Information Manual

Version: FDA 1.0C22

Drive Medical Fingertip Pulse Oximeter

**Item # 18705**

**1. Measurement principle**

The Oximeter is calibrated to display functional oxygen saturation. Principle of the Oximeter is as follows:

- The 18705 must be able to measure the pulse property to obtain an accurate SpO2 measurement.
- Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
- Do not use the 18705 in an MRI or CT environment.
- Do not use the 18705 in locations where alarms are required. The device has no alarms.
- Do not use the 18705 in an explosive atmosphere.
- The 18705 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 positioning 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 blisters.
- Ensure the site of application is clean and dry.
- The 18705 has no SpO2 alarms. It is not for continuous monitoring, as indicated by the symbol.
- Prolonged use of 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.

**2. Precautions for use**

- The Oximeter 18705 may be affected by the use of an electro-surgical unit (ESU).
- The 18705 must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
- Do not use the 18705 in an MRI or CT environment.
- Do not use the 18705 in situations where alarms are required. The device has no alarms.
- Do not use the 18705 in an explosive atmosphere.
- The 18705 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 positioning 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 blisters.
- Before use, carefully read the manual.
- The 18705 has no SpO2 alarms. It is not for continuous monitoring, as indicated by the symbol.
- Prolonged use of 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(Position) the device using autolavage, ethylene oxide sterilizing, or immersing the sensor in liquid which may cause inaccurate readings. The device is not intended for sterilization.
- Significant levels of dysfunctional hemoglobin (such as carbonyl-hemoglobin or met hemoglobin) may affect the accuracy of the measurement. The 18705 is calibrated to display functional oxygen saturation.
- Intravascular dyes such as indocyanine green or methylene blue may affect the accuracy of the measurement. The 18705 is calibrated to display functional oxygen saturation.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- Evasive patient movement
- High-frequency electro-surgical interference and defibrillators
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may affect the accuracy of the measurement. The 18705 is calibrated to display functional oxygen saturation.
- The patient has hyperthermia, severe vasoconstriction, severe anemia, or hypothermia
- The patient is in cardiac arrest or is in shock
- Fingernail polish or false 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 type: OLED display
- SpO2 display range: 0-99%
- 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 could be continuously operated as long as 30 hours.
- 4.4 Resolution:
  - ±1% for SpO2 and ±1 BPM for Pulse rate
- 4.5 Measurement Accuracy:
  - SpO2: 70%~100%, ±2%, ≤2% in storage
  - 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
- 4.6 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 Outline dimension:
  - Length: 59mm
  - Width: 32mm
  - Height: 34mm
- Weight: 50g (including two AAA batteries)
- 4.8 Environmental requirements:
  - Storage Temperature: -20-70°C
  - Operation Temperature: 5-40°C
  - Humidity: 15%-85% in operation
  - N99 in storage
- Declaration: EMC of this product comply with IEC60601-1-2 standard.

**5. Operation principle**

- 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.

**6. Product 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 Intensive/surgery, 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 Install 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 is best to plug the finger thoroughly) before releasing the clamp.
7.4 Press the switch button once on front panel.
7.5 Your finger do 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.

After turn on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode, there are 2 display modes shown as follows:

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 15 levels on brightness; the default level is level four.

When your finger is plugged into the Oximeter, your nail surface must be upward.

**8. Display Mode**

<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></td>
</tr>
<tr>
<td>After one click, the display is vertical and normal facing</td>
<td></td>
</tr>
</tbody>
</table>

**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>Item # 18705</th>
<th>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.</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Battery Accessory</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 One lanyard</td>
<td>9.2 Two batteries</td>
</tr>
<tr>
<td>9.3 One instruction manual</td>
<td></td>
</tr>
</tbody>
</table>

**10. Battery Installations**

- 10.1 Insert the two AAA batteries into battery cassette in correct polaires.
- 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. Hanag Lace Installations**

- 11.1 Thread thimer of the 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 lighted.
- 12.2 Clean surround 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 bad to preserve the product in a place where ambient temperatures -50~40 (-14°F~104°F) and humidity 10%-85%.
- 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 and 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 Biotec 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 establish 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 their Solutions

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</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. 2. Patient’s SpO2 value is too low to be measured.</td>
<td>1. Retry by plugging the finger. 2. Patient’s SpO2 value is less than 1% for more than 30s.</td>
</tr>
<tr>
<td>SpO2% or pulse rate is shown unstably</td>
<td>1. Finger might not be plugged deep enough. 2. Excessive patient movement. 3. The Monitor might be damaged.</td>
<td>1. Replace the battery. 2. Please reinstall the battery. 3. Please contact with local customer service centre.</td>
</tr>
<tr>
<td>The Monitor cannot be powered on</td>
<td>1. No battery or low battery. 2. Battery might be installed incorrectly. 3. The Monitor might be damaged.</td>
<td>1. Replace the battery. 2. Please reinstall the battery. 3. Please contact with local customer service centre.</td>
</tr>
<tr>
<td>Indication is suddenly off</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Err3&quot; or &quot;Err4&quot; displayed on screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error 6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Declaration

Guidance and Manufacturer’s declaration – electromagnetic emissions - For all EQUIPMENT and SYSTEMS

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions - Group 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions - Group 2</td>
<td></td>
<td></td>
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<tr>
<td>Harmonic emissions</td>
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<tr>
<td>Voltage Ratings / Risker emissions</td>
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Guidance and Manufacturer’s declaration – electromagnetic immunity - For all EQUIPMENT and SYSTEMS

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharges (ESD) IEC 61000-4-2</td>
<td>+/- 4kV contact +/- 8kV air</td>
<td>+/- 4kV air</td>
<td>+/- 8kV air</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td></td>
</tr>
</tbody>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the equipment or SYSTEMS

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<tr>
<th>Field strength (μT)</th>
<th>Separation distance (m)</th>
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<td>1.168</td>
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<tr>
<td>10</td>
<td>3.685</td>
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</table>

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

The Pulse Oximeter (18705) is intended for use in 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.

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

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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 structures, objects and people.

16. Symbol Definitions

Your Drive brand product is warranted to be free of defects in materials and workmanship for two years of the original consumer purchaser.

This device was built to exacting standards and carefully inspected prior to shipment. This 2 year Limited Warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

In the event of a defect covered by this warranty, we will, at our option, repair or replace the device. This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear.

If you have any question about your Drive device or this warranty, please contact an authorized Drive dealer.