Distributor:
DeVilbiss Healthcare GmbH
Kamenzer Str.3
68309 Mannheim Germany

CE 0123

www.drivedevilbiss-int.com

Fingertip Pulse Oximeter

User's Manual

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HbO-Smart

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Statement

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1. Product Overview

Thank you for purchasing HbO-SMART Fingertip Pulse Oximeter.The main use of this product is for measuring patients oxygen saturation (SpO2), Pulse Rate (PR) and Perfusion Index (PI). Perfusion Index (PI) is related to the strength of the patients pulse at the site of measurement. PI is measured as a percentage(%) and the optimal value is 20% indicating a very strong pulse. The product includes both visual and audible alerts for high/low SpO2 and Pulse Rate. The applied part of the HbO-SMART is constructed from silica gel. Please carefully read the User Manual before use.

1.1 Appearance

Figure 1 Figure 2 Figure 3

1.2 Name and Model

Name: Fingertip pulse oximeter Model:HbO-SMART

2. Intended Use

The HbO-SMART Fingertip Oximeter is intended for use in homes or hospitals for non-invasive measurement of oxygen saturation, pulse rate and perfusion index. The device can be used for both children and adults.This device is intended only for spot checking.

3. Principles of measurement

The measuring principles of pulse oximeter is based on Lambert-Beer law, The spectrum absorption characteristics is different of Reductive hemoglobin(RHb) and Oxyhemoglobin (Hbo2) in red light and near-infrared light zones. The pulse oximeter calculate Spo2, PR and PI from the light intensity absorption difference by measuring the ratio of absorbed red and infrared light with each pulse.

4. Warnings

4.1 Precautions

1. Please carefully read the User's Manual before use.
2. The product cannot be used for continuous measurement.
3. Electrosurgical devices and defibrillators will affect the use of this device.
4. The product shall not be used in combination with MRI or CT equipment.
5. Do not squeeze,crush or apply excessive pressure to the silicone pad during use.
6. The product shall not be used in flammable or explosive environment.
7. The product plays a supporting role in the patients analysis. Final diagnosis should be made based on clinical manifestations and symptoms.
8. During long term use, The test site should be changed periodically.The patients skin integrity and circulation conditions should be checked every 2 hours to make adjustmests accordingly
9. Autoclaving, vinyl oxide disinfectant or immersing the sensor in liquid disinfectant will damage the device and cause erroneous readings.
10. The device specified in this manual along with its accessories and batteries should comply with local law and regulations.

11. The device complies with electromagnetic compatibility requirements for electronic medical products or systems in IEC60601-1-2. Radio transmission equipment or other electromagnetic interference may affect the performance of this device.
12. Portable radio communication equipment may affect the performance of this device.
13. The device should not be used in the vicinity of other radio equipment or stacked on any other equipment.
14. Use of the device is not recommended during transportation of patients, such as in ambulances or other vehicles.
15. Do not disassemble,or attempt repair of this device without prior authorization.
16. The materials that will come into contact with the patient is a medical silica gel pad that conforms to ISO 10993.
17.Temperature shall not exceed 40°C when in contact with patient. The recommended maximum application time should not exceed 2 hours.
18. The device is not intended for patients weighing less than 20kg,Pregnant women and nursing Mothers.
19.Please comply with local authority regulations when disposing of batteries. Never dispose of batteries in fire!
20.This device has no audible alarms.
21.The device is ready for its intended use when the ambient temperature is 40°C ,The time required to reach ambient temperature from the minimum/maximum storage temperature is 15±5mins.

