belun

shed light on your sleep

BLR-100X

Operator's Manual

Rx ONLY

CONTENTS

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-100X 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.

belun˙ring

is designed and manufactured by

Belun Technology Company Limited

Unit 218, 2/F, Core Building 2
No. 1 Science Park West Avenue
Hong Kong Science Park, Shatin, Hong Kong

+852-3706 5640

info@beluntech.com

beluntech.com

belun.
shed light on your sleep

2. PRODUCT DESCRIPTION

2.1 Intended Use

Belun Ring BLR-100X is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for 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. It is not intended for single-use and out-of-hospital transport use.

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.

📋 **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 "10. CARE AND MAINTENANCE" on page 29.

✧ 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) and PC (Polycarbonates) 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 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 ring 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

Ring
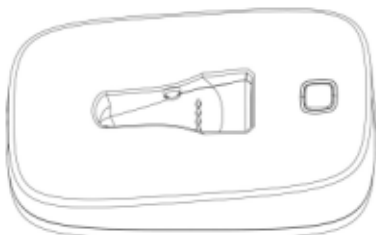
Cradle

Spare Ring Arm x 2

USB Cable (Type-C to Type-A)

Operator's Manual

5. PARTS AND STATUS LIGHTS

5.1 Parts

5.1.1 Ring

Ring Arm

Sensor Area

Ring Status Light

Connection Area

5.1.2 Cradle

Connection Base

Cradle Button

Cradle Status Light
(the rim around the button)

USB-C Port

Reset Button

5.2 Status Lights

5.2.1 Ring

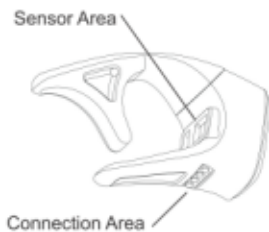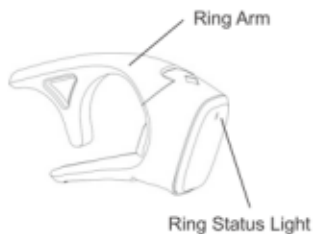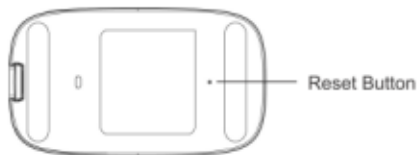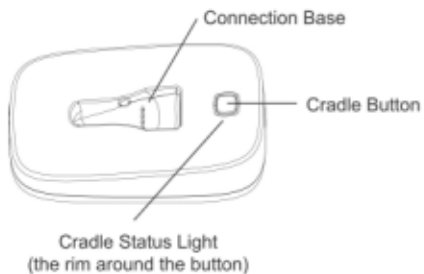| Colors & Patterns	Meanings
Solid Green	The Ring is ready for recording.
Flashing Green	The Ring is charging.
Solid Red	The Ring is not ready for a new recording. Refer to the section "9. TROUBLESHOOTING" on page 27 for details.
Flashing Red	There is a hardware issue in the Ring. Refer to the section "9. TROUBLESHOOTING" on page 27 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.

5.2.2 Cradle

Colors & Patterns	Meanings
Solid Green	The Cradle is normal.
Flashing Green	The Ring is transferring data to the Cradle.
Flashing Blue	The Cradle is connected to a computer via Bluetooth.
Solid Orange	The Cradle is low on battery. Charge the Cradle immediately.
Flashing Orange	The Cradle is charging.
Solid Red	The Cradle memory is full, or the device clock is not initially synchronized. Refer to the section "9. TROUBLESHOOTING" on page 27 for details.
Flashing Red	There is a hardware issue in the Cradle. Refer to the section "9. TROUBLESHOOTING" on page 27 for details.
Flashing Green/Orange/Red Once	The Ring is connected to the Cradle or the Cradle is connected to a power source or a computer via USB.
Solid Purple	The Cradle is in the Mass Storage Mode. Refer to the section "6.1 Install the Companion Application - Belun Ring Management" on page 11 for details.
Off	The Cradle is standby. Press the Cradle Button to wake it up. Or, the Cradle is power off.

