Instructions for Use

Onyx® II Model 9560 Finger Pulse Oximeter

Indications for Use
The NONIN® Model 9560 Finger Pulse Oximeter is a small, lightweight, portable, wireless device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 - 1.0 inch (0.8 – 2.5 cm) thick.

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Contraindications
- Do not use the device in an MR environment.
- Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- This device is not defibrillation proof per IEC 60601-1:1990 clause 17h.

Warnings
- Use the Model 9560 within its designated range (approximately 328 feet/100 meters, spherical radius, line of sight when connected to a class I device, from patient module to the display). Moving outside this range may cause missing, lost, and/or inaccurate data.
- 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 SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 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).
- The use of batteries other than those specified in these instructions may result in increased electromagnetic emission and/or decreased immunity of this device.
- 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.
- Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

Cautions
- This device has no audible alarms and is intended only for spot-checking.
- Inspect the device application site at least every 6 to 8 hours to ensure correct device alignment and skin integrity. Patient sensitivity to the device may vary due to the medical status or skin condition.
- This device is intended 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.
- 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.
- Do not sterilize, autoclave or immerse this device in liquid.
- Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
- 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/strain relief.
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  - methemoglobin
  - dysfunctional hemoglobin
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- Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
- 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/strain relief.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
- This equipment complies with IEC 60601-1-2:2004 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 health care 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.
Declaración de Conformidad con las Reglas FCC y de la Ministra de Salud de Canadá para laCompatibilidad Electromagnética

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declara bajo su responsabilidad exclusiva que el Modelo 9560 cumple con la parte 15 de las Reglas FCC. Operación sujeta a las siguientes dos condiciones: (1) no causará interferencia perjudicial, y (2) aceptará cualquier interferencia recibida, incluidas las interferencias que puedan provocar operaciones no deseadas.
- La Ministra de Salud (Canadá), Código de Seguridad 6: los estándares incluyen un margen de seguridad sustancial diseñado para garantizar la seguridad de todos los usuarios, sin importar la edad y la salud. El estándar de exposición para teléfono móvil de radiofrecuencia emplea el término de absorción específica, o SAR. El límite SAR establecido por la FCC es 1.6 W/kg.

Notas de la Comisión Federal de Comunicaciones (FCC) 
Esta equipación ha sido probada y se ha comprobado que cumple con los límites para un dispositivo digital de Clase B, conforme a la parte 15 de las Reglas FCC. Estas limitaciones han sido diseñadas para proporcionar una protección razonable contra interferencias dañinas en una instalación residencial. Este equipo genera, utiliza y puede radiar energía de radiofrecuencia. Si no se instala y se utiliza de acuerdo con las instrucciones, podría causar interferencias perjudiciales a la recepción de radio o televisión, lo cual se puede determinar apagando y encendiendo el equipo. Se recomienda al usuario que intente corregir la interferencia de una o más de las siguientes medidas:
- Reorientar o reubicar la antena del receptor.
- Incrementar la distancia entre el equipo y el receptor.
- Conectar el equipo a un tomacorrientes en un circuito diferente al del tomacorrientes al que se ha conectado el receptor.
- Consultar al distribuidor o a un técnico radio/TV experimentado.
- Para la exposición RF: en el funcionamiento de cuerpo, para mantenerse en cumplimiento con las directrices de exposición de la FCC, debe usar solo accesorios que no contengan componentes metálicos y provean un espacio de separación de 15 mm (0.6 pulgadas) con respecto al cuerpo. El empleo de otros accesorios puede violar las directrices de exposición de RF del FCC y debe evitarse.
- El Modelo 9560 se diseñó y fabricó para no sobrepasar los límites de exposición a la energía de radiofrecuencia (RF) establecidos por la FCC. Estos límites son parte de las directrices de seguridad comprehensivas y establecen límites permitidos de RF para el público general. Estas directrices se basan en los estándares de seguridad previamente establecidos por los entes de seguridad de los EE.UU. e internacionales. Este EUT ha sido probado y probado para cumplir con los límites de absorción específica localizada (SAR) para exposiciones de público general en un ambiente no controlado especificados en ANSI/IEEE Std. C95.1-2005 y ha sido probado de acuerdo con los procedimientos de medición especificados en FCC/OET Bulletin 65 Suplemento C (2001) y IEEE Std. 1528-2003.
- La FCC requiere la notificación al usuario de que cualquier cambio o modificación en este dispositivo que no esté expresamente aprobado por Nonin Medical, Inc. puede invalidar el permiso del usuario para utilizar el equipo.

