

Oxy9Wave

User's Manual

Pulse Oximeters

Rev. 1.54

2023.05.22



Warning

To ensure proper use of this medical equipment, you must read and comply with this user manual.

Oxy9Wave User Manual

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Before using Bionet devices, read all the manuals that are provided with your device carefully.

Patient monitoring equipment, regardless of the complexity of the equipment, should never be used as a substitute for the patient care, attention, and critical judgment that only trained health care professionals can provide.

Warranty Period

- This product was made with strict quality control and examination procedures of our company. Criteria of compensation on the repair or replacement of the product follow the 'consumer damage compensation regulations' from Fair Trade Commission.
- Warranty period of this product is regulated to be 1 year. However, accessory warranty period is six months.
- In case of breakdown during the normal usage, service center of our company will repair for free during the warranty period.
In case of the issues on the device during the warranty period, please notify our company of the model name, manufacturing number, purchasing date and breakdown of the device.

Caution
Federal law restricts this device to sale by or on the order of a physician

Notes
The product does not have shelf life. Its expected use life is 6.5 years. After 6.5 years, though the product still works normally, it is recommended to have it checked by Bionet.

Contact Bionet

If you have any questions or comments relating to our products or purchasing, please contact the telephone numbers or E-mail below. You can talk to our sales people. Bionet always welcomes your enquiries. Please contact us.

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※ In the event of a malfunction or failure, contact Service Dept. Of Bionet Co., Ltd. along with the model name, serial number, date of purchase and explanation of failure.

Paid Service

If requesting the service without the breakdown, fee is charged. Therefore, make sure to read the user manuals.

<ul style="list-style-type: none"> - In case of simple checkup without user instructions or disassembly - In case of re-installation due to poor installation from the stores 	<p>Paid service from the second time Free for the first time</p>
<ul style="list-style-type: none"> - Poor installation from the movement of products or move out - In case of re-installation from purchasing after the installation from the request of a client - In case of re-installation from poor installation by a consumer - In case of request for the service from foreign substances or poor cleaning 	<p>Paid service from the first time</p>

1. Machine cleaning, adjustment, or instructions do not constitute breakdown of a product.

(Apply separate criteria if repair is not available)

2. In case of faults by a consumer

In case of breakdown from reckless of consumers for handling or wrong repair

- In case of breakdown by using the product in wrong electronic capacity
- In case of breakdown or damage by the falling while moving the product after the installation
- In case of breakdown with consumables or optional items not designated by the company
- In case of breakdown from repair by a person does not engineer from Bionet Corporation or branches

3. Other cases

- In case of breakdown by natural disasters (fire, damage from sea wind, flood damage, or earthquake, etc.)
- In case of expired life span (accessories)

REVISION HISTORY

Revision No.	Date	Contents	Page
1.00	2021-04-14	- Create New	All
-			
1.52	2021-11-15	<ul style="list-style-type: none"> - Reflects UI additions in the manual according to password additions. - Add installation and usage of Oxy9Wave Viewer - Change low alarm LED color to blue 	All
1.53	2023-02-23	<ul style="list-style-type: none"> - Add Warranty Period - Add Paid Service - Revision History Additional - Deleting a European Agent - Change to overseas email 	All
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Table of Contents

Intended Use	10
Functional safety.....	10
Warning, Caution, Note	11
Define groups.....	12
General precaution on environment	13
Electromagnetic Compatibility.....	15
1. Basic.....	16
1.1 General description.....	16
1.2 Principle of operation	16
1.3 Safety information	17
1.4 Electric safety precautions	18
1.5 Equipment connection	19
1.6 Biocompatibility	19
1.7 Product Configuration	20
1.8 Basic Unit.....	21
1.9 Device Markings.....	23
1.10 Power.....	24
1.11 Battery Power	25
1.12 How to Use the Sensor and Precautions.....	30
1.13 Connecting a sensor to Oxy9Wave.....	32

1.14 Connecting a clamp.....	32
1.15 Connecting a computer.....	33
2. Operation.....	34
2.1 Introduction	34
2.2 Basic Setup	34
2.3 Details of Use.....	35
2.3.2.1 Signal and Data Validity.....	37
2.4 Factory-preset default values.....	53
3. Alarm	55
3.1 Overview	55
3.2 Alarm priority.....	55
3.3 Visual alarm indication	55
3.4 Audible alarm indication	56
3.5 Alarm Audio paused (Silence).....	56
3.6 Alarm password.....	57
4. Maintenance and Troubleshooting	59
4.1 Inspection Equipment	59
4.2 Inspection Cables	59
4.3 Maintenance Task and Test Schedule.....	60
4.4 Trouble Shootings.....	60
5. Install and Use the Program.....	62
5.1 Installing the Program	62
5.2 How to use Oxy9Wave Viewer PC program	62
6. Clean and Care.....	64
6.1 Overview	64
6.2 Monitor and Peripherals.....	65

6.3	Care	66
7.	Technical Specification.....	67
7.1	Overview	67
7.2	EMC Compatibility (EMC).....	67
7.3	System Specification.....	71
	Product Certificate.....	73

Intended Use

Oxy9Wave (Pulse Oximeter) is designed to measure SPO₂ (arterial hemoglobin) and pulse rate using the non-invasive method on unconscious patients.

By simply connecting the sensor to a patient, the operator or doctor can see the SPO₂ level quickly and easily.

No special training is needed for the measurements; this unit is designed to be easy to use and read. Oxy9Wave is suitable for use in rooms. When you move outdoors, the unit can be operated off the charged battery.

The targeted patients are not relating to their skin color, age or gender.

Note
All Bionet hardware and screenshots in this user guide are for illustration purposes only. Actual products or screens may vary slightly.

Functional safety

The essential performance of the Pulse Oximeters is to provide the clinician with meaningful parameter values and to sound an alarm when the established parameter value is exceeded or the function that provides the value is not working properly. We assessed the risks associated with the use of these monitors considering these essential performance features and mitigated the risk of lowering the residual risk to a level that could be used without compromise if the product maintained its regular lifecycle maintenance and service recommendations.

Warning, Caution, Note

The following terms are defined in the User Guide to emphasize the agreement as follows:

The user must follow all warnings and precautions.

The specifications and functions shown in this manual are subject to change without prior notice.

Warning

"Warning" A warning contains important information regarding possible danger to you or the patient that is present during normal operation of the equipment

Caution

"Caution" A caution provides information or instructions that must be followed to ensure proper operation and performance of the equipment.

Note

"Note" A note presents information that helps you operate the equipment or connected devices.

Define groups

The define groups for this product are users, service personnel, and experts.

Define groups should read the user manual before using the product and be trained in the use, installation, reprocessing, maintenance, and repair of the product.

This product can only be used, installed, reprocessed, maintained, and repaired by a defined group.

User

Users use the product for their intended use.

Service personnel

Service personnel are responsible for the maintenance of the product.

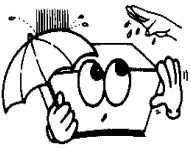
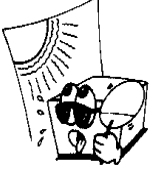
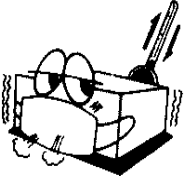
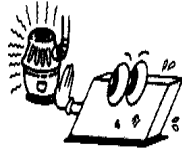
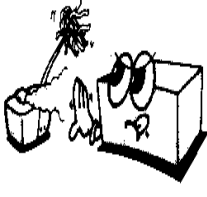
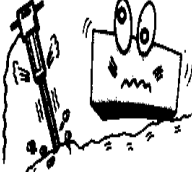


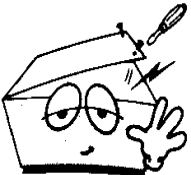

They must be trained in the maintenance of the medical device, install, reprocess, and maintain the product.

Expert

The specialist repairs the product or performs complex maintenance tasks. The expert Have the knowledge and experience to perform complex maintenance tasks on your product.

General precaution on environment

– Do not keep or operate the equipment in the environment listed below.

	<p>Avoid placing in an area exposed to moist.</p> <p>Do not touch the equipment with wet hand.</p>		<p>Avoid exposure to direct sunlight</p>
	<p>Avoid placing in an area where there is a high variation of temperature.</p>		<p>Avoid in the vicinity of Electric heater</p>
	<p>Avoid placing in an area where there is an excessive humidity rise or ventilation problem.</p>		<p>Avoid placing in an area where there is an excessive shock or vibration.</p>
	<p>Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.</p>		<p>Avoid being inserted dust and especially metal material into the equipment</p>
	<p>Do not disjoint or disassemble the equipment.</p> <p>We take no responsibility for it.</p>		<p>Power off when the equipment is not fully installed.</p> <p>Otherwise, equipment could be damaged.</p>

Electromagnetic Compatibility

The monitor has been designed and tested for compliance with current regulatory standards as to its capacity to limit electromagnetic emissions (EMI), and also as to its ability to block the effects of EMI from external sources.

The monitor complies with the following standards pertaining to EMI emissions and susceptibility: EN60601-1-2.

To reduce possible problems caused by electromagnetic interference, we recommend the following:

- Use only Bionet approved accessories.
- Ensure that other products used in areas where patient monitoring and life support is used comply to accepted emissions standards (CISPR 11, Class A).
- Try to maximize the distance between electro-medical devices. High-power equipment related to electrical simulators, electrosurgical instruments, and radiators (X-ray machines) as well as evoked potential devices may cause monitor interference.
- Strictly limit exposure and access to portable radio frequency sources (e.g., cellular phones and radio transmitters). Be aware that portable phones may periodically transmit even when in standby mode.
- Maintain good cable management. Do not route cables over electrical equipment. Do not intertwine cables.
- Ensure all electrical maintenance is performed by qualified personnel.

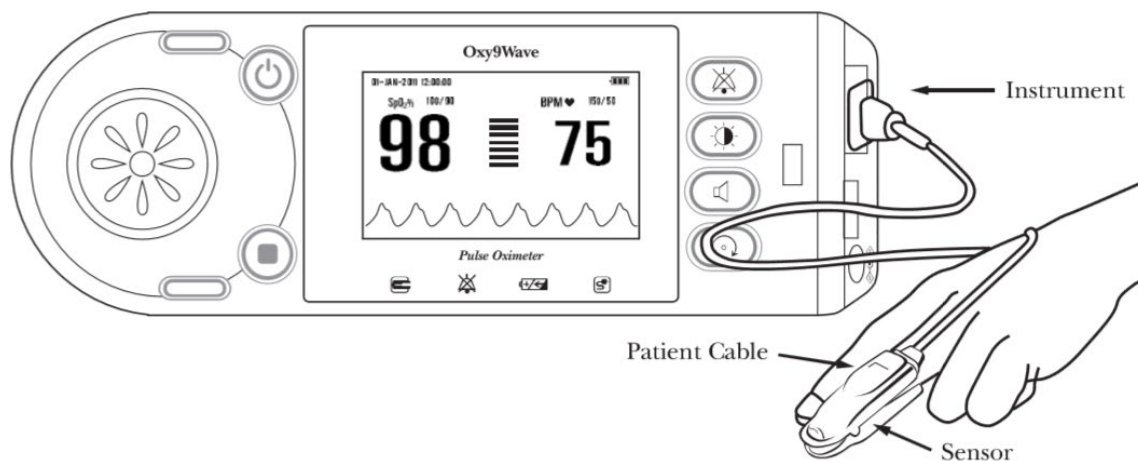
Caution
Infectious devices and parts must be sanitized and cleaned before disposal.

