BIOSENCY

Connected oximeter & heart / respiratory rate smart band monitor

Bora band® Model BB100

User manual

CE 2797

BORA-Band_IFU-6.0 – DATE : June 2023

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Introduction

About this user manual

This manual is a user guide for the Bora band® Model BB100 wearable device, designed by Biosency.

⚠ WARNINGS

INSTRUCTIONS FOR USE

Please do not use the Bora band® wearable device without first reading and understanding all of the instructions contained within.

Please always use the Bora band® in accordance with the instructions contained within this manual, which includes where to locate and place the oximeter. Failure to follow the instructions in this manual may result in malfunctions, including inaccurate readings.

The Bora band® device should only be used with the equipement supplied by Biosency and the applications developed by Biosency or its partners.

To ensure safe and optimal use of the device, please carefully read the precautions for use marked with an ⚠ symbol.

Intended use

Bora band® is a wearable device used for measuring (intermittent data collection), recording, processing and storing physiological parameters that will later be transmitted to a web platform for remote review to support the follow-up of patient's care. There is no display on Bora band®. Bora band® measures, records and processes:

- functional oxygen saturation of arterial hemoglobin (%SpO_2),
- heart rate (HR),
- respiratory rate (RR),
- skin temperature (T°C).

Bora band® is suitable for use with adult with chronic respiratory diseases and satisfactory perfusion.

It is intended for use at home, outdoors, and within medical settings.

Bora band® is intended to be used in combination with one of the following platforms: Bora connect®, EPOCA (EIIS), Dom'air Santé.

⚠ WARNINGS

MAGNETIC RESONANCE IMAGING

Do not use the Bora band® during surgery or in a magnetic resonance imaging (MRI) setting.

DEFIBRILLATION

Do not use the Bora band® during defibrillation procedures as this device is not shock proof (in accordance with IEC 60601-1).

ELECTROSURGERY

Do not use the Bora band® during electrosurgery.

FLAMMABLE SUBSTANCES

To avoid the risk of explosion, do not use the Bora band® in the presence of flammable anaesthetics or other flammable substances, or within oxygen- or nitrous oxide-enriched environments.

COMPLEMENTARY DEVICE FOR PATIENT DIAGNOSIS

This device should be used in conjunction with other methods for the assessment of symptoms and clinical evidence.

Target population

The device, which is prescribed by a doctor, is intended to measure the cardio-respiratory parameters of patients suffering from chronic respiratory disease. The patients are adults with a satisfactory blood supply.

The Bora device is intended for use by several types of users :

1. Patients wear the Bora band® bracelet. They can consult their data on a mobile version of Bora connect® (except with Bora Connect for Research / Bora Connect for Home).

2. Medical staff have access to patient data collected by Bora band® using the Bora connect® web version.

3. The client structure (e.g. home care provider) has access to Bora band® status information (device in use or available for use, battery level, etc.) using the Bora connect® web version.

Contraindications

The Bora band® does not trigger an alarm and does not allow for continuous readings.

The Bora band® is not designed to continuously monitor patient vital signs.

The Bora band® is not intended for use in patients with low perfusion.

⚠ WARNINGS

ALARM

Do not use the device when alarms are required.

CONTINUOUS MONITORING

Do not use the Bora band® for continuous monitoring purposes. The Bora band® is intended to periodically record physiological parameters (SpO_2, respiratory rate, heart rate, temperature). No alarm is provided to allow continuous monitoring.

Side effects

Skin irritation, superficial burn and temporary injury may occur.

When not used as intended, a delay in patient care may occur.

About Bora band® technology

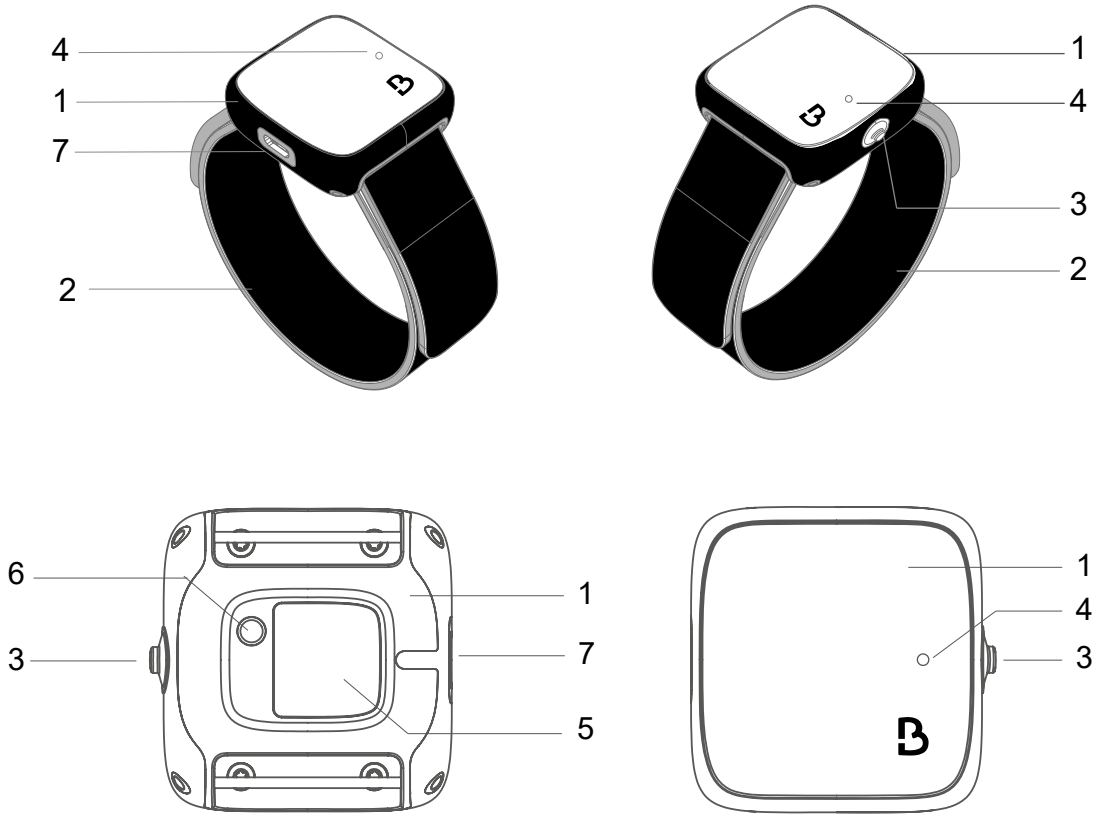
The Bora band® pulse oximeter is a communication device designed to be worn on the wrist and acquire real-time readings several times a day, while maintaining user comfort at all times.

