



# Polso™ Watch

## Instructions for Use



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It is important to read the Instruction for Use in its entirety prior to using the Poslo™ Watch

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**Investigational device use only, not for sale in the USA**

This product is protected by the following:

US patent no. 10470692  
US patent no. 10687742  
and other pending US patents



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## 1 System Overview

The Polso™ Watch is a wearable device for non-invasive measurement and display of pulse rate, SpO<sub>2</sub> (blood oxygen saturation), respiration rate, and blood pressure. The Polso™ Watch is worn on the wrist, with specialized sensors that are located at the radial artery, for measurement of physiological information. The Polso™ Watch screen displays measurements, battery status, and time of day. The User Interface Control Button (Figure 1a, 2) allows navigation between different display screens.

The Wrist Holder (Figure 1a, 3), is intended to secure a precise positioning of the Polso™ Watch on your wrist. The form factor of the sensors is positioned and spaced with the intention of offering easy placement over the radial artery. The watch is available in sizes S, M and L to cover wrist sizes from 6.5" to 9" diameter.

A control-button control provides device control. Vibratory feedback is also provided with dedicated hardware. An Android application furnishes further system functionality for display of current and prior results. A rechargeable lithium-polymer battery powers the Polso™ Watch and will be charged using a proprietary Polso™ Watch Charger.

To maintain accuracy, the Polso™ Watch requires re-initialization of blood pressure every 30 days. This involves performing a blood pressure measurement with a standard cuff device. Your HCP should make sure that you have a suitable device.

### 1.1 Polso™ Watch Overview

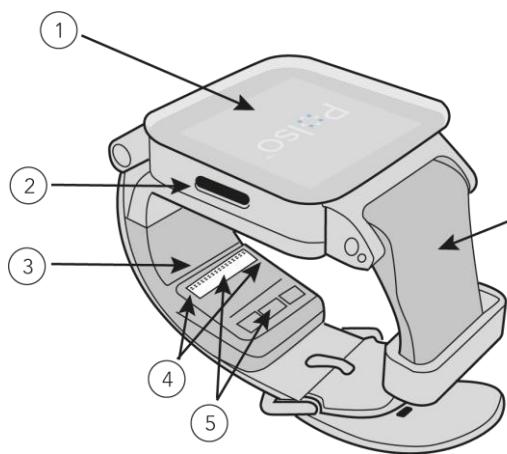


Figure 1a

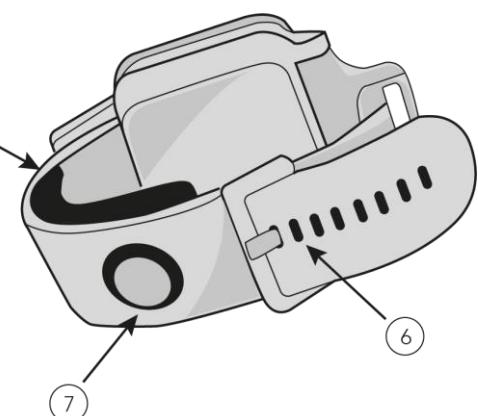


Figure 1b



|   |   |
|---|---|
| 1 | User information is visible on the (AMOLED) Display   |
| 2 | <p>User interaction is through the Control Button</p> <p>There are two modes for use of the Button:</p> <ul style="list-style-type: none"><li>• Press and hold - only used for turning the Polso™ Watch on and off</li><li>• Short press - less than 2 seconds. Used for:<ul style="list-style-type: none"><li>◦ Toggling between screens</li><li>◦ Release from standby mode</li><li>◦ Clear message on screen</li></ul></li></ul> |
| 3 | The Wrist Holder positions the sensor modules.  |
| 4 | ECG leads   |
| 5 | PPG arrays  |
| 6 | Wrist Strap keeps the Polso™ Watch securely and comfortably on the patient's wrist.   |
| 7 | Finger ECG sensor activates the Polso™ Watch physiological monitoring.  |

### 1.1.1 Home Screen Display



|   |                     |  |
|---|---------------------|--|
| 1 | Charge indicators   | Shows amount of remaining charge in percent next to the battery icon, which also changes as the battery discharges.<br><b>i Note</b><br>When the battery is critically low, at 15%, the percentage power number will turn red. |
| 2 | Bluetooth indicator | Shows status of Bluetooth connection to the Polso™ App.  |
| 3 | Time indication     | Hours and minutes of local time. May be in 24-hour or 12-hour mode.  |
| 4 | Date indication     | Day, month, and year.  |

#### **i Note**

After a short period of inactivity, the Polso Watch display will enter sleep mode to conserve power. A short press of the control button will reactivate the display.



## 1.2 Polso™ Application Overview

The Polso™ Watch monitors and displays SpO<sub>2</sub>, pulse rate, respiration rate and blood pressure. It stores these data, and transmits them via Bluetooth to the Polso™ App on an Android device.

The Polso™ App allows examination of these data, including up to 3 months of readings stored previously. It is also used for setting up the Polso™ Watch, and for initializing and entering descriptive patient data. Download The Polso™ App prior to watch setup and use.

Navigation through the Polso™ App is assisted by the native Android keys.

### Note

The power-saving feature of the Polso™ Watch turns Bluetooth off when not in use for an extended period. Before using the Polso™ App, turn the Polso™ Watch display on by pressing the control button. The Polso™ App will then automatically connect to the Polso™ Watch via Bluetooth.

### 1.2.1 Home screen

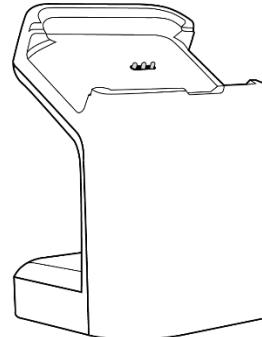
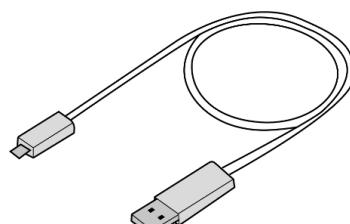
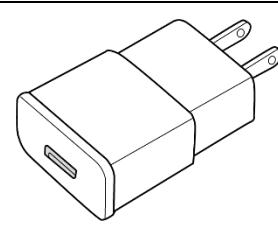




|                                    |   |   |
|------------------------------------|---|---|
|                                    | <b>Battery status</b>                               | Indicates the charge status of the Polso™ Watch battery.  |
|                                    | <b>Bluetooth (BT) connection status&amp; button</b> | Indicates whether the Polso™ Watch and Android device are connected by BT. A green checkmark indicates a working connection. A red dot indicates no connection.<br>Pressing the button will initiate a BT connection.                     |
| <b>Blood Pressure</b>              | <b>Parameter name</b>                               | The parameter of interest.  |
|                                    | <b>Parameter Icon</b>                               | The icon the Polso™ App associates with the parameter.  |
| 120/80 <small>SYS/DIA mmHg</small> | <b>Value&amp; units</b>                             | Displays measurements by parameter (NOT in real-time).  |
| 15 Oct 2020 09:45                  | <b>Time stamp</b>                                   | This indicates the date& time of the last measurement of this parameter   |
|                                    | <b>Navigation arrow</b>                             | Pressing this advances to the history screen for this parameter.  |
|                                    | <b>Home button</b>                                  | Returns the user to the Polso™ App home screen.   |
|                                    | <b>Blood Pressure initialization button</b>         | Launches the <b>Blood Pressure, initialization</b> wizard.<br><br><b>Note:</b> When blood pressure initialization has expired, an alert will appear in the blood pressure section reminding you to initialize and the icon will turn red. |
|                                    | <b>Settings button</b>                              | Opens the settings menu.  |