1. Basic

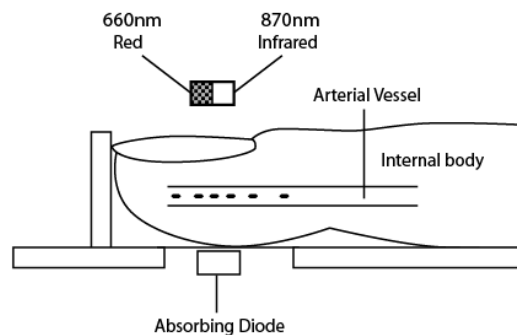
1.1 General description

Oxy9Wave (Pulse oximetry) is a continuous, non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient – usually on the fingertip for adults—and the hand or foot for neonates. The sensor is connected to the pulse oximetry instrument with patient cable, collecting signal data from the patient and sending it to the instrument

The following figure shows the general monitoring setup:



1.2 Principle of operation



Oxy9Wave uses the difference in absorbance that occurs when two lights with unique wavelength pass through a substance with different density. The principle of spectrum

measurement is used. Specifically, it measures the ratio of absorbed red(660nm) and infrared (870nm) light generated from these two light sources using the oxygen sensor after passing through an artery such as that in the fingers while the heart is beating. In other words, it uses the nature of absorbing more red light when passing through dark red blood - which contains less oxygen -- and absorbing more infrared light when passing through scarlet blood -- which contains lots of oxygen

1.3 Safety information

Warning

- Explosion hazard: Do not use the pulse Oximeter near flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- The pulse oximeter cannot be used as an apnea monitor.
- A Pulse Oximeter should be considered an early warning device. Given the trend toward patient hypoxemia, blood samples should be analyzed by laboratory instruments to understand the patient's condition completely.
- Severe anemia may cause erroneous SpO₂ readings.
- Do not use the pulse oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- When using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed the irradiation, the reading may be inaccurate, or the unit may read zero for the duration of the active irradiation period.
- In case of home use, make sure that the pulse oximeter's alarm can be heard from other rooms in the house especially when noisy appliances such as vacuum cleaner, dishwasher, clothes dryer, television, or radio are being used.
- Do not place the pulse oximeter in an area where the controls can be changed by the patient.
- Patient Safety – If a sensor is damaged in any way, discontinue use immediately.

- High oxygen levels can make premature babies vulnerable to retrolental fibroplasia. When this is the case, do not set the maximum alarm limit to 100%, such as the effect of turning off the alarm. Percutaneous SpO₂ monitoring is recommended for premature infants receiving supplemental oxygen.

Caution

- Do not place the pulse oximeter or accessories in a place that may cause it to fall on the patient. Do not lift pulse oximeter by the power cord or any other cable.
- Failure of Operation – If the pulse oximeter fails any part of the setup procedures or leak tests, discontinue the operation of the pulse oximeter until qualified service personnel have corrected the situation.

1.4 Electric safety precautions

Caution

Please check the following before using the product.

1. Be sure that AC power supply line is appropriate to use. (AC100 - 240V)
2. Be sure that the power source is the one supplied from Bionet. (5VDC 2.0A, BPM010 Made in BridgePower Co., Ltd.)
3. Be sure that the entire connection cable of the system is properly and firmly fixed.
4. Be sure that the equipment is completely grounded. (If not, there might be the problem occur in the product.)
5. The equipment should not be placed in the vicinity of electric generator, X-ray, broadcasting apparatus to eliminate the electric noise during operation. Otherwise, it may cause incorrect result.

Caution

The Equipment should be placed far from generator, X-ray equipment, broadcasting equipment or transmitting wires, to prevent the electrical noises from being generated during the operation, when these devices are near the Equipment, it can produce inaccurate measurements. For Oxy9Wave both independent circuit and stable grounding are essentially required. If the same power source is shared with other electronic equipment, it can also

produce inaccurate output.

Note

Oxy9Wave is classified as follows:

- Oxy9Wave classifies as Class II, BF concerning electric shock. It is not proper to operate this Equipment around combustible anesthetic or dissolvent.
- Noise level is A class regarding IEC/EN 60601-1, and the subject of Noise is A level concerning IEC/EN60601-1-2.

Warning

In case the Equipment does not operate as usual or damaged, do not use on patient, and contact to the medical equipment technician of the hospital or the equipment supply division.

1.5 Equipment connection

Caution

Doctors and patients in hospitals are exposed to the risk of uncontrollable currents. This current is caused by a potential difference between the equipment and a conductive object that can be contacted. Use auxiliary equipment to meet this requirement in accordance with IEC 60601-1.

1.6 Biocompatibility

When used as intended, the parts of the product described in this operator manual, including accessories that are in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions about this matter, please contact Bionet or its representatives.

1.7 Product Configuration

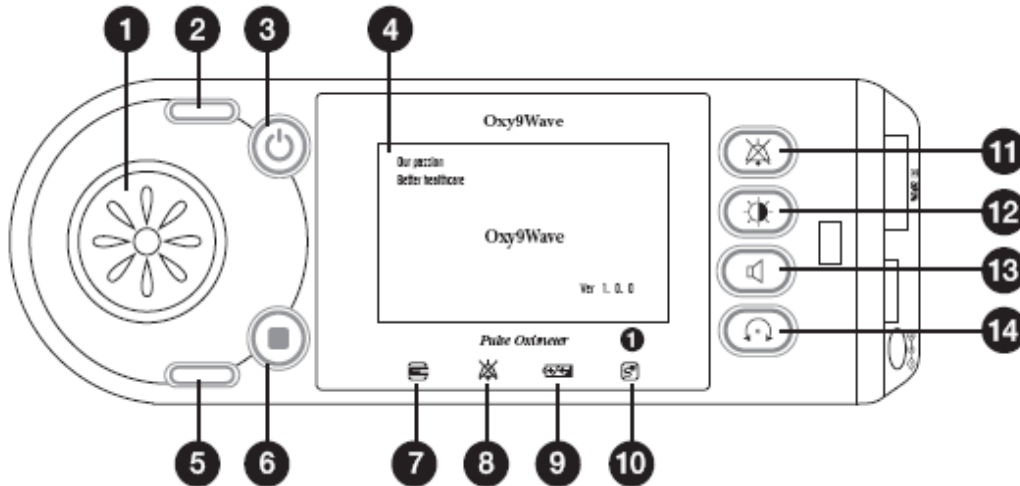
1. Oxy9Wave Main Body	1 EA
2. Adaptor	1 EA
3. SpO ₂ Sensor	1 EA
4. Lithium-ion Battery	1 EA
5. Pole Clamp	1 EA
6. User Manual	1 EA
7. Power Cord	1 EA
8. Patient Cable	1 EA
9. USB cable (Option)	1 EA
10. Setup CD (Option)	1 EA

Warning

In Electric shock hazard: Do not open the pulse oximeter cover except to replace the battery of the Handheld unit. Only a qualified operator may perform the maintenance procedures specifically described in this manual. Refer the servicing to Bionet for repair of this equipment.

1.8 Basic Unit

Front view

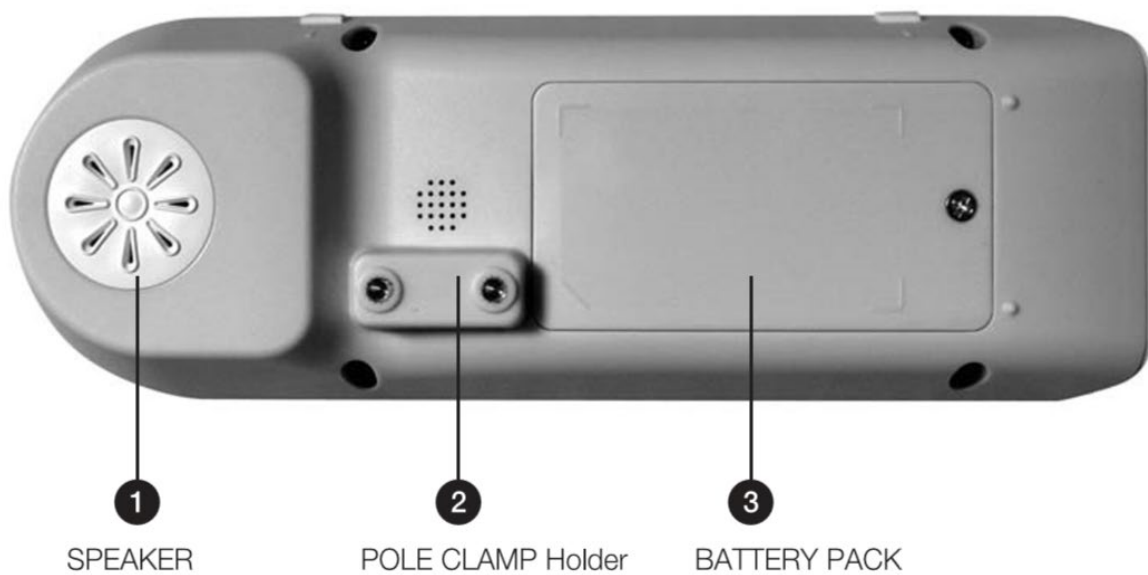


- | | | | |
|---|----------------------|----|------------------------------|
| 1 | Speaker | 8 | ALARM Silence Indicator |
| 2 | ALARM LED | 9 | BATTERY Charging Indicator |
| 3 | POWER ON/OFF Button | 10 | POWER Indicator |
| 4 | DISPLAY Monitor | 11 | Alarm Silence Setting Button |
| 5 | PULSE RATE LED | 12 | BACKLIGHT Setting Button |
| 6 | MENU Button | 13 | Pulse beep Setting Button |
| 7 | SENSOR OFF Indicator | 14 | Rotate Display Button |



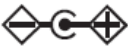


















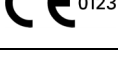


Side view



Back side view



1.9 Device Markings

	Caution: Consult accompanying documents		TYPE BF APPLIED PART
	Connect DC power (Existing)		DC Input Indicator
	USB port		Power button on/off
	Menu button		IP (Ingress Protection)
	Alarm silence		Alarm OFF
	Screen brightness Adjusted as one of 5 levels based on the brightness		Pulse beep Volume Adjusted as one of 5 levels based on the volume
	Screen rotation		Data Save
	Back to the previous mode icon		Enter/Go to
	Up/Change setting		Down/Change setting
	Battery charging		WEEE (Waste Electrical and Electronic Equipment)
	Date of manufacture		European Medical Device Directive 93/42/EEC
	Consult instructions for use. This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.		Safety Sign: To signify that the instruction manual must be read. Reading the instruction manual before starting work or before operating equipment.

1.10 Power

The Oxy9Wave monitor uses a DC adapter (100-240 VAC / 5VDC 2.0A). In the event of a power outage or cable shortage, the monitor automatically switches to battery power to continue patient monitoring without data loss. The built-in battery is intended for back-up use only during power-off.