Guía de Símbolos

<table>
<thead>
<tr>
<th>Símbolo</th>
<th>Definición de Símbolo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult Instructions for Use</td>
<td></td>
</tr>
<tr>
<td>Caution!</td>
<td></td>
</tr>
<tr>
<td>Type BF Applied Part (patient isolation from electrical shock)</td>
<td></td>
</tr>
<tr>
<td>UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1 and CAN/CSA-C22.2 No. 601.1.</td>
<td></td>
</tr>
<tr>
<td>CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices</td>
<td></td>
</tr>
<tr>
<td>Radio Equipment Class Identifier</td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td></td>
</tr>
<tr>
<td>Battery Orientation</td>
<td></td>
</tr>
<tr>
<td>Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.</td>
<td></td>
</tr>
<tr>
<td>Indicates separate collection for electrical and electronic equipment (WEEE).</td>
<td></td>
</tr>
<tr>
<td>Remote Alarms; Not for Continuous Monitoring.</td>
<td></td>
</tr>
<tr>
<td>Bluetooth</td>
<td></td>
</tr>
<tr>
<td>Indoor use (France only)</td>
<td></td>
</tr>
<tr>
<td>Continua Certified™ signifies that this product has been tested and proven to be interoperable with other products that carry the “Continua Certified™” symbol.</td>
<td></td>
</tr>
<tr>
<td>RoHS Compliant (China)</td>
<td></td>
</tr>
<tr>
<td>Personal Identification Number</td>
<td></td>
</tr>
<tr>
<td>BDA</td>
<td></td>
</tr>
<tr>
<td>Bluetooth Device Address</td>
<td></td>
</tr>
<tr>
<td>Ver</td>
<td></td>
</tr>
<tr>
<td>Version</td>
<td></td>
</tr>
</tbody>
</table>

NOTA: donde sea aplicable, un etiqueta adicional mostrando su licencia de comunicaciones radiofrecuencia se aparecerá en el lado de su dispositivo. Esto no es un número de serie o identificador de dispositivo.
Installing Batteries

Two 1.5 volt AAA-size batteries power the Model 9560 for approximately 600 spot checks. NONIN® recommends using alkaline batteries (included with each new Model 9560). 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.

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

1. Hold the Model 9560 as shown at left, pressing upward and then pulling outward slightly with the thumb to release the device’s battery tray.
2. Remove the battery cover and the depleted batteries, disposing of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated. Proper positioning of the batteries is essential for operation.
4. Carefully guide the battery cover back onto the Model 9560, pressing downward and pushing inward slightly to re-secure the battery cover. Do not force it into place; it fits only when properly positioned.
5. Visually inspect to ensure that the battery cover is properly placed.
6. After installing batteries, for proper initialization and detection of the battery status, wait a minimum of 5 seconds before activating the device. Should the device be activated within 5 seconds after battery installation, low battery indication may result. Simply allow the device to turn off for proper initialization.

Using Model 9560 and Verifying Operation

The Model 9560 contains numeric LEDs that display oxygen saturation and pulse rate. A tricolor LED display 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, and red indicates an inadequate pulse signal.

Activate the Model 9560 by inserting the patient’s finger into the unit. The Model 9560 detects the inserted finger and automatically illuminates the displays. Correct positioning of the light emitter and photodetector on the finger is critical for accurate measurements. All emitted light must pass through the fingertip.

