Biologix

User Guide

Oxistar BX2 and Bodystar BD1

User Guide: Oxistar BX2 and Bodystar BD1

Registered with the Brazilian Health Regulatory Agency (ANVISA) under No. 83369939001.

Certified by the Brazilian National Telecommunications Agency (ANATEL) under No. 06748-25-08536.

The Oxistar BX2 and Bodystar BD1 were developed, their technology is patented, and they are the exclusive property of:

Biologix Sistemas S.A.

Teodoro Sampaio Street, 1756, Office 31, Pinheiros, City of São Paulo, São Paulo State, Brazil. Postal code: 05406-150. Registered under CNPJ/MF [Brazilian National Registry of Legal Entities/ Ministry of Finance] No. 21.892.103/0001-83 | www.biologix.com.br | Phone: +55 11 3815-4766

The Oxistar BX2 and Bodystar BD1 were manufactured by:

Hi-Mix Eletrônicos S.A.

João Viganó Neto Street, No. 170 – Núcleo Bom Retiro, Pato Branco, Paraná State, Brazil. Postal Code: 85501-970. Registered under CNPJ/MF [Brazilian National Registry of Legal Entities/ Ministry of Finance] No. 14.785.345/0001-02 | www.hi-mix.com.br | Phone: +55 46 3313-8500

Technical Manager:
Tácito de Almeida - CREA: SP-167084/D

Document Code:
000007 | Version No. 07

Publication Date:
June, 2026

INDEX

1. SYMBOLS

Symbol	Description	Symbol	Description
	Stacking limit by number of boxes		Keep dry
	Protect from sunlight		Subject to regulations on the disposal of electronic devices; therefore, do not discard with common waste
	Consult instructions		Non-ionizing electromagnetic radiation
	Serial number		Manufacturer
	Type BF applied part		Date of manufacture
	Expiration date		Direct current
	Temperature limit	IP22	Provides protection against vertical water-drop penetration when the device is inclined up to 15 degrees within the vertical plane. It also provides protection against solid ingress
	Humidity limit	%SpO_2	Oxygen saturation
	Atmospheric pressure limit		No SpO_2 alarm
	This side up	BPM	Heart rate
	Fragile, handle with care		Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. INTRODUCTION

The Biologix Sleep Test® offers two modalities: one version without sleep position monitoring and another with sleep position monitoring. The version without sleep position uses only the Oxistar BX2 sensor, while the version with sleep position includes the Oxistar BX2 and the additional accessory Bodystar BD1.

The Oxistar BX2 is a high-resolution oximeter that enables the diagnosis of obstructive sleep apnea by measuring oxygen saturation (SpO_2), pulse rate, and actigraphy.

In turn, the Bodystar BD1 registers the patient's sleep posture during the test. This includes identifying cases of positional apnea in which oxygen desaturation events occur in specific positions. It is important to note that the Bodystar BD1 is a complementary accessory and cannot be used independently to perform the test.

3. CASE CONTENTS

Image 1: Cases with and without sleep position sensor

Accessory/Device	Without position monitoring	With position monitoring
Oxistar BX2 Sensor	✓	✓
Bodystar BD1 Sensor	x	✓
USB-C Cable	1	2
Hypoallergenic Tape 25mm	✓	✓
Case	✓	✓
Simple User Guide	✓	✓

4. DEVICES' INFORMATION

Before using the sensors, carefully read this guide to ensure proper operation.

Oxistar BX2

Substances containing dyes that alter blood pigmentation may result in inaccurate readings.

Clinical conditions such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease, and anemia may cause inaccurate SpO_2 and pulse rate measurements.

The Oxistar BX2 may not function properly on extremely cold fingers due to low blood perfusion. Use the Perfusion Index (PI) to identify a suitable area to place the Oxistar BX2. A PI over 1% is recommended.

Do not apply the hypoallergenic tape too tightly, as it may impair blood circulation and compromise SpO_2 and pulse rate readings.

Avoid excessive finger movement during measurement, as this may result in inaccurate SpO_2 and pulse rate readings.

Do not use the Oxistar BX2 near intense light sources, as excessive light exposure may interfere with signal processing and cause incorrect readings.

The Oxistar BX2 does not include an alarm system and is not intended for use as an alert device for dangerous oxygen or heart rate levels.

In compliance with IEC Standard No. 62471-6:2022, the sensor's light emissions are classified as Class 1 and require no special safety precautions.

The device is calibrated for monitoring functional oxygen saturation.

Improper or prolonged use of the pulse oximeter with excessive pressure may cause pressure injuries.

Bodystar BD1

The Bodystar BD1 must be fixed onto the patient's skin using the hypoallergenic tape provided in the case, following the instructions indicated (see page 8).

General Information | Oxistar BX2 and Bodystar BD1 Sensors

They are portable and durable, but may be damaged if dropped.

While taking measurements, remain within Bluetooth range of your smartphone (average range: approx. 10 meters) to avoid connection loss.

Use the sensors exclusively with the Biologix app. Improper use with other software may result in inaccurate SpO_2 and heart rate measurements.

The sensors do not function while charging.

Safety Information | Oxistar BX2 and Bodystar BD1 Sensors

Use the sensors only on intact skin. Do not place them over wounds, rashes, burns, or sensitive skin.

Respect the maximum application time for each sensor on the same site: minimum 4 hours, maximum 12 hours.

Discontinue use immediately if any allergic reactions or skin irritation occur at the application site.

Only individuals with the physical, sensory, and cognitive ability to use the device properly should operate the sensors.

Keep the devices out of the reach of children and domestic pets. Both sensors contain small parts that may pose choking hazards.

The devices are fully sealed to prevent access to internal components. Do not open or disassemble them. Their electronic components must be protected, and maintenance must be performed only by manufacturer-authorized technical support personnel.

Do not use the sensors in MRI environments.

Do not use the sensors in oxygen-rich environments or in the presence of flammable anesthetic agents or nitrous oxide. The materials used in the sensors meet the applicable biocompatibility and material-toxicity criteria and do not pose a biological hazard.

The sensors are not protected against defibrillator discharges.

The sensors are designed with biocompatible and non-toxic materials in all components that come into contact with the patient. These materials do not pose any risk to the user or to others who may handle the device. The Oxistar BX2 does not present any residual risks for children, pregnant women, or individuals who are lactating. They are made from biocompatible and non-toxic materials in all parts that come into contact with the patient.

Charge the sensors' internal batteries only with chargers or USB ports that comply with the specifications in Section 12.3.