DC Product information

Manufacture: BridgePower Corp.

Model name: BPM010S05N07

Input Power: 100~240V 0.3A

Output Power: 5 Vdc, 2.0 A



DC Power LED is lighted on when the DC Power is plugged into the inlet on the side of the product. A press of power key makes the machine ready for use.

If you use the adaptor of other companies, the Power LED will flicker, and the battery will not charge. Take the necessary caution.

Caution

- This equipment must be connected to a protective earth grounded power supply.
- Using non-standard products other than the adapters supplied by us may cause signal distortion or noise. Be sure to use a genuine adapter that is supplied by our company and is insulated.

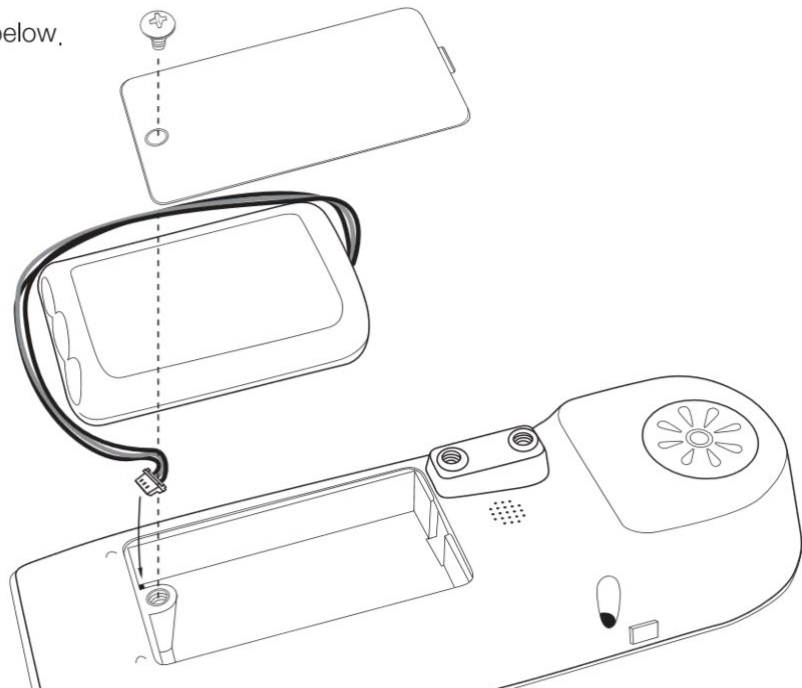
Note

- Appliance inlet of separate power supply unit is used as mains disconnecting device.

1.11 Battery Power

Battery power can be supplied to enable portable use or for use in case of power failure. The battery is attached to the bottom of the equipment.



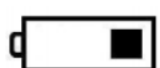
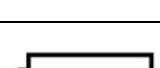
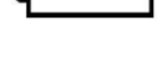
Connect the battery as shown below.



1.11.1 Operation

1. The Battery Power LED lights up when the machine is in use.
2. Battery power lasts for 15 hours.
3. The battery is automatically charged when the machine is connected to DC Power Supply. The Battery LED lights up after blinking.

4. The charging status of the batteries is displayed as 4 boxes, each indicating a different charging level.

Battery charge/discharge display		
Display	Charging State	Description
	Your battery is fully charging	Not applicable
	Your battery is middle charged	Not applicable
	Your battery is low charged	If possible, connect it to the AC adapter.
	Your battery is charged at 10% (The power will turn off about 5min.)	Immediately connect the monitor to the AC adapter.
	There is no built-in battery.	Connect the battery.

Caution

The battery charge display is displayed correctly only when the battery is operating normally.

Note

If no AC power is applied, the battery charge display will take up to 15 seconds to reflect the actual capacity of the internal battery.

1.11.2 Battery Product information

- 2BL550BIO (3.65V / 5500mAh, Li-ion)
- Battery Charging Time: more than 6.5 hours
- Continuous Battery Usage Time: 15 hours or more when fully charged (2BL550BIO)

Note

The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.

Warning

Older or defective batteries will have significantly reduced capacity or operating time.

Note

- To maximize the charge for transport, keep the monitor connected until you are ready to transport the patient. Reconnect the monitor immediately after transport.
- Bionet recommends replacing the lithium-ion battery after 24 months of use.
- Battery life depends on usage. If battery life continues, battery life will decrease, and frequency of replacement will increase.
- To prevent pre-discharge, recharge after the battery is discharged.

Warning

- Be careful of the polarity when replacing the battery.
- We strongly recommend that you use the battery supplied by Bionet.
- Using unauthorized batteries may damage the equipment.

Note

- Charging is not possible at low power (below 5V).
- When replacing the battery, be sure to remove the DC adapter and replace it.

1.11.3 when to replace the battery

Once you start using the battery, be sure to use it continuously until it is completely discharged.

Frequent charging and discharging shorten the service life of the battery.

Do not use a damaged battery in this device. If the device is supplied with power, the battery will be charged automatically.

1.11.4 The Impact of Lithium-Ion Battery Technology on the Battery

The following are the key points you should know about Lithium-Ion battery technology: The battery will discharge on its own, even when it is not installed in a monitor. This discharge is the result of the Lithium-Ion cells and the bias current required for the integrated electronics.

By the nature of Lithium-Ion cells, the battery will self-discharge.

The self-discharge rate doubles for every 10°C (18°F) rise in temperature.

The capacity loss of the battery degrades significantly at higher temperatures.

As the battery ages, the full-charge capacity of the battery will degrade and be permanently lost. As a result, the amount of charge that is stored and available for use is reduced.

1.11.5 Storage Guideline

Store the battery outside of the monitor at a temperature between 20°C to 25°C (68°F to 77°F).

When the battery is stored inside a monitor that is powered by an AC power source, the battery cell temperature increases by 15°C to 20°C (59°F to 68°F) above the room's ambient temperature. This reduces the life of the battery.

When the battery is stored inside a monitor that is continuously powered by an AC power source and is not powered by battery on a regular basis, the life of the battery may be less than 12 months. Bionet recommends that you remove the battery and store it near the monitor until it is needed for transport.

1.11.6 How to Recycle the Battery

When the battery no longer holds a charge, it should be replaced. The battery is

recyclables. Remove the old battery from the monitor and follow your local recycling guidelines.

Warning
EXPLOSION HAZARD — DO NOT incinerate the battery or store at high temperatures. Serious injury or death could result.

1.12 How to Use the Sensor and Precautions

1.12.1 Preparation before use the sensor

The accuracy of SpO₂ monitoring is largely dependent on the strength and quality of the SpO₂ signal.

The age, sex and race of the clinical study report used to assess SpO₂ accuracy are as follows.

- Age: 20 – 36 years
- Race: White, African, American, Hispanic
- Sex: Male, Female

If you use your fingers as a monitoring site, remove the nail polish. Cut the patient's fingernail if needed to improve placement of the sensor. Only use sensors provided by Bionet and apply them according to manufacturer's recommendations on a per-sensor basis.

If the sensor is not attached correctly, the ambient light may interfere with the pulse oximetry, making the measurement irregular or causing the value to disappear. If you suspect interference from ambient light, make sure that the sensor is properly positioned and that the sensor cover with the opaque body is covered.

Warning

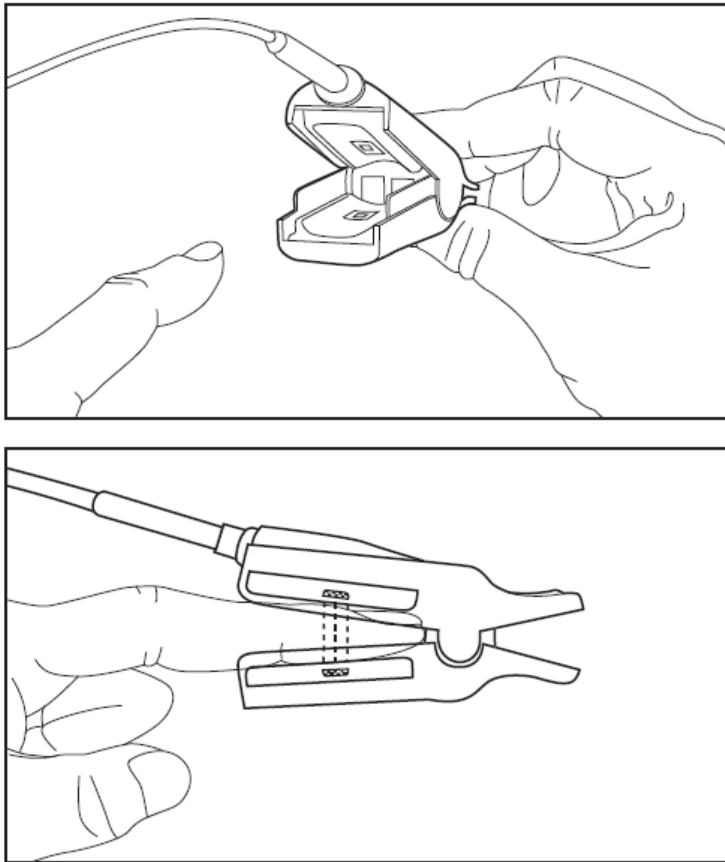
- Read the documentation that came with your sensor for the best application technology and safety information. Never use a damaged sensor.
- If the sensor does not turn on after connecting the sensor, observe that a message appears on the monitor. If the sensor-LED does not turn on, replace the sensor.

Caution

- If the sensor can be reused, please wash it before use for each patient.
- Do not place the toes or a manicured finger into the sensor unit.
- Disposable accessories should be used only once. Do not reuse disposable accessories.

1.12.2 How to use the sensor

1. Position the sensor correctly and attach it to the hand or foot of the patient.



2. Check the application area of the sensor from time to time. If the sensor is too tight, it may delay blood flow or overheat the skin and damage the tissue. Do not use a damaged sensor.

Warning

- Our SPO₂ Sensor is a medical product and should be used accordingly.
- Improper use or use of other sensors may cause harm to the user.

