Wireless, continuous, fully disposable, single-use pulse oximeter

For Sports and Aviation

User Guide

Version 1.3.0

Requires Oxxiom App for iOS devices

Made in USA

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Read this entire guide carefully before using the Oxxiom Pulse Oximetry System.

This device is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. **NOT A MEDICAL DEVICE.**

At the time of publication, this guide is believed to be accurate and current. In the interest of continued product development, True Wearables, Inc. reserves the right to make changes and improvements to this guide, and the products described herein at any time, without notice, or obligation.

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LABEL INFORMATION

Consult User Guide for instructions on how to use device.

Warning!

Type B Applied Part (Comply with specified requirements for protection against electric shock).

Device should not be used in a sterile field and should not be sterilized.

Do not re-use.

Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
LABEL INFORMATION, CONT.

Storage temperature range: 15°C to 30°C.

IPX1 Resistant to liquid ingress.

LOT Lot number.

Expiration date.

Serial number.

Manufacturer.
WARNINGS: INTENDED USE

Oxxiom is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. **NOT A MEDICAL DEVICE.**

Oxxiom is not intended for use in remote monitoring.

Oxxiom is not intended to be used as a diagnostic tool.

Keep Oxxiom away from children and pets. This device is not a toy.
WARNINGS: WIRELESS

Use Oxxiom only when within the specified maximum wireless range – approximately 10 meters (spherical radius) from the iOS (host) device. Moving outside this range may cause data loss or inaccuracy.

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

This is a wireless device. Other equipment may interfere with this device, even if they comply with CISPR emission requirements.

The wireless connection between Oxxiom and the iOS device (host) may be affected by other Bluetooth audio equipment also connected to the same iOS device.
WARNINGS: EMC

This device has been tested and found to comply with IEC 60601-1-2 for Electromagnetic Compatibility (EMC). This standard is designed to provide reasonable protection against harmful interferences. However, given the increased number of radio-frequency transmitting equipment and other interference sources in the environment of operation, high interference levels might occur, and disrupt the operation of this device.

The general operation of this device may be affected when in proximity of a Electrosurgical Unit (ESU).

Do not use this device in a Magnetic Resonance (MR) environment.

This device is not defibrillation proof (IEC 60601-1).
WARNINGS: IOS DEVICE

⚠️ Make sure the iOS device’s battery is properly charged before use.

⚠️ Always keep iOS device within 33 ft (10 m) from the Oxxiom device. The (wireless) path must be unobstructed.

⚠️ During operation with the Oxxiom device, the iOS device does not have to be connected to the internet. Oxxiom connects to the iOS device via Bluetooth. Internet access is only required when downloading the Oxxiom App from the App Store, or when sharing data through methods that require internet connection.

⚠️ Oxxiom connects to the iOS device via Bluetooth. If the iOS device is in Airplane mode, then the Bluetooth radio is turned off by default. The Bluetooth radio can be tuned on with Control Center, even when the iOS device is in Airplane mode. Just open the Control Center from the iOS Home screen, and tap the Bluetooth symbol.
WARNINGS: MEASUREMENT SITE

Oxxiom might not work on cold extremities due to reduced circulation. Warm or rub the extremity to increase circulation.

Avoid excessive pressure to the measurement site as this may cause damage to the skin beneath the device or inaccurate measurements.

Inspect the measurement site, at least every 8 hours, to ensure correct sensor alignment and placement, following the steps below:

1. Remove self-adhering breathable gentle tape from the user’s finger, or headband/adhesive tape from the user’s forehead, or adjustable hat from the user’s head, or adhesive tape from the user’s ear.

2. Inspect the device to make sure it is placed correctly on the fingertip, forehead, or ear. Adjust if necessary.

3. Wrap (same or new) breathable gentle tape around Oxxiom and fingertip, or place headband back on user’s forehead, or place adjustable hat back on user’s head, or place (same or new) adhesive tape on user’s ear or forehead. Aim for a comfortable, snug fit.
WARNINGS: MEASUREMENT SITE, CONT.

User sensitivity to the Oxxiom’s biocompatible adhesive may vary due to skin condition.

The self-adhering breathable gentle tape provided in the Oxxiom’s blister pack does not contain adhesive, and can be applied and re-applied to the same user as many times as needed.

Oxxiom might misinterpret motion as good pulse quality. Minimize motion of the measurement site whenever possible.

Intravascular dyes may affect SpO2 accuracy or make readings unreliable.

Dyshemoglobinemia (Dysfunctional hemoglobin) may affect SpO2 accuracy or make readings unreliable.
WARNINGS: AMBIENT LIGHT

Exposing Oxxiom’s optical detector to direct sunlight or strong ambient light will cause Oxxiom to malfunction.

Protect user’s head against sunlight exposure when wearing Oxxiom on the ear. Direct sunlight defused through the user’s ear cartilage may cause Oxxiom to malfunction. Use an adhesive tape, or some other means to cover head (Oxxiom and ear) in order to minimize sunlight exposure.

Protect user’s head against sunlight exposure when wearing Oxxiom on the forehead. Direct sunlight may cause Oxxiom to malfunction. Use a headband, hat, or adhesive tape to cover Oxxiom in order to minimize sunlight exposure.

Protect user’s hand against sunlight exposure when wearing Oxxiom on the finger. Direct sunlight may cause Oxxiom to malfunction. Use self-adhering tape to cover Oxxiom in order to minimize sunlight exposure.
WARNINGS: OXXIOM BATTERY

Oxxiom is a single-use disposable device. It is powered by a non-rechargeable and non-removable internal battery that typically enables 24 hours of continuous monitoring. Do not attempt to remove or recharge the Oxxiom’s internal battery.

Oxxiom uses a non-rechargeable LiMnO2 battery. Do not recharge, heat, expose to open flames, or disassemble Oxxiom.

Changes in the measurement site optical properties, environmental conditions, and device stand-by operation time affect battery life. Tests conducted in laboratory conditions have shown that the battery life may be significantly shortened depending on the aforementioned changes.
WARNINGS: USER’S PRIVACY

The Oxxiom device and the Oxxiom App do not collect or store information that can identify the user.

The wireless connection between the Oxxiom device and the iOS device does not broadcast data that can identify the user.

Reports and/or measurement/waveform data can only be shared by the user. Any data sharing transaction with third-parties (through the Oxxiom App) must be started by the user.

The user is not required to register with True Wearables, or have an account with True Wearables in order to purchase Oxxiom device(s) or purchase/download the Oxxiom App from the App Store, and use it with a purchased Oxxiom device.
WARNINGS: ENVIRONMENTAL

Do not take a shower or bath, and do not swim while using this device. This device is not waterproof, and may malfunction if immersed in water or exposed to high levels of humidity.

Do not place liquids on this device. Do not immerse this device in any liquids, and do not use caustic or abrasive cleaning agents on the device.

Do not use this device in an explosive atmosphere.

Do not gas sterilize or autoclave this device.
WARNINGS: MAINTENANCE AND TAMPERING

This device does not require maintenance.

This device is a precision electronic instrument. Do not attempt to open the case or repair the electronics.

No modifications to this device are allowed as they may affect its performance.

Do not use a damaged device. If the device is damaged, discontinue use immediately, and replace the unit.

Do not use this device if there is any sign or evidence that its blister pack has been tampered with.
WARNINGS: RECYCLING

Follow governing ordinances and recycling instructions regarding disposal or recycling of this device and its components, including batteries.

This device contains WEEE materials. In compliance with the European directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose this device as unsorted waste. Please contact True Wearables regarding disposal or recycling of this device and its components.
PACKAGE LAYOUT AND CONTENT

- **Blister pack**
- **Anti-tamper tab**
- **Headband**
- **Oxxiom device**
- **Self-adhering breathable gentle tape roll**
- **Product label with barcode**

**Notes:**
- Blister pack with anti-tamper tab.
- **Oxxiom device**.
- Self-adhering breathable gentle tape roll.
- Product label with barcode.