5. OXISTAR BX2 FUNCTIONING

The Oxistar BX2 sensor is a high-resolution pulse oximeter that measures blood oxygen saturation (SpO_2) non-invasively. It operates based on the Beer-Lambert Law , which describes the transmission of light through a material. The device estimates SpO_2 by detecting the difference in absorption of red and infrared light by oxygenated and deoxygenated hemoglobin, using the relationship between the sensor's emitted and received light.

The Oxistar BX2 also calculates the pulse rate by analyzing light absorption variations during the cardiac cycle: red light is more absorbed during systole, while infrared light is more absorbed during diastole. This pulse rate may differ from heart rate (HR) due to different calculation methods. Additionally, the device uses the Perfusion Index (PI) to monitor pulse quality and help identify the most suitable finger for measurement. A PI above 1% is considered ideal. The Oxistar BX2 does not perform measurements when the PI is below 0.4%, thereby helping ensure the accuracy of the readings.

The sensor also includes an actimeter that records the user's movements through an internal accelerometer, which measures acceleration along three axes (X, Y, and Z). SpO_2 and pulse rate data are calculated every second, while movement is recorded every 0.1 seconds.. The device stores the information in its internal memory and sends it to the smartphone via Bluetooth every five minutes.

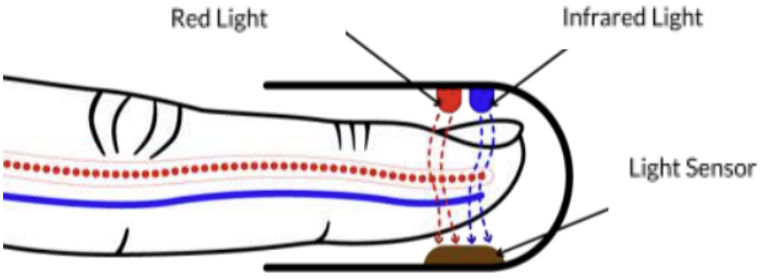


Image 2: Oxistar BX2 functioning

6. BODYSTAR BD1 FUNCTIONING

The Bodystar BD1 includes a three-axis accelerometer that detects the patient's sleeping position. Accelerometers, also known as MEMS (microelectromechanical systems), measure linear acceleration along their sensitive axes. They generate an inertial force acting on a test mass, which is transmitted to the support structure where the sensor is installed. This displacement produces a signal proportional to the applied acceleration.

This three-axis accelerometer records its position along each axis and tracks movement. By adding the vector components, the system accurately identifies the patient's body posture. The Bodystar BD1 registers four different positions: dorsal decubitus (supine), right lateral decubitus, left lateral decubitus, and ventral decubitus (prone).

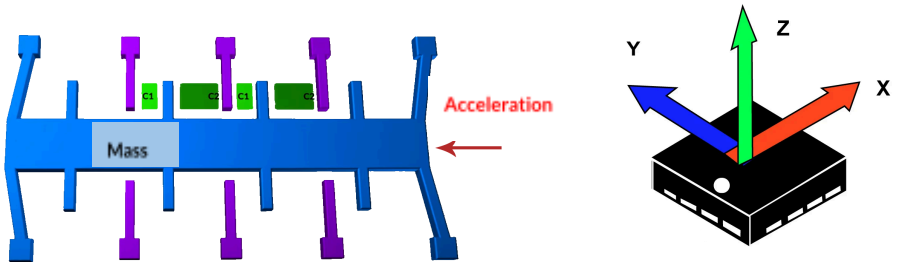


Image 3: Bodystar BD1 functioning

7. OXISTAR BX2 AND BODYSTAR BD1 INTENDED USE

The Oxistar BX2 is intended for the diagnosis and follow-up of sleep apnea. This wireless, compact, and portable sensor measures blood oxygen saturation (SpO_2), pulse rate (PR), and actimetry in adult users, for use in clinical or home environments. Its primary intended purpose is to continuously record nighttime oxygen desaturation events with the support of the Biologix application. An oxygen desaturation event occurs when SpO_2 drops by 3% or more. These events are directly associated with obstructive sleep apnea.

The Bodystar BD1 is an optional accessory that can be used with the system. Its intended use is to monitor the patient's posture during sleep. This device makes it possible to identify the postures in which desaturation events and snoring occur, supporting the diagnosis of positional apnea. This condition is characterized by the occurrence of events exclusively in certain positions, particularly in the supine position (supine decubitus).

DISCLAIMER:
These devices do not include an alarm system and are therefore not intended for use as alert devices in dangerous or high-risk situations.

8. LIGHT INDICATORS OF THE OXISTAR BX2 AND BODYSTAR BD1

In addition to the application, the Oxistar BX2 and Bodystar BD1 feature LED indicators on the upper part of the devices to verify operational status.

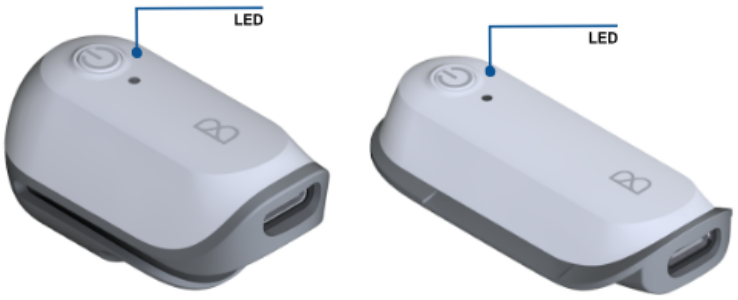


Image 4: LED indicators of the Oxistar BX2 and Bodystar BD1 sensors

LED Color/Light Pattern	Sensor Status
No LEDs on	The sensor is off or its battery is completely charged.
Solid red	The battery is currently charging.
Blue blinking	The sensor is on and waiting to be paired with the Biologix application.
Red and blue blinking	The sensor is on and currently below 50% of its total battery capacity and is awaiting pairing.
Green blinking slowly	The sensor is connected and collecting data normally.
Green blinking quickly	The sensor is connected, but low signal quality (signal inadequacy) has been detected continuously for more than five seconds (e.g., excessive finger movement, low perfusion, or incorrect placement).
Alternating green and red blinking	The sensor is measuring data while the battery is below 50% of its total capacity.