4.2 Causes of Incorrect Measurements
1. Dysfunction of important indicators of hemoglobin (such as carbon-containing hemochrome or methemoglobin);
2. Excessive intravascular staining agent (such as indocyanine green or methylene blue);
3. Impact of surrounding light; add a protective housing to the sensor if necessary;

4. Excessive patient movement may be erroneously identified as pulse signals and may affect the measurements of this device.
5. Venous rhythmic beating;
6. Placement of the sensor and blood pressure cuff at the same artery or blood vessel.
7. Excessively low blood pressure, systolic blood pressure, severe anemia or hypothermia;
8. Cardiac arrest or shock;
9. Excessively smooth nails or false nails;
10. Weak pulse or weak perfusion;
11. Low hemoglobin;
12. Excessively long nails or nail polish and other cosmetics on nails.
13. Blood oxygen waveform is not normalized; when the signal is too weak, waveform amplitude decreases; excessively low waveform amplitude may lead to inaccurate measurement results;

5. Symbol Description

Symbol	Description
	Type BF applied part
$\%SpO_2$	Pulse oxygen saturation
PI%	Perfusion index
PR	Pulse Rate
	Battery power indication
	Attention

Symbol	Description
	Battery orientation
CE 0123	CE marking
	Reference instructions for use
IP22	Moisture rating
SN	Serial number
	Manufacturer information
	Date of manufacture
EC REP	European Authorized Representative
	Please comply with local authority regulations when disposing this device
	Storage temperature
	Storage humidity
	Storage atmospheric pressure
SpO_2	Not for continuous monitoring (no alarm for Spo2)
	Pulse intensity bargraph

6. Battery Installation

1. Open the battery cover according to the direction of arrows as shown in Fig 4.
2. Place 2*AAA batteries into the battery compartment, and ensure correct positioning as shown in Fig 4.
3. Close the battery cover.

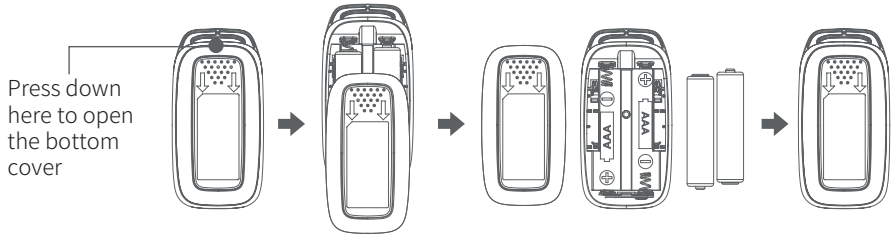

Figure 4

Note:
The device is at risk of damage if the batteries are installed incorrectly. For long periods of none use, always remove the batteries

7. Operating Instructions

1. Install batteries in accordance with item 6. Battery installation.
2. Open the oximeter as shown in Fig 5.
3. Fully insert finger as shown in Fig 6.
4. Press the power button to switch on the oximeter.
5. Ensure minimum movement of finger and body during measurement.
6. Read measurement from the device screen.
7. The HbO-SMART has 4 different user screen options. Once the screen. measurement is stable, pressing the power button will change the screen display as shown in Fig 7.

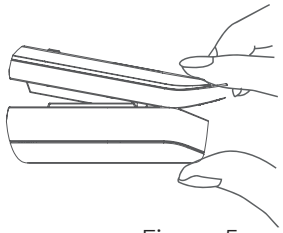

Figure 5

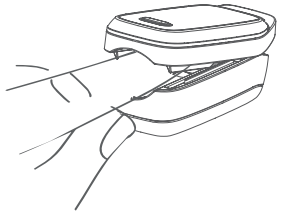

Figure 6

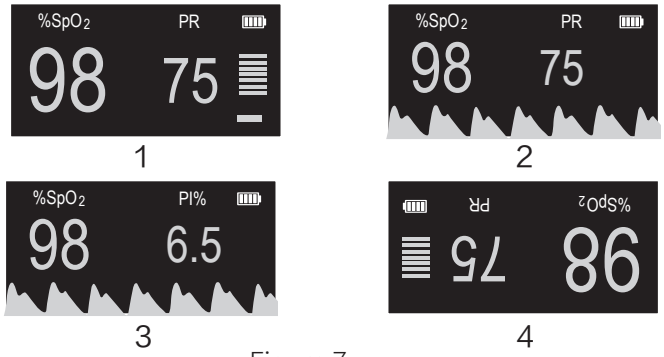

Figure 7

8. Once the patients finger has been removed from the device the screen will dispaly “Finger out” (Fig8). After a period of 8 seconds the device will shut down automatically

9. When the battery power is low,the screen will display a low battery symbol(Figure 9).The device will shut down automatically after 8 seconds.

