



# PulseOn Arrhythmia Monitor

## Patient Guide

### Use Instructions for Patients

The PulseOn Arrhythmia Monitor is a wrist-worn device that measures the electrical activity of the heart electrically (ECG) and the pulse optically. Its purpose is to help with diagnosis and monitoring of the heart in a home environment.

These patient instructions are intended to guide a lay operator in the safe use of the PulseOn Arrhythmia Monitor. The system is safe to use when these guidelines are followed.

## Warning and Safety Notices for Patients

### Warnings



- In case of significant skin reactions, discontinue using the device. The device should not be used if the user suffers from hypersensitivity to silicone. The device should not be used on a wrist with infected eczema or otherwise broken skin.
- Not a toy. Not for small children. Choking hazard. The equipment may contain small parts. Keep out of reach of small children. Strangulation may result from baby or child entanglement in power cables.
- The wrist device may give an ECG measurement notification when it is not safe to take an ECG measurement (e.g. while driving a car). In such situations, ignore the notification and do not take an ECG measurement.
- Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be inspected to verify that it operates normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the medical equipment or medical system, including cables specified by the manufacturer. Otherwise the performance of this equipment be adversely affected.
- Do not position the power supply for the charging dock (or gateway) in a place or position that makes it difficult to disconnect.
- Do not use an additional multiple socket outlet or extension cord.
- Never remove the silicone cover from the charging dock as it provides IP21 protection against dripping water (vertically falling drops).

### Caution



- The wrist device is waterproof (IP57) up to an underwater depth of 1 metre. Nevertheless, moisture can affect measurements.
  - The device should be taken off when swimming or having a sauna.
  - The device can be worn while showering, taking a bath or doing housework such as washing dishes or doing laundry. However, it may be necessary to dry the wrist and the device afterwards in order to be able to take an ECG measurement.
  - A moist (for example sweaty) or wet hand can prevent the initiation of an ECG measurement. Try to make measurements when the palm and wrist are dry.
  - Try to keep the space between the wrist device and the skin both clean and dry. If necessary, take the device off to clean and dry both the wrist and the bottom of the device with a soft cloth.

- A wet environment, such as a shower, can cause accidental ECG measurements to start and the device may then give the relevant notifications erroneously. These notifications should be ignored.
- If the red LED light on top of the wrist device is continuously on, the device is in irrecoverable error mode. Please contact the personnel that provided the device. NOTE: If there is a continuous red LED only during charging, please ensure that you are using the power supply unit provided with the product.
- The wrist device is not defibrillation-proof. The device should not be subjected to unnecessary electromagnetic or mechanical stress and should thus be removed in an ultrasound, x-ray etc.
- Damaged or suspected inoperative equipment must be removed from use. It must be checked and repaired by qualified service personnel prior to continuing use.
- The device or its accessories should not be serviced or undergo maintenance while being worn or in use.
- Motion affects the performance of the wrist device. PPG-based arrhythmia analysis is performed when the patient is stationary. When taking an ECG measurement, the patient should stay still.
- Non-scheduled ECG measurement notification may sometimes be triggered due to signal artefacts or by the user having high non-pathological heart rate variation.
- The equipment should be used by only one patient at a time.
- When taking an ECG measurement, make sure that another person is not touching you or the wrist device as this may affect the result.
- Correct tightness of the wrist band is important for optimal contact of the wrist device with the skin. Refer to the instructions within this guide.
- Accumulating dust and dead skin on the wrist device can cause skin irritation or problems with measurement and charging. If this arises, the wrist device can be cleaned. Refer to the cleaning instructions within this guide. The device can also be worn on the other wrist.
- No modification of the equipment is allowed. Do not try to disassemble, repair, or modify any parts of the equipment.
- If for any reason the device feels hot, do not wear it.
- To prevent possible damage to the equipment, maintain the following environmental conditions:
  - Operating Temperature: +5°C to +38°C
  - Storage Temperature: -20°C to +60°C
  - Relative Humidity: 5% to 90%, non-condensing
  - Ambient Air Pressure: 700 hPA to 1060 hPA

## Notes

- The wrist device and its LEDs do not emit harmful radiation.

