plusmed
health management

Model: OxyCheck II

PULSEOKSİMETRE CİHAZI
PULSEOXIMETER
OXYMÈTRE DE POULS
OXÍMETRO DE PULSO

TR **Kullanım Kılavuzu**
EN **Instruction Manual**
FR **Mode d'emploi**
RU **Руководство Пользователя**
KU **Rêbera Bikaranînê**
AR **كتيب التعليمات**
FA **دستورالعمل راهنما**

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Warning:

- The Pulse Oximeter is not for diagnostic or therapeutic use.
- This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Never use the Pulse Oximeter during MR or CT environment, in an explosive atmosphere, or on infant or neonatal patients.
- Never use the Pulse Oximeter in an environment of anesthetic gases.
- The material that the pulse oximeter contacted to body is non-toxic silica gel which meet the ISO10993 requirements, so can be safety used.
- Only use accessories recommended by the manufacturer. Using other kinds of accessories might cause damage or personal injury. Modification of the Pulse Oximeter could be unsafe as applicable. The degrade sensor may degrade the performance.
- This device is not defibrillation proof per IEC 60601-1.
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

Caution:

- To avoid personal injury, only use accessories and parts produced or recommended by Trimpeks. Otherwise, damage to the Pulse Oximeter can occur.
- This device has no audible alarms and is intended only for spot-checking.
- The Pulse Oximeter must conform to the international standard IEC 60601-1-2 and other applicable EMC standards. Interference takes place when electromagnetic energy is extremely high. Ensure that any nearby instruments are also in compliance with EMC standards. Never turn on or use portable communication devices like mobile phones or portable dual-channel radios near a Pulse Oximeter.
- The Oximeter is calibrated to display functional oxygen saturation in the factory before sale, so there is no need to calibrate it during its life cycle.
- The SpO2 waveform is normalized, and the “--” symbol will be displayed when there is signal inadequacy.
- Periodically check the Pulse Oximeter for damage. When necessary according to your local hospital waste

disposal regulations.

- Clean the Pulse Oximeter and accessories according to local requirements. Turn off the Pulse Oximeter before cleaning.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- Keep all Pulse Oximeter packing materials away from children, pet or pests, or dispose of them in accordance with your local environmental regulations.
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Always properly dispose of the Pulse Oximeter and all accessories at the end of their service life. Dispose of batteries according to your local regulations. Never incinerate batteries or expose them to high temperatures.

1. Product Operation Scope

This Pulse Oximeter is a kind of innovated medical detection device with non-invasive and continuous features for artery SPO2 and PR detection. It is portable and easy to measure the SPO2 and PR value quickly and precisely.

This can be through the finger Pulse Oximeter to measure human blood oxygen saturation and heart rate. This product is suitable for family, clinic, oxygen bar, sports health (use before and after exercise is not recommended for use during exercise), community health and other ranges. This product is not suitable for monitoring the patient's prolonged use.

2. General Description

Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2) capacity , compounded with oxygen , by all combinativable haemoglobin (Hb) and (HbO2) capacity in blood . In other words, it is consistence of Oxyhemoglobin in blood . it is a very important ecological parameter for Respiratory circulation System . Many respiratory diseases can result in haemoglobin saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient’s life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.

The fingertip pulse oximeter features in small volume, low power consumption convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis,

and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

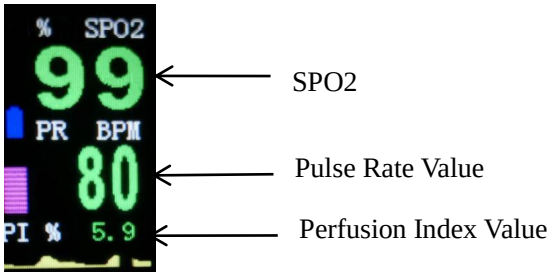
3. Measurement principle

Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert beer Law according to Spectrum Absorption Characteristics of reductive hemoglobin (R Hb) and Oxyhemoglobin (O2 Hb) in glow and near- infrared zones. Operation principle of the instrument is photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with capacity pulse scanning and recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED through process in electronic circuits and microprocessor.