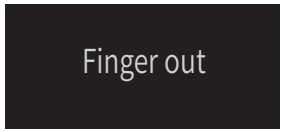

Figure 8

Figure 9

8. Setting

Menu	Setting range	Default setting
SpO_2 Limit Lo	85%~99%	90%
PR Limit Lo	30bpm~100bpm	50bpm
PR Limit Hi	100bpm~200bpm	120bpm
Sound	Volume Level 1~5 and Off can be selected	
Exit	Long press to exit	

During a non-measurement condition “Finger out”, by pressing and holding the power button the user can enter the menu settings as shown below.

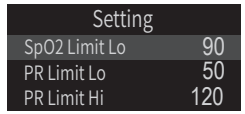

Figure 10

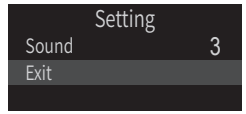

Figure 11

Once in the menu setting as shown in Fig 10, short presses of the power button will advance through the menu options.Long presses will allow the user to adjust the parameters in that setting.

To exit the menu setting, select “Exit” press and hold the power button. The device will automatically exit the menu settings after 30 seconds in the absence of user activity.

During measurement, if the SpO2 or PR values exceed their setting limit, the device will periodically beep and the numerical value will flash to alert the user.

Pressing and holding the power button will disable the alert for approximately 100 seconds before the alert is reinstated.

9. Lanyard Installation

1. Pass the thinner end of the lanyard through the slot on the device as shown in Fig 12.
2. Then Pass the thicker end of the lanyard through the thinner loop of the lanyard and pull tightly as shown in Fig 13.

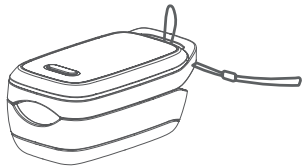

Figure 12

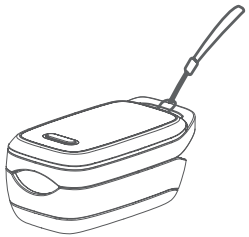

Figure 13

Warning ! ⚠

1.Due to small parts, always keep the device out of reach of children.
2.Never leave the device hanging on its lanyard in reach of small children.

10. Product Accessories

No.	Name	Unit	Quantity
1	Lanyard	Piece	1
2	AAA batteries	Piece	2
3	User's Manual	Piece	1

11. Maintenance, Storage and Transportation

The life cycle of this device is 5 years when used daily for a number of 10 measurements, for periods of 10 minutes each measurement. In order to conform to this service life please pay information below:
1. Please replace the batteries immediately when the low battery power symbol is indicated.
2. Wipe the surfaces of the device before and after use.
3. Remove batteries for extended periods of none use.
4. Expected service life is 5 years.
5. The device has been calibrated before delivery,Therefore there is no need for user calibration.
6. A packaged device should be stored in a clean and well ventilated environment with an ambient temperature of -20°C ~55°C with relative humidity ⩽ 93% and in the absence of corrosive gases,strong mechanical vibration or electromagnetic fields.
7. For transportation requirements, devices should be loaded correctly according to the symbols on the outer packaging and should be protected against collision and impact, severe vibration and severe weather conditions whilst in transit.
8. The device shall be kept dry at all times.High moisture enviroments will afect the service life of the device and potentially cause damage.
9. Do not attempt to disassemble, repair or service the device.
10.To recycle or dispose of the device and batteries, please comply with local authority regulations.
·If there is dust or dirt on the surface of the oximeter, wipe the device with 70% alcohol.Dip a dry cloth or alcohol pad in a small amount of alcohol before wiping. Avoid drip or flow of alcohol in the device. Dry the device in the air after wiping. Avoid permeation of any liquid into the device.
·The device does not need scheduled maintenance or calibration except for battery replacement.
·Please stop using the device and contact your local service center immediately if any of the following conditions occurs:
1. Abnormal alphabet or number appears on the screen.
2. The device cannot be turned on despite replacement of batteries.
3. The device cannot perform measurement due to squeezing, loose spring, button failure and so on.