Caution

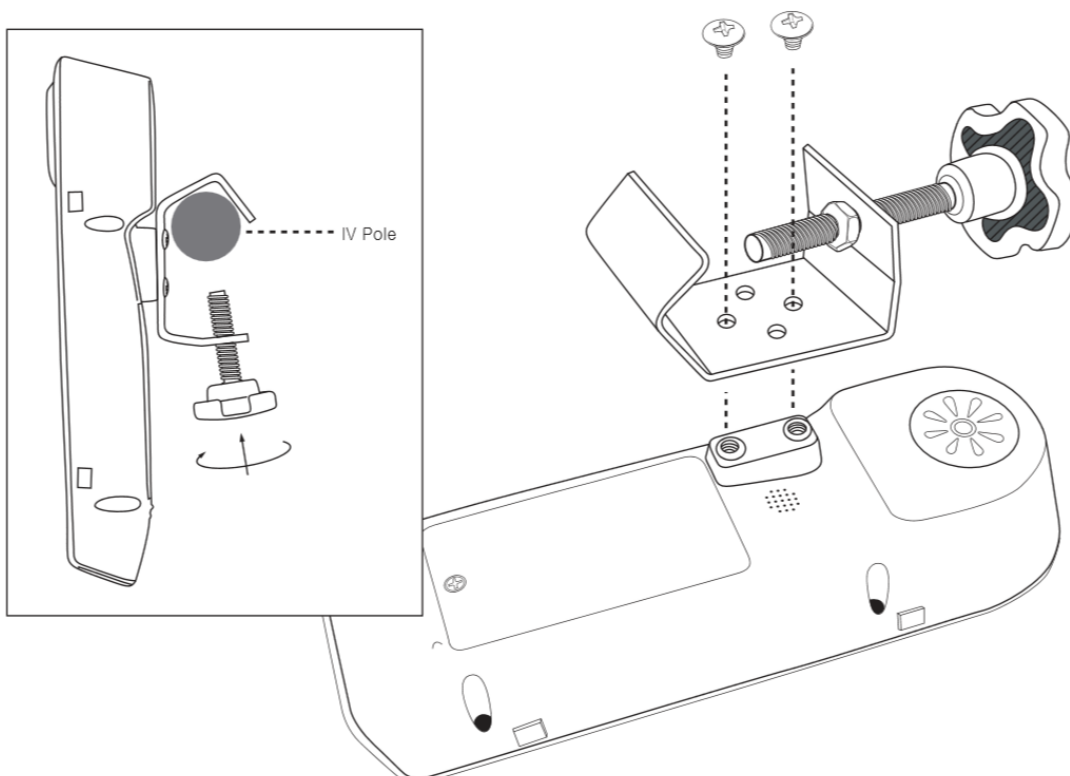
- When used near EMI devices such as microwave oven or high-frequency RF electronics, the readings may not be correct.
- When used continuously.
- Check the sensor every 8 hours and cycle power on the unit every 4 hours.
- When not in use, store the unit at -20 °C to 70°C.

1.13 Connecting a sensor to Oxy9Wave

Connect a SpO2 sensor cable to the SpO2 sensor port (2) of the side panel.



1.14 Connecting a clamp



1.15 Connecting a computer

Oxy9Wave can be connected to a computer. You can check and print the saved measuring data through a monitoring program. Connect the USB on the right side to the No.3 Port.



Warning

Use our USB cable to prevent performance deterioration.

Note

Install the program first before connecting Oxy9Wave and the computer.

2. Operation

2.1 Introduction

To operate the Oxy9Wave Pulse Oximeter effectively, the device must be set up properly, and the operator must:

- Know how the pulse oximeter derives its readings.
- Familiarize himself/herself with its controls, components, and operation.
- Understand its status and the alarm messages.

2.2 Basic Setup

2.2.1 General setup and use

1. Check whether the case is damaged.
2. Connect the cable and connector and check whether the lines are twisted, or a corner is worn out.
3. Connect the power cord and turn on the power.
4. Check whether the SpO₂ sensor is the one we approved and provided and remove objects that can interfere with the transmission of light between the light source and the photo detector.
5. Press the power button.
6. Attach the sensor to the hand or foot of the patient. (See section 1.11)
7. Check the following on the screen:
 - %SpO₂, max/min alarm value of BPM
 - %SpO₂, and value of BPM

Note
If it is displayed as a bar rather than as a value, please wait about 10 seconds

8. You can set the volume of Pulse beep and alarm.
 - When the value exceeds the designated range, the alarm rings, and the color is changed.
9. Check the status of the sensor (message).

- "Check Probe" (not connected to patient) is displayed in the message zone.
- "Lead Fault" (sensor is not connected) is displayed in the message zone.
- "Artifact signal" (sensor is moving too fast) is displayed in the message zone.

10. Alarm Silence

- Button to stop the alarm that sounds when the designated range is exceeded.
- Press the Alarm Silence button.
- The alarm will stop during the designated period.

11. Monitor the patient.

12. After monitoring, you can save and back up the data.

13. Press the power button.

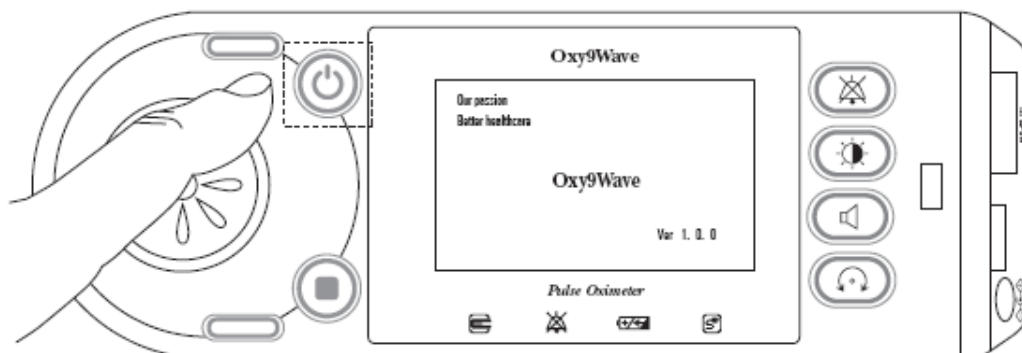
2.3 Details of Use

2.3.1 Turning on the monitor

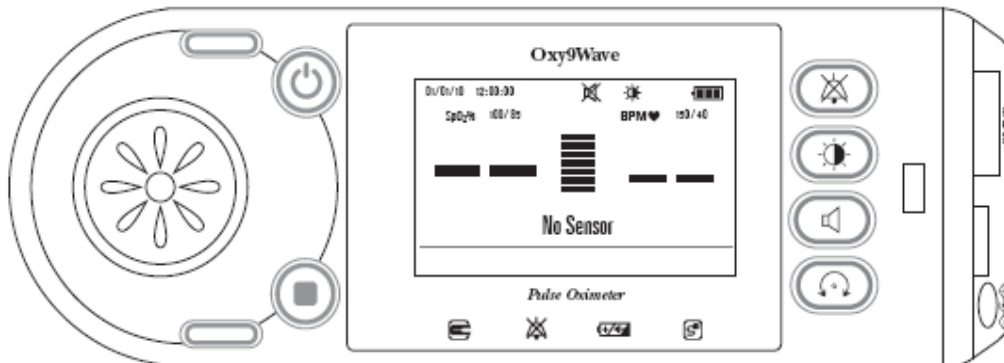
Before using Oxy9Wave in a clinical setting, you must verify whether the monitor is working properly and is safe to use. Proper working condition will be verified each time Oxy9Wave is turned on as described in the following procedure:

Caution
<p>If any indicator or display element does not light up when the pulse oximeter is turned on, do not use the pulse oximeter. Instead, contact any qualified service personnel, your local Bionet representative, or the Bionet Technical Services Department.</p>

1. Turn on Oxy9Wave by pressing the POWER ON/OFF button for 1-2 seconds.
2. The Oxy9Wave software version is displayed for approximately 2 seconds.

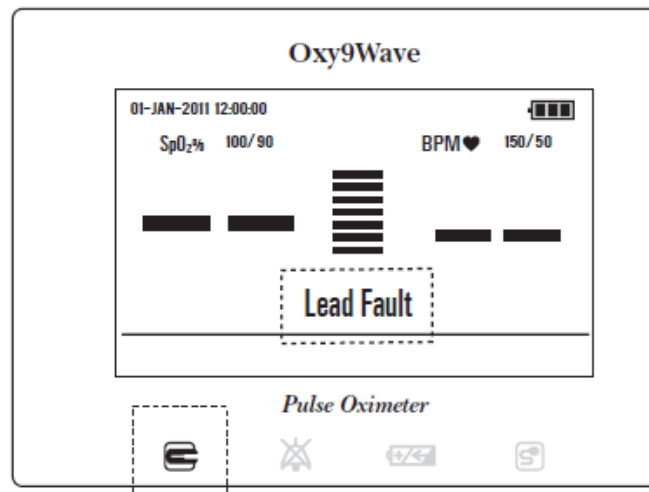


3. The Oxy9Wave Monitoring Mode is displayed.

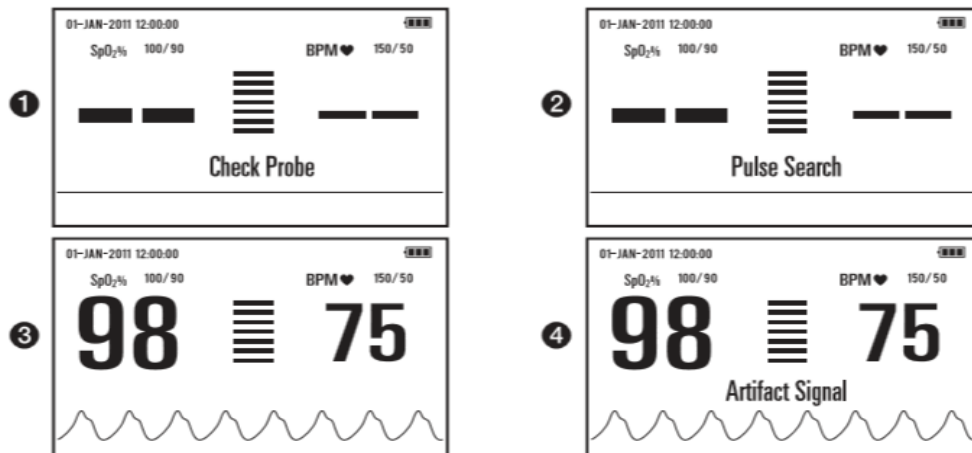


2.3.2 Attach sensor

When a sensor is not attached to the monitor, the measured value of the monitor screen displays a bar (-- --) and "Lead Fault" message would appear on the system message of the monitor.



When a sensor is attached to the monitor, the sensor status is displayed on the monitor. The monitor displays a bar in the %SpO₂ and the Pulse Rate while Oxy9Wave is searching for a valid pulse. Once a valid pulse is detected, the monitor shifts to Monitoring Mode and displays the patient parameters. Check for the movement of the level bar or waveform, which indicates that the monitor is displaying real-time data.



The tables below describe the condition for sensor message.

Sensor message	Description
Check Probe	Sensor is not connected to a finger
Pulse Search	Sensor is connected to a finger (searching a pulse)
Message is not displayed.	During normal measurement after the sensor is connected
Artifact signal	Sensor is moving too fast during measurement

2.3.2.1 Signal and Data Validity

It is extremely important to determine that the probe is attached to the patient correctly and the data is verifiable. To make this determination, three indications from the monitor are of assistance—signal strength bar, quality of the SPO2 waveform, and the stability of the SPO2 values. It is critical to observe all three indications simultaneously when ascertaining signal and data validity.

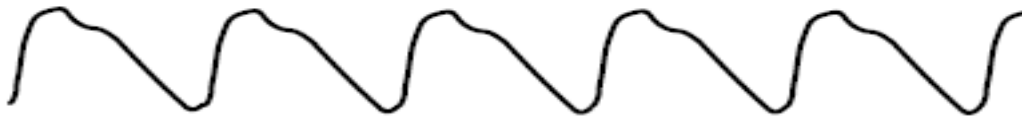
- **Signal Strength Bar**

The signal strength bar is displayed within the SPO2 values window. This bar consists of 10 blocks set depending on the strength of the signal. Proper environmental conditions and probe attachment will help to ensure a strong signal.