9. HOW TO USE THE OXISTAR BX2

Operating the Oxistar BX2 is simple. Follow the steps below to carry out the test:

1. Turn on the Oxistar BX2 sensor by pressing the power button once.
2. If only the blue LED starts to blink, follow step 3. If the red LED also starts blinking, it indicates that the sensor has less than 50% battery and needs to recharge before beginning the test. Connect the sensor to the charger by using the USB cable included in the kit. The charging time may vary according to the battery level, but generally 30 minutes is enough to reach at least 50% charge, regardless of the initial level.
3. Place the Oxistar BX2 on the index or middle finger. We do not recommend using the thumb or the little finger. Ensure you have short nails without nail polish and no acrylic nails.
4. Position the sensor so that the power button faces the palm of the hand, as shown in Image 5a.

a. *b.*

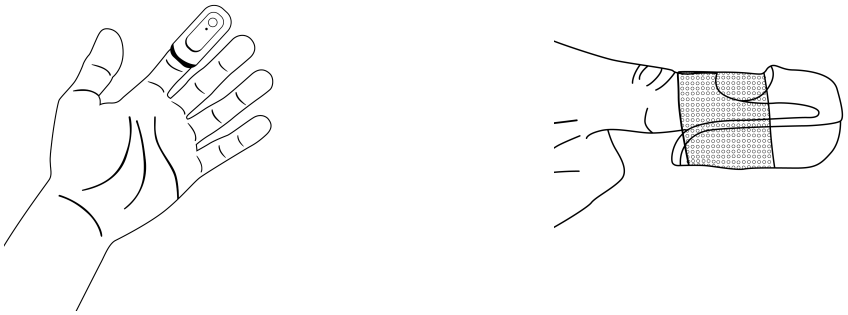


Image 5: Placement and positioning of the Oxistar BX2 on the finger

5	Secure the Oxistar BX2 with hypoallergenic tape using the fixation area shown in Image 5b.
6	When the blue LED starts blinking, start the test on the Biologix app.
7	In the initial stage of the test, the app will connect via Bluetooth to the Oxistar BX2 sensor. After establishing a connection, the sensor will start blinking with a green LED.
8	Follow the instructions that appear on the app to start and finish the test on the next day upon waking up. The test with the Oxistar BX2 sensor must last at least 4 hours.
9	If needed, you may take out the sensor during the test. No additional actions will be required within the app. To prevent the test from being automatically terminated, ensure that the sensor does not remain off the finger for more than 30 minutes.
10	Upon waking up, finish the test on the app. The app will confirm if the test has been completed correctly. After that, remove the Oxistar BX2 sensor from the finger and put it back in the kit.

NOTE:
Long nails may prevent proper positioning of the finger inside the Oxistar BX2 and affect SpO_2 readings. The user must insert the finger fully until it cannot go further, ensuring that the internal red LED aligns near the base of the nail. Nail polish or artificial nails may hinder the light path and result in significantly lower SpO_2 readings.

CAUTION:
When securing the Oxistar BX2 with tape, avoid applying excessive pressure. Excess pressure may restrict blood circulation and compromise measurement accuracy.

DISCLAIMER:
If irritation or an allergic reaction occurs while using the Oxistar BX2, stop using the device immediately and contact the manufacturer.

NOTE:
If you experience any issues with the Biologix app or need assistance with the Oxistar BX2, please contact: sac@biologix.com.br.

10. HOW TO USE THE BODYSTAR BD1

Operating the Bodystar BD1 is simple. Follow the steps below to carry out the test:

1	Turn on the Bodystar BD1 by pressing the power button once.
2	If only the blue LED starts blinking, proceed to step 3. If the red LED also starts blinking, the battery is below 50% and the sensor must be charged before use. Connect it to the charger using the USB cable included in the kit. About 30 minutes is generally sufficient to reach 50% charge, regardless of the initial level.
3	The sensor must be placed on the thorax, in the pectoral region, as shown in Image 6. If necessary, remove hair

from the area to ensure maximum contact between the sensor and the skin.

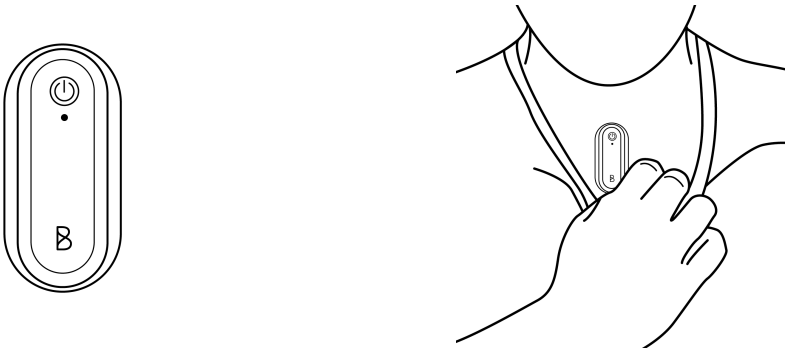


Image 6: Placement and positioning of the Bodystar BD1 on thorax

4	Position the sensor vertically, with the button facing upward as shown in Image 6. Use approximately 10 cm of hypoallergenic tape to secure it firmly to the thorax.
5	When the blue LED starts blinking, start the test in the Biologix app.
6	At the beginning of the test, the app will connect via Bluetooth to the Bodystar BD1. Once connected, the sensor will begin blinking with a green LED.
7	Follow the instructions in the app to start the test and to finish it upon waking up. The test must last at least 4 hours.
8	You do not need to remove the sensor to use the bathroom or perform similar activities. Remove it only when the test is complete.
9	Upon waking up, finish the test in the app. The app will confirm if the test was completed correctly. Then remove the Bodystar BD1 and place it back in the kit.

CAUTION:
When placing the Bodystar BD1 on the thorax, ensure that the sensor is firmly secured to the skin. If the sensor shifts or loosens, the collected data may be compromised.

DISCLAIMER:
If irritation or an allergic skin reaction occurs while using the Bodystar BD1, stop using the device immediately and contact the manufacturer.

NOTE:
If you experience any issues with the Biologix app or need assistance with the Bodystar BD1, please contact: sac@biologix.com.br.

11. THE BIOLOGIX APP

The Oxistar BX2 and Bodystar BD1 must be used with the Biologix application, which is part of the Biologix solution. Available in Google Play (Android) and the App Store (iOS), the application connects the sensors to the Biologix cloud platform, which enables the transmission and processing of collected data.

The app includes support materials to address common questions, available in the “Help” option or on the website: www.biologix.com.br/ajuda.

Android: Google Play Store (https://play.google.com) – Requires Android version 7.1 or higher

iOS (Apple): App Store (https://itunes.apple.com) – Requires iOS version 13 or higher.

The quick user guide included in the product kit contains a QR code that links directly to the app store and provides essential

information for using the sensors.