The Bora band® has three sensors:

- A photoplethysmography (PPG) sensor, for measuring SpO_2 and heart rate
- A 6-axis inertial measuring unit, to count steps, monitor physical activity and measure respiratory rate
- A thermal sensor, to measure skin temperature

The Bora band® stores data in an internal memory. The data is then transmitted using Bluetooth® Low Energy technology.

Bora band® Model BB-100 presentation



1	Case
2	Fabric wristband
3	Button
4	Indicator light
5	SpO_2 and heart rate sensor window
6	Temperature sensor
7	Micro-USB B Port

Figure 1 : Bora band® presentation

Standard Bora band ® kit

Upon delivery, please ensure that the following parts and elements are present. Please contact the carrier immediately if the package is damaged.

Kit equipment :

- 1 Bora band®, smart bracelet, oximeter and heart and respiratory rate sensor
- 1 BB100S fabric bracelet
- 1 BB100DC, AC adaptor conforming IEC 60601-1-2
- 1 BB100UC, micro USB cable
- 1 BB100IFU, User manual (this document)
- 1 BB100QUG, Quick user guide (patient)

Equipment

The Bora band® cannot be used with elements other than those supplied by Biosency.

Model number	Description
BB100DC	AC adaptor, IEC 60601-1-2 compliant
BB100UC	Micro USB cable
BB100S	Fabric wristband

⚠ WARNING

ELECTROMAGNETIC INTERFERENCE

The use of AC adaptor and cables other than those listed in this manual, may result in increased electromagnetic emissions and / or decreased immunity of this device. As a result, this may lead to malfunction.

Bora band® identification

The serial number is listed on the base of your device as indicated in Figure 2.

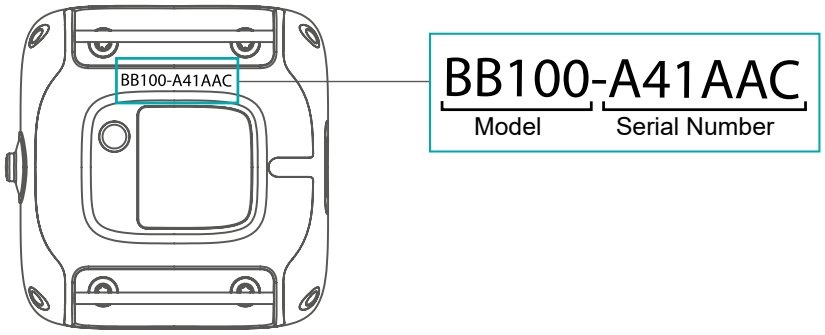


Figure 2 : Bora band® identification number

The Unique Device Identifier appears on the plastic carring case labelling, as a 2D datamatrix code and a readable alphanumerique sequence, after the UDI symbol.

Pairing Bora band ® with the mobile application

The data's transmission stored in Bora band® is done through a mobile application. This operation requires the installation of the mobile application on a phone or a tablet and the pairing of Bora band® with it.

The installation and pairing procedure varies depending on the mobile application used :

- The Bora connect for home application
- The Bora connect® application
- Partner mobile application

Bora connect for home

The installation of the application and pairing of Bora band® are already done by your healthcare provider or by the Biosency team since you are using a Bora box™, a mobile phone provided and configured beforehand by Biosency.

Bora connect ®

Installation of the application

The user should install the application on their mobile phone (the use of the Samsung Galaxy A20e phone is recommended) or on a tablet. The app is available on the Google Play Store. Type Bora connect® in the store search bar. Make sure that the application found is indeed published by BIOSENCY. Follow the store instructions to install the app.

In order to ensure the application works correctly, the mobile phone on which Bora connect® is installed must have the following minimum technical characteristics :

- 1,4 GHz processor
- RAM : 2GB
- Resolution : 360 x 640 pixels
- Bluetooth ® : 4.2 (BLE)
- Operating system : Android version N-5 ou iOS version N-3 where N is the last version
- Access to a WiFi network or a cellular network with mobile data (3G/4G/5G)

Pairing of the Bora band®

Bora band® must then be paired with this phone or tablet. To do this, the first time you use the application, you will be asked to associate a Bora band® : fill in the serial number which is under Bora band® as shown in Figure 2 : Bora band® Identification number.

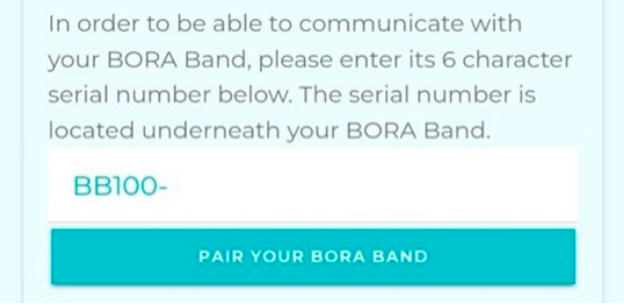


Figure 3 : Pair a Bora band®

In order for data transfer to take place, make sure that Bora band® is in the same room and close to (less than 10 metres) the laptop or tablet to which it is connected.

Data access for patient

It is possible to check the correct functioning of the service thanks to the mobile application: it must indicate that Bora band® is connected. This mobile application allows you to consult your physiological data.

For more information on the installation and use of the application, refer to the Bora connect® user manual.

Partner mobile application

Bora band® can be paired with mobile applications designed by partners. Please refer to the instruction for use of these applications for a safe combination with Bora band®.

Wearing the Bora band®

Fastening the BB100S fabric wristband

Figure 4 shows how to attach the wristband to the Bora band® case.