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OPERATION AND INTENDED USE

The Oxxiom Pulse Oximetry System consists of the Oxxiom pulse oximeter and the Oxxiom App, currently operating on iOS (host) devices. The Oxxiom pulse oximeter is a completely cordless, wireless, continuous, fully disposable, single-use device, with the combined functions of a pulse oximeter monitor, and a disposable sensor, integrated into one single instrument. Oxxiom is small, lightweight, easy to operate and has a 24-hour battery life (typical value). The Oxxiom Pulse Oximetry System measures functional arterial oxygen saturation (SpO2), pulse rate (PR), perfusion index (PI), and waveforms (photoplethysmographs). Oxxiom continuously, simultaneously, and wirelessly transfers all collected data to the Oxxiom App, based on the iOS device, for immediate display, warnings, and data analysis and storage. Oxxiom is indicated for the continuous monitoring of adults in sports (wellness and recreation) and aviation settings.

This device is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. NOT A MEDICAL DEVICE.
DEFINITION OF SPO2, PR, PI, AND WAVEFORMS

The Oxxiom Pulse Oximetry System measures SpO2, PR, PI, and waveforms continuously. These measurement parameters are defined as:

- **SpO2** is the functional saturation of peripheral oxygen. It is the ratio (in percentage) of oxygenated hemoglobin concentration over the total concentration of oxygenated and non-oxygenated hemoglobin in blood. A healthy person should be able to achieve a normal SpO2 level between 94% and 100%.

- **PR** is the number of heartbeats per minute (bpm). A normal resting PR for adults ranges from 60 to 100 bpm.

- **PI** is the normalized peak-to-peak amplitude of the pulsatile signals (plethysmographs) generated at the measurement site by the heart activity, and detected by an optical sensor (photoplethysmographs). PI values range from 0.02% (very weak pulsatile signal) to 20% (very strong pulsatile signal).

- **Waveforms** are the pulsatile signals generated at the measurement site by the heart activity, and detected by an optical sensor (photoplethysmographs). Motion in the measurement site affects the displayed photoplethysmographs.
The red and infrared light rays penetrate the blood perfused dermis and interact with the heart’s pulsatile signal in order to create red and infrared optical pulsatile signals.

1. Red and Infrared lights are applied to the measurement site by the light emitter.
2. The optical pulsatile signals (photoplethysmographs) are captured by the light detector, filtered, and conditioned to produce readings of SpO2, PR, and PI.

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**QUICK START**

1. In your iOS device:
   (i) Select App Store
   (ii) Search for **Oxxiom** in the App Store
   (iii) Select **Oxxiom** to download App

The **Oxxiom** App will be now available in your iOS device.

Make sure to download True Wearables’ **Oxxiom** App, and not a third-party App with similar name.

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QUICK START, CONT.

2 Tear off anti-tamper tab. You may also use scissors to cut off tab.

3 Pull off back lid and product label with barcode.
Pull out Oxxiom and self-adhering breathable gentle tape roll from blister pack. Save product label with barcode for later use.

Remove headband from inside the tape roll.
QUICK START, CONT.

1. Pull tab 1

2. Press the blue dot until the green light turns on.

3. The green light indicates Oxxiom is activated. It blinks once every 10 seconds.

4. Pull tab 2

5. Oxxiom is ready for placement on measurement site (i.e., finger, forehead, or ear).

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QUICK START, CONT.

Finger Placement...

Place Oxxiom on fingertip with green light facing down

Take 6-8 inches of self-adhering tape from the roll provided, and wrap it around fingertip and Oxxiom. Aim for a comfortable, snug fit.
QUICK START, CONT.

...or Forehead Placement with Headband...

Place Oxxiom on forehead with green light facing down

Use a headband to apply slight pressure on the Oxxiom device. Aim for a comfortable, snug fit

Oxxiom works on the forehead without a headband in most users. However, we recommend the use of a headband, or tape, or hat in order to protect Oxxiom against mechanical shocks, dislodging, and direct sunlight exposure, as well as to prevent false readings that may occur in some users.
…or Forehead Placement with Adhesive Tape…

Place Oxxiom on forehead with green light facing down

Use adhesive tape (bandage) to apply slight pressure on the Oxxiom device. Aim for a comfortable, snug fit

The Oxxiom’s blister pack does not come with adhesive tape (bandage). Any over-the-counter adhesive tape for skin (1/2 to 2 inches wide) can be used.

Oxxiom works on the forehead without adhesive tape in most users. However, we recommend the use of a headband, or tape, or hat in order to protect Oxxiom against mechanical shocks, dislodging, and direct sunlight exposure, as well as to prevent false readings that may occur in some users.

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...or Forehead Placement with Adjustable Hat...

Place Oxxiom on forehead with green light facing down

Use an adjustable hat to apply *slight* pressure on the Oxxiom device. Aim for a comfortable, snug fit.

The Oxxiom’s blister pack does not come with an adjustable hat. Any adjustable hat that fits the user’s head can be used, provided it covers the Oxxiom device and applies *slight* pressure to it.

Oxxiom works on the forehead without an adjustable hat in most users. However, we recommend the use of a headband, or tape, or hat in order to protect Oxxiom against mechanical shocks, dislodging, and direct sunlight exposure, as well as to prevent false readings that may occur in some users.
QUICK START, CONT.

…or Back-of-the-Ear Placement

Place Oxxiom on the back of the ear (posterior auricle). Press firmly against the ear to ensure proper adhesion.

After placement, the green light will be seen through the ear’s cartilage (intensity may vary with skin color and placement). Use an adhesive tape (optional) to ensure Oxxiom stays in place.

The Oxxiom’s blister pack does not come with adhesive tape. Any over-the-counter adhesive tape for skin (around 1/2 inch wide) can be used.
QUICK START, CONT.

Select Settings

Select Bluetooth
Only start the Oxxiom App if the Bluetooth option (radio) is ON. If you inadvertently start the Oxxiom App with the Bluetooth radio OFF, then terminate the Oxxiom App, turn ON the Bluetooth radio, and restart the Oxxiom App.
QUICK START, CONT.

Start the Oxxiom App

The Oxxiom App launch screen will be briefly displayed
QUICK START, CONT.

Select the Scan button

Select Dismiss
Select OK

Scan product label’s barcode
Visual and audible warnings will be active until Oxxiom connects to iOS device.
As soon as Oxxiom connects, waveforms are displayed. Visual and audible warnings will be active until measurements are displayed.

After approximately 15 seconds, SpO2, PR, and PI measurements are displayed continuously.
QUICK START, CONT.

In rare occasions, the Oxxiom device may not connect to the iOS device. In this case, terminate (as shown below) and restart the Oxxiom App in the iOS device.

If the Oxxiom device loses wireless connection with the iOS device multiple times, within a short period of time, the iOS device may (at some point) not reconnect automatically. In this case, terminate (as shown below) and restart the Oxxiom App in the iOS device.

How to force the Oxxiom App to close (terminate) on iPhone 8 or earlier
1. Double-click the Home button to show your active Apps;
2. Swipe right or left to find the Oxxiom App;
3. Swipe up to close the Oxxiom App.

How to force the Oxxiom App to close (terminate) on iPhone X
1. From the Home screen, swipe up and pause;
2. Firmly touch and hold the Oxxiom App, then tap —;
   You can also swipe up to close the Oxxiom App as soon as you see —.
The green light indicates Oxxiom is on, ready for application, and not connected to the iOS device.

Oxxiom is ready for placement on measurement site

The red light indicates Oxxiom is on, and connected to the iOS device.