4. Appearance introduction

Model No. OxyCheck II

Display screen



5. Features

5.1 TFT display, 4 display interface, figure and oxygen volume chart display together on interface;
5.2 Adjust the display interface direction manually, according to the patient observation data needs;
5.3 Low power consumption, that can be long working by two brand new AAA batteries;
5.4 Low Perfusion ≥0.6%.
5.5 A prompt will show on display when low voltage happens;

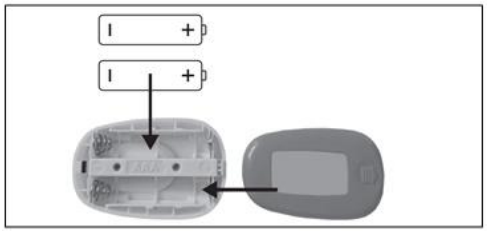
5.6 Automatic power off when no signal in 8s

5.7 Small and light weight, convenient to carry.

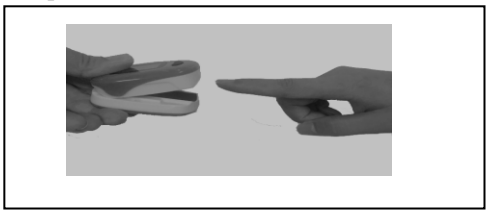
6. Operation Instructions

6.1 The product Operation Instructions

6.1.1 Installing two AAA batteries into battery cassette in correct polarities and cover it.



6.1.2 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) nail surface upward, then releasing the clamp.



6.1.2.1 Press the switch button once on front panel.

6.1.2.2 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.

6.1.2.3 Read correspondent date from display screen.

6.2 Operation Instructions

6.2.1 Display Description（4 interface diagrams）

Interface 1

Interface 2

Interface 3

Interface 4

6.2.2 OxyCheck II button operating instructions:

6.2.2.1 Put into two AAA batteries according to the instructions, the OxyCheck II will turn on automatically and display interface 1; then put into finger for measuring, if there is finger for detection and without operation, it will power off automatically in 8s.

6.2.2.2 When there is battery, but the Pulse Oximeter power off, press the button, it will be opened.

6.2.2.3 During the measurement (there is a measurement signal and figure), press the button shortly, the interface can turns from interface 1 to interface 4 circularly.

6.2.2.4 Short Press the button during the measurement; it can turn to settings menu interface.

6.3 Low power prompt

When the battery power appears low, the battery power indicate for empty on screen, reminding the user to replace the battery; (the battery capacity indicates symbol of "▭"in screen to remind user to replace battery.)

6.4 Pulse rate and SPO2 prompt

When a certain physiological parameter of the patient exceeds the set prompt high and low range, a prompt is triggered, and the parameter in the parameter area will change color, reminding the user to pay attention to the measurement parameter.

The font color of SPO2 parameter values within the range of 85-99 is green, and the font color of parameter values outside the range is orange;

If the PR parameter value is within the range of 50-120, the font color is green, and the parameter value outside the range is orange;

Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using medical alcohol before and after each test. (The rubber inside of the Oximeter belongs medical rubber, which has no toxin, and no harmful to the skin of human being).

When your finger is plugged into the Oximeter, you nail surface must be upward.

7. Product Classification

Product classification information of pulse oximeter is shown in Table 1.

Table 1 Product Classification

Classification basis	**Safety classification**
Classification by electric shock prevention type	Internal power supply equipment
Classification by electric shock resistance	BF type application part
Classification by operating mode	Continuous
Classification by protection against harmful ingress	IP22
Classified by safety when used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide	Equipment not to be used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide

Classification according to the disinfection and sterilization methods recommended by the manufacturer	As recommended by manufacturer
Classification by electromagnetic compatibility	Group I Class B equipment.

8. Power Specification

Table 2 Power Specification

Parameter	**Specification**
Battery	d.c. 3V AAA(×2)
	When the battery is almost exhausted, the pulse oximeter will automatically shut down

9.Technical Specification

Table 3 Pulse oximeter specification

Parameter	**Specification**
SpO_2 measurement range	35% ～99%
SpO_2 measurement accuracy	90%-99%, accuracy: ±1%; 70%-89%, accuracy±2%; ≤70%, no specified
Pulse Rate Measurement range	30 bpm ～240 bpm
Pulse Rate measurement accuracy	±1 bpm
Update frequency of SpO2 value and pulse rate	around 1 second
Pulse Rate Volume	Non-modulated
Wavelength range	500nm ～1000nm

Maximum luminous power	150 mW
PR Display	Digital
Screen	TFT display "0.96" inch
Power consumption	150mW in normal measurement; 0.2uA in shutdown state;

Note:

A functional tester cannot be used to assess accuracy of the pulse oximeter.

The electronic pulse simulator is applied evaluation of pulse rate accuracy.

The pulse oximeter is calibrated to display functional oximetry and does not need to be calibrated during use.

Understanding the wavelength range can help clinicians to perform photodynamic therapy.

The SpO2 accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.

The SpO2 measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

Since the measurement results of the pulse oximeter device conform to the statistical distribution, only about 2/3 of the measurement results fall within the ± marginal value measured by the CO-oxygen saturation meter. The oxygen volume map of the pulse oximeter has been normalized.

