vive®
PRECISION

PULSE OXIMETER

Owner's Manual
DMD1046

vivehealth.com

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The Smart Phone Compatible Pulse Oximeter will aid you in tracking your O_2 levels and pulse. It provides accurate and easily readable results.

The Oximeter is easy to operate with just your fingertips. The top of the device features a screen to display results and a button to operate the device. The battery compartment is located on the bottom of the device.

OVERVIEW

We are constantly answering questions and recording helpful videos to make using your Vive Precision Pulse Oximeter as easy as possible. Check out the included links and QR codes to help you through the process.

To see all of the FAQs in one place visit **vhealth.link/wwi**

WHAT'S INCLUDED

- Case
- Pulse Oximeter
- 2x Batteries (AAA)
- Lanyard
- Manual

OPERATION GUIDE

For initial setup instructional video check out **vhealth.link/9fe**

1. Enable wireless device connectivity for your phone and turn on the pairing setting to allow the phone to locate and connect with other devices.
2. Download and install the Vive Precision app on your smartphone from the relevant app store.
3. Open the app and allow storage and location permissions (if prompted), so that measurement data can be stored on the device.
4. Create an account, or log into the app if you've already created a Vive Precision account on another device.
5. Install the 2 AAA batteries into the bottom of the Pulse Oximeter and ensure the cover is securely attached.
6. Allow the device to power on and perform "Synchro nous Mode" for several minutes.
7. Go to "Device Setup" in the main menu of the app.
8. Select "Pair New Pulse Oximeter" and follow the on-screen instructions to pair the device.
9. Once a device appears, press the + icon on screen to finish pairing, and provide a name for the device to help identify it.

10. Once the device finishes pairing, it will default to the pedometer screen, which will display an estimate of the steps taken and calories burned by the user dependent on the movement the device detects.
    a. The device must be in your possession (in your pocket or bag, around your neck on the provided lanyard, etc)
11. Proceed to step 12 to take a measurement and test the connection.

Usage

12. Power the device on, open the Vive Precision app, and insert your finger into the device and take a measurement.
    a. Make sure your finger is fitted into the device as much as possible with your fingernail facing in the same direction as the oximeter screen. Readings can take up to 30 second to measure, and another 30 seconds to transmit to the app.
    b. The results on the device screen will be labelled SpO_2 for the oxygen saturation, and PR for the pulse rate.
13. Switch the Auto-Sync to ON. Wait a few moments for the reading to transfer.
    a. If the reading does not transfer and appear on the main screen of the app after 60 seconds, move the smartphone and the device closer together and take another reading.

14. When you want to transfer your results, go to "Export Data" in the app main menu.
15. Select the desired metric and the time frame of readings you wish to export.
16. Enter the email address that you wish to send the data to.
    a. You can type in an address (like your doctor's) or select the "Default Address" (yours) which will then fill in automatically.
17. Press Send to transmit the data report.
18. Check the applicable email address box to ensure the report has been sent. Be sure to check the Spam folder as well.
    a. The report will come from VivePrecision@vivehealth.com. To make sure your reports don't end up lost, add VivePrecision@vivehealth.com to your email contacts list.

Battery Tips

- Make sure that the batteries are properly inserted according to polarity to avoid damage to the device.
- Remove the batteries if the device isn't used for a long period of time.
- Replace the batteries promptly when a low battery notice appears.

- Replace both batteries at the same time. The replacement batteries should both be AAA alkaline batteries.
- After replacing the batteries, perform "Synchronous Time" through the Vive Precision app again. Refer to "Data Measurement" in this manual for further details on Synchronous Time.
- Battery disposal should adhere to local environmental and safety regulations.

Routine Maintenance

a. Cleaning and Disinfection

   i. Turn off the device before cleaning. Use medical ethanol to clean and disinfect the device. Allow the device to air dry or clean it with a dry, clean cloth.

   ii. Avoid any liquid entering the device.

b. Maintenance

   i. Keep the device away from dust, high temperatures, and humidity.

   ii. Avoid strongly shaking or hitting the device.

   iii. When the device needs to be cleaned, wipe its surface with a gentle cleaning solution. Avoid using strong corrosive liquids or cleaners, like alcohol, gasoline, etc.

iv. Before use, clean and disinfect the device according to the provided guidelines.

v. Replace the batteries promptly when a low battery notice appears.

vi. Remove the batteries if the device isn't used for a long period of time.

vii. The device needs to be calibrated periodically, or according to the hospital calibrating program.

c. Transportation and Storage

i. The packaged device can be transported by ordinary conveyance or according to the transport contract.

ii. The device can't be transported in combination with toxic, harmful, or corrosive materials.

iii. The packaged device should be stored in a well-ventilated room free of corrosive gases.