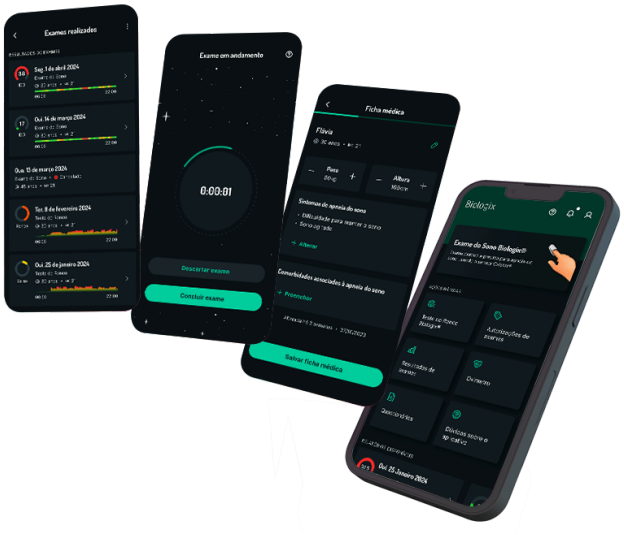


Image 7: Biologix Application

12. TECHNICAL SPECIFICATIONS (OXISTAR BX2 AND BODYSTAR BD1)

12.1 - Environmental Conditions for Storage and Transport

	Oxistar BX2	Bodystar BD1
Temperature	+5 °C to +40 °C	
Humidity	15% to 93 %, non-condensing	
Atmospheric Pressure	700 hPa to 1,060 hPa	

12.2 - Environmental Conditions for Operation

	Oxistar BX2	Bodystar BD1
Temperature	+5 °C to +40 °C	
Humidity	15 % to 93 %, non-condensing	
Atmospheric Pressure	700 hPa to 1,060 hPa	

12.3 - Charger or USB Port

	Oxistar BX2	Bodystar BD1
Output Voltage	4.5 to 5.5 VDC	

	Oxistar BX2	Bodystar BD1
Output Current	Above 0.1 A	

12.4 - Internal Battery

	Oxistar BX2	Bodystar BD1
Type	Rechargeable	
Technology	Lithium-ion	
Operating Voltage	3.7 VDC	
Maximum Charging Voltage	4.2 VDC	

	Oxistar BX2	Bodystar BD1
Charging Current	70 mA	
Charging Power	0.25 VA	
Battery Life (Fully Charged)	30 hours	60 hours
Full Charging Time	Standard Charge: 3 hours Fast Charge: 1.5 hours	

12.5 - Measurement Range

	Oxistar BX2	Bodystar BD1
Oxygen Saturation (SpO_2)	70 to 100%	N/A
Pulse Rate (PR)	30 to 250 bpm	N/A
Perfusion Index	0.1 to 20%	N/A
Actimetry	X-axis: ±19.61 m/s2 Y-axis: ±19.61 m/s2 Z-axis: ±19.61 m/s2	
User's Decubitus	N/A	Dorsal decubitus (supine), Right lateral decubitus, Left lateral decubitus, Prone

12.6 - Resolution

	Oxistar BX2	Bodystar BD1
Oxygen Saturation (SpO_2)	0.1 %	N/A
Pulse Rate (PR)	1 bpm	N/A
Actimetry	X-axis: 0.382 m/s2 Y-axis: 0.382 m/s2 Z-axis: 0.382 m/s2	

		decubitus

12.7 - Accuracy

	Oxistar BX2	Bodystar BD1
Oxygen Saturation (SpO_2)	+- 2% from 70 to 100%	N/A
Pulse Rate (PR)	+-2 bpm from 30 to 250 bpm	N/A
Actimetry	X-axis: ±1,528 m/s2 Y-axis: ±1,528 m/s2 Z-axis: ±1,528 m/s2	

Note: Pulse oximeter measurements follow a statistical distribution. Approximately two-thirds of readings are expected to fall within ± 1.71 of the co-oximeter reference value used for calibration.

12.8 - Response Time

	Oxistar BX2	Bodystar BD1
Oxygen Saturation (SpO_2)	4 heartbeats *	N/A
Pulse Rate (PR)	4 heartbeats *	N/A
Perfusion Index (PI)	1 heartbeat	N/A
Actimetry	1 second	

** Reference: "The AASM Manual for the Scoring of Sleep and Associated Events - Rules, Terminology and Technical Specifications".*

12.9 - Sensor Dimensions

	Oxistar BX2	Bodystar BD1
Length	49.68 mm	59.93 mm
Width	22.06 mm	27.69 mm

	Oxistar BX2	Bodystar BD1
Height	27.38 mm	12.25 mm
Weight	20g	20g

12.10 - Bluetooth

	Oxistar BX2	Bodystar BD1
Version	4.0 low energy (BLE)	
Range	Less than 10 meters	
Operating Frequency	2.4 GHz	

	Oxistar BX2	Bodystar BD1
Output Power	Up to +5 dBm	
Modulation	2 Mb/s	
International Standards Compliance	ETSU international standards: EN 300 328 (Europe) EN 300 440 Class 2 (Europe) FCC CFR47 Part 15 (USA) ARIB STD-T66 (Japan)	

12.11 - Classification

	Oxistar BX2	Bodystar BD1
Power Type	Internally powered	
EMC Compliance	Class B	
Applied Part	Type BF	

	Oxistar BX2	Bodystar BD1
Ingress Protection Code	IP22	
Operation Mode	Continuous	

Protection		
Standards According to IN 283:2024. Complies with the following ANATEL resolutions and technical standards	*ABNT NBR IEC 60601-1:2010 + Emenda 1:2016 + Emenda 2:2022* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Electrotechnical Commission 60601-1:2010 + Amendment 1:2016 + Amendment 2:2022]. *ABNT NBR IEC 60601-1-2:2017 + Emenda 1:2022 - Parte 1-2 s* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Electrotechnical Commission 60601-1-2:2017 + Amendment 1:2022 - Part 1-2] *ABNT NBR IEC 60601-1-6:2011 + Emenda 1:2020 + Emenda 2:2022* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Electrotechnical Commission 60601-1-6:2011 + Amendment 1:2020 + Amendment 2:2022]. *ABNT NBR IEC 60601-1-9:2010 + Emenda 1:2014 + Emenda 2:2022* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Electrotechnical Commission 60601-1-9:2010 + Amendment 1:2014 + Amendment 2:2022].	*ABNT NBR IEC 60601-1-11:2012 + Emenda 1:2022* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Electrotechnical Commission 60601-1-11:2012 + Amendment 1:2022]. *ABNT NBR ISO 80601-2-61:2015 + Segunda edição de 25/02/2022* [Brazilian National Standards Organization, Brazilian Regulatory Norms, International Organization for Standardization 80601-2-61:2015 + Second edition from February 25, 2022]. ANATEL Act No. 442. ANATEL Act No. 529. ANATEL Act No. 680. ANATEL Act No. 11542, Annex I. ANATEL Act No. 11542, Annex II.

