JOHN BUNN*



JB3000 HANDHELD PULSE OXIMETER

Operation Manual

Important: Do not operate the John Bunn JB3000 Handheld Pulse Oximeter without first reading and understanding this manual. Save this manual for future use.

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1 INTRODUCTION

OVERVIEW

Thank you for purchasing the John Bunn JB3000 Handheld Pulse Oximeter for ${\rm SpO_2}$ and Pulse Rate (PR) measurement. This device features PR tone modulation, data storage, and optional data transmission capabilities. Please read this operation manual carefully before using this instrument.

Intended Use:

The intended use of the JB3000 Handheld Pulse Oximeter is to measure and display the functional oxygen saturation of arterial hemoglobin (SpO $_{\!2}$) and pulse rate (PR) for adults and pediatric patients in the home and hospital (including clinical use in internist/surgery, Anesthesia, Intensive Care and similar) environments. The Pulse Oximeter is intended for spot-checking these levels. It can assist the clinician diagnostically by quickly displaying the patient's SpO $_{\!2}$ percentage and pulse rate and can optionally store 72 hours of data.

Contraindications:

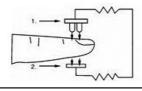
- WARNING: This instrument should be used only by a medical professional trained in its use.
- WARNING: This device is not intended for continuous monitoring.
- WARNING: Do not use this device in an explosive atmosphere, in the presence of a flammable anesthetic mixture, or with oxygen or nitrous oxide.
- WARNING: Do not use this device in an MRI or CT environment.
- ✓ WARNING: Federal law restricts this device to sale by or on the order of a physician.

Principle of Measurement

The principle of pulse oximetry is based on the red and infrared (IR) light absorption of oxygenated and deoxygenated hemoglobin present in the circulating blood. Oxygenated hemoglobin absorbs more IR and allows more red light to pass through. Deoxygenated hemoglobin conversely absorbs more red light and allows IR light to pass through. The sensor (detector probe) is placed on the finger. The sensor contains two **Light Emitting Diodes** (LEDs), one in the visible red spectrum (660 nm) and one in the IR spectrum (940 nm). The beams of light from this detector probe pass through the tissues; some light is absorbed by the blood and soft tissues depending on hemoglobin concentration. The amount of light absorption at each light frequency is dependent on the degree of oxygenation of hemoglobin within the tissues. As a result of electronic circuitry and microprocessor operation, the oximeter's LCD will display a measured signal obtained by a photosensitive element.

Principle of Operation

See illustration and descriptions below.



- 1 Red and Infrared Emitter Diode
- 2 Red and Infrared Receptor Diode

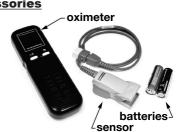
UNPACKING

Confirm that items 1-3 below, Standard Included Accessories, are packed with the Pulse Oximeter. If any item on this list is missing or damaged, contact your GF distributor. Contact the carrier immediately if the shipping carton is damaged.

ACCESSORIES

Standard Included Accessories

- 1. Operation manual
- 2. Adult finger sensor (Item JB3000-AP)
- 3. Two AA Alkaline batteries



Optional (Not Included) Accessories

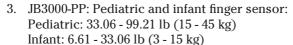
Items 1-4 below are available from your authorized GF Health Products, Inc.

¬ MedView™ softw

distributor.

1. JB3000-B: Replacement protective cover for oximeter

2. JB3000-AP: Adult finger sensor



 JB3000-USB: MedView[™] software CD (includes software license and USB cable)



2 SAFETY INFORMATION

The safety statements presented in this chapter refer to the basic safety information that should be observed by those using the JB3000 Handheld Pulse Oximeter. 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.

Info: For routine equipment maintenance, please refer to the service procedures in the *MAINTENANCE* section of this manual.

Info: For other concerns, please carefully read the specific relevant material in this manual. A Table of Contents is provided at the beginning, and an index at the end, to assist you in finding information.