Oxxiom is connected to the iOS device
## MEASUREMENT SITES

<table>
<thead>
<tr>
<th>Site</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| Finger | • More convenient when user is in prone or supine positions (e.g., laying down, sleeping).  
• Higher perfusion when user is not exposed to cold.  
• Nail polish and/or nail fungi do not affect readings. | • Can be inconvenient during physical activity.  
• Finger deformities, skin callouses, or lack of wrapping tape may cause Oxxiom to display false readings (i.e., SpO2 under-reading, etc.).  
• Strong wrapping tape pressure may cause arterial occlusion and Oxxiom may stop reading.  
• Stronger vasoconstrictor response to cold.  
• Slower response to changes in physiological conditions (i.e., SpO2, and/or PR, and/or PI changes) when compared to forehead and ear measurement sites. |
<table>
<thead>
<tr>
<th>Site</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forehead</td>
<td>• More convenient during physical activity.</td>
<td>• Requires headband, or adhesive tape, or adjustable hat (for some users)</td>
</tr>
<tr>
<td></td>
<td>• Blood supply is well maintained, shows less vasoconstrictor response to cold.</td>
<td>• Lack of headband, or adhesive tape, or adjustable hat may cause Oxxiom to display false readings (i.e., SpO2 under-reading, etc.), or dislodge and fall (for some users)</td>
</tr>
<tr>
<td></td>
<td>• Faster response to changes in physiological conditions (i.e., SpO2, and/or PR, and/or PI changes) when compared to the finger site.</td>
<td>• Strong headband, or tape, or hat pressure may cause arterial occlusion and Oxxiom may stop reading.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Strong applied pressure, caused by the user’s head weight (e.g., when in prone position), may cause arterial occlusion and Oxxiom may stop reading or cause Oxxiom to display false readings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lower perfusion.</td>
</tr>
<tr>
<td>Site</td>
<td>Pros</td>
<td>Cons</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ear (posterior auricle)</td>
<td>• More convenient during physical activity.</td>
<td>• Requires adhesive tape (for some users)</td>
</tr>
<tr>
<td></td>
<td>• Shows less vasoconstrictor response to cold.</td>
<td>• Lack of adhesive tape may cause Oxxiom to dislodge and fall (for some users)</td>
</tr>
<tr>
<td></td>
<td>• Faster response to changes in physiological conditions (i.e., SpO2, and/or PR, and/or PI changes) when compared to the finger site.</td>
<td>• Ear deformities and/or piercing may cause Oxxiom to display false readings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Strong applied pressure, caused by the adhesive tape, and/or by the user’s head weight (when in supine/prone positions, with the head turned over the ear where Oxxiom is attached), may cause arterial occlusion and Oxxiom may stop reading or cause Oxxiom to display false readings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lower perfusion.</td>
</tr>
</tbody>
</table>
Other Sites

Nose, ear lobe, toe, leg, arm, wrist, temple, chest, head, etc.

- The Oxxiom device has been tested on a subject population with sensors on finger, ear (posterior auricle), and forehead, and has shown acceptable performance throughout.
- Given Oxxiom’s small form factor, lightweight, cordless design, and continuous monitoring capabilities, it is natural to assume that some users may decide to experiment with Oxxiom’s monitoring technology in other measurement sites (i.e., nose, ear lobe, toe, leg, arm, wrist, temple, chest, head, etc.)
- Performance in these additional sites is not guaranteed and may vary from user to user, and from time to time.
- Thus, for continuous monitoring of SpO2, PR and PI, one particular measurement site may be more appropriate than others depending on the user’s physiological conditions, and measurement site’s anatomy. As a result, some “trial-and-error” may be necessary to find an alternate site with acceptable performance.
## OXXIOM APP: SYMBOLS

<table>
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<tr>
<th>Description</th>
<th>Symbol</th>
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</thead>
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<td>Side Drawer menu</td>
<td>![Side Drawer menu symbol]</td>
</tr>
<tr>
<td>Start screen</td>
<td>![Start screen symbol]</td>
</tr>
<tr>
<td>Settings screen</td>
<td>![Settings screen symbol]</td>
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<tr>
<td>Share Data screen</td>
<td>![Share Data screen symbol]</td>
</tr>
<tr>
<td>About Oxxiom screen</td>
<td>![About Oxxiom screen symbol]</td>
</tr>
<tr>
<td>Visual warning</td>
<td>![Visual warning symbol]</td>
</tr>
<tr>
<td>Oxxiom’s battery</td>
<td>![Oxxiom’s battery symbol]</td>
</tr>
<tr>
<td>Audible warning</td>
<td>![Audible warning symbol]</td>
</tr>
<tr>
<td>Oxxiom App</td>
<td>![Oxxiom App symbol]</td>
</tr>
</tbody>
</table>
OXXIOM APP: PORTRAIT MODE

SpO2 gauge

SpO2 97%

PR gauge

PR 66 bpm

PI gauge

PI 1.9%

Side Drawer menu

Waveform (Photoplethysmograph)

Audible warning status

Oxxiom’s battery status

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To enable landscape mode, make sure the Portrait Orientation Lock in the iOS device’s Control Center is disabled.
OXXIOM APP: SIDE DRAWER MENU

Select to display Side Drawer menu

Select to access Start screen
Select to access Settings screen
Select to access Share Data screen
Select to access About Oxxiom screen

Side Drawer menu

The user can also slowly swipe in from the right side of the iOS device screen to open the Side Drawer menu.
OXXIOM APP: START SCREEN

Select to make changes effective, and return to main screen

Select to scan Oxxiom Barcode

Only the Oxxiom product label barcode will be successfully scanned. Any other barcode will produce an error.
OXXIOM APP: START SCREEN, CONT.

The user cannot delete from the Oxxiom App a valid barcode that has been scanned. This is to prevent unintentional disconnection between the iOS device and the Oxxiom device.

The only way to change the current barcode in the Oxxiom App is to scan the barcode of a new Oxxiom unit.

If the user scans the barcode of a new Oxxiom unit, then the current Oxxiom unit will be automatically disconnected, regardless the state of the new Oxxiom unit (i.e., tuned on or off). If the new Oxxiom unit is turned on (and in wireless range of the iOS device), then it will be automatically connected to the iOS device.
OXXIOM APP: SETTINGS SCREEN

Select to set trend data chart memory (Default = 5’)

Select to set trend data maximum storage time (Default = 24h)

Select to enable or disable audible warnings/Measurements (Default = enabled)

Select to set audible warning silence duration (Default = 30s)

Select to set time gap between audible measurements (Default = never)

Select to make changes effective, and return to main screen
OXXIOM APP: SETTINGS SCREEN, CONT.

Select to set upper and lower SpO2 warning limits (Defaults = 100, 89)

Select to set upper and lower PR warning limits (Defaults = 187, 35)

Select to enable or disable waveform storage for 12 hours (Default = enabled)

Select to make changes effective, and return to main screen
OXXIOM APP: SHARE DATA SCREEN

Select to choose the type of data to be shared (i.e., Reports, Trends, or Waveforms)

Select to return to main screen

Select to share data
Depending on the data collection duration, and the iOS device model, it may take up to:

- 30 seconds to create and attach **Reports** or **Trends** file
- 5 seconds to attach **Waveforms** file
Select to choose sharing method (AirDrop, Message, Mail, iCloud, Print, etc.)

Available data sharing methods may vary depending on the iOS device configuration and data being shared.
The following provides a detailed description of each data type (i.e., Reports, Trends, and Waveforms) and its use.

**Reports**

After the Oxxiom device is connected and operating (displaying SpO2, PR, and PI measurements) for **at least 30 minutes** (data collection time), the user may share a report in PDF format. The report (10 pages) comprises of the following charts:
1. SpO2 Measurements Over Time.
2. PR Measurements Over Time
3. PI Measurements Over Time
4. SpO2 Distribution
5. PR Distribution
6. PI Distribution
7. SpO2 Desaturations per Hour
8. Cumulative Time Percentage with SpO2 Less than Threshold
9. PR Volatility Distribution
10. PI Log-Volatility Distribution

The user may share (create) a report any time during data collection. However, if the user decides to create a report with less than 30 minutes of data collected, then only the first 3 charts (SpO2, PR, and PI Measurements Over Time) will be displayed in the report.
If the user chooses to connect to a new Oxxiom unit (i.e., scans a new valid Oxxiom barcode), the report data from the previous Oxxiom unit will no longer be available. Therefore, the user should make sure to share (save) a report before connecting to a new Oxxiom unit.

