HANDY OX HAND HELD PULSE OXIMETER INSTRUCTION MANUAL

Model # 18715

drive
WWW.DRIVEMEDICAL.COM

Contents

1 Introduction

1.1 Brief Introduction

Thank you for purchasing this handheld pulse oximeter. The device is designed to measure oxygen saturation (SpO_2) and Pulse Rate (PR), delivering visual and audio alarm. Please read this manual carefully before using it.

1.2 Safety Information

Concepts of Warning, Caution and Notice

The Warning, Caution and Notice labels in this document are intended to facilitate safe user operation of this product.

- Warning - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.
- Caution - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- Notice: - Provides application tips or other useful information to ensure that you get the most from your product.

WARNINGS

- Before putting the system into operation, verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
- Do not use the oximeter in the presence of flammable anesthetics, vapors or liquids.

- Do not use the oximeter in an MRI or CT environment.
- Do not open the equipment housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.
- The pulse oximeter is specified for use by medical professionals only.
- Prolonged use of the probe/sensor or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.
- When connecting this oximeter to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. The equipment connected to the pulse oximeter's data interface must be certified according to the respective IEC standards, i.e., IEC950 for data processing equipment or IEC 601-1 for medical electrical equipment. All combinations of equipment must be in compliance with IEC601-1-1 systems requirements.
- Sensor malfunction may cause inaccurate data possibly resulting in patient injury or death, so pay close attention to the sensor and inspect it often.
- The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used

for diagnostic interpretation.

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to “off” may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.
- Worn-out data cables may also cause inaccurate data, so if the data is used as a reference to treat a patient, pay special attention to data cable and check it more frequently.
- When using the equipment with electrosurgical units (ESU), make sure the patient is safe.
- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- Single-use accessories should never be reused.
- To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patients or personnel.

CAUTIONS

- Autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
- To ensure patient safety, use only parts and accessories specified in this manual.

- The operator must be thoroughly familiar with the information in this manual before using the device.
- Unplug the sensor from the oximeter before cleaning or disinfecting it.
- If liquid is accidentally spilled on the unit, clean and dry thoroughly before reuse.
- Do not try to use the SpO_2 and NIBP measurement on the same arm at the same time. This could potentially affect measurement accuracy.
- At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.
- Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

NOTES

- Put the equipment in a location where you can easily see the screen and access the operating controls.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.
- The software was developed in compliance with IEC60601-1-4. The possibility of hazards arising from software errors is minimized.
- SpO_2 measurements may be influenced by high ambient light,

especially sunlight. Shield the sensor area if necessary.

- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may influence the accuracy of the SpO_2 reading.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO_2 readings.
- Remove fingernail polish or artificial fingernails before applying SpO_2 sensors. Fingernail polish or artificial fingernails may cause inaccurate SpO_2 readings.
- Optical cross-talk can occur when two or more sensors are located in adjoining areas. It can be eliminated by covering each site with opaque material. Optical cross-talk may adversely affect the accuracy of the SpO_2 readings.
- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

- This manual describes all features and options. Your equipment may not have all of them.
- Federal Law restricts this device to sale by or on the order of a physician.

1.3 Equipment symbols

Symbol	Definitions
	Attention！Read the operator's manual carefully before using the oximeter.
	Type BF applied part
	Production date
	Manufacturer's address.
	Low power indicator
	European union approval

SN	Serial number

1.4 Electromagnetism interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances) it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.5 Equipment classification

Classification according to IEC-60601	
According to the type of protection against Electrical shock:	Internal electrical power source equipment
According to the degree of protection against	Type B equipment

Electrical shock:	
According to the degree of protection against harmful ingress of water.	Ordinary equipment (enclosed equipment without protection against ingress of water)
According to the methods of sterilization or disinfection	Non-sterilizable: Use of Liquid surface disinfectants only.
According to the mode of operation:	continuous operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture air or with oxygen or nitrous oxide.	

