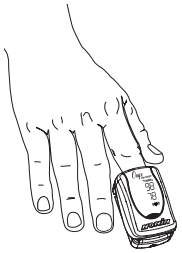
℞ Only *Instructions for Use—English*

Onyx® Vantage 9590 Finger Pulse Oximeter



Indications for Use

The Nonin® Onyx Vantage 9590 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits (fingers, thumb, toes) that are between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.

CAUTION: Regulatory authorities outside the U.S. recognize the use of this device in motion conditions.

Warnings

- Do not use the device in an MR environment, in an explosive atmosphere, or on neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- The device 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.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- General operation of the device may be affected by the use of an electrosurgical unit (ESU).
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.
- Before changing batteries, make sure the device is off and is not applied to a digit.

⚠ Cautions

- This device has no audible alarms and is intended only for spot-checking.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs)
  - excessive light, such as sunlight or direct home lighting
  - excessive motion
  - moisture in the device
  - improperly applied device
  - finger is outside recommended size range
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiogreen and other intravascular dyes
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - artificial nails or fingernail polish
  - residue (e.g., dried blood, dirt, grease, oil) in the light path
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- This device's display will go blank after 30 seconds of no readings or poor readings.
- In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Clean the device before applying it to a patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.
- This device is a precision electronic instrument and must be repaired by Nonin Technical Service. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor.
- This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. 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. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
- Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.
- When using the device in the home, avoid exposing the device to lint and dust.

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EC REP MPS, Medical Product Service GmbH
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8339-001-05

Symbols

Symbol	Description
	Caution!
	Follow Instructions for Use
EC REP	Authorized Representative in the European Community
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Type BF Applied Part (patient isolation from electrical shock)
	Not for continuous monitoring (no alarm for SpO_2)
	Battery orientation
	Indicates separate collection for electrical and electronic equipment (WEEE).
CLASSIFIED C UL US	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with: • ANSI/AAMI ES60601-1:2005/(R)2012 and CAN/CSA-C22.2 No. 60601-1:14 • ISO 80601-2-61:2011

Symbol	Description
SN	Serial number
REF	Catalogue number
QTY	Quantity
	Manufacturer
US	Country of manufacture
	Date of manufacture
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm (0.1 in.) diameter per IEC 60529.
	Storage/shipping temperature range
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
	RoHS compliant (China)
Rx Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

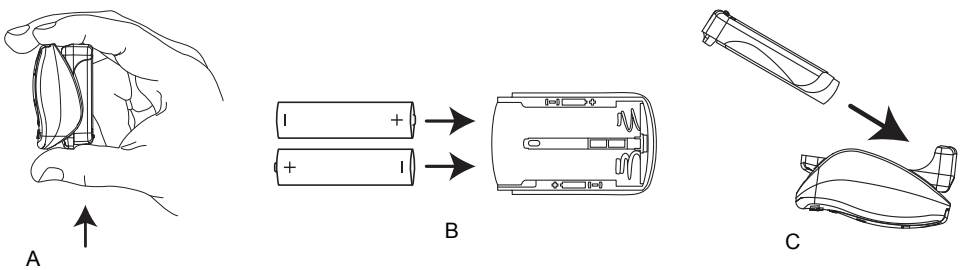
Installing Batteries

Two 1.5 volt AAA-size batteries power the 9590 for about 6,000 spot checks or 36 hours of operation. Nonin recommends using alkaline batteries (included with each new device). When batteries are low, the numeric displays flash once per second. Remove batteries if the device will be stored for more than 30 days. Replace low batteries as soon as possible, using the instructions below.

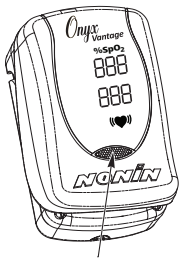
WARNING: Before changing batteries, make sure the device is off and is not applied to a digit.

NOTE: Rechargeable batteries may be used; however, they require more frequent replacement.

1. Hold the 9590 as shown in figure A. To release the device's battery tray, press upward and then pull outward slightly with the thumb.
2. Remove the old batteries from the battery tray. Dispose of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated in figure B. *Proper positioning of the batteries is essential for operation.*
4. Carefully guide the battery tray back onto the device. Press downward and then push inward slightly to re-secure the battery tray (figure C). *Do not force it into place; it fits only when properly positioned.*
5. Insert your finger into the device to verify operation. See the Activating the Onyx Vantage 9590 and Verifying Operation section for more information.



Activating the Onyx Vantage 9590 and Verifying Operation



Pulse Quality Indicator

The device contains numeric Light-Emitting Diodes (LEDs) that display oxygen saturation and pulse rate. A tricolor LED display (pulse quality indicator, shown at left) provides a visual indication of the pulse signal quality, while blinking at the corresponding pulse rate. This display changes colors to alert you to changes in pulse quality that may affect the readings:

- Green indicates a good pulse signal.
- Yellow indicates a marginal pulse signal.
- Red indicates an inadequate pulse signal.

