PulseOn
Arrhythmia Monitor System

Model AMS-1

User Guide

MANUFACTURER

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PulseOn Arrhythmia Monitor System User Guide

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1 Introduction

The PulseOn Arrhythmia Monitor System (AMS-1) consists of a wrist-wearable device, a data management service and data transfer software. The collection of patient data is based on photoplethysmography (PPG) and electrocardiography (ECG) technologies. AMS-1 is used to assist in the diagnosis, screening and monitoring of cardiac arrhythmias.

Before operating, please read this user guide carefully and retain it for future reference.

1.1 Terms, Definitions and Acronyms

This document uses the following terms in the meaning indicated:

arrhythmia	A group of conditions in which the heart rhythm is irregular or abnormal.
data management service	The software itself. Used for managing and visualizing medical data, and for managing user accounts and their roles within the system.
data transfer software	A desktop system tray application handling communication between the PulseOn wrist device and the DMS.
desktop software	Software that can be installed on non-dedicated computers.
device	A combination of hardware and associated software (firmware and/or desktop software) which is capable of performing a specific intended medical use.
electrocardiography	A process of recording the electrical activity of the heart over a period using electrodes placed on the skin. These electrodes detect the electrical changes on the skin that arise from the heart muscle's electrophysiological pattern of depolarizing during each heartbeat.
firmware	Software which provides low-level control for device-specific hardware.
gateway	An optional compatible product used to transfer measurement data from the wrist device to the data management service.
inventory management system	Part of the DMS that is used to control and manage the devices used.
patient	The home user wearing the PulseOn wrist device.
wrist device	The PulseOn Arrhythmia Monitor, a wrist-worn ECG and IBI measuring device used to record patient measurement data.

Acronym	Description
BLE	Bluetooth Low Energy
DMS	Data Management Service
DTS	Data Transfer Software
ECG	Electrocardiogram
GDPR	General Data Protection Regulation
IMS	Inventory Management System
IBI	Interbeat interval
IT	Information Technology
PC	Personal Computer
PPG	Photoplethysmography
UI	User Interface
USB	Universal Serial Bus
WD	Wrist Device

1.2 The Scope of the User Guide

This user guide describes the operation, characteristics, specifications and use recommendations of the PulseOn Arrhythmia Monitor System and its components. This manual relates to the Arrhythmia Monitor AM-1 and the charging device CD-1.

This guide explains how to use the arrhythmia monitor and its accessories, prepare the patient, configure the monitor, install and use the service, and troubleshoot.

This user guide as a whole is for an operator who is a healthcare professional and has a working knowledge of the medical procedures and terminology required for monitoring cardiac patients.

Chapter 3 includes instructions for lay operators, such as patients, for using the wrist device alone or in combination with a gateway and a wrist device charging dock.

The information in this document is subject to change without notice.

1.3 General Safety

This user guide gives important information about the use and safety of the PulseOn Arrhythmia Monitor System.

For assistance in using, maintaining or setting up the PulseOn Arrhythmia Monitor System, or if any unexpected operation, event or incident occurs, please contact the manufacturer (local PulseOn representative).

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

1.3.1 Symbols

Table 1. Symbols used in the equipment and documentation

CE 0537	CE marking and Notified Body (NB) number. The device is CE-marked according to European Regulation (EU) 2017/745 regarding medical devices.
	Caution! Caution is necessary close to where the symbol is placed. The situation needs operator awareness or operator action in order to avoid undesirable consequences.
	User guide/operating instructions that should be read for additional information.
	Refer to instruction manual/booklet (mandatory).
	The device is equipped with type BF (Body Floating) applied parts fulfilling the EN 60601-1 (IEC60601-1) standard. Type BF classification is given to applied parts that are electrically connected to the patient and must be floating and separated from the earth ground.
	A Bluetooth Low Energy radio within the equipment sends radio frequency radiation at a 2.4 GHz frequency. The radiation is non-ionizing.
	Do not dispose as unsorted waste. Requires separate handling for waste disposal according to national requirements. The Waste Electrical and Electronic Equipment Directive (WEEE Directive).
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Lot/batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.

Reference/catalogue number

Medical device

Unique Device Identifier

Keep away from rain / keep dry (storage and transport)

Temperature limits (storage and transport)

Humidity limits (storage and transport)

Atmospheric pressure limits (storage and transport)

For indoor use only

Class II equipment

Power-supply efficiency level VI

Polarity marking – centre positive

1.3.2 Warning and Safety Notices

Warnings

- The user must be instructed to discontinue using the device in case of significant skin reactions.
- Not a toy. Not for small children. Choking hazard. The equipment may contain small parts. Keep them 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 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 observed to verify that it is operating 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 could be adversely affected.

- 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 therefore result in improper operation.

- 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.

- The total leakage current may increase when several items of medical equipment are interconnected.

- Do not touch the recharger (charging dock) and the patient simultaneously. Do not remove the silicone cover from the charging dock as it provides IP21 protection against dripping water (vertically falling drops).

Caution

- The PulseOn Arrhythmia Monitor System provides an indication of possible arrhythmias to doctors but it does not provide diagnosis.

- The automated analysis result is not a diagnosis. The results must be reviewed by a trained professional (e.g. cardio-tech or cardiologist) in order to verify the result. Additional information may be needed before a trained professional can establish a complete diagnosis.

- The automated analysis relies on the quality of the recorded signals. Signals with disturbances may cause problems for the analysis and may result in miss-detection, mislabelling or non-detection of events.

- The automated analysis software (ECG Parser) is not complete diagnostic ECG software. Only beat and rhythm classification, HR and HRV interval measurements are validated in the ECG Parser output. Other output parameters may be used for indication only.

- It may be difficult to notice arrhythmia from the ECG signal if the heartbeat rhythm is not irregular and the heart rate is slow. For example, this can be the case with atrial flutter; it is possible that the flutter waves of the atrial contractions are not clearly visible in the Lead I ECG signal.

- It is also possible that, for some subjects, normal p-waves are not clearly visible in the Lead I ECG signal.

- If many signals are rejected as poor-quality signals by the automated analysis, then:
    - seek alternative ECG examination using other means, and/or
    - make sure the ECGs are manually reviewed, despite the signals being rejected as being of poor quality.

- According to current care guidelines, atrial fibrillation is the only cardiac arrhythmia that can be diagnosed from single-lead ECG such as the PulseOn arrhythmia monitor. If another arrhythmia is suspected, confirm the diagnosis with other methods recommended by your local care guideline, such as 12-lead ECG.

- In case of atrial fibrillation, verify that your local care guideline allows diagnosis with single-lead short-term ECG.

- Optical arrhythmia detection is based on analysis of heartbeat interval variations. Cardiac arrhythmias showing stable rhythm, such as common types of atrial flutter, are thus not recognized by the optical measurement device.

- The polarity of the ECG depends on which hand the device is worn on. ECG algorithms recognize the polarity and convert the signal if needed (the signal needs to be converted if the device is worn on the right hand). However, the polarity recognition is not always perfect and the ECG may be displayed with incorrect polarity.

- The wrist device is waterproof (IP57) up to an underwater depth of 1 metre. Nevertheless, moisture can affect measurements.
    - The device must 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 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 unrecoverable 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.

- Damaged or suspected inoperative equipment must be removed from use. It must be checked and repaired by qualified service personnel prior to continuing use.

- Only the accessories and detachable parts mentioned in this user guide should be used with the PulseOn Arrhythmia Monitor. Only the supplied charger should be used to recharge the device.

- *Battery low notification*. When the wrist device battery is running low, the device will vibrate every 15 minutes and continuously – but faintly – blink red until it is placed in the charging dock. The low-battery warning does not disrupt any of the device's normal functions. To ensure prolonged proper functioning of the device, it must be recharged.

- During charging at the 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.

- If for any reason the device feels hot, do not wear it.

- 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 be still.

- A 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 wrist device is not intended for use at the same time as the use of high frequency (HF) surgical equipment or a defibrillator. A defibrillator may break the device; the wrist device is not defibrillation-proof.

- The wrist device is not intended to be used in a magnetic resonance imaging (MRI) environment.

- The device is not intended to be used with a pacemaker.

- A healthcare professional needs to inspect the equipment for damage or excessive wear prior to each use.

- The equipment should be used by only one patient at a time.

- When taking an ECG measurement, make sure that no one else is touching you or the wrist device as this may affect the result.

- The wrist device and other physical parts always need to be properly cleaned before they are used by a patient. Refer to the cleaning instructions within this user guide.

- The device needs to be configured for each patient by a healthcare professional. Refer to the instructions within this user guide.

- Correct tightness of the wrist band is important for optimal contact of the wrist device with the skin. Refer to the instructions within this user guide.

- No modification of the equipment is allowed. Do not try to disassemble, repair or modify any part of the equipment.

- The device and its accessories must not be serviced or undergo maintenance on while being worn or in use.

- The charging dock can be connected to a personal computer (PC) to download/upload wrist device data. Only a CE-approved PC complying with IEC 60950-1 or a similar safety standard should be used. The PC must be kept outside the patient environment and have restricted access. The PC should have anti-virus, firewall and operating system updates in use.

- To prevent possible damage to the equipment, maintain to 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 in order to start an ECG measurement. If there is no vibration, the device is not operational. It is possible to inspect the operation of the optical measurement by looking underneath the device. If the yellow LED lights are on, the 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.

- Tattoos, dense body hair or dark skin in the wrist area can have a negative effect on the performance of the wrist device, as can cold skin or otherwise reduced blood perfusion.

- Excessive light does not harm the device, but it can affect 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. Wrist device electrodes should not come into contact with any other conductive parts, including the ground.

- The device is not intended for ST segment analysis.

1.3.3 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.

1.3.4 Residual Risks

It is important for AMS-1 users, whether medical personnel or patients, to understand the following known risks:

- Not using AMS-1 correctly can result in no usable medical data being available after the measurement period.
- Not using AMS-1 correctly can cause bad signal quality that is not flagged correctly. Then there is a risk of the trained professional not reacting to the data correctly.
- Wearing the AMS-1 wrist device too tightly can cause inconvenience and discomfort for the patient.
- Not cleaning the AMS-1 wrist device properly and allergic reactions can cause skin irritation.
- If the medical professional or patient does not use the electrical device safely, electric shock may result.
- The AMS-1 device can overheat if it is charged or left in a hot environment.
- AMS-1 includes small parts and cables that can cause strangulation or asphyxiation if left within reach of small children.

These issues are covered in this user guide, especially in section 1.3.2 Warning and Safety Notices.

1.3.5 Intended Purpose

The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening and monitoring of atrial fibrillation and other cardiac arrhythmias visible in Lead I ECG. It consists of a wrist-worn device and a data management service. The wrist device optically monitors pulse rate during periods of no motion, in order to detect possible atrial fibrillation, and it is used to take intermittent single-lead electrocardiogram (ECG) measurements between the arms. The wrist device stores the measured data, which is later transferred to the data management service where the data can be analysed by medical professionals. The device is intended to be used inside or outside a hospital environment. The usage period of the device can vary from days to several weeks.

1.3.6 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.

1.3.7 Intended Users

The intended users of the PulseOn Arrhythmia Monitor System are medical professionals, administrators (support staff) and patients.

Medical professionals, such as nurses, do not require additional background education or work experience. The medical professional hands the device to the patient and instructs the patient in the use of the wrist device and its optional accessories. The medical professional also always cleans the device before it is used by a patient. The wrist device is reset (data and settings) automatically between patients. In addition, the medical professional uses the data management service (DMS) to view and export the collected data. The final interpretation and diagnosis is the responsibility of the overseeing physician.

The administrator should be someone with the skills for configuring the wrist devices for use and tracking them. The administrator can be the same person as the medical professional.

It is intended that the patient wearing the PulseOn Arrhythmia Monitor wrist device be an adult with suspected or already diagnosed heart problems, or a person with no suspected cardiac arrhythmias participating in cardiac screening, for example. The patient is required to wear the device and should start ECG measurements manually by placing the palm of the opposite hand on the device. The healthcare professional should inform the patient of any action that is required (e.g. removal of the wrist device for swimming, manual activation of ECG measurement, etc).

The PulseOn Arrhythmia Monitor wrist device is intended for use in the normal living and working environments of the patient. It is not designed to be used while swimming or in the sauna, however. It is designed to be worn constantly at other times. However, the wrist it is worn on can be alternated.

Pregnancy does not affect device usage.

1.3.8 Electromagnetic Compatibility (EMC)

EMC information is listed in *Appendix A*.

1.3.9 Standards

The PulseOn Arrhythmia Monitor System is composed of software and hardware components which are subject to other directives in addition to the Medical Device Regulation. The regulations, directives and standards are identified in *Appendix B*.

1.3.10 Essential Performance

Essential Performance (EP) denotes performance which is necessary for freedom from unacceptable risks. It may be best understood by identifying an operation/performance which, when absence or degraded, leads to unacceptable risk.

No essential performance has been defined for the PulseOn Arrhythmia Monitor.

1.3.11 Clinical Benefits

The PulseOn Arrhythmia Monitor System has the following clinical benefits:

- enables monitoring of a patient for a prolonged period of time, e.g. for 2 weeks, which increases the probability of detecting atrial fibrillation
- is comfortable for patients, which enables long-term monitoring
- facilitates recording of symptomless arrhythmia episodes due to the built-in continuous PPG monitoring which prompts the patient to take an intermittent ECG measurement
- is easy for the patient to use and therefore suitable for people who are not technically oriented
- has been clinically validated to provide ECG data to medical professionals for diagnosis of arrhythmia

1.3.12 Declaration of Conformity

EU Declaration of Conformity

Trade Name: PulseOn Arrhythmia Monitor System
Model: AMS-1
Basic UDI-DI: 643005433AMSD4
Manufacturer: PulseOn Oy, Tekniikantie 12, 02150 Espoo, Finland
SRN: FI-MF-000009325
Certificate number:CR-03-1224-781-22
Notified Body: Eurofins Electric & Electronics Finland Oy (0537), Kivimiehentie 4, 02150 Espoo, Finland

Assessment procedure: Assessment based on the quality management system and on the assessment of technical documentation

Device Purpose: The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening and monitoring of cardiac arrhythmias.

We hereby declare, with our sole responsibility, that the PulseOn Arrhythmia Monitor System conforms with the provisions of the (EU) 2017/745 Regulation of the European Parliament and of the Council on Medical Devices issued on 5 July 2017 concerning medical devices.

Classification: Class IIa

The following standards were used to meet the requirements:

- EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- EN 60601-1-11:2015 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
- EN 60601-1-2:2015 Medical Electrical Equipment – Part 1–2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- ECG functions are evaluated using relevant parts of the EN60601-2-47:2015 standard, considering the intended use of the device.
- According to the manufacturer of the Bluetooth modules, the Bluetooth modules meet the requirements of the Electromagnetic Compliance Directive 2014/30/EU and Radio Equipment Directive (RED) 2014/53/EU.
- The CE marking requirement 93/68/EE and RoHS Directive and (EU) 2017/2102 RoHS 2 Directive 2011/65/EU and WEEE Directive 2012/19/EU.
- This declaration is also supported by the Quality Management System in accordance with EN 13485:2016, and EN 14971:2019 Risk Management.

Jari Kaija
CEO
Espoo, 20 December 2023

1.4 General Care

The wrist device and its accessories should be properly cleaned before being used by a patient. Use care and proper procedure whenever cleaning the equipment as improper cleaning products and processes can damage the device.

1.4.1 Cleaning

As it is mostly in contact with the skin, the wrist device in particular must be meticulously cleaned by the operator or the operating organization before being used by a patient.

Regularly clean and disinfect the wrist device and other parts of the system. This should be done before giving the device to a patient and after receiving the device back from a patient. The device requires no specific cleaning after having been stored suitably.