- **Quality of SPO2 Waveform**

Under normal conditions, the SPO2 waveform corresponds to (but is not proportional to)

the arterial pressure waveform. The typical SPO2 waveform indicates not only a good waveform, but helps the user find a probe placement with the least noise spikes present. The figure below represents an SPO2 waveform of good quality.



Good Quality SPO2 Waveform

If noise (artifact) is seen on the waveform because of poor probe placement, the photo detector may not be flush with the tissue. Check that the probe is secured, and the tissue sample is not too thick. Pulse rate is determined from the SPO2 waveform which can be disrupted by a cough or other hemodynamic pressure disturbances. Motion at the probe site is indicated by noise spikes in the normal waveform. (See the figure below.) It has been noted that letting the patient view the SPO2 waveform enables them to assist in reducing motion artifact.



SPO2 Waveform with Artifact

- **Stability of SPO2 Values**

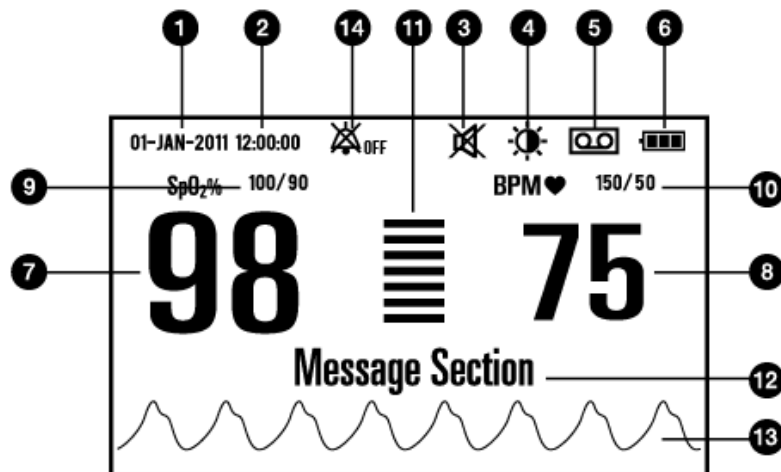
The stability of the displayed SPO2 values can also be used as an indication of signal validity. Although stability is a relative term, with a small amount of practice one can get a good feeling for changes that are artifactual or physiological and the speed of each. Messages are provided in the SPO2 values window to aid you in successful SPO2 monitoring.

WARNING

In the monitoring of patients, the coincidence of adverse conditions may lead to a disturbed signal going unnoticed. In this situation artifacts can simulate a plausible parameter reading, so that the monitor fails to sound an alarm. To ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

2.3.3 Patient monitoring mode description

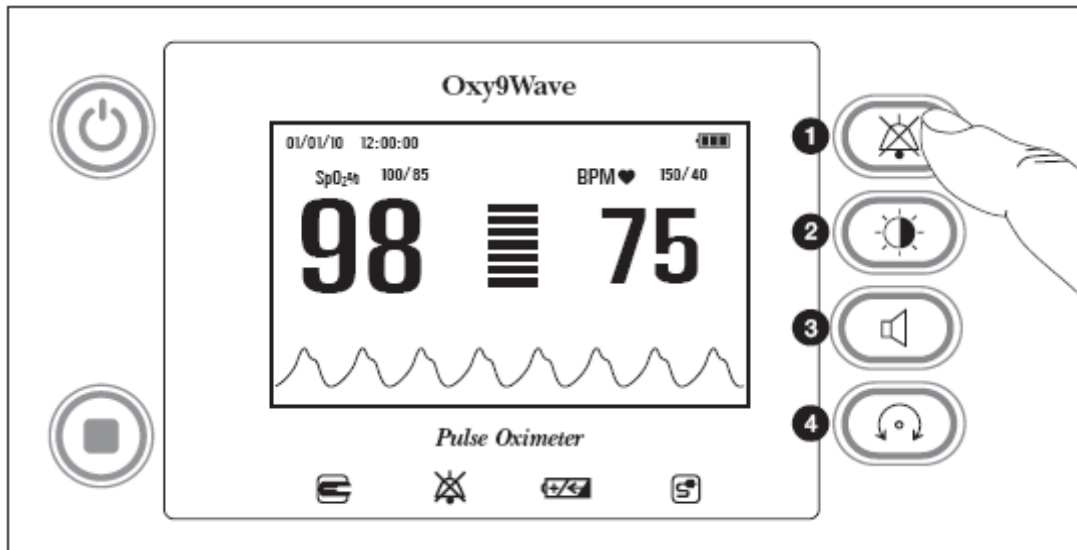
The user can configure the display settings.



- | | |
|---------------------------|---|
| 1. Calendar | 8. Pulse rate |
| 2. Clock | 9. SpO ₂ Max/Min ALARM limit |
| 3. Pulse rate Volume icon | 10. BPM Max/Min ALARM limit |
| 4. Brightness icon | 11. Level bar |
| 5. Save data icon | 12. SYSTEM Message |
| 6. Battery icon | 13. Signal Graph |
| 7. %SpO ₂ | 14. Silence icon |

2.3.4 Button description

Description of 4 buttons on the right in the patient monitoring mode



① Alarm Silence

The user can adjust the period of alarm silence duration.

Pressing this button stops the alarm temporarily for the designated period when the alarm sounds.



1. Press the Alarm Silence button when the alarm sounds in the patient monitoring mode.

Note

The alarm silence can be set for these duration (90, 120, OFF) A timer is shown next to the bell indicating the remaining alarm silence duration.

② Brightness Adjustment

To adjust the backlight when it is dark, follow the procedures below.



1. Press the Brightness Adjustment button.
2. You can change the level of backlight to any of the 5 levels by pressing the button.

Each level is displayed on the upper right side.

Note

To use the battery efficiently, select the lowest brightness.

③ Setting the Pulse Beep Volume



1. Press the Pulse Beep setting button.
 2. Each step is displayed on the upper part of the screen.
- The Button is used to change the sound level, five levels of volume are available.

Note

During measurement, the pulse beep sound (tone) is changed automatically according to the value of SpO₂.

④ Rotate Display



1. Press the Rotate Display Button.

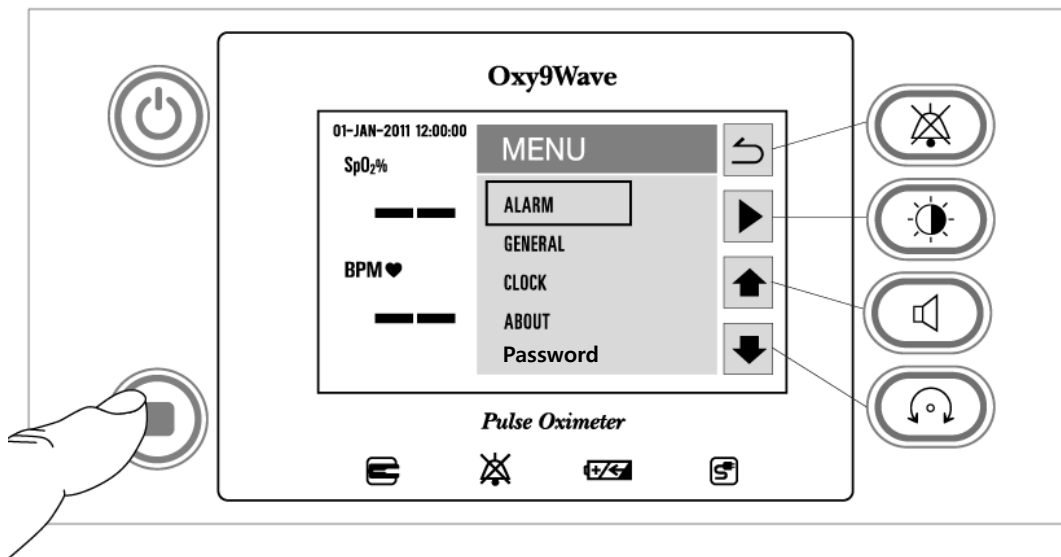
Note

The display rotates 90 degrees.

2.3.5 Manu setup

In menu setup, you can adjust the alarm setting, screen composition, data save, time and date display, password setting etc.

The menu screen consists of ANIMAL TYPE, ALARM, GENERAL, CLOCK, ABOUT and PASSWORD.






1. Press the menu button to go to the corresponding menu setup screen.
2. The icons on the right side show the functions of the 4 buttons.

Note

The menu setup screen and monitoring and measurement screen are shown alternately when you press the menu button.

[Select Menu]

1. Press the menu button.
2. Press the   button to go to menu you want to change.
3. Press the  button to go to the desired menu.

2.3.6 Menu tree

This section gives an overview of the menu selections that are available. To navigate through the menus, press the menu button on the right side using the touch keys. The icons of the menu items that can be set appear on the screen. The following sub-sections describe each menu item in more detail:

ALARM	% SpO ₂ high/low limit
	BPM high/low limit
	LEVEL (% SpO ₂ , BPM)
	VOLUME
	ALARM

GENERAL	VIEW
	SAVE
	INTERVAL
	DELETE

CLOCK	TIME (hour/minute/second)
	DAY
	MONTH
	YEAR
	FORMAT


ABOUT	VERSION
	KEY SOUND
	PULSE LED
	DEFAULT

PASSWORD	Password Use
	Password Change

2.3.6.1 Alarm Setup

Set the proper alarm when monitoring each patient.












Alarm setup is used to indicate that the designed range is exceeded during measurement.

To proceed alarm preset function, press  MENU -> ALARM button.

In order that the only authorized person can change the alarm setting, the password is required when entering Alarm setting menu.

Warning
<p>The initial Preset Password in Factory mode is "2222". Change the preset password after installation to avoid being used by an unauthorized person. To change the preset password, use MENU -> PASSWORD -> Password Change menu. Please be aware, when the changed password is lost by users, the only way to use password is to use the factory preset password by resetting the device with factory mode. When initialized, all data will be removed. Please keep the password in safe place.</p> <p>If you do not want to use password in the alarm setting and transferring the saved data to the PC software, you can set Password Use setting to "No" by moving to MENU -> PASSWORD -> Password Use setting menu.</p>

You can set the Max/Min Value, volume, and silence period of alarm.

