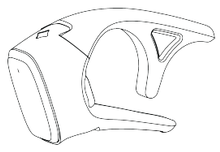
Belun Ring
Wireless Pulse Oximeter

Model: BLR-200

Operator's Manual



Rev01

1. INTRODUCTION

This Operator's Manual is written and compiled according to US FDA 21 CRF part 820. Subject to modifications and software upgrades, information in this document may change without notice.

This manual describes the guidelines of using Belun Ring BLR-200 wireless pulse oximeter. Please read this manual carefully before using this product. This manual which describes the operating procedures should be followed strictly. Failure to follow may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issue and any monitoring abnormality, human injury, and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

This product is calibrated before leaving factory.

Belun reserves the right to revise and improve this manual and the products it describes at any time, without notice or obligation.

2. PRODUCT DESCRIPTION

2.1 Intended Use

Belun Ring BLR-200 is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for spot-checking and/or continuous data collection and recording of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult patients through index finger in hospital and home environment for up to ten hours, during no motion and motion conditions, and for patients who are well or poorly perfused. It is not intended for single-use and out-of-hospital transport use and does not have alarms.

2.2 Contraindications

- ✧ Do not use this device in a Magnetic Resonance (MR) environment or in the presence of flammable anesthetics or gases.
- ✧ This device is not defibrillation proof per IEC 60601-1.
- ✧ This device should not be used:
  - ✧ during cardiopulmonary resuscitation,
  - ✧ on hypovolemic patients,
  - ✧ for assessing the adequacy of ventilator support, or
  - ✧ for detecting worsening lung function in patients on a high concentration of oxygen.

Attention: This device should not be used for treatment nor monitoring. Do not use this device when SpO_2 or pulse rate alarms are required.

Attention: This device should not be used for life-support and diagnosis purposes.

Attention: This device has motion tolerant software that minimizes the likelihood of motion artifacts being misinterpreted as good pulse quality.

Note: If you have difficulties in understanding this operator's manual, you should operate this device only with the assistance from someone who can understand this operator's manual.

3. SAFETY WARNINGS AND CAUTIONS

3.1 General

- ✧ Check the package before use to ensure the device and parts are in accordance with the package list. Please contact customer service if there is any missing component.
- ✧ The included device and parts are designed to use together. Using other parts may cause injury to the patient or damage to the device.
- ✧ To prevent malperformance and/or patient injury, verify the compatibility of any accessory before use.
- ✧ When this device is used by the patient, the patient is the intended operator. The patient can use and maintain this device and its parts according to this manual.
- ✧ This device should not be used or interconnected with any other parts, accessories or equipment not specified in this manual.
- ✧ For cleaning and disinfecting, follow the direction of the section "15. CARE AND MAINTENANCE".
- ✧ The expected service life of the device is 3 years since its first use.

3.2 Safety

- ✧ The light emitting from this device is harmful to the eyes. Refrain from staring at the light.
- ✧ Keep this device away from children or pets. This device contains small parts that could cause choking; the cable could cause strangulation.
- ✧ Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.

3.3 Limitation of Use

- ✧ This device is to put into service according to the EMC information provided. Portable and mobile RF communication equipment may affect this device.
- ✧ Use the Ring on index finger only. Using it with any other fingers may affect the performance.
- ✧ Patient should not use skin-care product on the finger being measured (index finger).
- ✧ Pain or discomfort may occur when using this device continuously, especially for microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 10 hours.
- ✧ For patients with special needs, please be cautious when using the device. This device cannot be used on edema or tender tissue.
- ✧ Patients allergic to TPE (Thermoplastic elastomers),PC (Polycarbonates) and ABS (Acrylonitrile Butadiene Styrene) should not use this device.
- ✧ This device is not recommended for patients who have significant skin pigmentation on the measurement site, e.g., tattoos, skin wound, etc.
- ✧ This device is not recommended for patients who suffer from smoke inhalation or carbon monoxide poisoning.
- ✧ This device may not work on every patient. If stable readings are unachievable, consider stop using this device.
- ✧ The accuracy for patients with BMI > 39.5 is not guaranteed.
- ✧ The interferences that may affect the accuracy of measurement include, but not limited to, excessive ambient light, excessive motion, restriction in blood flow, moisture in the sensor, low perfusion, venous pulsations, anemia, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, improperly applied device, electrosurgical interference, and intravascular dyes.