1.4.1.1 Cleaning the wrist device

1. Remove the wrist strap from the device.
2. Rinse the device with water. Do NOT use soap.
    a. Alternatively, wipe both the device and the strap with an antibacterial cleaning agent such as a ~70% isopropyl alcohol (isopropanol, IPA, propan-2-ol, i-PrOH) solution.
    b. Do NOT scrub the device with force.
    c. Do NOT use strong solvents such as acetone (i.e. nail polish remover).
    d. Do NOT submerge the device or leave it in liquid for a long period. The straps can be soaked.
    e. Do NOT attempt to clean any parts of the equipment by autoclaving or steam cleaning them as this may damage the equipment.
3. Rinse the straps with water, which can have soap in it.
4. Let the device and straps dry properly before giving them to the patient, as any traces of cleaning agents might cause skin irritation.
5. Perform a visual inspection to ensure that no dirt, such as dead skin cells, remains on the device or straps after cleaning.

1.4.1.2 Removing the straps

The straps can be removed to facilitate cleaning or to change them if necessary. This is done by pressing the lock pins (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 strap clicks into place.

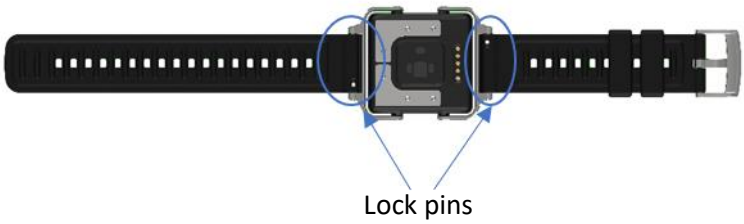


Figure 1-1. Wrist device strap removal

1.4.1.3 Cleaning the dock and the charger

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 to the dock again once the cover is back on.

1.4.1.4 Cleaning the gateway device

1. Disconnect the gateway from the power supply.
2. Wipe the gateway with a slightly damp cloth.
3. Make sure the gateway is dry before reconnecting it to the power supply.

1.4.2 Periodic Maintenance

The wrist device has a lithium-ion battery inside. If the device is not in regular use, the battery should be recharged at least once a year to maintain its condition. The expected battery life is five years.

It is advisable to conduct a visual inspection of the equipment before and after every use for any possible defects, such as:

- The PPG sensor lenses on the bottom of the wrist device having become covered in dirt (or something else that blocks the LED light) or having fully become milky opaque, and when cleaning does not help. Small scratches or blemishes on the PPG sensors do not affect the performance of the device.
- The ECG sensors on either the top or the bottom having been bent or having otherwise physically changed shape. Scratches on the ECG sensors do not affect the performance of the device.

The wrist device ECG and PPG sensors do not require any periodic calibration or maintenance.

1.5 Warranty and Replacement

PulseOn Oy (“PulseOn”) hereby warrants that the products are free from defects in material and workmanship that result in product failure during normal usage, for the number of years specified in the documentation accompanying the product, or for a period previously agreed between the purchaser and PulseOn, or if not otherwise stated, for a period of one (1) year from the date of shipment.

If the shipping package of a new product is damaged, please inspect the contents for possible damage.

In case of product replacement needs, please contact your distributor or PulseOn support: support@pulseon.com

Before returning the device to the manufacturer, the wrist device must be cleaned as instructed in section 1.4.1.

PulseOn strives to act promptly on replacement needs. However, the company is unable to provide compensation of any sort.

2 PulseOn Arrhythmia Monitor System Overview

The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening and monitoring of cardiac arrhythmias.

2.1 General

The PulseOn Arrhythmia Monitor System consists of a wrist device, a data management service (DMS) and data transfer software (DTS), as shown in the figure below. An optional compatible gateway can be used with the PulseOn Arrhythmia Monitor System.

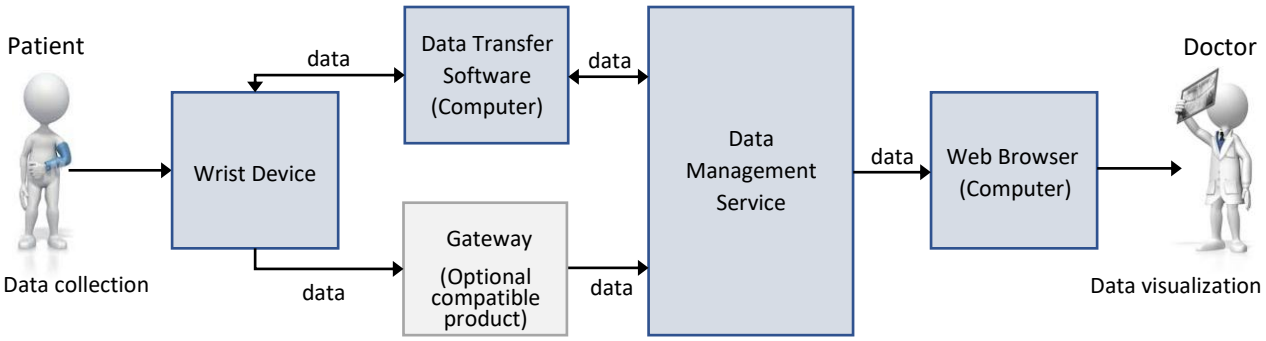


Figure 2-1. The components and data flow of the PulseOn Arrhythmia Monitor System

The wrist device obtains PPG by illuminating the skin using LED lights and then measuring the amount of light scattered back to a photodiode. The wrist device also measures acceleration data, which is used to assess the level of movement at the wrist. The acceleration is measured using an embedded accelerometer. These signals are then analysed for heartbeat information and the analysis results are saved in the wrist device memory, from which they can later be uploaded and further analysed in the DMS.

A known limitation of PPG-based measurements is their susceptibility to artefacts caused by motion. Therefore, PPG-based arrhythmia analysis can only be performed when the patient is stationary.

An electrocardiogram (ECG) is a recording of the electrical activity of the heart represented as a graph of voltage versus time. An ECG is obtained using electrodes placed on the skin. These electrodes detect the small electrical changes that are a consequence of cardiac muscle depolarization followed by repolarization during each heartbeat. The PulseOn wrist device uses two electrodes to measure a single lead ECG signal. The wrist device includes a third electrode that is used in a similar way to a driven right leg electrode to reduce common-mode interference in the signal. The ECG is measured between the arms and corresponds to standard Lead I of the 12-lead ECG.

The PulseOn Arrhythmia Monitor wrist device and optionally a charger and a gateway are given to the patient for independent use for a period of several days to several weeks. The wrist device analyses the patient's heartbeats for possible cardiac rhythm irregularities. When an episode of irregular rhythm is detected, the wrist device instructs the patient to take an ECG for further analysis.

Once the wrist device has been returned to the medical professional, the data on the device can be uploaded to the DMS using either a computer with internet access and installed DTS or an optional gateway device. The

gateway device may also be given to the patient for the duration of the data collection period so that it can transfer the data to the DMS during the period for possible monitoring by the doctor.

After upload to the DMS the data is accessible through a front-end user interface used with a web browser. The web browser and local computer software is used to configure the wrist device and to assign it to specific patients. Between patients and during use, the wrist device can be cleaned using standard disinfectant and a swab. The device and accessories are reusable.

The DMS itself is provided primarily as a centrally hosted cloud-based system and can be accessed with a computer and a suitable web browser. Additional computing and analysis on the collected data, such as analysing the ECG data, is done in the back-end software of the DMS. All recorded and processed heartbeat information can be viewed by accessing the DMS over the internet. The DMS may also be locally deployed on the hospital premises to be hosted on the hospital IT infrastructure.

2.1.1 Specifications

Table 2. PulseOn Arrhythmia Monitor wrist device specifications

PulseOn Arrhythmia Monitor AM-1	
Length (strap size L)	250.4 mm
Length (strap size S)	215.5 mm
Width	39 mm
Depth	13 mm
Weight (with strap size L)	45 g
Ingress protection classification	IP57
Storage/transport conditions	Temperature -20°C to +60°C Humidity 5% to 90% (non-condensing) Pressure 500 hPA to 1060 hPA
Operating conditions	Temperature +5°C to +38°C Humidity 5% to 90% Pressure 700 hPA to 1060 hPA
Battery type	Li-ion polymer rechargeable battery 350 mAh Nominal voltage 3.70V Integrated safety circuit Battery recharging time from depletion to 90% charge is less than 2 hours in normal conditions.
Operating time	More than 7 days without recharging (with full battery)
Internal memory	128 MB flash memory (can store 1 month of patient data)
Sensors	ECG, PPG, 3-axis accelerometer
Indicators	LED lights (green, white and red), vibration motor

Connectivity	Bluetooth (micro USB port in charging dock)
Materials	Device: ABS plastic, polycarbonate and stainless steel Straps: Silicone and stainless steel
Measurement details	ECG sample rate: 512 Hz ECG measurement resolution: 1 µV (microvolt) ECG measurement bandwidth*: • high-pass cut-off frequency < 0.6 Hz • low-pass cut-off frequency > 150 Hz *bandwith tests apply for raw filter configuration in DMS PPG measurement peak wavelength: 590 nm

Optical atrial fibrillation detection performance

- The PulseOn Arrhythmia Monitor has the following performance in detecting atrial fibrillation in Caucasian over-50-year-olds when evaluated in 5-minute segments: sensitivity > 90 %, specificity > 95 % (disregarding the segments of undetermined rhythm, ~40 %)

ECG analysis algorithm performance

- The ECG analysis algorithm has achieved the following performance for atrial fibrillation detection in a large-scale clinical trial* with a different measurement device but based on the same approach, i.e. short Lead I ECG measurements between the hands: sensitivity 92.4%, specificity 94.4% as reported by the *Possible arrhythmia* label in the ECG measurement.

  *E. Svennberg, M. Stridh, J. Engdahl, F. Al-Khalili, L. Friberg, V. Frykman, M. Rosenqvist. Safe automatic one-lead electrocardiogram analysis in screening for atrial fibrillation. *EP Europace* 19: 9,1 (2017) pp. 1449–1453, https://doi.org/10.1093/europace/euw286

Supported web browsers

- Data Management Service supports the following web browsers on a PC:
  - Microsoft Edge
  - Google Chrome
  - Mozilla Firefox

Workstation requirements

Technically, any operating system that can run supported browsers is applicable for viewing and analysing the data (Data Management Service). However, Windows 10 or newer with relatively modern hardware is needed for device operations (Data Transfer Software). Most of the processing power required is for viewing ECG graphs. The following minimum recommended setup should work in most scenarios:

- Processor: 1.5 gigahertz (GHz) or faster processor
- RAM: 4 GB
- Graphics card: DirectX 9 or later with WDDM 1.0 driver
- Display: 1920x1080 pixels
- USB port

Power supply specifications

- The charging dock power supply is made by Friwo.

- Model: FOX6-XM-USB 5V 1400mA MEDICAL FW8002M/USB (code: 1960267)
- Ratings and principal characteristics:
  - Input: 100–240 Vac, 50-60 Hz, 160–80 mA, Class II
  - Output: voltage 5.0 Vdc, current 1400 mA
- Ingress protection: IP42
- Conformity: CE, IEC 60601-1 approved

2.1.2 Service Life and Shelf Life

Expected service life of the device

The wrist device's life expectancy is five (5) years in continuous use with proper care. The wrist device has a lithium-ion battery inside. It is recommended that the battery be charged at least once a year to maintain its condition.

Expected service life of the parts and accessories shipped with the device

The life expectancy of the parts and accessories is five (5) years in continuous use with proper care.

Shelf life of the device

The shelf life of the wrist device is three (3) years due to the nature of lithium-ion batteries. To keep the batteries in good condition, they should be recharged at least once a year.

Shelf life of parts and accessories shipped with the equipment

No expiry date.

The manufacturer is committed to supporting the device (hardware and software) for the specified lifetime.

2.2 Device Components

The PulseOn Arrhythmia Monitor System (AMS-1) is a device that consists of a wrist-wearable, a data management service, and data transfer software. The data is transmitted from the wrist device to the data management service (DMS) after the measurement period using a PC or during the measurement period via a separate gateway device (an optional compatible product).

2.2.1 Wrist Device

The PulseOn Arrhythmia Monitor wrist device continuously measures a patient's heartbeats in order to analyse pulse rate during periods of no motion for possible cardiac rhythm irregularities. The device instructs the patient to take an ECG recording if an episode of irregular rhythm is detected. An ECG is taken by placing the free hand on top of the wrist device and keeping it steady for 35 seconds. Additionally, the wrist device

can be configured to prompt the user periodically to take an ECG measurement. The user can also take an ECG on their own initiative if they experience symptoms.

The wrist device uses light-emitting diodes (LEDs) and one photo diode for PPG measurement. PPG data is analysed by estimating heartbeat intervals and analyzing their variation to determine the cardiac rhythm. The cardiac rhythm is classified either as sinus rhythm or irregular rhythm. This continuous assessment requires approximately 30 seconds of good-quality PPG data measured when there is no or very little motion.

The device uses yellow LEDs for PPG measurement. The intensity of the LEDs is suitable for long-term monitoring, i.e. the energy emitted by the LEDs into the tissue is minimal and it does not cause any risk to the patient.

The wrist device has steel electrodes on both sides of the measurement unit for ECG measurement. An additional electrode on the device is used as a so-called right leg drive for decreasing the common mode electrical noise sensed by the device.

In addition, the device has a 3D accelerometer for movement measurement.

The materials used in the wrist device are safe and do not cause skin irritation. The wristband is made of silicone and the PPG sensing unit is made of ABS plastic and polycarbonate. The ECG electrodes are made of stainless steel, as is the strap buckle.

The wrist device stores ECG, heartbeat and analysis data in its memory for later sharing with medical personnel. The data is transmitted from the wrist device to the data management service via two alternative methods:

- after the measurement period using a PC and data transfer software, or
- during the measurement period via the gateway device.

The wrist device must be configured for a patient before use. This is done using the data management service and requires a PC with the data transfer software installed on it.

Arrhythmia monitor
(*ref.* AM-1)

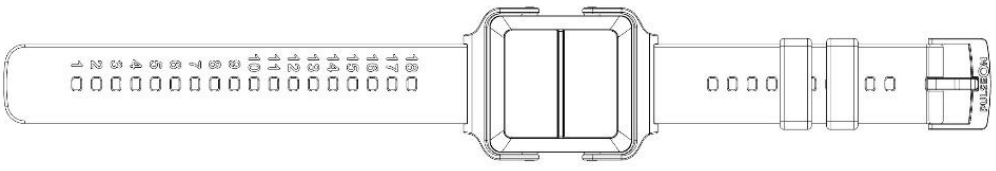


Figure 2-2. PulseOn Arrhythmia Monitor wrist device

PulseOn Arrhythmia Monitor straps are replaceable. The large strap is attached to the device.

Spare straps are available in three sizes: small (*ref.* ST-S-1), large (*ref.* ST-L-1), extra-large (ref. ST-XL-1).

2.2.1.1 Charging Dock

The wrist device may be handed to patients with or without the charger. With the charger, patients may charge the wrist device battery during the measurement period. Without the charger, the length of the measurement period is limited to the battery life of the wrist device.

The wrist device recharger consists of a charging dock, a USB cable and a power supply.

The charging dock and USB cable are also needed for connecting the wrist device to a PC for data transfer and set-up.

For more information, see the ***Recharging*** section.

2.2.2 Data Management Service

The PulseOn Data Management Service (DMS) is a software service used to manage, store and display patient data. It is provided primarily as a centrally hosted service but it may also be deployed on the hospital/healthcare-provider premises to be hosted on the local IT infrastructure.

The DMS includes an inventory management module for managing and keeping track of the individual wrist devices.

The DMS is accessed with a web browser on a PC.

For more information, see the ***Data Management Service*** section.

2.2.3 Data Transfer Software

PulseOn Data Transfer Software (DTS) is a separate stand-alone software application installed on a hospital Windows* PC. It is used:

- to transfer configuration parameters from the DMS to the wrist device when starting a measurement, or
- to transfer the data from the wrist device to the DMS after a measurement period.

The data transfer software communicates with the wrist device via Universal Serial Bus (USB) using the charging dock as a USB adapter.

