Information Manual

Version: FDA 1.0C22

Drive Medical Fingertip Pulse Oximeter  

**Item # 18705**

1. Measurement principle

The Oximeter is designed to display functional oxygen saturation. Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reducing hemoglobin (R-Hb) and Oxygen hemoglobin (O2-Hb) in glod and near-infrared zones. Operation principle of the instrument is Photoelectric Oxymoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (809nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp-finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs through process in electronic circuits and microprocessor.

2. Precautions for use

- Operation of the Oximeter may be affected by the use of an electrocautery unit (ESU).
- The Oximeter must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before replying on the SpO2 measurement.
- Do not use the Oximeter in an MRI or CT environment.
- Do not use the Oximeter in situ where alarms are required. The device has no alarms.
- Exposure hazard: Do not use the Oximeter in an explosive atmosphere.
- The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the pulse oximeter sensor application site frequently to determine the position of the sensor and circulation and skin sensitivity of the patient.
- Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blistering.
- Before use, carefully read the manual.
- The Oximeter has no SpO2 alarms, it is not for continuous monitoring, as indicated by the symbol.
- Prolonged use or the patient’s condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

3. Inaccurate measurements

- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device components, including batteries.
- Significant levels of dysfunctional hemoglobin (such as carboxy-hemoglobin or met hemoglobin).
- Intraocular dyes such as indocyanine green or methyl blue.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel) or direct sunlight, if necessary.
- Excessive patient movement.
- High-frequency electrocautery interference and defibrillators.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- The patient has hypotension, severe vasocostriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or fake fingernails may cause inaccurate SpO2 readings.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

4. Technical Specifications

- **Display types:** OLED display
- **SpO2 display range:** 0-100%
- **PR display range:** 30-254 BPM
- **PR display mode:** bar graph
- **Data update time:** < 15 s

4.2 LED Wavelengths

Red: 660nm
Infrared: 940nm

4.3 Battery life

Two AAA 1.5V alkaline batteries can be continuously operated as long as 30 hours.

4.4 Resolution:

- ±1% for SpO2 and ±15 BPM for Pulse rate

4.5 Measurement Accuracy:

- SpO2: 70%-95%, ±3%, ±7% no definition
- PR: 30–235 BPM, ± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-254 bpm

4.8 It is equipped with a function switch, through which the Oximeter can be powered off in case no finger is the Oximeter longer than 8 seconds.

4.7 Dimension outline:

- Length: 59mm
- Width: 32mm
- Height: 34mm
- Weight: 50g (including two AAA batteries)

4.8 Environment requirements:

- Operation Temperature: 5-40°C
- Storage Temperature: -20-70°C
- Humidity: <15%-80% in operation
- <93% in storage

Declaration: EMC of this product comply with IEC60601-1-2-2 standard.

5. Product properties

- 5.1 Operation of the product is simple and convenient
- 5.2 The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying
- 5.3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.

5.4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.

<table>
<thead>
<tr>
<th>Display Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display mode when opening the device, horizontal and normal facing</td>
<td>After one click, the display is vertical and normal facing</td>
</tr>
</tbody>
</table>

5.6 The product will automatically powered off when no signal is in the product for longer than 8 seconds.

6. Product Intended Use

**Intended Use**

Fingertip Pulse Oximeter 18705 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in an Intermittent, Anesthesia, intensive care and etc). Not for continuously monitoring.

The 18705 requires no routine calibration or maintenance other than replacement of batteries.

7. Operation Instructions

7.1 Installing two AAA batteries into battery cassette before covering its cover.
7.2 Open the clamp as illustrated in the picture below.
7.3 Plug one finger into rubber hole of the Oximeter (it's best to plug the finger thoroughly) before releasing the clamp.
7.4 Press the switch button once on front panel.
7.5 Your finger does not tremble during the Oximeter is working. Your body is not recommended in moving status.
7.6 Read correspondent datum from display screen.
7.7 Two display modes.