·Clinical testing is a commonly used method for determining oxygen saturation accuracy. The arterial hemoglobin oxygen saturation measured with the device should be compared with the result of sampled arterial blood analyzed with CO-oximeter.
·The name of the simulator used is Index2 FLUKE simulator, version number: 3.0.0.
·Simulator is used for testing of consistency only; equipment measurement accuracy is tested by clinical comparisons.

	Possible causes	Solutions
Boot failure	Low or dead battery, wrong battery installation, device failure	Please replace the battery, re-install the battery or contact your local customer service center
Abnormal display of SpO2 or PR	Shallow placement of finger, hard ambient light, weak perfusion, or excessively low oxyhemoglobin for correct measurement	Correctly put your finger and retry; avoid use in strong ambient light; go to the hospital for accurate diagnosis
Unstable display of SpO2 or PR	Shallow placement of finger, shaking finger or patient movement	Correctly put your finger and retry; avoid movement

12. Technical Specifications

Display mode		OLED
Oxygen saturation	Measuring range	70%~99%
	Accuracy	80%~99% ±2%; 70%~79% ±3%; No requirement for 70% below
	Resolution	1%
Pulse rate	Measuring range	30 bpm~240 bpm
	Accuracy	30 bpm~240 bpm, ±2 bpm or ±2% (which is larger)
	Resolution	1 bpm
Measuring range of blood perfusion index		0.3%~20%
LED probe wavelength		RED 660 ±3 nm IR 905 ±10 nm
Radiation power		RED 2 mW IR 2 mW
Battery model		2 AAA batteries
Power consumption		< 30 mA
Battery life		Continuous use for 25 hours with 2 AAA1.5 V alkaline batteries
Operating temperature		5 °C ~40 °C
Storage temperature		-20 °C ~+55 °C
Relative humidity		⩽ 80%: No condensation in working status ⩽ 93%: No condensation in storage status
Operating atmospheric pressure		86 kPa~106 kPa
Storage atmospheric pressure		70 kPa~106 kPa
Response time		< 20 s

Anti-shock protection category		Internal power supply
Anti-shock protection measure		Type BF applied part
Waterproof protection measure		IP22
Net Weight		approx. 60 g (including batteries)
Dimensions		69 mm (L) x 35 mm (W) x 29 mm (H)
Operating mode		Non-continuous operation
Data averaging	Spo2	Average of successive five detected pulses, with exponential smoothing followed
	Pulse rate	Average within 8 seconds
Update time	Spo2	Update per second, the update period is less than 20 seconds.
	Pulse rate	Update per second, the update period is less than 12 seconds.

13. Electromagnetic Compatibility Guide

Note: ⚠

·This device should not be used close to or stacked with other devices. If it must be used close to or stacked with other devices, care should be taken to verify that it functions properly under its intended use.

·Except for the cables of this product sold by the manufacturer as spare parts for internal components, use of the accessories and cables other than those specified may result in increased emission or reduced immunity of this product.

·Since portable and mobile RF communication equipment may affect the performance of this product, please avoid strong electromagnetic interference during use, such as mobile phones, microwave ovens and so on.

·The user should install and use the device according to the electromagnetic compatibility information provided in the random file.

(1)

Guide and manufacturer's statement - Electromagnetic emissions		
This product is intended for use in the following electromagnetic environment.The purchaser or user of theproduct should ensure that it is used in this electromagnetic environment		
Emission test	Compliance	Electromagnetic environment - Guide
RF emissions	Group 1	This product uses RF energy only for its internal functions. As a result, its RF emissions are low and there is very little chance of interference with nearby electronic equipment.
RF emissions	Class B	This product is intended for use in all facilities including domestic facilities and the facilities connected directly to public low-voltage power supply network for residential homes.
Harmonic emissions	Not applicable	
Voltage fluctuation / flickering emissions	Not applicable	

(2)

Guide and manufacturer's statement - Electromagnetic immunity			
This device is intended for use in the following electromagnetic environment. The purchaser or user of this device should ensure that it is used in this electromagnetic environment			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - Guide
Electrostatic discharge	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The floor should be wood, concrete or ceramic tile; if the floor is covered with synthetic materials, the relative humidity should be at least 30%.

