JOHN BUNN®
by graham-field

JB02020 Fingertip Oximeter

User Manual

Important: Do not operate the Finger Pulse Oximeter without first reading and understanding this manual! Save this manual for future use.

Info: The most current version of this manual can be found online at www.grahamfield.com.

JBO2020-INS-LAB-RevA20

CONTENTS

1 INTRODUCTION

Read and understand all instructions before using the John Bunn JB02020 Finger Pulse Oximeter.

Intended Use

This Fingertip Oximeter is intended to measure the pulse rate and functional oxygen saturation (SpO_2) through a patient's finger. It is applicable for spot-checking SpO_2 and pulse rate of adult and pediatric patients in homes and medical clinics.

Contraindications

⚠ **WARNING: The oximeter is not intended for continuous patient monitoring. DO NOT use the oximeter while patient is undergoing MRI or CT scanning. This device is NOT MRI Compatible.**

2 IMPORTANT SAFETY GUIDELINES—READ BEFORE USE

The safety statements presented in this chapter refer to the basic safety information that the operator of the Finger Pulse Oximeter shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to the operations.

⚠ **WARNING: Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠ **CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury.**

▲ **NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product or property damage.**

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

WARNINGS

⚠ **WARNING: Important! Read and understand this manual before using the oximeter. Do not use this device without proper instruction from a Healthcare Professional. If the oximeter is not properly operated, personal injury and/or damage to the oximeter could result.**

⚠ **WARNING: EXPLOSION HAZARD: Do not use the oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.**

⚠ **WARNING: Inspect the device before use to ensure that there is no visible damage that may affect patient or user's safety or measurement performance. If there is visible damage, do not use the device. Thereafter, inspect the device at least once a week.**

⚠ **WARNING: DO NOT open the oximeter housing. It contains no serviceable parts. Service must be performed by trained, authorized personnel only. Otherwise, device failure and health hazard may occur.**

⚠ **WARNING: The oximeter is designed for real-time and rapid measurement. It is not suitable for long-time continuous patient monitoring. DO NOT apply the sensor to the same finger for more than two hours. If any readings are found to be abnormal, please change the position of the sensor.**

⚠ **WARNING: DO NOT clip this device on edema or tender tissue.**

⚠ WARNING: The oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. It is intended as a measuring, not a treatment, device.

⚠ WARNING: The infrared light emitted from the device (it is invisible) is harmful to the eyes. DO NOT stare into the light.

⚠ WARNING: Keep this device out of the reach of children.

⚠ WARNING: Magnetic and electrical fields are capable of interfering with the proper performance of the oximeter. For this reason, ensure that all external devices operated in the vicinity of the oximeter comply with the relevant EMC requirements. Mobile phones, X-ray equipment, and / or MRI devices are a possible source of interference, as they may emit high levels of electromagnetic radiation. This device complies with IEC 60601-1-2.

⚠ WARNING: Use only parts and accessories specified in this manual.

⚠ WARNING: If components are damaged or missing, contact your distributor immediately. DO NOT use substitute parts.