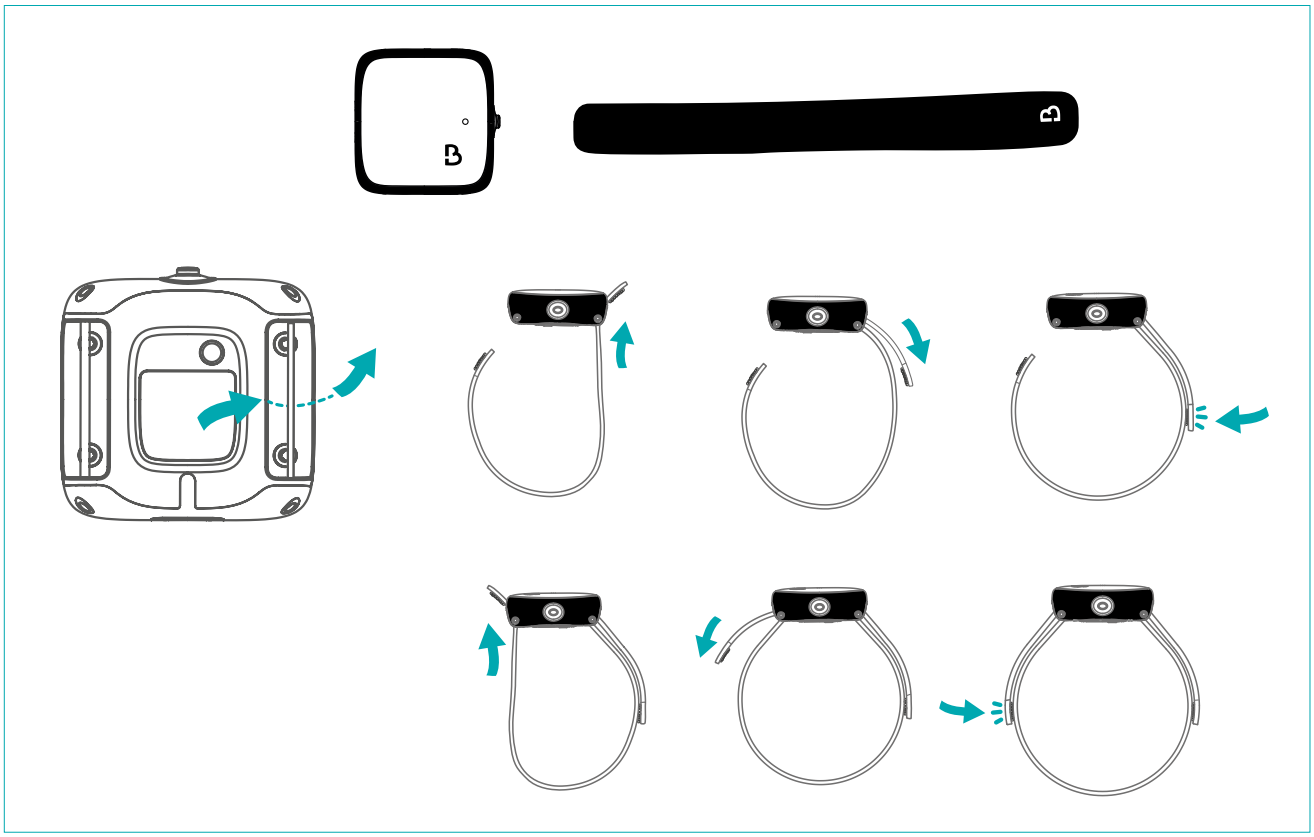


Figure 4 : Fastening the fabric wristband

Fabric wristband adjustment

Adjust the size of the wristband as illustrated in Figure 5 below.

- Undo the fabric strap's Velcro fastening and adjust to the size of your wrist, then simply secure back in place.
- To ensure optimal comfort and reading accuracy, make sure the Bora band® fits snugly on your wrist (neither too tight nor too loose).

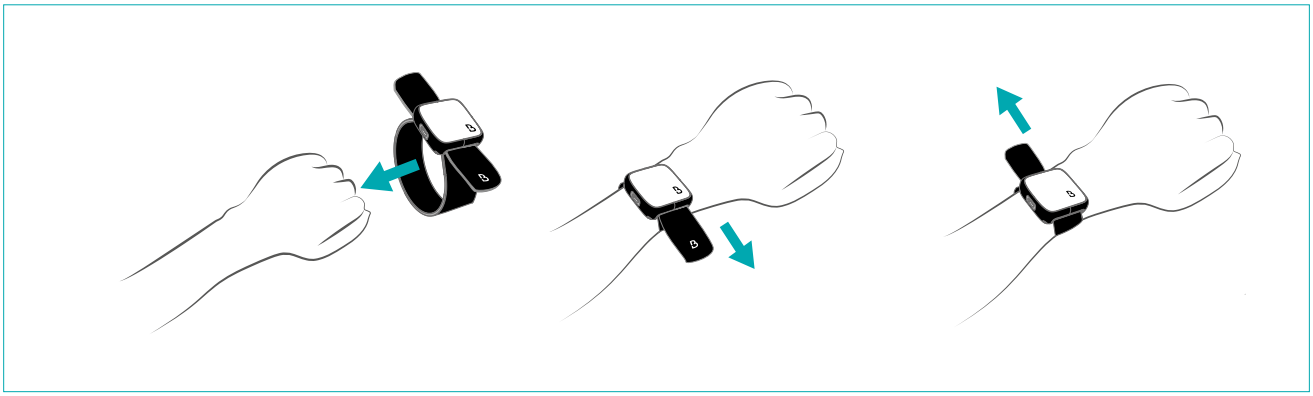


Figure 5 : Adjusting the length of the fabric wristband

Positioning the Bora band®

The Bora band® is worn on the back of the forearm, slightly below the wrist bone, as illustrated below in Figure 6. This placement ensures optimal comfort and reading accuracy.

The Bora band® can be worn on the left or right wrist.

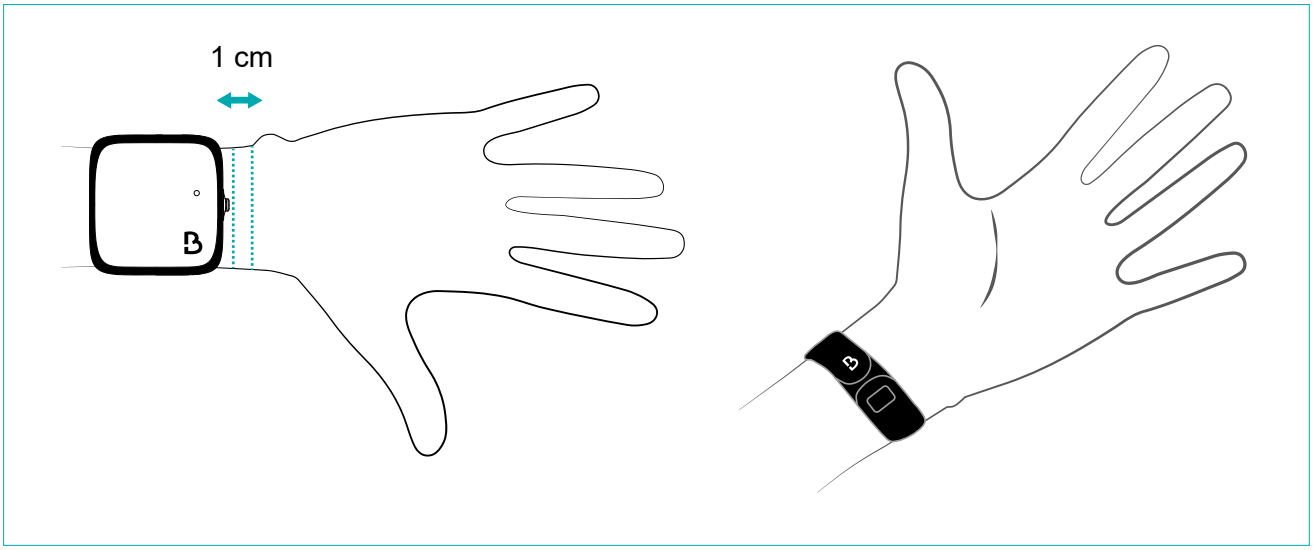


Figure 6 : Wearing the Bora band®

⚠ WARNINGS

ALLERGIES

This device should not be used by people with known allergies to the fabric strap material (polyamide) or case (Polycarbonate / ABS - SEBS).

