

Fingertip Pulse Oximeter

MEDICAL GRADE ACCURACY

YK-80A



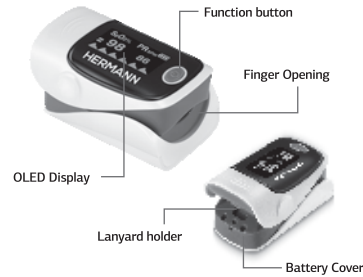
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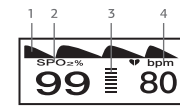
+ medical supplies



5 Product Description

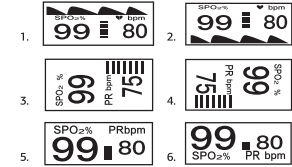


DISPLAY description



1. Pulse wave
2. Oxygen Saturation (value in percent)
3. Pulse bar
4. Pulse rate (value in beats per minute)

Key function description: In standby mode, start the key instrument into the working state, push down this button under working state and then you can change the display mode.



PARAMETER SETUP

Press the start button (>3s), into parameter setup. As Menu 1. 1. In menu 1, when the "signal is shown on the "Alm Setup", press the button (>3s) and enter into the menu. 2. Press the button (<1s) can select item, then press button (<3s) to set the on/off for alarm, beep, demo and screen brightness adjustment (optional "1", "2", "3" and "4"). When the "*" is shown on the "Restore", press the button (>3s) and all the settings are back to the factory settings.

Settings		Settings	
Alm Setup	*	Sounds Setup	*
Alm	off	SpO2 Alm Hi	100
Beep	off	SpO2 Alm Lo	85
Demo	off	PR Alm Hi	130
Restore	OK	PR Alm Lo	50
Brightness	3	Exit	+
Menu 1		Menu 2	

1 General Description

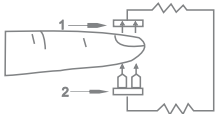
Hemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinative hemoglobin (Hb) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce hemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human hemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects. The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for the patient to put one finger into the fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses high precision and repeatability.

This Fingertip Pulse Oximeter is a kind of innovated medical device with non-invasive and continuous features for artery SPO2 and PR (pulse rate) detection. Being portable, it is able to measure SPO2 and PR values quickly and precisely.

2 Measurement principle

The principle of the oximeter is as follows: An experience formula of data process is established by exerting Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and oxyhemoglobin (O2 Hb) in red light and infrared light zones. Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm glow and 940nm near infrared light) can be focused onto human nail 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 LEDs through process in electronic circuits and microprocessor.

1. Diagram of Operation Principle



1. Red-ray and Infrared-ray emission tube
2. Red-ray and infrared-ray receipt tube

3 Product and Accessories

1. 1pc Finger pulse Oximeter
2. 2x1.5V AAA Batteries
3. 1pc Lanyard
4. 1 carry pouch
5. One user manual

4 Features

- Portable and ideal on the go.
- Two -colour OLED display
- Compact and Lightweight
- The Fingertip Pulse Oximeter has 5s automatic signal detection function, when you insert your finger, the time will automatically start.
- Adjustable Display brightness

6 Directions for Use

1. Install two AAA batteries into battery cassette before covering its cover.
2. Insert one finger into the rubber opening of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp with the nail upwards.
3. Press the ON/OFF button on the front panel to turn the device on.
4. Don't shake your finger during the test. It is recommended that you do not move your body whilst taking a reading.
5. Press the button on the front panel, if we want to change display direction.
6. Read relevant datum from display screen.
7. The device will automatically switch off after 5sec after the finger has been removed.
8. Replace new batteries when indicates the batteries are in low power.
9. Declaration: Insert one finger and mind the nail to be side up; index or middle finger is recommended into the finger opening of the device. Please use medical alcohol to clean the rubber before each test and clean the tested finger with alcohol before and after the test.

Battery Installation

After you have unpacked your device, first insert the batteries. The battery compartments is on the bottom of the device.

1. Slide the battery compartment lid to open.
 2. Insert the batteries into the compartment (2x1.5V, size AAA) following the correct polarity as it shown on the device.
- Note: pay attention to the positive and negative polarity, must be installed correctly, otherwise it may cause damage to the device
3. Close the battery compartment again
 4. Replace the batteries when indicated in the screen of your device.

Attaching the Lanyard

In order to transfer the Oximeter more easily, you can attach the lanyard to the device

1. Insert the narrow end of the lanyard through the holder.
2. Draw the other end of the lanyard through the loop at the narrow end and tighten.

7 Technical Specifications

1. Type:	Fingertip Pulse Oximeter	Transport and storage environment:	
2. Display Type:	OLED display	Temperature:	-10C ~ 40C
3. SpO2:		Humidity:	< 95%
Measurement range:	70%~99%	Atmospheric Pressure:	50kPa~106kPa,
Accuracy:	80%~99%: ± 2%(including 80%); 70%~79%: ±3% ±1%	6. Battery:	Two AAA 1.5V Alkaline batteries
Resolution:		7. Dimension:	58mm×36mm×33mm
4. PR:		8. IP Class:	IPX1
Measurement range:	30BPM~240BPM	9. Automatic switch -off:	Automatically shutdown in 5sec
Accuracy:	±1BPM or ±1% (the larger one)	10. Sensor to measure SpO2	
Resolution:	1BPM		
5. Operation Environment:			
Operation Temperature:	5°C~40°C		
Storage Temperature:	-10°C~40°C		
Ambient Humidity:	15%~80% on operation 10%~80% in storage		
Air Pressure:	86kPa~106kPa		

This parameter can be especially useful to clinicians

Declaration:
 Management Class for Medical Devices: II equipment
 Anti-electric Shock Type: Internally powered equipment
 Anti-electric Shock Degree: Type BF equipment

Technical information is subject to change without prior notification
 This device conforms with the European standards EN60601-1 and EN60601-1-2 (In accordance with CISPR, IEC 61000-4-2, IEC 61000-4-3 and IEC 61000-4-8) is subject to particular precautions with regard to electromagnetic compatibility.
 This device complies with EU Directive 93/42/EEC concerning medical devices.