10.Physical Specification

The physical specifications of the host are shown in Table 4.

Table 4 The physical specification of the host

Parameter	OxyCheck II
Size(mm)	63×41×31

11. Environment Specification

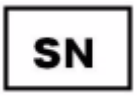
The environmental specifications of the pulse oximeter are shown in Table 5.

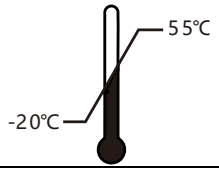
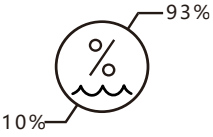
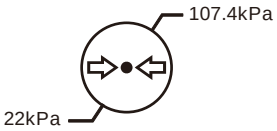
Table 5 The environmental specifications of the pulse oximeter

Parameter	**Specification**
Operating Temperature	0℃ ～40℃

Storage and transportation Temperature	-20℃ ～+55℃
Relative humidity in operation	15%~80%, Non-condensing
Relative humidity during storage and transportation	10%~93%, Non-condensing
Operating atmospheric pressure	59kPa ～107.4kPa
Atmospheric pressure during storage and transportation	22kPa ～107.4kPa

12. Logo Description

Signs	Notes on the signs
CE 0123	CE mark
--	Signal inadequacy indicator
IP22	Protected against solid foreign objects of 12.5mm and greater Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
	Type BF Applied Part
	Attention, see instruction for use!
	Refer to instruction manual
	No alarm system
	Manufacturer
	Date of manufacture
	Serial Number
	The carton should be lift in the right way of upward during transportation

	The goods is fragile, please handle with care
	Keep moisture off the packing carton
	Temperature limitations
	Humidity limitations
	Atmospheric pressure limitations
	Compliance to WEEE standard

13. Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate display instable	1. The finger is not places inside enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device can not turn on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction.	1. Change batteries. 2. Re-install batteries. 3. Please contact the local service center.
The indicator light is off suddenly	1. The device will power off automatically when it gets no signal for 8 seconds. 2.The batteries are almost drained.	1. Normal. 2. Change batteries.

14. Accessory

AAA battery----------2 pcs (optional)
Hang String----------1 pcs (optional)
User Manual ----------1 pcs

15. Maintenance and clean

If there is dust or dirt on surface, 75% density of medical alcohol can be used to clean the surface. Pls use dry fabric with little alcohol to avoid alcohol permeates into the device.

1. Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.
2. No flammable substance, overtop or lower temperature and humidity existed in operation conditions.
3. When the device is dabbled or there is hydraulic set existed, stop operating.
4. When lower power capacity light, pls replace the battery right away.
5. Pls clean the surface before applying for detection.
6. Pls take out the battery when device is not used for a period of time.
7. Pls dispose the battery according to the local statute.

16. EMC

Note:

1. Pulse Oximeter meets the requirement of electromagnetic compatibility in IEC60601-1-2.
2. The user needs to install and use according to electromagnetism compatibility information which is attached with it.
3. Portable and mobile RF communication devices may influence pulse Oximeter performance, so pulse Oximeter should be kept away from them during using.
4. Guidance and manufacturer's declaration stated in the appendix.

Warning:

1. The user needs to install and use pulse Oximeter according to electromagnetism compatibility information which is attached with it.
2. Portable and mobile frequency communication devices may influence its performance, so it should be kept off these devices.
3. Pulse Oximeter should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Pulse Oximeter should be observed to verify normal operation in the configuration in which it will be used.
4. Pulse Oximeter could not be used for transport using, like ambulances (land and air ambulances).

Table 1: Electromagnetic Emissions

Guidance and Declaration - Electromagnetic Emissions
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.

Emission test	**Compliance**
RF emissions CISPR 11	Group 1, Group B

Table 2: Electromagnetic Immunity

Guidance and Declaration - Electromagnetic Emissions		
Immunity test	**Compliance**	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Radiated RF IEC 61000-4-3	80MHz- 2.7GHz	10 V/m
	380MHz- 390MHz	27 V/m
	430MHz- 470MHz	28 V/m
	704MHz- 787MHz	9 V/m
	800MHz- 960MHz	28 V/m
	1.7GHz- 1.99GHz	28 V/m
	2.4GHz- 2.57GHz	28 V/m
	5.1GHz- 5.8GHz	9 V/m

Table 3: Not Applicable

Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6)
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

17. Warranty and Manufacturer Information

17.1 Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by Trimpeks. The unit is guaranteed for a period of 24 months, valid from the date of purchase. Trimpeks warrants that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

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