01-JAN-2011 12:00:00		ALARM			
SpO ₂ %		%SPO2	BMP		
		UPPER	100	150	
BPM 		LOWER	90	50	
		LEVEL	H	H	
		VOLUME	4		
		ALARM	ON		
					

- **How to set the alarm**

1. Press the button to go to the desired value.
2. Press to set the value.
3. Press the button to return to the Menu.

● **Description**

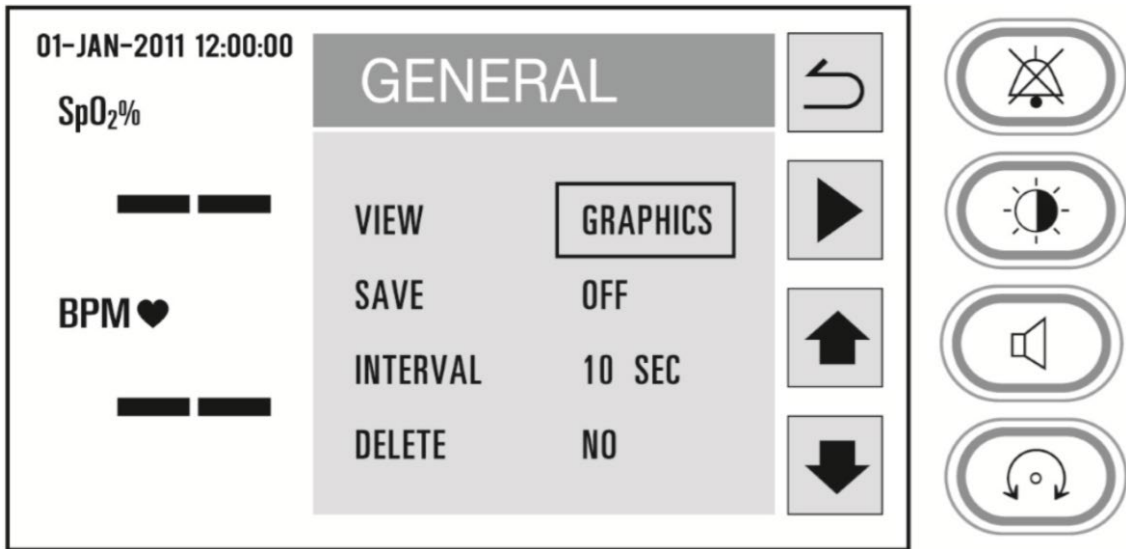
Setup Menu	Description
Max SpO ₂ (UPPER)	Max SpO ₂ for alarm can be 41-100%. It can be adjusted by 1% (Menu) (Alarm setup Screen) (Adjust Max Limit)
Min SpO ₂ (LOWER)	Min SpO ₂ for alarm can be 40~99%. It can be adjusted by 1% (Menu) (Alarm Setup) (Move to Min Limit) (Adjust Min Limit) NOTE: limit must be smaller than Max limit.
Max PULSE RATE (UPPER)	The max BPM for alarm can be 31bpm~250bpm, and it can be adjusted by 10bpm.
Min PULSE RATE (LOWER)	The min BPM for alarm can be 30bpm~249bpm, and it can be adjusted by 1bpm NOTE: The Min limit must be smaller than the Max limit.
LEVEL (% SpO ₂ , BPM)	This menu allows the user to set the alarm level. (HIGH, MEDIUM, LOW)
VOLUME	This menu allows the user to set the alarm volume (5step.)

Warning
<ul style="list-style-type: none"> ● Any alarm levels can be turned off. ● Parameters configured to use All Off do not have any visual or audio alarm indicators.

2.3.6.2 General Setup

Menu for setting the screen display and saving and deleting data

● **General Setup Screen**



● **Procedure for General Setup**

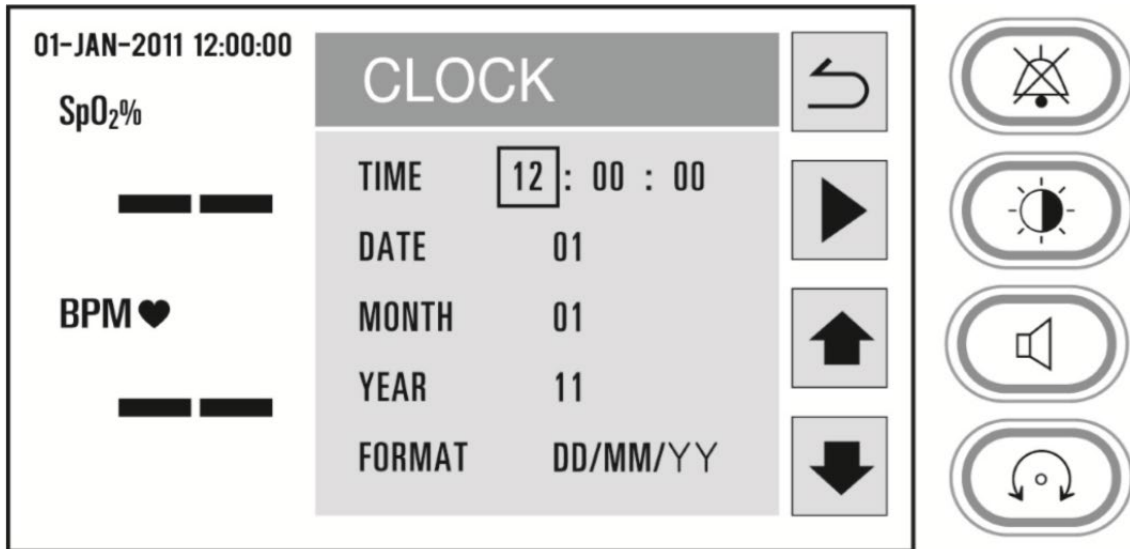
1. Press the button to go to the desired value.
2. Press to set the value.
3. Press the button to return to the Menu.

Setup Menu	Description
VIEW	Menu for the screen settings GRAPHICS %SpO ₂ and Pulse rate are displayed as a figure; the LEVEL bar of the middle signal is displayed. In addition, the Pulse rate wave is displayed at the bottom of the screen. NUMBERS %SpO ₂ and Pulse rate are displayed as a figure; the LEVEL bar of the middle signal is displayed
SAVE	AUTO: Data is saved automatically. EVENT: Data is saved after in the Event happen. NOTE: The saving icon is displayed when saving data.
INTERVAL	Set interval of saving among 10/30/60
DELETE	YES/NO: Delete saved data.

2.3.6.3 Clock Setup

Set the current time and date.

- **Clock Setup Screen**



- **Procedure for Clock Setup**

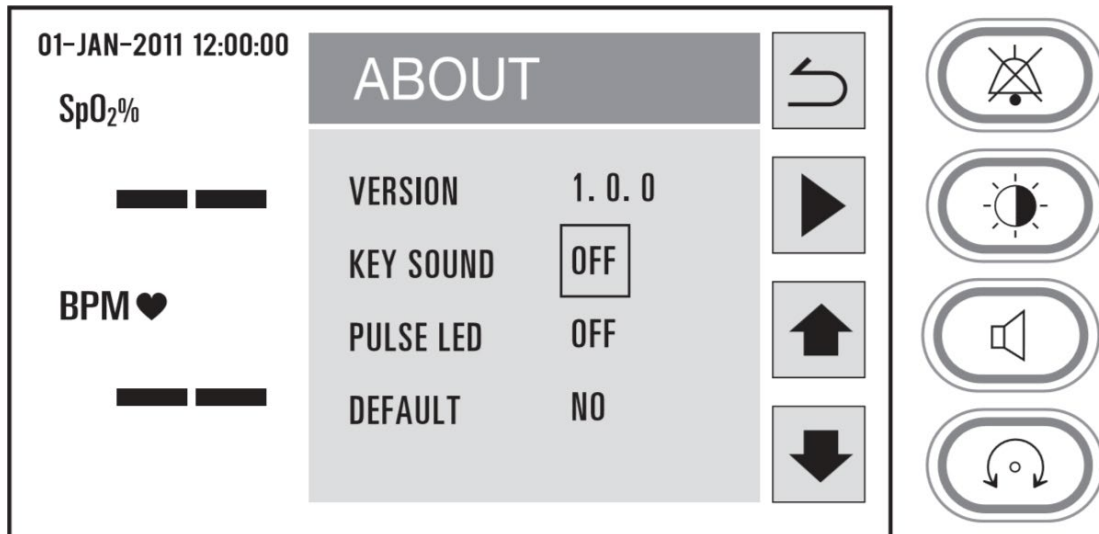
1. Press the button to go to the desired value.
2. Press to set the value.
3. Press the button to return to the Menu.

Setup Menu	Description
TIME	Adjust the hour, minute, and second Time is displayed based on 24-hour notation.
DATE/ MONTH/ YEAR	Adjust the date.
FORMAT	DD/MM/YY, MM/DD/YY, YY/MM/DD It is the form of the clock displayed on the screen. The default setting is DD/MM/YY.

2.3.6.4 ABOUT

Menu for checking the version and resetting the system and other settings.

- **ABOUT Screen**



● **Procedure for About Setup**

1. Press the button to go to the desired value.
2. Press to set the value.
3. Press the button to return to the Menu.

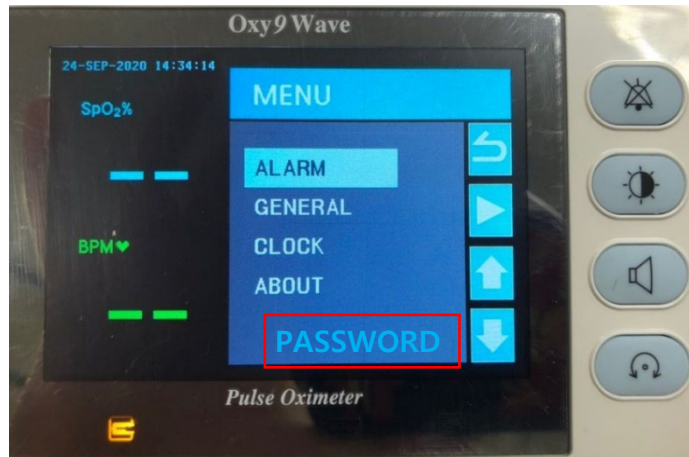
Setup Menu	Description
VERSION	Display software version
KEY SOUND	- ON: Turn on the KEY tone. - OFF: Turn off the KEY tone.
PULSE LED	- ON/OFF - OFF: Turn off the Pulse Rate LED indicator.
DEFAULT	- YES/NO Factory Default is used to reset the system. If you select YES, the product will return to the initial status.

Warning
If the product is reset, all saved data will be lost, Therefore, take the necessary caution.

2.3.6.5 PASSWORD

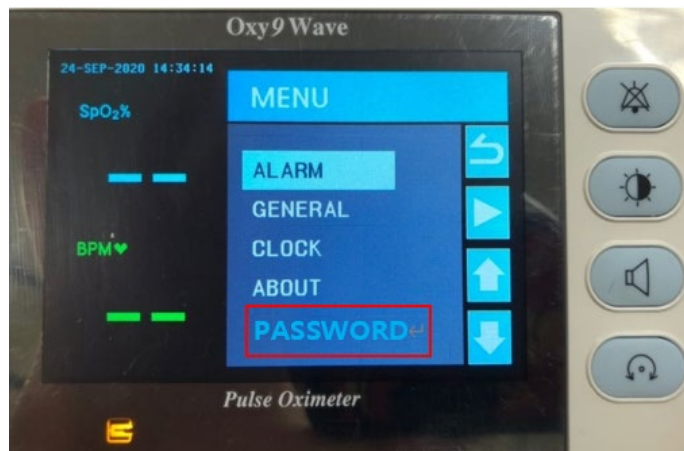
Menu for setting and changing password.