6. SETUP FOR THE FIRST USE

Before the first use, the following steps should be performed

❖ **Install the companion application (6.1)**

❖ **Synchronize the device clock (6.2)**

❖ **Check the device information (6.3)**

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

6.1.1 System Minimum Requirements

❖ Operating system: Windows 10 Home/Professional 64 bit

❖ RAM: 4GB

❖ Hard drive space: 13 MB

❖ Display resolution: 1280*960

❖ USB 2.0

❖ Bluetooth 4.2

6.1.2 Locate the BRM Installer

The installer is stored inside the Cradle. Follow the steps below to access it.

1. Connect the Type-A side of the USB cable to the computer.
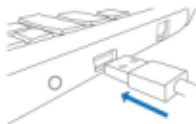
2. While pressing and holding the Cradle button, connect the Type-C side of the USB cable to the Cradle.

1. Press and hold the Cradle Button

2. Connect the Cradle to the computer with the USB cable

3. Wait until the Cradle Status Light turns Solid Purple to indicate that it is in the Mass Storage Mode.

Solid Purple

4. Go to "This PC" in File Explorer in the computer and find the drive "Belun".

5. The installer is stored in the drive "Belun".

6.1.3 Install the BRM Application

1. Run the installer "Belun Ring Management vX.X.X.msi" in the drive "Belun".

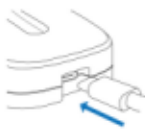2. The installation will start automatically. Follow the on-screen instructions until the installation is complete.
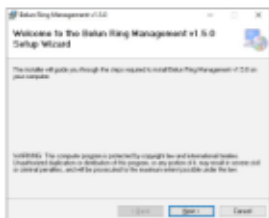
3. If a dialog asking "Do you want to allow this app from an unknown publisher to make changes to your device?" shows up, click **Yes** to allow the installation to continue.
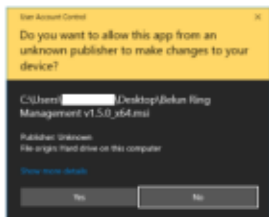
4. Unplug the Cradle from the computer and wait for the Cradle to restart in the normal operation mode (Cradle Status Light turns Solid Green or Solid Red if the device clock has not been synchronized).

Solid Green
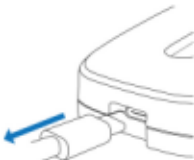
6.2 Synchronize the Device Clock

1. Insert the Ring into the Cradle. Press the Ring down until it clicks with the Cradle. The Cradle Status Light will flash Green once and the Ring will vibrate for ~1 second.
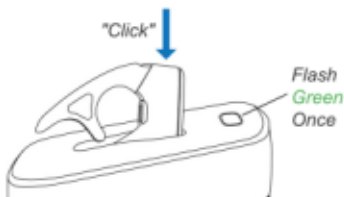
2. Connect the Cradle to the computer with the USB cable.
3. Run BRM by double clicking the shortcut icon on the desktop.
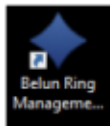
4. Log in with the password "SleepWell222".

5. BRM will connect to the Cradle automatically. If not, select the computer communication port (COM) used by the Cradle and click the button **Connect**.

"COM9" is an example only. The port is usually COM3 or COM4 in most computers.

6. The device clock will be synchronized to the computer clock automatically when the connection is established.
7. The current device clock will be shown in the Device Info (See next section).

6.3 Check the Device Information

The following information of the device are shown. Check if the device clock and other device information are shown properly.

Cradle status

Cradle battery level

Cradle

24/11/2020 11:40:57 UTC+8 — Device clock (DD/MM/YYYY HH:MM:SS)

S/N
PJC01400F — Cradle serial number

Firmware
v1.2 — Cradle firmware version

COM Port
COM9 — Computer communication port used by the Cradle

Disconnect

BLE Cradle — BLE Cradle List

BLE Connect

Ring status

Ring battery level

Ring

S/N
MJC01F00F — Ring serial number

Firmware
v1.2 — Ring firmware version

6.3.1 Cradle/Ring Status

Move the mouse pointer to the symbol will show the status information of the Cradle/Ring.

Low battery

6.3.2 Cradle/Ring Battery Level

The symbol ✦ indicates that the battery is charging.

6.4 Ready to Use

When the above steps are completed, the device is ready to use.

> ⚠️ **Attention** If the device clock has not been initially synchronized, the device cannot record any measurement.