SKIN SENSITIVITY

Monitor the skin contact area closely to ensure no sensitivity occurs. If irritation occurs, check the cleanliness of the sensor, and clean the device if necessary. Should the problem persist, please contact a sales representative.

FASTENING TOO TIGHT ON THE WRIST

Do not over tighten the device on the wrist. Fastening the device too tightly can cause discomfort.

FACTORS THAT MAY NEGATIVELY EFFECT DEVICE PERFORMANCE: INCORRECT FASTENING TO THE WRIST

The wristband must be tight enough so that it does not slide on the skin but should not cause any compression marks. Too tight or too loose a fastening can negatively affect the device's performance.

FACTORS THAT MAY NEGATIVELY AFFECT THE PERFORMANCE OF THE PULSE OXIMETER: SIGNIFICANT TATTOOS OR EXCESS HAIR

Do not place this device on a tattoo or an area with significant hair growth. A tatoo and excess hair can cause inaccurate readings.

PRESENCE OF BRUISING ON THE WRIST

Should bruising appear where the device has been placed, move to the other wrist.

⚠ PRECAUTIONS

FACTORS THAT MAY NEGATIVELY EFFECT PULSE OXIMETER READINGS: INCORRECT PLACEMENT OF STRAP

Ensure the device is placed 1 cm from the wrist bone.

Taking off the Bora band®

To release, undo the Velcro fastenings on both sides of the fabric strap (as shown in Figure 7).

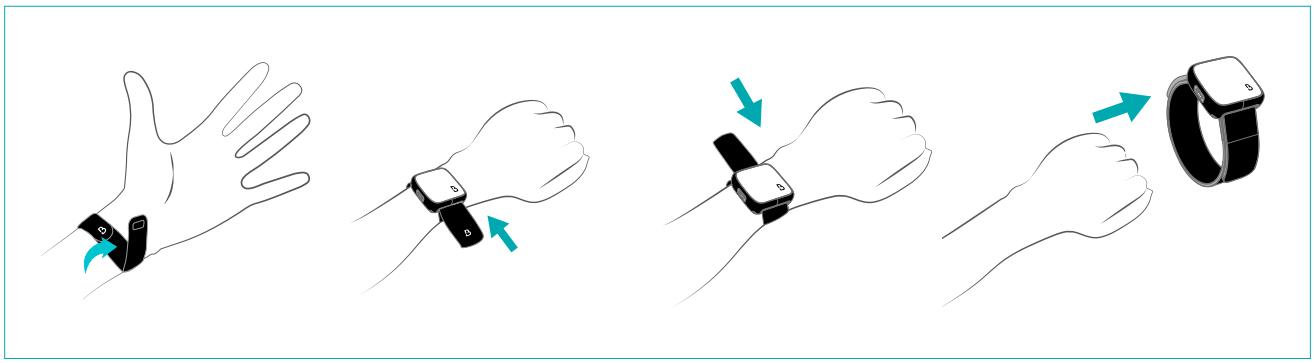


Figure 7 : Removing the Bora band®

How the Bora band® works

Starting the Bora band®

Make sure that the device is not connected to the mains, then simply start by pressing button (3). The indicator light (4) turns green for 5 seconds, indicating that the Bora band® is starting up.

What you should do	What you will see	What it means
Press button (3)	● → ● → ● Off → Fixed GREEN (4) light for 5 seconds → Off	Bora band® has started.

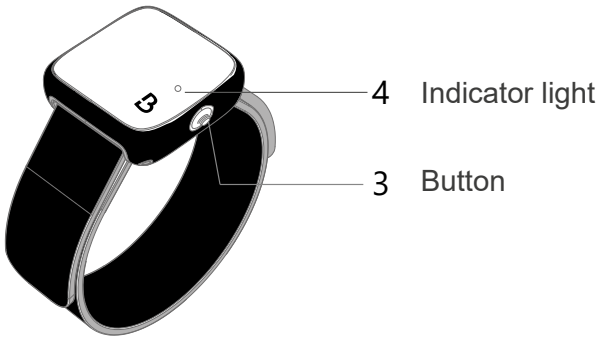


Figure 8 : Switch on the Bora band®

Once switched on, the Bora band® automatically collects and records readings for oxygen saturation (SpO_2) levels, heart rate, respiratory rate, skin temperature, number of steps and activity.

In order to be as discreet as possible, the Bora band® indicator light (4) goes out once it has started up. Please note that if the battery charge is less than 10%, Bora band® does not start.

⚠ WARNING

TROUBLESHOOTING

If the device does not perform as expected, refer to the Repair section or discontinue use and contact a sales representative.

⚠ PRECAUTIONS

EXPOSURE TO LIQUIDS

Do not submerge the device in water or any other liquid solution as this will cause permanent damage.

SKIN TEMPERATURE

The Bora band® pulse oximeter may not work if the skin temperature is too low. Make sure that the skin temperature at the area of application is 24°C or above.

FACTORS THAT MAY NEGATIVELY EFFECT PULSE OXIMETER READINGS

This device is intended to determine the amount of oxygen-carrying haemoglobin in the blood. Some factors may negatively affect the oximeter's performance or reading accuracy. These include:

- Movement
- Moisture in the sensor
- Electrosurgical interference
- Restricted blood circulation (arterial catheters, blood pressure cuffs, infusion tubing, etc.)
- Anaemia or low haemoglobin levels
- Weakened pulse rate
- Indocyanine green or other intravascular dyes
- Carboxyhaemoglobin
- Methaemoglobin
- Dysfunctional haemoglobin
- Venous pulsations
- Residue on the sensor window (5)

Turning off the Bora band ®

Stop the device by pressing button (3) until the green indicator light (4) flashes. This indicates that the Bora band® is turning off.

Malfunction

In the event of malfunction :

- Stop using the device immediately.
- Try to identify or eliminate the cause using this document (see Repair section).
- If it is not possible to identify or eliminate the cause using this document, turn off the device and call a sales representative.

Battery charging

Low battery indicator

The indicator light starts flashing ORANGE when the battery is low (less than 20% battery).

What you will see	What it means	What you should do
 Flashing orange indicator light	The battery is low.	Charge the device as described below.

Device charging

To charge the device, proceed as explained in the figure below.