- **Password Screen**

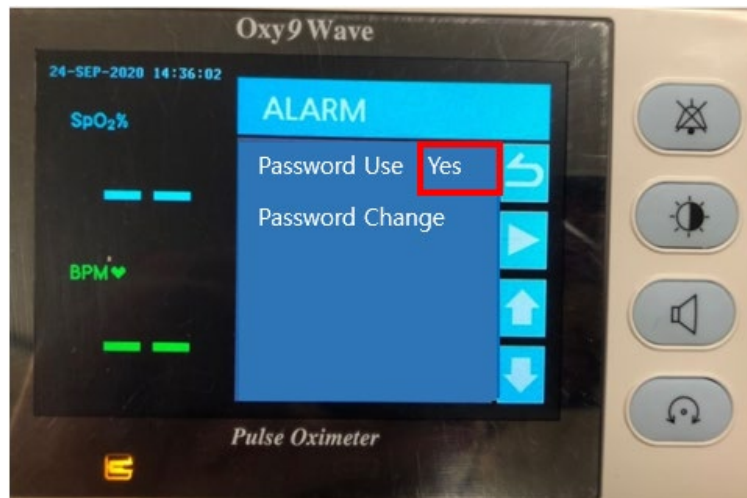


- **Procedure for Password Setup**

1. Press the menu button to pop up MENU window.
2. Move to PASSWORD in the MENU window.



3. In the PASSWORD setting menu, there are Password Use and Password Change setting menus.
 - 4.1 When the Password Use is set to "Yes" on the screen, the password input screen appears when entering Menu >> ALARM.
 - 4.2 When the Password Use is set to "No", the password input screen doesn't appear when entering Menu >> ALARM.



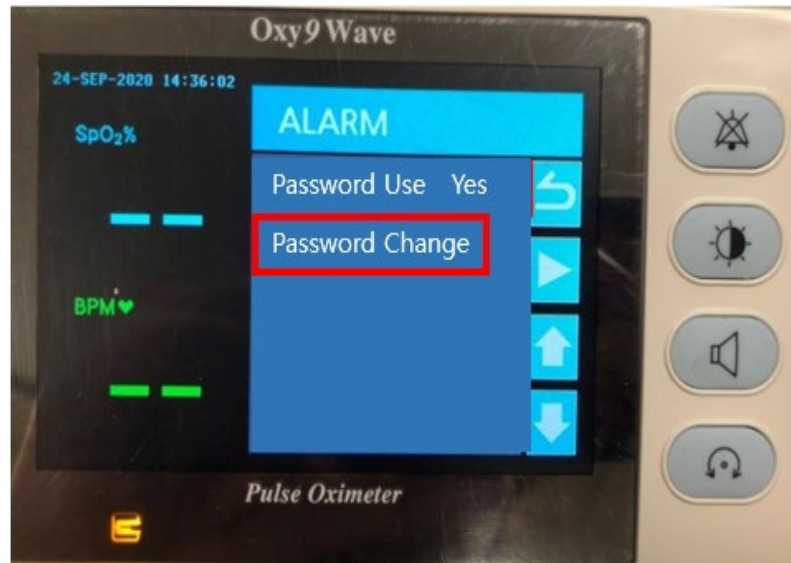
- 5 In order that the only authorized person can change the Alarm Password setting, entering the current password is required.
- 6 Type the password on the password input screen and then click OK button. If the password entered is right, Password Use can be changed with Yes or No.



- ▶ Move cursor
- ▲ ▼ Move Password numbers, Click OK.
- ↶ Cance(previous screen, state without password screen)

- **Procedure for Password Change**

1. Press the menu button and go to the Password >> Password Change.



2. Enter your current password and select OK to display the New Password input screen.



- ▶ Move cursor
- ▲ ▼ Move Password numbers, Click OK.
- ↶ Cance(previous screen, state without password screen)

- 2.1 If the entered password is wrong, "Incorrect Password" message screen will appear. Click OK to return to MENU.



⬆️⬆️ Click OK.

3. If the entered password is right, the password can be changed in the New



Password screen.

- ▶ Move cursor
- ⬆️⬆️ Move Password numbers, Click OK.
- ↶ Cance(previous screen, state without password screen)

- ※ Factory default password is '2222'.
- ※ If you forget your password, you can reset the settings with factory default settings by selecting ABOUT >> Default as YES.

2.4 Factory-preset default values

The parameters of the Oxy9Wave monitor are preset to factory default.

The factory/default setting for the parameters may be changed to institutional default setting by following the procedures in the Oxy9Wave service manual.

The table below lists the parameters, ranges available, and factory default.

The parameters may be set on an individual basis by the clinician; these settings will remain in effect until Oxy9Wave is turned off.

Parameter	Range	Factory Default
%SpO ₂ Upper Alarm Limit	41~100%	100%
%SpO ₂ Lower Alarm Limit	40 ~ 99%	90%
BPM Upper Alarm Limit	31 ~ 250 bpm	150 bpm
BPM Lower Alarm Limit	30 ~ 249 bpm	50 bpm
%SpO ₂ LEVEL	H / M / L	H
BPM LEVEL	H / M / L	H
Alarm Volume	1~5	4
Alarm	ON / OFF	ON
Alarm Silence Duration	90, 120, OFF	OFF
Brightness	1~5	4
Pulse beep	1~4 OFF	3
Display View	GRAPHICS / NUMBERS	GRAPHICS
SAVE	AUTO / EVENT / OFF	OFF
INTERVAL	10 / 30 / 60 SEC	10 SEC
DELETE	NO / YES	NO
KEY SOUND	ON / OFF	ON
PULSE LED	ON / OFF	ON

DEFAULT	NO / YES	NO
Password	0000~9999	2222

3. Alarm

3.1 Overview

The following section outlines the system alarms and messages displayed on the LCD screen: Familiarize yourself thoroughly with this information before operating the pulse oximeter

3.2 Alarm priority

Oxy9Wave visually and audibly indicates the alarm conditions detected by the system. In particular, the integrated loudspeaker indicates the alarm conditions audibly. The LCD screen and the LED lights indicate the visual alarms. When multiple alarm occurs at the same time, the higher priority alarm will be displayed. Audible alarms may be silenced without affecting the operation of visual alarms.

The following table outlines the alarm priority specifications:

ALARM	DESCRIPTION
HIGH PRIORITY	- Audible and visual alarms for low saturation (%SpO ₂ range:40~100%) And pulse rate (pulse rate range: 30~250 bpm).
MEDIUM PRIORITY	- Audible and visual alarms for low saturation (%SpO ₂ range:40~100%) And pulse rate (pulse rate range: 30~250 bpm).
LOW PRIORITY	- Audible and visual alarms for low saturation (%SpO ₂ range:40~100%) And pulse rate (pulse rate range: 30~250 bpm). - Finger is not connected to the %SpO ₂ Sensor. - Main body and %SpO ₂ Sensor are not connected properly.

Note

High-priority alarms indicate that immediate operator response is required. Low-priority alarms indicate that operator awareness is required.

3.3 Visual alarm indication

A visual alarm will be displayed in a different color and rate defined in the table below depending on its priority.

Alarm Level	LED Color	LED Flashing Duty Cycle
High Level	Red	2 flickers per 1 second
Medium Level	Yellow	1 flicker per 2 seconds
Low Level	Blue	keep ON state

Caution

Place the Oxy9Wave in a position where the user can easily recognize the visual alarms.

3.4 Audible alarm indication

Audible alarm settings are defined by Bionet. Audible alarm priority is defined by the alarm interval and beep rate as shown in the table below.

Alarm Level	Audible Alarm Interval	Beep Rate	Sound Pressure level
High Level	Continuous	5 beeps	66.4 dB ~ 75.8 dB
Medium Level	Every 10 sec	3 beeps	62.0 dB ~ 75.8 dB
Low Level	Every 15 sec	1 beep	58.2 dB ~ 74.6 dB

Caution

Place the Oxy9Wave in a position where the user can easily recognize the visual alarms.

Note

- The maximum audible alarm latency is less than 5 seconds after the Alarm Delay time.
- If the system is returned to normal status within the alarm range, the alarm will be turned off automatically.

3.5 Alarm Audio paused (Silence)

Audio_Paused: Stop the audible alarm for period (90 or 120) selected via the alarm setup menu. but the visual alarm is activated still. Silence icon are displayed on the screen. After the timeout period has elapsed if the alarm occurs still, visual and audible

alarms will be activated again

Alarm_Paused: Stop visual and audible alarms during user defined time. Silence icon are displayed on the screen. After the user switches to another alarm mode or after the timeout period has elapsed if the alarm occurs still, visual, and audible alarms will be activated again

3.6 Alarm password

1. Click MENU >> ALARM
2. Password screen will appear. Input passwords.



- ▶ ▶ Move cursor
- ▶ ▲ ▼ Move Password numbers, Click OK.
- ▶ ↶ Cance(previous screen, state without password screen)

3. When you enter a number one by one and the cursor moves to the next box, and the number appears as a * sign.

* * **1** _

4. After clicking **OK** button, you can move on to the ALARM setting screen.



4. Maintenance and Troubleshooting

4.1 Inspection Equipment

You should perform a visual inspection before every use, and in accordance with your hospital's policy. With the monitor switched off:

- Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
- Inspect all accessories (cables, sensors and so forth). If any show signs of damage, do not use.

Warning

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

4.2 Inspection Cables

- Examine all system cables, the power plug for damage. Make sure that the prongs of the plug do not move in the adaptor. If damaged, replace it with an appropriate Bionet power cord and adaptor.

Warning

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the monitor appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

4.3 Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation

Maintenance and Test Schedule	Frequency
Monitor Tests	
Safety checks. Selected tests based on IEC 60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped
Parameter Module Tests	
Performance assurance for all measurements.	At least once every two years, or if you suspect the measurement values are incorrect.
Battery Maintenance	
Battery	See the section on Maintaining Batteries in chapter 1.

4.4 Trouble Shootings

The chart below alphabetically lists all system messages displayed on the LCD screen (The cause of the message and action(s) to be taken are also shown)

The operator should thoroughly familiarize himself/herself with this information before using the oximeter for patient monitoring.

Message	State	Solution
ARTIFACT	The SPO ₂ signal is the patient's motion artifact and noise.	Put the sensor on the patient's finger and make sure that there is not much movement or shaking.
Check Probe	The sensor is separated from the finger	Put the sensor on the patient's finger.
Lead Fault	The sensor is disconnected from the main unit.	Connect the sensor to the main unit.
Low Battery	Battery charge is low.	Provide the main unit with AC line power. Replace

		battery if necessary.
Poor Signal	The SpO ₂ signal is too low.	This can be caused by the weak patient pulse signal, lots of patient motion, or some other interference. Check the patient and the probe.
Pulse Search	Detection of a repeatable pulse has ceased.	If the signal does not appear for more than 30 seconds and the message persists, remove the sensor from the patient's finger and put it on again.

Note

- When 'Artifact Signal' is displayed, measured values are displayed in gray. These indicate the most recently measured value among those measured under normal conditions.
- No SPO₂ data is displayed. One of the following conditions is indicated:
 - Defective or damaged probe
 - Defective or damaged cable
 - Probe is detached from the patient.
 - Detection of repeatable pulse has ceased.
 - Check the probe and cable: reposition or replace as needed.