STATEMENTS OF SIGNIFICANCE

- 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 moderate or minor personal injury.
- ▲ NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product/ property damage.

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

WARNING

WARNING: Please read this manual carefully before using this device. The operator must ensure that the equipment functions safely and is in proper working condition before being used.

WARNING: The Pulse Oximeter contains no serviceable parts. Do not disassemble. Only authorized personnel may perform service or adjustments on this device.

WARNING: When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's operation manual for full instructions. The equipment connected to the Pulse Oximeter's optional data interface must be certified according to the respective IEC standards, i.e., IEC 950 for data processing equipment or IEC 601-1 for medical electrical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements.

WARNING: Sensor malfunction may cause inaccurate data, possibly resulting in patient injury or death — pay close attention to the sensor and inspect it often.

WARNING: Optional worn-out data cables may 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.

WARNING: Do not tangle the oximeter cable with ES (Electrosurgery) equipment wires.

MARNING: Do not reuse single-use accessories.

MARNING: Notice for California Customers- California Proposition 65 WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive or developmental harm.

CAUTION

⚠ CAUTION: Prolonged use of the 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 four hours. Prolonged use may cause blisters, skin deterioration, and discomfort.

NOTICE

- ▲ NOTICE: The operator must be thoroughly familiar with the information in this manual before using the device.
- ▲ NOTICE: Autoclaving, ethylene oxide sterilizing, or immersing the oximeter or sensor in liquid may cause permanent damage as well as inaccurate readings.
- ▲ NOTICE: Unplug the sensor from the monitor before cleaning or disinfecting it.
- ▲ NOTICE: If liquid is accidentally spilled on the unit, clean and dry thoroughly before reuse.

Electromagnetic Compatibility

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the medical electrical 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.

Equipment Classification According to IEC 60601-1

Type of protection against electrical shock	Internal electrical power source equipment
Degree of protection against electrical shock	Type BF equipment
Degree of protection against harmful ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water)
Method of sterilization or disinfection	Non-sterilizable; use liquid surface disinfectants only
Mode of operation	Continuous operation

WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture or with oxygen or nitrous oxide.

3 SETUP OUTER VIEW Front View



Rear View



OXIMETER SETUP

Install the Batteries

The oximeter can be powered by two AA alkaline batteries, which will typically provide 50 hours of normal operation, or by optional rechargeable batteries (NiMH or Li).



When battery power is lower than 2.4V, "\[\bigcirc\]" will flicker in the display area. Replace the batteries, as shown above, as soon as possible.

Ensure the batteries are inserted with the correct polarity, as indicated by polarity marking (+ and -) inside the battery compartment.

Connect the Sensor



Connect the oximeter sensor to the top of the oximeter as shown above. Ensure that the sensor is firmly plugged in.

4 OPERATION

MONITORING

Position the Finger



Clip the sensor to the patient's finger and ensure the patient's nail surface is facing upward as shown above.

Power On the Oximeter

Press the function (left) key to power the oximeter on. Several seconds later, the measurement value will appear.

Info: To maintain the highest degree of accuracy, keep the finger and oximeter sensor as still as possible.

Adjust the Brightness



When you press the function key for longer than one second, the brightness level will display on the top right of the screen as shown above. Adjust the brightness level one level at a time by pressing the setting key. There are 10 levels of brightness (1 - 10); the default is level four, as shown above

Switch the Display Graph Mode







After turning on the oximeter, each time the function key is pressed, the oximeter will switch to another display **GRAPH MODE**, shown above, described in **5 DETAILED OPERATION** — **SETTINGS**.

FACTORS THAT MAY AFFECT MEASUREMENT

- CAUTION: Tissue damage can be caused by incorrect operation or sensor misuse; for example, by wrapping the sensor too tightly. Inspect the sensor site to ensure the skin's integrity and that the adhesion position of the sensor is correct. More frequent inspection should be taken if necessary.
- ▲ NOTICE: Use only SpO₂ sensors provided by GF Health Products, Inc. Other SpO₂ sensors may cause improper performance.
- NOTICE: Do not use an SpO₂ sensor with exposed optical components.

