

Actual Size: B4 (36.4x25.7cm)

Folded in: 12.8x9.5cm



OP2HEALTH Fingertip Pulse Oximeter (DB12) User Manual
MODEL: DB12
Spot Monitor for Sports and Outdoor Use

Measurement Principle :
The measurement of SpO₂ (blood oxygen saturation concentration) is made by determining the absorption of infrared and far-infrared passing through the tissues. Such absorptions may vary with the blood pulsation in the capillary bed allowing the blood oxygen saturation and pulse alteration to be determined.

2.2 Package Contents
The Fingertip Pulse Oximeter (DB12) package includes the following:
1. Fingertip Pulse Oximeter (DB12) x 1
2. User Manual x 1
3. AAA Alkaline Battery x 1
4. Pouch x 1
Please verify all of the above items are in the package. If any one item in this list is missing or damaged, please contact the distributor.

The standard configuration does not include the accessories of the system. For the accessories and the detailed information about the Fingertip Pulse Oximeter (DB12), please contact the distributor or DELBio Inc.

2.3 Fingertip Pulse Oximeter (DB12) Instruction
1. Device Appearance and Display



Blood Oxygen Display, Pulse Strength Display, Power Switch & Backlight ON/OFF, Battery Level Display, Pulse Rate Display, Battery Box

To turn on the backlight, please insert your fingertip into the device and press the power switch to turn on the device then press the switch again to turn on and off the backlight

2. The Fingertip Pulse Oximeter (DB12) Display Alarm
When test data exceeds the factory default setting, the reading will flash.
Blood Oxygen Alarm : When the test result falls below 90, the reading of SpO₂ will flash.
Pulse Rate Alarm : When the test result falls below 50 or goes above 160, the PR reading will flash. The Fingertip Pulse Oximeter (DB12) has no audible alarms. It will not sound if the amount of oxygen in your blood is low or if your pulse rate is too high or too low.

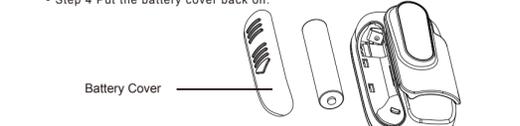
Chapter 3 Fingertip Pulse Oximeter (DB12) Pre-operational Procedures
3.1 Battery Installation and Replacement
This device uses one AAA battery for its power supply. When the device displays low battery level, the battery power of the Fingertip Pulse Oximeter (DB12) can last only for approximately 15 minutes more. However, it may vary with different brands of batteries. Therefore, replacing the battery immediately is recommended to ensure accurate measurements.

Battery Indicator

- Indicates full of power
- Indicates the device may be out of power in 15 minutes
- Indicates the power is insufficient to make measurement and the device will shut down

Please follow the steps below for battery replacement.

- Step 1 Turn off power
- Step 2 Push the battery back cover down toward the end of the Fingertip Pulse Oximeter (DB12) and detach the battery cover
- Step 3 Install one AAA alkaline battery as illustrated in the figure below
- Step 4 Put the battery cover back on



Chapter 4 Fingertip Pulse Oximeter (DB12) Operations
4.1 Fingertip Pulse Oximeter Measurements

- Step 1 Press the power switch to turn on the device
- Step 2 Insert the finger
- Step 3 When the pulse signal is detected, the oxygen saturation level and pulse rate will be displayed 6-8 seconds later
- Step 4 Take the finger out of the device. The results will be displayed on the screen

Chapter 5 Fingertip Pulse Oximeter (DB12) Cleaning & Maintenance
For the cleaning and maintenance of the Fingertip Pulse Oximeter (DB12), please follow the following recommendations:

- Prior to cleaning, turn off the Oxicare Pulse Oximeter.
- Use a gentle detergent or medical grade alcohol (75% ethanol solution) to moisturize a swab to wipe the surface of the Oxicare Pulse Oximeter.
- When you spot any soiling, dust, or clogging on the surface of the Fingertip Pulse Oximeter (DB12), please clean it.
- Make sure the optical components of the device are not polluted by dust or soil.
- The same solution can be used for the cleaning and sterilization of the internal probe of the Fingertip Pulse Oximeter (DB12). Please ensure that the probe is wiped dry prior to another use. The plastic material of the probe of the Fingertip Pulse Oximeter (DB12) is of medical grade. Therefore, it is not harmful or poisonous to the human skin.
- Keeping the Fingertip Pulse Oximeter (DB12) dry at all times is highly recommended. Placing it in a humid environment may affect the life of the device or even cause damage to it.
- Caution: Do not spray, spill, or dump any liquid on the Fingertip Pulse Oximeter (DB12), its components, power switch or crevices.
- If the Fingertip Pulse Oximeter (DB12) will not be used for a certain period of time, please take the battery out of the battery chamber.

When the low battery level is displayed, please replace the battery and comply with the local government regulations to dispose of the dead batteries.