Data sharing may be done at any moment during or after data collection, or when the Oxxiom unit is disconnected, or even after its battery dies out, as long a new unit has not been scanned.

The data collection period is from the moment the Oxxiom unit is first connected to the iOS device, until the moment the user chooses to share the report (assuming that the data collection duration is less than or equal to the trend data maximum storage time (i.e., either 12, 24, 36 or 48 hours, set in the Settings screen), and that the Oxxiom unit is connected to the iOS device and working at the time the report is shared).
SpO2 Measurements Over Time Chart
The chart below shows an example of SpO2 trend created by the Oxxiom App, from data collected overnight by an user wearing Oxxiom. Normal SpO2 levels are between 94% and 100%. However, during sleep, exercise, or situations of high stress, or in high altitude places, SpO2 readings may reach lower values (i.e., lower than 94%).

PR Measurements Over Time Chart
The chart below shows an example of PR trend created by the Oxxiom App, from data collected overnight by an user wearing Oxxiom. Normal resting PR for adults ranges from 60 to 100 bpm. However, during sleep, exercise, or situations of high stress, or in high altitude places, PR readings may reach higher values.
OXXIOM APP: SHARE DATA SCREEN, CONT.

PI Measurements Over Time Chart
The chart below shows an example of PI trend created by the Oxxiom App, from data collected overnight by an user wearing Oxxiom. PI values range from 0.02% (very weak pulsatile signal) to 20% (very strong pulsatile signal). Extreme PI values may indicate a situation of discomfort (e.g., cold, hot, stress, etc.).
OXXIOM APP: SHARE DATA SCREEN, CONT.

SpO2 Distribution Chart
The chart below shows an example of SpO2 distribution created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, in 87.4% of the time (i.e., 497 minutes), the SpO2 values were within 94% and 100%, and in 12% of the time (i.e., 68 minutes), the SpO2 values were between 88% and 93%.
PR Distribution Chart

The chart below shows an example of PR distribution created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, in 58.1% of the time (i.e., 331 minutes), the PR values were within 60 bpm and 80 bpm, and in 39.1% of the time (i.e., 222 minutes), the PR values were between 50 bpm and 59 bpm.
OXXIOM APP: SHARE DATA SCREEN, CONT.

PI Distribution Chart
The chart below shows an example of PI distribution created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, in 64.2% of the time (i.e., 365 minutes), the PI values were within 0.1% and 0.5%, and in 35% of the time (i.e., 199 minutes), the PI values were between 0.01% and 0.1%.

OXXIOM APP: SHARE DATA SCREEN, CONT.

SpO2 Desaturations Per Hour Chart
The chart below shows the number of desaturations per hour from baseline, created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, the user had 1.9 desaturations per hour with amplitude greater than 4%. A healthy person will typically have less than 5 or so desaturations per hour with amplitude greater than 4%. These values may increase during exercise, or in situations of high stress, or in high altitude places.
Cumulative Time With SpO2 Less Than Threshold Chart

The chart below shows the cumulative time percentages with SpO2 less than threshold, created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, in 1.5% (i.e., 8.5 minutes) of the time, the user’s SpO2 values were less than 90%. A healthy person will typically stay for a very small time percentage with SpO2 less than 90%. This time percentage may increase during exercise, or in situations of high stress, or in high altitude places.

Cumulative Time Percentage with SpO2 Less than Threshold (100% = 569 Minutes)
PR Volatility Distribution Chart

The PR Volatility express the heart rate short-term variability. Typically for health adults, the higher the PR Volatility values, the better. Increasing PR Volatility trends are positive, and indicative of positive adaptation and/or increase in fitness. The chart below shows an example of PR Volatility distribution created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, over 50% of the time (i.e., 286 minutes), the PR Volatility values were between 0.46 bpm and 1 bpm.

PI Log-Volatility Distribution Chart

The PI Log-Volatility express the perfusion short-term variability. Typically for health adults, the lower the PI Log-Volatility values, the better. Decreasing PI Log-Volatility trends are positive, and indicative of positive adaptation and/or decrease in overall stress levels. The chart below shows an example of PI Log-Volatility distribution created by the Oxxiom App, from data collected overnight (569 minutes) by an user wearing Oxxiom. According to the chart, over 52% of the time (i.e., 286 minutes), the PI Log-Volatility values were within 9.4% and 15%.

![PI Log-Volatility Distribution Chart](chart.png)
Trends
After the Oxxiom device is connected to the iOS device and operating (displaying SpO2, PR, and PI measurements), the user may share SpO2, PR, and PI measurement trends in a Comma-Separated Values (CSV) file (i.e., spreadsheet format) at anytime through the Oxxiom App. The file can be opened and visualized by the iOS device directly or by most spreadsheet softwares, such as Excel, Numbers, etc. The CSV file contains 5 columns:
1. Date/Time. Stores date and time of each measurement taken. Measurements are stored once a second (for 12h trend storage), once every 2 seconds (for 24h trend storage), once every 3 seconds (for 36h trend storage), and once every 4 seconds (for 48h trend storage).
2. Oxxiom Barcode. The 8-digit hexadecimal number that identifies the Oxxiom unit being used at the corresponding time and date.
4. PR (bpm). PR measurements.
5. PI (%). PI measurements.
Content sample of a OxxiomMeasurementLogCSV.csv file where measurements are saved once a second (for 12-hour maximum storage time)

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Oxxiom Barcode</th>
<th>SpO2 (%)</th>
<th>PR (bpm)</th>
<th>PI (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018-07-03 22:09:31</td>
<td>DE4B6CC6</td>
<td>100</td>
<td>65</td>
<td>0.58</td>
</tr>
<tr>
<td>2018-07-03 22:09:32</td>
<td>DE4B6CC6</td>
<td>99</td>
<td>65</td>
<td>0.59</td>
</tr>
<tr>
<td>2018-07-03 22:09:33</td>
<td>DE4B6CC6</td>
<td>99</td>
<td>64</td>
<td>0.54</td>
</tr>
<tr>
<td>2018-07-03 22:09:34</td>
<td>DE4B6CC6</td>
<td>99</td>
<td>64</td>
<td>0.54</td>
</tr>
<tr>
<td>2018-07-03 22:09:35</td>
<td>DE4B6CC6</td>
<td>99</td>
<td>64</td>
<td>0.56</td>
</tr>
<tr>
<td>2018-07-03 22:09:36</td>
<td>DE4B6CC6</td>
<td>98</td>
<td>64</td>
<td>0.54</td>
</tr>
<tr>
<td>2018-07-03 22:09:37</td>
<td>DE4B6CC6</td>
<td>99</td>
<td>63</td>
<td>0.57</td>
</tr>
<tr>
<td>2018-07-03 22:09:38</td>
<td>DE4B6CC6</td>
<td>97</td>
<td>62</td>
<td>0.60</td>
</tr>
<tr>
<td>2018-07-03 22:09:39</td>
<td>DE4B6CC6</td>
<td>98</td>
<td>62</td>
<td>0.68</td>
</tr>
</tbody>
</table>

The frequency on which SpO2, PR, and PI measurement trends are saved to the CSV file is selected by the user in the Settings screen, Trend Data, Store For. They are:

- For 12 hours = once a second.
- For 24 hours = once every 2 seconds.
- For 36 hours = once every 3 seconds.
- For 48 hours = once every 4 seconds.
Waveforms

The user may share the waveform raw data collected by the Oxxiom unit (up to 12 hours) through the Oxxiom App. The waveform raw data is stored in a database file (WaveformsDB.db) using True Wearables’ proprietary data format.