- The wrist device will automatically turn off (LEDs on the bottom turn off) if the battery level gets too low.
- The wrist device vibrates when a palm is placed on top of it to start an ECG measurement. If there is no vibration, the device is not operational. The operation of the optical measurement can be inspected by looking under the device. If the yellow LED lights are on, optical measurement is operational.
- The quality of the measured ECG data may be affected by the use of other medical equipment, including but not limited to ultrasound machines.
- A wrist area with tattoos, dense body hair or dark skin can have a negative effect on the performance of the wrist device, as well as cold skin or otherwise reduced blood perfusion.
- Excessive light does not harm the device, but it can cause issues with the optical sensors and result in false notifications.
- The wrist device is a type-BF applied part fulfilling the EN 60601-1 (IEC60601-1) standard. The wrist device electrodes should not come into contact any other conductive parts, including the ground.

If any unexpected operation, event or incident occurs while using the PulseOn Arrhythmia Monitor System, please inform the healthcare personnel who provided the equipment to you and/or PulseOn at [support@pulseon.com](mailto:support@pulseon.com) or through the website: [www.pulseon.com/support](http://www.pulseon.com/support).

In case of serious incident, immediately contact your national competent authority and the manufacturer (local PulseOn representative).

## Contraindications



- Do not use the wrist device if you suffer from hypersensitivity to silicone. In the event of significant skin reactions, do not continue using the device.



- Do not use the wrist device on a wrist with infected eczema or otherwise broken skin.



- Do not use the wrist device for life-sustaining measurements.



- The wrist device is not intended to be used by children (under 18 years old) or for assessment of cardiac arrhythmias in children (under 18 years old).



- The wrist device is not intended to be used on people who have a pacemaker.



- The wrist device is not intended for use by people without the mental capacity to react to device notifications and/or symptoms.

## Indications for Use

The PulseOn Arrhythmia Monitor System can be used in:

1. diagnosis of atrial fibrillation that is suspected on the basis of symptoms such as shortness of breath or palpitations;
2. follow-up of the effect of treatment given for atrial fibrillation; and
3. screening of atrial fibrillation and other cardiac arrhythmias, e.g. in the general population.

The PulseOn Arrhythmia Monitor wrist device's optical heartbeat interval measurement and analysis detects atrial fibrillation episodes lasting for at least 30 seconds while the subject is stationary. Other arrhythmias causing heartbeat irregularities may be detected by the device. The wrist device reacts to the detected arrhythmias by giving a notification that an ECG record should be taken.

The ECG signal that is measured by the device is taken between the arms and is thus comparable with Lead I ECG. Cardiac arrhythmias including atrial fibrillation can be observed with the measured Lead I ECG. Therefore, with symptom-based or pre-scheduled ECG recordings, the device can also be used in the diagnosis of cardiac arrhythmias that do not cause irregular heartbeats.

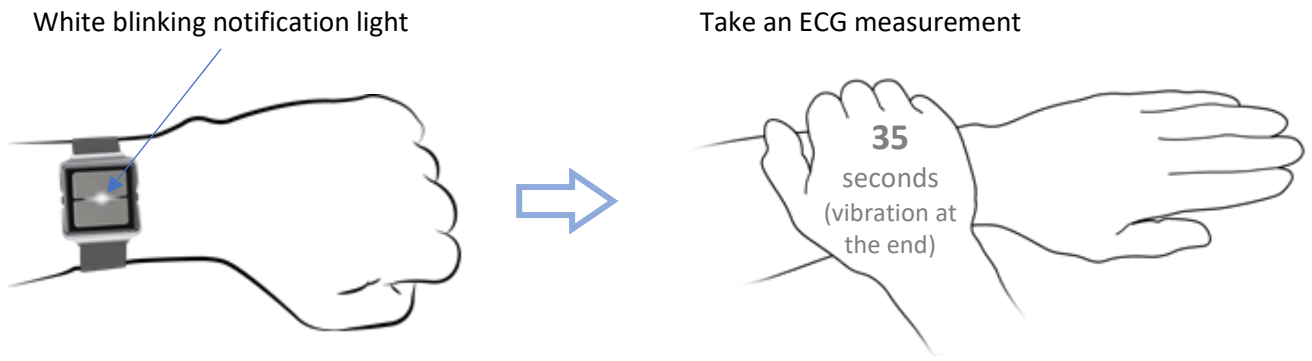
## Interference with Medical Devices

The device may emit radio waves, which could affect the operation of nearby electronics, including cardiac pacemakers, hearing aids and defibrillators. The PulseOn Arrhythmia Monitor is not intended to be used with a pacemaker. If you have another implanted medical device, do not use the PulseOn device without first consulting your doctor or the manufacturer of your medical device.