The data upload is carried out by placing the wrist device on the charging dock attached to a computer with a USB cable. The computer needs to have the Data Transfer Software installed.

For more information, see the ***Data Transfer Software*** section.

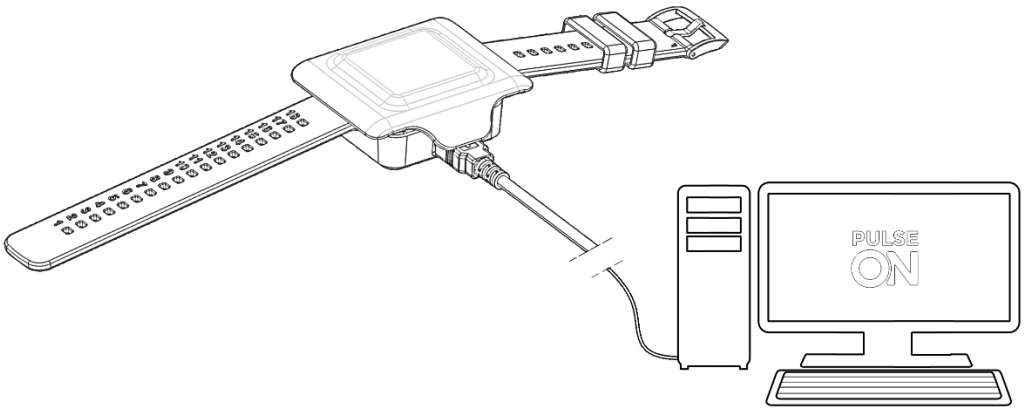


Figure 2-3. Wrist device connected to a computer

**Windows is a registered trademark of the Microsoft Corporation.*

3 Use Instructions for Patients

The contents of this chapter should be passed to patients as the healthcare provider sees relevant.

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 device is safe to use when these guidelines are followed.

3.1 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 unrecoverable 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.

- 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.

- Accumulation of dust and dead skin on the wrist device can cause skin irritation or problems with measurement and charging. If this arises, the wrist device should 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 or through the website: www.pulseon.com/support.

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

3.2 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.

3.3 Quick Instructions

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

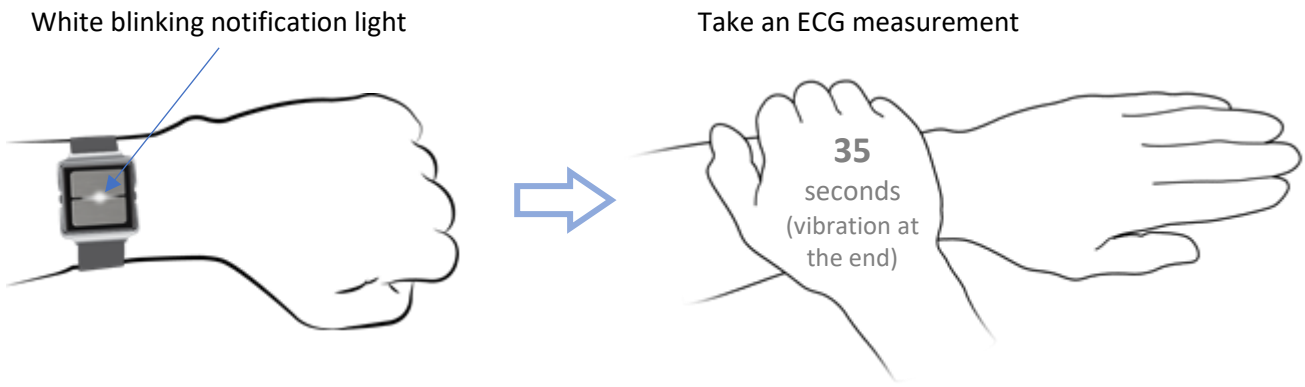


Figure 3-1. Notification to take an ECG measurement

3.4 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.

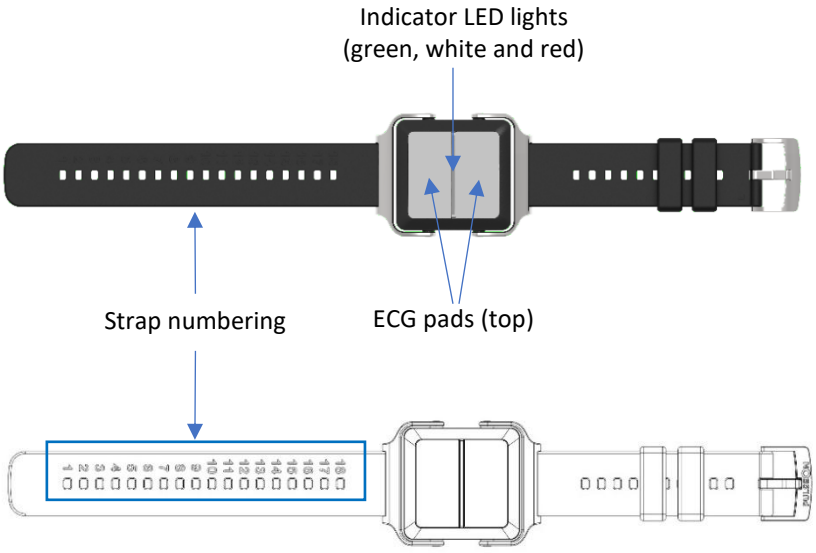


Figure 3-2. Wrist device details (top)

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.

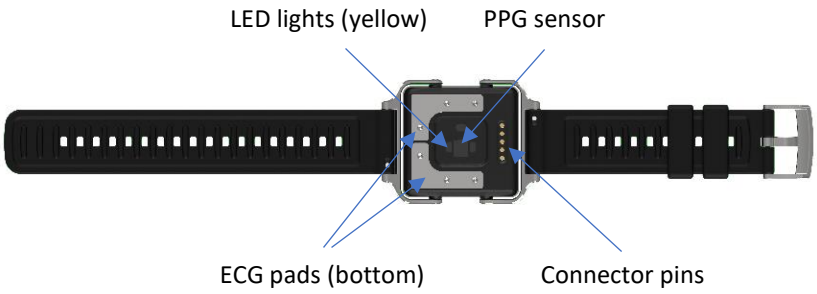


Figure 3-3. Wrist device details (bottom)

3.4.1 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).

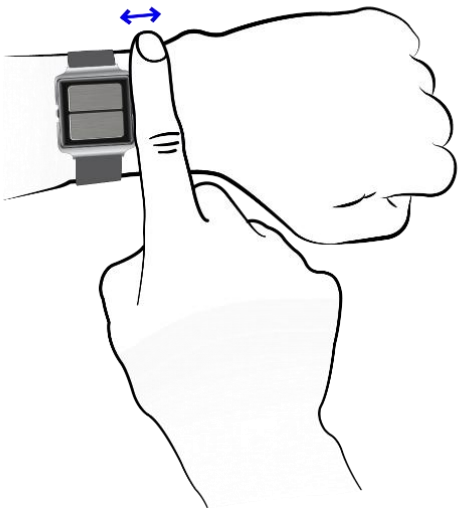


Figure 3-4. Correct position of the wrist device

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.

3.4.2 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.

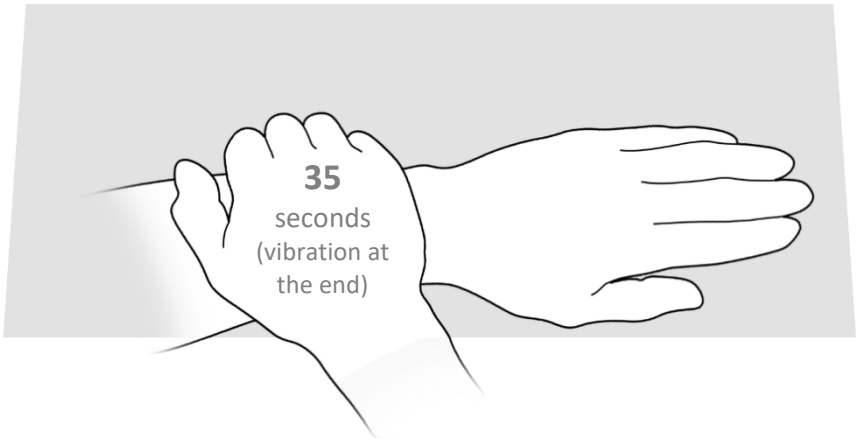


Figure 3-5. Taking an ECG measurement

- 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.

3.4.3 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 15 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 alert the user about every episode.

The device administrator can set a night-time period 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. 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.

⚠ 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 the table below.

Table 3. 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 ✱	Several 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

3.4.4 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.

3.4.4.1 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 strap) to allow for better cleaning of the strap. When removed from the device, the straps can be washed with soap.
3. Do NOT let the device soak in liquid. When removed, the strap 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 strap are completely dry before wearing them again.

3.4.4.2 Removing the straps

The straps can be removed to facilitate cleaning or to change them if necessary. This is done by pressing the lock pins (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 strap clicks into place.

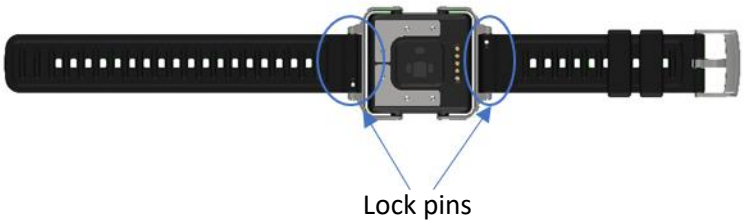


Figure 3-6. Wrist device strap removal

3.4.4.3 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.

3.4.4.4 Cleaning the gateway device

Cleaning the gateway is only necessary if it is visibly dirty.

1. Disconnect the gateway from the power supply.
2. Wipe the gateway with a slightly damp cloth.
3. Make sure the gateway is dry before reconnecting it to the power supply.

3.4.5 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.

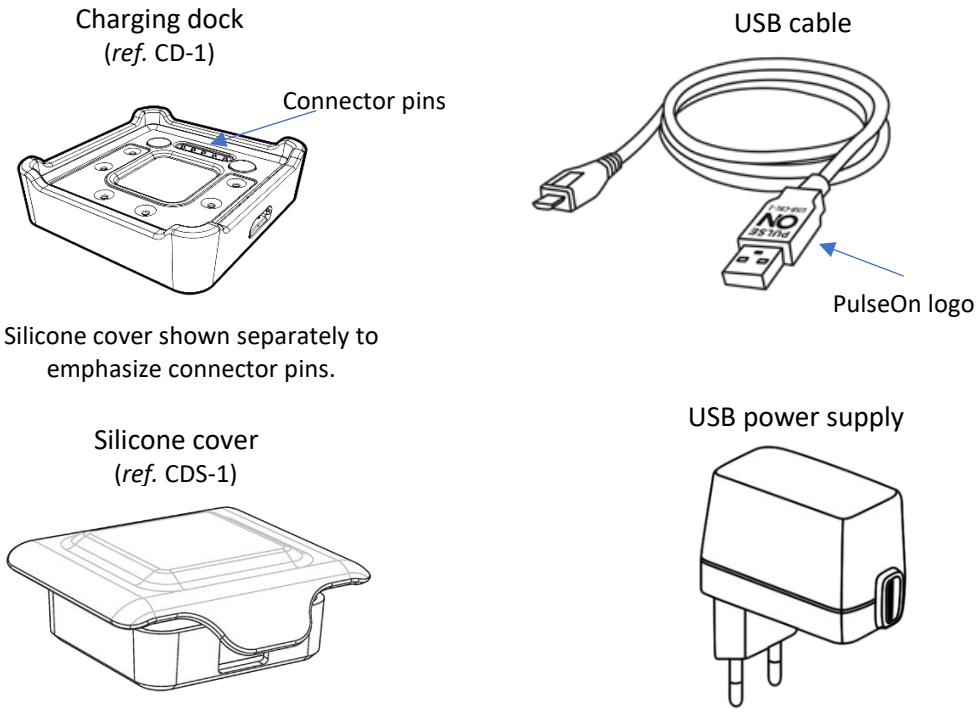


Figure 3-7. Wrist device charger parts

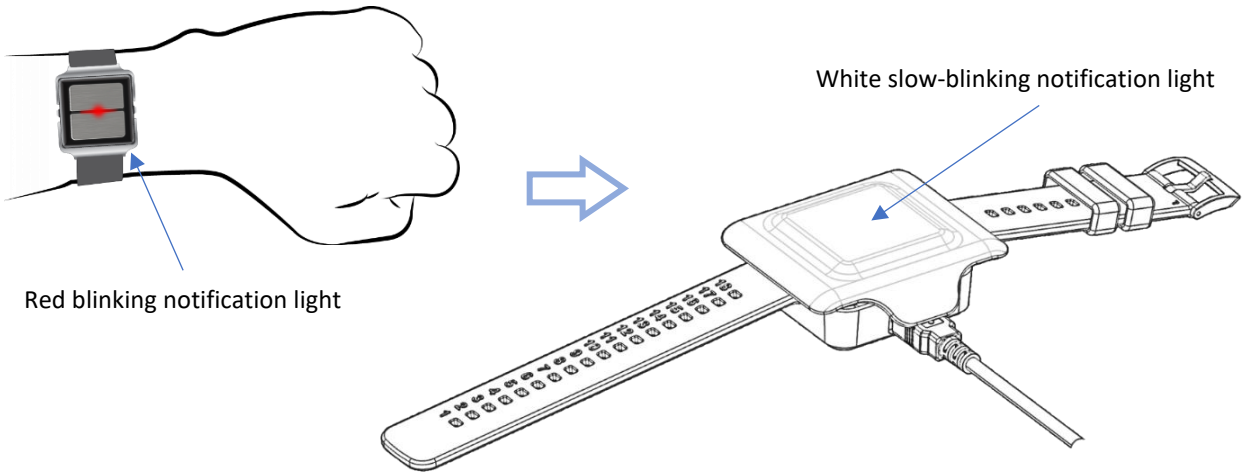


Figure 3-8. Recharging the wrist device

Caution

- Battery low notification. When the wrist device battery is running low, the device will vibrate every 15 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.

3.5 Wrist Device and Charging Dock Labels

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

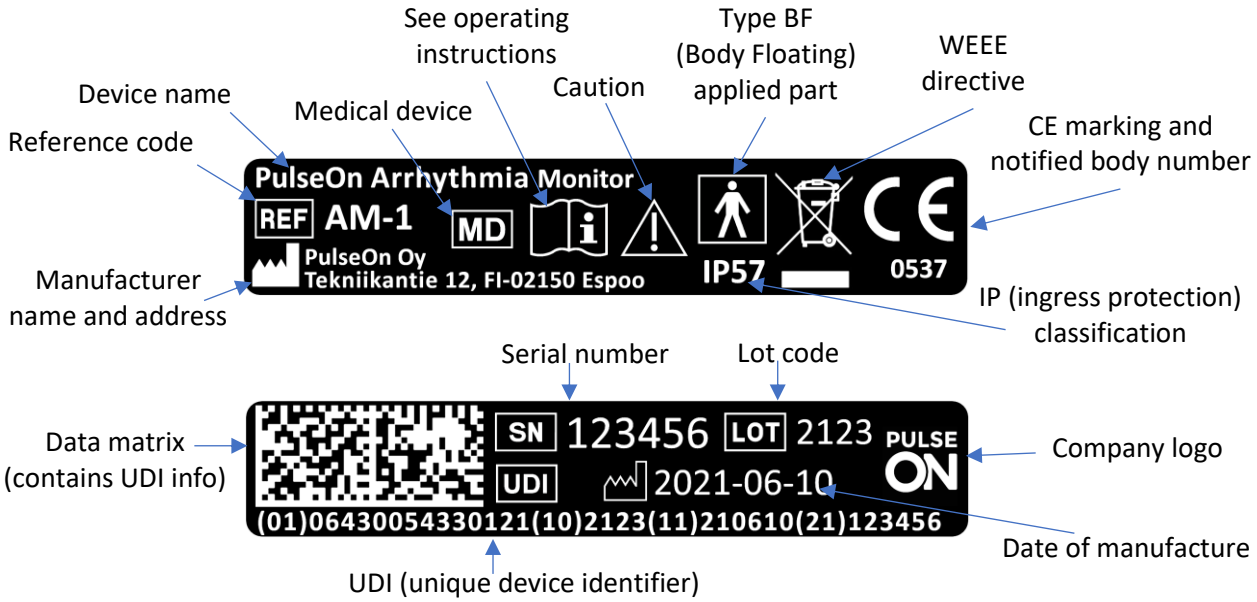


Figure 3-9. Wrist device labels

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.