3.4 Battery

- ✧ The battery should be charged at least every 3 months to maintain its working life.
- ✧ Connect to a 5V DC power source to charge the battery, or else it may damage the device.
- ✧ Do not use this device while charging.
- ✧ The battery is non-removable and not user-replaceable.

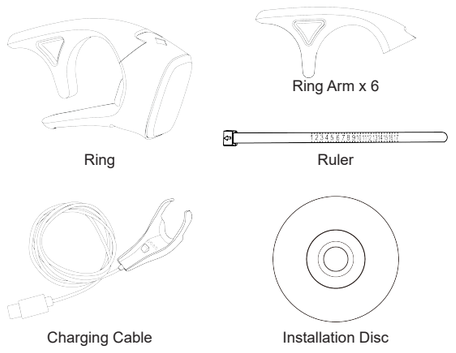
3.5 Maintenance

- ✧ This device is a precision electronic device and necessary maintenance must be performed by Belun Technical Service ONLY except charging the battery.
- ✧ No modifications to this device are allowed as it may affect the device performance.
- ✧ Do not break the casing of the device as it may damage the sensor, which may lead to malfunction, and/or inaccurate measurement.
- ✧ Check the device and other parts at least once a week to ensure there is no visible damage that may affect safety and performance of this device. When obvious damage is observed, stop using this device.
- ✧ Do not service or maintain any part of this device while it is being used with a patient.
- ✧ A functional tester cannot be used to assess the accuracy of this device.

3.6 Environment

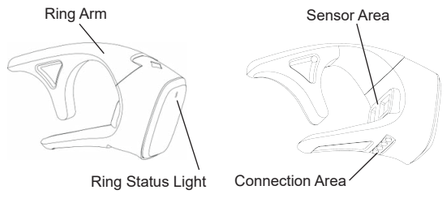
- ✧ Keep this device away from dust, lint, vibration, corrosive substances, explosive materials, high temperature and moisture.
- ✧ If this device gets wet, stop using it and let it completely dry before use.
- ✧ When it is carried from cold environment to warm or humid environment, do not use it immediately.
- ✧ The performance will be affected if there is any obstacle such as dust, lint, or stain on the sensor area. When necessary, clean the sensor area by following the direction in this manual.

4. PACKAGE CONTENT



5. PARTS AND STATUS LIGHTS

5.1 Parts



5.2 Status Lights

Color(s) & Pattern(s)	Meaning(s)
Solid Green	The Ring is ready for recording.
Breathing Green	The Ring is charging.
Solid Red	The Ring is not ready for a new recording. Refer to the section "14. TROUBLESHOOTING" for details.
Flashing Red	There is a hardware issue in the Ring. Refer to the section "14. TROUBLESHOOTING" for details.
Off	The Ring is standby. Move the Ring to wake it up. Or, the Ring is recording a measurement, or the Ring is power off.

6. PREPARATION

Before the first use, the following steps should be performed

- ✧ **Install the Companion Application (6.1)**
- ✧ **Configure Belun Ring (6.2)**

6.1 Install the Companion Application - Belun Ring Management (BRM)

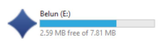
System Minimum Requirements

- ✧ Operating system: Windows 10 Home/Professional 64 bit
- ✧ RAM: 4GB
- ✧ Hard drive space: 13 MB
- ✧ Display resolution: 1280*960
- ✧ Bluetooth 5.0

Locate the BRM Installer

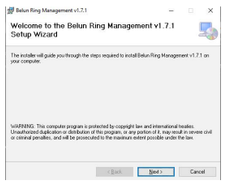
The installer is stored in the installation disc. Follow the steps below to access it.

1. Insert the installation disc into the disc drive of the computer.
2. Go to "This PC" in File Explorer in the computer and find the drive "Belun".
3. The installer is stored in the drive "Belun".

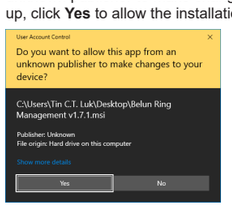


Install the BRM Application

1. Run the installer "Belun Ring Management vX.X.X.msi" in the drive "Belun".
2. The installation will start automatically. Follow the on-screen instructions until the installation is complete.



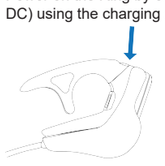
3. If a dialog asking "Do you want to allow this app from an unknown publisher to make changes to your device?" shows up, click **Yes** to allow the installation to continue.