High: The Oximeter, each time you press the power switch, the Oximeter will switch to another display mode, there are 2 display modes as shown below:
When you press the power switch for a long time (more than one second), the brightness of the Oximeter will be changed by degrees, there are 10 levels on brightness, the default level is level four.
When your finger is plugged into the Oximeter, your nail surface must be upward.

8. Brief Description of Front

Patient pulse quality signals are indicated as such by bar graph. The higher the amplitude of the bar, the higher the quality of the pulse signal.

9. Product Accessories

9.1 One lamp band
9.2 Two batteries
9.3 One instruction manual

10. Battery Installations

10.1 Use the two AAA batteries into battery cassette in correct polarities.
10.2 Push the battery cover horizontally along the arrow shown as below:

Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device. Please put or remove batteries in right order, or is likely to damage the device bracket. Please remove the battery if the Oximeter will not be used for long time.

11. Hang Lace Installations

11.1 Thread thinner end of the hang lace through the hanging hole.
11.2 Thread thicker and of the lace through the threaded and before pulling it tightly.

12. Maintenance and Storage

12.1 Replace the batteries timely when low voltage lamp is tilted.
12.2 Clean surfaces of the fingertip Oximeter before it is used in diagnosis for patients.
12.3 Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
12.4 It is best to preserve the product in a place where ambient temperatures –10+4°C and humidity 10%-80%

It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.

Please follow the law of the local government to deal with used battery
Cleaning the 18705
Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter with a soft cloth dampened with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test. Do not pour or spray liquids onto the Oximeter, and do not allow any liquid to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

13. Calibrating the 18705
- The functional tester cannot be used to assess the accuracy of the Oximeter.
- Index 2 that made by Biotek company is a function tester. Set Tech to 1, R curve to 2, and then user can use this particular calibration curve to measure the Oximeter.
- The test methods used to measure the SpO2 accuracy is clinical testing. The oximeter used to measure the arterial hemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-Oximeter.

14. Possible problems and res

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2% or pulse rate can not be shown normally</td>
<td>1. Finger is not plugged correctly</td>
<td>1. Retry by plugging the finger</td>
</tr>
<tr>
<td>2. Patient's SpO2 value is too low to be measured</td>
<td>2. Patient's SpO2 value is too low to be measured</td>
<td>2. Ensure the patient's SpO2 is within the normal range</td>
</tr>
<tr>
<td>IS04% or pulse rate is shown unsatisfactory</td>
<td>1. Finger might not be plugged deep enough</td>
<td>1. Ensure the finger is firmly plugged into the Oximeter</td>
</tr>
<tr>
<td>2. Excessive patient movement</td>
<td>2. Ensure the patient is still during measurement</td>
<td></td>
</tr>
<tr>
<td>The Monitor can not be powered on</td>
<td>1. No battery or low battery of battery</td>
<td>1. Replace the battery</td>
</tr>
<tr>
<td>2. Battery might be installed incorrectly</td>
<td>2. Ensure the battery is correctly installed</td>
<td></td>
</tr>
<tr>
<td>The Monitor might be damaged</td>
<td>3. The Monitor might be damaged</td>
<td>3. Contact local customer service centre</td>
</tr>
</tbody>
</table>

15. Declaration

Guidance and Manufacturer’s declaration – electromagnetic emissions

Guidance and Manufacturer’s declaration – electromagnetic emission specified below. The customer of the Pulse Oximeter (18705) should use it in such an environment.

**Emission test**

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Electromagnetic Environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>This pulse oximeter (18705) is suitable for use in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Group B</td>
<td>The pulse oximeter (18705) is suitable for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (18705) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (18705) as recommended below, according to the maximum output power of the communications equipment.</td>
</tr>
</tbody>
</table>

**Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter (18705)**

<table>
<thead>
<tr>
<th>Field strength of fixed RF transmitters</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>1.0 m</td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NO2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection structures, objects and people.