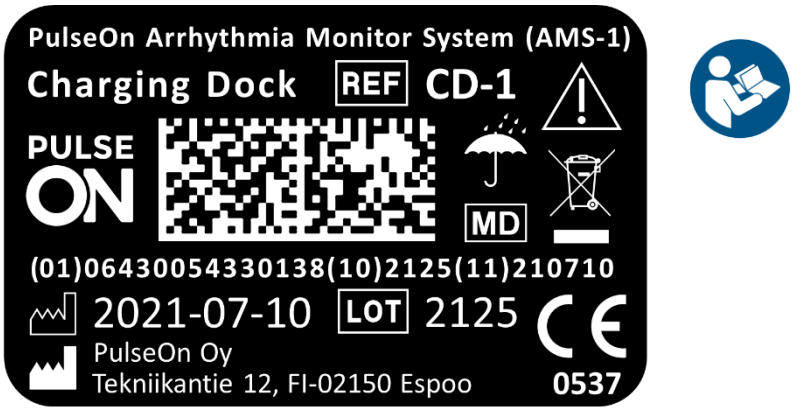


Figure 3-10. Charging dock label

3.6 Optional: Using Gateway

Medical personnel can provide the user with a PulseOn gateway for data transfer. If you have been given such a device, follow these instructions.

The gateway device is an optional non-medical product compatible with the PulseOn Arrhythmia Monitor System. It is an alternative way of transferring the measurement data from the wrist device to the Data Management Service (DMS) to provide a way for doctors to access the data during the measurement period.

The gateway connects to the wrist device via Bluetooth Low Energy (BLE) and to the DMS via mobile cellular networks. The gateway starts operating without any user interaction when it is powered on.

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 in 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.

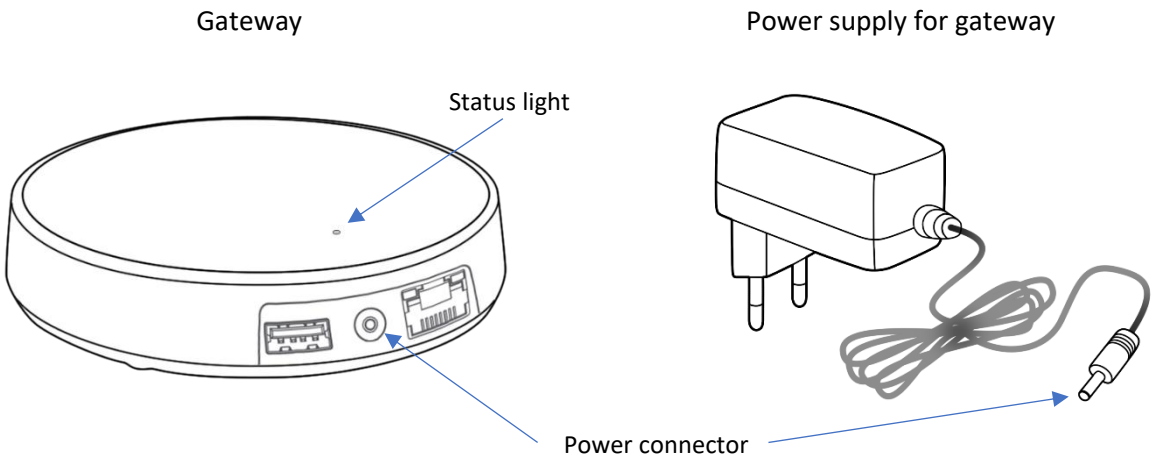


Figure 3-11. Gateway

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

3.6.1 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.
- The gateway needs to be situated so that it has a connection with the cellular network. Environments in which the associated BLE frequency range has a lot of traffic can reduce the data transfer speed.

Gateway specifications

- The gateway device is made by Treon.
    - Product name: Treon Gateway
    - Model number: 1111
    - Conformity: CE, FCC, IC

- The gateway power supply is made by GlobTek.
    - Model: GTM96180-1807-2-0
    - Ratings and principal characteristics:
        - Category: ICT / ITE / Medical Power Supply/Class 2/Household Power Supply
        - Input: 100–240 V~, 50–60 Hz
        - Output: voltage 5.0 V, current 3600 mA
    - Ingress protection: IP42
    - Conformity: CE, IEC 60601-1 approved

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 device does not affect the PulseOn Arrhythmia Monitor.

3.7 List of Parts and Accessories

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

Table 4. 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 device	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	

4 Instructions for Healthcare Personnel

4.1 Patient Preparation

The wrist device and accessories should be properly cleaned between each patient.

⚠ Ensure that the wrist device is thoroughly cleaned. See ***Cleaning*** for additional details.

⚠ Ensure that the wrist device is fully charged. See ***Recharging*** for additional details. If the recharger is given to the patient, instruct them on proper use of it.

The wrist device must be configured for the user before handing it over to the patient using the Data Management Software.

Good skin contact of the wrist device is important to ensure good signal quality when recording patient data. Poor contact may cause disturbances in the measurement signals, which can affect the analysis of the data. The wrist device should be tight enough to ensure that the device is connected to the skin, but not so tight as to impede blood flow or cause discomfort.

Instruct the patient on how to wear the device. Check the position and correct the tightness. See ***Wearing the Wrist Device*** for details. Write the tightness down with some variability e.g. holes 8–10, for the patient to remember.

The wrist device is shipped with strap size L (total length 25.0 cm). For a small wrist, a shorter strap will be needed. Strap size S has total length of 21.5 cm.

The straps can be changed by pressing the lock pins (see figure below) towards the centre of the strap and then removing the strap from the device. Likewise, the straps are put into place by pressing the lock pins so that the strap clicks into place.

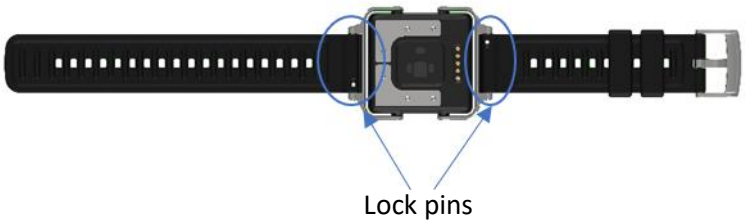


Figure 4-1. Strap removal lock pins

⚠ The two constantly glowing yellow LED lights on the bottom of the wrist device should be facing the patient's skin.

If the gateway device is given to the patient, instruct the patient in proper use of it. See ***Using the Gateway*** for additional details.

⚠ The wrist device needs to be linked to the patient in the Data Management Service. See ***Data Management Service (DMS)*** for instructions.

Instruct the patient on how to take an ECG measurement. See ***Taking an ECG Measurement*** for details.

Demonstrate the notification that the wrist device will give to prompt the patient to make an ECG recording. At a session start, the device is automatically set to one-time demonstration mode. After removing the device normally from the USB connection, the next failed ECG measurement will be followed by an arrhythmia notification. This notification is the standard ECG notification and will be over after 300 seconds or a successful ECG measurement. After a single demonstration notification, the device will function as normal.

Provide the patient with instructions and the equipment needed.

5 Data Management Service (DMS)

This part of the user guide describes common use cases of the Data Management Service (DMS). It directs the user in executing actions in the DMS by describing workflows related to those actions. Reading this carefully will help avoid misuse of the software and possible confusion that may arise while using it.

The instructions are divided into role-specific functionalities: common functionalities, administrative functionalities, and functionalities related to healthcare professionals.

Gathering and analyzing patient data requires, in addition to DMS, a local installation of DTS, as well as the wrist device (PulseOn Arrhythmia Monitor).

5.1 DMS-Specific Terminology and Abbreviations

Table 5. DMS-specific terminology and abbreviations

Term	Description
Two-Factor Authentication (2FA)	An additional layer of authentication is required for authorization. The DMS uses time-based one-time passwords from common authenticator apps.
Time-based One-Time Password (TOTP)	A single use, time-based verification code, provided by an authenticator app. Used for enabling two-factor authentication and logging in with user accounts with two-factor authentication enabled.
Authenticator App	A smartphone application that produces time-based one-time passwords for two-factor authentication (2FA) related tasks (login, enabling 2FA) Examples: Microsoft Authenticator, Google Authenticator.
Recovery Code	A code used for logging in, in case of loss of access to the authenticator app set up for the user account's 2FA.
DMSSystem (Customer System, Customer, System)	A way to distinguish different Customers of the owner of the software. Each customer and their users can be given access to data limited to the Customer/DMSSystem.
ContactPerson (Contact Person)	A contact person related to a Customer System/DMSSystem. One must be specified for each new Customer.
Organization	An Organization is always related to one DMSSystem. The Organization will have its own employee users. The Organization's admins will be responsible for user management.
Internal Organization	An Organization to which patients belong and under which measurement sessions are created.
External Organization (External Annotation Organization)	An Organization responsible for external annotations. External Organization users have a limited view of patient data and a special WorkflowManager user role.
External Annotation	A Patient's measurement session can be assigned to an External Organization for annotation.

OrganizationOffice (Organization office, office)	A sub item of an Organization. An organization, in addition to general contact details, may have one or more OrganizationOffices listed under it, with their own contact details.
User (ApplicationUser)	A user of the DMS application. An administrator or a medical professional.
SuperUser (Administrative user, PulseOn admin)	The role with the highest authorization within the system. The term “SuperUser” is also directly used to describe a User with the role of SuperUser. Can manage all users within the system. Can manage Customers/DMSSystems. Can manage Organizations.
SystemAdmin (DMSSystem admin, System admin.)	The role with the second highest authorization. Can manage Organizations that are associated with the system admins DMSSystem. Can also manage System and organization admins that are associated with those DMSSystems
Admin (Administrative user, Customer admin, Organization admin)	The term “Admin” is also directly used to describe a User with the role of Admin. Can manage Users associated with Organizations under the Admin user’s Organization.
Doctor (Medical professional)	A role describing a medical employee (doctor) of an Organization. The term “Doctor” is also directly used to describe a User with the Doctor role.
Nurse (Medical professional)	A role describing a medical employee (nurse) of an Organization. The term “Nurse” is also directly used to describe a User with the Nurse role.
WorkflowManager (Medical professional)	A role describing a medical employee (nurse or doctor) of an External Organization. The term “WorkflowManager” is also directly used to describe a User with the WorkflowManager role.
Patient	A patient describes a person associated with an Organization as a medical customer. The organization’s medical personnel can manage the patient’s data and measurement session information.
Social Security Number (SSN)	The unique social security number of a patient. Not required when creating a Patient.
Patient Identifier (Identifier)	A string used to identify a Patient. Social Security Number is not a requirement for a Patient entry, so the Identifier field can be used to distinguish between Patients.
Measurement session (MeasurementSession, session)	A measurement session is associated with a Patient. A measurement session can contain heart rate data (IBI data) and ECG measurements. It has a start/end date, and an associated device, and medical personnel (Doctor/Nurse users).
Assignment (Internal Assignment, External Assignment)	Assignments are a way to track who is responsible for annotating measurement sessions. Internal Assignments are used to link the Organization doctor to the patient measurement session. External Assignments are used when the Organization user moves annotation responsibility to an External Organization.
ShareCode	A Code External Organization shares with an Internal Organization to enable the Internal Organization to make External Assignments.

5.2 Disclaimer

The images and screen captures in this document are taken during development or from wire frame designs. This document is intended to work as instructional tool. A new user should become familiar with the system they are starting to use.

The ECGs measurements are analysed and processed by ECG Parser software provided by Cardiolund. The ECG Parser is advanced ECG analysis software. In addition to the ECG curve, the graphs may contain markings, essentially coloured lines with descriptions, related to beats (e.g. 'Short', 'SVES') and data sequences (e.g. 'Irregular Rhythm'). These are also produced by the ECG Parser. Additionally, the displayed beat lengths are calculated by the ECG Parser.

The Cardiolund ECG Parser is a medical software product for automated beat and rhythm analysis of 1-12 leads ECGs. The product is developed and put on the market by Cardiolund AB (Cardiolund AB, Scheelevägen 17, 223 63 Lund, Sweden). The ECG Parser is medical device software classified as Class IIa on the MDD (Medical Device Directive) classification scale, not MDR (Medical Device Regulation).

NOTE: The intended use of the Data Management Service (the software this document refers to) is to display sensitive patient data. Secure information related to patients of Organizations using this software will be stored in the database associated with the software and displayed by the software itself. This data can contain very sensitive information, such as social security numbers, addresses and phone numbers, as well as medical data. Managing user privileges and data access is of vital importance.

5.3 User Roles

The Data Management Service uses role-based authorization. The roles can be separated into two types: administrative roles and healthcare professional roles. Administrative roles can be given to users who are not healthcare professionals. Healthcare professional roles should be limited to users with medical degrees or other acceptable experience.

NOTE: Healthcare professional type roles can give users access to sensitive patient data. These roles should ONLY be given to authorized people.

The following table shows roles and their descriptions.

Table 6. User roles with descriptions

Role name	Role type	Description
SuperUser	Administrative	The SuperUser role is generally reserved for PulseOn employees. The SuperUser role allows a user to manage any user within an instance of DMS. The SuperUser role allows the creation of new DMSSystems and new Organizations under any DMSSystem (Customer System), as well as the editing of any DMSSystem or Organization.

SystemAdmin	Administrative	The Admin role is generally reserved for distributor (i.e. DMSSystem/Customer System) employees. The SystemAdmin role allows creating and editing Organizations under the DMSSystem that the SystemAdmin administrates The SystemAdmin role allows creating Other SystemAdmins and organizational Admins to the SystemAdmins DMSSystem
Admin	Administrative	The Admin role is generally reserved for Organization employees. The Admin role allows Organization-specific user management. The Admin role allows creating Doctors and nurses under the Organization
Doctor	Healthcare professional	The Doctor role should ONLY be given to healthcare professionals, essentially doctor employees working within a hospital or other healthcare organization. The role is Organization specific and allows a user to manage and create Patients under the specific Organization, and to manage measurement sessions. Most importantly, users with the Doctor role view measurement session data. This data, i.e. ECG graphs, is reviewed and assessed by the medical professional user. The role allows the addition of annotations to this data according to the assessment.
Nurse	Healthcare professional	The Nurse role should ONLY be given to healthcare professionals, essentially nurse employees working within a hospital or other healthcare organization. The role is Organization specific and allows a user to manage and create Patients under the specific Organization, and to manage measurement sessions. Most importantly, users with the Nurse role view measurement session data. This data, i.e. ECG graphs, is reviewed and assessed by the medical professional user. The role allows the addition of annotations to this data according to the assessment.
WorkflowManager	Healthcare professional	The WorkflowManager role should ONLY be given to healthcare professionals, essentially doctor or nurse employees working within a hospital or other healthcare organization. The role is specific to the External Organization and allows the user to forward External Assignments to doctors belonging to the External Organization.

5.4 Common Functionalities

Required privileges	**Description**
Any role	A user with any role in the system

5.4.1 Login

Figure 5-1. A screen capture of the login form

Logging in requires an authorized and confirmed user account. To log in, the user navigates to the URL of the DMS deployment. The web application will then present the login page to the user.

The user inputs their login credentials, email and password, and presses “Log in”.