4. Wait until the installation is done.

6.2 Configure Belun Ring

1. Power on the Ring by connecting it to a power source (5V DC) using the charging cable.

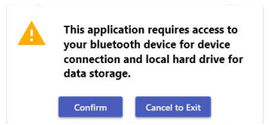


2. Start BRM by double clicking the shortcut icon on the desktop.

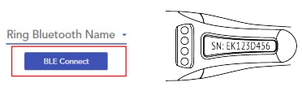
3. Choose the Device Model and log in using the default password "BeWell222".

Note: The password can be changed by clicking Change Password at the menu bar.

4. Conform to allow the necessary access permission.



5. Connect the Ring via Bluetooth by selecting the Ring SN and click the button **BLE Connect**.



6. Enter the device PIN for authentication.

7. The Ring will be configured automatically i.e. synchronize the clock when the connection is established.

6.3 Device Self-Test

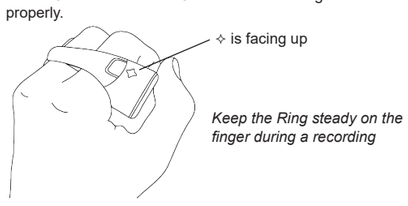
The Ring performs a self-test when it is power on. In case of any error, the Ring Status Lights will Flash Red. Refer to the section "14. TROUBLESHOOTING"for solution.

7. USE BELUN RING FOR SPOT CHECK

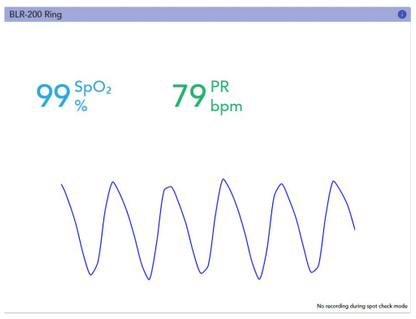
Perform spot check of the oxygen saturation (SpO_2) and pulse rate (PR).

1. Start BRM and go to the **Spot Check** Mode.

2. Connect the Ring to BRM (Refer to section "6.2 Configure Belun Ring")
3. Wear the Ring and the measurement will start. Refer to "9. TIPS TO WEAR THE RING" to ensure the Ring is worn properly.



4. The measurement result will be shown on BRM.



- When this symbol is shown, motion artifact is detected.

Note: The measured parameters are updated in every second.

Note: The Ring should be close to the computer to ensure a stable connection.

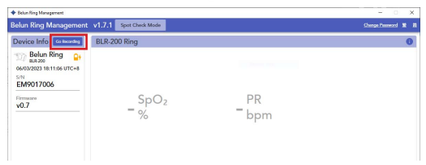
Note: BRM will disconnect the Ring if no data is received for 4 seconds. Reconnect the Ring if need.

8. USE BELUN RING FOR RECORDING

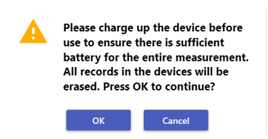
Perform continuous data recording of oxygen saturation (SpO_2) and pulse rate (PR).

8.1 Start the Recording Session

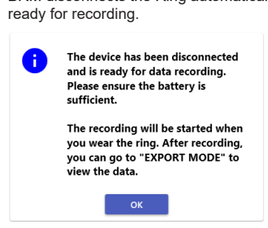
1. Start BRM and go to the **Spot Check** Mode.
2. Connect the Ring to BRM (Refer to section "6.2 Configure Belun Ring")
3. Click the button **Go Recording** .



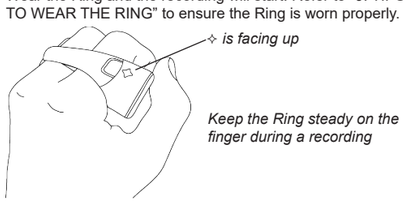
4. Confirm the device battery is sufficient and any record in the device can be erased.



5. BRM disconnects the Ring automatically and the Ring is ready for recording.



6. Wear the Ring and the recording will start. Refer to "9. TIPS TO WEAR THE RING" to ensure the Ring is worn properly.



Note: The Ring sensor emits red and infrared lights throughout the whole recording until the Ring is removed from the finger.

Note: Only measurement of 30 seconds or longer will be recorded.

Note: If the Ring battery has been completely depleted, the Ring should be configured again before use.

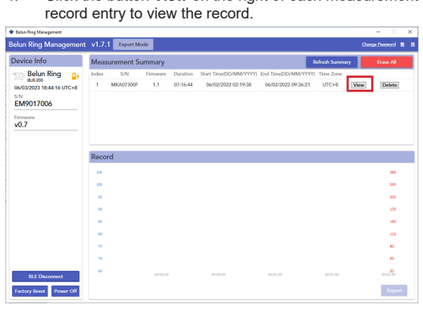
Attention: If the Ring has not been configured, it cannot record any measurement.