Activate the 9590 by inserting the patient's finger into the device. The device detects the inserted finger and automatically illuminates the displays. Correct positioning of the device on the finger is critical for accurate measurements.

NOTE: While on the finger, do not press the device against any surface and do not squeeze or hold it together. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

1. Insert the patient's finger, nail side up, into the 9590 until the fingertip touches the built-in stop guide.
2. Make sure the finger is lying flat (not on its side) and is centered within the device. For best results, keep the device at the patient's heart or chest level.
3. If the device does not turn on, remove the finger and wait a few seconds before reinserting it.

When a finger is inserted, the device performs a brief startup sequence. Verify that all LEDs illuminate during the startup sequence. If any LED is not lit, do not use the 9590; contact Nonin Technical Service for repair or replacement.

After the startup sequence, the device begins sensing the pulse (indicated by the blinking pulse quality indicator). Allow the device to stabilize and observe about 4 seconds of continuous green-colored pulse quality before relying on the displayed values. Continually verify operation. It is common for the displayed values to fluctuate slightly over a period of several seconds. If the pulse quality indicator blinks yellow or red, try another finger.

A minus sign (-) appears in the left-most digit of the $\%SpO_2$ display when the device senses the finger has been removed. The last measured SpO_2 and pulse rate values display for 10 seconds while the device automatically turns off. The device will automatically shut off (to conserve battery life) approximately 10 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signals.

If the 9590 does not turn on or if it shuts off unexpectedly:

- Verify batteries are correctly inserted. ***Note:*** If batteries are installed backwards, the unit will not function.
- The batteries are depleted. Replace batteries.

If the problem persists, remove the batteries and contact Nonin Technical Service.

The Oxitest^{Plus7} by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

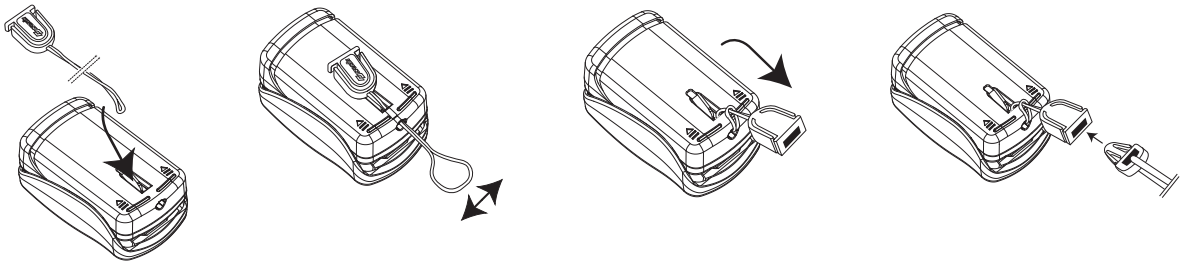
Using the Lanyard

WARNING: Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.

⚠ **CAUTION:** A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.

A lanyard is provided for convenience. The device will function with or without the lanyard.

If lanyard use is desired, thread the lanyard as shown below.



Onyx Vantage 9590 Care, Maintenance, and Cleaning

The advanced digital circuitry within the device requires no calibration or periodic maintenance other than battery replacement. The device's expected service life is 5 years. Field repair of the 9590 circuitry is not possible. Do not attempt to open the case or repair the electronics. Opening the case will damage the device and void the warranty. Do not open the 9590 more than 90°, and do not twist or pull on the device when cleaning.

Cleaning the Onyx Vantage 9590

⚠ **CAUTIONS:**

- Clean the device before applying it to a patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

1. To clean, wipe the surfaces with a soft cloth dampened with mild detergent or a 10% bleach solution (household bleach [5.25% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result.
2. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 10 seconds and are then replaced with dashes.

SpO_2 Values	**Average**	**Latency**
Standard/Fast Averages SpO_2	4 beat exponential	2 beats

Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averages Pulse Rate	4 beat exponential	2 beats

Equipment Delays	**Delay**
Display Update Delay	1.5 seconds

Example: SpO_2 Exponential Averaging
SpO_2 decreases 0.75% per second; pulse rate = 75 BPM
The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy and low perfusion testing was conducted by Nonin Medical, Inc. as described below.

SpO_2 Accuracy Testing

At an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light-to-dark-skinned subjects that are aged 18 years and older. The measured arterial hemoglobin saturation value (SpO_2) of the device is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the device is 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 and ISO 9919, Standard Specification for Pulse Oximeters for Accuracy.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings of various SpO_2 levels. The device must maintain accuracy in accordance with ISO 80601-2-61 and ISO 9919 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Performance in Motion

Motion artifact simulation introduced by a pulse oximeter tester determines whether the oximeter meets the criteria of ISO 80601-2-61 and ISO 9919 for pulse rate during simulated movement, tremor, and spike motions.