After pressing the login button there are four possible outcomes:

1. The user is redirected to the front page relevant to their role within the DMS instance and can begin using the service.
2. The user is redirected to the two-factor authentication (2FA) page, and must enter a 2FA verification code from their authenticator app.
3. The user is redirected to their User Account’s 2FA settings, and informed that they must enable 2FA in order to use the DMS (this is because some Organizations may require 2FA). In this case, the user must download an authenticator application (e.g. Google Authenticator or Microsoft Authenticator) and enable 2FA.
4. The user fails to log in. The user may have input an invalid email/password combination, or their user account may be disabled.

5.4.2 Account recovery

A link with the title “Can’t log in?” is displayed on the login page. If the user has forgotten their password, they can click on the link. This opens a page for account recovery, where the user can input the email address associated with their account. The DMS then sends an email with further instructions to the given email address.

For regular users, the sent email contains a link that can be used to reset the user’s password. By clicking the link, the user is redirected to a page where they enter a new password for their account. After this, the user can no longer log in with their old password. For users who have activated ‘Organization login’ the email will contain a link that redirects them to log in using the configured ‘Organization login’. For users who have not yet confirmed their email address for their account, the email will contain a link that can be used to confirm their email address.

5.4.3 Enabling Two-Factor Authentication

A user may be required to enable 2FA by their Organization's settings. They may also enable 2FA at their own choosing.

To enable 2FA, a user navigates to their account management page by clicking on their username from the top right corner. A page titled "Manage Account" should open. The user then clicks on "Two-factor authentication" in the list under the title.

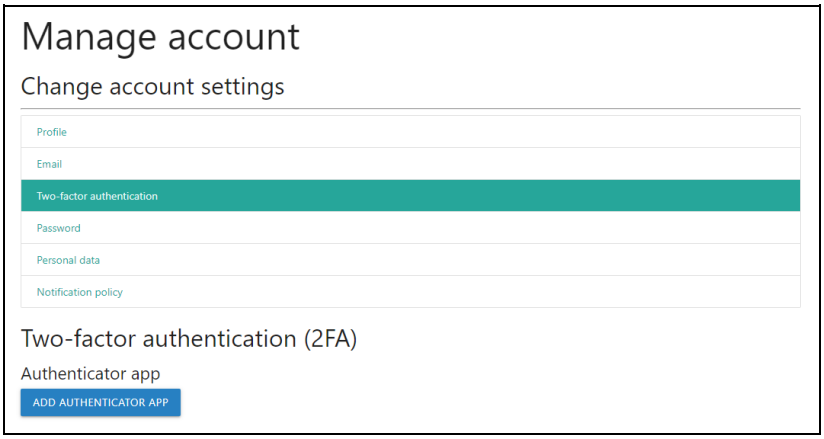


Figure 5-2. A screen capture of the two-factor authentication page

On the 2FA page, the user selects "ADD AUTHENTICATOR APP" to move forward with enabling 2FA and setting up an authenticator app on their mobile phone.

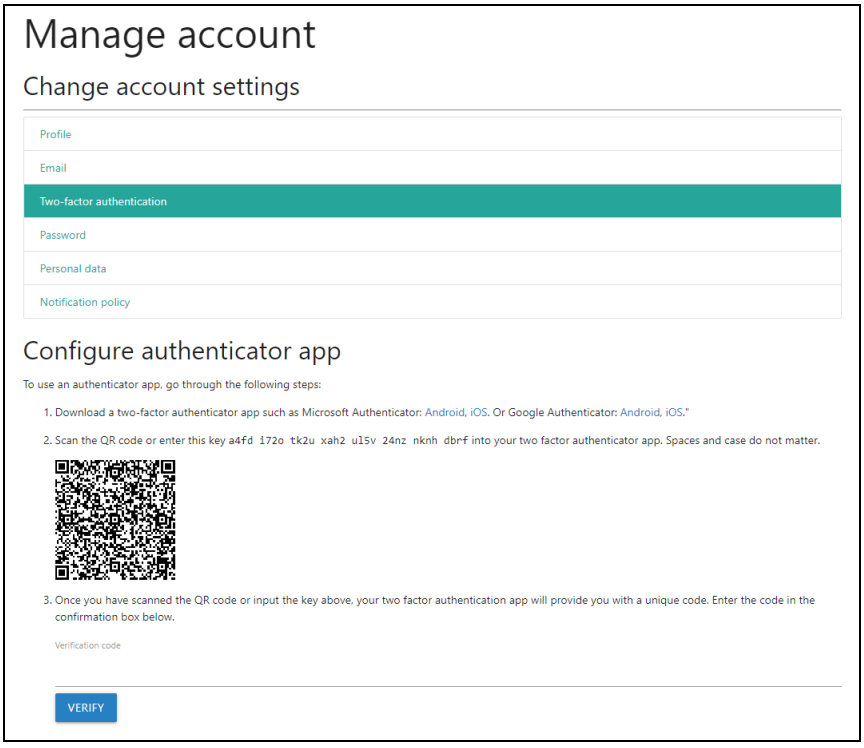


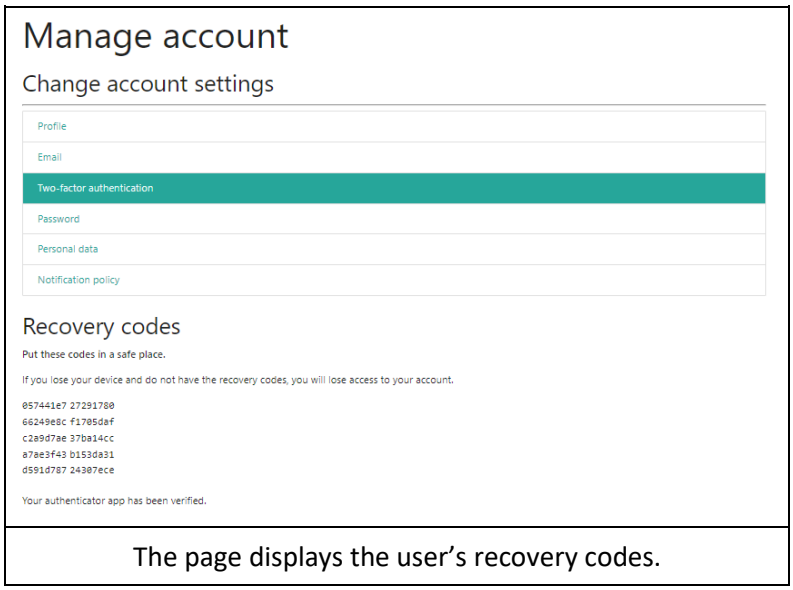
Figure 5-3. A screen capture of the page for configuring an authenticator app

According to the instructions, the user then downloads an authenticator app (preferably Google Authenticator or Microsoft Authenticator) or uses one they already have installed. After following the instructions on screen, i.e. inputting the text code or reading the QR code from DMS, and subsequently entering the time-based one-time password (TOTP) verification code from the authenticator app, the user clicks “Verify”.

There are two possible outcomes from clicking “Verify”.

1. The verification code is wrong and the user is informed about it.
2. The verification code is correct and the user is informed about it. Additionally, the user is presented with their recovery codes. The user should store these securely in a place of their choosing. They are needed if access to the designated authenticator application is somehow unavailable.

NOTE: Securely storing the recovery codes is essential. They essentially provide an alternative 2FA method.



The page displays the user’s recovery codes.

Figure 5-4. A screen capture of the page after successful authenticator app setup

The user can now log in using 2FA.

5.4.4 Login with Two-Factor Authentication

The login with 2FA process begins with the standard login process, i.e. the user inputs their email and password and clicks “Log in”. After that, if the user has two-factor authentication enabled, they are presented with a page asking for the TOTP 2FA verification code. The user enters the code, and presses “Log in”. The possible outcomes are:

1. The verification code is invalid and the user is informed about it.
2. The verification code is valid and the user is logged in and redirected to the front page view relevant to their roles.

On the 2FA login page there is also a link to logging in using the aforementioned recovery codes. A user can log in with a single recovery code only once. After login, the specific recovery code becomes invalid.

5.4.5 Managing Two-Factor Authentication Settings

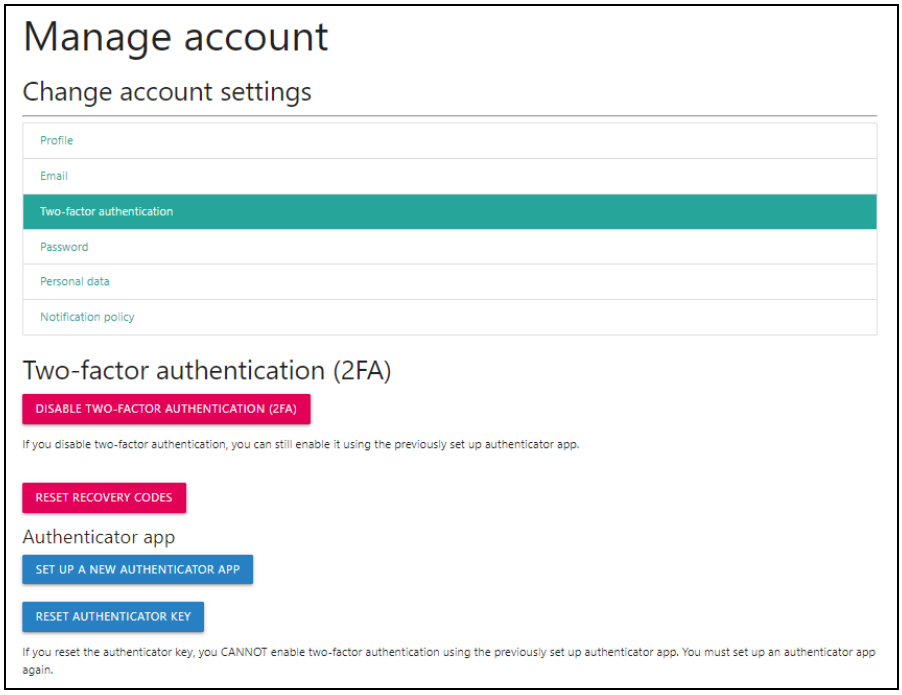


Figure 5-5. A screen capture of the two-factor authentication page after enabling 2FA and setting up an authenticator app

Managing two-factor authentication after enabling it involves a few functionalities.

1. The user can elect to “DISABLE TWO-FACTOR AUTHENTICATION”, in which case they can log in without entering a 2FA code and enable 2FA later with a TOTP verification code from the previously configured authenticator setup.
2. The user can “RESET RECOVERY CODES”, which creates new recovery codes in case the previous ones are running out or lost.
3. The user can “SET UP A NEW AUTHENTICATOR APP” using the same key or QR code as previously.
4. The user can “RESET AUTHENTICATOR KEY”, generating a new key and QR code. This will require the user to set up their authenticator app again.

5.4.6 Enabling Organization login (single sign-on, SSO)

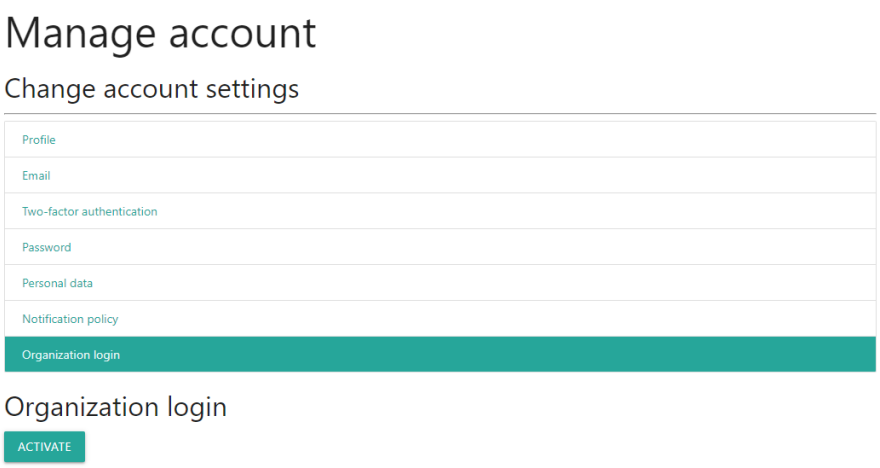


Figure 5-6. A screen capture of the Organization login settings page

A user may be required to enable Organization login by their Organization's settings. If it is required, the user is directed to their Organization login management page automatically, where they can activate the authentication by clicking the "Activate" button.

Enabling Organization login removes the possibility of logging in normally using an email address and password. Similarly, password recovery is also disabled.

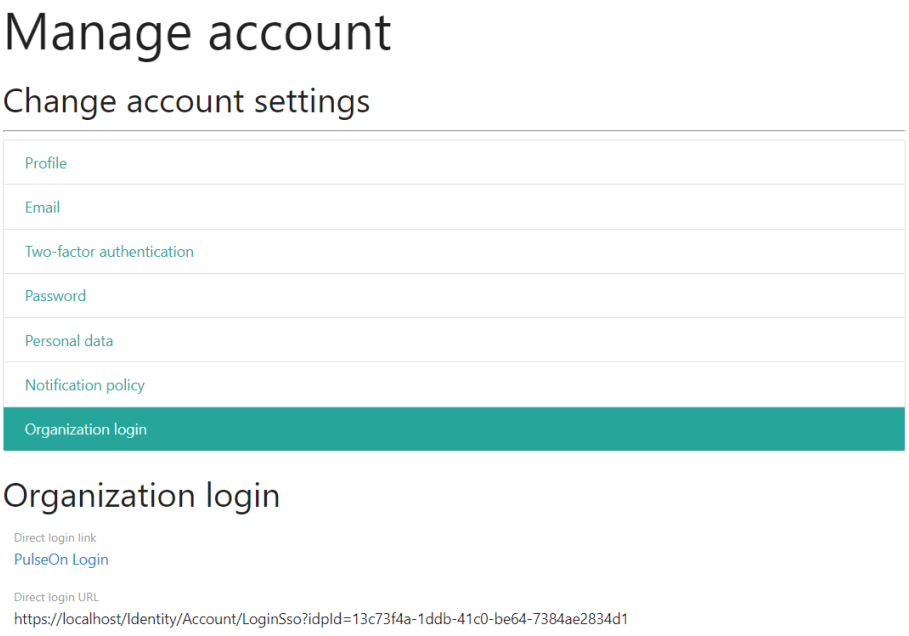


Figure 5-7. A screen capture of the Organization login settings page after activation

After enabling Organization login, the user can view their Organization login settings to find a link that can be used to authenticate DMS directly. The link can be easily bookmarked by dragging it to the bookmarks bar. If the link does not work, the URL address for the direct login can be found on the same page.

5.4.7 Login with Organization login

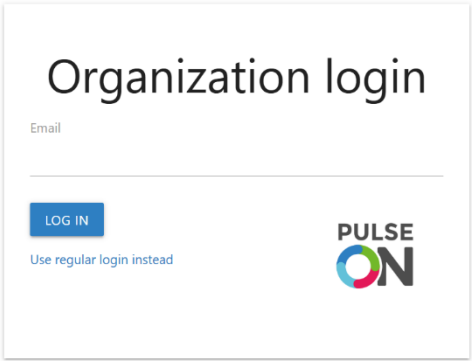


Figure 5-8. A screen capture of the Organization login page

Logging in with Organization login can be done using the link found in the user's Organization login management page. Alternatively, the page can be navigated to using the "Use organization login instead" link in the regular login page. Here the user can log in simply by giving the email address that was used to create the account.