8.2 End the Recording Session

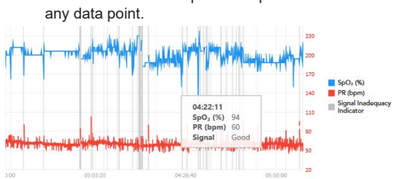
Remove the Ring from the finger to end the recording session.

8.3 View and Export the Results

1. Start BRM and click the button **Spot Check Mode** to switch to the **Export** Mode.
2. Connect the Ring to BRM (Refer to section "6.2 Configure Belun Ring")
3. BRM displays the device information and list out the measurement summary of the connected Ring.
4. Click the button **View** on the right of each measurement record entry to view the record.



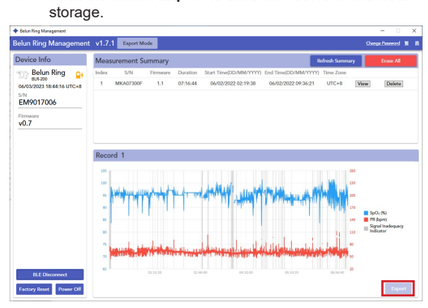
5. The measurement data of the selected record are shown in the chart. A data tooltip shows up when the mouse hovers on any data point.



Data Tooltip	Chart	Descriptions
03:20:39	X-axis	Data time in HH:MM:SS format
SpO₂ (%) 98	Blue line	Oxygen saturation in percentage (%) Range: 70 - 100%
PR (bpm) 52	Red line	Pulse Rate in beat-per-minute (bpm) Range: 30 - 250 bpm
Signal Good	Gray bar	Signal Inadequacy Indicator: Signal quality of the overlapping data area is bad due to motion, low perfusion or poor pulse signal Value: Good or Bad

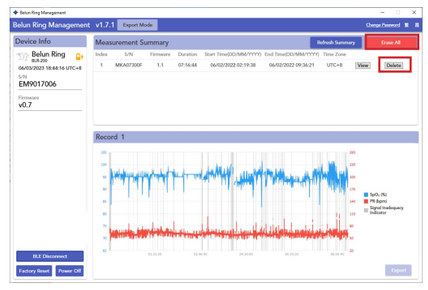
If the data value is "--", the data value is not available.

6. Click the button **Export** to save the record to the local storage.



8.4 Erase the Measurement Record

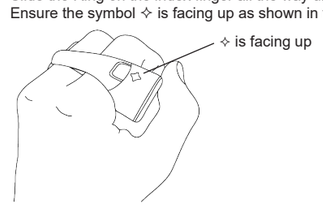
Erase any unwanted record by clicking the button **Delete** next to each record or erase all the records by clicking the button **Erase All**.



Attention: Any records that are erased are not recoverable.

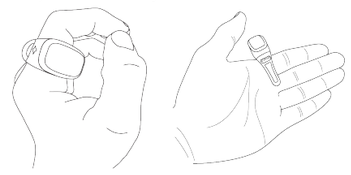
9. TIPS TO WEAR THE RING

Slide the Ring on the index finger all the way until it meets the palm. Ensure the symbol ✧ is facing up as shown in the illustration..

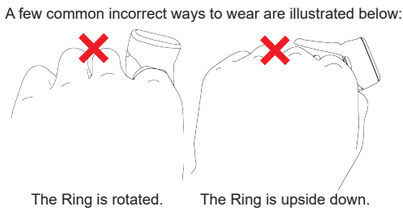


The Ring operates on the side of an index finger. It is designed to function on either left or right hand. The non-dominant hand is recommended.

The Ring should be worn to the base of the finger (proximal phalanx). The correct way to wear is illustrated below:



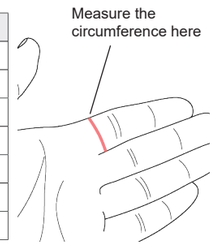
A few common incorrect ways to wear are illustrated below:



10. CHANGE THE RING ARM

The Ring is pre-installed a Ring Arm and there are spare Ring Arms included. The Ring Arms are designed to fit for different fingers. Refer to the table below for the range of finger size of each Ring Arm.