1.6 Accessory

Standard accessories:

1. Two AA-Size Alkaline batteries
2. Operator's manual
3. One finger sensor
4. One bind

Specification for SpO_2 Sensor

Sort	Materials
clip sensor	ABS+Medical Silicon
clip sensor	ABS+Medical Silicon
binding sensor (is not intended for use in neonates when used with this device.)	Medical Silicon
clip sensor	ABS+Medical Silicon
Soft-fingertip sensor	Medical Silicon
Soft-fingertip sensor	Medical Silicon

2 General Descriptions

The handheld pulse oximeter adapts 8-segment digital LED for displaying data. It can display the SpO_2 and pulse rate value pulse bar as well as battery status etc.

2.1 Front panel

Please refer to Fig 1. The display in fig.1 is normal screen.

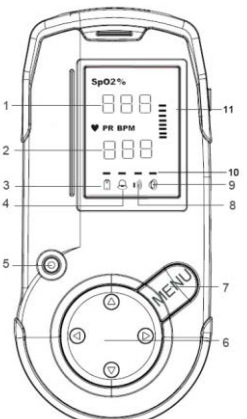

Fig1 Front panel

Instruction of figure 1：

1, SpO_2： SpO_2 value

2, PR： Pulse rate

3, ：Low power indicator. When the power is lower than 2.4V, the lamp indicated by it will be lighted. And the oximeter will

power off automatically when the power is lower than 2.3V.

4,  Alarm Indicator： When technical alarm or physiological alarm occurs, the lamp indicated by it will turn red.

5, Power button

6.  Pulse bar：The pulse bar is in proportion to the Pulse volume.

Note: This manual describes all features and options. Your equipment may not have all of them.

2.2 Rear panel

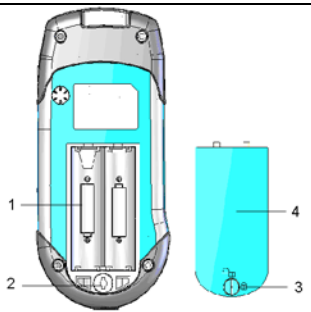

Fig.2 Rear panel

Rear panel introduction:

- 1: Batteries
- 2: Fixing hole
- 3: Fixing screw
- 4: Battery Wharf cover

Batteries Installation :

1) **Open the battery cover**: Rotate the fixing screw slightly in the rear panel to the up position which is marked with "" and then open the cover.

2) Install 2 batteries lightly as indicated by the polarity sign.

Note: Be sure to insert the batteries in the correct polarity, as indicated by polarity markings (+ and -) inside the battery wharf.

3) **Close battery cover**: Close the battery cover and rotate the screw to the position. And the batteries are locked.

⚠ Make sure that the polarity of the batteries is correct. Otherwise the unit cannot operate normally.

Battery life and replacement

When the low-power indication lamp is lighted, please replace the batteries with new ones timely.

- ✧ Always turn the unit off before replacing the batteries.
- ✧ Dispose of the used batteries according to the applicable local regulations.

⚠ Warnings!

If battery fluid should get into your eyes, immediately rinse with plenty of clean water. Consult a doctor immediately.

Cautions!

- ✧ Do not use batteries not specified for this unit. Do not insert the batteries with the polarities in the wrong direction.
- ✧ Do not dispose of batteries in fire.
- ✧ If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.
- ✧ Remove the batteries from this unit when you are not going to use it for a long period of time (approximately three months or

more).

✧ Do not use batteries of a different type together.

✧ Do not use new and used batteries together.

2.3 Right-side panel

A band delivered together with the oximeter can be inserted into the 8-shape hole on the right side of the oximeter,. The band can help with continuous operation.

2.4 Product features

✧ Rubber grip design offers special protection

✧ Compact, light-weight design for simple, one-hand operation

✧ High brightness LED displays SpO_2, pulse rate and pulse bar.

✧ Visual & audio alarm, low battery alarm

✧ Convenient 2 AA-size alkaline batteries

2.5 Intended use

The handheld pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (%SpO_2) and pulse rate (PR) of single adult, pediatric patients in hospitals and home care.

3. Getting started

3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for damage. If any damage is detected, contact the carrier. If the

packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials as per the packing list and check for any mechanical damage.

WARNINGS

- Keep the packing material out of children's reach. Disposal of the packaging material should observe the applicable waste control regulations.
- The equipment might be contaminated during storage and transport. Before use, please verify whether the packages, especially the packages of the single use accessories, are intact. In case of any damage, do not apply it to the patient.

