Product Manual

CIRCUL RING

Manufacturer: Hangzhou Megasens Technology Co.Ltd

Address: room 802, building 3, No.1795, Tongwen road, District Xiaoshan, Hangzhou

FCC ID:2BEVE-CCR0301

PLEASE READ THIS MANUAL CAREFULLY BEFORE USING THIS DEVICE

1. Introduction

Model: MegaRing C30

The MegaRing C30 is a small ring that you can wear on your index finger which has an adjustable fit for comfort. It can be worn on either hand. The ring automatically adjusts its tightness to your finger to make its sensor touch your skin. The ring detects your blood oxygen levels and pulse rate by reading signals from your body.

Wear the MegaRing C30 at the base of your index finger. It works best if you don't move while it is measuring. The MegaRing C30 can be used to spot-check your blood oxygen and pulse rate, or for continuous data collection. You can see the recorded data by downloading the free MegaRing+ APP, provided by Megasens, from either an Android or iPhone-compatible device (smartphones, tablets, or iPads). The MegaRing+ APP will store your data, show how your data may change over time, and give you reports.

Indications for Use

The MegaRing C30 is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot-check and/or continuous data collection of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) through the index finger in adult patients. It can be used in hospitals and home environments for up to twelve hours in non-motion and well perfused conditions. It is not intended for single-use and out-of-hospital transport use and does not have alarms.

1.1 Warnings

1. Do not use the information from the MegaRing C30 as a clinical diagnosis. It's meant to be an additional tool alongside your doctor's assessment and any symptoms you may have.
2. Putting the Ring's sensor array on your finger incorrectly could hurt you and delay medical help. Human factors testing (testing of how easy or comfortable it is for a person to use the Ring) wasn't done on the MegaRing C30.
3. Charge the MegaRing C30's battery at least once a month to keep it working well. If you don't, the battery might not work as well or last as long .
4. Please follow your local instructions on how to throw away the MegaRing C30, its parts, and packaging. If you don't, it could harm the environment.
5. The part of the MegaRing C30 that touches your skin is safe and made of stainless steel material, but don't use the MegaRing C30 if you're allergic to either stainless steel.
6. Keep the MegaRing C30 away from kids or pets to prevent them from swallowing it, which may cause choking, intestinal perforation, suffocation, or other injuries.

7. Only use the parts that come with the MegaRing C30 or are

recommended in this manual. Using other things could hurt you or damage the Ring.
8. Please do not take apart, try to fix, or change the MegaRing C30 yourself as this may cause it to not work properly and cause you harm.
9. Do not wear the MegaRing C30 during either Magnetic Resonance Imaging (MRI) or Computerized Tomography (CT) Scans. It might interact with the machines and potentially burn your finger or cause other harm.

1.2 Precautions

1. The MegaRing C30 doesn't have alarms for SpO_2 or Pulse Rate.
2. Avoid using or storing the MegaRing C30 in very hot, humid, dusty, or polluted places.
3. Use a 5V DC adapter or Universal Serial Bus (USB) adapter to charge the battery of the MegaRing C30 charging cradle. This prevents damage. You can't remove or replace the battery.
4. Certain conditions like bright lights, moving your body or finger, low blood flow, and more might affect the MegaRing C30's measurement accuracy.
5. Do not use the MegaRing C30 if you have skin problems or conditions where you wear the ring (for example, tattoos, skin wounds, or excessive callusing).
6. Clean the MegaRing C30 as instructed in Section 7, and don't use high temperature, high pressure, gas fumigation, or liquid immersion.

2. Technical Parameters

2.1 MegaRing C30 Technical Parameters

Technical Parameters		
Power Supply	Internal power supply	Built-in 3.8V lithium-ion battery with a capacity of 13-23mAh
Interface	Bluetooth	BLE 5.0 Operating Frequency: 2.4 – 2.4835 GHz Modulation method: GFSK
Structure	The MegaRing C30 uses stainless steel materials. Charging of the device is made when the charging contacts on the inside of the Ring structure connect to the metal contacts on the included charging cradle (when the charging adaptor is seated in either a Personal Computer USB port or 5V AC Adapter).	
Service Life	Three years	
Shelf Life	Three years	
Waterproof Level	IP65	
Environmental Requirements	Working environments	5-40°C Relative Humidity: 30% - 80% (non-condensing) Atmospheric Pressure: 70 - 106 kPa.
	Storage environment	-10-50°C Relative Humidity: 15% - 95% (non-condensing) Atmospheric Pressure: 50.0 - 107.4 kPa.
	Shipping conditions	Device packaging includes an outer hard shell cardboard box, and inner formed plastic ring, and charger holders to prevent damage in shipping. This packaging is suitable for aviation, railway, road and marine transportation. Avoid excessive moisture, high impact and high pressure transportation conditions