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

Pulsatile Character of the Artery

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

- Temperature of the digit
- After the administration of a cardiovascular drug
- Anemia
- Evidence of ventilation-perfusion mismatch

<u>Wavelength Absorption for Oxyhemoglobin and Deoxyhemoglobin</u>

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 ${\rm SpO_2}$ values. The following may affect these values:

- Carboxyhemoglobin
- Methemoglobin
- Methylene blue
- Indigo carmine

Extremely High Illumination / High Ambient Light

Extremely high illumination, especially sunlight, could affect measurement. Use a semi-translucent or opaque cover to shield the sensor.

Other Factors That May Affect Measurements

- High-frequency electrosurgical interference from external devices, including defibrillators
- Operation of this device in an electromagnetic field
- Placement of a sensor on an extremity that currently has a blood pressure cuff, arterial catheter, or intravascular line installed
- Installing SpO₂ and NIBP measurement on the same arm at the same time

- Optical cross-talk that can occur when two or more sensors are located in adjoining areas (it can be eliminated by covering each site with opaque material)
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- An arterial occlusion proximal to the sensor
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance
- Fingernail polish or artificial fingernails
- Excessive patient movement
- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure; ensure there are no obstructions and the sensor is clean

Loss of Pulse Signal

Loss of pulse signal can occur in any of the following situations:

- The sensor is too tight
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
- A blood pressure cuff is inflated on the same extremity as the one to which an SpO₂ sensor is attached

5 DETAILED OPERATION — SETTINGS

GRAPH MODE DISPLAY

This device uses an LCD (Liquid Crystal Display) for a readout. It displays, in graph form, the ${\rm SpO_2}$ and pulse rate (PR) value, as well as a pulse column and ${\rm SpO_2}$ waveform. Illustrations of the three **GRAPH MODES** and their descriptions follow.







- a Figure a shows FILLED WAVEFORM GRAPH MODE.
- **b** Figure b shows **LINE WAVEFORM GRAPH MODE** indicating SpO₂% trend.
- c Figure c shows PULSE COLUMN GRAPH MODE. This is used for signal identification and quality indication during motion and low signal to noise situations. The column rises and falls with the pulse, its height indicating signal quality. When the column is very low, the SpO_2 and pulse rate values may be suspect. Signal strength indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity. The column is highest when the quality of the perfusion state is best and lowest when the perfusion is poor.
- SpO₂: Percent oxygen saturation value displayed above is 98%.
- PR: Pulse rate value displayed above is 72 BPM.
- PR tone modulation: Beeps in sync with patient's pulse, even under most challenging patient motion conditions.

MODE INTRODUCTION

There are three display modes: **MEASURE MODE**, **INFORMATION DISPLAY MODE** and **TROUBLE DISPLAY MODE**.

Display Mode Descriptions

- MEASURE MODE: The sensor is plugged into the oximeter correctly, the finger is properly positioned in the sensor, and the oximeter is in MEASURE MODE for both SpO_a and PR.
- INFORMATION DISPLAY MODE: The system is unable to enter MEASURE MODE because either of the following conditions exists:
 - a. The sensor is not plugged into the oximeter, in which case "Probe off" will display, or
 - The sensor is plugged into the oximeter but the finger is not in the sensor, in which case "Finger off" will display, and

The oximeter will automatically power off if INFORMATION DISPLAY MODE (either condition a or b above) lasts for longer than eight seconds.

 TROUBLE DISPLAY MODE: In this mode (failure state), the oximeter will display error information, and will automatically power off if TROUBLE DISPLAY MODE lasts for longer than eight seconds. For error information details and definitions, please refer to TROUBLESHOOTING section.