Caution

Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs).

While on the finger, do not press the Model 9560 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 Model 9560 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 Model 9560 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 Model 9560 performs a brief startup sequence. Verify that all LEDs illuminate during the startup sequence. If any LED is not lit, do not use the Model 9560; contact NONIN® Technical Service for repair or replacement. In the factory default mode after the startup sequence, the two flashing red bars will appear on the left hand side of the Model 9560 display. Wait until these bars disappear before removing the finger.

A minus sign (-) appears in the left-most digit of the %SpO2 display when the Model 9560 senses that the finger has been removed. The last measured SpO2 and pulse rate values freeze for 10 seconds, and then “OFF” will appear in the display while the device turns off. The device will automatically shut off (to conserve battery life) approximately 20 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signals.

When the Model 9560 is placed on the finger and powered on, and not in a connection with an electronic medical record (EMR) system, it will be available for a wireless connection (Bluetooth®) for a minimum of 90 seconds. It will remain in this mode until:
- a successful wireless connection occurs with your EMR system,
- two minutes have passed without a successful wireless connection with your EMR system, or
- the Model 9560 is powered off.

Using the Lanyard and Carrying Case

A lanyard and carrying case are provided for convenience. The Model 9560 will function with or without the lanyard. If lanyard use is desired, thread the lanyard as shown below.

Model 9560 Care, Maintenance, and Cleaning

The advanced digital circuitry within the Model 9560 requires no calibration or periodic maintenance other than battery replacement. Field repair of the Model 9560 circuitry is not possible. Do not attempt to open the Model 9560 case or repair the electronics. Opening the case will damage the Model 9560 and void the warranty. Do not open the Model 9560 more than 90°, and do not twist or pull on the device when cleaning.

Cleaning the Inner Surfaces of the Model 9560

1. Wipe the surfaces with a soft cloth dampened with a mild detergent; see CAUTION below. Do not use 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.

Caution

Do not sterilize, autoclave or immerse this device in liquid. Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
Testing Summary

SpO2 accuracy and low perfusion testing was conducted by NONIN® Medical, Incorporated as described below.

SpO2 Accuracy Testing

SpO2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the sensors is compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors is in comparison to the co-oximeter samples measured over the SpO2 range of 70-100%. Accuracy data is calculated using the root-mean-squared (A rms value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy.

Low Perfusion Testing

This test uses an SpO2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings of various SpO2 levels. The module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO2 at the lowest obtainable pulse amplitude (0.3% modulation).

Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Saturation Display Range:</td>
<td>0% to 100% SpO2</td>
</tr>
<tr>
<td>Pulse Rate Display Range:</td>
<td>18 to 321 beats per minute (bpm)</td>
</tr>
<tr>
<td>Oxygen Saturation Declared Accuracy Range (A rms):</td>
<td>70% to 100% SpO2 ±2 digits</td>
</tr>
<tr>
<td>Low Perfusion Oxygen Saturation Declared Accuracy Range (A rms):</td>
<td>70% to 100% SpO2 ±2 digits</td>
</tr>
<tr>
<td>Pulse Rate Declared Accuracy Range (A rms):</td>
<td>20 to 250 bpm ±3 digits</td>
</tr>
<tr>
<td>Low Perfusion Pulse Rate Declared Accuracy Range (A rms):</td>
<td>40 to 240 bpm ±3 digits</td>
</tr>
</tbody>
</table>

Measurement Wavelengths and Output Power**:

<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red:</td>
<td>660 nanometers @ 0.8 mw maximum average</td>
</tr>
<tr>
<td></td>
<td>910 nanometers @ 1.2 mw maximum average</td>
</tr>
<tr>
<td>Infrared:</td>
<td></td>
</tr>
</tbody>
</table>

Temperature (Operating): +41° to +104°F / +5° to +40°C

Temperature (Storage/Transportation): -40° to +158°F / -40° to +70°C***

Humidity (Operating): 10% to 95% non-condensing

Humidity (Storage/Transportation): 10% to 95% non-condensing

Altitude (Operating): Up to 40,000 feet / 12,192 meters

Battery Life (Continuous): Two 1.5 volt AAA-size batteries power the Model 9560 for approximately 600 spot checks.