## Quick Instructions

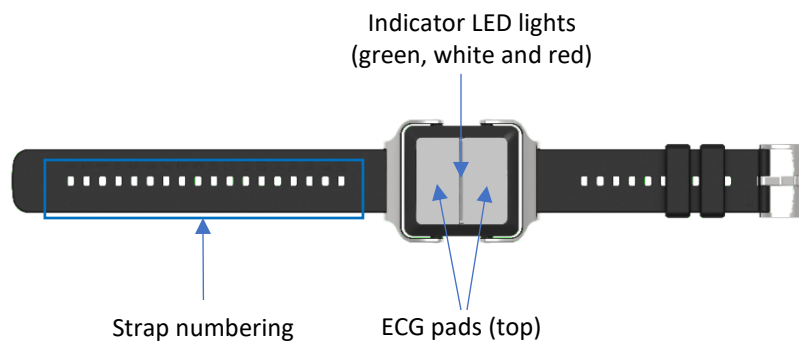
Use of the device is explained briefly here. Please read the following chapter carefully for more information.

- Wear the wrist device on your wrist during daily life and during sleep. (See: ***Wearing the Wrist Device***)
- If a white light is blinking, take a ECG measurement by placing your other hand on the device for 35 seconds. (See: ***Taking an ECG Measurement***)
- You can take an ECG measurement at any time, especially if you feel symptoms.
- If a red light is blinking, recharge the device. (See: ***Recharging***)



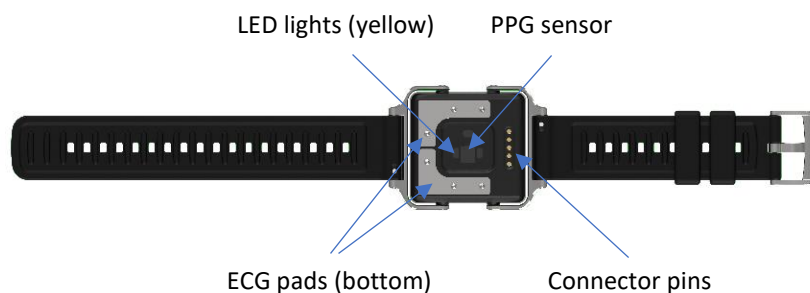
### Using the Wrist Device

The design of the Arrhythmia Monitor resembles a watch. The wrist strap, made from silicone, has numbers next to the holes in the strap to assist with finding the right tightness and to make locking with the steel latch easier and repeatable. The tightness of the device can be adjusted while in use, but the device should stay tightly on the skin to ensure the best performance of optical measurement.



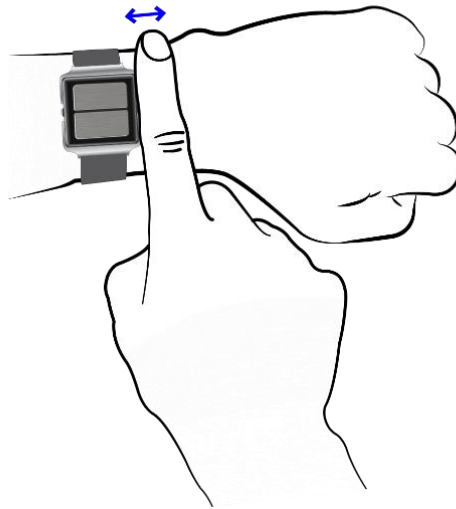
In the previous figure, the Arrhythmia Monitor is shown from the top. On the cover there are two metal sheets, which are used for the ECG measurement. Between the sheets, a strip of plastic is visible, under which the notification LEDs are located.

