MANUFACTURED FOR

North American market /
Marché Nord Américain

BEWELLCONNECT CORP
185 Alewife Brook Parkway 410
CAMBRIDGE - MA 02138 - USA
support.bewell-connect.com
www.bewell-connect.com

European market /
Marché Européen

VISIOMED GROUP SA
112, Avenue Kléber
75116 PARIS - France
contact@visiomed-lab.fr
Tel : +33 (8) 92 350 366
(0,34€/mn)
www.visiomed-lab.com
www.bewell-connect.fr

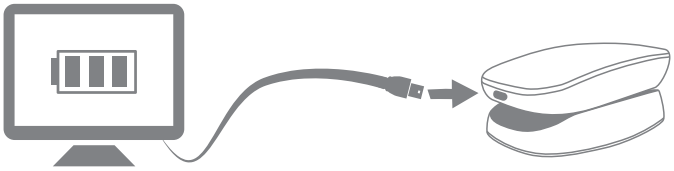
MyOxy

BW-OX1

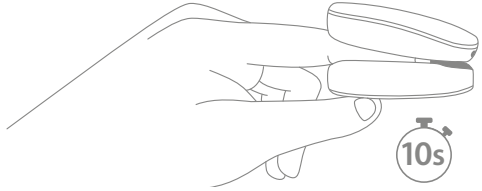
By Visiomed

A

B



C



1. Readings screen
2. USB port
3. SpO_2 level
4. Pulse rate
5. Bluetooth LED
6. Signal indicator
7. Battery indicator

SAFETY PRECAUTIONS

	Caution
	Keep dry
	Refer to instruction manual. Note on the equipment "Follow instructions for use".
	The device, accessories, and the packaging must be disposed of correctly at the end of usage. Please follow local ordinances and regulations for disposal.
	Pulse frequency
SpO_2	Hemoglobin saturation in oxygen
PRbpm	Pulse rate (BPM = beats per minute)
	No SpO_2 alarm
IP22	Protection against accidental water spray
SN	Serial number
	Federal Communications Commission approval
FCC	FCC ID: 2AB359322-0B

SN Serial number

SN: ☐☐☐☐ ☐☐ ☐☐ ☐☐☐☐☐

Year Month Day Serial number

EN

MyOxy

BW-OX1

By Visiomed

COMPLIANT WITH EUROPEAN STANDARDS AND WITH PART 15 OF THE FCC RULES.

CONTENTS

Find out how to install and use the BewellConnect® application by visiting our website **www.bewell-connect.com/bewellconnect-app**

The manufacturer reserves the right to modify the technical characteristics of the product without prior notice.

Dear Customer,

Thank you for purchasing MyOxy, the BewellConnect® digital pulse oximeter. We hope that you enjoy using it and recommend reading this user guide carefully to measure your arterial oxygen saturation (SpO_2) and your pulse rate (PRbpm) effectively.

1. WARNING

- Only use this device for the purpose for which it was designed as outlined in this guide.
- This device is adapted for spot-checking in hospitals and hospitals facilities.
- Use this device in a temperature range between 41°F and 104°F / 5°C and 40°C.
- Do not expose this device to extreme temperature conditions (over -13°F / 70°C or minus 158°F / 25°C).
- Do not use this device in over 93% of relative humidity.
- This device must always be kept in a clean and dry place.
- Do not expose the device to sunlight or water.
- Do not expose the device to electric shocks.
- Do not drop the device.
- Follow the maintenance instructions given in this guide.
- Do not try to open the device. In the event of malfunctions, contact your customer service.
- Keep out of reach of children.
- The measurement results are given as a guide. If you have any doubts about your results, please contact your doctor.
- Stop using the device in the event of an anomaly or malfunction.
- This device is not designed for use by people (including children) with reduced physical, sensory or mental capacities, or by people lacking experience or knowledge, unless they are assisted by a person who is responsible for their safety and supervision or who has been given instructions about using this device.

2. INFORMATION

2.1. OXYGEN SATURATION (SpO_2)

Oxygen saturation measures the percentage of hemoglobin binding sites in the bloodstream that is occupied by oxygen. Many factors can modify hemoglobin's affinity for oxygen and reduce oxygen saturation in the blood. A finger pulse oximeter can help monitor oxygen saturation.