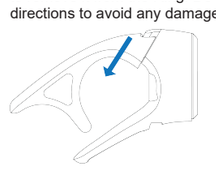
Ring Arm	Finger Size Ranges*
5	48 - 51 mm
6	52 - 54 mm
7	55 - 57 mm
8	58 - 60 mm
9	61 - 63 mm
10	64 - 66 mm
11	> 66 mm



**The circumference of the base section of the index finger (round down to the nearest integer).*
** The accuracy for patients with BMI > 39.5 is not guaranteed.*

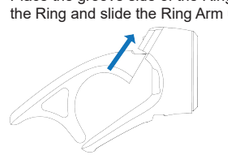
10.1 Remove the Ring Arm

Press the Ring Arm at the top along the indicated direction below to remove it from the Ring. Do not push the Ring Arm in other directions to avoid any damage.



10.2 Install the Ring Arm

Place the groove side of the Ring Arm against the tongue side of the Ring and slide the Ring Arm upward until it clicks.



Note: The Ring Arm may become loose and fall off easily after prolonged use. If that happens, please contact the local distributor or Belun Technical Support for a replacement.

11. CHARGE THE BATTERY

1. Connect the Ring to the charging cable.

2. Connect the charging cable to a 5V DC power source.
3. The Ring Status Light will Breathe Green during charging.

4. The Ring Status Light will become Solid Green when the Ring is fully charged.

12. POWER OFF THE DEVICE FOR STORAGE

1. Disconnect the Ring from the charging cable.
2. Start BRM and go to **Spot Check** Mode.
3. Connect the Ring to BRM
4. Click the button **Power Off**

5. The Ring will vibrate for ~1 second to indicate it is power off.

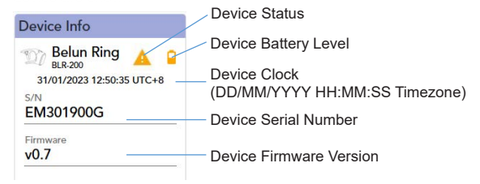
13. FACTORY RESET

1. Disconnect the Ring from the charging cable.
2. Start BRM and go to **Spot Check** Mode.
3. Connect the Ring to BRM
4. Click the button **Factory Reset**

5. The Ring will vibrate for ~1 second and power off.
6. Power on the Ring by connecting it to a power source.

14. DEVICE INFORMATION

Connect the Ring to BRM and the following information of the device are shown.



14.1 Device Status

Move the mouse pointer to the symbol will show the status information of the device.

14.2 Device Battery Level

The symbol ϟ indicates that the battery is charging.

15. TROUBLESHOOTING

Problem	Possible Cause(s)	Possible Solution(s)
The Ring Status Light is Flashing Red.	The Ring is malfunctioning.	Connect the Ring to Belun Ring Management to determine the error.
The Ring Status Light is Solid Red.	The Ring battery is too low to start a measurement.	Charge the Ring. Refer to the section "11. CHARGE THE BATTERY" for details.
	The device clock has not been synchronized.	Synchronize the device clock by connecting it to Belun Ring Management.
The Ring Status Light does not turn On when the Ring is moved.	The Ring is in the power saving mode because the battery is nearly depleted.	Charge the Ring. Refer to the section "11. CHARGE THE BATTERY" for details.
The Ring does not vibrate when it is worn on the finger.	The Ring Status Light is Solid Red and the Ring is not ready for a new recording.	Refer to this section for details.
	If the Ring Status Light is off, the Ring is in the power saving mode.	Charge the Ring. Refer to the section "11. CHARGE THE BATTERY" for details.
The Ring does not charge (Ring Status Light is not Breathing Green) when it is inserted in the Cradle.	The Ring is fully charged.	The Ring does not charge when the battery is full.

Note: The Ring will not start a measurement when the Ring Status Light is Solid Red.

Please contact the local distributor or Belun Technical Support,

- ✧ if any problem persists after performing the above possible solutions
- ✧ if you have any other problems with this device, such as setting up, maintaining, or using the device
- ✧ if any unexpected operations or events occur.

Belun Technical Support
Email: support@beluntech.com

Attention: Do not attempt to open or repair this device by yourself.

