TJ SpO2 Sensor Instruction Manual

This manual provides in detail that instructions of product intended use. function and operation, please read this manual carefully before use, which is the prerequisite for correct operation and safety of patient or operator.

Taijia is responsible for the safety, reliability and performance of the product, only if:

1.The product is used according to the instruction manual.
2.The product is not damaged by human factors. Human factors refer to unintentional falling or intentional damage, etc.
Please contact our sales dept. for return, and let's know the product REF number, series number and return reason, if the goods are returned to us without recognizable series number, the return shipment will not be accepted.

Taijia It is the registered trademark owned by Tajiia in China

Product Introduction

1.Product Name: TJ Pulse Oximeter Probe Series
2.Product Model: Refer to the mark on the label
3.Manufacturer: Shenzhen Taijia Electronics Co.,Ltd.
4.The Medical Device Manufacturing Enterprise License number : GD FDA 20142210008
5.Execution Standard No.: YZB/YUE 0293-2014
6.Operation principle. Function and Structure:
This product mainly refers to that red and infrared light from light-emitting diode transmit the blood, and photo detector would detect the photo absorption level of the blood and then send the signal to multi-parameter monitor and pulse oximeter to enlarge the signal, perform analog computation and display physiological data of human body. To provide patient's physiological information to healthcare workers.This product composes of three parts, medical device interface, signal cable and probe. Parts that contact with skin are meet the requirements of ISO10993 biosecurity.
7.Main Technical Parameters：
1)Emitted light wavelength: 660±5nm, Absorbed light wavelength: 905±5nm/940±5nm;
2)SpO2 test range: 70%-100%;
SpO2 measurement accuracy: ±1% in 90%~100%, ±2% in 80%～89%, ±3% in 70%～79%.
3)Range of pulse rate : 30bpm～245bpm
Measurement accuracy of pulse rate:±1bpm for 30bpm~59bpm, ±2bpm for 60 bpm~149bpm, ±3bpm for 150bpm~245bpm
4)Max optical output :2.0mW
5)The above technical parameters are obtained by clinical validation
8. Working Environment Requirements:
Temperature:5℃～40℃;
Relative humidity:≤80%;
Air pressure:700hPa～1060hPa
9.Intended Use:
TJ SpO2 sensor is suitable for adult patient (weight >40kg), pediatric patient (weight:10-40kg) to conduct a spot check or continuous noninvasive measurement of arterial oxygen saturation and pulse rate.

Applying the SpO2 sensor

1.The best site to be monitored is index finger. Considering other fingers when the index finger is not available or can not be located correctly.
2.Place an index over the monitoring window of the sensor with the fingertip against finger stop in the sensor, the fingertip touches the sensor top.
3.Position the cable along the top of the hand with tape
4.Plug the sensor into the instrument (or if appropriate, into the adapter cable) according to the instruction manual, and then check whether the sensor can work normally.

Precautions:

1.Check the sensor and the cable before use, and don't use them for monitors if they are damaged, deteriorated or visible contaminated.
2.The interface location of luminous tube and skin is high temperature site. The highest temperature is below 41℃ when measuring. To keep safety of patient the measured site should be changed every two hours .
3.To decrease the electromagnetic interference, please keep the sensor cable away from electric surgical equipment power line
4.Try to keep the patient still (especially measured site) and avoid the measured site suffering excessive motion.
5.Strong light will result in inaccurate measurement, please use opaque material to cover the sensor if the light is strong.
6.Please choose a site that is well perfused and will completely cover the sensor's detector window. Site should be cleaned and dry prior to sensor placement.
7.The measurements also depend on absorption of special wavelength ray by oxidized hemoglobin and deoxyhemoglobin. Concentration of nonfunctional hematoglobin (COHb/MetHb) may affect the accuracy of the measurement.
8.Shock, anemia, hypothermia and the application of vasoconstriction drug may decrease arterial blood flow to an unmeasurable level.
9.Pigment or deep color (for example: nail polish, dye or pigmented cream) may cause inaccurate measurements.