## 1.3 Package contents

|  |   |  |
|--|---|--|
| Polso™ Watch with Wrist Strap:<br>SMALL/MEDIUM/LARGE | 1 |   |
| Polso™ Watch Charger Stand                           | 1 |   |
| Micro USB cable                                      | 1 |  |
| Power Supply   | 1 |  |
| Polso™ Watch Instructions for Use                    | 1 | This guide   |

### 1.3.1 Receiving and Inspection

**i Note:** Open only with the assistance of your HCP.

Remove the Polso™ Watch from the packaging and inspect for damage. Remove the protective layer before using the Polso™ Watch.

If the Polso™ Watch or other components are damaged, DO NOT USE and contact [Support@pol sowatch.com](mailto:Support@pol sowatch.com).



## 2 General Considerations

### 2.1 Indications for Use

The Polso™ Watch is a wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO<sub>2</sub>), pulse rate, and respiration rate.

The Polso™ Watch can track blood pressure changes based on Pulse Arrival Time (PAT). PAT is obtained utilizing pulse rate measurements from the integrated PPG (SpO<sub>2</sub>) sensor and ECG electrodes, following an initiation process using an oscillometric blood pressure monitor.

The Polso™ Watch is a prescription use device intended for spot-checking measurements of patients aged 18 years and older in the home use environment.

### 2.2 Contraindications

The Polso™ Watch is not intended for use by:

- Pregnant patients.
- Patients with deformities or abnormalities that may prevent proper application of the Polso™ Watch. These include but aren't limited to significant swelling or irritation, injuries, localized infection, ulceration or skin lesions, scarification, tattoos, and body art on the wrist.
- Patients with sustained or non-sustained ventricular/atrial arrhythmia (Ventricular tachycardia, supraventricular tachycardia, atrial fibrillation, bigeminy, and trigeminy), and left bundle branch block.
- Patients with implantable defibrillators, pacemakers, neurostimulators, or other implantable or worn devices which may interfere with the Polso™ Watch, or be affected by the Polso™ Watch in normal operation and use.
- Patients with Parkinson's disease, essential tremor, convulsive disorders, or other disorder which prevents them from keeping their forearm at rest.
- Patients with compromised circulation or peripheral vascular disease.
- Patients with elevated levels of Methemoglobin (MetHb) or Carboxyhemoglobin (COHb), or with anomalous hemoglobins.



- Patients with severe anemia.
- Patients with any known allergy to plastic, metals, and/or rubber.

## ! 2.3 Warnings

- The Polso™ Watch is intended only as an adjunct in patient assessment.
- DO NOT diagnose or treat yourself based on your readings, instead, consult with your physician.
- DO NOT adjust medication or alter any instructions from your physician based on readings from the Polso™ Watch.
- The Polso™ Watch should not be used in conjunction with these medical assist devices: Intra-Aortic Balloon Pump (IABP), Left Ventricular Assist Device (LVAD), and cardio-pulmonary bypass systems.
- The Polso™ Watch should not be used in conjunction with systems which generate high radiation or magnetic fields, which may disrupt Polso™ Watch sensors and/or other hardware. These include, but are not limited to, irradiation systems, X-ray, MRI, CT, electrosurgery systems, and extreme lights such as strobes.
- DO NOT use the Polso™ Watch on a wrist under medical treatment. This includes but isn't limited to a cast, brace, or wrap-bandage.
- DO NOT use the Polso™ Watch on wrists that have restricted blood flow e.g. tourniquet, pressure cuff, or IV line.
- The Polso™ Watch contains small parts, so to avoid choking hazard keep away from children.
- The Polso™ Watch should not be used during patient exercise or motion.
- The Polso™ Watch should not be used by patients treated with injected dyes, or any substance containing dyes, that change usual blood pigmentation.
- No SpO<sub>2</sub>, pulse rate, respiration rate, or blood pressure alarms are provided.
- DO NOT use the power supply when wet.



- DO NOT disassemble or attempt to repair any part of the Polso™ Watch, Polso™ Charger Stand, or power supply.



## 2.4 Cautions

- DO NOT operate the Polso™ Watch without appropriate training by a certified HCP.
- DO NOT use the Polso™ Watch together with lotion or moisturizer. Polso™ Watch can be used only after lotion or moisturizer has been removed by washing.
- Remove any jewelry or accessories from your wrist wearing the Polso™ Watch while taking a measurement.
- The Polso™ Watch can only measure while the patient is at rest.
- Make sure the Polso™ Watch is used on the same wrist for all reference initialization measurements.
- The Polso™ Watch should be used only for the purpose described in the indications for use.
- Do not use the Polso™ Watch if the package has been opened, or appears used, or damaged.
- Incorrect handling, excessive force, or dropping the Polso™ Watch may cause malfunction or permanent damage.
- Do not re-manufacture, recondition or recycle Polso™ Watch to prevent harm or damage to the device.
- DO NOT subject the Polso™ Watch to strong shocks or vibrations.
- DO NOT immerse the Polso™ Watch in water or any other liquid.
- If the Polso™ Watch fails to operate, contact ChroniSense customer support at [support@pol sowatch.com](mailto:support@pol sowatch.com).
- Misapplication of the Polso™ Watch with excessive pressure can result in inaccurate readings.
- Mispositioning of the Polso™ Watch can result in inaccurate readings.