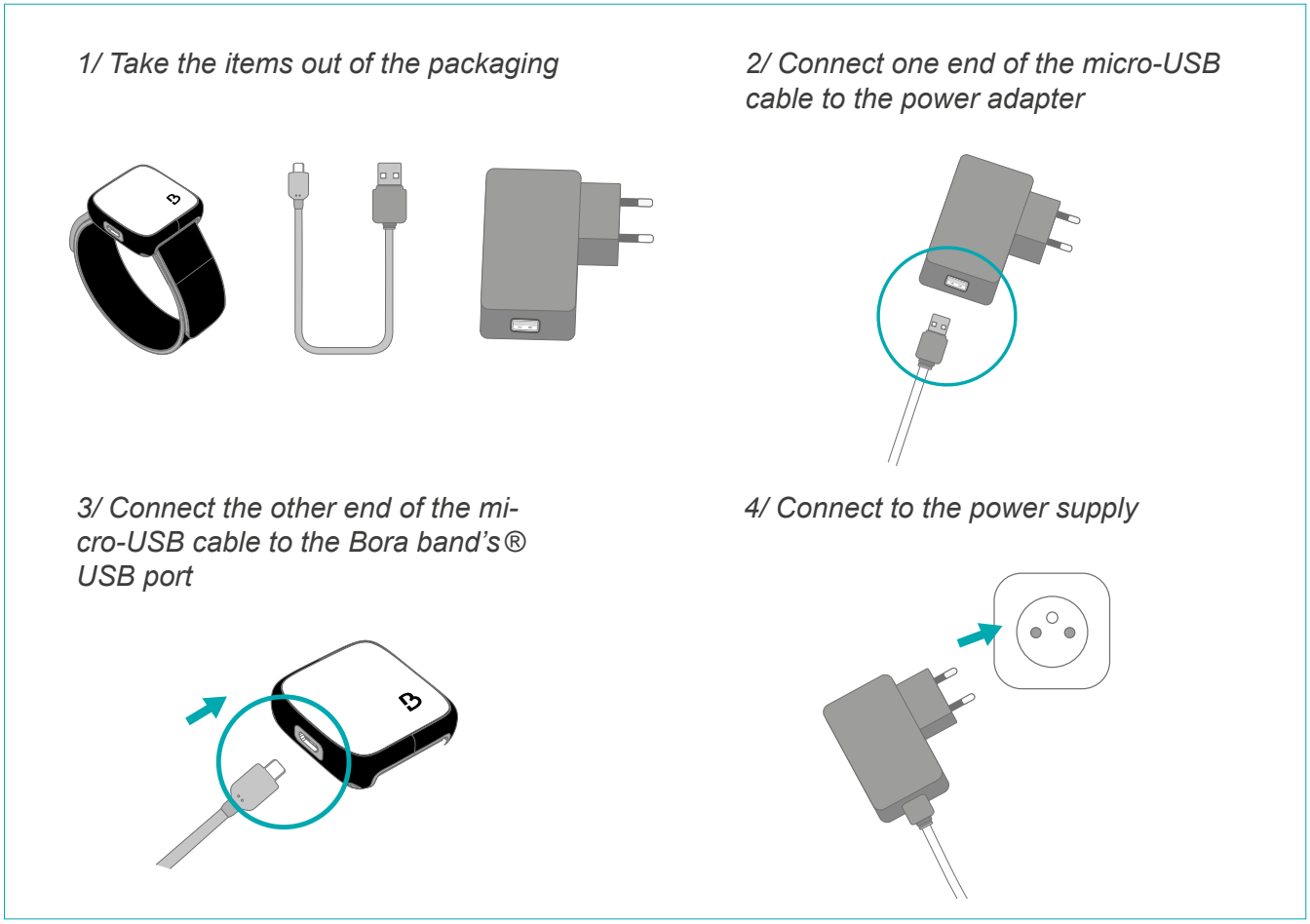


Figure 9 : Battery charging

What you will see	What it means	What you should do
Flashing WHITE indicator light	The device is charging.	Leave the device connected to the power supply
Indicator light off	The device is fully charged.	Disconnect from the power supply

Charging the Bora band® takes approximately 2 hours.

The autonomy of the Bora band® battery is more than 3 days.

NOTE :

1. If you are charging the device for the first time, or after a long period of storage (over 6 months), be sure to charge it for at least 2 hours.
2. This product should not be used in an environment which may cause electromagnetic interference.
3. During charging, the reading functions are disabled as a safety precaution.

⚠ WARNINGS

BATTERY CHARGING

Before charging the device, check that the micro-USB cable is not damaged. Use only the micro-USB cable supplied by Biosency. If the micro-USB cable is faulty, contact a sales representative.

BATTERY CHARGING

Do not wear the device while charging.

CHARGER

Use only the BB100DC AC adapter supplied by Biosency. The use of an unauthorised charger may cause an electric shock. If the AC adapter is damaged, contact a sales representative.

BATTERY

The battery may leak or explode if not used or disposed of in accordance with regulations. Do not remove the battery.

Indicator light signification

In order to be as discreet as possible, the Bora band® indicator light goes out once it has started up.

The Bora band® indicator light will be off most of the time.

	A fixed GREEN light indicates that the device is in operation.
	A flashing GREEN light indicates that the device is switching off.
	A fixed BLUE light indicates that the device is installing a software update.
	A flashing BLUE light indicates that the device is transmitting or receiving data via a Bluetooth connection.
	A flashing ORANGE light indicates that the device battery is low.
	A RED light indicates that the device is faulty.
	A flashing WHITE light indicates that the device is charging.

Bora band® software update

The Bora band® updates automatically when it is switched on; during the update, the indicator light will be blue. Be careful not to turn off the Bora band® when the blue indicator light is on.

What you will see	What it means	What you should do
 Fixed BLUE light	The device is installing a software update.	Do not turn off the Bora band®.

Data access for health professionnals

The mobile application, once installed on a mobile phone or a tablet, and connected to your Bora band®, allows you to send data to healthcare professionals on a Bora connect® web platform or a partner's platform.

To learn more about the visualization of physiological data and the setting of accounts as well as alert thresholds, please refer to the user manual of the Bora connect® platform for health professionals.

Cleaning

Cleaning the case

Wipe the device case with a soft cloth moistened with soapy water.

To avoid irreversible damage, do not use undiluted products such as bleach, or any other cleaning solution not recommended in this leaflet.

Wipe with a soft cloth and allow to air dry. The surface cleaner should be used between individual patients and as often as needed.

BB100S fabric wristband cleaning

To clean the fabric wristband, put it in the washing machine at 30°C. It is recommended to fold back the ends of the wristband to protect the Velcro hooks. Allow to air dry.

NOTE: Detergents such as hand soaps and washing-up liquid dissolve dirt and grease. You can clean the bracelet using these products (diluted in hot water).

Cleaning and disinfection between patients

The Bora band® is designed to be used multiple times by multiple users. To avoid the transmission of bacteria, the client must ensure that the case is properly disinfected before being worn by a new user.