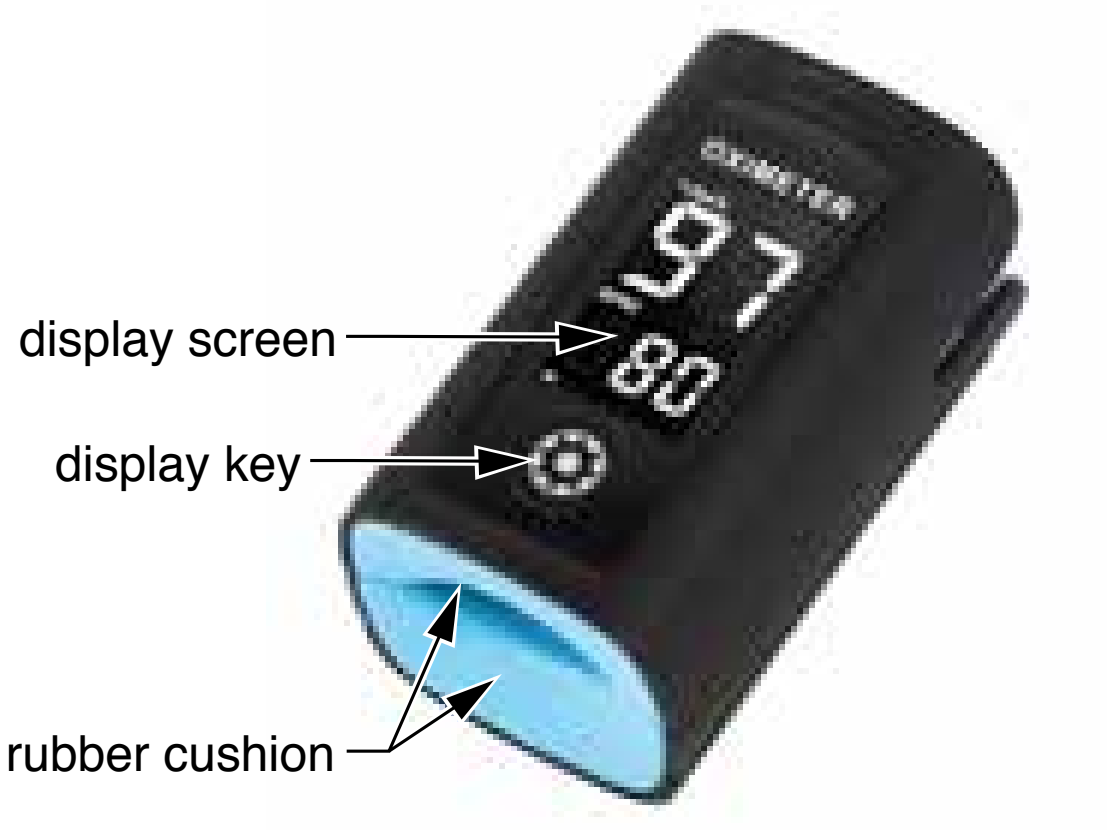
⚠ WARNING: GF Health Products, Inc. assumes no responsibility for any damage or injury caused by improper installation or use of this product.

⚠ WARNING: WARNING: Cancer and Reproductive Harm - www.p65warnings.ca.gov.

Notices

- ▲ **NOTICE: Keep the Oximeter away from dust, lint, vibration, corrosive substances, explosive materials, high temperature, sunlight, and moisture.**
- ▲ **NOTICE: If the Oximeter gets wet, stop using it and do not resume operation until it is dry and checked for correct operation.**
- ▲ **NOTICE: When the oximeter is taken from a cold environment to a warm and humid environment, do not use it immediately — allow at least fifteen minutes for the Oximeter to reach ambient temperature.**
- ▲ **NOTICE: DO NOT operate the button on the front panel with sharp materials or sharp point.**
- ▲ **NOTICE: DO NOT use high temperature or high pressure steam disinfection on the Oximeter. Refer to Chapter 7 for instructions regarding cleaning and disinfection.**
- ▲ **NOTICE: The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid: i.e., the equipment is protected against solid foreign objects of 12.5mm in size and greater, and protected against vertically falling water drops when enclosure is tilted up to 15°.**

3 PRODUCT DESCRIPTION AND FEATURES



JB02020 Finger Pulse Oximeter

Contents — Packing List

1) One JB02020 Fingertip Oximeter
2) One Lanyard
3) Two AAA Alkaline Batteries
4) One User Manual

JB02020 Finger Pulse Oximeter Features

- S-L-M Display type
- Displays SpO_2, PR, PI
- Auto on/off
- PR and PI shifts
- Pulse bar
- Over-limits indicator
- Two-direction display