Technical Parameters

Physical Parameters	Dimensions	MegaRing C30 sizes:
		● Size Small (S):
		  ○ Inner Perimeter (IP): 46.8 mm - 54.8 mm (adjustable)
		● Size Medium (M):
		  ○ Inner Perimeter (IP): 55 mm - 65 mm (adjustable)
		● Size Large (L):
		  ○ Inner Perimeter (IP): 64.8 mm - 76.8 mm (adjustable)

Bluetooth Communication Distance	Bluetooth interface	The MegaRing C30 needs to be within 3 feet (1 meter) of the linked MegaRing+ APP smart device (smartphone or tablet) to upload data to the MegaRing+ APP
Range	Pulse rate	30 – 240 bpm
	Blood oxygen	70% - 100%
Data Update Period	Pulse rate	1 second
	Blood oxygen	1 second
Pulse Rate Measurement Error	±2% or ±2bpm	whichever is greater (within 30 – 240 bpm range)
Blood Oxygen Saturation Measurement Error	±3.5% RMS (within 70% - 100% SpO_2 range)	
Peak Wavelength	Red light：660 ± 10 nm Infra-red light：940 ± 20 nm	Red light power: less than 10 mW Infra-red light power: less than 10 mW
Charging interface / charging cradle	Input voltage	5V DC
	Input current	<=0.02 A

Technical Parameters	
Safety Requirements	• Classified according to the type of anti-electric shock protection: internal power supply equipment; • Classified according to the degree of anti-electric shock: BF type application parts; • Classified according to the degree of protection against liquid entry: IP65; • Classification according to the safety level of products used in flammable anesthetic gases mixed with air, oxygen or nitrous oxide: This equipment shall not be used in flammable anesthetic gases mixed with air, oxygen or nitrous oxide; • Classification by mode of operation: continuous operation of equipment; • Does the device have an anti-defibrillation application part: **No**; • Does the device have a signal input or output part: **No**; • Permanent installation equipment or non-permanent installation equipment: no permanent installation equipment; • Input power: not applicable; • Electromagnetic compatibility belongs to Group1, Class B according to CISPR11

2.2   Principles of Operation

The body gets oxygen by a substance called hemoglobin. Hemoglobin comes in four types:
- Oxygenated hemoglobin (HbO_2)
  - This hemoglobin carries oxygen.
- Reduced hemoglobin (Hb)
  - This hemoglobin doesn't have oxygen attached to it.
- Carbon-oxygen hemoglobin (COHb)
  - This hemoglobin holds carbon monoxide instead of oxygen.
- Methemoglobin (MetHb)
  - This is another rare type of hemoglobin that also doesn't hold oxygen.

The oxygenated hemoglobin (also called blood oxygen saturation) in the blood is an important way to tell if your body is getting enough oxygen to stay healthy. It's like the amount of gas in your car's tank – the more oxygenated hemoglobin you have, the more full your tank is and the more fuel you have to power your body. Normally, the oxygen saturation of arterial blood (blood moving away from your heart) is around 98%, while the oxygen saturation of venous blood (blood moving back towards your heart) is around 75%. If the value of your arterial blood oxygen saturation level drops below 94%, you might not have enough oxygen.

The MegaRing C30 uses two light-emitting diodes (LEDs) that send two different wavelengths of light into your finger. The MegaRing C30 can determine your blood oxygen saturation based on measuring the how much of these two wavelengths of light pass through your finger.

2.3   Detection Parameters

（1）**SpO$_2$（%）**
Blood oxygen saturation (SpO_2) refers to the percentage of hemoglobin that binds to oxygen to reach saturation. SpO_2 data is detected and displayed every second.

（2）**Pulse Rate（Beats Per Minute）**
Pulse rate refers to the number of heart beats per minute. Pulse rate data are detected and displayed every second.

2.4 Product Use Scope

This prescription-only device is intended for use in hospitals and home environments to measure a patient's blood oxygen saturation and pulse rate.

2.5 Operation Precautions

1. Wear the MegaRing C30 on your index finger.

2. Cold or thin fingers can affect measurement. Make sure your hand is warm, relaxed, and lower than your heart when taking measurements.

3. Choose the right size of the MegaRing C30 for snug contact of the ring's sensor to your skin (See Section 4.4 for ring sizing information).

4. Keep still and do not move the hand or finger upon which you are wearing the MegaRing C30 during measurement.

5. After linking your MegaRing C30 to the MegaRing+ APP you will need to wait a few seconds (up to 15 seconds) until the MegaRing+ APP displays steady data (SpO_2% and Pulse Rate).

6. If you get what you think are odd results during measurement, take off the MegaRing C30, put it back onto your finger, and restart the measurement.

7. Let the MegaRing C30 stabilize for at least 15 seconds each time you put it on your finger before measuring your SpO_2 and Pulse Rate.

8. Recharge the MegaRing C30 after you use it or if the battery is low. The MegaRing C30 can't collect your data while charging.

9. Use the charging cradle supplied with the MegaRing C30 to charge the battery.

10. The service life of the MegaRing C30 is 3 years.

11. If your pulse rate (PR) or blood oxygen saturation (SpO_2) measurements are outside of your normal range, see a doctor for further examination and diagnosis.