In the following picture, the bottom side of the device is shown. Two additional metal sheets, used for the ECG measurement, are located on the underside. In addition to the lenses and a light, necessary for the optical measurement, charging pins can be seen on the underside. When the device is on, yellow lights can be seen in the centre of the underside.



## *Wearing the Wrist Device*

The device should be worn on a wrist, approximately one finger width away from the wrist bone (as shown in the next figure).



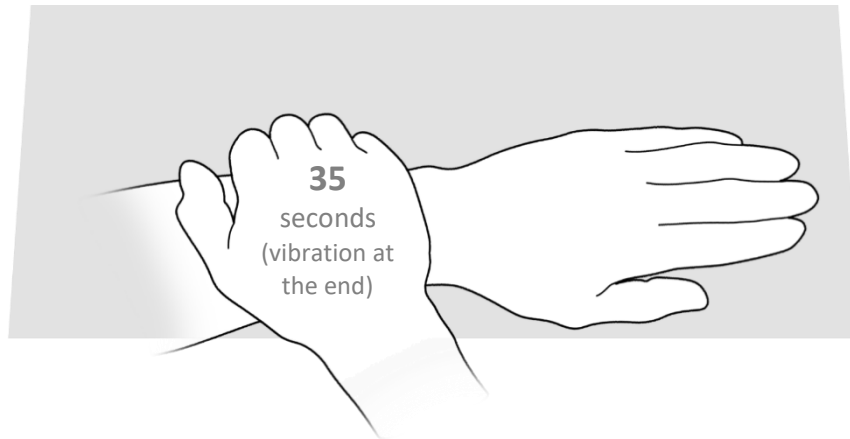
The strap should be tight enough, so that the bottom sensors (including the two yellow LED lights that are on) are pressed against the skin. However, the device should not be so tight as to cause discomfort and obstruct blood flow to the hand.

Good skin contact of the wrist device is important to ensure good signal quality when recording patient data. Poor contact may cause an artifact (noise) to be included in the recording, which can affect analysis of the data.

## *Taking an ECG Measurement*

When wanting to take an ECG measurement, whether due to a notification or feelings of arrhythmia, go through the following steps:

- Sit down and breathe calmly.
- Rest the hand with the device on your lap or on a table if possible.
- Cover the device with the palm of your other hand and attempt to keep both arms as relaxed as possible (as shown in the figure below).
- Once the device recognizes the palm, it will vibrate once to indicate that an ECG measurement has been initiated.
- Stay relaxed and still for approximately 35 seconds.
- During the measurement, the device will not vibrate.
- After about 35 seconds, the ECG measurement is considered successful and the device will vibrate once and show a continuous white notification light.
- If the ECG measurement fails, for example due to disrupted contact with the sensors, the device will vibrate sharply twice, and a white, fast-blinking notification light will be shown. In this case, the measurement should be redone. If the measurement was carried out due to a notification, the notification will continue with the white blinking light and vibrations.



- If you do not have a table to use, the measurement can be taken while sitting with the hands resting on the lap.
- If necessary, the measurement can be taken while standing. In this case, attempt to keep the arms as relaxed as possible.

Note: An LED light notification after an ECG measurement only indicates whether the measurement was recorded correctly or not. It does not signal any information concerning a regular or irregular heart rhythm.

### *Notifications*

The PulseOn Arrhythmia Monitor wrist device can give out a notification for three different reasons:

1. The device has observed an irregular cardiac rhythm.
2. The device has been set up to notify the user at a certain time.
3. The battery charge is running low.

In the first two cases, a white notification light will blink and the device will vibrate constantly for 5 minutes or until a successful ECG measurement is made.

When the battery is running low, the device will vibrate every 30 minutes and a red light will blink continuously – but faintly – until it is placed into the charging dock. A low battery warning does not disrupt any normal functions of the device.

Some users may experience numerous arrhythmia episodes. To avoid unnecessarily disturbing the user, the device does not notify the user about every episode.

The device administrator can set a nighttime for the device, during which there is even less disturbance for the patient.



When the device notifies the user, this does not automatically mean there are issues with the heart. The device is intended to help medical professionals with diagnosis.












If the red notification light is continuously on, the device has encountered an unrecoverable error. In this case, contact the device provider.