3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

Warning: Make sure that the operating environment of the equipment meets the specific requirements. Otherwise the equipment may not meet the specifications defined in this manual and unexpected consequences, e.g. damage to the equipment, may result.

3.3 Connect the sensor

1. Before use, check the pulse oximeter for mechanical damage.
2. Install the alkaline batteries and ensure that the batteries have sufficient power.
3. Plug the SpO_2 extension cable in the multifunctional connector on top of the oximeter, as shown in figure 3. Ensure that the sensor is firmly plugged in.

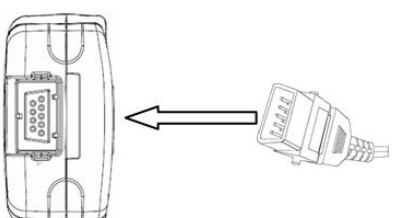

Fig.3

3.4. Starting or shutting off the oximeter

To start the pulse oximeter,

1. Press and hold the Power button for about 3 seconds. The LED and alarm indicating lamp flashes, and then goes out. The system gives a beep and displays the startup screen. The startup screen displays the version no. of software.
2. The startup screen disappears and the pulse oximeter enters the

normal screen.

To shut off the pulse oximeter,

1. Confirm that the patient measurement is finished.
2. Disconnect the SpO_2 extension cable from the pulse oximeter.
3. Press and hold the Power button for 4 seconds.

WARNING

Do not use the pulse oximeter if you suspect it is not working properly, or if it is mechanically damaged. Contact the carrier or our service department immediately.

5 Take a measurement

SpO_2 measuring is a non-invasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light emitted by a red and infrared light-emitting diodes passes through the tissue and is converted into electrical signals by a photodiode.

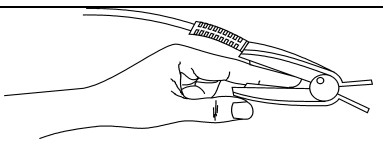

Fig 6 placement of the sensor

- Select the suitable sensor in terms of type and dimension.
- Clip the sensor to the patient's finger as shown above. And ensure that the patient's nail surface is facing upward.
- Plug sensor into SpO_2 port on top panel of pulse oximeter.

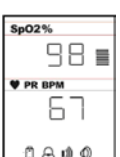

Fig.7

Note: To maintain the highest degree of accuracy, it is recommended that the finger and the oximeter sensor/probe are kept as still as possible.

Description of Fig.7:

SpO_2: SpO_2 value（displayed value is 98% now）

PR：Pulse rate（displayed value is 67 bpm now）

2.5 Factors that may affect the measurement

During operation, the accuracy of oximetry readings can be affected by the following factors:

2.5.1 Instrument performance depends on the pulsatile character of the artery. The measurement would not be

considered reliable and accurate if the following conditions are present during measurement:

- Shock or cardiac arrest
- Extreme temperature of the digit
- After the administration of a cardiovascular drug
- Anemia
- Evidence of ventilation-perfusion mismatch

2.5.2 Instrument performance depends on the wavelength absorption for oxyhemoglobin and deoxyhemoglobin. If there are substances absorbing the same wavelength, this would induce false or low SpO_2 values. The following may affect these values:

- carboxyhemoglobin
- methemoglobin
- methylene blue
- Indigo carmine

2.5.3 Extremely high illumination could affect the SpO_2 measurement. Use a semi-translucent or opaque cover to shield the sensor.

2.5.4 Other factors

a) High-frequency electrosurgical interference from external devices, including defibrillators.

b) Placement of a sensor on an extremity that currently has installed a blood pressure cuff, arterial catheter, or intravascular line;

c) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;

d) An arterial occlusion proximal to the sensor.

⚠WARNINGS!

- Use only SpO_2 sensors provided by manufacturer. Other SpO_2 sensors may cause improper performance.
- Do not use an SpO_2 sensor with exposed optical components.
- Excessive patient movement may cause inaccurate measurements.
- Tissue damage can be caused by incorrect operation or misusing sensor; for example, by wrapping the sensor too tight. Inspect the sensor site to ensure the skin's integrity and the adhesion position of the sensor is correct. More frequent inspection should be taken if necessary.
- Loss of pulse signal can occur in any of the following situations:

a) The sensor is too tight;

b) There is excessive illumination from light sources

such as a surgical lamp, a bilirubin lamp, or sunlight;

c) A blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 sensor is attached.