Warnings:

1. This product must be used in connection with the specified equipment only. Please choose the suitable SpO2 extension cable according to equipment connector.
2. Disposal must be in accordance with local regulation or hospital waste disposal system。Don't casually discard.
3. Carefully route cables to reduce the possibility of patient entanglement or strangulation
4. Don't use SpO2 during MRI scanning, Conducted current may cause burns.
5. If using SpO2 sensor during full body irradiation, keep the sensor out of he irradiation filed. If sensor is exposed to the irradiation, the reading might be inaccurate or the product might read zero for the duration of the active irradiation period.
6. A proper sensor shall be selected according to different patients and application sites. Tight sensor may cause venous pulsation, obstructed blood circulation, pressure marks, pressure necrosis, artifacts and inaccurate measurement, while loose sensor may lead to erroneous optical alignment or falling off. If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.

Cleaning/Disinfection
Cautions
1.Never immerse or soak the sensor
2.Exercise caution during cleaning/disinfection to avoid wetting the pins.
3.We recommend that the sensor be disinfected only when necessary as determined by your hospital's policy, to avoid long term damage to the sensor
4.Never use cleaning agents/disinfectants other than the recommended.

Cleaning
1.Clean the sensor with cotton or soft cloth moistened with water
2.After cleaning, wipe off the water with the soft cloth
3.Allow the sensor to air dry

Disinfection
The recommended disinfectants include: ethanol 70%. Isopropanol 70%. Glutaraldehyde type 2% liquid disinfectants.
1. Clean the sensor as instructed above before disinfection
2. Disinfect the sensor with cotton or soft cloth moistened with one of the recommended disinfectants.
3. After disinfection, be sure to wipe off the disinfectant left on the sensor with a soft cloth moistened with water
4. Allow the sensor to air dry.

Symbol

Attention, please refer to the file attached.	Production batch number sign
Series number sign	Product life time sign
Production date sign	Manufacturer Sign
Don't use it because of damaged package	Comply with the requirements of the Council Directive 2007/47/EEC.
Refer to the user manual sign	Feed liquor level sign

product model	compatible model
TJS0011J1 、TJS0011T1、TJS0012J1、TJY001001、TJS2011Y1、TJS2012Y1、TJS2013Y1、TJS2021Y1、TJS2031Y1、TJS2041Y1、TJS2051Y1	NELLCOR
TJS0021J2、TJS0031J2、TJS0031K2、TJY002002、TJS2021J2、TJS2021T2、TJS2023K2、TJS2022J2、TJS2031T2、TJS2032J2	MINDARY
TJS0041J3、TJS0041T3、TJS0041K3、TJS0042K3、TJS2011J3、TJS2011T3、TJS2022J3、TJS2041J3、TJS2042J3、TJS2061Y3	PHILIPS
TJS0051J4、TJS2013K4、TJS2011T4、TJS2012J4	GOLDWAY
TJS0061J5、TJS2011T5、TJS2013K5、TJS2012J5	BIOLIGHT
TJS2021J6、TJS2021T6、TJS2013K6、TJS2012J6	SPACELABS
TJS2031J7、TJS2031T7、TJS2013K7、TJS2012J7、TJS2041J7、TJS2041T7、TJS2023K7、TJS2022J7	GE
TJS2011T2、TJS2013K2、TJS2012J2	MINDARY/ENAN
TJS2011J8、TJS2011T8、TJS2013K8、TJS2012J8、TJS2014R8	ADEKA
TJS2011J9、TJS2011T9、TJS2013K9、TJS2012J9、TJS2021J9、TJS2021T9、TJS2023K9、TJS2022J9	CNNATIN/ZONCARE/TECHLAND/OTHER

Transportation and storage
Transportation: The pack carton should be placed properly according to the mark on the carton, and to prevent a collision, severe vibration and direct pouring of rain and snow
Storage: Packed sensor should be stored in a no corrosive gas, clean and well-ventilated room.
With the temperature range: -20℃～55℃ and relative humidity <93%

Product Life Time : one year

Shenzhen Taijia Electronics Co.,Ltd.
Add:East 4F, Aimeite Science Park,HuangFengling Industry area, ShiYan town,Bao' An district,ShenZhen city, GuangDong province.
Postal code: 518108
Tel: (+86)0755-81795727 81795618 Fax: (+86)0755-81795638
Website: www.taijia.com

EU agent
Company name: DongBang AcuPrime (EU) Limited
ADDRESS: 1 Forrest Units, Hennock Road East, Exeter, EX2 8RU UK