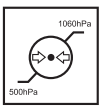
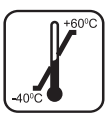
iv. The safe temperature range for this device is -40 °C to 60 °C. The safe relative humidity is less than 95%. The safe atmospheric pressure is 500 hPa to 1060 hPa.

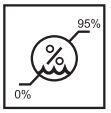
TROUBLESHOOTING

Trouble		Solution
The SpO_2 or pulse rate isn't displayed normally.	1. The testee's finger is not properly inserted. 2. The SpO_2 value of the testee is too low to be detected.	1. Insert the testee's finger properly and try again. 2. Try several times, then go to a hospital for a diagnosis if you're sure the device is working properly.
The SpO_2 or pulse rate display isn't stable.	1. The testee's finger isn't inserted deep enough into the probe. 2. The testee is moving or their finger is shaking.	1. Insert the testee's finger properly and try again. 2. Do not move while the measurement is being taken.
The device can't be turned on.	1. The batteries are drained or almost drained. 2. The batteries aren't installed properly. 3. The device is malfunctioning.	1. Replace the batteries. 2. Install the batteries again properly. 3. Please contact the manufacturer.

The display disappears suddenly.	1. The device is working off of low voltage. 2. The device enters standby mode automatically if there's no operation for one minute.	1. Replace the batteries 2. This is normal.
Data can't be stored.	1. The wrong time is displayed. 2. The measurement time is too short.	1. Sync the time. 2. This is normal.

SYMBOL MEANING

Symbol	Meaning
	Atmospheric pressure
	Fragile
	Keep dry
	This way up
	Storage temperature

	Storage humidity
	Refer to instruction manual/booklet
%SpO_2	Pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
Calorie	Calorie
	Low voltage
	Battery anode
	Battery cathode
IP22	Ingress of liquids rank
	Type BF applied part
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
SN	Serial number
	WEEE (2002/96/EC)
	Alarm inhibit

SPECIFICATIONS

Display Information	Display Mode
Pulse Oxygen Saturation (SpO_2)	2-digit digital OLED display
Pulse Rate (PR)	3-digit digital OLED display
Pulse Intensity (bar-graph)	Bar-graph OLED display
Calorie	5-digit digital OLED display
Steps	5-digit digital OLED display
Time	MM-DD-YY hour-minute OLED display
SpO_2 Parameter	
Measurement Range	O%~99% (resolution: 1%)
Pulse Parameter	
Measurement Range	30 bpm~250 bpm (resolution 1 bpm)
Pedometer	
Measurement Range	O~65,535 steps (resolution: one step)
Safety Classification	Internally powered equipment, type BF applied part
Pulse Intensity	

Range	Continuous bar graph display, the higher display indicates the stronger pulse
Power Supply	
Two "AAA" batteries	
Dimension and Weight	
Dimension	58 (L.) x 32 (W.) x 34 (H.) mm.
Weight	~ 52 g. (including batteries)

APPENDIX I

Guidance and manufacturer's declaration - electromagnetic emissions - for all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's Declaration -- electromagnetic Emission
The DMD1046 is intended for use in the electromagnetic environment specified below. The user of the DMD1046 should ensure that it's used in this environment.

Emission Test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group A	The DMD1046 uses RF energy only for its internal function. Therefore, its RF emissions are very low and aren't likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The DMD1046 is suitable for use in all establishments, including domestic and those directly connected to a low voltage power supply network supplying to businesses for domestic purposes.

Guidance and Manufacturer's Declaration -- Electromagnetic Immunity
The DMD1046 is intended for use in the electromagnetic environment specified below. The user of the DMD1046 should ensure that it's used in this environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Air Discharge: ±2kV, ±4kV, ±8kV, ±15kV, contact: ±8kV air	Air Discharge: ±2kV, ±4kV, ±8kV, ±15kV, contact: ±8kV air	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30 %.
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Main power quality should be that of a typical commercial or hospital environment

Guidance and manufacturer's declaration -- electro-magnetic immunity for equipment and systems that are not life-supporting

Guidance and Manufacturer's Declaration -- Electromagnetic Immunity
The DMD1046 is intended for use in the electromagnetic environment specified below. The user of the DMD1046 should ensure that it's used in this environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DMD1046, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = [3.5/V_1] \sqrt{P}$ $d = [3.5/E_1] \sqrt{P}^{80}$ MHz to 800 MHz $d = [7/E_1] \sqrt{P}^{800\ MHz}$ to 2.7 GHz

			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 distances in meters (m), interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- 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 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 the location in which the DMD1046 is used exceeds the applicable RF compliance level above, the DMD1046 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DMD1046.