Declaration of Conformity

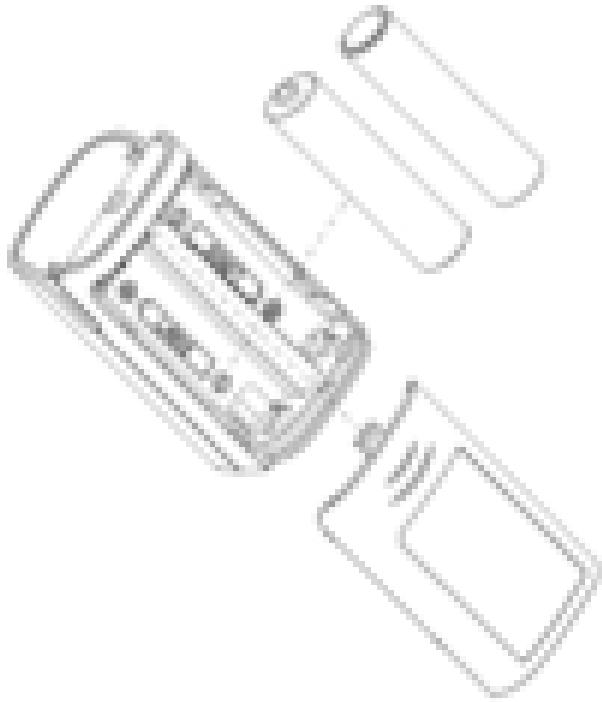
This device complies with the following standards:

IEC 60601-1: 2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

BS/EN/ISO 9919:2009 or the equivalent ISO 80601-2-61:2011 - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment.

And it also follows the provisions of the council directive MDD 93/42/EEC.

4 SETUP—BATTERY INSTALLATION



Battery Installation

1. Slide battery cover open as shown above.
2. Install two AAA size batteries into the battery compartment as shown above. **Note polarity markings and ensure batteries are correctly installed, or device may not function.**
3. Replace the cover.

▲ **NOTICE: Change the batteries when the low-voltage indicator illuminates.**

▲ **NOTICE: Remove the batteries if the device will not being used for more than seven days to prevent potential damage from battery leakage.**

5 OPERATION INSTRUCTIONS

Before use: surface-clean sensor with a soft cloth damped with a solution of 75% isopropyl alcohol, then surface-clean with a cloth damped ONLY with clean water and dry with a clean, soft cloth.

Open Oximeter and Position Finger

1. Open clip, place finger between the rubber cushions as shown above, and gently close clip on finger.
2. After two seconds, the Oximeter will automatically power on and begin to measure.
3. The display screen is shown above; short press the display key to shift the display direction; long press the display key to see the measured PI value.

Info: During measurement, if SpO_2 or Pulse Rate value exceeds the preset limit (see Preset Over-limits in TECHNICAL SPECIFICATIONS section), that measured value which exceeds limit will flash on the screen.

Correct Measurement Procedures

- Ensure finger is correctly positioned in sensor.
- Relax; do not move; do not move finger during measurement.
- Do not place wet finger in sensor.
- Do not place the device on a limb with with a blood pressure cuff applied.
- Do not place the device on a limb receiving venous infusion.
- Nail polish or paint may affect the measuring accuracy, and too long a fingernail on measurement finger may cause failure of measurement or inaccurate result.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- Existence of high intensive light sources, such as fluorescence light, ruby lamp, infrared heater or strong sunshine, etc. may cause inaccuracy of measurement result. Place an opaque cover on the sensor or change location.
- If the first measurement displays irregular waveform, then the measurement is probably inaccurate; wait or restart.

6 SERVICE LIFE, REPAIR, MAINTENANCE, AND DISPOSAL

Expected Service Life

Info: The expected service life (not warranty) of this device is five years.

Repair

⚠ **WARNING: DO NOT open the oximeter housing. It contains no serviceable parts. Service must be performed by trained, authorized personnel only, or device failure and health hazard could occur.**

Maintenance

▲ **NOTICE: In order to ensure a long service life, adhere to the following maintenance instructions.**

- Change batteries when low-voltage indicator illuminates.

Cleaning / Disinfection

▲ **NOTICE: DO NOT use high pressure, high temperature, irradiation steam, or ethylene oxide sterilization on the device.**

Surface-clean sensor with a soft cloth damped with a solution of 75% isopropyl alcohol, then surface-clean with a cloth damped ONLY with clean water, and dry with a clean, soft cloth.

Storage

- Remove batteries if the Oximeter will not be used for more than seven days.
- Store the device in a dry, dust-free environment free from high temperature, sunlight, and dust. Humidity may damage or reduce the life of the device. When the oximeter is taken from a cold environment to a warm and humid environment, do not use it immediately — allow at least fifteen minutes for the Oximeter to reach ambient temperature.