> 📋 **Note** The device clock will be reset when the device battery is completely depleted. Synchronize the clock again before use.

> 📋 **Note** The device clock can also be synchronized when the device is connected to the BRM via Bluetooth (BLE).

7. USING BELUN RING

7.1 Record a Measurement

7.1.1 Start a New Recording Session

1. If the Ring is not in the Cradle, insert it in the Cradle first to refresh the recording session.

2. Take the Ring off the Cradle and check the Ring Status Light.

   ❖ If it is Solid Green, the Ring is ready for recording.

   ❖ If it is Solid Red, the Ring is not ready for recording. Refer to the section "9. TROUBLESHOOTING" on page 27. for details.

7.1.2 Wear the Ring

1. 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. Refer to the section "7.2 Tips to Wear the Ring" on page 18 for more details.

Keep the Ring steady on the finger during a recording

2. Once the Ring is worn on the finger, it will vibrate twice, and the sensor area will emit a red light to indicate the start of the recording. The Ring Status Light will turn Off during recording.

> **Note** The sensor would emit the red light throughout the whole recording until it is put back to the Cradle to finish recording.

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

7.1.3 End the Recording Session

When the recording is done, take the Ring off the finger and insert it back in the Cradle.

7.1.4 Transfer the Measurement Record

The measurement data recorded in the Ring will be transferred to the Cradle automatically when the Ring is insert back in the Cradle. The Cradle Status Light will Flash Green during data transfer.

> **Attention** Do not remove the Ring when it is transferring data to the Cradle.

7.2 Tips to Wear the Ring

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 incorrected ways to wear are illustrated below:

The Ring is rotated.   The Ring is upside down.

7.3 Battery Charging

7.3.1 Charge the Ring

1. Insert the Ring on the Cradle. The Cradle Status Light will Flash Once (the color depends on the Cradle status).

2. The Ring Status Light will Flash Green during charging.

7.3.2 Charge the Cradle

1. Connect the Type-A side of the USB cable to a 5V DC power source.
2. Connect the Type-C side of the USB cable to the Cradle.
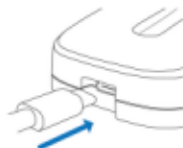
3. The Cradle Status Light will Flash Orange when the Cradle is charging.

7.4 Power On, Off, and Reset

7.4.1 Power On the Device

1. Insert the Ring on the Cradle.

2. Press and hold the Cradle button for ~3 seconds until the Cradle Status Light turns On (the color depends on the Cradle status).

Press & hold for ~3 seconds

Turn On

3. Release the button to complete the power on.
4. The Ring will vibrate for ~1 second to indicate it is power on.
5. The Cradle can also be power on by connect it to a 5V DC power source.

7.4.2 Power Off the Device

1. Unplug the Cradle from any power source or computer.
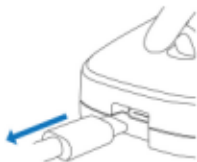
2. If the Ring is not on the Cradle, insert it on the Cradle.

"Click"

Flash Green Once

3. Press and hold the Cradle button for ~3 seconds until the Cradle Status Light is Flashing Green.

Press & hold for ~3 seconds

Flash Green

4. Release the button to complete the power off.
5. The Ring will vibrate for ~1 second to indicate it is power off.

> **Note** It is not necessary to power off the device unless the device is going to be stored for a long time.

7.4.3 Reset the Cradle

1. Insert a pin (not included) to press the reset button at the bottom of the Cradle. Press until there is a clicking feedback.

Reset Button

2. Turn the Cradle facing up. Power on the Cradle by pressing and holding the Cradle button for ~3 seconds until the Cradle Status Light turns On (the color depends on the Cradle status).

Press & hold for ~3 seconds

Turn On

3. Release the button to complete the reset.

> **Note** Refer to the section "9. TROUBLESHOOTING" on page 27 for details about when the Cradle should be reset.

> **Note** The Ring will not be reset if it is on the Cradle when the Cradle is being reset.

7.5 Device Self-Test

The device performs a self-test whenever the Ring is connected to the Cradle. In case of any error, the Ring and/or Cradle Status Lights will Flash Red. Refer to the section "9. TROUBLESHOOTING" on page 27 for solution.

