accbiomed A403S-01 Reusable SpO2 Sensor User Manual

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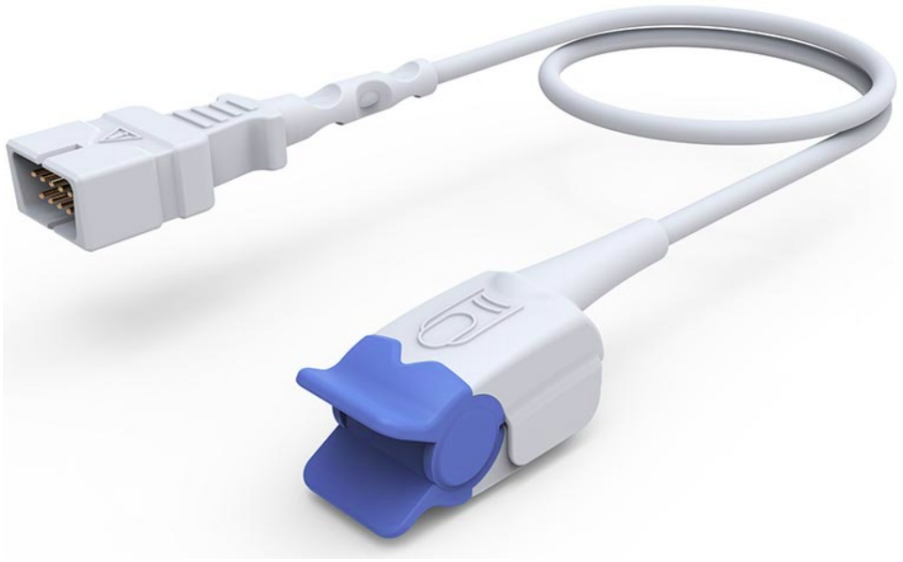

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Contents

Intended use

SpO2 sensor is intended for monitoring of functional arterial oxygen saturation (SpO2) and pulse rate

Product usage period: 3 years

Users: adult

Product overview

Accurate reusable Sp02 sensors are classified in the following categories: adult finger(A4XX series), adult soft tip(A4XXS series)

Model
A403S-01 A410S-01 A403-01 A410-01.

Warning:

- Accurate SpO2 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.
- Do not use damaged sensors and extend cables.
- Make sure the sensors are free of dirt and rust before use. Clean the sensors or replace them if necessary.
- Do not reuse the sensors and extend cables on a different patient until they have been disinfected.
- Try to keep the patient still and avoid excessive motions at the measured site, or use wrap or multi-site type sensors to reduce interference.
- 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 avoids in damage.
- The measurement may be inaccurate, if the perfusion is very low at the measured site.
- Avoid using sensors 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 communication 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.

Sensor applications

Before applying sensors

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

Selecting appropriate sensors for different patients

Adult type sensors suit for adult patients(weight:>30 Kg).

Applying sensors

Finger and soft tip type

1. Place sensor to patient’s finger as shown below. 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. Be sure that the side with a finger pattern is placed on the top.

2. Patient fingertip should touch but not exceed the end of sensor. Trim the fingernail tocorrect the position if necessary.
3. Connect sensor to pulse oximeters (with an extend cable if needed).
4. Inspect and change the measurement site periodically.

Applying pulse oximeters

Applying pulse oximeters
Operate pulse oximeters under the instruction manuals.

Specifications

Accuracy

Sp02 Range	**Sp02 accuracy**
70%-100%	±2%
70%	not specified
Note: When the SpO2 Sensor is used with the pulse oximeter, please refer to the accuracy specifications of the pulse oximeter.	

	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 original package under specific storage conditions to maximize their storage life. Storage conditions re as follows:

- Ambient temperature: -25 to+55°C
- Relative humidity: ≤85%

Operation environment

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

Safety

- Degree of protection from electric shocks: type BF

Cleaning and disinfection

Cleaning

1. Clean sensors and cables with cotton or soft cloth moistened with warm soapy water.
2. Clean sensors and cables with cotton or soft cloth moistened with clean water.
3. Wipe off the water with a soft cloth.
4. Allow sensors to air dry.

Disinfection

Recommended disinfectant: 70% isopropyl alcohol.