5. Install and Use the Program

5.1 Installing the Program

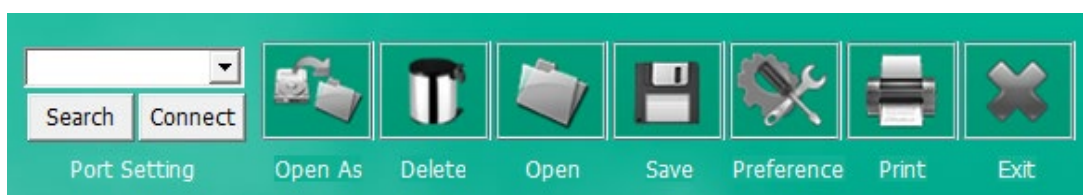
1. Install the USB driver by running the Oxy9Wave_dirver.exe in the Setup CD.
2. Connect the device to the computer with the USB cable and turn on the device power.
3. Check Oxy9Wave Port (CDC) in Device Manager
 - * My computer → Properties → Hardware → Device Manager → Port(COM)
4. Run Oxy9Wave_viewer.exe in the Setup CD to start the program.
 - Windows 10 operating system is needed.

5.2 How to use Oxy9Wave Viewer PC program

1. Starting and exiting the program

After connecting the Oxy9Wave to the computer with a USB cable, use it with the Oxy9Wave turned on. The Oxy9Wave should not be used to a patient while it is being connected with Oxy9Wave Viewer.

2. The meaning of each icon



Icon	Function	Description
Search	Search COM port	Search COM port automatically which is allocated to the Oxy9Wave which is connected to the PC via USB cable.
Connect	Connect	Connect the Oxy9Wave to the PC to get the saved trend data in Oxy9Wave and then the button name is changed to 'Disconnect'
Disconnect	Disconnect	Disconnect the Oxy9Wave from the PC and then the button name is changed to 'Connect'
Open As	Retrieve the	Retrieve the trend data stored in Oxy9Wave. The

	saved data	retrieved data is automatically saved, and the path of the saved file can be specified by the user in the Preference menu. The default folder path is the folder where the program is installed.
Delete	Delete the data	This function deletes the data stored in the Oxy9Wave. NOTE: Please bring in the data and save it. Otherwise, the data can be deleted and cannot be retrieved any more.
Open	Open the file	Open the saved file in the PC
Save	Save the file	Save the file after entering the patient ID and name and gender. NOTE: The save file path can be designated by the user. NOTE: If there is a file with the same name in the folder, it will not be saved, and an error message will appear.
Preference	Setting the configuration	Set %SpO ₂ and pulse rate view scale in the viewer. Set Directory Path to save the data in the PC. Time Update transmits the current time information of the PC to Oxy9Wave.
Print	Print the trend data	Print out the retrieved trend data through the printer connected the PC.
Exit	End of program	Exit the program.

3. Reviewing the saved trend data in Oxy9Wave

Click "Search" button to find the connected COM port and then click "Connect" button. To retrieve the saved trend data in Oxy9Wave, click "Open As" button and double click the file from the file list in the pop up dialog box.

4. Save the reviewed data in the PC

Enter the patient information and click "Save" button. The data will be saved in the directory which is set in the "Preference" menu.

5. Print the reviewed data

Click "Print" button and check the preview of print-out. If it is okay, click "Print" button.

6. Delete the saved trend data in Oxy9Wave

Click "Delete" button and all the saved data in Oxy9Wave will be deleted.

-
- Oxy9Wave Viewer (Program) is an optional item.
 - This optional item includes Setup CD and USB cable.
-

Note
<ul style="list-style-type: none">■ Oxy9Wave Viewer is not available in Europe.

6. Clean and Care

6.1 Overview

Clean the monitor and all accessories after each patient or daily according to your hospital's standard protocol. We recommend the following cleaning solution and procedures. To avoid contamination and unnecessary damage to the equipment, follow the instructions below.

Bionet does not claim the right to the following chemical efficacy, disinfectant method, the ability of the drug to inhibit bacterial infection, environmental impact, safe handling or precautions related to use. For more information on these topics, see the information provided by the detergent manufacturer.

6.2 Monitor and Peripherals

Moisture can damage the monitor and peripherals.

Please read the following instructions carefully before cleaning the basic unit or peripherals.

The following pages contain precautions for cleaning certain equipment and peripherals.

- Do not spray detergent on the monitor or peripheral devices. Make sure that the cables and accessories are free from dust and dirt, then wipe them with a soft cloth moistened with 40 ° C water. Please wipe it with clinical alcohol at least once a week.
- Clean the exterior of the equipment at least once a month using a soft cloth moistened with lukewarm water or alcohol. Do not use lockers, thinners, ethylene, or oxidizers that could damage the equipment.
- Dry thoroughly with a lint-free cloth.
- Carefully inspect the main unit and sensor after cleaning the equipment. Do not use damaged or old equipment.

Caution

- Do not wet or rinse the monitor and accessories. Disconnect the unit from the power source if you accidentally spilled liquid on the equipment. Contact your technician for stability before operating the equipment.
- To prevent damage to the equipment, do not use sharp tools or abrasives. Never immerse the electrical connector in water or other liquids. When cleaning, be careful not to let the liquid stick to the edge of the screen.

- **Reusable SpO2 sensor**

Reuse Clean the SpO2 sensor by wiping it with soapy water gauze. Disinfect the sensor by wiping with 70% alcohol solution. Allow the patient to dry completely with a lint-free cloth before applying to the patient.

Caution

Never boil or autoclave the cable. Vinyl withstands temperatures up to 100°C but begins to soften at around 90°C. Handle gently when hot and wipe away from the tip toward the cable.

Caution

Decisions on disinfection should be made by the user organization in accordance with the integrity of the wires or lead wires.

6.3 Care

If you suspect the installation or disposition of the external ground wire, operate the equipment by means of the internal power supply.

If the unit is not used for a certain period, remove the backup battery if safety hazards do not occur.

Note

The equipment should be inspected regularly once a year. For inspection items, refer to the user manual or service manual.

Caution

Do not dispose of the disposable probe in a potentially hazardous area.
Always be careful about environmental pollution.

Caution

There is a backup battery inside the system.
When disposing of the battery, dispose of it in an appropriate place for environmental protection.

Warning

When replacing the backup battery, check the battery electrode.

7. Technical Specification

7.1 Overview

The monitor is not user installable. It must be installed by qualified service personnel. The monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities. The device is to be used by trained health care professionals.

The monitor is intended for use in health care facilities; Oxy9Wave Monitor is additionally intended for use in transport situations within the hospital setting.

7.2 EMC Compatibility (EMC)

- Medical electrical equipment requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the documents accompanying the equipment.
- It is possible that radiated or conducted radiofrequency (RF) electromagnetic interference from portable and mobile RF communications equipment or other strong or nearby RF sources can affect medical electrical equipment and could result in performance disruption of the Oxy9Wave system. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning.

Manufacturer's declaration - electromagnetic emission		
The Oxy9Wave is intended for use in the electromagnetic environment specified below. The customer or the user of Oxy9Wave should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
Main terminal disturbance voltage CISPR 11	GROUP1, CLASS A	The EMISSIONS characteristics of Oxy9Wave make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential

Radiated disturbance CISPR 11	GROUP1, CLASS A	environment (for which CISPR 11 class B is normally required) Oxy9Wave might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Current Emission IEC 61000-3-2	Class A	The Oxy9Wave is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage change, Voltage fluctuations and Flicker Emission IEC 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% DC: 3.3%	

Manufacturer's declaration - electromagnetic immunity			
The Oxy9Wave is intended for use in the electromagnetic environment specified below. The customer or the user of the Oxy9Wave should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment -guidance
Electrostatic Discharge Immunity (ESD) IEC 61000-4-2	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Electromagnetic Field Immunity IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Oxy9Wave is suitable to use in professional healthcare environment. RF communication equipment is used no closer than 30 cm to any part of the Oxy9Wave, including cables specified by Bionet
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	Mains power quality should be that of a typical commercial or hospital environment.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±2 kV, 100 kHz repetition frequency	±2 kV, 100 kHz repetition frequency	The quality of supplied power should be suitable for general business site or hospital environment.
Surge Immunity IEC 61000-4-5	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	The quality of supplied power should be suitable for general business site or hospital environment.

Immunity to Conducted Disturbances Induced by RF fields IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	The strength of RF field in the frequency range higher than 150 kHz~80 MHz, the strength of the RF field is smaller than 3 V
Power Frequency Magnetic Field Immunity IEC 61000-4-8	30 A/m 60 Hz	30 A/m 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 30 cycles Single phase: at 0°	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oxy9Wave requires continued operation during power mains interruptions, it is recommended that the
Voltage interruptions IEC 61000-4-11:	0% U_T ; 300 cycles	0% U_T ; 300 cycles	Oxy9Wave be powered from an uninterruptible power supply or a battery be used with the system power source.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Warning

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment should not be used closer than 30 cm to any part of the Oxy9Wave, including cables. Otherwise, the Oxy9Wave may experience performance degradation

7.3 System Specification

Physical	
Dimension (H x W x D)	45 x 217 x 75 mm
Weight	Approx. 300g
Indicator	2 LED, 4 LED indicator
Power	AC 100-240V (50/60Hz) Adapter 5 V, 2.0 A
Power consumption	24VA (max)
Operating Mode	Continuous
Display	TFT-LCD
Resolution	320 X 480
Display size	3.5"
Displayed Data	SpO ₂ , BPM, SpO ₂ Limits, BPM Limits, Level Bar, Pulse rate Wave, Time and Date, Alarm Volume, Battery Status, and Brightness
LED Display	Sensor Separation, Alarm Silence, Charging Status, and Power Connection
Measurement Parameter	SpO ₂ , Pulse rate, PI (Perfusion Index)
Interface	DC input connector: 5V, 2.0A USB digital output for transferring data
Battery	Rechargeable Li-ion battery
Data Storage	SpO ₂ , BPM (30days at 10 second intervals)
Language	English, French, Spanish, Italian, Germany, Chinese, Russian, Czech, Bulgarian, Portuguese, Romanian, Hungarian, Turkish, Polish
Environments	
Temperature	Operating: +5 ~ +40 °C Storage: -20 ~ +70 °C
Humidity	Operating: 30% ~ 85%, Storage: 5% ~ 95% (PACKAGE)
Operating Attitude	Operating: 525 ~ 795 mmHg (70 ~ 106 kPa) Storage: 375 ~ 795 mmHg (50 ~ 106 kPa)

SpO₂ Performance

Saturation range	40 to 100%
Saturation accuracy	70 to 100% ± 2 digits 0 to 69% unspecified
Pulse rate range	30 to 250 bpm
Pulse rate accuracy	± 2 bpm

Product Certificate

Product Name	Pulse oximeter
Model Name	Oxy9Wave
Type Name	
License Number	
License Date	
Serial Number	
Warranty Period	1 year (other countries)
Purchasing Date	(yyyy/mm/dd)
Customer Information	Hospital name: Address: Name Telephone:
Seller Name	
Manufacturer Name	

- ※ Thank you for purchasing Oxy9Wave.
- ※ This item is 'medical device.'
- ※ This product has passed through quality management and strict inspection.
- ※ Compensation criteria for the repair, replacement, or refund of this product follow 'consumer damage compensation regulations' from Fair Trade Commission



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Bionet Co., Ltd

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