Disposal

▲ **NOTICE: Do not treat this device as household waste; separate collection is required. Dispose of this device and its batteries in accordance with local laws and regulations.**

- See TECHNICAL SPECIFICATIONS section for recommended operation and storage environment of the device.

7 TROUBLESHOOTING

Problem	Solution
SpO_2 / Pulse Rate display unstable	Position the finger carefully as described in ***OPERATION INSTRUCTIONS***; try again
Unable to turn on device; no display	1. Patient must relax as described in ***OPERATION INSTRUCTIONS***; try again
	2. Change batteries
Display direction doesn't change	Shake Oximeter ***gently***; if problem persists, orientation-sensor may not be not working properly
If above problem persists, contact the distributor	

8 TECHNICAL SPECIFICATIONS

SpO_2 Measurement	**Transducer**		Dual-wavelength LED sensor with wavelength
	Red light		663 nm, Infrared light: 890 nm.
	Maximal average optical output power		≤2mW
	SpO_2 display range		35%~100%
	SpO_2 measuring accuracy		≤ 2% for SpO_2 range from 70% to 100%
Pulse Rate measurement	**PR display range**		30bpm~240bpm
	PR measuring accuracy		±2bpm or ±2% (whichever is greater)
Perfusion Index (PI) Display range	0%~20%		
Preset over-limits	**SpO_2 low limit**		90%
	Pulse Rate Limit	**High**	120bpm
		Low	50bpm

TECHNICAL SPECIFICATIONS CONTINUED			
Visual alert function	When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the measured value which exceeds limit will flash on the screen.		
Power supply requirement	Two AAA alkaline batteries		
	Supply voltage		3.0VDC
	Operating current		≤40mA
Environmental Conditions	**Temperature**	**Operating**	41°F ~ 104°F (5°C ~ 40°C)
		Storage	-4ºF ~ 140ºF (-20ºC ~ 60ºC)
	Humidity	**Operating**	30% ~ 80%
		Storage	10% ~ 95%
	Atmospheric pressure	**Operating**	70kPa ~ 106kPa
		Storage	50kPa ~ 107.4kPa
Low Perfusion Performance	The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.		
Ambient Light Interference	The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.		

TECHNICAL SPECIFICATIONS CONTINUED		
Dimensions	56 mm (L) × 34 mm (W) × 30 mm (H)	
Net Weight	Approximately 60g	
Classification	**Type of protection against electric shock**	Internally powered equipment.
	Degree of protection against electric shock	Type BF applied parts.
	Degree of protection against harmful solid foreign objects and ingress of liquid	IP22 with protection against harmful solid foreign objects and ingress of liquid (equipment is protected against solid foreign objects ≥ 12.5mm, and vertically falling water drops when enclosure tilted < 15°).
	Electro-Magnetic Compatibility	Group I, Class B

9 SYMBOL KEY

Symbol	Description
%SpO_2	Pulse Oxygen Saturation
♥BPM	Pulse Rate (Beats per Minute)
PI	Perfusion Index (%)
	Pulse Strength Bar Graph
	Low Battery Voltage
CE	CE Mark
SN	Serial Number
	Date of Manufacture
EC REP	Authorized Representative in the European Community
	Manufacturer (including address)
	BF Type Applied Part
	Attention: Refer to User Manual
	Dispose of this Device in Accordance with Local Laws and Regulations

10 LIMITED WARRANTY

SCOPE OF WARRANTY

GF Health Products, Inc. (“GF”) warrants to the Original Purchaser only that it will replace or repair components, at GF’s sole discretion, that are defective in material or workmanship under normal use and service. All warranties are conditioned upon the proper use of the products strictly in accordance with good commercial practice and applicable GF instructions and manuals, including proper use and maintenance. To the extent that a component is warranted by a third party, GF conveys all of its rights under that warranty to the original purchaser, to the extent permitted. Original Purchaser is one who purchases this product new and unused from GF or a GF Distributor.

This limited warranty shall only apply to defects that are reported within the applicable warranty period and which, upon examination by GF or its authorized representative, prove to be a warranty item. This limited warranty is not transferable.Within the guidelines set forth in this document, this product is warranted for one (1) year. The applicable warranty period shall commence from date of shipment to the Original Purchaser, unless there is an expiration date on the component in which case the warranty shall expire on the earlier of warranty period or the expiration date.