USER INSTRUCTIONS

This manual is written and compiled in accordance with the council directive IEC 60601-1, IEC60601-1-11 and ISO 80601-2-61 for medical devices and harmonized standards. In case of modification and software updates, the information contained in this document is subject to change without notice. The manual describes, in accordance with the pulse oximeter's features and requirements, amin structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance, storage, etc. as well as the safety procedures to protect both the user and equipment.

Refer to the respective chapters for details.

Please read the manual very carefully before using this device. These instructions describe the operating procedures that should be strictly followed. Failure to follow these instructions can cause measurement abnormality, equipment damage, and personal injury. The manufacturer is not responsible for safety, reliability, and performance issues. The manufacturer is also not responsible for any monitoring abnormalities, personal injuries, and equipment damage due to the user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be entirely in accordance with the descriptions in the user manual. We sincerely regret any discrepancies.

This device is a medical device and can be used repeatedly.

Note: Please read the manual very carefully before using this device.

SAFETY

1. Instructions for safe operation

    a. Periodically inspect the device, cables, and transducers for damage that may impact patient safety or monitoring performance. It's recommended to inspect the device at least once per week. Stop using the device if there is visible damage.

b. Necessary maintenance must be performed only by qualified service engineers appointed by our company. Users aren't permitted to maintain the device by themselves.

c. The oximeter can't be used in combination with devices not specified in the user's manual. Only accessories appointed or recommend ed by the manufacturer can be used with this device.

d. The device was calibrated before leaving the factory.

2. Attention

a. Keep the device away from dust, vibration, corrosive substances, explosive materials, high temperatures, and moisture.

b. If the device gets wet, stop use immediately.

c. When the device is moved from a cold environment to a warm or humid environment, don't operate it immediately.

d. Don't use sharp objects to operate the switch on the front panel of the device.

e. High temperature or high pressure steam disinfection of the device isn't permitted. Refer to the corresponding chapter of this user manual for cleaning and disinfection instructions.

f. Don't immerse the device in liquid. When it needs to be cleaned, wipe its surface with medical ethanol. Don't spray any liquid directly onto the device.

g. Fingers that are too thin or too cold can affect measurement accuracy. Use a larger finger for testing, such as the thumb or middle finger. Ensure that the finger is deeply inserted into the probe for measurement.

h. Don't use this device on infants or neonatal patients.

i. The device is suitable for adults and children over four years old weighing between 33 lbs. and 242 lbs.

j. The device may not work for all patients. If you're unable to achieve stable readings, discontinue use.

k. If abnormal readings appear on the screen during use, remove the testee's finger and reinsert it to resume normal operation.

l. The device has a lifespan of three years.

m. The lanyard is made of material that may irritate sensitive skin. Don't use the lanyard if the testee has sensitive skin or is allergic to the lanyard. Don't wrap the lanyard around the neck.

n. The device has a low voltage alarm function. Only the low voltage notice is displayed. Replace the batteries when the battery voltage has been used up.

o. The device doesn't have an alarm function for exceeded limits. Don't use the device in circumstances in which alarms are required.

p. The maximum temperature of the device surface that makes contact with the testee is 41 °C.

q. The batteries must be removed if the device is going to be stored for more than one month. Otherwise, the batteries may leak.

r. Don't twist or pull the connection circuit.

3. Warnings

a. Explosive hazard: Don't use this device in an environment with flammable gas, such as ignitable anesthetic agents.

b. Don't use the device while the testee is being scanned by MRI or CT.

c. In use for optical treatment, follow the doctor's instructions.

d. To avoid dropping the device and potential damage, don't strand the lanyard. Don't wrap the lanyard around the neck.

e. People who are allergic to rubber should not use this device.

f. The disposal of a damaged device, accessories, and packaging (including batteries, plastic bags, foam, and paper boxes) should follow local guidelines.

g. Check packaging before use to ensure that the device and accessories are completely in accordance with the packing list. Otherwise, the device may malfunction.

h. Overuse of this device may cause pain or discomfort, especially for people with a microcirculatory disorder. Don't apply the sensor to the same finger more than once within two hours.

i. The SpO_2 probe can't be clipped to the edema and tender tissue.

j. The infrared light, which is invisible, is harmful to the eyes. Don't look directly at the light portion of the SpO_2 probe.

k. The testee shouldn't be wearing nail polish or other cosmetic products. The testee's fingernails should be trimmed.

l. For information on medical interactions and restrictions, please refer to relevant medical resources.