Chapter 1 Safety Information
1.1 Warning

- Explosion Hazard : Please do not use this device in the presence of flammable gas.
- Please do not use this device in an MRI environment.
- The sole objective for the use of this device is to serve as an aid in clinical diagnosis. It must be used in combination with clinical manifestations and symptoms for the diagnosis.
- Should the subject's measurement site experiences trauma or other medical conditions resulting in incorrect result, the user shall consult the physician prior to using it.
- In the event of malfunction, please do not use this device.
- This device is able to accurately measure the pulse and blood oxygen saturation. When the blood flow is limited (such as using a sphygmomanometer), the pulse measurement may be affected. The device function may be influenced if the test object is moving.

1.2 Caution

- This is a device with a highly sophisticated electronic instrument and its maintenance and repair can only be performed by professionally trained personnel.
- Please do not expose this device to sterilization under high pressure or immerse it in liquid such as directly under the rain, as it may cause device malfunction or inaccurate measurement.
- Please refer to the cleaning procedure in this User Manual. Please do not use corrosive or corrosive detergent or cleansing apparatus.
- This device is not intended for respiratory measurement.
- This device is designed to measure the ratio of the arterial blood oxygen saturation to the functional hemoglobin. Functional disorders such as carboxyhemoglobinemia or methemoglobinemia may affect measurement accuracy.
- Indigo cyanine green or certain pigments in the blood vessels may have an impact on the blood oxygen concentration measured depending on its concentration.
- Defibrillators may influence the functioning of this device.
- This device may not be used under all kinds of circumstances. If unstable readings appear during measurement, please cease to use it.
- This device possesses some resistance to shaking. However, under certain circumstances, the movement may be accepted as normal pulses. Therefore, moving the patient should be avoided as much as possible.
- If the battery has not been used for a long period of time, some chemical substances may be released. If the device is to be left unused for more than 3 months, the battery should be removed.
- After the battery is installed properly, turn on the device. The device will detect the pulse signals after the finger is placed inside the device. The standby mode will be displayed within 30 seconds if no finger is placed inside the device. Please do not use it and contact the dealer for instruction if there is no display.
- The disposal and recycling of the device and its components should be in compliance with local environmental regulations.
- Under conditions of normal battery power supply, there is no limitation on the longest time of use for the Fingertip Pulse Oximeter at one single location.
- The silicon used in the Fingertip Pulse Oximeter to be in contact with the finger is a bio-compatible material and not harmful to the human body. You can therefore use it at without harm.

Chapter 2 Introduction of Fingertip Pulse Oximeter (DB12)
2.1 Product Introduction

Intended Use :
The Fingertip Pulse Oximeter (DB12) is used for spot-checking of functional arterial oxygen saturation (SpO₂) and pulse rate (PR) of adult in sports, aviation and outdoor settings. The Fingertip Pulse Oximeter (DB12) is not intended for continuous monitoring.

Chapter 6 Trouble Shooting

In the event of device failure during its use, please follow the recommended solutions below.

Table 1 Recommended Breakdown Solutions

Incident	Potential Cause	Solution	
Device unable to power on	No battery installed	Install battery	
	Battery power depleted	Replace battery	
	Battery not installed properly	Re-install battery	
	Partial damage to metal dome in contact with battery	Contact DELBio's authorized distributor	
No display on screen	Damaged display or connector	Contact DELBio's authorized distributor	
No data displayed on device	Low perfusion	If the pulse wave is not displayed 1) Readjust finger position 2) Keep finger warm 3) Try another finger	
		LED display not illuminating	Contact DELBio's authorized distributor
		Automatic power off failure	Contact DELBio's authorized distributor

Chapter 7 Fingertip Pulse Oximeter (DB12) Specifications
7.1 Technical Specifications

Product Model No.	DB12	
Measurement Range	SpO ₂	35% ~ 100%
	Pulse Rate	30 bpm ~ 200 bpm
	Perfusion Range	0.5% ~ 20%
Oxygen Saturation Precision	Normal Condition	70% ~ 100% Tolerance±2%
	Blood Deficiency Subject	70% ~ 100% Tolerance±3%
Pulse Rate Precision	Normal Condition	30 bpm ~ 200 bpm Tolerance±3 bpm
	Blood Deficiency Subject	30 bpm ~ 200 bpm Tolerance±3 bpm
Measurement Duration		30s
Environmental Conditions	Temperature	41 °F ~ 113 °F (5 °C ~ 45 °C)
	Atmospheric Pressure	70kPa ~ 106kPa (25.4 inHg ~ 31.3 inHg)
	Relative Humidity	15% ~ 95% non-condensing
Shipping and Storage	Temperature	-4 °F ~ 140 °F (-20 °C ~ +60 °C)
	Atmospheric Pressure	50kPa ~ 106kPa (14.7 inHg ~ 31.3 inHg)
Physical Characteristics	Weight	40g (battery included)
	Dimension	65mm x 37mm x 29mm
Electric Specifications	Electricity Type	One AAA alkaline battery
	Voltage	1.5V DC
Compliance	Protection Category	Type BF - applied apart
	Operating Mode	Spot-Checking
Blood Oxygen Probe	Safety Standard	IEC-60601-1
	EMC	IEC-60601-1-2
	Performance Standard	ISO 80601-2-61
	LVD	IEC60950
Wavelength		660 nm - 905 nm
Total Optical Energy Released from Probe		<15mW