In some specific cases, the device may give out arrhythmia notifications while not being worn. The user should not react to these in any specific way.

All notifications are listed in table here below.

*PulseOn Arrhythmia Monitor wrist device notifications*

Reason	LED light indication	Vibration
Arrhythmia notification	Blinking white 	Several short
Scheduled notification	Blinking white 	Several short
Battery low	Blinking red 	Three long
Charging (while docked)	Slow blinking white 	None
Battery full (while docked)	Continuous green 	None
ECG measurement started	None	One long
ECG measurement successful	Continuous white 	One long
ECG measurement failed	Fast blinking white 	Two short
Error mode (unsuitable charger)	Continuous red (only when charging) 	None
Error mode (unrecoverable)	Continuous red (when not on the charger) 	None

*Cleaning the Wrist Device*

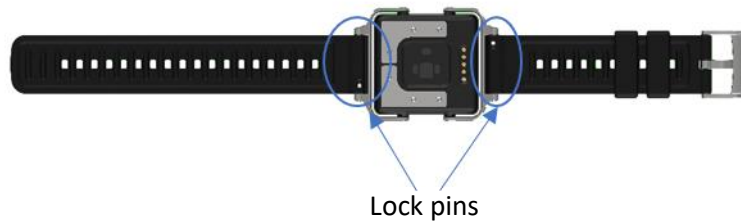
Do not submerge any other parts of the equipment than the wrist device, rinse them with liquid or leave them in touch with liquid or a wet tissue for a prolonged time.

*Cleaning the wrist device*

1. Regularly – e.g. once per week – rinse the device and the strap in water or use an antibacterial cleaning sheet to wipe the device.
2. Do NOT use soap on the wrist device.
  - a. If necessary, the straps can be removed temporarily (see: Removing the straps) to allow for better cleaning of the straps. When removed from the device, the straps can be washed with soap.
3. Do NOT let the device soak in liquid. When removed, the straps can be soaked in soapy water.
4. Do NOT scrub the device with force.
5. Make sure no visible dirt is left on the straps or the device after cleaning.
6. Be sure the device and the straps are completely dry before wearing them again.

*Removing the straps*

The straps can be removed to facilitate cleaning or to change them if necessary. This is done by pressing the lock pin (see figure below) towards the centre of the strap and then removing the strap from the device. Likewise, replace the straps by pressing the lock pins so that the straps click into place.



### [Cleaning the dock and the charger](#)

Cleaning the dock and charger is only necessary if they are visibly dirty.

1. Disconnect the dock from the USB cable.
2. Wipe dust off the cable and the power supply.
  - a. Do NOT use liquids to clean the cable or the power supply.
3. Remove the silicone cover from the dock.
4. Rinse the silicone cover in water.
  - a. This water can contain soap.
5. Wipe the dock with a damp, lint-free cloth.
  - a. Do NOT use soap on the dock.
  - b. Do NOT submerge the dock in water.
6. Before putting the cover back on, let the dock and the cover dry properly.
7. Connect the cable back to the dock once the cover is back on.

### [Recharging](#)

The wrist device should only be recharged with its own charger. Recharging is not necessary in all use cases and in those cases the user is not provided with the charging accessories.

If you are provided with the charging dock, follow these instructions:

The charger consists of a charging dock connected to the provided USB power supply with the provided USB-cable. The charging dock has a silicone lid that functions as a cover to provide IP21 protection against dripping water (vertically falling drops). When recharging the wrist device, open the silicone lid, place the device on the charging dock and close the lid. Never remove the silicone cover from the charging dock.

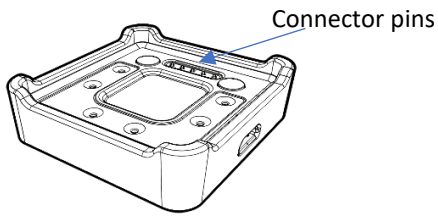
When placing the wrist device on the charging dock, make sure that the charging pins on the bottom of the device and on the dock are in contact. Magnets in the charging dock help keep the device still while charging. If the device does not start to charge, slide the docked device gently to ensure electric contact.

While charging, a slowly blinking white light is shown. When the battery is full, a green light is shown.

