Intended Use

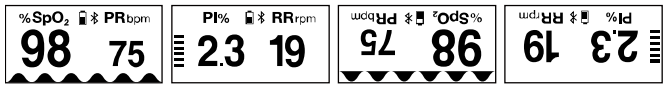
The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients, respiratory rate (RR) for adult.

The device is only for general wellness, sports and aviation to maintain or encourage a general state of health and healthy lifestyle. Not to be used for any diagnostic or medical purposes.

7. Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the power button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.
6. Short press the power button to switch the display modes shown as follows.





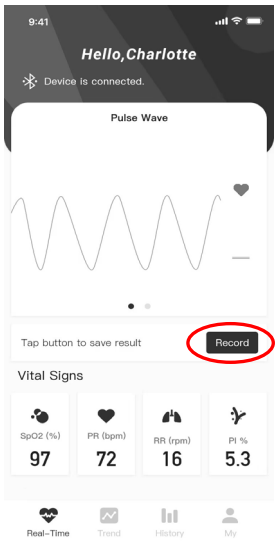
7. Press and hold the power button, the display brightness is adjusted by degree of 1 to 10. The default brightness level is 4.
8. Remove your finger, the screen displays "Finger out", then the unit automatically powers off after 8 seconds.

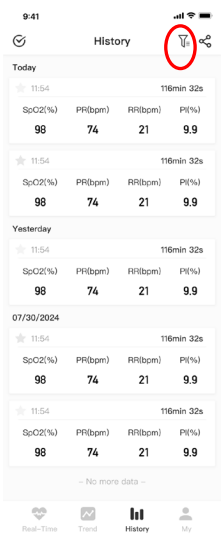
- **Description of the display:**

%SpO_2	Oxygen saturation		Pulse waveform
PRbpm	Pulse rate		Pulse bar
RRrpm	Respiration rate	**PI%**	Perfusion index
	Full battery indicator		Low battery indicator. The batteries should be replaced.
	Bluetooth symbol. It flashes if no connection.	**Br 5**	Brightness level (5)
?	The "?" appears when the signal is unstable. Keep your hands still and try to measure again.		

- **Using *Super Oxygen* APP**
- Open the APP and log into your account.
  For new users, download and install ***Super Oxygen*** APP from the APP Store or Google Play on your mobile device running Android 4.3+ or iOS 8.2, then register for a new account and log in.

  NOTE: Make sure the Network of your smart phone is available.
- The APP automatically searches for your oximeter.
  Logging into the *Super Oxygen* App will take you directly to the measurement page. Power on your MD300CN358R, then the oximeter will connect with the *Super Oxygen* APP automatically. When Bluetooth connection is successful, the APP shows "Device is connected". The Bluetooth icon of the oximeter stops flashing.
- Start your measurement by using the oximeter, and the real-time measurement data are uploaded to the APP continuously.

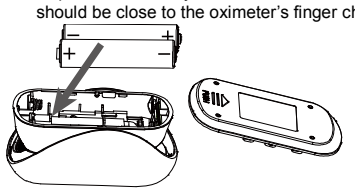


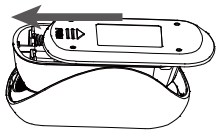


NOTE: During your measurement, if no finger is detected, the APP indicates "Finger out" on screen; if the Bluetooth connection is broken, it indicates "Device disconnected".
NOTE: During your measurement, tap SpO2 reading or PR reading to view real-time SpO2 or PR measurement trend.
NOTE: Tap "***Record***", you can choose any recording duration that you want (30 Sec, 60 Sec or 90 Sec), then the APP starts to record the measurements with a countdown; the record stops at the end of countdown.
Tap "***Trend***", you can view and share the records about *Day, Last 7 days, Week, Month and Year*.
Tap "***History***", you can select the measurement records of any date range to view the details, and you can also share the health report.
NOTE: On screen "My", you can edit your account information, read quick guide, and log out the APP.

8. Battery Installation

1. Slide the battery door cover horizontally along the arrow on the cover.
2. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Replace the battery door cover. The battery cover's end with the PUSH arrow should be close to the oximeter's finger chamber opening.

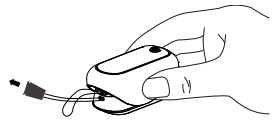




NOTE: Please remove the batteries if the pulse oximeter will not be used for long periods of time.

9. Using the Lanyard

1. Thread thinner end of the lanyard through the loop.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.



⚠ **WARNINGS!**

- ✧ Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- ✧ Do not hang the lanyard from the device's electrical wire.
- ✧ The lanyard tied to the oximeter may cause strangulation due to excessive length.

