Accurate AF543-01 Disposable SpO2 Sensor User Manual

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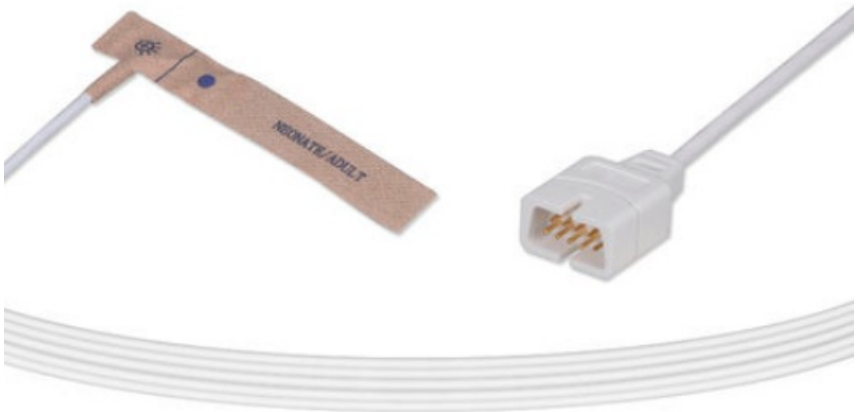
Accurate AF543-01 Disposable SpO2 Sensor



Specifications

- **Product Name:** Disposable SpO2 Sensor
- **Manufacturer:** Hunan Accurate Bio-Medical Technology Co., Ltd.
- **Address:** Accurate Industrial Park, No.108, Zhixian Road Xuelian Community Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF China
- **Revision Number:** 1.1
- **Release Time:** 2023/7/4

Product Usage Instructions

- **Intended Use:**
  - Accurate disposable SpO2 sensors are indicated for single-patient use and are intended to provide accurate oxygen saturation readings.
- **Precautions and Recommendations:**
  - Only use the sensor for a single patient.
  - Avoid using incompatible components that can degrade accuracy.
  - Do not use the sensor if the packaging is damaged.
  - Avoid cleaning or sterilizing the sensor as it may result in product failure.
  - Keep the patient still during measurements to ensure accuracy.
  - Avoid placing sensors on heavily pigmented or coloured areas for accurate readings.
  - Change the measurement site every 4 hours for long-term use to prevent skin damage.
  - Avoid strong light and irradiation fields during measurement to prevent inaccuracies.
- **Storage and Handling:**
  - Avoid placing sensors near MRI equipment or in cleaning solutions.
  - Avoid exposure to portable RF communications equipment to ensure measurement accuracy.
- **Disposal:**
  - Dispose of the sensor in compliance with local regulations after single-patient use.
- **Frequently Asked Questions (FAQ):**
  - **Q: Can the sensor be reused?**
    - **A:** No, the disposable SpO2 sensor is intended for single-patient use only and should not be reused.
  - **Q: How often should the measurement site be changed for long-term use?**
    - **A:** The measurement site should be changed every 4 hours to prevent skin damage and ensure accurate readings.

Product Information

- **Product Name:** Disposable SpO2 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.
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- **Revision number:** 1.1
- **Release time:** 2023/7/4

Intended use

Accurate disposable SpO2 sensors are indicated for single-patient use and are intended for continuous noninvasive arterial oxygen saturation(Sp02) and pulse rate monitoring. Accurate disposable Sp02 sensors are designed to match the specifications of the original manufacturer's equipment. It is important to get compatibility information from the product labels and/or Accurate Company while selecting proper sensors and extending cables to match the equipment.

- **Product usage period:** Disposable
- **Product storage period:** 3 years
- **Users:** adult neonate
- **Model** AF543-01 AF543-01X

Product Overview

Accurate disposable Sp02 sensors are classified into the following categories: adult and neonate foam adhesive(AF543 series)type.