Key Definition

There are two keys on the oximeter's front face: **Function Key** (left) and **Setting Key** (right).

 Function Key: This key acts as a Power On switch when the unit is off. When the unit is on, it acts as a function key. 2. **Setting Key:** This key has no function when the power is off. When the unit is on, it acts as a setting key.

Key Press Definition

There are three ways to press the keys:

- 1. **Press:** Press and release the key quickly (for less than one second).
- 2. **Double Press:** Press and release the key twice quickly (less than 0.5 second between the two press actions).
- 3. **Extended Press:** Press the key for more than 1.5 seconds before releasing.

KEY FUNCTIONS

Power On/Off

Press the function key to power on.

The oximeter will power off automatically if either INFORMATION DISPLAY MODE or TROUBLE DISPLAY MODE lasts for longer than 8 seconds.

Graph Mode Setting

The GRAPH MODE selection can be performed only while in MEASURE MODE or INFORMATION DISPLAY MODE. By pressing the function key or setting key, the GRAPH MODE may be changed sequentially between FILLED WAVEFORM GRAPH MODE, LINE WAVEFORM GRAPH MODE and PULSE COLUMN GRAPH MODE, as shown in 5 DETAILED OPERATION — SETTINGS. Once you select a GRAPH MODE, the oximeter will display it until you select a different GRAPH MODE.

Setting Mode

Entering or exiting **SETTING MODE** can be done only while in **INFORMATION DISPLAY MODE**. You can set Brightness, Patient ID, Date and Time while in **SETTING MODE**. Current

parameter and data will display at the top right corner which is used to display PR. The parameters eligible for adjustment display as follows:

Order	Symbol	Setting	Adjustment Range
1	Br	Brightness	1 - 10
2	ID	Patient ID	1 - 10
3	Υ	Year	0 - 99
4	М	Month	1 - 12
5	D	Day	1 - 31
6	Н	Hour	0 - 23
7	М	Minute	0 - 59
8	S	Second	0 - 59

1. To enter **SETTING MODE**:

- a) While in INFORMATION DISPLAY MODE, extendedpress the function key (for more than one second); the oximeter will enter SETTING MODE and display a parameter's title and value in the top right corner.
- b) While in SETTING MODE, press the function key repeatedly; the current parameter will change sequentially in the same order as above table.

Info: Do not insert finger while in SETTING MODE.

- 2. To adjust parameter, save and exit from **SETTING MODE**:
 - a) While in **SETTING MODE**, press the function key to select the desired parameter to set.
 - b) Press the setting key to adjust the value.
 Each time you press the setting key, the current parameter value will increase by 1 unit.
 Double press the setting key to increase the current parameter by 10 units. All use circular logic.

c) To finish and save parameter setting, press both function and setting keys simultaneously to confirm. The modification will be saved and the system will exit SETTING MODE.

Info:

- Only one parameter can be adjusted at a time. You must repeat steps 2. a - c to finish each parameter's setup.
- Parameter adjustment only can be performed while in SETTING MODE during INFORMATION DISPLAY MODE.
- 3. To cancel and exit **SETTING MODE**:
 - a) While in SETTING MODE, double-press the function key; the modification performed during SETTING MODE will be canceled and the system will exit from SETTING MODE, or
 - b) If there is no operation for more than 10 seconds while in **SETTING MODE**, the system will exit **SETTING MODE** automatically without saving.

DATA REPLAY AND TRANSMISSION (OPTIONAL)

The oximeter can record SpO₂ and PR value for more than 24 hours, and can analyze records one by one.

You can transmit the history data to a PC using optional MedView $^{\text{\tiny TM}}$ software and a special data cable, available from your Graham-Field authorized distributor. For detailed setup and operation, please refer to the MedView $^{\text{\tiny TM}}$ operation manual.

Info: transmission software and data cable are not standard accessories. Contact your GF distributor for purchase.