16. CARE AND MAINTENANCE

16.1 Cleaning and Disinfecting

For cleaning and disinfecting the Ring, the following procedures are recommended:

- ✧ Clean and disinfect the Ring whenever you see any type of contamination.
- ✧ Clean and disinfect the Ring prior to giving to a new patient.
- ✧ Before cleaning and disinfecting, disconnect the Ring from any power source or computer.
- ✧ Clean the Ring and once per week or more frequently if needed.
  - ✧ Gently wipe the exposed surface of the Ring with a soft cloth dampened with 70% isopropyl alcohol.
  - ✧ Dry with a soft cloth or allow it to air dry before use.
- ✧ Disinfect the Ring when needed after cleaning.
  - ✧ Disinfect by gently wiping the cleaned sensor area of the Ring with a soft cloth dampened with 70% isopropyl alcohol.
  - ✧ Dry with a soft cloth or allow it to air dry before use.
- ✧ Ensure the cloth is not dripping with liquid as the excessive liquid could damage the device.
- ✧ 70% isopropyl alcohol is both a cleaning agent and a disinfecting agent. Refer to the agent labeling for preparation and use instructions.
- ✧ Do not spray any liquid on this device directly or let water drop or flow into any part of the device.
- ✧ High temperature or high-pressure steam disinfection is not recommended for this device.

16.2 Maintenance and Battery Charging

- ✧ This device requires no calibration or maintenance other than battery charging.
- ✧ Please charge the Ring when the Ring Status Light is Solid Red indicating the battery is low
- ✧ The Ring can be charged by connecting the USB-C port to a 5V DC power source using the provided charging cable.
- ✧ When the Ring is charging, the Ring Status Light will Breathing Green.
- ✧ The device should be recharged every 3 months when it is not regularly used. If the battery is depleted, it may take longer charging time ~10 minutes before it returns to normal function.
- ✧ Do not use the device when the Ring is being charged.

16.3 Transportation and Storage

The packaged or unpackaged device can be transported by ordinary conveyance or according to transport contract. The device cannot be transported with toxic, harmful, or corrosive material.

The packaged or unpackaged device should be stored indoor without corrosive gases and with good ventilation. The environment parameters are:

Temperature	-10 °C - +60 °C
Relative Humidity	≤95%
Atmospheric Pressure	500hPa - 1060hPa

After being transported or stored in the minimum or maximum temperature, the device should wait for~ 1 hour before use if the ambient temperature is 20 °C.

16.4 Disposal

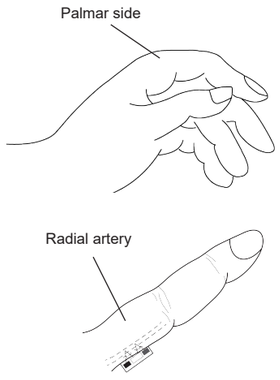
Follow the local laws and regulations to dispose of scrap parts, accessories, and packaging (including battery, plastic bags, foams, and paper boxes).

17. TECHNICAL INFORMATION

17.1 Principle

Using spectrophotometric methodology, BLR-200 measures oxygen saturation by illuminating the skin and measuring changes in light absorption of oxygenated (oxyhemoglobin) and deoxygenated blood (reduced hemoglobin) using two-wavelengths light: red and infrared. The ratio of absorbance at these wavelengths is calculated and calibrated against direct measurements of arterial oxygen saturation (SaO_2) to establish the pulse oximeter's measurement of functional oxygen saturation of arterial hemoglobin (SpO_2).

Also, the sensor should be placed on the palmar side of the proximal phalanx of the index finger and along the radial artery such that the accuracy of the device will be minimally affected by the skin color.



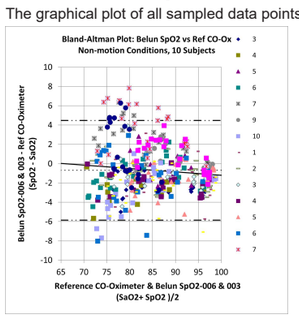
17.2 Function Specification

SpO_2 Parameter

Accuracy	70% - 100%: ±2.7% below 70%: unspecified
Average	8 seconds
Data Update Period	8 seconds

% - percentage, unit of SpO_2

The graphical plot of all sampled data points:



Please note that certain data tables and plots were obtained from a controlled, induced hypoxia study in healthy adult volunteers. The performance below 80% in one individual gave high positive bias. Further details can be found in the section Testing Summary.

Pulse Rate Parameter

Measuring range	30 bpm - 250 bpm
Resolution	1 bpm
Accuracy	±2.5 bpm or ± 2% whichever is larger
Average	Average over 8 beats

bpm - beat per minute, unit of pulse rate

Measurement in Low Perfusion

SpO_2 and pulse rate can be shown correctly when the perfusion index is greater than 0.1%.

Resistance to Surrounding Light

The deviation between the values measured under the condition of artificial light or indoor natural light and that of darkroom is less than ±1%.