NOTES：

- **Pulse sensor should obviate the light source, e.g. radial lamp or infrared lamp.**

5 VISUAL ALARM INDICATORS:

If an alarm threshold is exceeded, the corresponding data area will flash. If the alarm is activated by more than one physiological alarm, each parameter will flash.

5.1 AUDIBLE ALARM INDICATORS:

Audible alarms can be heard, provided the mute features is not engaged. The audible alarm has different tone pitch and on-off beep patterns for each alarm priority.

High priority: SpO_2 alarm

beeps every 8 seconds.

Medium priority: PR alarm

beeps every 8 seconds.

Low priority: Sensor off or finger out

beeps every 20 seconds.

5.2 **ALARM ACTIVATION**

Alarm will be activated on following conditions:

Physiological alarm:

Technical alarm (error code):

a) Error Definitions

E 1: program memory is damaged.

E 3: Signal strength is too weak to be detected.

E 4: Sensor is unplugged.

E 5: No finger is inserted or sensor goes wrong.

E 6: The oximeter can not search for pulse.

E 7: It takes too long to search pulse.

E 8: Pulse alarm is malfunctioning.

E 9: The SpO_2 value is lower than the low limit

E 10: The SpO_2 value is higher than the high limit

E 11: The value of pulse rate is lower than the low limit

E 12: The value of pulse rate is higher than the high limit

E 13: Power supply is insufficient.

When the E9, E10, E11 or E12 occurs, the value of parameter will flash.

- Check the error code
- Press the right arrow key under normal screen, it will indicate any existing error codes. To return to normal

screen, please press menu button again.

⚠

Warnings!

When alarm occurs：

- Check which type of alarm is issued.
- Check patient's condition if parameter alarm is issued.
- Make the alarm mute if necessary.
- Check whether the alarm is in proper condition in case of no warning.

8 Beep on/off

Press the menu key five times under the normal screen to enter access to this function, associated screen will be displayed.

Press up or down key to set the pulse beep on/off.

9 Maintain and Cleaning

Use only the substances approved in this manual and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection

Control Officer or Epidemiologist. Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

9.1 Safety Checks

Before every use, or after your pulse oximeter has been used for 6 to 12 months, or whenever your pulse oximeter is repaired or upgraded, a thorough inspection should be performed by qualified service personnel. Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical

damage.

- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the pulse oximeter is in good working condition.

In case of any damage or abnormity, do not use the pulse oximeter.

Cleaning

Your equipment should be cleaned on a regular basis. If the unit is dirty, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery wharf.

2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated place.

Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter.

CAUTION

Never use EtO or formaldehyde for disinfection.

9.2 Calibration and Verification

The performance should be checked every one year and after maintenance and repair.
Required Test Equipment: SpO_2 signal Simulator

Notice: The simulator cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

9.2. SpO_2 & Pulse Rate Measurement Value Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger sensor, the SpO_2 measured value of healthy person should be from 95% to 100%, and the pulse rate is same as heart rate,

c). If SpO_2 Simulator is available, verify the accuracy of Oxygen Saturation Value with probes as follows:

Oxygen Saturation	Tolerance
96%	±2%
86%	±2%
70%	±3%

9.2.4 SpO_2 & Pulse Rate Alarm Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger sensor, the SpO_2 measured value of healthy person should be more than 95%.

c). Set the SpO_2 high limit as 90, low limit as 80.

d). Verify the SpO_2 visual and auditory alarms, the background color of the SpO_2 data should be red and beep sound should be heard.

9.3 Trouble Shooting

a) Can't power on the oximeter

Please check the batteries voltage.

b) "SEn oFF " alarm

Please check if the probe was connected with the oximeter correctly or the finger is inserted fully. If the sensor is with extension cable please check if the extension cable is connected with the sensor correctly.

c) "E1, E2, E8, E14" alarm

Please contact our service department.

d) “E3, E6, E7” alarm

Check the patient’ condition and other please contact our service department.

