DATA SHEET WESTMED® Fingertip Oximeter

WESTMED

Bestellnummer
5810091

Description

Our WESTMED® Finger Pulse Oximeter is a compact medical device used to determine and monitor pulse and functional oxygen saturation (SpO2) via the patient's finger. It is suitable for random checks of SpO2 and pulse on adults and children at home and in clinics.

The shapely finger oximeter keeps its promise. Not only repeated falls from a height of 1m but also splash water does not bother the small device and is therefore suitable for constant and professional use. Even in hectic situations, heart rate and oxygen saturation can be quickly read on the two-color LCD display. The display can be easily aligned at the touch of a button.

Technical information	
Reference number	PC-60B1
Dimensions (LxWxH)	58.5 mm x 33.5 mm x 30 mm
Weight	47 g
Packaging unit	1 piece per package 50 packages per box 10 boxes per pallet
Lifetime	5 years from production date
Power supply	2 x AAA batteries, supply voltage: 3.0V DC, Operating current: ≤40 mA

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Intended use	This finger pulse oximeter is used to measure pulse and functional oxygen saturation (SpO2) via the patient‘s finger. It is suitable for random checks of SpO2 and pulse in adults and children at home and in clinics. Models with an external sensor and an overshoot indicator can be used for longer periods depending on the suitability of the selected sensor.
SpO2 signal transmitter	Dual wavelength LED sensor; wavelengths: red light: 663 nm, infrared light: 890 nm
SpO2 measuring range	35%–100%
SpO2 measuring accuracy	≤ 2% in the range of 70% to 100%
Max. average optical output power	≤ 2 mW
Measuring range of pulse frequency	30 bpm–240 bpm
Measuring accuracy of pulse rate	±2bpm or ±2%, whichever is greater
Display range Perfusion index	0%–20%
Standard alarm limit SpO2 lower limit	90%
Standard alarm limit pulse rate	Upper limit: 120 bpm Lower limit: 50 bpm
Electromagnetic compatibility	Group I, class B
Ambient temperature and humidity	5 °C to 40 °C; 30–80 %
Atmospheric pressure	70 kPa–106 kPa
Warnings	• Discomfort or pain may occur if the device is used continuously on the same part of the body for long periods of time, especially in patients with poor microcirculation. It is recommended to use the oximeter on the same body part for a maximum of 2 hours. In unusual conditions, change the position of the oximeter. • DO NOT attach the device to areas with swelling or soft tissue. • The light generated by the appliance (infrared light is invisible) is harmful to the eyes. Do not look directly into the light. • The oximeter is not a treatment device. • Local laws and regulations must be observed when disposing of the appliance.

Cleaning and disinfection	Clean the surface of the sensor with a soft cloth moistened with 75% isopropanol. For gentle disinfection, use a mild bleach solution. Then clean the surface ONLY with a cloth moistened with water and dry the surface with a clean, soft cloth. Do not immerse the appliance in liquids. Do not clean with a steam jet or ethylene oxide.
Sterilization	Non-sterilizable

General information	
Safety instructions	• Explosion hazard - DO NOT use the oximeter in places with flammable gases, such as highly flammable anesthetics. • DO NOT use the oximeter on patients during MRI or CT examinations. This device is NOT MRI compatible. • Protect the device from dust, vibrations, corrosive substances, explosive materials, high temperatures and moisture. • The device should not be used by children. • If the oximeter gets wet, stop using it and only use it again after it has dried and been checked to ensure that it is in perfect condition. If you move the device from a cold to a warm, damp location, please wait 15 minutes for the device to reach ambient temperature before use. • Do NOT press the buttons on the control panel with sharp objects. • DO NOT use high-temperature or high-pressure disinfectants on this appliance. • The device complies with protection class IP22 and is protected against the ingress of hazardous solids and liquids. This means that the device is protected against the ingress of solids with a size of 12.5 mm or larger and against vertically falling drops of water when the housing is tilted by up to 15°. • Please also note the effects of lint, dust, light (including sunlight), etc.

Regulatory information	
Classification	Classification Medical device class IIa MDD 93/42/EEC (applicable regulation (EU) 2023/607) The device complies with the requirements of IEC 60601-1-2:2014

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Packaging symbols	
CE	The CE marking is short for „Conformité Européenne“, which means „European Conformity“. It symbolizes the conformity of the product with the applicable requirements that the European Community places on the manufacturer.
SN	Serial number
	Date of production
	Observe instructions for use
UK REP	Authorized representative UK
EC REP	Authorized representative Europe
REF	Reference number/article number
	Temperature limits
	Humidity limits
	Atmospheric pressure limits
	For marking a type BF applied part that complies with the IEC 60601-1 standard.
	Follow the WEEE regulations for disposal
MD	Medical device

Directive and manufacturer‘s declaration - electromagnetic emissions			
The finger pulse oximeter is intended for use in the environment defined below. It is the responsibility of the customer or user to use the device in such an environment.			
HF emissions CISPR 11	Class B	The finger pulse oximeter is suitable for use in all establishments, including domestic establishments and those institutions which supply buildings used for domestic purposes with electricity.	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations/ flicker IEC 61000-3-3	N/A		
The finger pulse oximeter is intended for use in the environment defined below. It is the responsibility of the customer or user to use the device in such an environment.			
Immunity test	IEC 60601 Test level	Conformity	Electromagnetic environment & directive
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV contactess	±8 kV contact ±15 kV contactess	Preferably floors made of wood, cement or ceramic tiles. For synthetic floors, the moisture content must be at least 30%.
Fast electrical transients/ burst IEC 61000-4-4	±2 kV for power lines ±1 kV for input/output lines	N/A	N/A
Power surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	N/A
Voltage drops, short interruptions and voltage changes in power lines IEC 61000-4-11	< 5% U_T (> 95% drop from U_T) for 0.5 cycles < 40% U_T (60% drop from U_T) for 5 cycles	N/A	N/A

Mains frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the mains frequency should correspond to the typical values found in a business or hospital environment.
Note: U_T is the AC mains voltage before the test stage is applied.			
Guided HF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the oximeter (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, given below.
Radiated HF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	**Recommended distance** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in meters (m).
			The field strength of stationary RF transmitters is lower than the compliance level at all frequencies according to an on-site test. Interference may occur in the vicinity of devices marked with the symbol.
Note 1: At 80 MHz and 800 MHz, the higher frequency applies. Note 2: These guidelines do not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location in which the oximeter is used exceeds the applicable RF compliance level above, the oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the finger pulse oximeter.
b: Field strengths should be less than 3 V/m within the frequency range 150 kHz to 80 MHz.

Recommended distance to portable and mobile HF communication devices

The finger pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oximeter as recommended below, according to the maximum output power of the communications equipment.

Max. Rated output power of the transmitter in W (Watt)	Distance depending on the frequency of the transmitter m (meters)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters whose maximum output power is not listed above, the recommended distance d in meters (m) can be determined using an equation applicable to the frequency of the transmitter, where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the spacing of the higher frequency range applies.
Note 2: These guidelines do not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Fast electrical transients/ burst IEC 61000-4-4	±2 kV for power lines ±1 kV für for input/ output lines	N/A	N/A

Power surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	N/A

Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street,
Nanshan District, 518110 Shenzhen, P. R. China

EC REP Shanhai International Holdin Corp. GmbH (Europe)
Eiffestraße 80, Hamburg, Germany