8 Safety Instructions

- Follow the instruction for use. This manual provides information for the operation and safety of this product.
- Please read the manual carefully before your operation.
- Never immerse this device in water or other liquids
- Do not use this device if present any damage.
- Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
- The Fingertip Pulse Oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.
- Check the Fingertip Pulse Oximeter sensor application site frequently to make sure that the circulation and skin integrity of patient are under good condition.
- The sensor of the Oximeter is not suitable for contacting with adhesive tape, which may lead to the error of measurement data or mistaking that there are blisters on the tested skin.
- The Fingertip Pulse Oximeter has no SpO2 alarm, it is not for continuous monitoring.
- When used for a long time, it will produce discomfort or tenderness, especially for patients with microcirculation disorders. Please change the test sites periodically according to different situations of patients. The test site must be changed and the skin integrity and circulation condition of the patient must be checked at least every 2 hours, and the correct adjustment must be made.
- Do not use the Fingertip Pulse Oximeter together with MRI or CT equipment.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.
- Unexpected action may cause inaccurate reading.
- Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.
- It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.
- Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate reading.
- Bright nail or painted nail may cause inaccurate SpO2 reading.

Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including batteries.

Use of this device is not intended as a substitute for a consultation with your doctor.

Product Operation Scope

The fingertip Oximeter can be used to measure human hemoglobin saturation and heart rate through finger. The product applies to using in family, hospital (including clinical use in internist/surgery, anaesthesia, paediatrics, intensive care, etc.), oxygen club, social medical organizations, physical care in sports (It can be used before or after sports. Operation in sport procedure is not recommended). It is also applicable to monitor patients (convalescents at home or those need first aid treatment), elders over 60. The product is not suitable to monitor patient continuously.

9 Maintenance


















- Replace the batteries timely when the low battery indicator flashes.
- Clean the surface of fingertip oximeter before use
- Remove the batteries inside if you will not operate the Oximeter for a long time.
- It would be better to preserve the product in -10~40°C (14-104°F) and humidity is 10%-80%.
- It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.
- Please follow the law of the local government to deal with used batteries.

Guidance and manufacture's declaration-electromagnetic radiation-for other EQUIPMENTS and SYSTEMS


The Fingertip Pulse Oximeter is designed to be used in specified electromagnetic environment. Users of the Pulse Oximeter must use it in the following environments.

Radiation Test	Compliance	Electromagnetic environment-guidance
RF interference CISPR 11	Group 1	RF signal of Pulse Oximeter is simply created by its internal function. Therefore, its RF interference is very low and is not likely to cause any interference to nearby electronic equipment.
RF interference CISPR 11	Class B	The Pulse Oximeter applies to all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Symbols and Definitions

	BF type application part		IP degree		Serial number		Lot number
	Separate collection		Humidity range		Date of manufacture		Temperature range
	Reference manual		Keep dry		Manufacturer		Avoid sunlight
	Cautions		Product certification		Standby		Up toward
	European union representative						

Possible Problems and Resolutions

Problem	Possible reason	Solution
	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Try more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unsteady	1. The finger might not be plugged deep enough 2. Finger is trembling or the patient is on movement status	1. Retry by plugging the finger 2. Please remain at rest
The Oximeter can not be turned on	1. Inadequate power or power off 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace the batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1. Normal 2. Replace the batteries

Reserves the right to technical change appearance, our products are subject to change without prior notice.

10 Statement:

- Maintenance with data such as circuit diagram, components list, figure and the detailed rules of correction, injection, available only to the repair factory training qualified personnel and units.
- The company can be in the form of email or other electronic files provide users with random files.
- The instrument is not used for evaluation of blood oxygen probe pulse and pulse blood oxygen monitor accuracy.

11 Warranty

Hermann provides a warranty for this product subject to the requirement below:

- This device is covered by a 2-year warranty from the date of purchase.
 - The guarantee is valid only by presenting the warranty card completed by the dealer confirming date of purchase of the receipt.
 - Opening or altering the device invalidates the warranty.
 - Improper handling, accidents or non-compliance will not cover this warranty
- Will not cover the warranty for products :
- Damages arised during transport between manufacturer and customer, or between service centre and customer
 - Devices purchased as seconds or as used goods;
 - Devices that are used, cleaned, stored or maintained improperly
 - Devices that have been opened, repaired or modified by the buyer
 - Please contact your supplier in case of a claim under the warranty.
 - In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
 - The unit is warranted to be free of defects in workmanship and materials under normal use for a period of Two Years from the date listed on the purchase record.
 - For claim under this warranty the supplier must be advised of the fault within the period of the warranty. This warranty covers the parts and labor only under normal operations. Any defect resulting from natural causes is not within this warranty. This warranty does not cover the damage incurred by use of the unit not in accordance with the instructions. Accidental damage, or being tampered with or serviced by unauthorized service agents.
 - Monitor subjected to misuse, abuse and neglect of these manual content, non-instructional purposes; unauthorized repair or modifications will be excluded from this warranty.
 - The device requires no calibration.
 - The device is not repairable and contains no user serviceable parts.



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