OBTAINING WARRANTY SERVICE

This limited warranty shall only apply to defects that are reported to the Distributor from whom the Customer purchased the product within the applicable warranty period. If there is not a Distributor, you must contact GF directly by calling 1.770.368.4700, sending a fax request to 1.770.368.2386, or by e-mailing a request to cs@grahamfield.com. Specific directions will be provided by the Customer Service Representative. Failure to abide by the specific directions will result in denial of the warranty claim.

EXCLUSIONS

The warranty does not cover and GF shall not be liable for the following:

1) Defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering or failure to seek and obtain repair or replacement in a timely manner;
2) Products which are not installed, used, or properly cleaned and maintained as required in the official manual for the applicable product;
3) Products considered to be of a non-durable nature including, but not limited to: casters, filters, fuses, gaskets, lubricants, and charts;
4) Accessories or parts not provided by GF;
5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing, in advance, by GF;
6) Any labor or shipping charges incurred in the replacement part installation or repair;
7) Costs and expenses of regular maintenance and cleaning; and
8) Representations and warranties made by any person or entity other than GF.

ENTIRE WARRANTY, EXCLUSIVE REMEDY AND CONSEQUENTIAL DAMAGES DISCLAIMER

THIS WARRANTY IS GF'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. GF MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IF ANY MODEL OR SAMPLE WAS SHOWN TO THE CUSTOMER, SUCH MODEL OR SAMPLE WAS USED MERELY TO ILLUSTRATE THE GENERAL TYPE AND QUALITY OF THE PRODUCT AND NOT TO REPRESENT THAT THE PRODUCT WOULD NECESSARILY CONFORM TO THE MODEL OR SAMPLE IN ALL RESPECTS.

THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DEFECTIVE PARTS. GF SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO: DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER, OR EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

The warranties contained herein contain all the representations and warranties with respect to the subject matter of this document, and supersede all prior negotiations, agreements and understandings with respect thereto. The recipient of this document hereby acknowledges and represents that it has not relied on any representation, assertion, guarantee, warranty, collateral contract or other assurance, except those set out in this document. Some states do not allow the exclusion of certain remedies; in those instances that state's law will control. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

For additional information on this product or this warranty, please contact a GF Customer Service Representative.

NOTES:

1) Additional terms and conditions may apply.
2) Freight claims must be notated on the appropriate shipping documents and must be made with immediacy. International, federal and state regulations govern specific requirements for freight claims. Failure to abide by those regulations may result in a denial of the freight claim. GF will assist you in filing the freight claim.
3) Claims for any short shipment must be made within three (3) days of the invoice date.

APPENDIX I EMC

This equipment meets the requirements of IEC 60601-1-2:2014.

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Fingertip Oximeter 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.

Table 1 continued

RF emissions CISPR 11	Class B	The Fingertip Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies building used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compli-ance level**	**Electromag-netic environment -guidance**

Table 2 continued

Electrostatic discharge (ESD) **IEC-1000-4-2**	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst **IEC61000-4 -4**	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge **IEC 61000-4-5**	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A

Table 2 continued

Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<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 s	N/A	N/A

Table 2 continued

Power frequency (50Hz/60Hz) magnetic field **IEC61000-4-8**	3A/m	3A/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 a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Fingertip Oximeter should assure that it is used in such an electromagnetic environment.

Table 3 continued

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of The Fingertip Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-	3 V/m 80 MHz	3 V/m	

Table 3 continued

4-3	to 2.5 GHz		**Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz 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). [b]

Table 3 continued

			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. 

Table 3 continued

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Fingertip Oximeter is used exceeds the applicable RF compliance level above, The Fingertip Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Fingertip Oximeter.

Table 3 continued

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

Table 4

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

Table 4 continued

Rated maximum output	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	150MHz to 800MHz $d=1.2\sqrt{P}$	80MHz to 2,5GHz $d=2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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.

Table 4 continued

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

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

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

1.770.368.4700

Information contained herein is subject to change.
The most current and complete product information
can be found on our website.
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