

# Disposable SpO<sub>2</sub> Sensor User' s Manual

## Product Information

**Product Name:** Disposable SpO<sub>2</sub> Sensor



**Hunan Accurate Bio-Medical Technology Co., Ltd.**

Accurate Industrial Park, No.108, Zhixian Road,  
Xuelian Community, Xueshi Street of Yuelu District, 410208 Changsha, Hunan  
Province, PEOPLE'S REPUBLIC OF China.

Tel: +86-731-85598539 Fax: +86 731-84118539



**Shanghai International Holding Corp. GmbH (Europe)**

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 Fax: +49-40-255726

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## 1 Intended use

Accurate disposable SpO<sub>2</sub> sensors are indicated for single-patient use and are intended for continuous noninvasive arterial oxygen saturation(SpO<sub>2</sub>) and pulse rate monitoring.

Accurate disposable SpO<sub>2</sub> sensors are designed to match the specifications of the original manufacturer equipments. It is important to get compatibility information from the product labels and/or Accurate Company while selecting proper sensors and extend cables to match to the equipments.

**1.1 Product usage period:** Disposable

**1.2 Product storage period:** 3 years

## 2 Users:

adult; neonate;

## 2.1 Model:

AF543-01, AF543-01X

## 2.2 Product overview

Accurate disposable SpO<sub>2</sub> sensors are classified in the following categories: adult&neonate foam adhesive(AF543 series)type.

## 3 Warning:

- Accurate disposable SpO<sub>2</sub> sensors are for use with pulse oximeters.
- Check the compatibility of the equipment, sensor and extend cable before use. Incompatible components can result in degraded accuracy and performance.
- Select appropriate sensor type to avoid inaccurate measurement or even harmful events which may lead to serious patient injury.
- In the event of the packaging being damaged, do not use the sensor.
- Disposable SpO<sub>2</sub> sensor is intended for single patient use, and has been cleaned before

delivery. Do not attempt to clean or sterilize it, otherwise it may result in product failure.

- Try to keep the patient still and avoid excessive motions at the measured site.
- Do not locate the sensors on the same arm as the blood pressure cuff, arterial catheter or intravascular line if using any of those devices at the same time.
- Make sure the measured site is not deeply pigmented or deeply colored, otherwise inaccurate measurement will occur.
- For long-term use, the measurement site must be changed every 4 hours to avoid skin damage.
- The measurement may be inaccurate with very low perfusion at the measured site.
- Prevent the sensors from being under the condition of strong light and irradiation field, otherwise inaccurate measurement will occur.
- Do not use the sensor inside or near a MRI equipment.
- Do not immerse the sensors in any of the cleaning solutions, disinfectants, or other liquid.
- Portable and mobile RF communications equipment can affect measurement accuracy.
- Do not place the sensors in an environment that exceed the storage range.
- Functional tester or oximetry simulator cannot be used as the assessment tool for the accuracy of sensors.
- Disposal of the sensor shall comply with local regulation.
- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## **4 Sensor applications**

### **4.1 Before applying sensors**

Be sure to read, understand and observe all warnings listed in this manual and the manual of pulse oximeters.

### **4.2 Selecting appropriate sensors for different patients**

Adult type sensors suit for adult patients(weight:>30 Kg);neonatal type sensors suit for neonatal patients(weight:<3 Kg).

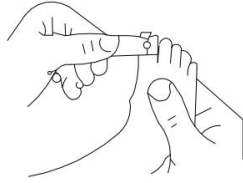
### **4.3 Applying sensors**

#### **Neonate/Adult Foam Adhesive**

1.Place sensor to patient as shown below.

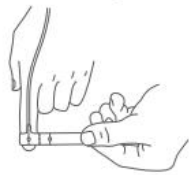
#### **Neonate:**

Place sensor to patient's toe or finger as shown below with optical components opposite each other.



#### Adult:

1. Place sensor to patient's finger as shown below with optical components opposite each other. Be sure that the side with LED is above the nail. Index finger is the best site, and other fingers except thumb can be considered either when the index finger is not available or cannot be located correctly.



2. Holding sensor and stretch strap slightly.
3. Connect sensor to pulse oximeters (with an extend cable if needed).
4. Inspect and change the measurement site periodically.

#### 4.1 Applying pulse oximeters

Operate pulse oximeters under the instruction manuals.

### 5 Specifications

#### 5.1 Accuracy

| SpO <sub>2</sub> Range | SpO <sub>2</sub> accuracy |
|------------------------|---------------------------|
| 70%-100%               | ±2%                       |
| 70%-90%                | ±3%                       |
| < 70%                  | not specified             |

|            | Range     | Accuracy |
|------------|-----------|----------|
| Pulse rate | 20-250bpm | ±2bpm    |

|                       | Wavelength range | Output power |
|-----------------------|------------------|--------------|
| Light emitting diodes | 600-1000nm       | < 18mW       |

|                      | Atmospheric pressure(kPa) |
|----------------------|---------------------------|
| Operating conditions | 70 to 106                 |
| Storage conditions   | 50 to 107.4               |

#### 5.2 Package and storage environment

The sensors are individually packaged and must be stored in original package under specific storage conditions to maximize their storage life.