Chapter 8 Manufacturer's Declaration

The Fingertip Pulse Oximeter (DB12) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output of the communications equipment.

Table 5: Recommended Separation Distances
Recommended separation distances between portable and mobile RF communications equipment and the Oxicare (IEC 60601-1-2)

Frequency of Transmitter	150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz
Equation	$d = \left[\frac{3.5}{P_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{P_1} \right] \sqrt{P}$	$d = \left[\frac{7}{P_1} \right] \sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts(W)	Separation Distance in Meters (m)	Separation Distance in Meters (m)	Separation Distance in Meters (m)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

Note : At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.
Note : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6: Cable Compliance
Cables Comply With:

RF Emissions, EN 55011, Class B/Group 1	
EN 60601-1-2: 2001	
Cables and Oxicare Sensors	Maximum Length
Oxicare Sensor	300 mm

Table 7: Electronic Emissions
The Fingertip Pulse Oximeter (DB12) is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should assure that it is used in such an environment.

Table 8: Electromagnetic Immunity
The Fingertip Pulse Oximeter (DB12) is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should assure

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	Class B	The Oxicare uses RF energy only for its internal function. Therefore, the RF emissions are very low and not likely to cause interference in nearby electronic equipment.
			The Oxicare is suitable for use in establishments, including diagnostic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
			Portable and mobile RF communications equipment should be used no closer to any part of the Oxicare, including the cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Power Frequency (50/60 Hz) magnetic field	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b .

Recommended Separation Distance

$$d = \left[\frac{3.5}{P_1} \right] \sqrt{P}$$

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

$$d = \left[\frac{3.5}{P_1} \right] \sqrt{P}$$

80MHz to 800MHz

$$d = \left[\frac{7}{P_1} \right] \sqrt{P}$$

800MHz ~ 2.5GHz

Note : At 80 MHz, the higher frequency range applies.
Note : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a) Field strength 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 with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the Oxicare is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m.

Chapter 9 System Performance Characteristics
Measurement Validation
The SpO₂ accuracy has been validated in human studies against arterial blood sample reference measured with CO-Oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70% and 100% SpO₂ were studied.

DB12 Inner Probe
(a) The table below shows A_{RMSE} values measured using DB12 in a clinical study

Item	70 ~ 100	90 ~ 100	80 ~ 90	70 ~ 80
# pts	249	93	83	79
Bias	-0.13	0.52	-0.30	-0.62
A _{RMSE}	1.60	1.23	1.47	2.02

(b) Bland-Altman Plot compares the SpO₂ difference of the DB12 fingertip pulse oximeter to the reference CO-Oximeter under non-motion conditions.



Upper 95% limit, Regression line, Line of identity, Mean difference, Lower 95% limit

Points analyzed	Sres (%)	Standard deviation	Bias	95% limits of agreement	# of Mean±2SD	# beyond the 95% limits of agreement
249	1.6	1.6	-0.13	-3.28, 3.02	15	16

Chapter 10 Customer Service Information
WARNING: This device is a precision medical instrument and should be only repaired by qualified technical professionals. Attempt to open the case without professional training may damage the device.
CAUTION: This device is not for continuous monitoring.

TURNER MEDICAL INC. warrants to the purchaser, for 2 year from the date of purchase, each Fingertip Pulse Oximeter (DB12) exclusive of the battery. TURNER MEDICAL will repair or replace any Fingertip Pulse Oximeter (DB12) found to be defective in accordance with this warranty for which TURNER MEDICAL has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period.

This warranty excludes cost of delivery to and from TURNER MEDICAL INC. TURNER MEDICAL INC. reserves the right to charge a fee for a warranty repair request on any Fingertip Pulse Oximeter (DB12) found to be within specifications. Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification would be excluded from this warranty. If you are not fully satisfied with your Fingertip Pulse Oximeter (DB12), please contact TURNER MEDICAL INC. for more information.

Manufacturer:
DELBio Incorporation 3F & 6F, No. 252, Shangying Road, Guishan Industrial Zone, Taoyuan County 33341, Taiwan, R.O.C

Distributor:
TURNER MEDICAL INC.
74 Chestnut St. Willimantic, CT 06226, U.S.A.

If you have any questions regarding this product, please contact 1-866-778-5890.

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