6 MAINTAINANCE

REPAIR / MAINTENANCE

⚠ WARNING: The Pulse Oximeter contains no serviceable parts. Do not disassemble. Only authorized personnel may perform service or adjustments on this device.

Battery Maintenance

- Remove the batteries if you will not be using the oximeter for an extended period of time.
- If using optional rechargeable batteries: Charge the batteries fully after use.
- If using optional rechargeable batteries: Charge at least 14 hours first time or battery life will be reduced.

CLEANING / DISINFECTION

It is very important for user to perform daily maintenance of oximeter and parts in order to maintain its function and appearance. Disinfection procedures may be performed with the use of the below-listed cleaner/disinfectants. Failure to perform these procedures may result in invalidating the warranty. Local disinfection protocols will apply.

- NOTICE: Remove batteries before cleaning the oximeter.
- ▲ NOTICE: Do not submerge the oximeter or sensor in any solution or liquid at any time.
- ▲ NOTICE: Use only the following permitted solutions.

The external surface of the oximeter can be cleaned by wiping with a clean, soft cloth dampened with:

Ammonia (diluted), or

- Glutaraldehyde, or
- 10% Bleach solution, or
- Mild soapy water (diluted).

▲ NOTICE: Do not use the following cleaners:

- Any kind of scrubbing or scouring solution
- Acetone
- Any alcohol-based cleaner

7 TROUBLESHOOTING

Error Definitions

Err 1	Program memory damaged
Err 2	Data memory damaged
Err 3	Sensor red emission diode damaged
Err 4	Sensor infrared emission diode damaged
Err 5	Sensor infrared receipt diode damaged
Err 6	Exterior crystal oscillator damaged
Err 7	Sensor emission diode or receipt diode damaged
Err 9	Real time clock damaged
Err 10	EEPROM chip damaged

Problem, Possible Reason, and Solution

Problem	Possible reason	Solution	
SpO ₂ or PR cannot be displayed normally	Patient's finger is incorrectly inserted Patient's oxyhemoglobin value is too low to be measured	Reinsert patient's finger Attempt several times to obtain a reading; If sure that no problem exists, obtain further clinical examination	
SpO ₂ or PR display is unstable	Finger may not be inserted deeply enough Finger trembling or patient moving	Reinsert finger Ask patient to remain still	

Troubleshooting continued			
Problem	Possible reason	Solution	
The Oximeter cannot be powered on	Battery power may be inadequate or batteries may not be installed Batteries may be installed incorrectly Oximeter may be damaged	 Replace batteries Reinstall batteries Contact GF distributor 	
"Error4" displays	Receiving diode and/ or connector may be shielded or damaged Mechanical misplace for receive-emission diode Amp circuit malfunction	Contact GF distributor Contact GF distributor Contact GF distributor	
"Error7" displays	Emission diode damaged Current control circuit malfunction	Contact GF distributor Contact GF distributor	
"Probe off" displays	The sensor is not connected The connection between the sensor and oximeter is loose	Connect the sensor Ensure sensor and oximeter are connected correctly	
"Finger off" displays	The sensor is plugged into the oximeter but the finger is not in the sensor	Plug the finger into the sensor	

8 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.

This limited warranty shall only apply to defects that are reported to GF's customer service team 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.

The warranted components and time period are set forth below:

Oximeter: two years Sensor: one year Accessories: six months

The applicable warranty period shall commence from date of shipment to the original customer, 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. The warranty does not extend to non-durable parts and does not include labor or costs of shipping. The warranty is void if the defect is caused by any other reason not related to defects in materials or workmanship.

OBTAINING WARRANTY SERVICE

GF's customer service team must be notified of any warranty claim within the applicable warranty period. Call 678-291-3207, or fax 770-368-2386 or e-mail cs@grahamfield.com. Failure to follow the specific directions provided by the GF customer service team will result in denial of the warranty claim.

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.