ANALYSIS OF RESULTS	
***Warning** : This table DOES NOT apply to individuals already suffering from certain illnesses (e.g. asthma, heart disease, respiratory diseases) or who are at altitudes above 4921 feet / 1500 meters. If you are already suffering from a disease, always consult your doctor to analyze your results. If you have any doubts about your results, contact your doctor.*	
SpO_2 (peripheral capillary oxygen saturation) result as a %	**Diagnosis**
99 - 95	Normal level
94 - 90	Reduced level (medical visit recommended)
< 90	Critical level : consult a doctor immediately or call for emergency help

Reference: World Health Organization (WHO): Pulse Oximetry Training Manual, 2011.

FALL IN PERIPHERAL CAPILLARY OXYGEN SATURATION DUE TO ALTITUDE		
***Please note**: The following table gives information about the effects of different altitudes on oxygen saturation levels as well as their effects on the human body. The following table DOES NOT apply to individuals already suffering from certain illnesses (e.g. asthma, heart disease, respiratory diseases). In people already suffering from illness, the symptoms (e.g. hypoxia) may already occur at low altitudes.*		
Altitude	**SpO_2 (peripheral capillary oxygen saturation) result as a %**	**Consequences for the individual**
1500 - 2500 m	**> 90**	No mountain sickness (in general)
2500 - 3500 m	**~ 90**	Mountain sickness, adaptation recommended
3500 - 5800 m	**< 90**	High probability of mountain sickness, adaptation imperative
5800 - 7500 m	**< 80**	Severe hypoxia, only a stay for a limited period of time is possible
7500 - 8500 m	**< 70**	Immediate life-threatening danger

Reference : Hackett PH, Roach RC: High-Altitude Medicine. Dans : Auerbach PS (ed): Wilderness Medicine, 3e édition ; Mosby, St.Louis, MO 1995 ; 1-37.

2.2. PULSE

Warning: the results below show the average for a person in good health whose measurements are taken in a calm environment.
An individual may have a higher or lower pulse rate as a result of numerous factors (illness, regular exercise, medical treatment, etc.).
In the event of irregularities in your results (lower or higher pulse rate than normal), we advise you to consult your physician.

ASSESSMENT OF RESULTS			
Normal pulse rate result (in beats per minute)	**High pulse rate result (in beats per minute)**	**Low pulse rate result (in beats per minute)**	**Age range**
120 - 150	**> 150**	**< 120**	Infant
80 - 150	**> 150**	**< 80**	Child aged 1 - 5
60 - 120	**> 120**	**< 60**	Child aged 5 - 12
60 - 105	**> 105**	**< 60**	Adolescent
60 - 80	**> 100**	**< 50**	Adult
90	**-**	**-**	Elderly person

Reference: Mistovich, Joseph J., Brent Q. Hafen, and Keith J. Karren. Prehospital emergency care. Prentice-Hall, Inc., 2007

3. FEATURES

The digital pulse oximeter is a portable device designed for occasional monitoring of arterial oxygen saturation (as a % of SpO_2) and pulse rate (PR) in beats per minute (bpm) on adults and children, in hospitals, health centers and at home. It should not be used for continuous monitoring (it does not include an alarm signalling an abnormal result).

- Simple and practical to use.
- A compact product that is light and easy to carry around.
- LED display.

4. USING THE OXIMETER

4.1. DESCRIPTION

The Bluetooth LED flashes red when searching for the Bluetooth signal and is fixed red when the connection is made.
If the screen shows "?", it means the signal is unstable. You need to take the reading again.
The battery indicator flashes when the battery is low. The device must be recharged using the USB cable (*See figure B page 2*).

4.2. PRECAUTIONS BEFORE USE

- Do not use this device near an Electrosurgical Unit (ESU), since it may function incorrectly as a result.
- The pulse oximeter must be placed so that the pulse can be recorded correctly and the main objective is to evaluate the oxygen saturation (SpO_2) level. Check that nothing is interfering with the readings.
- Do not use the device in an MRI (Magnetic Resonance Imaging) or CT (Computed Tomography) environment.
- Do not use this device in situations requiring the presence of an alarm.
- Do not use the device in hazardous environment.
- This device is not designed to be used while the user is being transported.
- The device must not be used near or on top of another device.
- The device must not be used when it is charging.
- Do not insert anything into the device except the USB cable during charging.
- Respect the temperature ranges and humidity levels shown in the specifications.