Warranty

Drive warrants to the purchaser, for 2 years from the date of purchase, each oximeter exclusive of the battery. Drive will repair or replace any oximeter found to be defective in accordance with this warranty, free of charge, for which Drive has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period.

This warranty excludes cost of delivery to and from Drive. Drive reserves the right to charge a fee for a warranty repair request on any oximeter found to be within specifications. The Drive handheld pulse oximeter is a precision electronic instrument and must be repaired by Drive Technical Support. Any sign or evidence of opening the oximeter, field service by non-Drive personnel, tampering, or any kind of misuse of the oximeter, shall void the warranty. The oximeter is warranted for consumer use only. All non-warranty work shall be done at Drive's standard rates and charges in effect at the time of delivery to Drive.

APPENDIX A Specifications

Display

Data: SpO_2%, PR

Others: connection status of probe and other alarm information.

Alarm

Alarm: SpO_2% and pulse rate value, probe off, battery exhausted

Alarm mode: audio alarm, visual alarm and error code

Alarm limits range: 70%-100%

Default limits: High 99%; low 90%

SpO_2

Display range: 0%~100%

Measurement range: 70%~100%

Resolution: 1%

Accuracy: ±3% (70-100%) Unspecified (0-69%)

Measurement Wavelengths and Output Power

Red 660nm @ 3mw nominal

Infrared 940nm @3mw nominal

Pulse Rate

Display range: 0~254bpm

Measurement range: 30~235bpm

Resolution: 1bpm

Accuracy: 30~99bpm: ±2bpm; 100~235bpm: ±2%

Operation Environment

Operating temperature: 5℃-40 ℃

Relative humidity: ≤ RH80%, no condensation

Atmosphere pressure: 86kPa～106kPa

Power supply: Two AA alkaline batteries;

Working time: work for 30 hours continuously

Abbreviations

CISPR International Special Committee on Radio Interference

EEC European Economic Community

EMC Electromagnetic Compatibility

ID Identification
IEC International Electrotechnical Commission
LED Light Emitting Diode
PR Pulse Rate
RF Radio Frequency
SpO_2 Arterial Oxygen Saturation from Pulse Oximeter

Abbreviations

A ampere	bpm beats per minute
ºC centigrade	g gram
kHz kilohertz	MHz megahertz
GHz Gigahertz	h hour
Hz hertz	K kilo
kg kilogram	kPa kilopascal
m meter, minute	M mega
min minute	mm millimeters
mW milliwatt	s second
nm nanometer	V volt

Symbols

– minus	– negative
% percent	/ per; divide; or
+ plus	= equal to
< less than	> greater than
≤ less than or equal to	≥ greater than or equal to
± plus or minus	× multiply
© copyright	

APPENDIX B

Guidance and manufacturer's declaration - electromagnetic immunity

The Handheld Pulse Oximeter is intended for use in an electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance Level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC610004-2	6kV contact 8kV air	6kV contact 8kV air	Floors should be wood, concrete or ceramic tile. If floor are converted with Synthetic material, the relative humidity should be at least 30%

Guidance and manufacture's declaration - Electromagnetic Immunity for Equipment and Systems that are not Life-Supporting

61000-4-6	3V/m	d= $\frac{3.5}{V_1}\sqrt{P}$ 80MHz to 800MHz d= $\frac{3.5}{E_1}\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	80Hz to 2.5 GHz	 Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE2 These guideline may not apply in all situations. Electromagnetic propagation is affected

by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base situation 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 Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, the Handheld Pulse Oximeter should be observed.

Recommended separation distances between portable and mobile RF communications equipment and the handheld Oximeter

The handheld Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the handheld Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transm-itter (W)	Separation distance according to frequency of transmitter (m)		
	150KHz to 80 MHz $d=\frac{3.5}{V_1}\sqrt{P}$	80MHz to 800 MHz $d=\frac{3.5}{E_1}\sqrt{P}$	800MHz to 2.5 GHz $d=\frac{7}{E_1}\sqrt{P}$
0.01	0.1167	0.1167	0.2334
0.1	0.3689	0.3689	0.7378
1	1.1667	1.1667	2.3334
10	3.6893	3.6893	7.3786
100	11.6667	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic interference is affected by absorption and reflection from structures, objects and people.

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