Warning:

- Accurate disposable SpO2 sensors are for use with pulse oximeters.
- Check the compatibility of the equipment, sensor and extended cable before use.
- Incompatible components can result in degraded accuracy and performance.
- Select the appropriate sensor type to avoid inaccurate measurements or even harmful events that may lead to serious patient injury.
- In the event of the packaging being damaged, do not use the sensor.
- The disposable SpO2 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 coloured, 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 an MRI equipment.
- Do not immerse the sensors in any of the cleaning solutions, disinfectants, or other liquids.

- Portable and mobile RF communications equipment can affect measurement accuracy.
- Do not place the sensors in an environment that exceeds the storage range.
- A 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 regulations.
- 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 theequipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

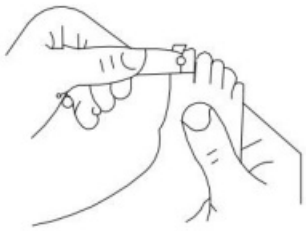
Sensor applications

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).

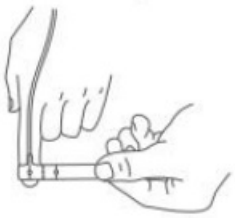
Applying sensors Neonate/Adult Foam Adhesive

1. Place the sensor on the patient as shown below.
    - **Neonate:** Place the sensor on the patient’s toe or finger as shown below with optical components opposite each other.



Adult

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



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

Applying pulse oximeters

- Operate pulse oximeters under the instruction manuals.

Specifications 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

Package and storage environment

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

Storage conditions are as follows:

- **Ambient temperature:** -25 to +55℃
- **Relative humidity:** ≤85%

Operation environment

- **Ambient temperature:** 0°to+40°°C
- **Relative humidity:** ≤85%

Safety

- **Degree of protection from electric shocks:** type BF

Warranty and Liability

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

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
							
HUMIDITY LIMITATION							

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) I EC 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 I EC 61000-4-4	±2 kV power supply lines ±1 kV sign al input/output 100 kHz repetition fre quency	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 magnetic field IEC 61000-4-8	frequency	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF		3 V	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
IEC61000-4-6		0,15 MHz – 80 MHz	
		6 V in ISM and amateur radio	
		bands 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. mains voltage before 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	450	430	GMRS	FM	28	28	
equipment)		–470	460,	± 5 kHz			
			FRS 460	deviation			
				1 kHz sine			

	710	704 –	LTE Band	Pulse	9	9	
	745	787	13,	modulation			
	780		17	217 Hz			
	810	800 –	GSM	Pulse	28	28	
	870	960	800/900,	modulation			
	930		TETRA 800,	18 Hz			
			iDEN 820,				
			CDMA				
			850,				
			LTE Band				
			5				
	1720	1 700	GSM	Pulse	28	28	
	1845	–	1800;	modulation			
	1970	1 990	CDMA 1900;	217 Hz			
			GSM				
			1900;				
			DECT;				
			LTE Band				
			1, 3,				
			4, 25;				
			UMTS				
	2450	2 400	Blueto oth,	Pulse	28	28	
		–	WLAN,	modulation			
		2 570	802.11	217 Hz			

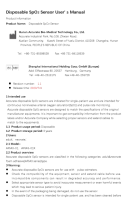
			b/g/n,				
			RFID				
			2450,				
			LTE Band				
			7				
	5240	5 100	WLAN	Pulse	9	9	
	5500	–	802.11	modulation			
	5785	5 800	a/n	217 Hz			
Electromagnetic environment – guidance							
RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance							

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 b. Interference may occur in the vicinity of equipment marked with the following symbol: ( )

Table 4

Guidance and manufacturer's declaration – electromagnetic Immunity				
Radiated RF IEC 61000-4 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

Documents / Resources

	Accurate AF543-01 Disposable SpO2 Sensor [pdf] User Manual AF543-01 Disposable SpO2 Sensor, AF543-01, Disposable SpO2 Sensor, SpO2 Sensor, Sensor

References

- User Manual