> **Do not rely only on the MegaRing C30 for self-diagnosis or treatment.**

12. Exposing the MegaRing C30 to very bright light, movement, weak blood flow in the finger, diseased hemoglobin, the wrong wearing positions, electromagnetic interference, or other disturbances may cause inaccurate measurements.

13. Do not use the MegaRing C30 continuously for more than 12 hours within a 24 hour period due to battery life limits.

14. Do not use the MegaRing C30 in temperatures above 105.8°F (41°C).

15. If the MegaRing C30 sensor fails, the APP's Home page display of SpO_2% or Pulse Rate values will be blank .

16. If it is confirmed that the blank display is not because of incorrect use or low battery power, it may be because of internal circuit damage, a short circuit, or other damage. While this usually does not represent a safety hazard, you should immediately stop using the MegaRing C30. DO NOT attempt to fix the MegaRing C30 yourself.

17. The MegaRing C30's sensor has been tested and shown to be partly compliant to ISO 80601-2-61:2017:

**Blood Oxygen Probe Test List**
No	**Data Type**	**Emulator Generates Data**	**Test Results of Blood Oxygen Probe of this Device**	**Error %**
1	SpO$_2$/%	100	100	0
	Pulse rate/bpm	75	75	0
2	SpO$_2$/%	100	100	0
	Pulse rate/bpm	60	59	1.67
3	SpO$_2$/%	100	99	1.00
	Pulse rate/bpm	30	30	0
4	SpO$_2$/%	100	100	0
	Pulse rate/bpm	120	118	1.67
5	SpO$_2$/%	100	100	0
	Pulse rate/bpm	180	182	1.11
6	SpO$_2$/%	100	99	1.00
	Pulse rate/bpm	240	237	1.25
7	SpO$_2$/%	90	89	1.11
	Pulse rate/bpm	75	76	1.33
8	SpO$_2$/%	80	78	2.5
	Pulse rate/bpm	75	73	2.67 (=2bpm)
9	SpO$_2$/%	75	74	1.33
	Pulse rate/bpm	76	75	1.32
10	SpO$_2$/%	70	68	2.86
	Pulse rate/bpm	75	74	1.33

As a result of this testing, **partial compliance is claimed for ISO 80601-2-61:2017** as discrete clauses within the standard do not apply to the MegaRing C30. The MegaRing C30 is not intended to be used during motion and therefore testing in accordance with Clause 201.12.1.102 of ISO 80601-2-61 was not conducted. BodiMetrics does not make any claims regarding the accuracy of SpO_2 measurements under conditions of low perfusion, and therefore testing in accordance with Clause 201.12.1.103 of ISO 80601-2-61 was not conducted. Per ISO 80601-2-61 Clause 201.7.9.3.1.101, a functional tester cannot be used to assess the accuracy of the MegaRing C30. The MegaRing C30 does not contain Functional Connections and therefore testing in accordance with Clause 201.12.4.101 was not conducted.

2.6 Clinical Restrictions

The measurement of the MegaRing C30 is based on the pulsation of the arterioles. The weaker the pulse (due to shock, cold or low body temperature, heavy blood loss, the use of vasoconstrictor drugs, etc.), the smaller the pulse oximeter (PLETH) waveform can be, increasing the Ring's measurement sensitivity to interference. Also, if the wearer has considerable staining dilution drugs (such as American blue, indigo blue, acid indigo), carbon monoxide hemoglobin (COHb), methionine (Me+Hb), or thio hemoglobin, as well as some jaundice patients in their body, measurement accuracy may be impacted. Additionally, drugs such as dopamine, procaine, alanine, lidocaine, and Buzocaine may also impact pulse oximetry measurement accuracy.
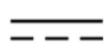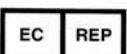
3. Appearance and Components

Device composition: The MegaRing C30 is composed of the MegaRing C30 (hardware) and the MegaRing+ APP (software).

The MegaRing C30 is made with stainless steel materials. The Ring can be charged when the charging contacts on the inside of the Ring are connected to the metal contacts of the charging cradle that came with the MegaRing C30 (when the charging cradle is connected to either a Personal Computer USB port or 5V AC Adapter).

When you receive the MegaRing C30, please check to make sure the packaging is not damaged and the size of the Ring matches your index finger size. The MegaRing C30 should be clean, of uniform color and texture, and have no obvious scratches, damage, or deformation.