Disinfecting the casing

If necessary, clean the device casing before disinfecting it. To do this, proceed as described in the previous section.

Disinfect the device casing with a soft cloth moistened with a surface cleaner that is suitable for cleaning and disinfecting medical devices.

To avoid irreversible damage, do not use undiluted products such as bleach, or any other cleaning solution not recommended in this leaflet.

Wipe with a soft cloth and allow to air dry. The surface cleaner should be used between individual patients and as often as needed.

BB100S fabric wristband

The BB100S fabric wristband is for single patient use. It therefore should be changed between patients.

⚠ WARNINGS

CLEANING

The Bora band® should only be cleaned with the products specified in this manual. Using different products could damage the device.

CLEANING - MULTI-USAGE FOR DIFFERENT PATIENTS

If the Bora band® is used successively by different patients, the bracelet must be changed and the Bora band® casing should be cleaned as directed by Biosency.

⚠ PRECAUTIONS

STERILISATION

Do not sterilise using autoclaves, irradiation, gas, ethylene oxide or any other method. This could seriously damage the device.

Storage

Store the device according to the specified environmental conditions. See the "Environmental conditions" section for more information.

⚠ PRECAUTION

STORAGE

The battery is designed to be stored for less than 6 months. Beyond 6 months, the battery should be charged fully.

Repair

Bora band® default status

What you will see	What it means	What you should do	If the fault persists
 Fixed RED light	The memory is full OR A serious fault has occurred.	1. Make sure that your latest data has been transferred.	If the indicator light does not go out, proceed to the next step.
		2. Turn off the device, and then switch back on.	Contact your sales representative.
 Indicator light goes out when I press the button.	A fault may have occurred.	1. Ensure the device is working.	If the indicator light does not turn on, proceed to the next step.
		2. Charge the device.	If the indicator light does not come on after 5 minutes, contact your sales representative.

When to consult a healthcare professional

If you have any new symptoms, or if your symptoms worsen, please contact your doctor.

Guarantee and Support

As part of its sales or rental contract, Biosency offers customers a two-year guarantee for the Bora band® - Model BB100. This is effective from the date of purchase or for the duration of the rental contract. In accordance with this guarantee, Biosency will repair or replace any faulty Bora band® - BB100 model free of charge, provided it has been reported to Biosency by the customer with details of the device's serial number. For any defective Bora band® - Model BB100 delivered to the customer, this warranty is the sole and exclusive remedy available, whether that be as part of a contract, a claim for redress or required by law.

This guarantee does not include the cost of sending the device to be repaired or replaced by Biosency. Biosency is liable for the reshipment of a replacement device. Biosency reserves the right to charge a repair fee (with guarantee) should the device not be found to be faulty.

No returned product will be accepted without a written agreement from Biosency or a return merchandise authorisation (RMA) number. This number will be provided by Biosency.

Any work carried out beyond the realm of the guarantee must be carried out in accordance with Biosency's standard rates (in effect at the time of delivery to Biosency).

Guarantee exclusions

The Bora band®, Model BB100, is a precision electronic instrument which should only be repaired by authorised personnel. Consequently, should there be any sign or proof that a Bora band®, Model BB100, has been opened or repaired by people outside of the Biosency company, the guarantee will be deemed null and void. The same applies to any alterations or improper use of the Bora band® Model BB100.

The guarantee does not cover indirect damages of any kind.

Guarantee disclaimer/exclusivity

The guarantees set forth in this manual are exclusive and no other guarantee, whether statutory, written, oral or implied, shall apply.

Incidents

Any serious incident which occurs in connection with the Bora care® solution should be reported to the manufacturer and to the competent authority of the Member State where the patient resides.

⚠ WARNINGS

GUARANTEE

Opening the case may damage the device and void the guarantee.

MODIFICATIONS / REPAIRS / GUARANTEE

No modification of the device is permitted, otherwise its performance may be compromised. This device is a precision electronic instrument and should only be repaired by a qualified service technician. On-site repair of the device is not possible. Never attempt to open the case or repair the electronics. Opening the case may damage the device and void the guarantee.

⚠ PRECAUTIONS

CALIBRATION

The advanced circuit design requires no calibration or maintenance. A functional test cannot be used to assess the accuracy of the Bora band®.

Disposal

⚠ PRECAUTIONS

RECYCLING

When disposing of or recycling fabric wristbands, please follow local, regional, and national guidelines as well as any current recycling instructions in force.

WEEE DIRECTIVE

In accordance with European directive 2002/96 / EC on Waste Electrical and Electronic Equipment (WEEE), please do not throw this product into unsorted household waste. This device contains WEEE materials; please contact the distributor to return or recycle it.

Cybersecurity

This chapter provides a set of precautions and warnings to guard against cybersecurity risks. In order to guarantee the confidentiality, integrity and security of your personal data, you are strongly advised to read the information below.

For more information, we invite you to consult this page describing the security management of our platform: https://doc.bora-connect.com/wp-content/uploads/2023/06/Bora-care-security-description.pdf

⚠ WARNING

IT RISK

As the Bora band® bracelet relies on Bluetooth technology, it is inherently exposed to denial-of-service (DoS) attacks that may prevent it from operating normally. This does not affect the security of your data but may prevent its proper transmission.

In the event of any suspicion, immediately alert a sales representative.

⚠ RECOMMENDATIONS

INTERNET CONNECTION

With the Bora care® solution, use an Internet connection secured by a minimum WPA2-type encryption protocol. This will ensure the security and confidentiality of your data.

YOUR PHONE'S OPERATING SYSTEM VERSION

Make sure you always have the latest version of the operating system (OS) installed on your phone before using the Bora care® solution. Having the latest version of the OS is very important, particularly because it allows you to take advantage of the latest security patches for your smartphone.

THEFT / DAMAGE

Do not leave the Bora band® device unattended. A malicious third party could compromise the integrity, security and/or confidentiality of your data by physically accessing the bracelet casing.

UPDATES

In order to allow the bracelet to update automatically, regularly connect the Bora band® device to the associated telephone.

In addition, in order to prevent IT risks, it is recommended to update the Bora connect® application as soon as a new version is available.

PLATEFORM IDENTIFIERS

Please store your login information (username and password) securely and also remember to secure access to your smartphone with a pin code or biometric recognition. This will prevent an unauthorised and/or malicious third party from accessing your data. Your connection information is strictly personal and must not be transmitted to a third party.

USE OF EQUIPMENT

The use of the Bora band® device is for personal use. In order to avoid misuse, it is recommended not to allow the device to be manipulated by third parties.