Flash Red

7.6 Change the Ring Arm

The Ring is pre-installed a Ring Arm and there are two 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 Arms	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

Measure the circumference here

*The circumference of the base section of the index finger (round down to the nearest integer).

7.6.1 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.

7.6.2 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.

8. EXPORTING AND VIEWING THE RECORDS

Export and view the measurement records from Belun Ring in the companion application Belun Ring Management (BRM).

8.1 Start the BRM Application

1. Connect the Cradle to your computer with the USB cable.

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

3. Log in with the password "SleepWell222".

4. BRM will connect to the Cradle automatically. If not, select the computer communication port (COM) used by the Cradle and click the button **Connect**.

"COM9" is an example only. The port is usually COM3 or COM4 in most computers.

5. BRM displays the device information and list out the measurement summary of the connected Cradle.

8.2 View the Measurement Record

1. Click the button **View** on the right of each measurement record entry to view the record. The record will be exported automatically.

> **Note**
> Ensure the measurement record has been transferred from the Ring to the Cradle.

2. The measurement data of the selected record are shown in a chart. A data tooltip shows up when the mouse hovers on any data point.
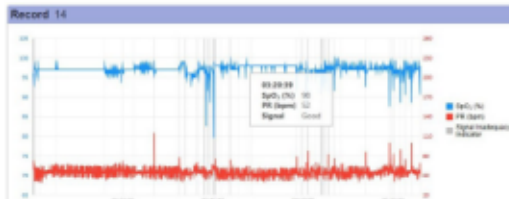
Data Tooltip	Chart	Descriptions
03:20:39	X-axis	Data time in HH:MM:SS format
SpO₂ (%) 98	Blue line	Blood oxygen saturation in percentage (%) Range: 70 - 100%
PR (bpm) 52	Red line	Pulse Rate in beat-per-minute (bpm) Range: 30 - 250 bpm
Signal Good	Gray bar	Signal Inadequacy Indicator: **Signal** quality of the overlapping data area is bad **Signal** quality is Good or Bad

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

3. Click the button **View in Directory** to open the folder of the exported records.

8.3 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 Cradle** at the top-right corner.

⚠ **Attention**   Any records that are erased are not recoverable.

8.4 Connect the Cradle to the BRM via Bluetooth (BLE)

The Cradle can connect to the BRM via Bluetooth (BLE) as well. BRM functions the same as via COM (USB) connection.

1. Check if the Cradle is connected to the BRM via COM (USB) connection. If so, disconnect it first by either clicking the button **Disconnect**, or unpluging the USB cable from the Cradle.

2. If BRM is not running, double click the shortcut icon on the desktop to run it.

3. After login, click the dropdown list **BLE Cradle** and select the Cradle from the list (Refer to the SN on the label of the Cradle).
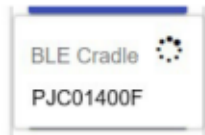
4. Click the button **BLE Connect** to initiate the connection to the Cradle.
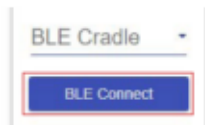
5. When the message below prompts, short press the Cradle button without holding it within 30 seconds to complete the connection.
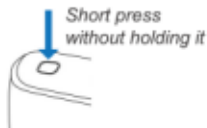
6. Cradle Status Light will Flash Blue when it is connected via Bluetooth.

7. BRM displays the device information and list out the measurement summary of the connected Cradle.

> 📋 **Note**
> When necessary such as traveling on a plane, the Bluetooth radio can be turned off by powering off the device.