- Dispose of the Polso™ Watch in accordance with federal, state, and local law for routine/non-hazardous electronic waste. This product should not be mixed with general household waste.
- If skin irritation or damage appears with use of the Polso™ Watch, stop using it immediately and inform your HCP.
- DO NOT let chemical products such as oils, lotions, creams, or cosmetics accumulate on the Polso™ Watch. Wipe and clean with 70% alcohol immediately if this happens.
- DO NOT attempt to sterilize the Polso™ Watch. DO NOT autoclave, or immerse the Polso™ Watch in liquid.
- If the temperature or humidity is outside of the recommended range (see chapter 10 Specifications), do not use the Polso™ Watch.
- DO NOT use the Polso™ Watch in a potentially explosive atmosphere, such as in the presence of flammable chemicals.
- DO NOT use the Polso™ Watch if sensors have become degraded, for example, discolored, peeling, or pitted. Such use may result in Polso™ Watch malfunction.
- DO NOT leave the Polso™ Watch within the reach of infants, toddlers, children, or pets, who may damage the Polso™ Watch.
- DO NOT use the USB cable and power supply with any device other than the Polso™ Watch.
- Use only the power supply and USB cable specified for the Polso™ Watch. Use of other power supplies or cables may damage and/or may be hazardous to the Polso™ Watch.
- DO NOT touch, press, or rub the display panels with anything that could scratch the display, such as abrasive cleaning compounds, instruments, brushes, or rough-surface materials. These can damage the device.
- If you suspect problems in accuracy or performance of the Polso™ Watch, contact ChroniSense customer support at [support@pol sowatch.com](mailto:support@pol sowatch.com)



## 2.4.1 Data Safety

- Use only the official Polso™ App downloaded from Google Play.
- Follow Android OS permission recommendations.
- Observe basic Android device safety precautions, including locking the Android device and not leaving it unattended.



## 2.5 Notes

- When using the Polso™ Watch with a device with wireless features, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.
- In accordance with international telecommunication requirements, the frequency band of 2.4 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Consult the dealer or an experienced radio/TV technician for help.



- This equipment has been tested and found to comply with the Class B limits for medical devices according to the IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

## 2.6 Risks and Benefits

Before using any medical device, it is important to consult your physician and weigh the risks and benefits.

The following section describes the Benefits and Risks associated with using the Polso™ Watch.

### 2.6.1 Potential Risks Associated with the Polso™ Watch

- As with all medical electrical devices, there is always a risk of electrical, mechanical, and fire hazards. However, these risks have been mitigated through the design and testing of the Polso™ Watch.
- As with all devices with small parts, there is always a risk of a child's swallowing a component or choking. Keep small parts away from small children to prevent such hazards.
- As with all items applied directly to the skin, there is always a risk of skin irritation, pressure injury, and general discomfort while a sensor or cuff is applied to a patient. Periodically check the areas where the patient's skin contacts the sensor to prevent potential issues.



## 3 Getting Started

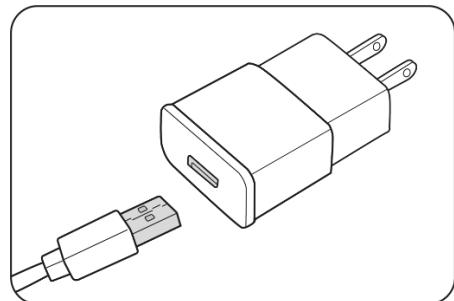
Take the Polso™ Watch out of the box and fully charge it.

### 3.1 Charging the Polso™ Watch

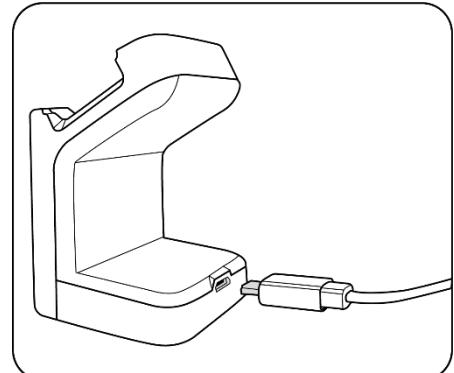
The Polso™ Watch requires periodic charging. Charge between uses, or when a low battery indication is presented.

The Polso™ Watch Charger Stand is used for charging the watch, along with a micro USB cable and a wall charger.

- 1 To charge, connect the large end of the micro USB cable to the power adapter.



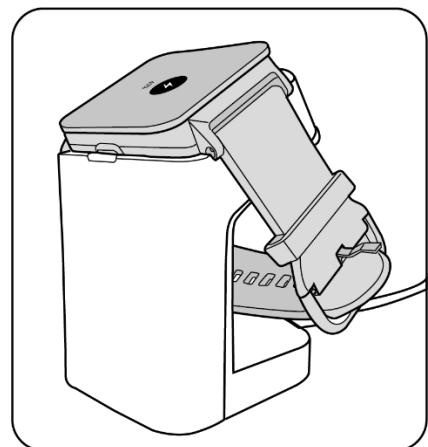
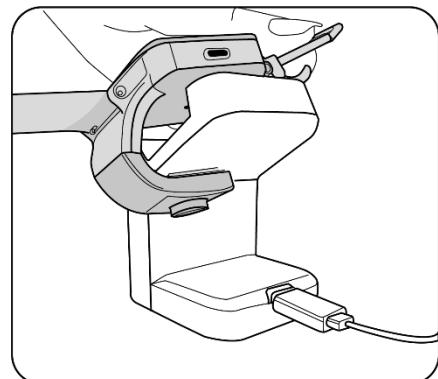
- 2 Connect the small end of the micro USB cable to the Polso™ Watch Charger Stand.



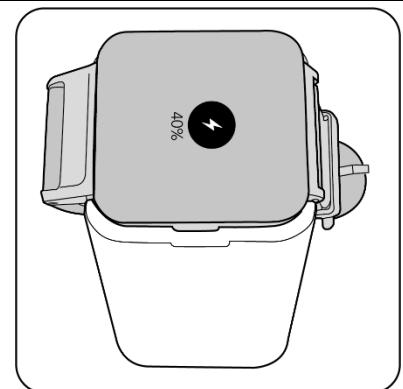
- 3 Plug the power adapter into the electrical power supply socket.



4 Place the Polso™ Watch on the Polso™ Watch Charger Stand platform in either orientation.



5 The Polso™ Watch will display the battery charging status.





### 3.2 Turn on the Polso™ Watch

- 1 Press and hold the Control Button to turn the Polso™ Watch on.



- 2 A QR code identifying the Polso™ Watch appears.



#### Note

You should not turn the Polso Watch off until you have completed setup. Instructions for turning the Polso Watch off may be found in chapter 7.1 Turning Off Your Polso™ Watch.



## 3.3 Wearing the Polso™ Watch

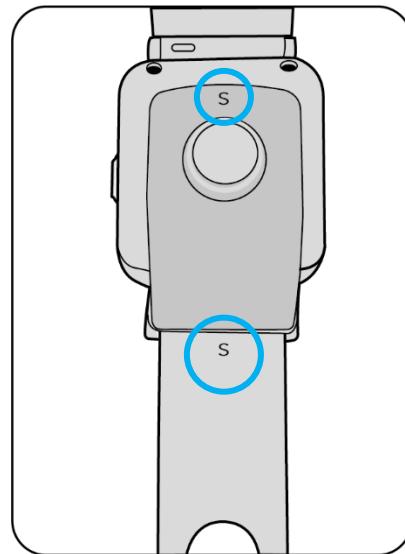
### 3.3.1 Which wrist is best?