Fully charging the wrist device takes approximately 2 hours (from depletion to 90% charge less than 2 hours) in normal conditions. If the wrist device battery is empty when charging is started, it may take a short while before the white LED becomes lit.

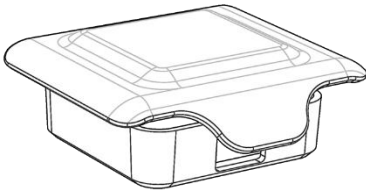
During recharging, the device is not being worn and thus not usable by the patient. It is recommended that the device be taken back into use (worn) soon after it has been recharged.

Charging dock

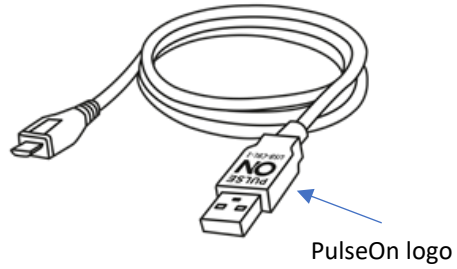


Silicone cover shown separately to emphasize connector pins.

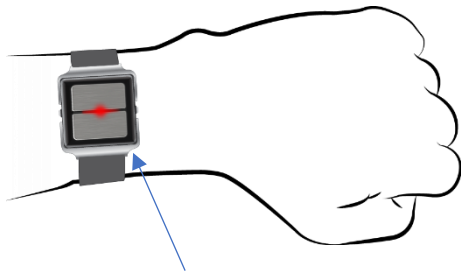
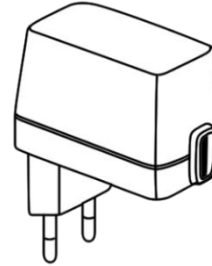
Silicone cover