These devices are not entitled to protection from harmful interference and must not cause interference to properly authorized systems.

For more information, visit the ANATEL website (http://www.gov.br/anatel/pt-br/).

To evaluate the accuracy of the Oxistar BX2, we used a NÉOS brand functional ECG/Oximetry simulator. Two simulators are used: one remains available while the other undergoes calibration. Both are calibrated annually.

Simulators used:
- NÉOS S0P100, Serial No. 20171020019
- NÉOS S0P100, Serial No. 20190307014

Currently, functional testers cannot be used to verify the accuracy of SpO_2 sensors or pulse oximeters. These devices only allow functional verification of electronic and optical performance and therefore do not replace clinical desaturation studies.

SpO_2 Accuracy – Oxistar BX2

Regarding SpO_2 accuracy, the Arms value (root-mean-square difference between the measured and reference values) was determined within a range of 70% to 100%.

$$Arms = \sqrt{\sum_{i=1}^{129597} \frac{(SpO2_i - SR_i)^2}{n}} = 1,71$$

Note: Because pulse oximeter measurements follow a statistical distribution, approximately two-thirds of the device's pulse oximetry readings are expected to remain within a ±1.71 margin of the value measured by the co-oximeter used during calibration.

Pulse Rate Accuracy – Oxistar BX2

As for pulse rate accuracy, the Arms value was determined within a range of 30 to 250 bpm

$$Arms = \sqrt{\sum_{i=1}^{129597} \frac{(HR_i - HRr_i)^2}{n}} = 1{,}57$$

The first stage of the study was conducted at the Clinical Research Laboratory – Autonomic Nervous System, Hypertension Unit of InCor, Faculty of Medicine, University of São Paulo. Data from 12 volunteers—7 men and 5 women—all self-declared as white, were used. Participants were evaluated in the supine position and connected to a reference oximeter (model 3012LP, Nonin Medical Inc., USA) and to two sensors requiring calibration (Oxistar BX2, Biologix Sistemas S.A.., Brazil). The reference oximeter data were continuously transmitted to a computer via a USB (Universal Serial Bus) connection, where they were stored. In parallel, data from the two Oxistar BX2 sensors were transmitted via Bluetooth to the Biologix Sleep app, where they were also stored. Subsequently, the collected data were compared offline using MATLAB software.

The reference oximeter and the Oxistar BX2 sensors were placed on the same hand of each participant, who was instructed not to move it during data acquisition. Participants underwent a controlled desaturation procedure using a nasal clip while breathing a gas mixture (10% oxygen and 90% nitrogen) through a mouthpiece connected to a gas-mixture reservoir. SpO_2 levels between 70% and 100% were achieved by adjusting the gas-mixture flow using a flow meter and a valve that allowed selection between the gas mixture or ambient air, producing different oxygen concentrations.

In accordance with current legislation (8), continuous data collection was performed during gradual saturation changes (ramp type), regardless of the levels, and time-paired samples were compared. At the end of each collection, the valve was adjusted to allow ambient air intake, returning SpO_2 levels to values above 98%, with a reoxygenation period of approximately five (5) minutes. Each participant underwent three ramps of approximately ten (10) minutes each, with reoxygenation intervals in between.

During the controlled desaturation procedure, continuous non-invasive arterial blood pressure monitoring was performed using a Nexfin® monitor (BMEYE, Amsterdam, Netherlands), placed on a finger of the participant's other hand. As a safety criterion, arterial blood pressure values were monitored; if a reduction of 40 mmHg from baseline (before the protocol) was detected, the procedure was immediately interrupted.

Emitted Wavelength Band – Oxistar BX2

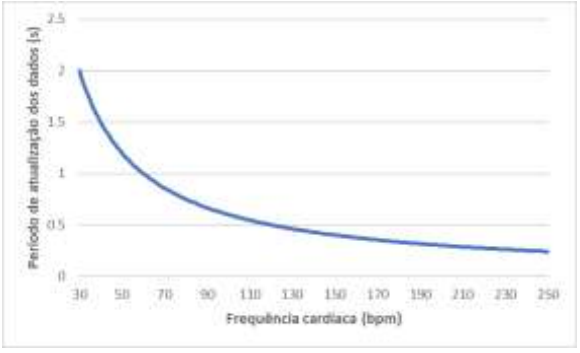
Peak Wavelength (λp) = 660nm (red LED) and 940nm (infrared LED).
Maximum Optical Power = 9.5 mW (red LED) and 8.5 mW (infrared LED).

Averaging Method Used – Oxistar BX2

Uses a 4-point moving average to calculate SpO_2 and pulse rate.

Data Update Frequency – Oxistar BX2

Updates SpO_2 and pulse rate with each heartbeat.*
The update rate follows the chart below:



** Reference: "The AASM Manual for the Scoring of Sleep and Associated Events - Rules, Terminology and Technical Specifications", 2007.*

As previously mentioned, the Oxistar BX2 performs continuous SpO2 and pulse rate data updates throughout the circadian cycle. Under no circumstances does the update interval exceed the 30-second period mandated by the applicable standard.
In situations of momentary signal loss,for example, due to a low perfusion index, excessive movement, or sensor removal,the green LED blinks quickly when the data update interval exceeds five seconds or when the signal quality is low or insufficient.

This condition is internally recorded by the software every second through a signal quality marker.
Each second identified as having low signal quality is recorded in the data file. During processing, these intervals are automatically excluded from the final report analysis, ensuring that only valid measurements are considered.

Waveform Normalization – Oxistar BX2

The plethysmographic waveform is displayed in normalized form: the mean value of the signal window is subtracted, and the graph is scaled so that the minimum and maximum values match the full range within that window.

13. CLEANING

The Oxistar BX2 and Bodystar BD1 are reusable devices supplied and used without the need for sterilization. The Oxistar BX2 and Bodystar BD1 must be cleaned before being made available to another patient, following the instructions below:

Clean the exterior surfaces of the sensors with a soft cloth moistened with 70% alcohol.

Do not immerse the sensors or pour liquid onto any part of them.

To remove adhesive residue, use a soft cloth moistened with a product intended for removing dressing and adhesive residue, such as Removex Sensitive. Rub the cloth over the residue until it has been completely removed.

Do not use the sensors until they are completely dry.