The Polso™ Watch can be worn on either the left or right wrist, according to your preference. Nevertheless, once set up is completed, the Polso™ Watch must always be worn on the same wrist to assure optimal performance.

If however, you will decide to change the watch position to the other hand, notify your HCP, who will reset the Polso™ watch to the new position.

### 3.3.2 Placing the Polso™ Watch on the wrist

The Polso™ Watch is available in 3 different sizes based on your wrist circumference. Your HCP will select the proper size for you.

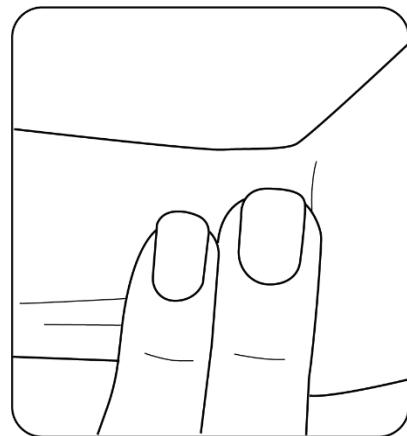


#### Polso™ Watch size markings

Apply the Polso™ Watch on clean, dry skin. The correct positioning for the Polso™ Watch is when the back of it is placed on top of the radial artery while it is touching the skin but not making pressure marks. An illustration for placing the watch on the left wrist is given below.

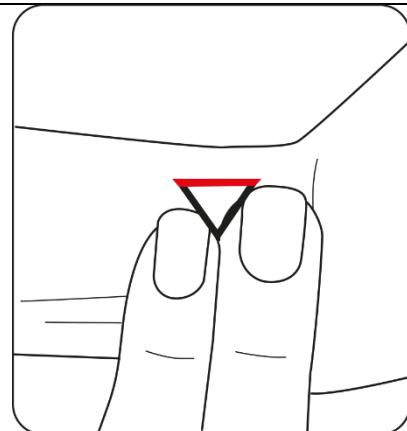


- 1 You should straighten your left hand, and place your right-hand index and middle fingers at the inner left wrist, against the base of the left thumb. The two fingertips should be in between the bone and the tendon over the radial artery, in sort of a valley. Find the pulse point. The radial artery pulse can be felt beneath the right index and middle fingertips. Moving those fingers slightly may help to locate the strongest pulse.

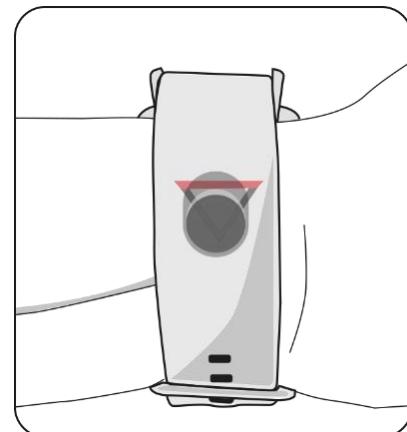
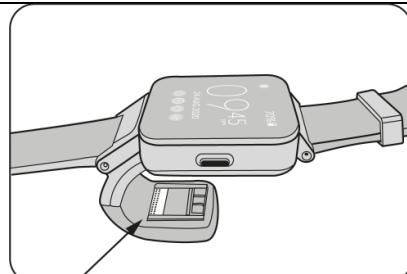


If you are unfamiliar with taking pulse, you should consult with your HCP.

- 2 The gap between both fingertips creates an imaginary triangle. Imagine a short horizontal line on the triangle base. This line will serve as a pulse point mark for placing the Polso™ Watch.



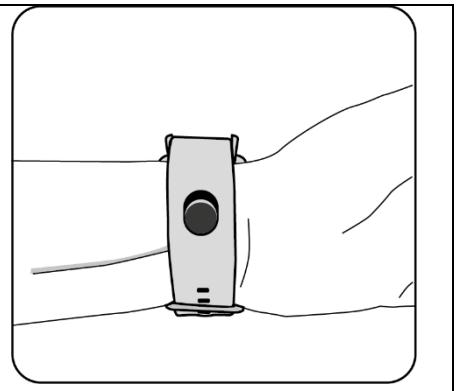
- 3 Place the upper edge of the sensor head (white) against the pulse point mark, as shown by the arrow.





**4** Tighten and close the watch strap, while keeping the sensor at that position on the wrist.

The Polso™ Watch should feel comfortable on the wrist. The Polso™ Watch should be as close as possible to the hand.





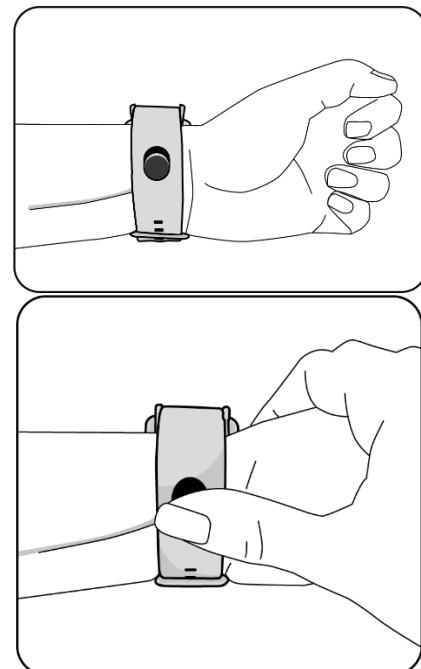
## 4 Taking a Measurement

The Polso™ Watch is designed for spot checks of blood pressure, pulse rate, SpO<sub>2</sub>, and respiration rate.

Before taking a measurement make sure that the Polso™ Watch is correctly positioned. Measurements should be taken while sitting still and not talking.

- 1 You should sit comfortably, **not talk, and avoid movement** while taking a Polso™ Watch measurement.

1. Place your hand with the Polso™ Watch on a table or desk, near chest level.
2. Initiate measurement by **placing and continuously holding** your thumb on the ECG Finger Sensor as shown.
3. The Polso™ Watch will then emit **1 vibration** notification to confirm measurement initiation.



- 2 The Polso™ Watch display will show the measurement screen, with an ongoing PPG signal and a status message.

A long green bar indicates high signal quality, medium yellow indicates moderate quality, and short red poor quality.



- 3 If you have selected the option **to display partial settings** (see chapter 7 Settings), the Polso™ Watch display will cycle between available results and the measurement screen.

Incomplete measurements will be represented by a dotted line.