GF'S TOTAL LIABILITY FOR ANY PRODUCT OR SERVICE PROVIDED IS LIMITED TO THE COST OF THE PRODUCT GIVING RISE TO THE CLAIM. IN NO EVENT WHETHER IN CONTRACT, INDEMNITY, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE WILL GF BE LIABLE FOR 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.

This warranty gives you specific legal rights. You may have additional rights which vary from state to state.

APPENDIX A: SPECIFICATIONS

SpO ₂	Range	0%-99%	
	Resolution	1%	
	Accuracy	0%-69% unspecifie	d; 70%-99% ±2%
	Data update time	< 15 seconds	
Measurement	Red	660 nm @ 3 mw nominal	
Wavelengths and Output Power	Infrared	940 nm @ 3 mw nominal	
Heart (Pulse)	Range	30-254 BPM	
Rate	Resolution	1 BPM	
	Accuracy	±2 BPM or ±2%	
Alarm	Alarm	Probe off, finger ou	t, low battery
	Modes	Visual Information	
Display	Туре	OLED, double color	r
	Parameters	SpO ₂ , pulse rate, pl and pulse bar	ethysmogram,
	Mode	3 display modes	
Record	Patient ID	10 patients	
	Data record	Up to 72 hours	
Environmental	Temperature	Operating	41°F to 104°F (5°C to 40°C)
		Storage	-4°F to +158°F (-20°C to +70°C)
	Humidity	Operating	15% to 95% RH
		Storage	10% to 95% RH
Dimensions	4.33 x 1.38 x 1.06 in (110 x 35 x 27 mm)		
Weight	.24 lb / 3.88 oz (110g) with alkaline batteries		

Classification	Type of protection	Internally powered	equipment	
per IEC 60601-1	Degree of protection	Type BF-Applied Part		
	Mode of operation	Continuous		
	Safety	IEC Standard 60601-1		
Power	Туре	2 AA alkaline or optional rechargeable batteries (NiMH or Li)		
	Operation time	~ 50 hours of typical operation with alkaline batteries		
Optional:	Transmission method	Cable Transmission		
Data Transmission	Data Cable Interface	DB9 (Connect to Pulse Oximeter)		
		USB (Connect to PC)		
GUIDE TO SYMBOLS				
Symbol	Definition			
\triangle	Attention, consult accompanying documents			
·	Type BF applied part Prevent from exposure to rain			
7				

Storage temperature and relative humidity

Protected against dripping water

Date of manufacture

Low power indicator

No Spo2 alarm

Serial number

 \mathbb{M}

∭ Spo₂

SN

IPX1

APPENDIX B: ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration - electromagnetic immunity

This device 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) IEC 610004-2	6kV contact 8kV air	6kV contact 8kV air	Floors should be wood, concrete or ceramic tile. If floors are converted with Synthetic material, the relative humidity should be at least 30%

Guidance and manufacturer's declaration - electromagnetic immunity for equipment and systems that are not life-supporting

61000-4-6 Radiated RF IEC 61000-4-3	3V/m 80Hz to 2.5 GHz	d= 3.5 \(\overline{P} \) 80MHz to 800MHz d= 3.5 \(\overline{P} \) 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). 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.		
Electromagnetic Immunity continued				

NOTE 1: At 80MHz and 800MHz, 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 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 JB3000 Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, the JB3000 Handheld Pulse Oximeter should be observed.

Recommended separation distances between portable and mobile RF communications equipment and the JB3000 Handheld Pulse Oximeter

This device is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the JB3000 Handheld Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the JB3000 Handheld Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150KHz to 80 MHz d= $\frac{3.5}{V_1}\sqrt{P}$	80MHz to 800 MHz $d = \frac{3.5}{\overline{g}_1} \sqrt{P}$	800MHz to 2.5 GHz $d = \frac{7}{81} \sqrt{P}$
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	7.7386
100	11.6667	11.6667	23.3334

Electromagnetic Immunity continued

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.

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

NOTE 2: 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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