- Please read this User Manual before using the MegaRing C30
- Please follow all warning signs and legends for proper wearing and use of the MegaRing C30.
- Symbols used in the labeling and their meanings are as follows:

Marks and Graphic Symbols			
	Consult the User Manual	⚠	Caution, always consult and follow accompanying documents
	Type BF applied part		Keep dry, do not submerge
	Low battery prompt		Avoid sunlight and other very bright light environments
↑↑	Straight up position	--- ---	Direct current
	Discard electronic or electrical equipment		Radio transmitting equipment
SN	Serial number		Date of manufacture
	Manufacturer		Supports wireless Bluetooth 4.1 protocol
	Product service life	EC REP	The authorized FDA/EU-representative

4. Operating Instructions

4.1 Device Composition

Open the box and remove the MegaRing C30 and charging cradle. A description of each part of the MegaRing C30 is given in **Figure 1**:

1. Charging contact electrode

2. SpO2/HR sensor

3. Stretchable structure
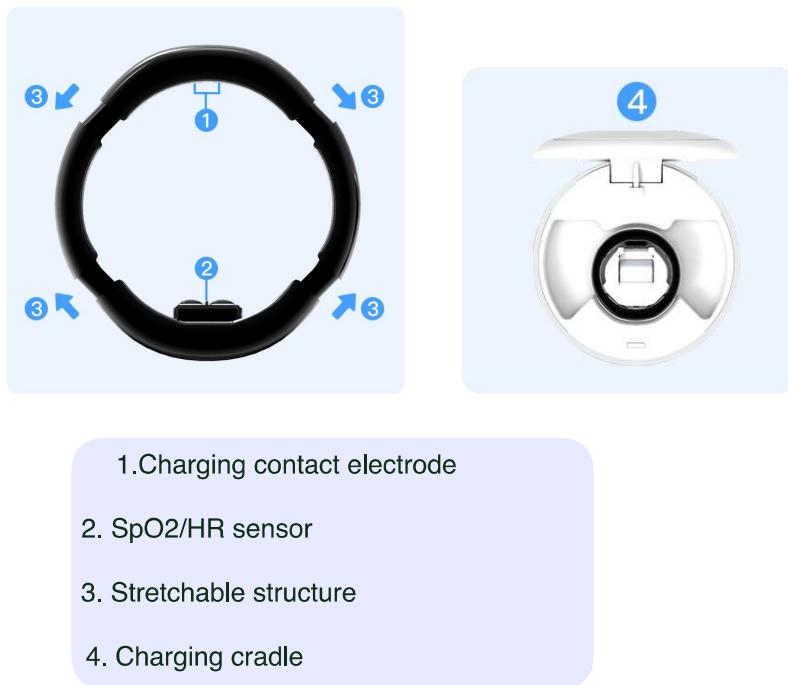
4. Charging cradle

Figure 1

4.2 Battery Charging

The MegaRing C30 has a built-in battery you can charge with the charging cradle that came with the Ring. Before your first use (and afterwards as needed based on how much you use the Ring), plug the USB adapter into the USB port of a power supply socket and make sure your socket is providing power to the USB port. Next, connect the MegaRing C30 to the charging cradle to begin charging. Be sure to place the MegaRing C30 correctly on the charging cradle for charging to happen. If the MegaRing C30 is charging, a green light (see Figure 1) will flash after about 5 seconds and continue flashing until the Ring is fully charged (once the Ring is fully charged, the light will stay illuminated and show a solid green color). If you do not see a green light, the ring isn't connected to the charger correctly.
The charging process is shown in **Figure 2**.
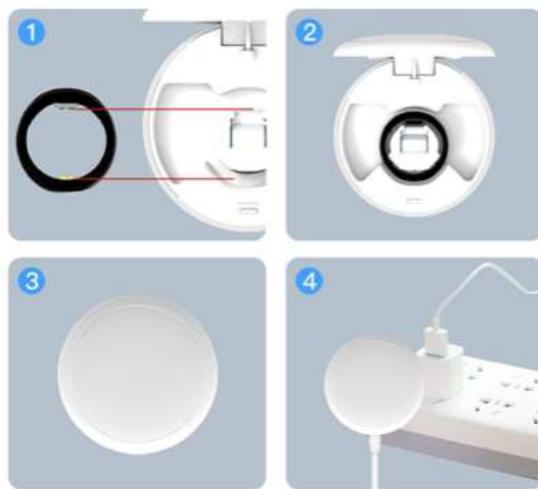
Figure 2

The MegaRing C30 takes about two hours to fully charge, and needs a full charge the first time you use it to complete activation and make sure it has the latest firmware (the Ring will automatically update the firmware when it connects to the MegaRing+ APP).

4.3 Downloading the MegaRing+ APP; APP Login, and Pairing the MegaRing C30

4.3.1 APP Download (First Time Use)

The MegaRing+ APP software supporting the MegaRing C30 can be downloaded from the Apple Store (iOS) or Google Play (Android), and will run on a mobile, smart device (e.g., iPhone, Android smartphone, iPad or Tablet) using Android 4.4 and above or iOS 10.0 and above.

4.3.2 APP Registration

Once you have downloaded the MegaRing+ APP from the app store (on your mobile device), you must register in the MegaRing+ mobile APP. This is a multi-step process as follows:

1. On the log in screen of the MegaRing+ APP, there is a Registration Link for you to create a secure login (see **Figure 3**)

2. Clicking the Registration Link will show a screen for you to enter an email address and create a personal password.

   a. The email address must be valid and the password should be 8-20 characters and include both numbers, letters and characters (i.e., !, @, #, $, etc.).

   b. The MegaRing+ APP will encrypt the account, password, and authentication response when they are transmitted.