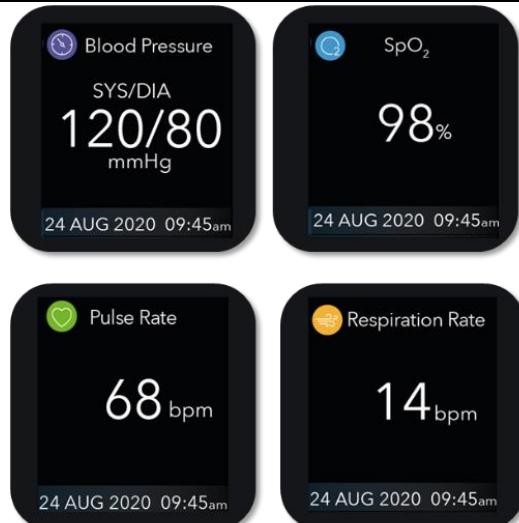


#### 4 End of Measurement

1. When the results screen appears, you can remove your thumb.
2. **Two short vibrations** confirm the end of measurement.



#### 5 To focus on individual parameters, press the control button to cycle through them.



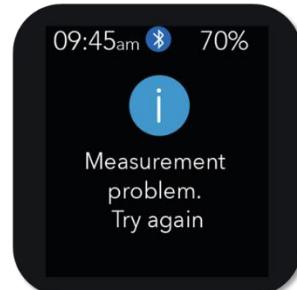
#### 6 If any measurement fails, a dashed line will be displayed instead of a result.



#### 7 Measurement Problem

1. An error message appears if all measurements fail.
2. This will be accompanied by **1 long vibration**.
3. Another measurement can be attempted, possibly after repositioning the Polso™ Watch on the wrist.

See chapter 8.2 Troubleshooting.





8 After a successful measurement, the Polso™ Watch will transmit the results to the Polso™ App, where they will appear on the screen.

The timestamp circled in yellow, indicates the date and time of the last reading for that parameter. If no new data were acquired, the date and time will be for an earlier reading.





## 5 Blood Pressure Initialization

To ensure accurate blood pressure readings, the Polso™ Watch must periodically be re-initialized against a reference blood pressure monitor. This monitor should be used for all subsequent initializations.

You should re-initialize **every 30 days**. An alert will appear on both the Polso™ App and the Polso™ Watch when the initialization must be performed. It is also possible to re-initialize the Polso™ Watch before the 30-day period has ended.

### Polso™ Watch initialization alert

On the **Polso™ Watch**, the initialization message may be ignored, but any measurements will not show blood pressure.



### Polso™ App initialization alert

On the **Polso™ App**, the message may be ignored, but the message will replace any subsequent blood pressure measurement.





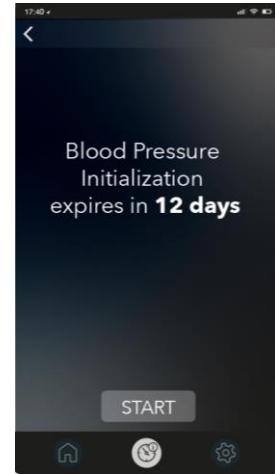
## 1 Blood Pressure initialization

Press the blood pressure initialization button on the Polso™ App.



- 2 The first screen of the blood pressure initialization displays the number of days before blood pressure initialization must be performed.

If the alert was displayed the number of days should be 0.



- 3 Perform an accurate blood pressure reading from the same arm that the Polso™ Watch is worn and record it in the Polso™ App data field.

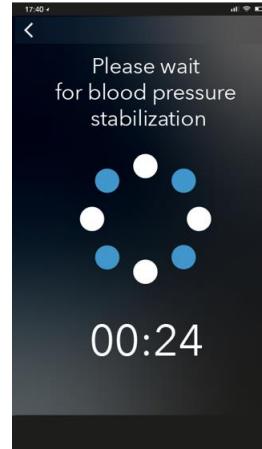
Press **SAVE** to continue.



### **i** Note

Make sure the same arm as the Polso™ Watch is worn is used for all reference initialization measurements.

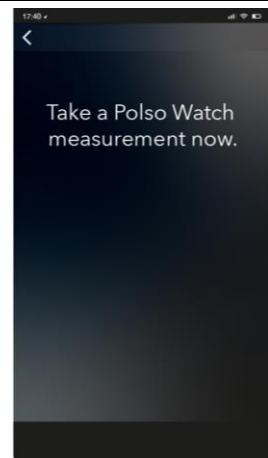
- 4 Using a blood pressure cuff changes some characteristics of your arterial circulation. Waiting one minute allows enough time for your circulation to reset.





5 For accurate initialization, make sure you sit quietly, so that blood pressure is stable.

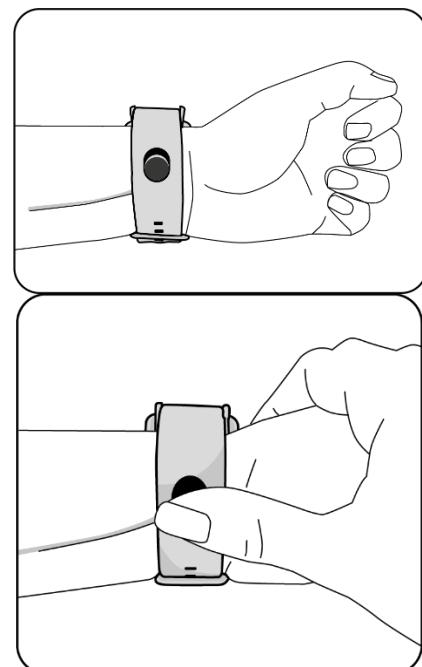
Take a Polso™ Watch measurement within the next 5 minutes for initialization to be valid.



## 6 Taking a Polso Watch Measurement

You should sit comfortably, **not talk, and avoid movement** while taking a Polso™ Watch measurement.

1. Place your hand with the Polso™ Watch on a table or desk, near chest level.
2. Initiate measurement by **placing and continuously holding** your thumb on the ECG Finger Sensor as shown.
3. The Polso™ Watch will then emit **1 vibration** notification to confirm measurement initiation.



7 The Polso™ Watch display will show the measurement screen, with an ongoing PPG signal and a status message.

A long green bar indicates high signal quality, medium yellow indicates moderate quality and short red poor quality.



## 8 End of Blood Pressure initialization

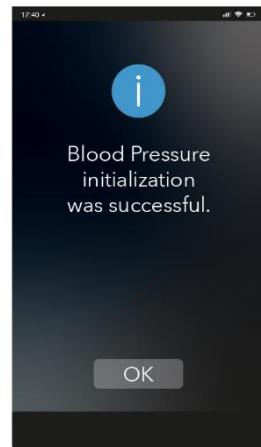
1. When the results screen appears on the Polso™ Watch, the patient can remove their thumb.
2. **Two short vibrations** confirm the end of measurement.





9 A message will appear on the Polso™ App to confirm successful blood pressure re-initialization.

Press **OK** to continue.