17.3 System Specification

Safety Type

Class II, internally powered, BF type

Power Source

Internal Battery	3.7V rechargeable lithium battery
Charging Voltage & Current	DC 5V, 150mA
Recording Time of a Fully Charged Battery	~10 hours[1,2]
Battery Lifetime	Charge and discharge no less than 300 times if recharge at least every 3 months

1 Charge the battery as soon as possible when the Ring Status Light turns Solid Red to ensure normal operation. The recording time is estimated on a new battery and it will be reduced as the battery degrades.
2 Based on the assumption that the sensor is emitting at the typical power. A higher power will lead to a reduction in the recording time.

Sensor (Wavelength and Power)

Red	658nm ± 2nm, 8.1mW max.
Infrared	886nm ± 6nm, 6.6mW max.

The sensor information is especially useful for clinicians performing photodynamic therapy.

Data Memory

Ring	Up to 10 hours of data[1]

1 The memory of the Ring will be automatically cleared after the data has been transferred to the Belun Ring Management.

Dimension and Weight

Dimension	Ring: 44 x 60 x 18mm[3]
Weight	Ring: approximately 14g[3]

3 The measurement is base on a Ring with a Ring Arm size of 11.

Operating Environment

Temperature	+10 – +38 °C
Relative Humidity	≤75%
Atmospheric Pressure	700hPa – 1060hPa

Expected Service Life

The expected service life is 3 years[1] since the first use.

1 Based on the assumption that the device is used to record for 8 hours per day in 80% of days and the battery is recharged at least every 3 months.

17.4 Testing Summary

SpO_2 accuracy, low perfusion and pulse rate accuracy testing was conducted by Belun Technology Limited as described below.

SpO_2 Accuracy Testing

A SpO_2 accuracy comparison was conducted by an independent clinical trial laboratory. The test was conducted in accordance to the US Code of Federal Regulations (CFR) for Non-Significant Risk (NSR) investigational studies, following ISO14155:2011 as appropriate and the pulse oximetry guidelines of ISO 80601-2-61:2017 application sections, and Pulse Oximeters – Premarket Notifications Submissions [510(k)s] Guidance For Industry and Food and Drug Administration Staff (issue: March 4, 2013, US FDA).

Healthy, adult, male and female, light- to dark-skinned subjects are recruited. During non-motion and normal operating environment conditions, subjects were in a reclined position and connected to a breathing circuit, for administering medical grade oxygen and nitrogen. The gas flow delivery was adjusted for subject comfort. The gas mixture was controlled to various levels of induced hypoxia resulting in stable oxygen saturation plateaus between 100% and 70% SaO_2 Arterial blood samples were drawn during simultaneous data collection from the control pulse oximeter and the test oximeter. The blood was immediately analyzed by Reference CO-Oximetry providing functional SaO_2 for the basis of the SpO_2 accuracy comparison. The Arms is calculated using weighted data, i.e., if the subject has both right and left sided data, each data will be weighted by 0.5, otherwise the data will be weighted by 1, such that the data is not skewed towards any individuals.

During the test, there was an individual who had an increasing high bias in the range below 80% of SaO_2 as measured by the Reference CO-Oximeter. During this period the perfusion index decreased. As seen historically with hundreds of hypoxia studies, it is typical for perfusion to decrease along with the lowering of the oxygen saturation level. It is also well established for those experienced in the field of oximetry for the SpO2 values to increase in scatter as the oxygen saturation levels decrease. This is especially observed when the oxygen saturation levels are below 80%.

Low Perfusion Testing

This test uses a SpO_2 functional tester to provide an artificial simulated pulse rate, with adjustable pulse amplitude at different SpO_2 levels for the oximeter to read. The oximeter should maintain accuracy in accordance with ISO 80601-2-61:2017 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude.

Pulse Rate Accuracy Testing

This test measures pulse rate oximeter accuracy by compared to reference heart rate provided by a 3-lead ECG monitoring. This test determines whether the oximeter meets the criteria of ISO 80601-2-61:2017 for pulse rate.

Motion Testing

This test measures SpO_2 and pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for SpO_2 and pulse rate during simulated movement, tremor, and spike motions.

> Attention: The accuracy for patients with BMI > 39.5 is not guaranteed.

17.5 Radio Information

Bluetooth LE Wireless Technology Information

Modulation Type	GFSK
Max. Output Power	see test report
Frequency Range	2402MHz - 2480MHz
Antenna Peak Gain	+1.8dBi
Recommended Range	<10m

Radio Compliance	
Radio Modes	Bluetooth LE 5.0

The wireless medical device is home-use in the 2.4GHz band. Potential interferers include: IEEE 802.11b/g/n networks (2.4GHz), B/T BTLE devices, and home wireless telephones (2.4GHz).