3. Once your email and password are submitted, you will receive an email from BodiMetrics to confirm your email.

4. Upon confirming, you will be set up in the system and can begin using the MegaRing+ APP by logging in with your registered email and password.

Note: This registration process is only to authenticate the serial number of your MegaRing C30 and your account to make sure your device is always using the latest ring firmware. No personal health data is collected.

4.3.2.1   APP Login and MegaRing C30 pairing

Once registered, log into the MegaRing+ APP with the email and password you created during registration. If you forget your password, you can recover it using the *Forgot Password* link on the Log in page of the MegaRing+ APP.

After the phone turns on Bluetooth, turn on "MegaRing+" to allow the APP to use Bluetooth. Click the *Add Device* touch screen button and place the MegaRing C30 close to the phone (within approximately 8 inches (20 cm)), and follow the instructions in the MegaRing+ APP to complete the pairing.

The account registration login screens are shown in **Figure 3**.
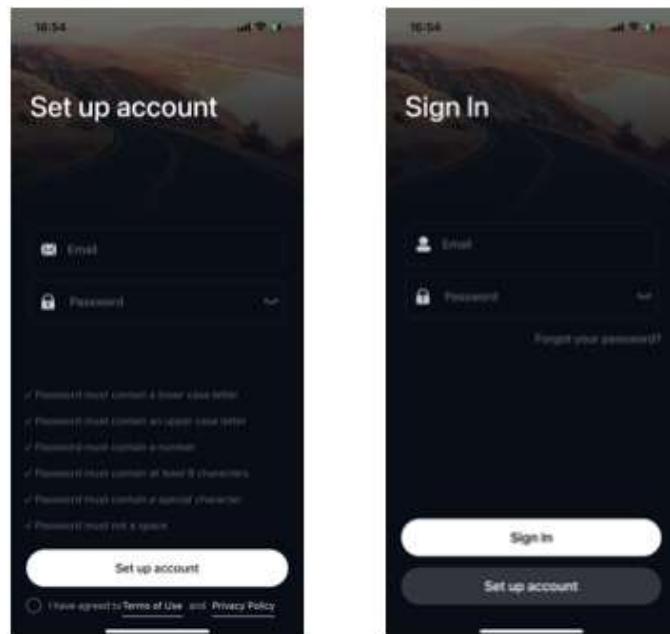
Figure 3

4.4   Wearing the MegaRing C30 Correctly

(1) The MegaRing C30 is offered in three sizes, based on the circumference of the your index finger (the distance around your index finger). The circumference of the index finger corresponds to the size of the three (3) available ring sizes as shown **Figure 4**:

Small (S):   46.8 - 54.8 mm

Medium (M):   55 - 65 mm

Large (L):   64.8 - 76.8 mm

S   57.62mm   69.55mm

L   62.8mm   74.73mm

XL 68.45mm   80.38mm
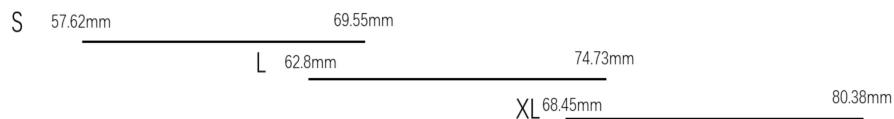
Figure 4

(2) Measure the your index finger circumference and choose the appropriate MegaRing C30 size as shown in the following steps:

- Measure your index finger circumference in advance using a string (not included - see **Figure 5**)

Figure 5

- The wearer should choose the correct ring size according to the measured index finger circumference as shown below:

Index Finger Circumference (mm)	MegaRing C30 size
Between 47 mm and 55 mm	S
Between 55 mm and 65 mm	M
Between 65 mm and 77 mm	L

(3) Wear the ring as shown in **Figure 6:**
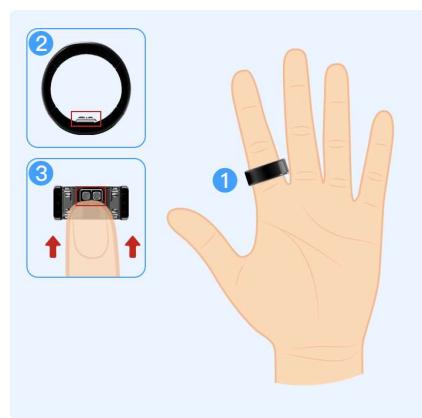
Figure 6

4.5 Activating Blood Oxygen and Pulse Rate Monitoring

After checking that the MegaRing C30 is worn correctly, opening the MegaRing+ APP, and pairing the MegaRing C30 (which you only need to do the first time you use the Ring), the MegaRing C30 will automatically begin measuring your blood oxygen saturation (SpO_2) and pulse rate (PR) data. The data and battery level will be shown on the MegaRing+ APP as shown in **Figure 7**.