The user may enable or disable waveform storage in the Settings screen, Waveform Storage, Store last 12 hours.

The waveform raw data’s primary use is for in-depth technical analysis of potential problems detected by Oxxiom users.

The waveform raw data can only be shared by the user. True Wearables does not collect, store, or analyze waveform data without the user’s consent.
**OXXIOM APP: ABOUT OXXIOM SCREEN**

<table>
<thead>
<tr>
<th>Identification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial Num:</td>
<td>FEDD35E705AE8...</td>
</tr>
<tr>
<td>Barcode:</td>
<td>3DF2DF61</td>
</tr>
<tr>
<td>Lot Num:</td>
<td>00004</td>
</tr>
<tr>
<td>Exp Date:</td>
<td>07/2019</td>
</tr>
<tr>
<td>Model:</td>
<td>2203</td>
</tr>
<tr>
<td>Version:</td>
<td>2801</td>
</tr>
<tr>
<td>App Version:</td>
<td>1.5.0</td>
</tr>
</tbody>
</table>

**Hardware Diagnostics**

| LED 1 Power:    | 24% |
| LED 2 Power:    | 32% |
| Electronic Gain | 30dB |
OXXIOM APP: ABOUT OXXIOM SCREEN, CONT.

Select to return to main screen

Hardware Diagnostics

- LED 1 Power: 24%
- LED 2 Power: 32%
- Electronic Gain: 28dB
- Ambient Light: 0%
- SoC Temperature: 22°C
- Battery Voltage: 2.2V
- Standby Time: 6 hr, 5 min
- Usage Time: 20 hr, 42 min
- Time Stamp: 09:42:58 08-03-...

Hardware Diagnostics section
OXXIOM APP: ABOUT OXXIOM SCREEN, CONT.

Select to return to main screen

Select to access this online User Guide

Select to access True Wearables’ website

Technical Support section

Select to send email message to True Wearables’ Technical Support Team

Contact Us

User Guide

Website

Regulatory

FCC ID: 2ALHN282203
Accuracy: ISO 80601-2-61
Safety: IEC 60601-1
EMC: IEC 60601-1-2
Biocompatibility: ISO 10993-5,-10

Legal
The following provides a detailed description of each section displayed on the About Oxxiom screen.

**Identification Section**

1. **Serial Num.** When the Oxxiom device is connected and operating, it displays a 16-digit hexadecimal number with the Oxxiom unit serial number.

2. **Barcode.** When the Oxxiom device is connected and operating, it displays an 8-digit hexadecimal number that identifies the Oxxiom unit in the Start screen (Oxxiom Barcode) and in the trend data CSV file, that can be downloaded from the Share Data screen, Trends.

3. **Lot Num.** When the Oxxiom device is connected and operating, it displays the Oxxiom device manufacturing lot number.

4. **Exp Date.** When the Oxxiom device is connected and operating, it displays the date after which the Oxxiom unit should not be sold.

5. **Model.** When the Oxxiom device is connected and operating, it displays an 4-digit hexadecimal number with the Oxxiom unit model number.

6. **Version.** When the Oxxiom device is connected and operating, it displays an 4-digit hexadecimal number with the Oxxiom unit version number.

7. **App Version.** Three-digit number with the software version.
Hardware Diagnostics Section
Whenever the Oxxiom device is connected and operating, the following hardware diagnostic parameters are reported by the Oxxiom App:

1. LED1 Power, and LED2 Power. They display the power levels (reported at Time Stamp) for the Oxxiom’s light sources 1 and 2. They vary between 0 and 100%.

2. Electronic Gain. It displays the Oxxiom’s analog frontend electronic gain (reported at Time Stamp). It varies between 0 and 40 dB.

3. Ambient Light. It displays the ambient light intensity detected by the Oxxiom’s light detector (reported at Time Stamp). It varies between 0 and 100%.

4. SoC Temperature. It displays the Oxxiom’s System on Chip (SoC) temperature in Celsius (reported at Time Stamp).

5. Battery Voltage. It displays the Oxxiom’s battery voltage in Volts (reported at Time Stamp).

6. Standby Time: It displays the amount of time the Oxxiom unit has been activate and disconnected from the iOS device (reported at Time Stamp).

7. Usage Time. It displays the amount of time the Oxxiom unit has been activate and connected to the iOS device (reported at Time Stamp).

8. Time Stamp. Date and time when hardware diagnostic parameters were reported.
OXXIOM APP: ABOUT OXXIOM SCREEN, CONT.

Technical Support Section

1. Contact Us. Select it to contact True Wearables’ technical support team by email. The iOS device must have email App service available and functional. An email message (as shown below) is pre-populated with information about the Oxxiom device (if connected and operating):

   To: contact@truewearables.com
   Cc/Bcc:

   Subject: Customer Service, Oxxiom

   ---- Type here your message ----

   -----------------------------

   Oxxiom Identification
   Serial Num: FEDD35E705AE867C
   Barcode: 3DF2DF61
   Lot Num: 00004
   Exp Date: 07/2019
   Model: 2203
   Version: 2801
   App Version: 1.5.0

   Hardware Diagnostics

2. User Guide. Select it to access this online User Guide.
3. Website. Select it to access True Wearables’ website.
OXXIOM APP: ABOUT OXXIOM SCREEN, CONT.

Regulatory Section
1. FCC ID. It is the Oxxiom’s Federal Communications Commission Identification number.
4. EMC. Adopted standard for Oxxiom’s electromagnetic compatibility requirements and tests.

Legal Section
1. Please refer to User Guide. Select it to access this online User Guide.
OXXIOM APP: TAKING SCREENSHOTS

There are situations where it is desirable to take screenshots of the Oxxiom App measurement gauges and trend data for your own records or for sharing with third parties.

To take an Oxxiom App screenshot on an iPhone 8 or earlier, iPad, or iPod touch:
1. Press and hold the Top or Side button;
2. Immediately click the Home button, then release the Top or Side buttons;
3. The screenshots taken will be available on the iOS Photos App.

To take an Oxxiom App screenshot on an iPhone X:
1. Press and hold the Side button on the right side of your device;
2. Immediately click the Volume up button on the left side, then release the buttons;
3. The screenshots taken will be available on the iOS Photos App.

Make sure the Oxxiom App is active and connected to the Oxxiom device before taking screenshots.
OXXIOM APP: GUIDED ACCESS MODE

There are applications where it is desirable to have the iOS device restricted to a single App (i.e., the Oxxiom App), with hardware buttons and the Oxxiom App side drawer menu disabled. The Oxxiom App was designed to be compliant with the iOS Guided Access mode. The Guided Access mode temporarily restricts the iOS device to a single App, and lets the user control which App features are available.

Oxxiom App default behavior during Guided Access section:
• Oxxiom App termination is disabled.
• Side drawer menu is disabled.
• Portrait and landscape views are enabled.
• Hardware buttons are disabled (i.e., volume, Sleep/Wake, etc.).
• User can silence audible warnings (if enabled and active) for a period of time by taping on any gauge bar. However, Audible warnings will resume automatically after silence duration (i.e., 30, 60, 90, or 120 seconds) expires. If required, audible warnings can be permanently disabled, before starting a Guided Access section (please refer to the OXXIOM APP: SETTINGS SCREEN section in this guide).
To set up Guided Access Mode on iOS device:
1. Tap Settings > General > Accessibility > Guided Access to set up Guided Access;
2. Turn Guided Access ON or OFF;
3. Set a passcode that controls the use of Guided Access, and prevents someone from leaving an active session.

To start a Guided Access section on iOS device:
1. Start the Oxxiom App. If an Oxxiom device is not yet connected to the iOS device, then follow steps described in Quick Start;
2. Triple-click the Home button;
3. Tap Start.

To end a Guided Access section on iOS device:
1. Triple-click the Home button;
2. Enter the Guided Access passcode;
3. Tap End.