10. Maintenance and Storage

1. Replace the batteries in a timely manner when low battery symbol is displayed.
2. Clean surface of the oximeter before it is used.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -25℃~+70℃ and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Clean and disinfect the device

- ◆ It is recommended to clean and disinfect the silicone touching the finger inside of device with a soft cloth dampened with recommended alcohol of 70% isopropyl or 70% ethanol before and after each use.
- ◆ Excessive disinfection may cause damage to the device and is therefore not recommended for this device unless otherwise indicated in your hospital's servicing schedule.
- ◆ Do not pour or spray liquids onto the device and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reuse.

Caution: Never use EtO (ethylene oxide) or formaldehyde for disinfection.

The Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.
The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement.

11. Specifications

1. Display Type: LCD display

2. SpO_2
Display range: 0%~100% Measurement range: 70%~100%
Accuracy: 70%~100%±2%; 0%~69% no definition
Resolution: 1%
Note: *A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (**SpO_2**) of the sensors is compared to arterial hemoglobin oxygen (**SaO_2**) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the **SpO_2** range of 70%~100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.*
A functional tester is used to measure how accurately Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.
Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of Pulse oximeter equipment measurements can be expected to fall within Arms of the value measured by a co-oximeter.

3. Pulse Rate
Display range: 30bpm~250bpm Measurement range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100~250bpm, ±2%; Resolution: 1bpm

4. Perfusion Index

Display range: 0.1%~20.0%; Measurement range: 0.3%~20.0%; Resolution: 0.1%

5. Respiration Rate

Display range: 4rpm~70rpm; Measurement range: 4rpm~70rpm; Resolution: 1rpm

6. Probe LED Specifications
RED: Wavelength: 660±3nm; Radiant Power: 3.2mW
IR: Wavelength: 905±10nm; Radiant Power: 2.4mW

7. Power Requirements: Two AAA alkaline Batteries
Power consumption: Less than 70mA
Battery life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 20 hours.

8. Environment Requirements
Operation Temperature: 0℃~40℃
Storage Temperature: -25℃~+70℃
Ambient Humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa
Note: *When the ambient temperature is 20°C (68°F), it is required 6 hours for the equipment to warm from the minimum storage temperature or 4 hours to cool from the maximum storage temperature between uses until it is ready for its intended use.*

9. Equipment data update period: The average data update period is 12.4 seconds.

10. Classification
According to the type of protection against electric shock: Internally powered equipment
According to the degree of protection against electric shock: Type BF applied part (applied part: the rubber hole of the device)
According to the degree of protection against ingress of water: IP22
According to the mode of operation: Continuous operation

12. Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1. Finger is not inserted correctly. 2. User's SpO_2 value is too low to be measured.	1. Retry by inserting the finger. 2. There is excessive illumination. 3. Try some more times. If you can make sure no problem exists in the product, go to a hospital timely for exact diagnosis.
SpO_2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive user movement.	1. Retry by inserting the finger. 2. Try not to move.
The oximeter cannot be powered on	1. No battery or low battery power. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact with local customer service center.
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds. 2. The battery power is too low to work.	1. Normal. 2. Replace the batteries.
"Err 7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact with local customer service center.

13. Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part		Attention
SpO_2	No SpO_2 Alarm		Follow instructions for use
+70℃ max, −25℃ min, RH ≤93% non-condensing	Storage temperature and relative humidity		Waste electrical and electronic equipment
	Manufacturer' s information		Date of Manufacture
LOT	Lot Number	IP22	Protected against dripping water

14. Electromagnetic Compatibility

The device conforms to IEC60601-1-2 Electromagnetic Compatibility (EMC) standard. Essential performance is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note: Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3) are not applicable.	

Table 2: Electromagnetic Immunity

Emissions Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	9 V/m Pulse mod. 217Hz
Note: Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a]	CW	8
134.2 kHz	Pulse modulation [b] 2.1kHz	65 [c]
13.56 MHz	Pulse modulation [b] 50kHz	7.5 [c]

[a] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] r.m.s., before modulation is applied.

15. Box Contents

1. Pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual
5. One carrying case

16. Applicable Model

MD300CN358R

Notes:

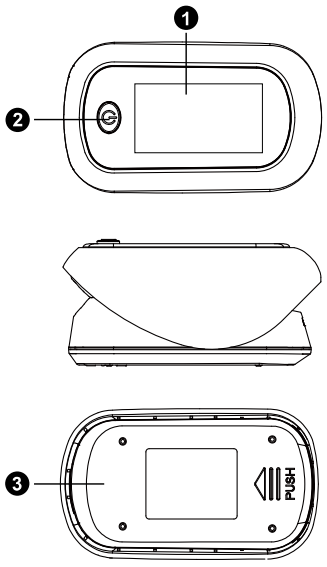
1. **The illustrations used in this manual may differ slightly from the appearance of the actual product.**
2. **The specifications are subject to change without prior notice.**

Quick Operation Guide

ChoiceMMed_MD300CN358R_Ver1.0

- **Appearance**

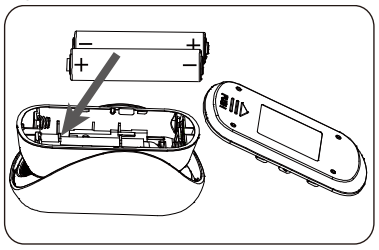
Before using the oximeter, please remove protective sticker covering the display.