Inaccurate readings may result from :

- Nail-polish (colorimetric interference) or artificial nails
- High levels of dysfunctional hemoglobin (carboxyhemoglobin or methemoglobin)
- Intravascular dyes (indocyanine green or methylene blue)
- Bright light. If necessary, protect the sensor positioning area
- Excessive movement of the user
- Defibrillators and interference from high-frequency electrosurgical devices
- Venous pulse

- Placing the sensor on a user with a blood-pressure cuff, an arterial or intravascular catheter
- High blood pressure, severe vasoconstriction, acute anemia or hypothermia
- Heart failure
- Stress
- Poor pulse quality (low perfusion)
- Low level of hemoglobin.

4.3. RECOMMENDATIONS BEFORE TAKING MEASUREMENTS

- When using the device for the first time, make sure that the battery has been charged via the USB port. Connect the USB cable of the device to a computer to charge it. Once the device has been charged, you can disconnect the USB cable.
- Avoid eating, smoking or exercising for 30 minutes before measuring your oxygen saturation.
- Remain calm for 15 minutes before the measurement.
- Keep still and do not speak during the measurement.

4.4. DOWNLOADING THE APPLICATION

The following information may be updated.

Download the BewellConnect® application to your smartphone or tablet :
- via the App Store or Google Play
- by scanning the QR Code on the side of the box.

Then click on the **My**Oxy icon.
The results are immediately transferred by the application via Bluetooth 4.0 Smart Ready.

4.5. HOW TO TAKE MEASUREMENTS

See figure C page 2
Insert your finger (generally the index finger) into the device. The fingernail must be facing upwards. The device turns itself on automatically when a finger is inserted. The readings appear on the device screen. When the result flashes, the data has been transferred to the application.
Important : the data will only be transferred to the application if the application is open while the device is being used and Bluetooth 4.0 Smart Ready is activated.
The device switches off automatically after eight seconds.
If it is difficult to obtain a reading, try with the other hand or with another finger on the same hand.

5. CLEANING AND MAINTENANCE

- To clean the silicone inside the oximeter that comes into contact with the finger, use 70°

rubbing alcohol. Apply the alcohol using a soft clean cloth. Also use the rubbing alcohol to clean the finger being measured, before and after use.

- Do not pour or spray liquid on to the surface of the oximeter. Make sure that liquid does not come into contact with the device openings. Leave the oximeter to dry before using again.
- Do not sterilize the device in an autoclave, with ethylene oxide or by immersing it in liquid. The device must not be sterilized.

6. TECHNICAL SPECIFICATIONS

Product name	BewellConnect® **My**Oxy
Model	BW-OX1
Classification	Classe II Applied part type BF IPX22
Display type	LED screen
LED Specifications	Wavelength: Red = 660 ±3nm - Infrared = 905 ±10nm Radiant power : Red = 3.2mW - Infrared = 2.4mW
Dimensions	1.3 x 1.3 x 2.4 in / 32 x 32 x 62 mm
Weight	1.41 oz / 40 g
Display and measuring ranges	SpO_2 : Display range : 35 - 99% / Measuring range : 70 - 99% Pulse: Display and measuring ranges: 30 - 250 bpm
Accuracy	SpO_2 : 70 - 100% : ± 3% Pulse : ± 2 bpm
Resolution	SpO_2 : 1% Pulse : 1 bpm
Normal working conditions	Temperature : 41°F - 104°F / 5°C - 40°C Humidity : 15-93%RH
Storage conditions	Temperature : -13°F - 158°F / -25°C - 70°C Humidity : ≤93%RH Atmospheric pressure : 86-106Kpa
Technology	Bluetooth 4.0 Smart Ready
Battery	Lithium 280mAh
Autonomy	400 readings
Automatic shut-down	8 seconds
Bluetooth transmission distance	10m
Frequency	2400 - 2483.5MHz
USB	USB port 2.0
Accessories provided	Pulse oximeter, instruction manual, protective pouch, USB cable

7. TROUBLESHOOTING

If one of the following issues arises when using your **My**Oxy, consult this trouble-shooting guide. If the problem continues, please contact our customer service department at www.support.bewell-connect.com.