Make sure the Oxxiom App is active and connected to the Oxxiom device before starting a Guided Access section.
OXXIOM APP: WARNINGS

Gauges blink in red

SpO2 80%

PR 134 bpm

PI 0.78%

Visual warning message is displayed

Bell indicates active audible warning

Tap any gauge bar to silence audible warnings for a period of time. Audible warnings will resume automatically after silence duration (i.e., 30, 60, 90, or 120 seconds) expires.
### OXXIOM APP: WARNINGS, CONT.

<table>
<thead>
<tr>
<th>Description</th>
<th>Visual</th>
<th>Audible</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 measurement has crossed either upper or lower limits</td>
<td>• ⚠ SpO2 warning</td>
<td>• Warning beep</td>
</tr>
<tr>
<td></td>
<td>• SpO2 gauge blinks in red</td>
<td>• &quot;Saturation warning&quot; voice message</td>
</tr>
<tr>
<td>PR measurement has crossed either upper or lower limits</td>
<td>• ⚠ PR warning</td>
<td>• Warning beep</td>
</tr>
<tr>
<td></td>
<td>• PR gauge blinks in red</td>
<td>• &quot;Pulse Rate warning&quot; voice message</td>
</tr>
<tr>
<td>SpO2 and PR measurements have crossed either upper or lower limits</td>
<td>• ⚠ SpO2 and PR warnings</td>
<td>• Warning beep</td>
</tr>
<tr>
<td></td>
<td>• SpO2 and PR gauges blink in red</td>
<td>• &quot;Saturation and Pulse Rate warnings&quot; voice message</td>
</tr>
</tbody>
</table>

This device is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. **NOT A MEDICAL DEVICE.**

© 2016-2018 True Wearables, Inc.
**Description**

<table>
<thead>
<tr>
<th>Oxxiom is not connected to iOS device</th>
<th>Oxxiom is searching for a valid signal</th>
<th>Oxxiom’s battery is empty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxxiom is not connected to iOS device</td>
<td>Oxxiom is searching for a valid signal</td>
<td>Oxxiom’s battery is empty</td>
</tr>
<tr>
<td>• ⚠️ Oxxiom not connected⚠️</td>
<td>• ⚠️ Searching signal⚠️</td>
<td>• ⚠️ Battery empty⚠️</td>
</tr>
<tr>
<td>• Dashed gauges blinking in red</td>
<td>• Dashed gauges blinking in red</td>
<td>• Gauges blink in red</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(dashed or not)</td>
</tr>
</tbody>
</table>

**Visual**

- ⚠️ Oxxiom not connected⚠️
- Dashed gauges blinking in red

**Audible**

- Warning beep
- "Oxxiom not connected" voice message

This device is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. **NOT A MEDICAL DEVICE.**
## OXXIOM APP: WARNINGS, CONT.

<table>
<thead>
<tr>
<th>Description</th>
<th>Visual</th>
<th>Audible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxxiom wireless connection with iOS device is not reliable</td>
<td>• ⚠️ Poor connection ⚠️</td>
<td>• Warning beep</td>
</tr>
<tr>
<td></td>
<td>• Gauges blink in red</td>
<td>• “Poor connection” voice message</td>
</tr>
<tr>
<td>iOS device’s battery is low (charge is less than 23%)</td>
<td>⚠️ Charge iOS device ⚠️</td>
<td>• Warning beep</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• &quot;Charge IOS device&quot; voice message</td>
</tr>
</tbody>
</table>

This device is intended for sports and aviation use only. Individuals who need a pulse oximeter due to a medical condition should contact their physician. **NOT A MEDICAL DEVICE.**
## OXXIOM APP: AUDIBLE WARNING STATUS

<table>
<thead>
<tr>
<th>Description</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audible warnings active</td>
<td>🔔</td>
</tr>
<tr>
<td>Audible warnings disabled</td>
<td>🔔 (red)</td>
</tr>
</tbody>
</table>

Audible warnings can be enabled or disabled in the Settings menu.
# OXXIOM APP: OXXIOM’S BATTERY STATUS

<table>
<thead>
<tr>
<th>Description</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxxiom’s battery full</td>
<td><img src="image" alt="Battery Full Symbol" /></td>
</tr>
<tr>
<td>Oxxiom’s battery not full</td>
<td><img src="image" alt="Battery Not Full Symbols" /></td>
</tr>
<tr>
<td>Oxxiom’s battery low (blinking red bar)</td>
<td><img src="image" alt="Battery Low Symbol" /></td>
</tr>
<tr>
<td>Oxxiom’s battery empty</td>
<td><img src="image" alt="Battery Empty Symbol" /></td>
</tr>
</tbody>
</table>

Oxxiom stops taking measurements when battery is empty. Audible and visual battery-empty warnings are issued.
### OXXIOM TECHNICAL SPECS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>1.2 x 0.7 x 0.3 in (30 x 17 x 7.5 mm)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>0.12 oz (3.5 g)</td>
</tr>
<tr>
<td><strong>Wireless Range</strong></td>
<td>33 ft (10 m)</td>
</tr>
<tr>
<td><strong>Battery Life</strong></td>
<td>24 h</td>
</tr>
<tr>
<td><strong>SpO2 Accuracy</strong></td>
<td>± 3.5% (70-100%)</td>
</tr>
<tr>
<td><strong>PR Accuracy</strong></td>
<td>± 3 bpm (25-250 bpm)</td>
</tr>
<tr>
<td><strong>Safety Standards</strong></td>
<td>ISO 80601-2-61, IEC 60601-1, IEC 60601-1-2, ISO 10993-5 and -10</td>
</tr>
<tr>
<td><strong>FCC ID</strong></td>
<td>2ALHN282203</td>
</tr>
<tr>
<td><strong>Wireless Protocol</strong></td>
<td>Bluetooth Low Energy (BLE) V4</td>
</tr>
<tr>
<td><strong>Required Host</strong></td>
<td>iOS device with iOS mobile operating system version 9.2 or later</td>
</tr>
<tr>
<td><strong>Required App</strong></td>
<td>Oxxiomi App for iOS (latest version)</td>
</tr>
</tbody>
</table>
## OXXIOM TECHNICAL SPECS, CONT.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optical Emitted Power</td>
<td>Less than 1 mW</td>
</tr>
<tr>
<td>Optical Range</td>
<td>490-1000 nm</td>
</tr>
<tr>
<td>Ingress Protection</td>
<td>IPX1 (Dripping water)</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>5-40°C (41-104°F)</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>95% RH max. at 40°C (104°F)</td>
</tr>
<tr>
<td>Operating Altitude</td>
<td>Up to 3,012 m (9,882 ft)</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>15-30°C (59-86°F)</td>
</tr>
<tr>
<td>Storage Humidity</td>
<td>60% RH max. at 30°C (86°F)</td>
</tr>
<tr>
<td>Storage Altitude</td>
<td>Up to 5,574 m (18,228 ft)</td>
</tr>
<tr>
<td>Battery</td>
<td>Non-rechargeable lithium/manganese dioxide (LiMnO2), 3 V, 150 mAh</td>
</tr>
</tbody>
</table>
Notes

(1) Unobstructed path between the pulse oximeter (Oxxiom) and the iOS (host) device. Physical obstacles and indoor room geometry may drastically reduce the effective wireless range.

(2) Typical value. Changes in the measurement site optical properties, environmental conditions, and device stand-by operation time affect battery life. Tests conducted in laboratory conditions have shown that the battery life may be significantly shortened depending on the aforementioned changes.