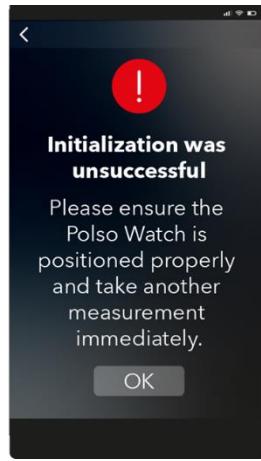
10 After a successful measurement, the Polso™ Watch will transmit the results to the Polso™ App, where they will appear on the screen.



## 11 Blood Pressure initialization failure

If the Polso™ Watch is incorrectly placed, a message appears on the Polso™ App screen.

Press **OK** to continue.





## 6 History

With history, you can review up to the last 3 months of data recorded and saved in the Polso™ application.

History is displayed by individual parameter.

There are two display options for historical data:

**Tabular mode** - displays historical data in table format.

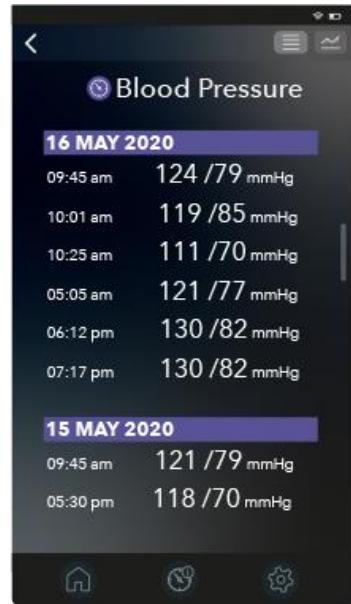
**Graphic mode** - displays historical data using a line graph.

Access the history from the home screen by pressing the **Navigation arrow** on the right of each parameter.



When you press the navigation arrow, history opens in **Tabular mode**.

Here your blood pressure history is displayed. The results are sorted by date and time. Scrolling through them is done by using conventional Android dragging.





Pressing the **graph mode** button will open the graphic mode.

Results can be displayed by DAY, WEEK, or MONTH by pressing the appropriate button.

Tapping on the dot indicating a reading will present all the data measured.

Switching between tabular and graphic mode is done by pressing the buttons.





## 7 Settings

Within settings, previously entered personal information and system settings can be edited. Further options are available on these screens.

### User Settings

- Changes to your personal details can be made here.
- Some changes will require blood pressure initialization.



### Weight change

A **weight change (gain or loss) of 20% or more** requires a change in the weight setting.

#### Note

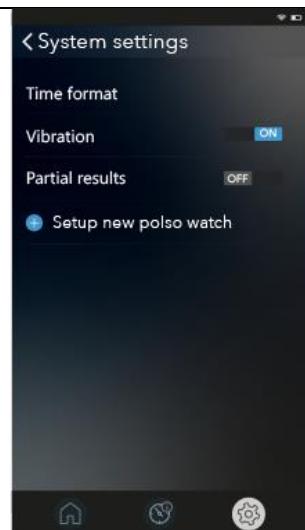
You cannot change the wrist used without assistance from your HCP.

### System settings

Changes to the user interface can be made here.

#### Note

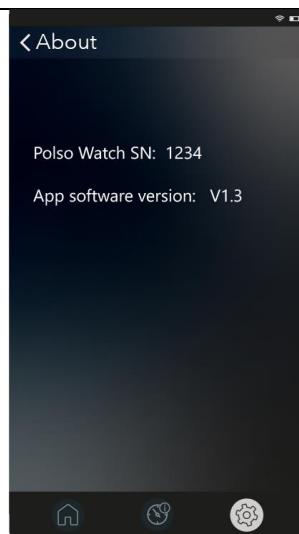
Setting up a new watch should only be done by your HCP. Incorrect setup can lead to inaccurate results.





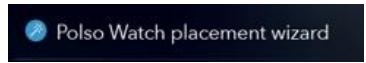
## About

Displays the Polso™ Watch serial number and the Polso™ App version number.



## Polso Watch placement wizard button

Starts the Watch placement wizard.



## 7.1 Turning Off Your Polso™ Watch

Shutting down the Polso™ Watch is done by holding the Control Button continuously until the shutdown screen appears.

The screen will display the shutdown message for about 3 seconds while shutdown is in progress.



## 8 Transferring to a new Android device

You can use a new Android device without losing your current data.

For reasons of information security, you will not be able to do this on your own.

Contact your HCP to perform the transfer.



## 9 Error list and Troubleshooting

### 9.1 Error list (Polso™ Watch)

| Display   | Cause   | Solution   |
|---|---|--|
|    | The Polso™ Watch battery is extremely low.  | Charge the Polso™ Watch.<br>Refer to sub-section 3.1   |
|   | The Polso™ Watch cannot connect to an Android device (Bluetooth icon is missing). | <ol style="list-style-type: none"><li>1. Press the Control Button to make sure the Polso™ Watch display is on.</li><li>2. Press the Bluetooth connection status &amp; button in the Polso™ App to scan for the Polso™ Watch.</li><li>3. Make sure Bluetooth is enabled on the Android device</li><li>4. If not successful, restart the Android device and/or the Polso™ Watch.</li></ol> |
|  | The Polso™ Watch is not optimally positioned.                                     | Reposition the Polso™ Watch according to instructions in this guide.   |
|   | The Polso™ Watch is not optimally sized.  | Consult with your HCP about verifying sizing.  |
|   | Thumb makes poor contact with Finger ECG sensor.                                  | Make sure that your thumb fully covers the Finger ECG sensor, and apply slightly increased pressure. Make sure there is no moisture or residue on the Finger ECG sensor.   |
|   | Movement affects measurement  | Re-do measurement being sure to remain still and not speak   |
|  | Measurement stopped by user.  | <ol style="list-style-type: none"><li>1. Try again.</li><li>2. Make sure that the thumb fully covers the Finger ECG sensor, and apply slightly increased pressure. Make sure there is no moisture or residue on the Finger ECG sensor.</li></ol>   |



| Display  | Cause  | Solution   |
|--|--|--|
|   | Blood pressure initialization timed out.                   | Perform blood pressure initialization See chapter 5.   |
|   |  |  |
|  | The Polso™ Watch isn't on the same hand used during setup. | <ol style="list-style-type: none"><li>1. Verify the correct wrist in the User Settings.</li><li>2. Remove the Polso™ Watch and place it on the correct hand and try again.</li></ol> |