1: Display Screen 2: Power Button 3: Battery Cover

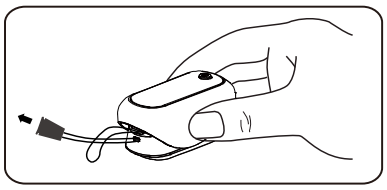
- **Battery Installation**

Please put in the batteries according to the polarity marked inside the battery compartment.

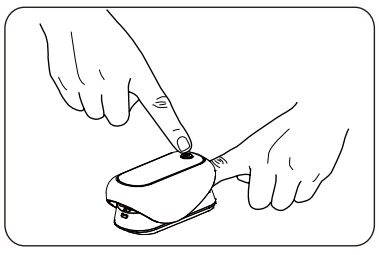


- **Lanyard Installation**

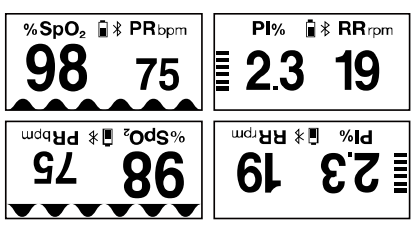
Tie the lanyard through the hole in the rear of the pulse oximeter



- **Operation Instruction**



Place one of your fingers into the pulse oximeter to the end and press the switch button one time on front panel to turn it on.
There are 4 display modes. After turning on the pulse oximeter, each time you press and release the power button, the pulse oximeter will switch to another display mode.



Keep your hands still for the reading.
When you press and hold the power button, the brightness of the pulse oximeter will be changed by degrees. There are 10 levels of brightness. The default is level four.
The pulse oximeter will power off automatically in 8 seconds if there's no finger inside.

- **Warnings and Notes**

Warnings:

1. Keep the pulse oximeter away from young children. Small parts such as the battery door and the batteries, etc., may be hazardous if swallowed.
2. The lanyard may cause strangulation in conditions that may cause it to twist around the neck.

Notes:

1. Read the manual carefully before use.
2. The illustration used in this manual may differ slightly from the appearance of the actual product.
3. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

- **Data Sync to *Super Oxygen* APP**

1) Enable the Bluetooth on your smart device.
2) Start *Super Oxygen* APP and log into your account (new users need to register for a personal account).
3) Power on your MD300CN358R, the APP connects the oximeter automatically via Bluetooth.
4) Insert your finger into the MD300CN358R to take measurements, real-time measurement data are uploaded to S*uper Oxygen* continuously.

What is a Pulse Oximeter?

A pulse oximeter is a non-invasive device that indirectly monitors blood oxygen saturation (SpO_2) and pulse rate (heart rate). It displays both blood oxygen saturation (SpO_2) and pulse rate (heart rate). Pulse oximeters provide an easy way of assessing your blood oxygen level and pulse rate.

What is SpO_2?

SpO_2 is also known as oxygen saturation. Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry.

What is the Perfusion Index(PI)?

Perfusion Index or PI is the ratio of the pulsatile blood flow to the non-pulsatile static blood flow in a patient's peripheral tissue.
Perfusion index is an indication of the pulse strength at the sensor site.

What is the normal range of SpO_2?

The normal range for SpO_2 is typically considered from 95%~99%. The SpO_2 measurement may be lower for people who live at high altitudes. Ask your health professional this question as it pertains to you.

What is the normal range for Respiration Rate?

At rest, a normal breathing rate for adults is 12 to 20 breaths per minute. During lack of oxygen, your respiration rate increases as is evident while exercising and mountain climbing. Reducing your respiration rate to 6-8 breaths per minute helps to reduce stress, calms you down, and improves health and focus.

What is the normal range for pulse rate?

The normal resting range for pulse rate is typically considered from 60~100 beats per minute. Ask your health professional this question as it pertains to you.

What kind of conditions may cause an inaccurate reading?

Cold hands, poor circulation, very weak pulse, movement, fingernail polish and acrylic nails may cause inaccurate results.

The SpO_2 is not changing – it's stuck?

SpO_2 does not change like pulse rate. It is slow to change.

The pulse rate is changing rapidly.

Your heart rate changes with emotions, excitement and exercise.

FCC Declaration

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following
two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

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