ISSUE	POSSIBLE CAUSE	SOLUTION
$Sp0_2$ or PRbpm do not appear correctly	Your finger must be correctly inserted.	*Change the position of your finger and try again.*
	SpO_2 reading too small to be measured.	*Try several times. If you have any doubts about a problem related to the product, seek medical attention to obtain an accurate diagnosis.*
$Sp0_2$ or PRbpm are unstable	Your finger may not be inserted deeply enough.	*Change the position of your finger and try again.*
	The user's finger is trembling or the user is moving.	*Try not to move.*
Impossible to turn on the device	Battery low	*Recharge the device with the USB cable*
	Oximeter is damaged	*Contact customer service*
The indicator lights turn off	The device switches itself off automatically after eight seconds when a signal is not detected.	*Normal*
	Low battery	*Recharge the device with the USB cable*
Error3	Low battery	*Recharge the device with the USB cable*
	Oximeter is damaged	*Contact customer service*
Error7	Low battery	*Recharge the device with the USB cable*
	Oximeter is damaged	*Contact customer service*
No data transferred to your smartphone/ tablet	Bluetooth connection deactivated	*Activate the Bluetooth on your smartphone/tablet*
	Smartphone or tablet incompatible	*Check that your smartphone or tablet has Bluetooth 4.0 Smart Ready and that your operating system is up to date*

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the retailer or an experienced radio/TV technician for help.

WARRANTY

WARRANTY CARD / CARTE DE GARANTIE
Purchase date Date :..... / ..... / .....
Serial number SN: .....
Retailer's seal Stamp

EN: The Bewellconnect® device limited warranty provides that the Bewellconnect® devices will be free from material defects impacting performance in accordance with the documentation for a period of one (1) year when used under normal conditions consistent with the documentation, subject to the terms and limitations set forth below.
The Bewellconnect® device limited warranty is granted only to the original purchaser of the Bewellconnect® device, and is non-transferable. For the sake of clarity, in the case of a refurbishment of the Bewellconnect® device for the use of a different end-user during the original one-year term of the Bewellconnect® device limited warranty, the Bewellconnect® device limited warranty shall continue to be in effect for the remainder of such original one-year term. A purchase invoice or other proof of purchase will be required for after-sales service, in accordance with the Bewellconnect® device limited warranty. The purchase invoice is mandatory to be able to benefit from the Bewellconnect® device limited warranty.
The Bewellconnect® device limited warranty will be invalidated where serial numbers on products are changed, replaced, illegible, absent or if a repair has been made without any outcome by any unauthorized service, including the user.
The Bewellconnect® device limited warranty covers only defective equipment or parts, and only defects that arise during normal use of the product for its intended purpose in accordance with the documentation. It does not cover damage caused during the dispatch or carriage of the device, caused by repairs made by a distributor, by alterations made, by the connection of equipment not approved by Bewellconnect®, or caused by use that is contrary to the documentation. Furthermore, the Bewellconnect® device limited warranty does not cover damage related to items being dropped, improper handling, improper installation, fire damage, flood, lightning, or any other natural disaster.
The Bewellconnect® device limited warranty does not cover product packaging, accessories, or any defective appearance due to the display of the product for sale, in showrooms, retail outlets, for demonstration purposes, etc. Normal use, cleaning and replacement of parts with normal wear and tear are not covered by the terms of this guarantee.
Repair or replacement of the defective Bewellconnect® device is the customer's sole remedy for the Bewellconnect® device limited warranty, or, if the defective Bewellconnect® device cannot be repaired or replaced, refund of the amounts paid by the customer for the defective Bewellconnect® device will be the customer's sole remedy.
BEWELLCONNECT® PROVIDES ONLY THIS BEWELLCONNECT® DEVICE LIMITED WARRANTY, AND MAKES NO OTHER WARRANTIES OF ANY KIND. WITHOUT LIMITING THE FOREGOING, BEWELLCONNECT® EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER ORAL OR WRITTEN, EXPRESSLY IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN TRADE. BEWELLCONNECT® SHALL NOT BE RESPONSIBLE FOR ANY WARRANTIES OR GUARANTEES GRANTED BY ANY DISTRIBUTOR OR OTHER THIRD PARTY.
TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL BEWELLCONNECT® OR ANY OF ITS AFFILIATES BE LIABLE WITH RESPECT TO ANY BEWELLCONNECT® DEVICE FOR (a) ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, RELIANCE OR PUNITIVE DAMAGES, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS, OR (b) ANY DIRECT DAMAGES IN EXCESS OF THE PRICE THAT CUSTOMER PAID FOR THE BEWELLCONNECT® DEVICE

EN: *The device, accessories, and the packaging must be disposed of correctly at the end of usage. Please follow local ordinances and regulations for disposal.*

© 02/2017 BW-OX1

EN: *BewellConnect® is a brand registered by Visiomed Group SA. The constructor keeps the right to modify the photographs and characteristics without previous notice. Registered design. The logos and trademarks are the property of their respective owners.*