5.4.8 Managing Common User Settings

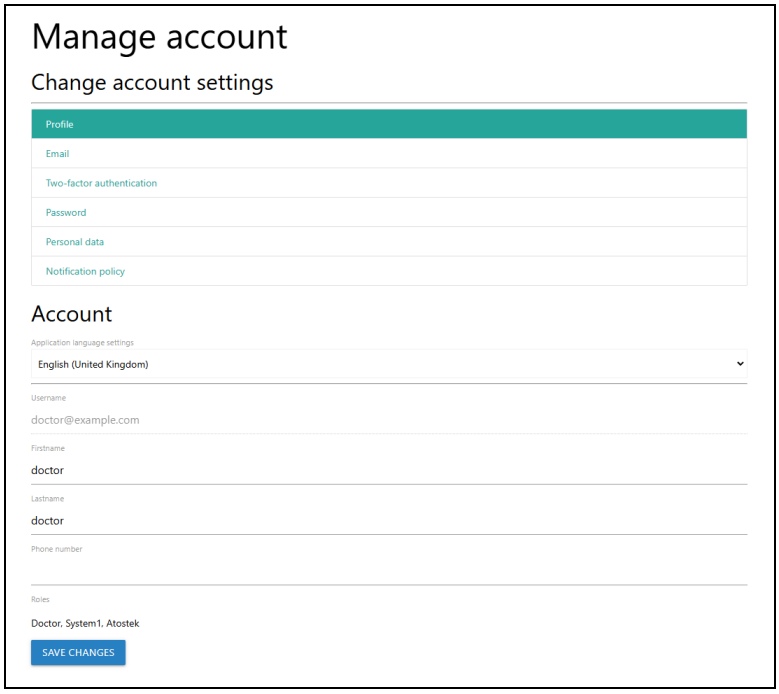


Figure 5-9. A screen capture of the Manage Account page. Profile section selected.

The Manage Account page is accessible by clicking the username of the currently logged in user. On this page, the user can manage settings related to their User Account. The page is split into sections:

1. Profile: General profile settings; Application language, First name, Last name, Phone number. The roles are also displayed, but a user cannot adjust their own roles. NOTE: This general rule has one exception, as follows. If a user has an Admin role and belongs to an organization that allows self-assigning medical roles for Admins, they can add/remove Doctor and Nurse roles for themselves in those organizations.
   NOTE: Adjusting language settings requires accepting functional cookies.
2. Email: Here the user can change their email address by inputting a new desired email address and clicking “CHANGE EMAIL”. If changed, an email is sent to the specified email address and the user can confirm the change by clicking a link in the email.
3. Password: Here the user can change their password by entering their current password and the new desired password twice, and clicking “UPDATE PASSWORD”.
4. Two-Factor Authentication: 2FA related functionalities are described in detail earlier.
5. Personal data: Here the user can download data related to their user account or choose to delete their account. NOTE: An admin authorized to manage the user can also download or delete a user’s data, if requested by the user.
6. Notification policy: Here the user can create or modify their user-level notification policy.

5.5 Administrative Functionalities

5.5.1 Organization Management

Required privileges	**Description**
SystemAdmin	Customer employee with admin role associated with the Customer System/DMSSystem.

NOTE: Patient data is Organization specific. The Doctor/Nurse role for an Organization should only be given to authorized personnel.

Organizations are designated to specific Customer Systems. Organizations can be managed by either a PulseOn administrator, i.e. a SuperUser, or a Customer administrator, i.e. a user with the role of SystemAdmin associated with the Customer/DMSSystem the Organization is (or will be) associated with.

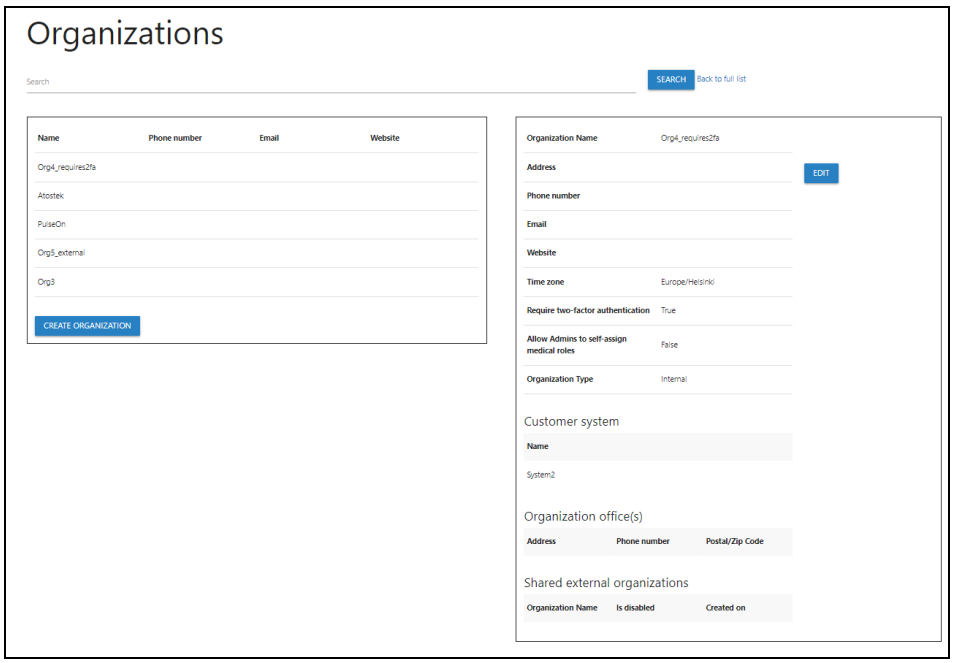


Figure 5-10. Organization system listing

5.5.1.1 Organization Security Settings

Organizations have the option to force Two-Factor Authentication (2FA). If 2FA is forced, any new or existing Users associated with that Organization must enable 2FA. If they do not have 2FA enabled, the DMS will redirect them to the two-factor authentication page until they enable it. An administrator is required to set the two-factor authentication to forced if the installation is publicly available. The required 2FA option is available when creating or editing organization information.

Inactive sessions are automatically logged out. The duration of inactivity can be configured in the edit organization settings. When the login timeout is not configured, the default 15 minute timeout is used. In addition, all active sessions are automatically closed after 8 hours.

5.5.1.2 Creating an Organization

To add a new Organization, a PulseOn admin, i.e. a SuperUser or a SystemAdmin user of the specific Customer system, first needs to be logged in.

The user navigates to the page listing Organizations, clicks on the link titled “ADD NEW ORGANIZATION” (or similar). After clicking the link, the CreateOrganization page will be displayed. There the user should input the data of the Organization that is being created. The user selects the desired Customer System from a dropdown (a SystemAdmin may be associated with multiple Customer systems, and the PulseOn SuperUser can manage all systems). The user clicks on the Is External Organization checkbox to make the created Organization External, otherwise the Organization stays as the default-type Internal Organization.

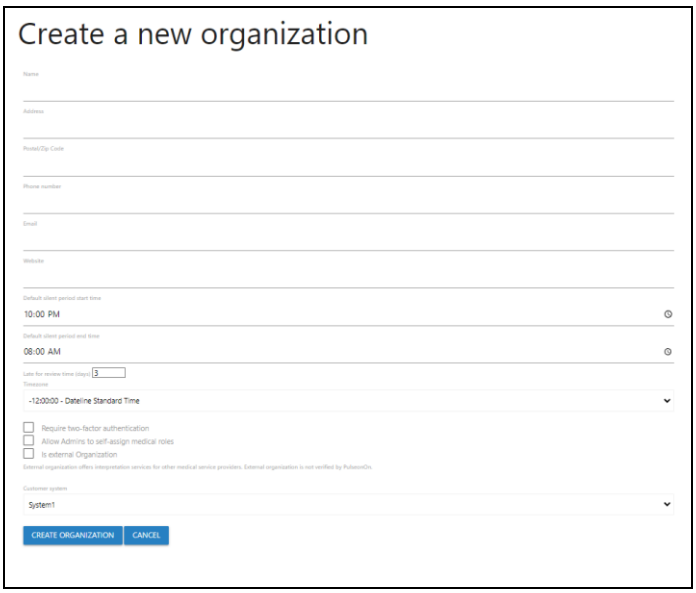


Figure 5-11. The CreateOrganization page

To create the Organization, the user clicks on a button titled “CREATE ORGANIZATION”.

5.5.1.3 Viewing and Editing an Organization

To view or edit an existing Organization’s information, a PulseOn admin, i.e. a SuperUser or a SystemAdmin user of the specific customer system, first needs to be logged in. Additionally, the Organization the user wants to edit should exist within the system. Organizations’ OrganizationAdmin can also view the Organization information but not edit it.

The user navigates to the page listing Organizations, selects the desired Organization from the list of Organizations and clicks on a link to edit its information, i.e. “EDIT” (see image titled “Customer System listing”). On the edit page, the user makes changes.

The contact information of the organization can be changed in the contact information section.

The measurement settings section contains the default configurations for measurement sessions.

The security settings contain configurations related to security. For example, the enforcement of MFA and login timeout configurations can be found within the security settings.

The organization offices section is used to provide additional information about the offices in the organization.

The user can add/modify the organization notification policy in the notification policy section. The organization notification policy acts as the default for the time of sending email notifications to the users. This is necessary in cases where the user has no notification policy of their own, so the system defaults to the organization notification policy of the first Organization the user belongs to.

The user can add External Annotation Organizations by entering the ShareCode of an External Organization in the External Organizations part of the organization settings page if the Organization is Internal. External Organizations use the same shareCode to share themselves with multiple Internal Organizations. After making the changes, the user can choose to click “SAVE CHANGES”, saving the changes to the database. Alternatively, the user can click “CANCEL” to return to the Organization list page and omit the changes made.

The user can view the Organization login (SSO) settings in the Organization login section. Here the user can view the name of the identity provider used for Organization login authentication as well as the link that can be used to directly authenticate to DMS using SSO.

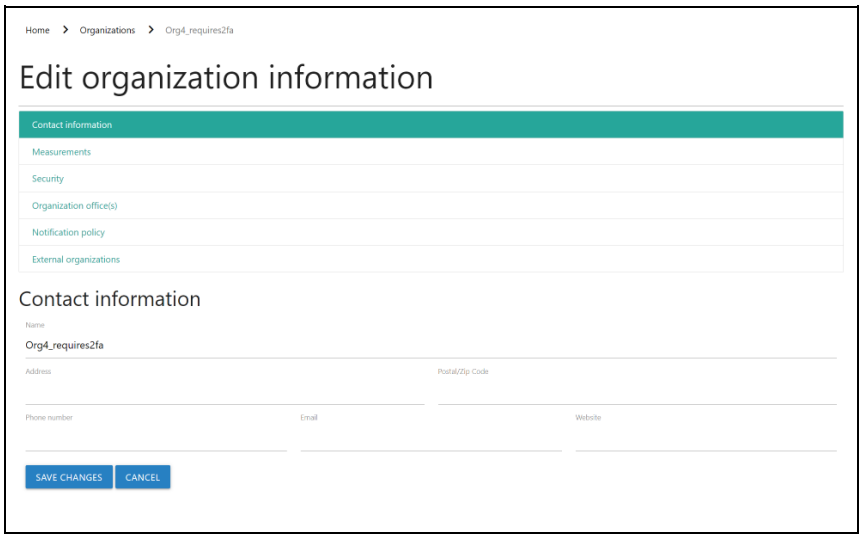


Figure 5-12. Editing an Organization

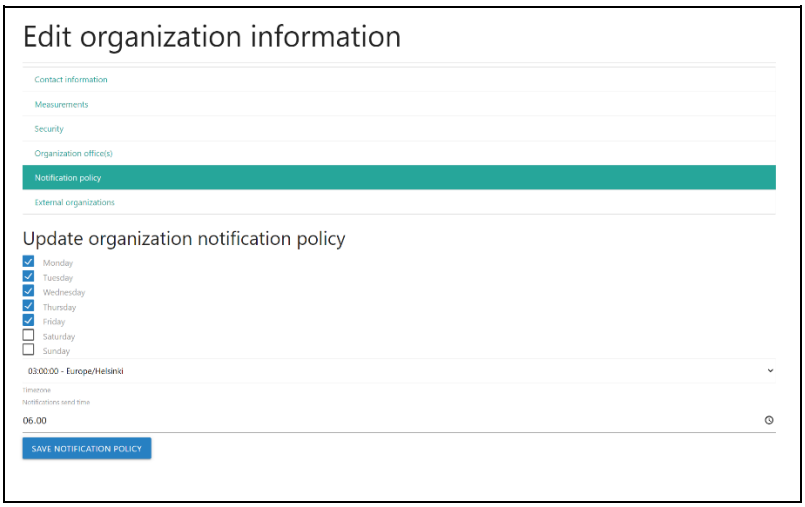


Figure 5-13. Editing organization notification policy

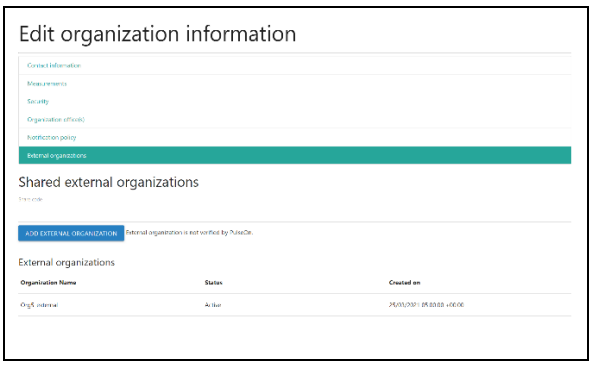


Figure 5-14. Adding shared external organizations

5.5.1.4 Deleting an Organization

To delete an existing Organization, a PulseOn admin, i.e. a SuperUser or an Admin user of the specific customer system, first needs to be logged in. Additionally, the Organization the user wants to delete should exist within the system.

The user navigates to the page listing Organizations, selects the desired Organization and clicks “EDIT” (see image titled “Customer System listing”). On the EditOrganization page, the user chooses “DELETE ORGANIZATION” (See image titled “Editing an organization”) and confirms their choice on a confirmation modal.

NOTE: The data deletion cannot be undone.

Certain factors can affect the ability to delete an Organization:

1. The Organization has MeasurementSessions
2. The Organization has patient data
3. The Organization has users with roles associated with it.

If the Organization has gathered patient data and MeasurementSessions, it cannot be deleted. It should be kept in the system for traceability.

5.5.2 User Management

Required privileges	**Description**
SuperUser	PulseOn administrative employee
SystemAdmin	Customer employee with admin role associated with the Customer System/DMSSystem.
Admin	Customer employee with admin role associated with the customer Organization

Users can be roughly divided in two categories: administrative users and medical personnel. Administrative personnel have the role of SuperUser, SystemAdmin or OrganizationAdmin. SuperUsers are generally PulseOn employees with full administrative privileges. SystemAdmin users have Customer/DMSSystem-specific

administrative privileges, i.e., they can manage Organizations and Users associated with a specific Customer/DMSSystem. OrganizationAdmins or just admins have Customer Organization-specific administrative privileges, i.e., they can manage Users associated with a specific Organization.

5.5.2.1 Creating a User

To add a new User, a PulseOn admin, i.e., a SuperUser, a SystemAdmin or an Organizational Admin user of the specific Customer System or Organization, needs to be logged in.

The user first navigates to the User list page.

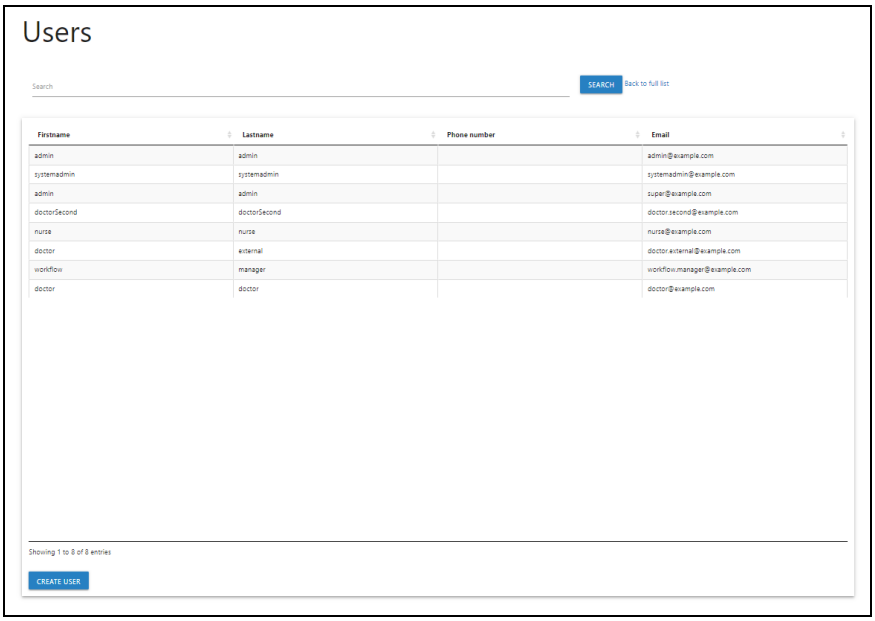


Figure 5-15. A screen capture of the user list page

On the User list page the logged in user clicks on “CREATE USER”, and will be redirected to the CreateUser page.