(3) ± 3.5% is the root-mean-square accuracy and represents approximately 68% of measurements. Accuracy evaluated during induced hypoxia study that compared SpO2 to SaO2 (Arterial Blood CO-Oximetry) measurements on 10 healthy adult male and female subjects, ranging in pigmentation from light to dark, and wearing 40 Oxxiom devices in total (4 devices per subject). The study followed the pulse oximetry guidelines of ISO 80601-2-61:2011 applicable sections.
Notes

± 3 bpm is the root-mean-square accuracy, and represents approximately 68% of measurements. Evaluated with electronic pulse simulator study, and during induced hypoxia study on 10 healthy adult male and female subjects, ranging in pigmentation from light to dark. In the hypoxia study, Oxxiom was compared to 4 different reference pulse oximetry systems, and the largest root-mean-square accuracy was reported. Forty (40) Oxxiom devices (4 devices per subject) were tested. Subjects had normal perfusion (PI) levels, and SpO2 levels between 70% and 100%. In the electronic pulse simulator study, PI was varied between 0.025% and 6%, and SpO2 between 70% and 100%. 4 Oxxiom devices were tested. The studies followed the pulse oximetry guidelines of ISO 80601-2-61:2011 applicable sections.
The Oxxiom Pulse Oximeter System has been certified to comply with the following safety standards:

- ISO 10993-10: Tests for irritation and skin sensitization (Biocompatibility of tape adhesives and self-adhering breathable gentle tape).
Notes

(6) Name of Grantee: True Wearables Inc.  
   Equipment Class: Digital Transmission, wireless,  
   continuous, fully disposable single-use pulse  
   oximeter.  
   Date of Grant: 04/07/2017.  
   Frequency range: 2402 - 2480 MHz.  
   Output power: 1 mW (conducted).

(7) Complies with FCC PART 15, SUBPART C IC  
    RSS-247, ISSUE 1, MAY 2015.

(8) Complies with 47 CFR Part 15 Subpart B for Class  
    B Devices and Innovation, Science, and Economic  
    Development Canada ICES-003 Issue 6 (Jan.  
    2016) for Class B Devices.
**OXXIOM APP TECHNICAL SPECS**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wireless Pairing</strong></td>
<td>Barcode scanning via iOS device’s camera</td>
</tr>
<tr>
<td><strong>Measurement Gauges/Trends</strong></td>
<td>SpO2, PR, and PI</td>
</tr>
<tr>
<td><strong>Waveform Chart</strong></td>
<td>Near-infrared photoplethysmograph</td>
</tr>
<tr>
<td><strong>SpO2, PR, and PI Audible</strong></td>
<td>Once every 30, 60, or 120 seconds, or never</td>
</tr>
<tr>
<td><strong>SpO2 Display Range</strong></td>
<td>1-100%</td>
</tr>
<tr>
<td><strong>PR Display Range</strong></td>
<td>25-250 bpm</td>
</tr>
<tr>
<td><strong>PI Display Range</strong></td>
<td>0-20%</td>
</tr>
<tr>
<td><strong>Trend Chart Memory</strong></td>
<td>Configurable 2, 5, 10, 30, or 60 minutes</td>
</tr>
<tr>
<td><strong>Trend Storage</strong></td>
<td>12h (1 meas. every second), 24h (1 meas. every 2 seconds), 36h (1 meas. every 3 seconds), or 48h (1 meas. every 4 seconds)</td>
</tr>
</tbody>
</table>

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### Visual and Audible Warnings

Adjustable low/high SpO2 and low/high PR, Oxxiom not connected, Oxxiom’s battery is empty, searching signal, poor wireless connection, iOS device’s battery is low

### Warning Silence

30, 60, 90, or 120 seconds

### Waveform Storage

12 hours

### Data Sharing

Reports with data analysis (PDF file); SpO2, PR, and PI trends (CSV file); Waveforms (database file, proprietary data format)

### Required Host Device

iOS device with iOS operating system version 9.2 or later

### Required Pulse Oximeter

Oxxiom for Sports and Aviation
Notes

(1) The Oxxiom pulse oximetry system applies True Wearables’ proprietary algorithms to real-time sampled signals in order to calculate SpO2, PR and PI measurements. These algorithms produce an effective data processing time delay that is less than or equal to 12 seconds. Motion in the measurement site, and/or low perfusion, and/or abnormally rapid changes in SpO2, and/or PR, and/or PI levels may cause additional delays of up to 18 seconds, which may increase warning detection and generation delays. Measurement gauges and trends are updated once a second. The following summarizes the Oxxiom Pulse Oximetry System absolute maximum delays:

<table>
<thead>
<tr>
<th>Delay Description</th>
<th>Max. Delay (seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data processing</td>
<td>12</td>
</tr>
<tr>
<td>Warning detection and generation</td>
<td>30</td>
</tr>
<tr>
<td>Measurement update</td>
<td>1</td>
</tr>
</tbody>
</table>
At True Wearables, we value our customers, and take great pride in our products and technology. We welcome your inquiries and comments.

**Method 1: Technical Support via Oxxiom App**
If you have purchased an Oxxiom device and downloaded the Oxxiom App from the Apple’s App Store:
• Please follow instructions in section OXXIOM APP ABOUT OXXIOM SCREEN, Technical Support, in this guide.

**Method 2: Technical Support and/or all other inquiries via email or mail.**
Please send email to contact@truewearables.com with:
• Subject: Customer Service, Oxxiom;
• Message: With inquiries and/or comments;
Or send correspondence to True Wearables, Inc., 29826 Avenida de Las Banderas, Suite 300, Rancho Santa Margarita, CA 92688 with:
• Subject: Customer Service, Oxxiom;
• Message: With inquiries and/or comments;
• Sender contact information: Name, Address, affiliation (if any), contact phone.
CARE AND MAINTENANCE

- **Warning**: Oxxiom is a disposable device and cannot be cleaned.

- **Warning**: Do not immerse Oxxiom in liquid, and do not use caustic or abrasive cleaning agents on Oxxiom.

- **Warning**: The Oxxiom device’s electronic circuitry does not require calibration or periodic maintenance.

- **Warning**: Field repair of the Oxxiom device is not possible. Do not attempt to open the Oxxiom device encapsulation or repair its internal electronics.

- **Warning**: Opening the Oxxiom device will damage it. If the system is not functioning properly, please refer to “Troubleshooting” section or contact True Wearables's technical support (Please refer to the CONTACT INFORMATION section in this guide).

- **Warning**: For information regarding iOS device care and maintenance, please refer to the manufacturer’s website, www.apple.com.
TROUBLESHOOTING

Oxxiom will not turn on (green LED will not blink ON and OFF every 10 seconds) after tab 1 was pulled off and blue dot pressed.

1. Make sure Oxxiom unit has not been tampered with.
2. Press blue dot harder.
3. If green LED blinks ON and OFF every 10 seconds, then proceed to apply Oxxiom to the measurement site as described in QUICK START section in this guide.
4. Otherwise, please contact True Wearables’ technical support (please refer to the CONTACT INFORMATION section in this guide).
Oxxiom cannot connect to iOS device.

1. Make sure the iOS device Bluetooth radio is enabled (ON).
2. Make sure Oxxiom is within the specified maximum wireless range – approximately 10 meters (spherical radius, unobstructed path) from the iOS (host) device.
3. Make sure the Oxxiom product label barcode provided has been successfully scanned.
4. Terminate and restart the Oxxiom App.
5. If problem persists, then please contact True Wearables’ technical support (please refer to the CONTACT INFORMATION section in this guide).
Oxxiom cannot connect to iOS device because iOS device is in Airplane mode.

Oxxiom connects to the iOS device via Bluetooth. If the iOS device is in Airplane mode, the Bluetooth radio is disabled by default. You can turn on the Bluetooth radio with Control Center:
1. Open the Control Center from the iOS Home screen.
2. Tap the Bluetooth symbol and exit Control Center.
3. Terminate and restart the Oxxiom App.
4. If problem persists, please contact True Wearables’ technical support (please refer to the CONTACT INFORMATION section in this guide).
TROUBLESHOOTING, CONT.

Oxxiom is ON and paired with iOS (host) device but does not produce measurement results.