Technical information

Specifications

Performance at rest

Oxygen saturation accuracy	± 3% (from 70% to 100% SpO2)
Heart rate accuracy	± 3bpm (from 35 bpm to 240 bpm)
Respiratory rate accuracy	± 3cpm (from 10 cpm to 50 cpm)
Skin temperature accuracy	± 0,2°C (from 25°C to 43°C)
Measurement wavelength and output power	
Red.....	660nm to 0.35mW/cm2 maximum average
Infrared.....	940nm to 1.37mW/cm2 maximum average
Green.....	530nm to 1.6mW/cm2 maximum average

Reading accuracy :

SpO_2 and heart rate accuracy tests are performed in induced hypoxia studies with fair to dark skinned, non-smoking, healthy subjects of both sexes, aged 18 years and over. The arterial haemoglobin saturation (SpO_2) value measured by the device is compared to the arterial haemoglobin oxygen (SaO2) value determined from blood samples analysed with a CO-oximeter in a laboratory. The heart rate value measured by the device is compared to the value determined by an electrocardiogram (ECG) carried out in a laboratory. The accuracy of the device is measured by comparison with CO-oximeter samples measured over the SpO_2 range (70 to 100%) and the measured ECG samples.

Respiratory rate accuracy tests are performed in non-smoking, healthy subjects of both sexes, aged 18 years and over. Respiration rate accuracy tests are performed over a range of 5 to 50 cycles per minute. The respiratory rate value measured by the device is compared to the value determined by a device used for monitoring end-expired carbon dioxide. Device accuracy is compared to samples from the end-expired carbon dioxide monitoring device which is measured over a respiratory rate range (5 to 50 cpm).

In accordance with ISO 80601-2-61, (medical electrical devices - particular requirements for basic safety and essential performance of pulse oximeter equipment), precision data is calculated using the root mean square value (Arms value) for all subjects. Device measurements are statistically distributed. The precision indicated is the average root mean square error (A_{RMS}). Two thirds of measurements made by the device will have an error less than the average root mean square error (A_{RMS}).

The Bland and Altman plot (i.e., (SpO_2- SaO_2) versus SaO_2) are available at biosency.com/clinique/#Vc.

Equipment response time

Equipment delay	Delay time
Display time delay on Bora connect®	The data measured by the Bora band® Model BB100 is time stamped and transmitted via BLUETOOTH® to the mobile application. The Bora connect® display takes into account the time stamp for measurements. The date of the displayed measurements is therefore the effective date and there is no difference between the date on which the measurement is taken, and the date displayed on the Bora connect®.

System

Interface connectivity	BLUETOOTH® 4,2 / 5.0
Memory	
Type	Non-volatile
Capacity	Up to 20 days

Electrical information

Power supply	DC 5V input, 210mAh, Rechargeable Lithium-Ion battery.
Battery charging port	Micro-USB B type
Charging time	2 hours
Power consumption	Battery life greater than 3 days, with regular control checks carried out (1m30s) every 10 minutes.

Physical characteristics

Case dimensions (length x width x height)	42mm x 40,2mm x 13,7mm
Weight	
Case	19,8 gr
Case and wristband	25,1 gr
Materials	
Case	Polycarbonate/ABS – SEBS
Wristband	Polyamide
Case IP rating	IP64 Protected from total dust ingress. Water sprayed from any direction should not have a harmful effect.
Lifespan	3 years

Environmental conditions

Working conditions	Environmental temperature: +10°C to +38°C. Skin temperature : ≥ 24°C. Relative humidity: 0% to 90 %, without condensation ; Atmospheric pressure : 700 hPa to 1,060 hPa. The temperature of the device should not exceed 43°C, when measured. in a controlled environment. Time required (after storage) for the device to be operational : 15 minutes to rise from a temperature of -20°C to + 10°C ; 5 minutes to drop from 40°C to 38°C.
Storage / transport conditions	Temperature : -20°C to +35°C Shelf life : 20 months (up to 5 years with a battery charge every 6 months Relative humidity : 20 % à 95 %, without condensation.

⚠ PRECAUTIONS

Please respect the environmental operating conditions, in particular the temperature. Should the device be exposed to environmental conditions other than those specified in the "Environmental Conditions" section, patients should wait 15 minutes before wearing it.

Conformity

Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10
EMC	IEC 60601-1-2 IEC 60601-1-11 ETSI EN 301 489-1 ETSI EN 301 489-17
Electrical safety	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 ISO 80601-2-61 IEC 60529-1
RF	ETSI EN 300 328 EN 62479
IEC 60601-1 classification Type of protection Degree of protection Operating mode	 Internally powered (Battery) BF type applied part Continuous

Wireless transmission

Bluetooth conformity	BLUETOOTH® LOW ENERGY 4.2
Operating frequency	2,4 to 2,483 GHz
Output power	<10dBm
Operating range	10 m range indoors
Network topology	Point to point
Operation	Slave
Antenna type	Internal
Modulation technique	Frequency shift modulation Frequency-hopping spread spectrum modulation
Bandwidth	1 MHz, 2MHz

Operating principles

Pulse oximetry is a non-invasive method that diffuses light (red and infrared) through irrigating tissues and detects signal fluctuations due to arterial blood pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines the functional oxygen saturation of arterial haemoglobin (SpO_2) from this colour difference. As blood volume fluctuates with each heartbeat, the ratio of absorbed red and infrared light is measured.

Clinical benefits

Improving the quality of life is a clinical benefit of setting up remote monitoring with Bora band® by increasing patient reassurance and his acceptation of the rehabilitation training (see table below for more details).

Improving the quality of patient care is a clinical benefit of setting up remote monitoring with Bora band®. The clinical parameters measured by the device can be used by practitioners to prevent post-discharge readmission and to detect a wrong oxygenotherapy prescription and generate a new O2 prescription and/or prescribe another exam (see table below for more details).

Benefits		Population	Source	Results
Quality of Life improvement	Acceptation of the rehabilitation training	BPCO, OSAS	eMEUSE clinical trial	84% (95% Confidence Interval : [75% - 93%]) of patients taking a personalized physical training in pulmonary rehabilitation with Bora care® solution did not quit the program
	Patient reassurance	BPCO, OSAS	eMEUSE clinical trial	95% of patients (95% CI : [91% - 99%]) were reassured by the Bora care® solution.