On the CreateUser page, the logged in user inputs the information of the user to be added. Role selection is done on the same page.

Role selection happens in the following way:

1. The user selects the desired role.

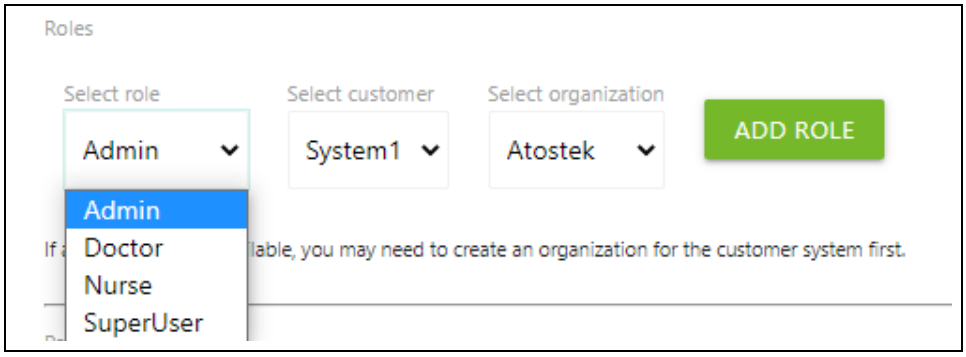


Figure 5-16. A screen capture of a User selecting a desired role from the dropdown

2. The user selects the desired Customer/DMSSystem.

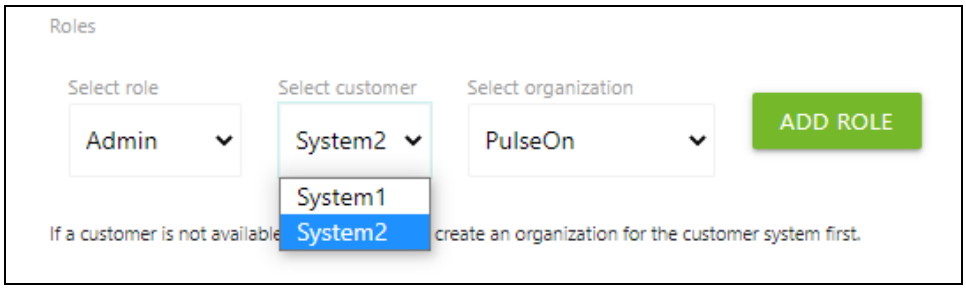


Figure 5-17. A screen capture of a User selecting a desired Customer/DMSSystem from the dropdown

3. The user selects the desired Organization.

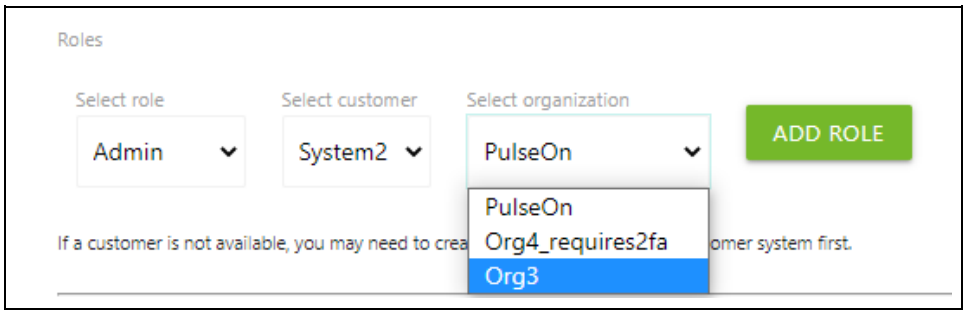
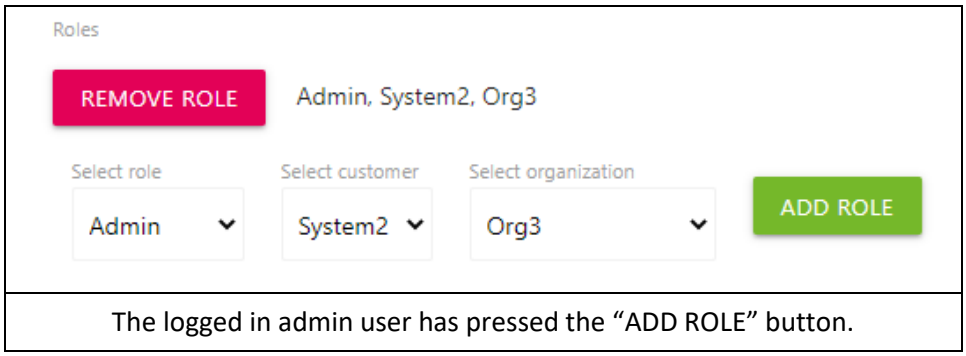


Figure 5-18. A screen capture of a user selecting the desired Organization from the dropdown

4. The user clicks on the “ADD ROLE” button.



The logged in admin user has pressed the “ADD ROLE” button.

Figure 5-19. A screen capture of the role selection field, with a single role added to the User to be created

After adding the role, the logged in administrator can choose to remove it by pressing the “REMOVE ROLE” button. The administrator can also select other role variations by making changes to the dropdown selections as desired and clicking “ADD ROLE” again.

NOTE: If the user is a SystemAdmin user of a specific Customer/DMSSystem, they can only see the Customer/DMSSystems they are associated with in the dropdowns. Additionally, the dropdown titled “Select

Organization" is filled with Organizations associated with the currently selected Customer/DMSSystem. This is also true for Organization admins who can only see organizations under their management.

NOTE: Patient data is Organization-specific. The Doctor/Nurse role for an Organization should only be given to authorized personnel.

NOTE: The user organizations added can belong only to Internal or External Organizations. An external user can only have roles belonging to a single External Organization, whereas Internal Organizations can have user roles belonging to multiple Internal Organizations.

NOTE: The user can only have one organization which requires Organization login (SSO) authentication. If the user has multiple organizations that require Organization login authentication, the user cannot log in at all.

After inputting the correct user information and desired roles, the user can choose to create the user. This happens by pressing the "CREATE USER" button under the form. If the form validation is passed, the user is directed to the User list page, and the new user should be visible.

5.5.2.2 Viewing and Editing a User

To view or edit another User Account's information, a PulseOn admin, i.e., a SuperUser, a SystemAdmin or an Admin user of the specific Customer System the user to be edited is associated with, first needs to be logged in.

The logged in user then navigates to the User list page depicted above. The logged in User then selects the User they want to edit from the list of users. After clicking on the desired user, the User page will be displayed.

Figure 5-20. A screen capture of the User page

On this page, the administrator will see the selected User's current information on the right, and a few links on the left.

1. By clicking on "Account Settings", the administrator is redirected to a "Manage Account" page similar to the one displayed under the title "Managing common user settings".
2. By clicking "Deactivate User", the User account is deactivated, and the User is unable to log in and use DMS. The administrator then clicks on the same button, now titled "Activate User" to undo the action.

The Manage Account page has limited options when an administrator enters it to manage another users settings. An administrator can change the user's name and phone number. Additionally, he can set a new email, which requires the user to confirm the email change via a link in their new email inbox.

Admins can also change the roles other users have. This is done in the Profile section of the Manage Account page. The process of adding and removing roles is identical to that described in the ***Creating a User*** section.

An administrator cannot change another user's password or manage authenticator application related settings. An administrator can, however, disable 2FA for the user for 24h. This is for cases where a user has lost access to their authenticator application and recovery codes.

To disable 2FA, the admin navigates to the two-factor authentication section of the user's Manage Account page. There, the admin can find a button titled "Disable 2FA for 24h" (or similar). After clicking on the button, the admin is required to confirm the action by clicking on a modal. After disabling 2FA, the user being managed can log in with only their email and password.

If the administrator chooses to disable 2FA for 24 hours, and the user does not log in and again setup their 2FA authentication, the 2FA will be enabled again automatically after 24 hours. Therefore, if the user still does not have access to the authenticator app or recovery codes, they cannot log in or use the application. In such a case, an administrator can redo the 2FA disabling process.

5.5.3 Reporting

Required privileges	**Description**
SuperUser	PulseOn administrative employee
Admin	Customer employee with admin role associated with the customer Organization

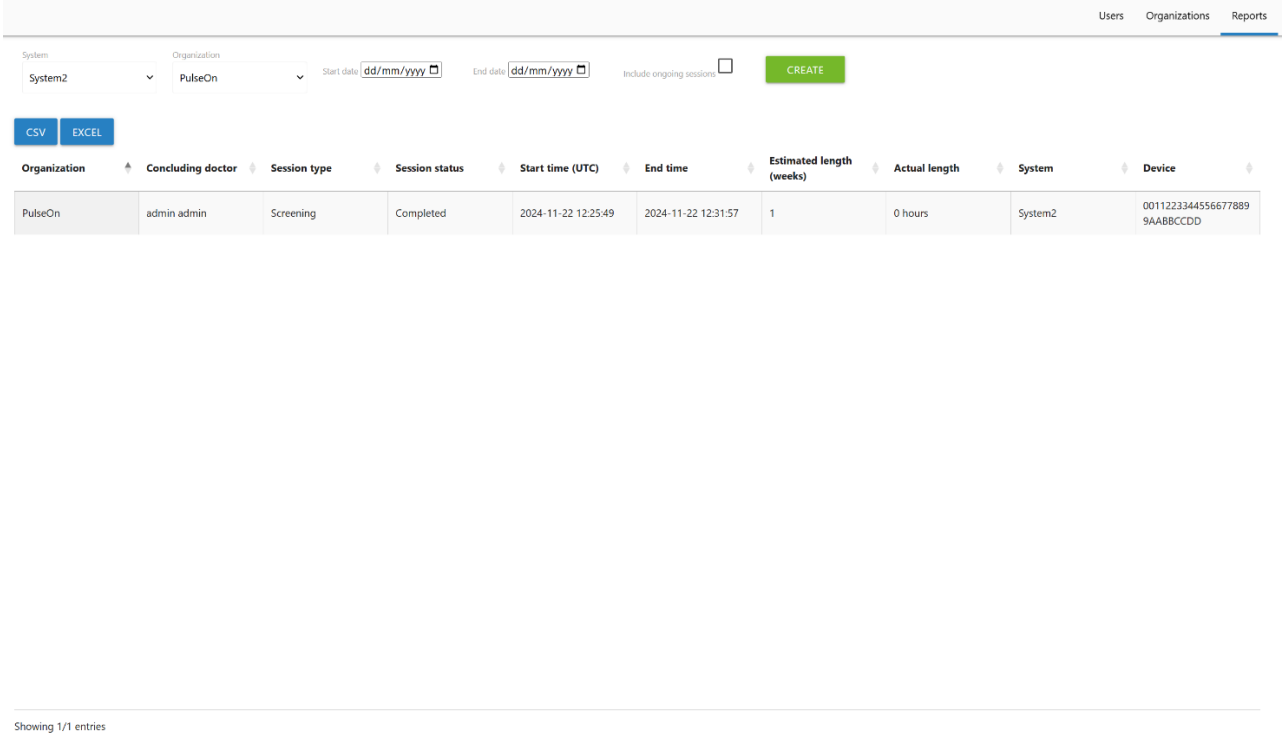


Figure 5-21. Reporting view

The reporting view can be used to generate reports of the measurement sessions for system or organization. The report can be downloaded as excel or csv from the corresponding buttons. The start time and end time can be used to search for specific sessions during a time span. The end time is used to determine if measurement session falls under the specified time span.

5.6 Functionalities Related to Medical Personnel

Required privileges	Description
Doctor	A doctor; medical professional. Employee of a Customer System.
Nurse	A nurse; medical professional. Employee of a Customer System.

5.6.1 Patient Management

Patients are managed by users with the Doctor or Nurse role. Patients are associated with an Organization. Only medical personnel associated with that Organization are allowed to manage and view the information of those Patients.

5.6.1.1 Creating a Patient

To create a new Patient, a Doctor or Nurse user first needs to be logged in.

The Doctor/Nurse navigates to the Patients page.

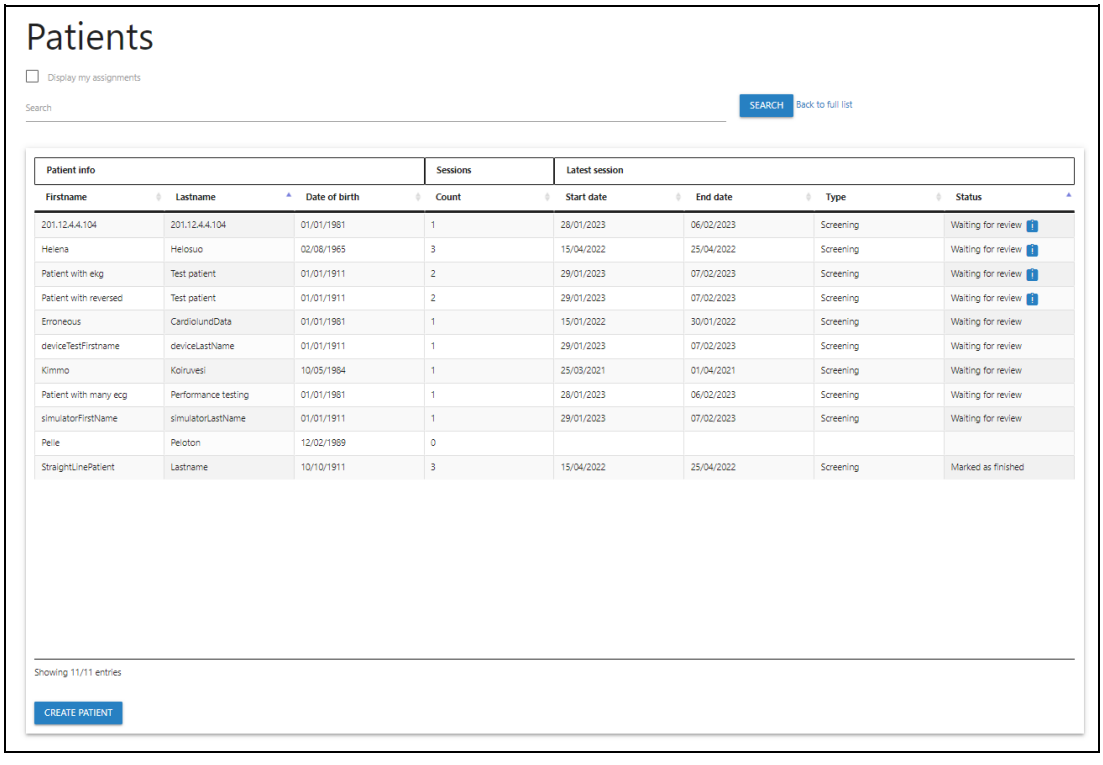


Figure 5-22. A screen capture of the Patients (Patient list) page

On the Patients page, the User selects “CREATE PATIENT”, which should redirect the User to the Create Patient page.