9. TROUBLESHOOTING

Problems	Possible Causes	Possible Solutions
The Ring Status Light is Flashing Red.	The Ring is malfunctioning.	Insert the Ring in the Cradle and connect the device to Belun Ring Management to determine the error.
The Cradle Status Light is Flashing Red.	The Cradle is malfunctioning.	Reset the Cradle. Refer to the section "7.4.3 Reset the Cradle" on page 21 for details.
The Ring Status Light is Solid Red.	The Ring battery is too low to start a new recording.	Charge the Ring in the Cradle. Refer to the section "7.3.1 Charge the Ring" on page 19 for details.
	The Ring memory is too low to start a new recording.	Insert the Ring in the Cradle to transfer data. Refer to the section "7.1.4 Transfer the Measurement Record" on page 17 for details.
	The current recording session has expired.	Insert the Ring in the Cradle and take it out to start a new session.
	The device clock has not been synchronized for the first time or the Ring battery has been completely depleted.	Synchronize the device clock. Refer to the section "6.2 Synchronize the Device Clock" on page 13 for details.
The Cradle Status Light is Solid Red.	The Cradle memory is full.	Clear the Cradle memory using Belun Ring Management. Refer to the section "8.3 Erase the Measurement Record" on page 25 for details.
	The device clock has not been synchronized for the first time or the Cradle battery has been completely depleted.	Synchronize the device clock. Refer to the section "6.2 Synchronize the Device Clock" on page 13 for details.
The Cradle Status Light is Solid Orange.	The Cradle battery is low.	Charge the Cradle. Refer to the section "7.3.2 Charge the Cradle" on page 19 for details.

Problems	Possible Causes	Possible Solutions
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 "7.3.1 Charge the Ring" on page 19 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 "7.3.1 Charge the Ring" on page 19 for details.
The Ring does not charge (Ring Status Light is not Flashing Green) when it is inserted in the Cradle.	The Ring is fully charged.	The Ring does not charge when the battery is full.
	The Cradle battery is depleted.	Charge the Cradle. Refer to the section "7.3.2 Charge the Cradle" on page 19 for details.
The Cradle cannot be power on (Cradle Status Light does not turn On).	The Cradle battery is depleted.	Charge the Cradle. Refer to the section "7.3.2 Charge the Cradle" on page 19 for details.
	The Cradle is malfunctioning.	Reset the Cradle. Refer to the section "7.4.3 Reset the Cradle" on page 21 for details.

> **Note** The Ring will not start a recording 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.

10. CARE AND MAINTENANCE

10.1 Cleaning and Disinfecting

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

- ✧ Clean and disinfect the Ring and Cradle whenever you see any type of contamination.
- ✧ Clean and disinfect the Ring and Cradle prior to giving to a new patient.
- ✧ Before cleaning and disinfecting, disconnect the Ring from the Cradle, and unplug the Cradle from any power source or computer.
- ✧ Clean the Ring and the Cradle once per week or more frequently if needed.
  - ✧ Gently wipe the exposed surface of the Ring and the Cradle 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 and the Cradle 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 connect the Ring to the Cradle until they are completely dry.
- ✧ 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.

10.2 Maintenance and Battery Charging

- ✧ This device requires no calibration or maintenance other than battery charging.
- ✧ Please charge the Ring or the Cradle when the Ring Status Light is Solid Red or Cradle Status Light is Solid Orange indicating the battery is low
- ✧ The Cradle can be charged by connecting the USB-C port to a 5V DC power source using the provided USB cable.
- ✧ The Ring can be charged by connecting it to the Cradle.
- ✧ When the Ring is charging, the Ring Status Light will Flash 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 Cradle is being charged.

10.3 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.

10.4 Disposal

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

11. TECHNICAL INFORMATION

11.1 Principle

Using spectrophotometric methodology, BLR-100X 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.
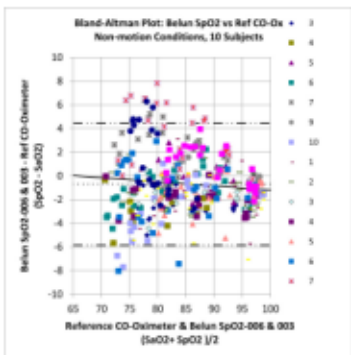
Palmar side

Radial artery
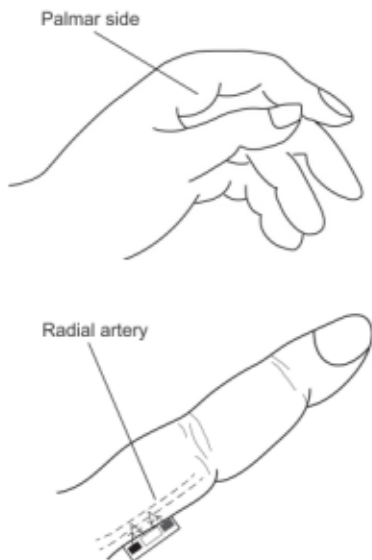
11.2 Function Specification

11.2.1 SpO₂ Parameter

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

% - percentage, unit of SpO₂

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. Further details can be found in the section Testing Summary.