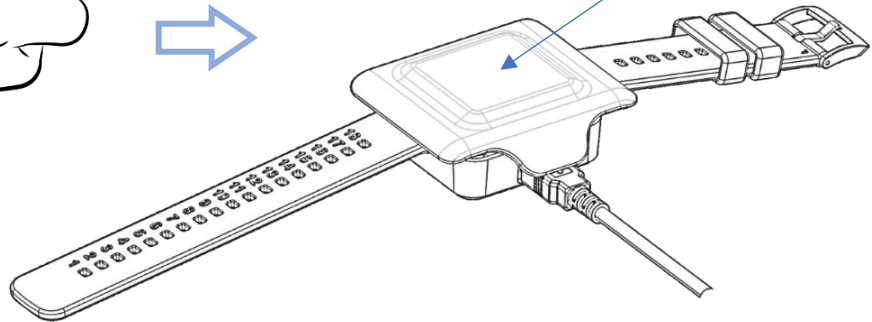
USB cable



USB power supply



White slow-blinking notification light



**Caution**

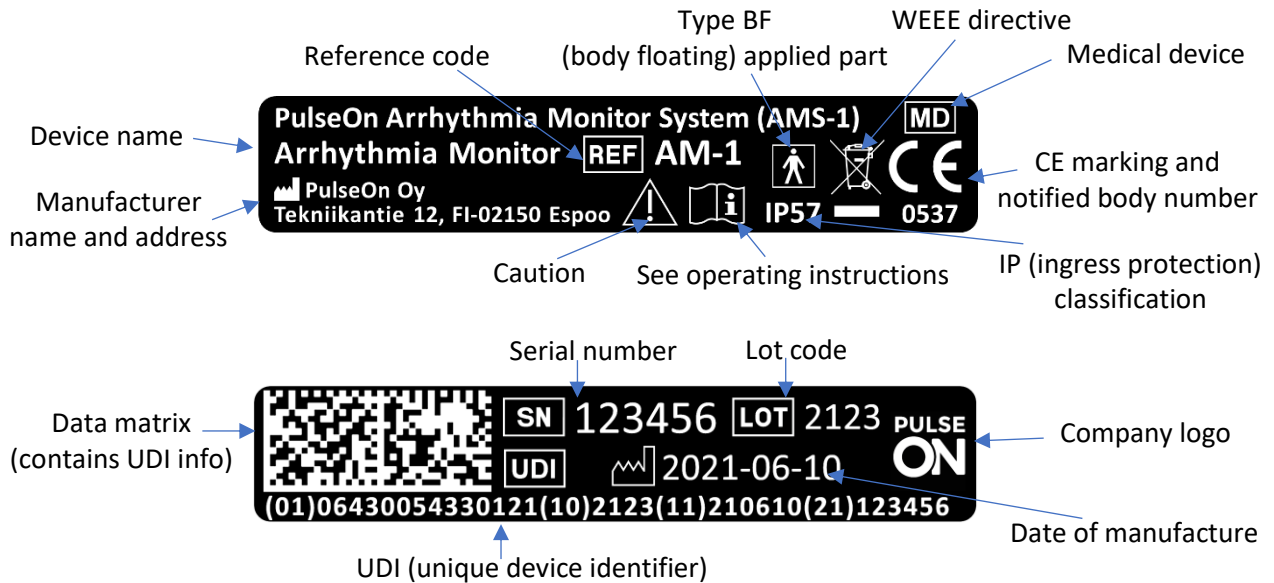


- Battery low notification. When the wrist device battery is running low, the device will vibrate every 30 minutes and continuously – but faintly – blink red until it is placed into the charging dock. A low battery warning does not disrupt any normal functions of the device. To ensure prolonged functioning of the device, it should be recharged.
- Only the accessories and detachable parts mentioned in this guide should be used with the PulseOn Arrhythmia Monitor. Only the supplied charger should be used to recharge the device.

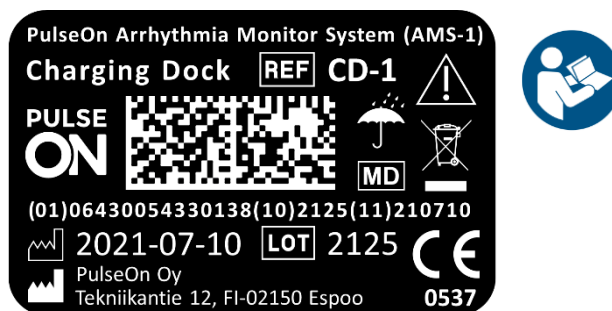
- During charging in maximum usage temperature (38°C), the wrist device may heat up to 42°C. Once removed from the charger and taken into use, the device will cool down. During normal operation, the device does not heat up to more than 1°C above ambient or wrist temperature.

## Wrist Device and Charging Dock Labels

The labels on the wrist device and on the charging dock are explained below.



The label on the bottom of the charging dock has the same elements as the wrist device labels, except that the charging dock is not a type BF applied part, it does not have a serial number, and IP protection is replaced with a keep dry symbol. The charging dock has a blue “Refer to instruction manual/booklet” symbol.

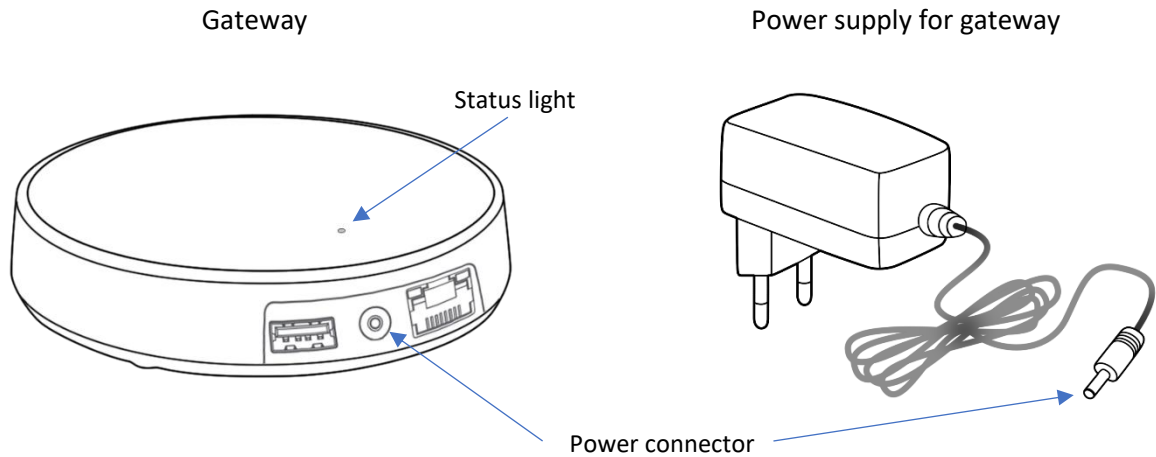


## OPTIONAL: Using Gateway

Medical personnel can provide the user with a PulseOn gateway for data transfer. It is an optional non-medical product compatible with PulseOn Arrhythmia Monitor System (AMS-1). If you have been given such a device, follow these instructions.