Federal Communications Commission (FCC) Notice

Potential For Radio / Television Interference (for U.S.A. only)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device 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 distance between the device and the receiver.
- ✧ Connect the device to an outlet on a circuit different from the outlet to which the receiver is connected.
- ✧ Consult the dealer or a qualified radio/TV technician for assistance.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

18. MANUFACTURER'S DECLARATION

The following tables describe specific information regarding this device's compliance to IEC 60601-1-2.

Essential performance of the BLR-200 is defined as SpO2 accuracy and pulse rate accuracy. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the PRODUCT DESCRIPTION and SAFETY WARNINGS AND CAUTIONS. If issues are experienced, move the Belun device away from the source of electromagnetic disturbances.

Emission table for IEC 60601-1-2, 4th edition:

Guidance and manufacturer's declaration - electromagnetic emissions		
This BLR-200 is intended for use in the electromagnetic environment specified below. The operator of BLR-200 should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF Emissions CISPR 11	Group 1	BLR-200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	BLR-200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Immunity test standard	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment—Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BLR-200 requires continued operation during power mains interruptions, it is recommended that the BLR-200 be powered from an uninterruptible power source.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
Portable and mobile RF communications equipment should be used no closer to any part of BLR-200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test IEC 60601	**Test Level**	**Compliance Level**	**Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	d = 1.2 √P 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	d = 0.35 √P 80 MHz to 800 MHz d = 0.7 √P 800 MHz to 2.7 GHz
	up to 28 V/m pulse modulation at frequencies in ISM bands *note 1*	27 V/m pulse modulation 385 MHz	d= 0.23√P 385 MHz
		9 V/m pulse modulation 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785 MHz	d= 0.39√P 710 MHz, 745 MHz, 780 MHz; d= 0.78√P 5240 MHz, 5500 MHz, 5785 MHz
		28 V/m frequency modulation 450, MHz; 28 V/m pulse modulation 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	d= 0.13√P 450 MHz; d= 0.25√P 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz
Radiated RF IEC 61000-4-3	up to 28 V/m pulse modulation at frequencies in ISM bands *note 1*	28 V/m frequency modulation 450, MHz; 28 V/m pulse modulation 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey *note 2* should be less than the compliance level in each frequency range *note 3*. Interference may occur in the vicinity of equipment marked with the following symbol:

note 1:	*Refer to IEC 60601-1-2:2014:Table 9*
note 2:	*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts 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 BLR-200 is used exceeds the applicable RF compliance level above, BLR-200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating BLR-200*
note 3:	*Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m*

Recommended separation distances table according to IEC 60601-1-2, 4th edition

Recommended separation distances between portable and mobile RF communications equipment and BLR-200			
BLR-200 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of BLR-200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BLR-200 as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter in watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 0.35 √P	800 MHz to 2500 MHz d = 0.7 √P
0.01	0.12	0.12	0.070
0.1	0.38	0.38	0.22
1	1.2	1.2	0.70
10	3.7	3.8	2.2
100	12	12	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Remark 1:	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
Remark 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

BLR-200 is in compliance with the following international standards:

IEC 60601-1:2005+AMD1:2012	IEC 60601-1-2:2014
IEC 60601-1-6:2013	IEC 60601-1-11:2015
ISO 62366-1:2015	IEC 62133:2012
IEC 62304:2015	ISO 10993-1:2018
ISO 10993-5:2009	ISO 10993-10:2010
ISO 80601-2-61:2017	

19. SYMBOLS

The symbols that are found in this manual and on the BLR-200 are described below.

Symbols	Description
	Caution
	Consult Instruction for Use
	Follow Instruction for Use
	No Alarms
	Type BF-Applied Part (patient isolation from electrical shock)
	Avoid Sunlight
	Keep Dry
IP22	Protected against dripping water and against access to hazardous parts with finger, per IEC60529.
	Direct Current
	Bluetooth Figure Mark
	Date of Manufacture
SN	Serial Number
LOT	Lot Number
	Recyclable material
	Separate collection for WEEE- Waste of electrical and electronic equipment from other household-type waste. Please recycle if possible.
	Storage/Shipping Temperature Range
	Storage/Shipping Humidity Range
	Storage/Shipping Pressure Range
Rx ONLY	Medical Prescription Required

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