1. Check if gentle breathable tape wrapped around Oxxiom and finger, or headband wrapped around user’s forehead and Oxxiom, or adhesive tape applied on Oxxiom and user’s forehead, or adjustable hat is not too tight or too loose. For back-of-the-ear placement, make sure Oxxiom is correctly attached to the ear (follow instructions in QUICK START section in this guide).

2. Check for finger, forehead, or ear deformities.

3. Reposition Oxxiom in case it still does not produce a result.

4. Check for cold hands, forehead or ears. Warm or rub the hands to increase circulation, or warm head by wearing appropriate warm clothing.

5. Minimize finger (hand) or forehead/ear (head) motion.

6. If problem persists, please contact True Wearables’ technical support (please refer to the CONTACT INFORMATION section in this guide).
TROUBLESHOOTING, CONT.

iOS device does not turn on.

1. Plug in the iOS device to a battery charger and let its battery charge for up to one hour. After a few minutes, you should be able to see the charging screen, and should be able to turn on the iOS device.

2. If the iOS host device still does not turn on, please contact the iOS device manufacturer (Apple, Inc.) for technical support.
FCC DECLARATION

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.
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“Product” includes software, applications, websites, and devices including associated firmware.

1. Placing orders. The purchaser will access True Wearables’ website, www.truewearables.com or www.oxxiom.com, and place an online order for True Wearables’ Products. During the transaction, True Wearables’ third-party payment service provider will ask for the purchaser’s credit card information and charge the purchaser’s credit card with all applicable payments in connection with the order. By placing the order, the purchaser agrees to make all payments in connection to the order through the credit card provided. True Wearables does not store credit card information and the purchaser is not required to have an account with True Wearables to place orders.

2. Shipping address. True Wearables will ask for the purchaser's shipping address and contact information through True Wearables’ third-party payment service provider so that the order can be processed and fulfilled.

3. Charges made to your credit card. The purchaser agrees to pay the listed price for each product purchased, as well as shipping and handling, and applicable taxes through a valid credit card. The purchaser agrees to provide true, correct, and complete information regarding the credit card to True Wearables’ third-party payment service provider, for the purpose of placing and paying for the order.

4. Order acceptance and fulfillment. All orders are subject to acceptance by True Wearables, which reserves the right not to accept your order for any reason, and also reserves the right to restrict multiple quantities of Oxxiom being shipped to any purchaser or postal address.

5. Resale. Orders placed through True Wearables’ website via its third-party payment service provider are intended for end users only, and not for resale.
6. **Software and firmware license.** True Wearables grants to the purchaser a nonexclusive, nontransferable license to use its proprietary software and firmware in executable form, only as embedded in True Wearables’ Products, and only for the purchaser’s personal and non-commercial use, and only for the purpose of using True Wearables’ Products according to their intended use and purpose. The purchaser acknowledges that True Wearables’ Products contain trade secrets and intellectual property that are only property of True Wearables, Inc. The purchaser agrees not to disassemble, decompile, relabel, reutilize, repurpose, or reverse engineer the software and/or firmware, nor permit, enable, or work in collusion with third parties to do so, except where such restrictions are prohibited by applicable law. In the case of single-use disposable devices, the license to use True Wearables’ proprietary software and firmware in executable form, only as embedded in True Wearables’ single-use disposable devices, is time-limited, and expires as soon as the device completes its single-use operation cycle. The single-use operation cycle starts when the single-use disposable device is activated by the user and ends when the single-use disposable device has its internal, non-removable, non-rechargeable original battery discharged to a point where the single-use disposable device can no longer operate. Reprocessing or tampering with a single-use disposable device for the purpose of replacing its internal non-rechargeable battery, reutilizing or disassembling its electronic circuitry or encapsulation, or for the purpose of decompiling, relabeling, repurposing, or reverse engineering its software and/or firmware void this software and firmware license.

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8. **Use of Products.** OXXIOM FOR SPORTS AND AVIATION IS NOT A MEDICAL DEVICE. Individuals who need a pulse oximeter due to a medical condition should contact their physician. The products have a heart rate tracking feature that may pose risks to users with certain health conditions. The Products may enable you to post, upload, store, share, send, or display photos, images, video, data, text, comments, and other information and content (“Your Content”) to and via the Products. You retain all rights to Your Content that you post to the Products. By making Your Content available on or through the Products you hereby grant to True Wearables a non-exclusive, transferable, sub-licensable, worldwide, royalty-free license to use, copy, modify, publicly display, reproduce, translate, and distribute Your Content, in whole or in part, in any media. The rights you grant us in this Section 7 are only for the limited purpose of offering and improving the Products. You are responsible for Your Content. You represent and warrant that you own Your Content or that you have all rights necessary to grant us a license to use Your Content as described in these Terms. You represent and warrant that Your Content, the use and provision of Your Content, and your use of the Products will not (a) infringe, misappropriate, or violate a third party’s patent, copyright, trademark, trade secret, moral rights, or other intellectual property rights, or rights of publicity or privacy; (b) violate, or encourage any conduct that would violate, any applicable law or regulation or would give rise to civil liability; (c) be defamatory, obscene, pornographic vulgar, or offensive; (d) promote illegal or harmful activities or substances. You further agree not to (1) upload any content that contains software viruses, malware, or is designed to interrupt, destroy, or limit the functionality of any equipment or services, or that contains other harmful, disruptive, or destructive files or content; (2) use or attempt to use another user’s account without authorization; (3) harvest solicit or collect information of other users for any reason whatsoever, including, without limitation, for sending unsolicited communications; or (4) post, advertise, or promote products or services commercially, or upload any content that is advertising, promotional material, junk mail, spam, or a contents or sweepstake, or that furthers or promotes criminal activity. True Wearables may, in its sole discretion, alter, remove, or refuse to display any of Your Content, and may forbid you from posting, uploading, storing, sharing, sending, or displaying Your Content to and via the Products.

9. **All sales are final.** All sales under this agreement are final. True Wearables will not accept Product returns. Any consequences arising from any unauthorized return shall be the sole responsibility of the purchaser.
10. **LIMITATIONS ON LIABILITY.** TRUE WEARABLES, INC. WILL NOT ACCEPT LIABILITY BEYOND THE REMEDIES SET FORTH IN THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO ANY LIABILITY FOR PUNITIVE, SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES, OR COSTS OF PROCUREMENT SUBSTITUTE PRODUCTS, PRODUCT UNAVAILABILITY, LOST PROFITS OR GOODWILL, LOST OF BUSINESS DUE TO CORRUPTED SOFTWARE, FIRMWARE AND/OR DATA IN CONNECTION WITH THIS AGREEMENT, SALE, USE, OR PRODUCT PERFORMANCE. THE PURCHASER AGREES THAT FOR ANY LIABILITY RELATED TO THE PURCHASED PRODUCT, TRUE WEARABLES IS NOT LIABLE OR RESPONSIBLE FOR ANY AMOUNT OF DAMAGES ABOVE THE ACTUAL AMOUNT PAID TO TRUE WEARABLES BY THE PURCHASER FOR THE PRODUCT THAT GIVES RAISE TO THE CLAIM. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, TRUE WEARABLES WILL NOT BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES BY ANY THIRD PARTY. IN SOME JURISDICTIONS, THE LIMITATIONS OR EXCLUSIONS OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES MAY NOT BE ENFORCEABLE. THEREFORE, ONLY THE LIMITATIONS THAT ARE LAWFULLY APPLIED IN THE PURCHASER’S JURISDICTION WILL APPLY.  

11. **Dispute resolution.** The purchaser agrees that any dispute between the purchaser and True Wearables arising out of or relating to the purchasing and utilization of True Wearables’ Products will be governed by arbitration administered by The American Arbitration Association (AAA) under its Commercial Arbitration Rules and the Supplementary Procedures for Consumer Related Disputes. The arbitration will be held in the United States, California, Orange County, or any other location the parties agree to.  

12. **Governing law.** The Terms and the resolution of any Disputes shall be governed by and construed in accordance with the laws of the State of California without regard to its conflict of laws principles.