Storage conditions are as follows:

- Ambient temperature:-25 to +55°C

- Relative humidity:  $\leq 85\%$

### 5.3 Operation environment

- Ambient temperature:  $0^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$
- Relative humidity:  $\leq 85\%$

### 5.4 Safety

Degree of protection from electric shocks: type BF

### 6 Warranty and Liability

Please refer to service announcement of Accurate. Accurate does not cover the damage or breakage due to the abusive use or negligent care of the sensors.

### 7 Symbol explanation

|                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                      |                                                                                                     |                                                                                       |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Caution                                                                             | Production lot number                                                               | Manufacturer                                                                        | Non-sterilization                                                                   | Latex free                                                                          | See the instructions                                                                 | Waste Electrical and Electronic Equipment                                                           | Medical devices                                                                       |
|   |   |   |   |   |   |                 |   |
| Date of manufacture                                                                 | Catalogue number                                                                    | Authorized Representative In The European Community                                 | Do not re-use                                                                       | Expiry date                                                                         | The product is protected against harmful effects of dripping water per IEC 60529.    | This item is compliant with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. | TEMPERATURE LIMITATION                                                                |
|  |  |  |  |  |  |                |  |
| HUMIDITY LIMITATION                                                                 |                                                                                     |                                                                                     |                                                                                     |                                                                                     |                                                                                      |                                                                                                     |                                                                                       |

|                                                                                   |  |  |  |  |  |  |  |
|-----------------------------------------------------------------------------------|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |
|-----------------------------------------------------------------------------------|--|--|--|--|--|--|--|

## 8 Clinical summary

The SpO<sub>2</sub> Sensor has completed clinical research at Sir Run Run Shaw Hospital (SRRSH), affiliated with the Zhejiang University School of Medicine. The study included 13 subjects -10 women and 3 men. Participants are in good health and aged 22-30 years.

### Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

| Guidance and manufacturer's declaration - electromagnetic emissions |                |
|---------------------------------------------------------------------|----------------|
| Emissions test                                                      | Compliance     |
| RF emissions<br>CISPR 11                                            | Group 1        |
| RF emissions<br>CISPR 11                                            | Class B        |
| Harmonic emissions<br>IEC 61000-3-2                                 | Not applicable |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3            | Not applicable |

Table 2

| Guidance and manufacturer's declaration - electromagnetic Immunity |                                                                                       |                                                  |
|--------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------------------------------------------|
| Immunity Test                                                      | IEC 60601-1-2<br>Test level                                                           | Compliance level                                 |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                     | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air                                      | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst<br>IEC 61000-4-4                   | ±2 kV power supply lines<br>±1 kV signal input/output<br>100 kHz repetition frequency | Not applicable                                   |

|                                                                                                        |                                                                                                       |                                                                                                               |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| Surge<br>IEC 61000-4-5                                                                                 | $\pm 0.5$ kV, $\pm 1$ kV differential mode<br>$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV common mode        | Not applicable                                                                                                |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | Not applicable                                                                                        | Not applicable                                                                                                |
| Power frequency magnetic field<br>IEC 61000-4-8                                                        | 30 A/m<br>50Hz/60Hz                                                                                   | 30 A/m<br>50Hz/60Hz                                                                                           |
| Conducted RF<br>IEC61000-4-6                                                                           | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM and amateur radio bands 0,15 MHz and 80 MHz<br>80 % AM at 2 Hz | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br>80 % AM at 2 Hz |
| Radiated RF<br>IEC61000-4-3                                                                            | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 2 Hz                                                          | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 2 Hz                                                                  |
| 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                             |                                |                      |                |                           |                                                              |                                  |
|------------------------------------------------------------------------------------------------|--------------------------------|----------------------|----------------|---------------------------|--------------------------------------------------------------|----------------------------------|
| Radiated RF<br>IEC61000-4-3<br>(Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless | <b>Test Frequency</b><br>(MHz) | <b>Band</b><br>(MHz) | <b>Service</b> | <b>Modulation</b>         | <b>IEC</b><br><b>60601-1-2</b><br><b>Test Level</b><br>(V/m) | <b>Compliance level</b><br>(V/m) |
|                                                                                                | 385                            | 380 – 390            | TETRA<br>400   | Pulse modulation<br>18 Hz | 27                                                           | 27                               |



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). 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: 

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 4

| Guidance and manufacturer's declaration - electromagnetic Immunity                                             |                |                             |                                      |                           |
|----------------------------------------------------------------------------------------------------------------|----------------|-----------------------------|--------------------------------------|---------------------------|
| Radiated RF<br>IEC61000-4-39<br>(Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields) | Test Frequency | Modulation                  | IEC 60601-1-2<br>Test Level<br>(A/m) | Compliance level<br>(A/m) |
|                                                                                                                | 30 kHz         | CW                          | 8                                    | 8                         |
|                                                                                                                | 134,2 kHz      | Pulse modulation<br>2.1 kHz | 65                                   | 65                        |
|                                                                                                                | 13,56 kHz      | Pulse modulation<br>50 kHz  | 7,5                                  | 7,5                       |