Warning: Please relax, stay still, avoid motion, and wait up to 15 seconds for the MegaRing+ mobile app   to display steady measurements.
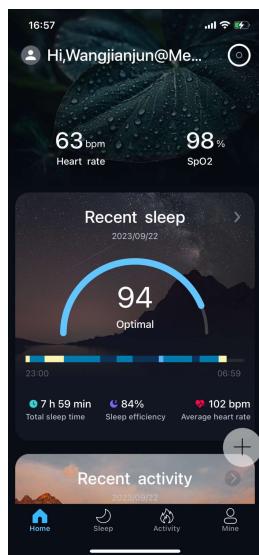
Figure 7

4.6 Ending Blood Oxygen and Pulse Rate Monitoring

When you are finished monitoring, press and hold the "Stop" button in the MegaRing+ APP until the button shows "complete". The MegaRing+ APP will automatically upload the measured data to the MegaRing+ APP and generate a report. Please make sure that the phone is within 3 feet (1 meter) of the MegaRing C30 until the data upload is completed and the report is displayed on the screen.

You can browse the list of blood oxygen data reports and tap any specific report to view the report detail.

4.7 Safe Operation of the MegaRing C30

The MegaRing C30 is calibrated in the factory, and only accessories designated

or recommended by the manufacturer can be used with it. Check regularly to ensure that there is no obvious damage to the MegaRing C30 or its accessories as this can affect safety or the Ring's monitoring performance. If there is any obvious damage, stop using the MegaRing C30 and contact the distributor or manufacturer.

5.1   Blood Oxygen (SpO$_2$) Accuracy Testing

SpO$_2$ accuracy comparison was conducted by an independent clinical trial laboratory. The clinical trial was designed according to ISO 80601-2-61:2017 and FDA guidance on pulse oximeters.

The MegaRing C30's SpO$_2$ measurement accuracy is ±3.5% RMS within a 70%-100% SpO$_2$ range. If the MegaRing C30 detects results which fall below 70% SpO$_2$, the MegaRing+ APP will remind the user that the result has exceeded the claimed SpO$_2$ accuracy range (i.e., accuracy is disclaimed).

5.2   Pulse Rate Accuracy testing

The MegaRing C30's pulse rate measurement accuracy was established by comparing it to a reference pulse rate produced by a Blood Oxygen Simulator. This test determined that the MegaRing C30 met the criteria of ISO 80601-2-61:2017 for pulse rate accuracy.

The MegaRing C30's pulse rate measurement accuracy is ±2% or ±2 bpm (whichever is greater) within a 30-240 bpm pulse rate range. If the MegaRing C30 detects pulse rates which are outside of this range, the MegaRing+ APP will remind the user that the results have exceeded the claimed pulse rate accuracy range (i.e., accuracy is disclaimed).

6. Troubleshooting

A list of general troubleshooting methods, including error messages, reason, and measures is presented below:

No	Error Message	Reason	Measures
1	**APP account log in failed**	Network failure	Please check whether the tablet or mobile phone (e.g. Cellular Data or WIFI Internet) you are using is connected to WIFI or the internet.
2	**APP cannot be connected to the MegaRing C30**	The battery of the MegaRing C30 has no charge	Connect the MegaRing C30 to a USB adapter that is connected to your PC or a 5V AC adapter to recharge the battery
		Bluetooth is not working properly	Please turn off and turn on the Bluetooth of your tablet or phone. If necessary, remove the MegaRing C30 from the list of Bluetooth-Connected devices under your mobile device Settings and try reconnecting.
		Bluetooth communication distance is too far	Please place the MegaRing C30 closer to the mobile phone (within 3 feet (1 meter))
3	**Abnormal blood oxygen saturation data detected**	Incorrect finger wearing method	Check whether the MegaRing C30 is correctly positioned on the finger according to Section 4.4. The MegaRing C30 should be worn at the base of the index finger. Make sure that the MegaRing C30's sensor is properly seated on the abdomen (e.g. belly) of the index finger. It should not be easy to rotate the Ring or have the Ring fit too tightly to the finger as per the fitting instructions in Section 4.4.

4	No SpO$_2$/PR data display on the App and prompt "please keep still"	Body movement will be detected by MegaRing in real-time, and the MegaRing+ APP will not output data during movement duration.	The MegaRing+ APP prompt "please keep still" means the Ring has detected movement. Please keep your finger and body still for up to 30 seconds to allow measurement. The MegaRing+ APP will once again display data
5	APP prompt "please charge the ring"	The battery level is lower than 3.2V, MegaRing C30 will stop detection.	The ring has detected that battery charge does not allow measurement. Please put the MegaRing C30 on the charger and charge it fully until the Ring displays a solid green light, indicating a full charge.
6	APP prompt: "off hand"	If finger is out of the MegaRing C30, APP will prompt user" off hand"	Please wear MegaRing C30 on your index finger correctly as described in this manual to allow SpO$_2$/PR measurement, which will be displayed on the MegaRing+ APP.
7	Failed to generate report	Detection time is too short	Continuous data collection is required for more than half hour to generate an effective blood oxygen saturation and pulse rate report. If you wear the ring for a shorter time, no report will be generated.