## 9.2 Troubleshooting

| Problem   | Cause  | Solution   |
|---|--|--|
| Nothing appears on the display of the Polso™ Watch.                 | The Polso™ Watch is off.<br>Battery has completely depleted. | Turn the Polso™ Watch on.<br>Charge the Polso™ Watch, see chapter 3.1.   |
| The operating time is short even when the battery is fully charged. | Rechargeable battery is near end of life.                    | Contact customer service at <a href="mailto:service@pol sowatch.com">service@pol sowatch.com</a>   |
| Measurement doesn't start   | The Polso™ Watch is not optimally positioned.                | Reposition the Polso™ Watch according to instructions in this guide.   |
|   | Thumb makes poor contact with Finger ECG sensor.             | Make sure that the thumb fully covers the Finger ECG sensor, and apply slightly increased pressure. Make sure there is no moisture or residue on the Finger ECG sensor.  |
|   | Polso™ Watch malfunction.                                    | Contact customer service at <a href="mailto:service@pol sowatch.com">service@pol sowatch.com</a>   |
| Unsuccessful measurement  | The Polso™ Watch is not optimally positioned.                | Reposition the Polso™ Watch according to instructions in this guide.   |
|   | The Polso™ Watch is not optimally sized.                     | Consult with your HCP about verifying sizing.  |
|   | Thumb makes poor contact with Finger ECG sensor.             | Make sure that your thumb fully covers the Finger ECG sensor, and apply slightly increased pressure. Make sure there is no moisture or residue on the Finger ECG sensor.   |
|   | Movement affects the measurement.                            | Re-do measurement being sure to remain still and not speak.  |
| No blood pressure results are displayed.                            | Blood pressure initialization timed out.                     | Perform blood pressure initialization, see chapter 5.  |
| Incomplete measurement  | The signal quality issue in one or more parameters.          | Try again.   |
| No Bluetooth connection when using the Polso™ App.                  | Bluetooth isn't active on the Polso™ Watch.                  | Press the control button on the Polso™ Watch to activate Bluetooth. Press the red Bluetooth connection status button to connect to the Polso™ Watch. The Bluetooth connection status button will turn green when communication is established. |



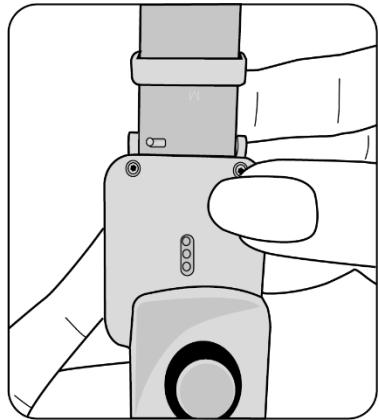
## 10 Maintenance

### 10.1 Replacing the wrist strap

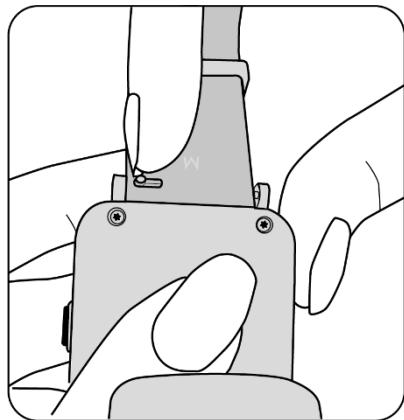
Under normal use, there is no need to replace the wrist strap. However, should you desire to replace the wrist strap follow the instructions below.

The Polso™ Watch uses a quick release system to make the process of replacing the wrist strap easy.

- 1 Hold the Polso™ Watch with the buckle upward, looking at the back of the Polso™ Watch.

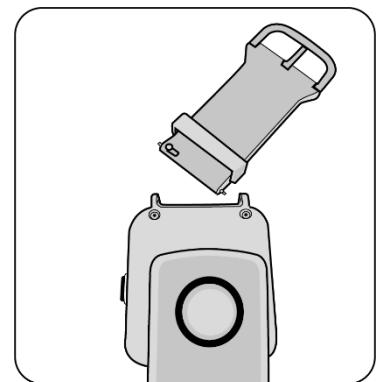
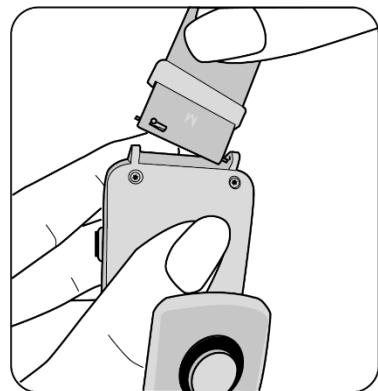


- 2 To remove the buckle part of the wrist strap, find the small knob at the left where the wrist strap meets the watch case. Slide the knob to the right using a fingernail, and lift the left side of the wrist strap up.

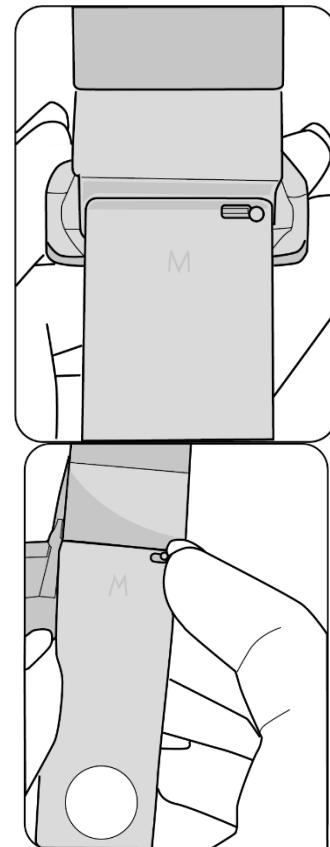




3 Release the knob and pull the wrist strap from the right side of the case. Set the buckle part of the wrist strap aside.

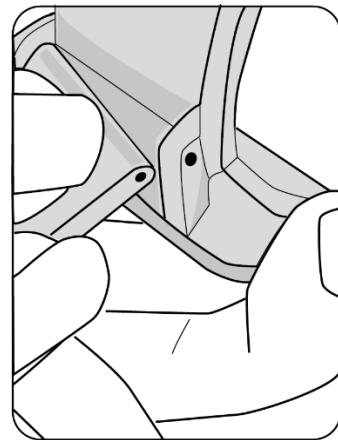


4 To remove the lower part of the wrist strap, find the small knob at the right where the wrist strap meets the watch case. Slide the knob to the left using a fingernail, and lift the right side of the wrist strap up.

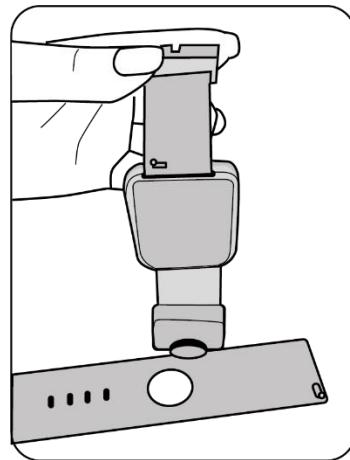




5 Release the knob and pull the wrist strap from the left side of the case. Set the lower part of the wrist strap aside.



6 To attach the replacement wrist strap, reverse this process. Make sure that the buckle part of the wrist strap is at the top.





## 10.2 Cleaning and Disinfecting the Polso™ Watch

To clean the Polso™ Watch, follow the instructions below:

- Wipe the outer surfaces using a dampened soft cloth twice with 70% Alcohol until the surfaces are free of any visible residue. Pay particular attention to cracks, crevices, and hard to reach areas of the device.
- Repeat the above cleaning step using a fresh wipe.
- Allow the Polso™ Watch to dry thoroughly before using it again.