Battery Life (Storage): 1 year, minimum

This product complies with ISO 10993-1.

*± 1 A rms represents approximately 68% of measurements.

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

*** When the Model 9560 is transferred from a non-operating temperature/humidity condition, allow one hour of stabilization to operating temperature/humidity specifications prior to use.

Antenna

| Type                     | L-shaped PWB whip-type antenna |

Transmitter

<table>
<thead>
<tr>
<th>Bluetooth Compliance</th>
<th>Version 2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Frequency</td>
<td>2.4 to 2.4835 GHz</td>
</tr>
<tr>
<td>Output Power</td>
<td>&lt;20 dBm</td>
</tr>
<tr>
<td>Operating Range</td>
<td>328 feet/100-meter radius indoors (line of sight when connected to a class I device)</td>
</tr>
<tr>
<td>Network Topology</td>
<td>Star</td>
</tr>
<tr>
<td>Operation</td>
<td>Bluetooth Slave</td>
</tr>
<tr>
<td>Antenna Type</td>
<td>Internal</td>
</tr>
<tr>
<td>Modulation Type</td>
<td>Frequency Shift Keying</td>
</tr>
</tbody>
</table>

Frequency Hopping Spread Spectrum

| Band Width | 1 MHz |

Warranty

NONIN® MEDICAL, INCORPORATED, (NONIN®) warrants to the purchaser, for a period of two years from the date of purchase, each Model 9560 exclusive of the batteries, spring, carrying case, lanyard, and lanyard lock. NONIN® shall repair or replace any Model 9560 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 Model 9560 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 Model 9560 found to be within specifications. Model 9560 is a precision electronic instrument and must be repaired by trained NONIN® personnel only. Any sign or evidence of opening the Model 9560, field service by non-NONIN® personnel, tampering, or any kind of misuse of the Model 9560, 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®.
### 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

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 2</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF Emissions</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic Emissions</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/Flicker Emissions</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Table 2: Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electrostatic Discharge (ESD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.</td>
</tr>
<tr>
<td><strong>Electrical Fast Transient/Burst</strong></td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surge</strong></td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Voltage dips, short interruptions, and voltage variations on power supply input lines</strong></td>
<td>±5% U_2 (&gt;95% dip in U_1) for 0.5 cycle ±40% U_1 (60% dip in U_1) for 5 cycles ±70% U_1 (30% dip in U_1) for 25 cycles &lt;5% U_2 (&gt;95% dip in U_1) for 5 sec.</td>
<td>N/A</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Power Frequency (50/60 Hz) Magnetic Field</strong></td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** U_2 is the AC mains voltage before application of the test level.
Table 3: Guidance and Manufacturer’s Declaration—Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Recommended Separation Distance**
  - **Conducted RF**
    - IEC 61000-4-6
      - 3 Vrms
      - 150 kHz to 80 MHz
      - N/A
      - 3 V/m
      - 80 MHz to 2.5 GHz
      - [3] V/m
    - IEC 61000-4-3
      - 3 V/m
      - 80 MHz to 2.5 GHz

  \[d = 1.17 \sqrt{P}\]
  - 80 MHz to 800 MHz
  \[d = 1.17 \sqrt{P}\]
  - 800 MHz to 2.5 GHz
  \[d = 2.33 \sqrt{P}\]

  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, should be less than the compliance level in each frequency range.¹

  Interference may occur in the vicinity of equipment marked with the following symbol:

  ![Interference 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.

Table 4: Recommended Separation Distances

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

<table>
<thead>
<tr>
<th>Separation Distance According to Frequency of Transmitter</th>
<th>Rated Maximum Output Power of Transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.