Electrical fast transient burst	± 2 kV for power cord ± 1 kV for input/ output lines	Not applicable	Not applicable
Surge	± 1 kV differential mode voltage ± 2 kV common-mode voltage	Not applicable	Not applicable
Voltage dips, short interruptions and voltage changes in power input line	<5% UT for 0.5 cycle (> 95% dips on UT) 40% UT for 5 cycles (60% dips on UT) 70% UT for 25 cycles (30% dips on UT) <5% UT for 5s (> 95% dips on UT)	Not applicable	Not applicable
Power frequency magnetic field (50/60Hz)	3 A/m	3 A/m, 50/60 Hz	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field of a typical place in a typical commercial or hospital environment.
Note: UT refers to the AC voltage before applying the test voltage.			

(3)

Guide and manufacturer's statement - Electromagnetic immunity			
This device is intended for use in the following electromagnetic environment. The purchaser or user of this device should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - Guide
RF conduction	3 V (effective value) 150 kHz ~ 80 MHz	Not applicable	Portable and mobile RF communication equipment should not be used near any part, including cables, of the product at a distance shorter than the recommended isolation distance. This distance should be calculated with the formula corresponding to the transmitter frequency.
RF radiation	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	Recommended isolation distance $d=1.2\sqrt{P}$ 80 MHz~800 MHz $d=2.3\sqrt{P}$ 800 MHz~2.5 GHz

Where:
P - The transmitter's maximum rated output power, in watts (W), provided by the transmitter's manufacturer;
d - Recommended isolation distance in meters (m) b.
The field strength of a fixed RF transmitter is determined by a survey of electromagnetic locations c, which should be lower than the compliance level in each frequency range d.
Interference may occur near equipment marked with the following symbol:

Note 1: The higher frequency band formula is used at the frequency of 80 MHz and 800 MHz.
Note 2: The guide may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

a. The field strength of a fixed transmitter, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasts and television broadcasts, cannot be accurately predicated in theory. Survey of electromagnetic sites should be considered to assess the electromagnetic environment of fixed RF transmitters. If the measured field strength of the place where the product is located at is higher than the above applicable RF compliance level, the product should be observed to verify that it can work properly. If abnormal performance is observed, additional measures may be necessary, such as readjusting the orientation or location of the product.
b. The field strength should be below 3 V/m over the frequency range of 150 KHz ~ 80 MHz.

Recommended isolation distances between portable and mobile RF communication equipment and this product

This product is intended for use in electromagnetic environments where radio frequency radiation harshness is controlled. Depending on the maximum rated output power of communication device, the purchaser or user of this product can prevent electromagnetic interference by maintaining the following recommended minimum distance between the portable and mobile RF communication equipment (transmitter) and this product:

Rated maximum output power of transmitter/W	Recommended isolation distances between portable and mobile RF communication equipment and this product		
	150 kHz 80 MHz $d=\sqrt{P}$	80 MHz 800 MHz $d=\sqrt{P}$	800 MHz 2.5 GHz $d=\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23

For the rated maximum output power of transmitter not listed in the above table, the recommended isolation distance d in meters can be determined using the formula in the corresponding transmitter frequency column, where P is the maximum output rated power of transmitter provided by the manufacturer in watts (W).
Note 1: The higher frequency band formula is used at the frequency of 80 MHz and 800 MHz.
Note 2: The guide may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

14. Registration Information

Distributor:

DeVilbiss Healthcare GmbH

Kamenzer Str.3

68309 Mannheim

Germany

Manufacturer:

Shenzhen Lepu Intelligent Medical Equipment Co., Ltd
Tel: 400-830-9392
Service E-mail: info@lepu-medical.com
Website: www.lepucare.com

EC	REP

Company name: Lepu Medical (Europe) Cooperatief U.A.
Add: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Tel: +31-515 573399
Fax: +31-515 760020