Contact regulatory@nonin.com for more information regarding motion testing.

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.

Specifications

Oxygen Saturation Display Range: 0% to 100% SpO_2

Pulse Rate Display Range: 18 to 321 beats per minute (BPM)

Declared Accuracy:

The tables below show A_{rms} values measured using the Onyx Vantage 9590 in a clinical study in non-motion conditions.

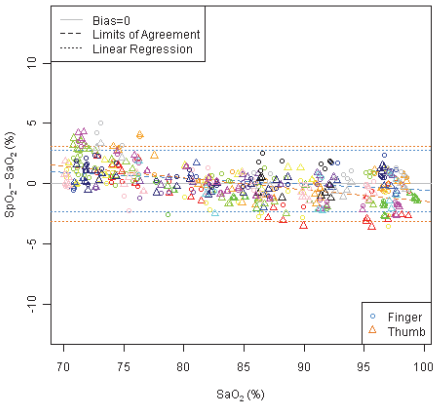
NOTE: If your national regulatory authority recognizes accuracy in motion, please contact regulatory@nonin.com for accuracy data.

Accuracy Summary by Decade – Finger and Thumb

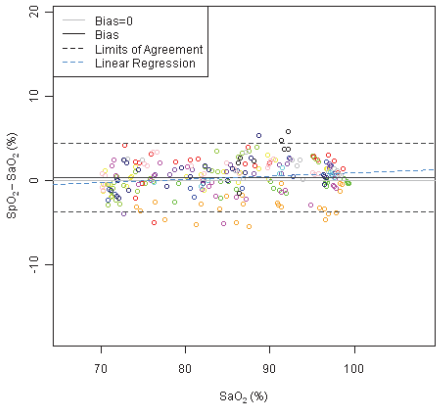
Decade	Oxygen Saturation (A_{rms})
70 – 80%	±2
80 – 90%	±2
90 – 100%	±2
70 – 100%	±2

Accuracy Summary by Decade – Toe

Decade	Oxygen Saturation (A_{rms})
70 – 80%	±2
80 – 90%	±3
90 – 100%	±3
70 – 100%	±3



This graph shows plots of the error (SpO_2 – SaO_2) by SaO_2 using the 9590 with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions.



This graph shows plots of the error (SpO_2 – SaO_2) by SaO_2 using the 9590 with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study using toes in non-motion conditions.

SpO_2 Low Perfusion Accuracy (A_{rms}*) 70 to 100% ±2 digits

Pulse Rate Declared Accuracy Range (A_{rms}*): 20 to 250 BPM ±3 digits

Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms}*): 40 to 240 BPM ±3 digits

Measurement Wavelengths and Output Power:**

Red: 660 nanometers @ 0.8 mW maximum average

Infrared: 910 nanometers @ 1.2 mW maximum average

Temperature:

Operating: 23 °F to 104 °F / -5 °C to 40 °C

Storage/Transportation: -40 °F to 158 °F / -40 °C to 70 °C

Time (from storage) for monitor to be ready for its intended use: 3 minutes to warm from -40 °C to -5 °C
5 minutes to cool from 70 °C to 40 °C

Humidity:

Operating: 10% to 90% non-condensing

Storage/Transportation: 10% to 95% non-condensing

*± 1 A_{rms} represents approximately 68% of measurements at zero bias.

**This information is especially useful for clinicians performing photodynamic therapy.

Altitude:

Operating:	Up to 13,123 feet / 4,000 meters
Hyperbaric Pressure:	Up to 4 atmospheres

Battery Life:

Operating:	Approximately 6,000 spot checks or 36 hours of continuous operation using new alkaline batteries.
Storage:	12 months

Classifications per ANSI/AAMI ES60601-1 / CAN/CSA-C22.2 No. 60601-1:

Degree of Protection:	Type BF-Applied Part
Enclosure Degree of Ingress Protection:	IP32
Mode of Operation:	Continuous

This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.

This device is not made with natural rubber latex.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 4 years from the date of purchase, each Onyx Vantage 9590 exclusive of the batteries, spring, lanyard, and lanyard lock.

Nonin shall repair or replace any Onyx Vantage 9590 found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Onyx Vantage 9590 delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any Onyx Vantage 9590 found to be within specifications.

Onyx Vantage 9590 is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the Onyx Vantage 9590, field service by non-Nonin personnel, tampering, or any kind of misuse of the Onyx Vantage 9590, shall void the warranty. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

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Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	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 Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% 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 sec.	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	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 AC mains voltage before application of the test level.

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	N/A	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
Radiated RF per ISO 9919 clause 36 and ISO 80601-2-61 clause 202.6.2.3	20 V/m 80 MHz to 2.7 GHz	20 V/m	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: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The following table details the recommended separation distances between portable and mobile RF communications equipment and this device.

Table 4: Recommended Separation Distances

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.