7. Maintenance

To protect the MegaRing C30, please:

- Do not store the MegaRing C30 or its accessories in hot or humid places, or in direct sunlight.
- Do not take apart or try to change the MegaRing C30 or its accessories by yourself.
- Do not shock or strongly vibrate the MegaRing C30 (for example, drop it to the ground)
- No calibration is needed to use the MegaRing C30.
- To protect the battery life, the MegaRing C30 should be fully charged if not used for a long time and recharged at least once a month.
- When cleaning the MegaRing C30, please use a clean, soft microfiber cloth (the same cloth you would use to clean your eyeglasses) with 5 mL of medical alcohol (also known as rubbing alcohol) at 75% concentration (three parts alcohol to one part of water). Gently wipe the MegaRing C30 for about 15 seconds until no visible dust or stains on the inside or outside of the ring can be seen. Do not use harsh solvents or soak the MegaRing C30 in water or other liquids.

8. Cybersecurity

We recognize that failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient illness, injury, or death. The following measures were taken to ensure effective cybersecurity risk management to reduce the risk to patients.

8.1 Personal data protection from Unauthorized User

The MegaRing C30 and MegaRing+ APP have been designed and developed to implement a robust framework for cybersecurity to assure functional safety and protection against unauthorized access to user information. Access is controlled by the user via a unique email and password defined during the registration process after downloading the MegaRing+ mobile APP from either the Apple Store (for iOS users) or Google Play Store (for Android users) to their mobile device. This is in addition to security inherent in the Apple (iOS) and Google (Android) operating systems. The data generated by the MegaRing C30 are encrypted at rest to ensure HIPAA compliance.

The user's email and password are verified via a link sent to the user's email address to enable access. Lost or forgotten passwords can be reset by using the same workflow and email verification process. All user data is maintained locally on the user's mobile device and can only be checked by the registered account login user and shared by the user via email or printed report. These reports cannot be checked by an unauthorized APP login user.

All communications between the MegaRing C30 and MegaRing+ APP are short-range Bluetooth (BTLE) communications after the MegaRing C30 is connected by the user through a set up process (controlled by their MegaRing+ APP), including:

- Auto-Pairing to ensure a unique connection
- Set BTLE encryption mode to ensure over-the-air security
- Validate device with encoded serial number check

8.2 Software / Firmware Updates

Software is maintained on a regular, agile, release schedule. Device firmware is updated automatically by sending the firmware to the user via the MegaRing+ APP. Every time the MegaRing C30 connects via Bluetooth, a unique signal and process begins to process the update on the users' device. The user cannot decline the firmware update or use the device until the latest firmware has been updated. All data is transferred encrypted (TLSv1.2) to the MegaRing+ APP and then sent via Bluetooth to the MegaRing C30. This connection is controlled by an Amazon Web Service (AWS) Cognito and S3 using (HTTPS) and the following:

- Verify email on registration
- Secure in transit (SSL)
- Firewalled, security group access to cloud
- Oauth2 authentication to prevent hacks
- Amazon Cognito service to provide security

8.3 Cloud Server Environment

The MegaRing+ APP securely communicates with the distributor's secure cloud environment hosted at Amazon (AWS) to register users, manage authorized accounts, update firmware, and provide tracking of the Ring's model, size, and unique serial number. The secure environment includes at minimum the following protocols, services and software to prevent unauthorized access to users' email or password; in transit communications of firmware updates, and barriers to malware or code injections:

- App detects updated, downloads from cloud
- Secure in transit (SSL)
- Firewalled, security group access to cloud
- Oauth2 authentication
- Amazon Cognito service to provide security

8.4 Mobile Phone Operating System Version Upgrade

To ensure your user data security and prevent unauthorized access to your mobile device or APPs, please be sure to regularly check that your mobile phone operating system (OS) is using the latest version of the OS, and update the OS if a new version is available.

9. Company Information

Manufacturer: Hangzhou Megasens Technology Co.Ltd
Address: Room 802, 8th Floor, Building 3
                        Tiande Industrial Park, No. 1795
                        Tongwen Road, Economic and Technological
                        Development Zone
                        District Xiaoshan, Hangzhou, Zhejiang Province, China

Contact information: 86-571-28187980

US Distributer: BodiMetrics, LLC
Address: 1601 N. Sepulveda Blvd, Suite 839
                        Manhattan Beach, CA 90266

10. Accessories

The items provided with this device are shown below.