11.2.2 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

11.2.3 Measurement in Low Perfusion

SpO₂ and pulse rate can be shown correctly when the perfusion index is greater than 0.1%.

11.2.4 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%.

11.3 System Specification

11.3.1 Safety Type

Class II, internally powered, BF type

11.3.2 Power Source

Internal Battery	3.7V rechargeable lithium battery
Charging Voltage & Current of the Cradle Battery	DC 5V, 700mA
Recording Time of a Fully Charged Cradle Battery	~168 hours[1, 2]
Recording Time of a Fully Charged Ring Battery	~10 hours[2, 3]
Battery Lifetime	Charge and discharge no less than 300 times if recharge at least every 3 months

1 Based on the assumption that the Cradle is used to charge the Ring fully once per day. Also, the Cradle transfers data to the computer via USB connection only.
2 Charge the battery as soon as possible when the Ring Status Light turns Solid Red, or the Cradle Status Light turns Solid Orange to ensure normal operation. The recording time is estimated on a new battery and it will be reduced as the battery degrades.
3 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.

11.3.3 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.

11.3.4 Data Memory

Ring	Up to 10 hours of data[1]
Cradle	Up to 120 hours of data[2]

1 The memory of the Ring will be automatically cleared after the data has been transferred to the Cradle.
2 If the Cradle memory is full, new Ring data cannot be transferred to the Cradle. Erase any records stored in the Cradle to clear the memory.

11.3.5 Dimension and Weight

Dimension	Ring: 44 x 60 x 18mm[3] Cradle: 32 x 100 x 59mm
Weight	Ring: approximately 14g[3] Cradle: approximately 97g

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

11.3.6 Operating Environment

Temperature	+10 – +40 °C
Relative Humidity	≤75%
Atmospheric Pressure	700hPa – 1060hPa

11.3.7 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.

11.4 Testing Summary

SpO₂ accuracy, low perfusion and pulse rate accuracy testing was conducted by Belun Technology Limited as described below.

11.4.1 SpO₂ Accuracy Testing

A SpO₂ 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% SaO₂ 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 SaO₂ for the basis of the SpO₂ accuracy comparison.

11.4.2 Low Perfusion Testing

This test uses a SpO₂ functional tester to provide an artificial simulated pulse rate, with adjustable pulse amplitude at different SpO₂ levels for the oximeter to read. The oximeter should maintain accuracy in accordance with ISO 80601-2-61:2017 for pulse rate and SpO₂ at the lowest obtainable pulse amplitude.

11.4.3 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.

11.5 Radio Information

11.5.1 Bluetooth LE Wireless Technology Information

Modulation Type	Frequency-shift Keying (FSK)
Max. Output Power	+6dBm
Frequency Range	2402MHz - 2480MHz
Antenna Peak Gain	+3.3dBi
Recommended Range	<10m

Radio Compliance	
Radio Modes	Bluetooth LE 5.0

11.5.2 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.

Changes or modifications to this unit not expressly approved by Belun could void the user authority to operate this device. A separation distance of at least 20 cm must be maintained between the antenna of this device and all persons. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

12. MANUFACTURER'S DECLARATION

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

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

Guidance and manufacturer's declaration - electromagnetic emissions		
This BLR-100X is intended for use in the electromagnetic environment specified below. The operator of BLR-100X should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF Emissions CISPR 11	Group 1	BLR-100X 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-100X 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-100X requires continued operation during power mains interruptions, it is recommended that the BLR-100X 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-100X, 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	$d = 1.2 \sqrt{P}$ 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	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.7 GHz

		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
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	d= 0.13√P 450 MHz; d= 0.25√P 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-100X is used exceeds the applicable RF compliance level above, BLR-100X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating BLR-100X
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-100X

BLR-100X is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of BLR-100X can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BLR-100X 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 $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2500 MHz $d = 0.7 \sqrt{P}$
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-100X 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 14971:2007	ISO 80601-2-61:2017

13. SYMBOLS

The symbols that are found in this manual and on the BLR-100X are described below.

Symbol	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

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Belun Technology Company Limited is under license. Other trademarks and trade names are those of their respective owners.

Notes

belun.

shed light on your sleep