4. Tips for Proper Operation

a. Ensure proper finger placement to avoid inaccurate measurements.

b. The testee's arteriole should be positioned between the SpO_2 sensor and photoelectric receiving tube.

c. The SpO_2 sensor shouldn't be positioned near an arterial canal, blood pressure cuff, or an area receiving intravenous injection.

d. Ensure that no obstacles, like rubberized fabric, are obstructing the optical path.

e. Excessive ambient light may impact measurement results. This includes fluorescent light, dual ruby light, infrared heaters, direct sunlight, etc.

f. Excessive movement in the testee or extreme electrosurgical interference may affect the accuracy of the measurements.

g. Clean and disinfect the device after operation according to instructions provided in the user manual.

5. Clinical Restriction

a. The device takes measurements on the basis of arteriole pulse. So, the testee must have a substantial pulse to get an accurate measurement. If the testee has a weak pulse from shock, low ambient or body temperature, bleeding, or a vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

b. For those taking a substantial amount of staining dilution drug (methylene blue, indigo green, and acid indigo blue), carbon monoxide hemoglobin (COHb), methionine (Me+Hb), or thiosalicylic hemoglobin, the SpO_2 measurement from this device may be inaccurate. The SpO_2 measurement may also be inaccurate for some people with iceturus problems.

c. Drugs like dopamine, procaine, prilocaine, lidocaine, and butacaine may cause errors in SpO_2 measurements.

d. The SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia. Some patients with serious anemia may also report healthy SpO_2 measurement.

Notice: This device isn't intended for frequent, consistent monitoring in patients. Overrating a patient will cause problems when the patient is suffering from toxicosis from carbon monoxide. Use of the device isn't recommended for patients suffering from toxicosis.

PRINCIPLE OF THE OXIMETER

The data process formula uses of the Lambert Beer Law according to Spectrum Characteristics of Reductive Hemoglobin (HbO_2) in glow and near-infrared zones. The operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology so that two beams of different light wavelengths can be focused onto a human nail tip through a finger clamp sensor. The measurement can then be obtained by a photosensitive element and displayed on the screen through processing in electronic circuits and a microprocessor.

TECHNICAL SPECIFICATIONS

1. Main Function
   a. Display of SpO_2 value
   b. Display of pulse rate and bar graph
   c. Low battery indication
   d. Storage function of SpO_2 and heart rate
   e. Sync time function
   f. Display of steps, calories, and time
   g. Pedometer data storage
   h. Automatically change display direction
   i. Height, weight, and target calorie set by the server
   j. Extra low-power consumption setting
   k. Automatic blank screen state when there is no operation for one minute
   l. Data storage and upload to app via smart phone capable connection

2. Main Parameters
   a. SpO_2 measurement range: 0~100%
   b. Accuracy: 70%~100% +-2%, 0-69%: unspecified
   c. PR measurement range: 30 -250 bpm, accuracy: +- 2 bpm or +- 2%, whichever is greater

d. Resolution: SpO_2: 1%, PR: 1 bpm

e. Measurement performance in weak filling condition: SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is O.4%. SpO_2 error is +-4%, pulse rate error is +-2 bpm or +-2%, whichever is greater.

f. Resistance to surrounding light: the deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than +-1%.

g. Pedometer measurement: Measurement Range: O-65,535 steps, Resolution: 1 step

h. Memory function: record 1,OOO groups of SPO_2 data, 24-day pedometer data

i. Working Voltage: DC 3V

j. Optical sensor: red light (wavelength is 66O nm, 6.65 mW) , infrared (wavelength is 88O nm, 6.75 mW)

3. Smart Phone Compatible Specifications

a. Smart Phone Compatible Communication protocol: smart phone compatible communication low energy

b. USB protocol: none

c. Operating frequency: 2.4 GHz ISM band

d. Modulation: GFSK (Gaussian Frequency Shift Keying)

e. Transmitting Power: O dBm, -6 dBm, -23 dBm

f. Sensitivity: <= 84 dBm @ O.1% BER

g. Transfer Rate: 1 mbps

h. Safety Features: authentication and encryption

i. Support services: Smart Phone Compatible Data Transfer

j. FCC ID: 2ABOGCMS5OD-BT

4. Environmental Requirements

a. Storage Environment

i. Temperature: - 4O deg. C. ~+ 6O deg. C.

ii. Relative humidity: <= 95%

iii. Atmospheric pressure: 5OO hPA ~ 1O6O hPa

b. Operating Environment

i. Temperature: 1O deg. C ~ 4O deg. C

ii. Relative Humidity: <= 75%

iii. Atmospheric pressure: 7OO hPA ~ 1O6O hPa

GOT MORE QUESTIONS?

Check out our list of Frequently Asked Questions at **vhealth.link/wwi** for helpful answers.

And if that doesn't answer your question, our customer service team would love to help! Feel free to connect with them by phone, e-mail, or chat on our website.

service@vivehealth.com

1-800-487-3808

vivehealth.com