1. Clean sensors with steps instructed above.
2. Disinfect sensors and cables with cotton or soft cloth moistened with 70% isopropyl alcohol.
3. Allow sensors to air dry.

CAUTIONS:

- Do not use any other disinfectants except 70% isopropyl alcohol.
- Never immerse or soak sensors into water or any solution.
- Keep the pins clean and dry.

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.

Symbol explanation

Caution	Production lot number	Manufacturer	Non-sterilization	Latex free	See the instructions	Waste Electrical and Electronic Equipment
						
Date of manufacture	Catalogue number	Authorized representative in the European	The product is protected against harmful effects of	This item is compliant with	Expire date	Medical devices
		Community	dripping water perIEC	REGULATION		
			60529.	(EU) 2017/745		
				OF THE		
				EUROPEAN		
				PARLIAMENT		
				AND OF THE		
				COUNCIL.		
		IPX2	CE 0123		MD	
HUMIDITY LIMITATION	TEMPERAT					
	URE					
	LIMITATIO					
	N					
						

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 -10women 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/ flicke r emissions IEC 61000-3-3	Not applicable

Table 2 w

Guidance and manufacturer's declaration – electromagnetic Immunity			
Immunity Test		**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic (ESD)I EC 61000-4-2	discharge	±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 transient/b urstIEC 61000-4-4	fast	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±1 kV signal input/output 100 kHz rep etition frequency
Surge		± 0.5 kV, ± 1 kV differential	Not applicable
IEC 61000-4-5		mode	
		± 0.5 kV, ± 1 kV, ± 2 kV	
		common mode	
Voltage dips, short interruptions a nd voltage variations on power su pply input linesIEC 61000-4-11		Not applicable	Not applicable
Power frequency magnetic fieldI EC 61000-4-8		30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF		3 V	3 V
IEC61000-4-6		0,15 MHz – 80 MHz	0,15 MHz – 80 MHz
		6 V in ISM and amateur radio	6 V in ISM and amateur radio
		bands 0,15 MHz and 80 MHz80 % AM at 2 Hz	bands between 0,15 MHz and 80 MHz80 % 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 UT is the a.c. mians voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration – electromagnetic Immunity						
Radiated RF	**Test**	**Band**	**Service**	**Modulation**	**IEC**	**Compliance**
IEC61000-4-3	**Frequency**	(MHz)				
(Test	(MHz)				**60601-1-2**	**level**
specifications for					**Test Level**	(V/m)
ENCLOSURE					(V/m)	
PORT	385	380	TETRA	Pulse	27	27
IMMUNITY to		–390	400	modulation		
RF wireless				18 Hz		
communications equipment)						
	450	430–470	GMRS460,	FM± 5 kHz	28	28
			FRS 460	deviation		
				1 kHz sine		
	710	704 –	LTE Band	Pulse	9	9
	780		17	217 Hz		
	810	800 –	GSM	Pulse	28	28
	870	960	800/900,	modulation		
			TETRA800,	18 Hz		
	930					
			iDEN 820,			
			CDMA			
			850,			
			LTE Band			
			5			
	1720	1 700	GSM	Pulse	28	28
	1845	–	1800;	modulation		
		1 990	CDMA1900;	217 Hz		
	1970					
			GSM			
			1900;			
			DECT;			

			LTE Band			
			1, 3,			
			4, 25;			
			UMTS			
	2450	2 400	Bluetooth,	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		
		5 800	a/n	217 Hz		
	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 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 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	**Test**	**Modulation**	**IEC 60601-1-2**	**Compliance level**
IEC61000-4-39(Test specifications for ENCLOSURE PORT IMMUNITY to	**Frequency**		**Test Level**(A/m)	(A/m)
	30 kHz	CW	8	8
proximity magnetic				
fields)				
	134,2 kHz	Pulse	65	65
		modulation		
		2.1 kHz		
	13,56 kHz	Pulse	7,5	7,5
		modulation		
		50 kHz		

Documents / Resources

	accbiomed A403S-01 Reusable SpO2 Sensor [pdf] User Manual A403S-01, A410S-01, A403-01, A410-01, A403S-01 Reusable SpO2 Sensor, Reusable SpO2 Sensor, SpO2 Sensor, Sensor