Benefits		Population	Source	Results
Quality of patient care improvement	Patient compliance	BPCO	DACRE clinical trial Brinchault, G., et al. "Évolution des signes vitaux en vie réelle de patients BPCO: facteurs préventifs d'une réadmission après une hospitalisation pour exacerbation sévère–étude clinique en vie réelle DACRE." Revue des Maladies Respiratoires Actualités 15.1 (2023): 70.	Mean patient compliance of 90% (95% CI : [87% - 92%])
		BPCO, OSAS	eMEUSE clinical trial Le Guillou, Y., et al. "Vital Signs Remote Patient Monitoring in Real-life for Early Detection of Acute Exacerbations of Chronic Obstructive Pulmonary Disease." C15. EMERGING COPD DIAGNOSTICS AND TREATMENTS. American Thoracic Society, 2023. A4496-A4496.	Mean patient compliance of 90% (95% CI : [88% - 91%])
		Chronic Respiratory Diseases	APOR clinical study	Mean patient compliance of 90% (95% CI : [82% - 93%])
	Prevention of post-discharge readmission	BPCO	DACRE clinical trial Brinchault, G., et al. "Évolution des signes vitaux en vie réelle de patients BPCO: facteurs préventifs d'une réadmission après une hospitalisation pour exacerbation sévère–étude clinique en vie réelle DACRE." Revue des Maladies Respiratoires Actualités 15.1 (2023): 70	Respiratory rate correlates with readmission (0,607, p-value=0,010) Heart rate correlates with readmission (0,416, p-value=0,097)
	Detection of wrong oxygenotherapy prescription and generation of a new O2 prescription and/or prescribe another exam	Chronic Respiratory Diseases	APOR clinical trial	Bora care® is useful to confirm the O2 prescription, or detect a wrong O2 prescription and generate a new O2 prescription, or prescribe another exam in 54% of the cases (95% confidence interval: [25% - 81%])

Manufacturer's declarations

All the information given below is taken from standard requirements to which manufacturers of electromedical devices must adhere to in accordance with standard IEC 60601-1-2.

The medical device complies with applicable electromagnetic compatibility standards. However, the user should ensure that possible electromagnetic interference does not create an additional risk, e.g., radio frequency transmitters or other electronic devices.

In this chapter you will find all the necessary information to ensure the effective installation and commissioning of your medical device in terms of electromagnetic compatibility.

The use of accessories other than those specified or sold by Biosency as replacement parts, may result in an increase in emissions or a decrease in the medical device's immunity.

The medical device must not be used near or placed on top of another device. If this cannot be avoided, please check its correct functioning before use (in accordance with the conditions of use).

The user or installer of the medical device can help prevent electromagnetic interference by maintaining a minimal separation distance, which will be dependent on the maximum radio frequency power of the transmitting equipment. Do not use any portable RF communications device (including peripherals such as antenna cables or external antennas) within 30 cm of the Bora band®, including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

⚠ WARNING

ELECTROMAGNETIC INTERFERENCE

This equipment complies with the international IEC 60601-1-2 standard relating to the electromagnetic compatibility of medical electrical equipment and / or systems. This standard is designed to provide reasonable protection against harmful interference when installed in a typical medical setting. However, given the proliferation of radiofrequency waves transmitted by equipment and other parasitic sources in healthcare settings and other environments, it is possible that high levels of interference, caused by close proximity or power from a source, could negatively impact the operation of the device. Medical electrical devices require special precautions regarding electromagnetic compatibility, and all devices must be installed and commissioned in accordance with the information specified in this manual. Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of the Bora band®, including cables specified by the manufacturer . Otherwise, the performance of these devices may be impaired..

Table 1: Electromagnetic emissions

Emission test	Conformity	Electromagnetic environment - notes
This medical device is intended for use in the electromagnetic environment described in this table. The user and installer should therefore ensure that the medical device is used in such an environment.		
Electromagnetic Radiation Disturbance (Radiated Emissions) (CISPR 11)	Group 1	The medical device uses RF energy for its internal functioning. Nearby electronic equipment may be affected.
Interference voltage at the power supply terminals (Conducted emissions) (CISPR 11)	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage systems supplying buildings for domestic use.
Harmonic current emissions (IEC 61000-3-2)	Compliant	/
Voltage variations, voltage fluctuations and flicker (IEC 61000-3-3)	Compliant	/

Table 2: Magnetic and electromagnetic immunity

Immunity test	Test level according to IEC 60601	Level of conformity	Electromagnetic environment - notes
This medical device is intended for use in the magnetic and electromagnetic environment described in this table. The user and installer should therefore ensure that the medical device is used in such an environment.			
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Home health care and professional health care facilities.
Electrical fast transients in bursts (IEC 61000-4-4)	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines	
Shock waves (IEC 61000-4-5)	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode	
Immunity to nearby magnetic fields	Not applicable since the product does not contain elements sensitive to magnetic fields.		
Voltage dips, short interruptions, and voltage variations (IEC 61000-4-11)	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT For 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase´: at 0 °	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT For 25 cycles at 50 Hz For 30 cycles at 60 Hz Monophase : at 0°	
Power Frequency Magnetic Field Immunity (IEC 61000-4-8)	30 A/m	30 A/m	
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Table 3: Manufacturer's declarations and notes - electromagnetic immunity

Immunity test	IEC test level 60601	Level of conformity	Electromagnetic environment - notes
This medical device is intended for use in the magnetic and electromagnetic environment described in the table below. The user and installer should ensure the compliance of the electromagnetic environment.			
WARNING : Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of the Bora band® Model BB100, including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.			
Conducted Disturbances, Induced by RF Fields (IEC 610004-6)	3V 150kHZ to 80MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz, including amateur radio band 80% MA to 1 kHz	3V 150kHz to 80MHz 80% MA to 1 Z 6 V in ISM band and band between 0.15 MHz and 80 MHz, including amateur radio band 80% MA à 1 kHz	Home health care environment.
Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Home health care environment.
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Home health care and professional health care.

Copyrights and Trademarks

Symbols

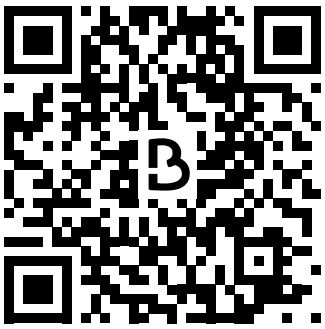
This chapter describes the symbols that are used on the product or its packaging.

	Please consult the user guide before using the device.
	Type BF applied part.
	No alarm trigger.
	Non-sterile.
	Non-ionising electromagnetic radiation. Includes Radiofrequency (RF) transmitters. The equipment contains radio transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
CE 2797	CE mark indicating compliance with current medical devices regulations. Notified body : BSI NL.
IP 64	Protected from total dust ingress. Protected from water spray from any direction.
	Indicates that separate collection for waste electrical and electronic equipment (WEEE) is required.
DM MD	Medical device.
SN	Serial number.
UDI	Unique device identifier
REF	Product reference
	The box should be recycled.
	BLUETOOTH® logo.
	Required temperature. Minimum and maximum temperature (°C).
	Humidity rate limit. Maximum and minimum humidity (% relative humidity, without condensation).

	Store in a dry place.
	Do not use if the packaging is damaged.
	Manufacturer and date of manufacture.

Manufacturer's contact details

	Biosency 13 rue Claude Chappe - Bat A Oxygène 35510 Cesson Sévigné France support@biosency.com



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