Never use abrasive materials or aggressive cleaning agents, such as acetone or acetone-based products.

Never sterilize the sensors using an autoclave, pressure, or gas.

DISCLAIMER:
Do not clean the sensors while connected to the power source, as this may pose a risk of electric shock. Always unplug the devices before cleaning.

14. MAINTENANCE

Repairs must be performed only by authorized technical support if either the Oxistar BX2 or Bodystar BD1 present any issues.

Both devices do not require periodic calibration, as they are calibrated by the manufacturer prior to commercialization. If irregularities are detected, the devices must be sent to manufacturer-authorized technical support or directly to the manufacturer.

The internal battery of the Oxistar BX2 and Bodystar BD1 accessory has an estimated lifespan of approximately 500 charge cycles. Over time, capacity may decrease. When autonomy drops below 18 hours despite a full charge, battery replacement is advised; send the device to authorized technical support.

The estimated lifespan of both devices is four years. To ensure proper functioning during this period, we recommend performing preventive maintenance every three months:

Check for any signs of external wear.

Verify the presence of any visible mechanical damage, such as fractures, surface cracks or clefts.

Evaluate battery autonomy according to the following parameters:
- At 100% charge: more than 17 hours of operation.
- At 50% charge: more than 8 hours of operation.

Verify battery charging time based on the following guidelines:
- From 10% to 100%: less than 2 hours.
- From 50% to 100%: less than 1 hour.

CAUTION:
To maintain battery health, charge the Oxistar BX2 and Bodystar BD1 at least once every three months.

15. WARRANTY

Preliminary Information and Supplier

The OXISTAR BX2 and BODYSTAR BD1 were developed by BIOLOGIX SISTEMAS S.A., the exclusive holder of its patentable technology. Biologix Sistemas S.A. is headquartered at Teodoro Sampaio Street, No. 1756, 3rd Floor, Office 31, Pinheiros, City of São Paulo, São Paulo State, postal code 05406-150. Biologix Sistemas S.A. is a private legal entity registered under CNPJ/MF [Brazilian National Registry of Legal Entities/Ministry of Finance] No. 21.892.103/0001-83 (hereinafter, "BIOLOGIX"). All rights reserved.

The OXISTAR BX2 and BODYSTAR BD1 were manufactured by Hi-Mix Eletrônicos S.A, a limited company headquartered at João Viganó Neto Street, 170 – Núcleo Bom Retiro, Pato Branco, State of Paraná, Brazil, postal code: 85501-970. Hi-Mix Eletrônicos S.A. is a private legal entity registered under CNPJ/MF No. 14.785.345/0001-02 (hereinafter, "Hi-Mix"). Hi-Mix is responsible for the performance warranty of the OXISTAR BX2 and BODYSTAR BD1.

This Warranty Statement outlines the scope and procedures applicable to the warranty under the terms set forth below.

The Warranty Statement for the OXISTAR BX2 and the BODYSTAR BD1 covers material and manufacturing defects for a statutory period of 180 (one hundred and eighty) days from the date the product is received by the consumer, in accordance with Section II of Article 26 of the Brazilian Consumer Protection Code (Federal Law No. 8.078/1990) (hereinafter, "CDC").

Hi-Mix shall be responsible for carrying out the necessary repairs to ensure the product's proper functioning, in accordance with Article 18 and related provisions of the CDC, or for implementing the alternatives provided therein, at the consumer's discretion. All repairs or component replacements require a technical evaluation by Hi-Mix's professional team or authorized technicians. Depending on the severity of the defect, Hi-Mix may decide to replace the defective product with a new one.

Procedure for Defect Evaluation

If the OXISTAR BX2 exhibits any defect, the consumer may request a technical evaluation within 90 (ninety) days for the internal battery and 180 (one hundred eighty) days for all other components, counted from the invoice or product-receipt date. To initiate the process, the consumer must contact Biologix by email (sac@biologix.com.br) or phone (+55 11 3031-1353) and follow the instructions to send the following to Hi-Mix:

The allegedly defective OXISTAR BX2 or BODYSTAR BD1, and the original or a copy of the purchase invoice for the OXISTAR BX2 and BODYSTAR BD1.

The technical analysis will be performed within 10 (ten) days from the date the product and invoice are received.

Once the analysis is complete, Hi-Mix's technical team will contact the consumer to inform them of the action taken and provide the delivery timeline for returning the device to the address provided.

Damages or defects caused by improper use, abuse, or undue stress resulting in wear, broken parts, or exposed components, including food or liquid spills.

Wear and tear of finishes, parts, or components resulting from intensive use or exposure to adverse conditions (weather, humidity, sea air, cold, or extreme temperatures).

Damages caused during transport or assembly not performed by Hi-Mix.

Removal or alteration of the serial number or any tampering that makes it illegible.

Issues resulting from assembly contrary to the instruction manual, or from product modifications or alterations.

Damages caused by accidents, drops, incidents, pest infestations, or natural events.

Oxidation or corrosion due to lack of cleaning, use of improper cleaning products, or exposure to weather, moisture, or sea air (except for products designed for such conditions).

Additional Notes

This Warranty Statement replaces any other express or implied warranties, including, but not limited to, implied warranties of merchantability or fitness for a particular purpose. Hi-Mix reserves the right to change technical, general, or aesthetic specifications or implement product improvements at any time, with no obligation to apply such modifications to items already sold or in stock.

If a defect covered by this Warranty Statement is identified, Hi-Mix is legally obligated to replace the defective part, component, or, if necessary, the entire OXISTAR BX2 or BODYSTAR BD1 device. Neither Hi-Mix nor BIOLOGIX shall be liable for compensation exceeding the purchase price of the product, nor for loss of use, time, inconvenience, commercial damages, lost income or savings, or any other direct or indirect damages arising from the use or inability to use the device.

This warranty becomes automatically void if any of the above exclusions is incurred.

By using this product, the user acknowledges having read, understood, and accepted terms outlined in this Warranty Statement.

16. PRODUCT DISPOSAL

To prevent environmental or human-health risks associated with improper waste disposal, dispose of the OXISTAR BX2 responsibly, keeping it separate from household and recyclable waste. This contributes to sustainable reuse of material resources.

The Oxistar BX2's internal battery is considered hazardous waste. Do not dispose of it with household garbage. When it reaches the end of its useful life, take the device to designated collection points for recycling electrical and electronic equipment, or return it to the manufacturer for proper disposal. For more information, contact the manufacturer.

17. TROUBLESHOOTING

The blue LED does not blink when pressing the power button

Possible Cause	Solution
The power button is damaged.	Contact an authorized service center for necessary repairs to the sensor.
The sensor's battery is depleted.	Recharge the sensor's battery.
The sensor's battery is damaged.	Contact an authorized service center for necessary repairs to the sensor.