### Warning

- Before cleaning, make sure the device is off and is not applied to a wrist.
- Improper cleaning of the Polso™ Watch may damage it
- Do not wash or immerse your Polso™ Watch in water

## 10.3 Disposal

Dispose of the Polso™ Watch in accordance with federal, state, and local law for routine/non-hazardous electronic waste. This product should not be mixed with general household waste.



## 11 Specifications

|                                    |   |
|------------------------------------|---|
| <b>Model</b>                       | Polso™ Watch 1865501<br>Polso™ Watch Charger Stand 1865502  |
| <b>Physiological data measured</b> | <b>Pulse Oximetry (SpO<sub>2</sub>)</b><br><br>No Motion<br>Measurement range 70 - 100%<br>Accuracy ±3.5% within 70 - 100% range<br>Display range 70 - 100%<br><br><b>Pulse Rate</b><br><br>No Motion<br>Measurement range 25 – 240 bpm<br>Accuracy ±3 bpm of reading<br>Display range 25 – 240 bpm<br><br><b>Respiration Rate</b><br><br>No Motion<br>Measurement range 5- 45 bpm<br>Accuracy 1 bpm<br>Display range 5- 45 bpm<br><br><b>Blood Pressure</b><br><br>No Motion<br>Measurement range<br>Sys<br>Dia<br>Accuracy<br>Display range |
| <b>Power&amp; Battery</b>          | Lithium-ion polymer researchable battery<br>(3.7 V/330mAh)<br><br>AC adapter<br><br>(INPUT AC100-240 V, 50-60 Hz 0.2-0.13 A)  |
| <b>Battery lifespan</b>            | At least 500 charge cycles.   |
| <b>Charging</b>                    | Under normal use, taking up to 12 readings per day, a full charge should last 24 hours. <ul style="list-style-type: none"><li>• USB charging</li><li>• Charging time: 3.5 hours</li></ul>   |
| <b>Compatibility</b>               | Android Version 5 or higher   |
| <b>Communication</b>               | Bluetooth 4.2   |
| <b>Display</b>                     | AMOLED  |



|  |  |
|--|--|
| <b>History Capacity</b>                        | 3 months   |
| <b>IP classification</b>                       | Polso™ Watch IP22<br>Polso™ Watch Charger Stand IP21                                     |
| <b>Operating Conditions</b>                    | 32÷104°F (0÷40°C) Temperature<br>Up to 90% relative maximum humidity, non-condensing     |
| <b>Storage &amp; Transport conditions</b>      | -4÷140°F (-20 ÷ 60°C) Temperature<br>Up to 90% relative maximum humidity, non-condensing |
| <b>Weight</b>                                  | 1.76 oz (50 gr)  |
| <b>Measurable wrist circumference</b>          | 5.5 – 8.4 inch (14 – 21.4 cm)  |
| <b>Applied part</b>                            | CF   |
| <b>Maximum temperature of the applied part</b> | 104 F (40°C)   |

The emitted wavelengths range from 600 nm to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.



## 12 Applicable standards

- IEC 60601-1:2005+AMD1:2012 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)
- IEC 60601-1-11 MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 80601-2-61: 2017 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes



## 13 FCC Radio frequency interference statement

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ChroniSense Medical Ltd. is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.



## 14 Bluetooth LE Wireless Technology Information

| Bluetooth LE Wireless Technology Information |                                    |
|--|------------------------------------|
| Modulation Type                              | DSSS / CCK/ OFDM                   |
| Max. Output                                  | 19dBm                              |
| Frequency Range                              | 2402 MHz - 2480 MHz                |
| Antenna Peak Gain                            | 2.5dBi                             |
| Recommended Range                            | ~10 feet (~3 meters) line-of-sight |
| Quality of Service (QoS)                     | Delay <10 seconds                  |
| Security                                     | Proprietary binary protocol        |



## 15 Limited Warranty

ChroniSense Medical Ltd. warrants to the original end-user purchaser the ChroniSense Medical-branded hardware product the Polso™ Watch and any software media contained in the original packaging against defects in material and workmanship when used in accordance with ChroniSense Medical's Instruction for Use and other ChroniSense Medical materials published guidelines for a period of 24 months from the original date the Product was obtained by the end-user purchaser.

ChroniSense Medical's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty. To request a replacement under warranty, purchaser must contact ChroniSense Medical Ltd and obtain a returned goods authorization number so that ChroniSense Medical Ltd can track the Product. If ChroniSense Medical Ltd determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

The above described warranty is in addition to any statutory rights provided to Purchaser under applicable laws and regulations of the region in which the product was sold to the extent that those rights cannot be disclaimed and are superseded by the above described warranty to the extent permitted under applicable laws and regulations of the region in which the product was sold.

## Customer service

For service-related issues with your Polso™ Watch, contact us at [support@pol sowatch.com](mailto:support@pol sowatch.com).

ChroniSense Medical LTD.

2 Hamada St.

Yokneam Illit 2069202

Israel

Tel: +972-4-8275095

[support@pol sowatch.com](mailto:support@pol sowatch.com)

[www.pol sowatch.com](http://www.pol sowatch.com)



## 16 General Symbols

|            |   |
|------------|---|
|            | Consult Instructions for Use  |
| <b>Rx</b>  | Prescription-only device  |
|            | Manufacturer  |
|            | Date of manufacture<br>YYYY-MM  |
| <b>REF</b> | Catalog number  |
| <b>SN</b>  | Serial number   |
| FCC ID     | Identifies unit has been registered as a radio device                     |
|            | Type CF applied part  |
|            | Separate collection for electrical and electronic equipment (WEEE symbol) |
|            | Keep dry  |
|            | Fragile; handle with care   |
|            | Storage humidity limitation   |
|            | Atmospheric pressure limitation   |
|            | Storage temperature range   |
|            | Wireless communication mark   |



|              |                         |
|--------------|-------------------------|
| IP22<br>IP21 | Protection from ingress |
|              | No Parameters Alarms    |
|              | Warning                 |
|              | Caution                 |
|              | Note                    |



## 17 Glossary

**Hemoglobin:** The protein in red blood cells that transports oxygen from the lungs throughout the body and carbon dioxide from the tissues back to the lungs.

**Oxygen Saturation:** The percentage of hemoglobin in the blood that is bound to oxygen.

**Parameter:** A parameter is an element of a system that is critical in evaluating the system's condition.

**Pulse Oximeter:** A medical device that uses a sensor to indirectly measure oxygen saturation of blood and pulse rate.

**Quality of Service (QoS):** Description or measurement of overall performance of the Bluetooth communication between the Polso™ Watch and the Polso™ App as seen by the user.