Accessory name	Quantity
MegaRing C30	1
Charging cradle	1
User Manual	1
Packing box	1

11. Wireless Information

Bluetooth Low Energy (BLE) Wireless Technology Information

Modulation Type	Gauss frequency Shift Keying (GFSK)
Max. Output Power	+8 dBm
Frequency Range	2402 – 2480 MHz
Antenna Peak Gain	+2.38 dBi
Recommended Range	Within 3 feet (1 meter)
Radio Modes	BLE 5.0

Appendix — MANUFACTURE'S DECLARATION

The following tables describe specific information regarding the MegaRing C30's compliance to EN 60601-1-2: 2015, IEC 60601-1-2:2014; Emission table for EN 60601-1-2: 2015, and IEC 60601-1-2:2014:

Guidance and Manufacturer's Statement - Electromagnetic Emission		
The MegaRing C30 is intended for use in the electromagnetic environment as specified below. The buyer or user should assure that it is used in such an environment:		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emission **CISPR 11** **EN 55011**	Group 1	The MegaRing C30 uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF Emission **CISPR 11** **EN 55011**	Class B	The MegaRing C30 is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Current Emissions **EN 61000-3-2** **IEC 61000-3-2**		
Voltage Fluctuation and Flicker **EN 61000-3-3** **IEC 61000-3-3**		

	Guidance and Manufacturer's Statement - Electromagnetic Immunity	
The MegaRing C30 is intended for use in the electromagnetic environment as specified below. The buyer or user should assure that it is used in such an environment:		
Immunity Test	**EN 60601-1-2, IEC 60601-1-2 Test Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge EN 61000-4-2 IEC 61000-4-2	±8 kV, contact discharge ±15 kV, air discharge	Floors shall be wood, concrete or ceramic tile. If floors are covered with the synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients / Bursts EN 61000-4-4 IEC 61000-4-4	±2 kV, input AC power port	Mains power quality should be that of a typical home healthcare or professional healthcare facility environment
Surges EN 61000-4-5 IEC 61000-4-5	Line to Neutral, ± 0.5 / ± 1 kV, Line to Earth, ± 0.5 / ± 1 kV, Neutral to Earth, ± 0.5 / ± 1 / ± 2 kV, input AC power port	Mains power quality should be that of a typical home healthcare or professional healthcare facility environment
Voltage Dips and Interruptions EN 61000-4-11 IEC 61000-4-11	0 % [% U_{NOM}], for 0.5 cycle 0 % [% U_{NOM}], for 1 cycle 70 % [% U_{NOM}], for 25 cycles 0 % [% U_{NOM}], for 250 cycles	Mains power quality should be that of a typical home healthcare or professional healthcare facility environment
Rated Power Frequency Magnetic Fields (50/60 Hz) EN 61000-4-8 IEC 61000-4-8	30A/m 50 Hz	Mains power quality should be that of a typical home healthcare or professional healthcare facility environment

Guidance and Manufacturer's Statement - Electromagnetic Immunity		
The MegaRing C30 is intended for use in the electromagnetic environment as specified below. The buyer or user should assure that it is used in such an environment:		
Immunity Test	EN 60601-1-2, IEC 60601-1-2 Test Level	Electromagnetic Environment - Guidance
Radiated RF EM Field Immunity EN 61000-4-3 IEC 61000-4-3	10 V/m @80MHz—2.7GHz, modulation AM	During the test it is verified if the equipment under test (EUT) has sufficient immunity against radiated electromagnetic fields. Industrial electromagnetic sources, walkie-talkies, radio transmitters, television transmitters and telecommunication equipment including cellular telephones and other emitting devices can generate these fields.
Proximity Fields from RF Wireless Communications Equipment EN 61000-4-3 IEC 61000-4-3	27 V/m @ 385MHz, TETRA 400; 28 V/m @ 450MHz, GPRS 460, FRS 460; 9 V/m @ 710/745/780MHz, LET Band 13,17; 28 V/m @ 810/870/930MHz, GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5; 28 V/m @ 1720/1845/1970MHz, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS; 28 V/m @ 2450MHz, Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7; 9 V/m @ 5240/5500/5785MHz, WLAN 802.11 a/n;	During the test it is verified if the equipment under test (EUT) has sufficient immunity against radiated electromagnetic fields. The frequencies and services listed in the table of requirements are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard.
Conducted Disturbances Induced by RF Fields Immunity IEC 61000-4-6	AC mains power input 3 V/ 6 V @0.15 MHz – 80 MHz	During this test the immunity of the equipment for induced or conducted electromagnetic fields is checked. Fields generated by radio and other transmitters cause RF voltages in long cables like the mains network. This test reproduces these induced disturbing voltages by injecting them to the EUT via the cabling.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and MegaRing C30 – for MegaRing C30 that is not LIFE-SUPPORTING

Recommended Separation Distances between Portable and Mobile RF communications equipment and the MegaRing C30		
The MegaRing C30 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pulse oximeter as recommended below, according to the maximum output power of the communications equipment.		

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

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

The devices has been evaluated to meet general RF exposure requirement, the device can be used in portable exposure condition without restriction