The battery does not charge and the red LED does not turn on when the device is connected to the charger

Possible Cause	Solution
The battery charger is not properly connected to the power outlet.	Ensure that the battery charger is securely connected to a working power source.
The power outlet has no current.	Verify that the electrical outlet is working properly.
The battery charger is not compatible.	Refer to Section 12.3 to confirm the charger's specifications.
The battery charger is damaged.	Try using a different compatible charger.
The sensor's battery is damaged.	Contact an authorized service center for necessary repairs to the sensor.

The battery takes longer than 4 hours to charge (red LED remains on)

Possible Cause	Solution
The battery charger is not compatible.	Refer to Section 12.3 to confirm the charger’s specifications.
The sensor’s battery is damaged.	Contact an authorized service center.

The battery life of the Oxistar BX2 is shorter than specified

Possible Cause	Solution
The sensor’s battery is damaged.	Contact an authorized service center for necessary repairs to the sensor.

The green LED blinks quickly

Possible Cause	Solution
Excessive movement during measurement results in an inadequate signal and data-update intervals >30 seconds.	Keep the hand steady and minimize movement to ensure proper signal detection.
The hypoallergenic tape is too tight, restricting blood circulation.	Reposition the sensor properly without over-tightening.
[Oxistar BX2] Low perfusion or cold finger.	Place the sensor on a different finger and ensure the Perfusion Index (PI) exceeds 1%.

The red LED blinks

Possible Cause	Solution
The sensor’s battery charge is below 10%.	Recharge the sensor’s battery.

The application displays the message “No sensor found”

Possible Cause	Solution
The sensor is turned off or out of Bluetooth range.	Press the power button once to activate the sensor. Ensure the sensor is within 10 meters of the smartphone.

The application displays the message “Disconnected Sensor”

Possible Cause	Solution
The sensor’s battery is depleted.	Recharge the sensor’s battery.
The sensor is more than 10 meters away from the smartphone.	Move the sensor closer to the smartphone.

18. ELECTROMAGNETIC COMPATIBILITY

The Oxistar BX2 and Bodystar BD1 require special care regarding electromagnetic compatibility and must be installed and operated according to the following specifications:

Install both sensors away from devices that generate strong electromagnetic fields (radiology, tomography, MRI, air-conditioning systems, electric motors).

Operation may be affected by nearby mobile or portable RF communication equipment that does not comply with applicable standards.

The Oxistar BX2 and Bodystar BD1 were tested and approved in accordance with the limits for medical devices under *ABNT NBR IEC 60601-1-2* [Brazilian Association of Technical Standards, Brazilian Regulatory Standards, International Electrotechnical Commission 60601-1-2]. Because they use Bluetooth radiofrequency energy, they may cause or experience interference if operated outside specifications or near other medical electrical equipment. If interference occurs, contact the manufacturer.

Refer to the following tables for details regarding the Oxistar BX2 and Bodystar BD1's compliance with "*ABNT NBR IEC 60601-1-2 Equipamento eletromédico Parte 1-2: Requisitos gerais para segurança básica e desempenho essencial - Norma colateral: Compatibilidade eletromagnética - Requisitos e ensaio*" [Brazilian Association of Technical Standards, Brazilian Regulatory Standards, International Electrotechnical Commission 60601-1-2, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests].

Do not place another device on top of these devices. Close proximity may cause malfunction. If it is necessary to use them in this manner, ensure continuous monitoring of both devices to confirm that they are operating correctly.

Manufacturer's Guidelines and Declaration - Electromagnetic Emissions

The Oxistar BX2 and Bodystar BD1 must be used in the specific electromagnetic environment. The CUSTOMER or USER is responsible for ensuring that this condition is met.

Test	**Compliance**	**Electromagnetic Environment - Guidelines**
RF Emissions (ABNT NBR IEC CISPR 11)	Group 1	The Oxistar BX2 and the Bodystar BD1 intentionally generate and use RF energy (Bluetooth) for their internal functions.
RF Emissions (ABNT NBR IEC CISPR 11)	Class B	The Oxistar BX2 and the Bodystar BD1 are suitable for use in facilities, including residential environments, that are directly connected to the public low-voltage power supply network that provides electricity to buildings for domestic purposes.
Harmonic Emissions (IEC 61000-3-2)	N/A	
Voltage Fluctuation/Flicker Emissions (IEC 61000-3-3)	N/A	
Test	Compliance	
RF Emissions (ABNT NBR IEC CISPR 11)	Group 1	
RF Emissions (ABNT NBR IEC CISPR 11)	Class B	

Table 1: Electromagnetic emissions for all equipment and systems.

Manufacturer's Guidelines and Declaration - Electromagnetic Emissions

The Oxistar BX2 and Bodystar BD1 should be used in the specified electromagnetic environment. The CUSTOMER or USER is responsible for ensuring that this condition is met.

Test	**Compliance**	**Electromagnetic Environment - Guidelines**
RF Emissions (ABNT NBR IEC CISPR 11)	Group 1	The Oxistar BX2 and the Bodystar BD1

		intentionally generate and use RF energy (Bluetooth) for their internal functions.
RF Emissions (ABNT NBR IEC CISPR 11) Harmonic Emissions (IEC 61000-3-2) Voltage Fluctuation/Flicker Emissions (IEC 61000-3-3)	Class B N/A N/A	The Oxistar BX2 and the Bodystar BD1 are suitable for use in facilities, including residential environments, that are directly connected to the public low-voltage power supply network that provides electricity to buildings for domestic purposes.

Table 2: Electromagnetic immunity for all equipment and systems.

Manufacturer's Guidelines and Declaration - Electromagnetic Immunity

The Oxistar BX2 and Bodystar BD1 should be used in the specified electromagnetic environment. The customer or user is responsible for ensuring that this condition is met.