To power up the gateway, attach the power supply to the gateway and plug it into a wall outlet. The gateway switches on automatically. Use only the power supply unit provided with the product.

Keep the gateway connected to an electrical plug in a central location of your apartment – such as the living room or bedroom. The location should be chosen so that the wrist device is near the gateway (less than 5 metres away) for at least 30 minutes per day. Note that the gateway functions using wireless connections and can experience disruptions from surrounding metal or thick structures. The device is correctly installed when the status light is continuously green.



**Gateway status light indications**

Green light	■	Connected to the internet
Blue light	■	Trying to establish a connection
Blinking blue light	✱	Configuration mode
Red light	■	Error state

*Gateway Information and Safety*

- Use the gateway indoors only. Do not use in humid environments. The operating temperature range of the gateway is from 0°C to +50°C.
- Do not cover the device, as this prevents the device from operating properly.
- Due to radio frequency exposure limits, the gateway should be installed and operated with a minimum distance of 20 cm between the device and the body of the user or nearby persons.

**Maximum transmit power**

Supported radio networks	Operating frequency bands	Max. transmitted radio-frequency power
LTE Cat M1	B2, B3, B4, B5, B8, B20	+23 dBm
LTE NB-IOT	B2, B3, B4, B5, B8, B20	+23 dBm
2G GPRS/EGPRS	B2, B3	+30 dBm
2G GPRS/EGPRS	B5, B8	+33 dBm
Wi-Fi	ISM 2.4 GHz	+17.3 dBm
Bluetooth LE/Wirepas Mesh	ISM 2.4 GHz	+4 dBm

## Care and maintenance

- Handle your device with care.
- Do not open the device.
- Unauthorized modifications may damage the device and violate regulations governing radio devices.
- Do not drop, knock or shake the device. Rough handling can break it.
- Only use a soft, clean, dry cloth to clean the surface of the device. Do not clean the device with solvents, toxic chemicals, or strong detergents, as they may damage your device.

## Interference with medical devices

The gateway may emit radio waves, which could affect the operation of nearby electronics, including cardiac pacemakers, hearing aids and defibrillators. The PulseOn Arrhythmia Monitor is not intended to be used with a pacemaker. If you have another implanted medical device, do not use the PulseOn device without first consulting your doctor or the manufacturer of your medical device. Maintain a safe distance between the device and your medical devices and stop using the device if you observe a persistent interference with your medical device. Note: The gateway does not affect the PulseOn Arrhythmia Monitor.

### *List of parts and accessories*

The physical parts of the PulseOn Arrhythmia Monitor System are listed in the table below.

### *List of parts and accessories*

Item	Type	Trade name	Code	UDI-DI / GTIN
Wrist device (WD)	Device (class IIa)	Arrhythmia Monitor	AM-1	06430054330121
Spare strap, size S	Detachable part	Spare Strap - Small	ST-S-1	06430054330169
Spare strap, size L	Detachable part	Spare Strap - Large	ST-L-1	06430054330152
Spare strap, size XL	Detachable part	Spare Strap - Extra Large	ST-XL-1	06430054330251
Charging dock (CD)	Accessory (class I)	Charging Dock	CD-1	06430054330138
Silicone cover (for CD)	Detachable part	Silicone Cover	CDS-1	06430054330237
USB cable (for CD)	Detachable part	USB Cable	USB-CBL-1	
Power supply (for CD)	Device (non medical)	Power Supply EU/UK	CD-PS-EU-1	
Gateway	Optional compatible product (non medical)	Gateway	GW-1	06430054330145
Gateway power supply	Optional compatible product (non medical)	Gateway Power Supply EU/UK	GW-PS-EU-1	