Disposable SpO_2 Sensor User' s Manual

Product Information

Product Name: Disposable SpO_2 Sensor

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- Revision number: 1.1
- Release time: 2023/7/4

1 Intended use

Accurate disposable SpO_2 sensors are indicated for single-patient use and are intended for continuous noninvasive arterial oxygen saturation($Sp0_2$) and pulse rate monitoring. Accurate disposable $Sp0_2$ 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 $Sp0_2$ sensors are classified in the following categories: adult&neonate foam adhesive(AF543 series)type.

3 Warning:

- Accurate disposable SpO_2 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_2 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).

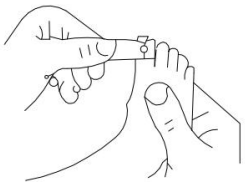
4.3 Applying sensors

Neonate/Adult Foam Adhesive

1.Place sensor to patient as shown below.

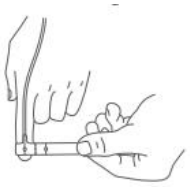
Neonate:

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

Sp02 Range	Sp02 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℃

- Relative humidity:≤85%

5.3 Operation environment

- Ambient temperature:0°to+40°℃
- Relative humidity:≤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	WasteElectrical 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 perIEC 60529.	This item is compliant with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.	TEMPERATURE LIMITATION
					IPX2		
HUMIDITY LIMITATION							

8 Clinical summary

The SpO2 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 CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

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

Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands 0,15 MHz and 80 MHz 80 % AM at 2 Hz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 2 Hz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27

communications equipment)	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Electromagnetic environment - guidance

RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

$$E = \frac{6}{d}\sqrt{P}$$

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 rang b.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 IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5