Immunity Test	Test Level (ABNT NBR IEC 60601)	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) (IEC 61000- 4-2)	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic. If synthetic materials are used, relative humidity must be at least 30%.
Electrical Fast Transient/ Burst (IEC 61000-4-4)	±2 kV power supply lines / ±1 kV input-output lines. ±1 kV line(s) to-line(s) ±2 kV line(s) to-ground.	N/A N/A	Power quality should be equivalent to that of a typical hospital or commercial environment.
Voltage dips, short interruptions, and voltage variations or power supply input lines (IEC 61000-4-11).	< 5% UT (> 95% dip in UT) for 0,5 cycles.	N/A	Power quality should be equivalent to that of a typical hospital or commercial environment. The Oxistar BX2 and the Bodystar BD1 operate exclusively on their internal batteries. The user must ensure that the battery is always charged.
	< 40% UT (> 60% dip in UT) for 5 cycles.	N/A	
	< 70% UT (> 30% dip in UT) for 25 cycles.	N/A	
	< 5% UT (> 95% dip in UT) for 5 cycles.	N/A	
Voltage dips, short interruptions, and voltage variations or power supply input lines (IEC 61000-4-11).		N/A	Power quality should be equivalent to that of a typical hospital or commercial environment. The Oxistar BX2 and the Bodystar BD1 operate exclusively on their internal batteries. The user must ensure that the battery is always charged.
Magnetic fields of the power supply (50/60Hz) - IEC 61000-4-8	3 A/m g 50 Hz or 60 Hz	3 A/m g 50 Hz or 60 Hz	The magnetic fields of the power supply should be equivalent to those of a typical hospital or commercial environment. The Oxistar BX2 and the Bodystar BD1 must not be used near an MRI unit.

Note: UT is the AC main voltage prior to the application of the test level.
Table 3: Electromagnetic immunity for equipment and systems not intended for life support.

Manufacturer's Guidelines and Declaration - Electromagnetic Immunity

The Oxistar BX2 and Bodystar BD1 should be used in the specified electromagnetic environment. The CUSTOMER or USER is responsible for ensuring that this condition is met.

Immunity Test	Test Level (ABNT NBR IEC 60601)	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) (IEC 61000- 4-2)	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic. If synthetic materials are used, relative humidity must be at least 30%.
Electrical Fast Transient/ Burst (IEC 61000-4-4)	±2 kV power supply lines / ±1 kV input-output lines.	N/A	Power quality should be equivalent to that of a typical hospital or commercial environment.
Conducted RF (IEC 61000-4-6)	3 V m 0,15 MHz - 80 MHz 6V m in ISM bands and amateur radio bands between 0,15 MHz and 80 MHz n 80% AM to 1 kHz e	N/A	No portable or mobile RF communication devices may be used near any part of the Oxistar BX2 or the Bodystar BD1 if their distance is shorter than the recommended separation distance, which is calculated according to the equation corresponding to the transmitter's frequency.
Radiated RF (IEC 61000-4-3)	10 V/m [f] 80 MHz to 2,7 GHz [b] 80% AM to 1 kHz [c]	10 V/m [f] 80 MHz - 2.7 GHz [b] 80% AM to 1 kHz [c]	

Table 4: Recommended separation distances

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not be applicable in all situations, since absorption and reflection from structures, objects, and people affect electromagnetic propagation.

It is not possible to accurately predict the field intensities generated by fixed transmitters (e.g., radio base stations, cordless telephones, land mobile radios, amateur radios, AM/FM or television broadcast transmitters). To assess the electromagnetic environment created by such fixed transmitters, an on-site electromagnetic inspection is recommended.

If the field intensity in the area where the Oxistar BX2 is used exceeds the compliance level, observe the equipment's performance. If abnormal operation is detected, consider implementing additional measures, such as reorienting or relocating the Oxistar BX2. For frequencies between 150 kHz and 80 MHz, the field intensity should remain below 3 V/m.

Recommended separation distances (d in meters, P in watts):

d=1.66√P 150 KHz to 80 MHz
d=1.66√P 80 MHz to 800 MHz
d=2.33√P 800MHz to 2.5GHz

The recommended separation distance in meters (m) can be determined using the applicable equation for the transmitter frequency, where P is the maximum rated output power of the transmitter in watts (W), as specified by the manufacturer.

It is recommended that the field intensity generated by RF transmitters, as determined by a local electromagnetic inspection, remain below the compliance level established for each frequency range.

Interference may occur near equipment bearing the following symbol: 

Warning
The use of accessories, transducers, and cables not specified or provided by the manufacturer may result in excessive electromagnetic emissions or reduced electromagnetic immunity of the equipment, which could impair its proper operation.

Manufacturer's Guidelines and Declaration - Electromagnetic Immunity

The Oxistar BX2 should be used in environments where radiated radiofrequency (RF) disturbances are controlled. The customer or user can help prevent interference by maintaining the minimum recommended distances between portable/mobile communication transmitters and the equipment, as indicated below, in accordance with the maximum output power of the communication devices.

Immunity Test	Test Level (ABNT NBR IEC 60601)	Compliance Level	Electromagnetic Environment - Guidelines

Transmitter Output Power (W)	Separation Distance According to Transmitter Frequency (m)		
	150 kHz - 80 MHz d = 1. 66√P	80 MHz - 800 MHz d = 1. 66√P	800 MHz - 2.5 GHz d = 2.33√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters with maximum rated output power not listed in this table, the recommended separation distance in meters (m) can be determined using the applicable equation for the transmitter frequency, where P is the maximum rated output power in watts (W), as specified by the manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not be applicable in all situations, as absorption and reflection from structures, objects, and people can affect electromagnetic propagation.

Table 9: Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications.

Immunity Test	**Test Level (ABNT NBR IEC 60601)**	**Compliance Level**	**Electromagnetic Environment - Guidelines**
Transmitter Output Power (W)	Separation Distance According to Transmitter Frequency (m)		
	150 kHz -80 MHz d = 1.66√P	80 MHz -800 MHz d = 1.66√P	800 MHz to 2.5 GHz d = 2.33√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

Test Frequency (MHz)	**Band[a] (MHz)**	**Service [a]**	**Modulation [b]**	**Max Power(W)**	**Distance(m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse Modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM c ± 5kHz deviation, 1 kHz sine	2	0.3	28
710 745 780	704-787	Band LTE 13, 17	Pulse Modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	Pulse Modulation [b] 217 Hz	2	0.3	28
1 720 1 845 1 970	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; Band LTE 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0.3	28
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, Band LTE 7	Pulse Modulation [b] 217 Hz	2	0.3	28
5 240 5 500 5 785	5 100 - 5 800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0.2	0.3	9

NOTE:
When it is necessary to achieve the specified Immunity Test Level, the distance between the transmitting antenna and the equipment or ME system may be reduced to 1 meter, in accordance with ABNT NBR IEC 61000-4-3.

a. For some services, only terminal transmission frequencies are included.

b. The carrier shall be modulated by a square wave signal with a 50% duty cycle.
c. As an alternative to FM modulation, 50% duty-cycle pulse modulation at 18 Hz may be used, provided that it does not represent actual modulation, as this constitutes the worst-case scenario.