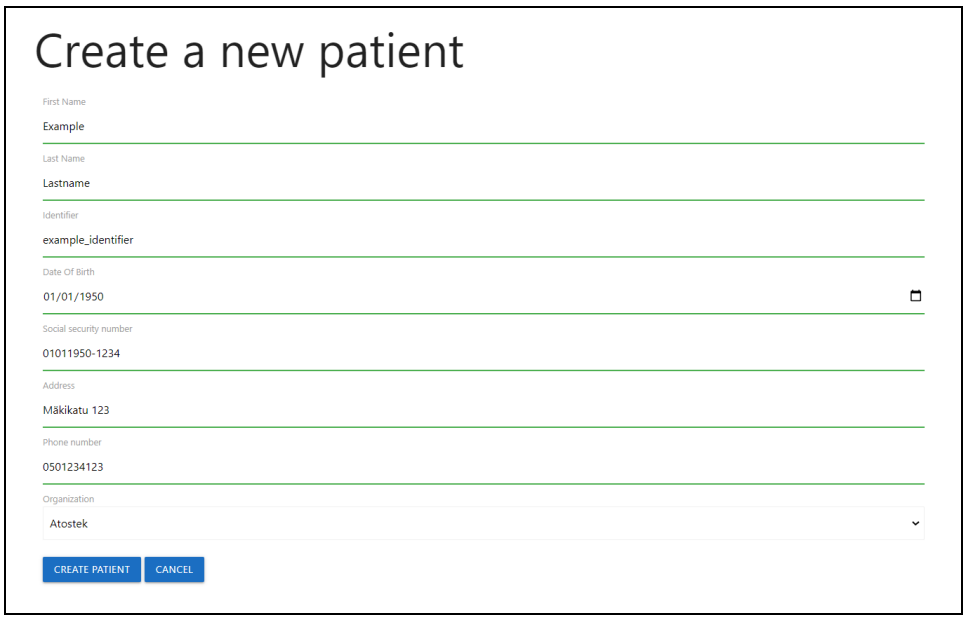


Figure 5-23. A screen capture of the Create Patient page

On the Create Patient page, the user fills in the Patient's information, including an identifier. The identifier is a required field that can be used to find a Patient on the Patients page. The social security number is not a required field, but can be given if the Patient so desires.

The medical professional User fills in the form with the Patient's information and the Organization they want to associate the Patient with. A medical professional may have multiple Organizations they are authorized to work for, but should select the Organization the Patient is currently visiting.

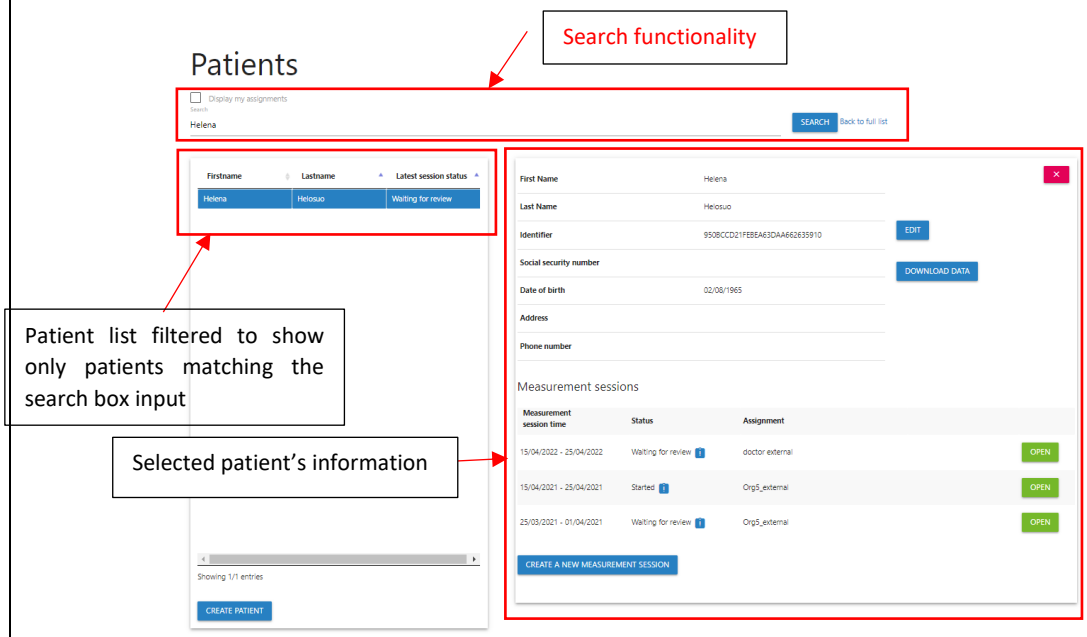
After filling in the form and verifying the information, the User clicks on "CANCEL" or "CREATE PATIENT". Clicking "CANCEL" results in redirection to the Patient list without a Patient entry being created. Clicking on "CREATE PATIENT" results in a redirection to the Patient list and a new Patient entry being created. The new Patient should now be displayed in the list of Patients.

5.6.1.2 Viewing and Editing Patient Information

To view or edit an existing Patient's information, a Doctor or Nurse user first needs to be logged in.

The Doctor/Nurse navigates to the Patients page, selects a Patient in the list and clicks on it. The User can also input the Patient's identifier into the search box at the top of the screen, and click "FILTER". This limits the results to those Patients with a Patient identifier matching the input. By pressing "Back to full list", the filtering can be undone. If the user is in a doctor role, by clicking the "Display My Assignments" button under the page heading, the user can filter patients based on whether the patients have measurement sessions assigned to them.

In the columns for session status, there can be icon which indicates that the measurement session is late or that the measurement session is late for review.



Note: The red parts of the image are not part of the software and were added for clarity.

Figure 5-24. A screen capture of the Patients page with filtered Patients displayed, and a Patient selected from the list

In the partial Patient Information view on the right of the image above, the User can choose to modify the Patient's information, by clicking "MODIFY", or Archive the patient, by pressing "ARCHIVE PATIENT".

If the user presses "DOWNLOAD DATA", a .csv file containing the Patient's data will be downloaded (GDPR). If the User presses "MODIFY", the Edit Patient page will open.

Here the user can choose to update the Patient's information, delete the Patient or cancel the process and go back.

Figure 5-25. A screen capture of the Edit Patient page

On this page, the User can choose to update the Patient's information. After updating the information, the User can choose to press "CANCEL" or "EDIT PATIENT". If the User presses "CANCEL", the DMS will redirect them to the Patients page and the changes will be discarded. If the User presses "EDIT PATIENT", the DMS will redirect them to the Patients page and the changes will be saved to the database. The updated information should now be visible in the Patient's information. In the measurement sessions list in the sidebar, the User can select doctors belonging to patient organizations for internal assignment or assign the measurement session to an External Organization where it is forwarded to the External Organization doctor for annotation.

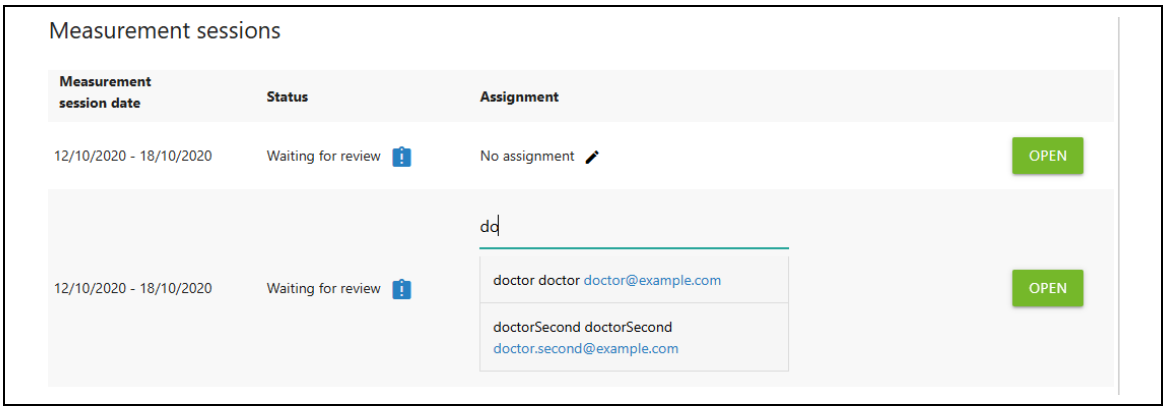


Figure 5-26. A screen capture of changing the assignment on the Patients page

5.6.2 Measurement Sessions

A measurement session is a time period during which a Patient is assigned a PulseOn wrist device by a Doctor. The Doctor will instruct the Patient on how to use the device correctly.

Measurement sessions are initiated via the DMS UI. The Patient for whom the healthcare professional wants to start the measurement session needs to exist in the system first. Additionally, the Data Transfer Software (DTS) needs to be running on the Doctor's computer, and the device needs to be connected to the same computer and recognized by the DTS. Having the DTS running and connecting the device to the computer should be all that is needed.

5.6.2.1 Creating a Measurement Session

To create a measurement session, a Doctor or Nurse user first needs to be logged in. A patient entry associated with (one of) the Doctor's Organization(s) needs to exist.

To create a patient, follow the instructions in the ***Creating a Patient*** section.

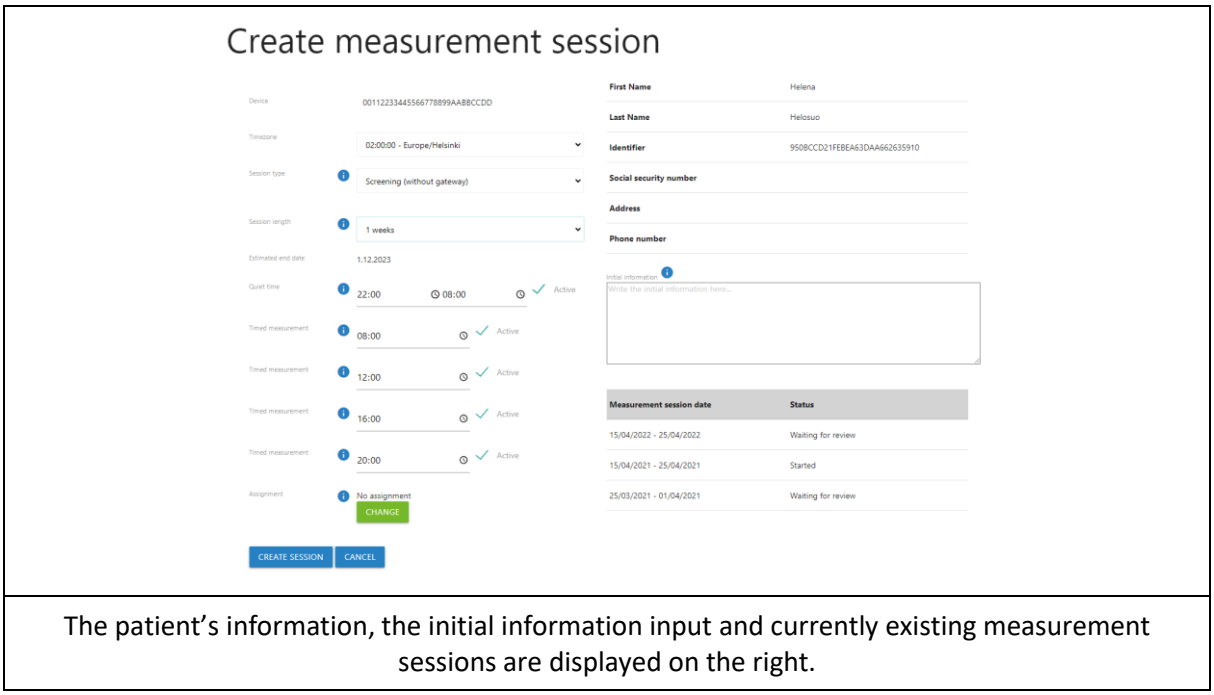
The User first navigates to the Patient list and selects the specific Patient by clicking the patient in the list. Search functionality can be used to filter the patient list. Patient information is displayed on the right side of the page after selecting a patient by clicking the patient in the list. Click the "create a new measurement session" button on the patient information dialogue to start a new measurement session. If the connected device is correctly identified by the DTS, and the information is successfully passed to the DMS, the Device

field should be automatically filled with the device's information. Otherwise, the user will be redirected back to the Patient list and informed that a connected device was not detected.

If the device is correctly connected, the user can proceed to fill in the information in the form. The "session type" option determines whether the gateway is being used with the measurement session. "Quiet time" determines times when the device should not alert the wearer, i.e. Patient. Generally, this means times when the Patient is sleeping. The user should also optimize the convenience of the scheduled notifications for the Patient by trying to find times that fit the Patient's daily routines best, e.g. before leaving for work, during lunch break, before going to bed, etc. In the assignment search list, the User can select doctors belonging to patient organizations for internal assignment or forward the measurement session to an External Organization for assignment to the External Organization's doctors. The "Initial information" input creates an initial information entry for the created measurement session. See the ***Annotations*** section for more on this.

Information about the fields can be found by hovering on the icons next to the fields.

After filling in the form, the User can choose to click "CANCEL" or "CREATE SESSION". If the User clicks "CANCEL", the DMS redirects the User back to the Patients page. If the User clicks "CREATE SESSION", the DMS redirects them back to the Patients page and informs the User of the successfully created session.



The patient's information, the initial information input and currently existing measurement sessions are displayed on the right.

Figure 5-27. A screen capture of the Create Measurement Session page

After the measurement session has been created, when the user selects the Patient from the Patients list, the new measurement session should be visible in the Patient information view on the right hand side.

Now the device can be passed to the Patient. The device will gather information, which will be transferred to the DMS database when it is later connected to a computer with DTS running, with an authorized user logged in to the DMS. After the transfer is done, the data can be visualized in the DMS for medical professionals associated with the Organization of which the Patient is a customer.

5.6.2.1.1 Failure to Create a Measurement Session

Measurement session creation can fail for several reasons:

1. The device is not connected
2. The device already has a running measurement session
3. The device is set to be recalled

5.6.2.2 Ending a Measurement Session and Controlling Wrist Device

DTS Version	Applicability
01.04.00 and newer	All operations are supported.
01.03.00 and older	Only closing of measurement is supported.

View the wrist device information connected to the computer by clicking the “Device” button on the top right, next to the “Log out” button. A modal is opened as displayed in Figure 5-28 and Figure 5-29. Common operations can be applied using the modal.

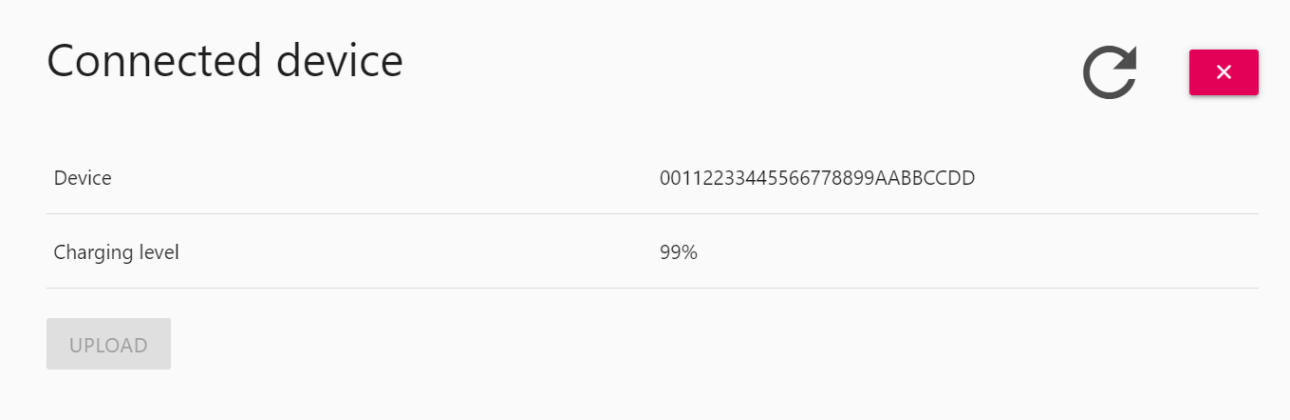


Figure 5-28. Device modal on empty device without session

The wrist device data can be transferred to the cloud by clicking the “Upload” button. The button might be disabled which indicates that the device does not contain data to be transferred.

The measurement session can be closed by clicking the “Close measurement session” button. The button might not be visible, which indicates that the device does not have an active measurement session.

The patient identification information for the active measurement session in the wrist device is displayed. The measurement can be opened for further examination by clicking the “View Measurement” button.

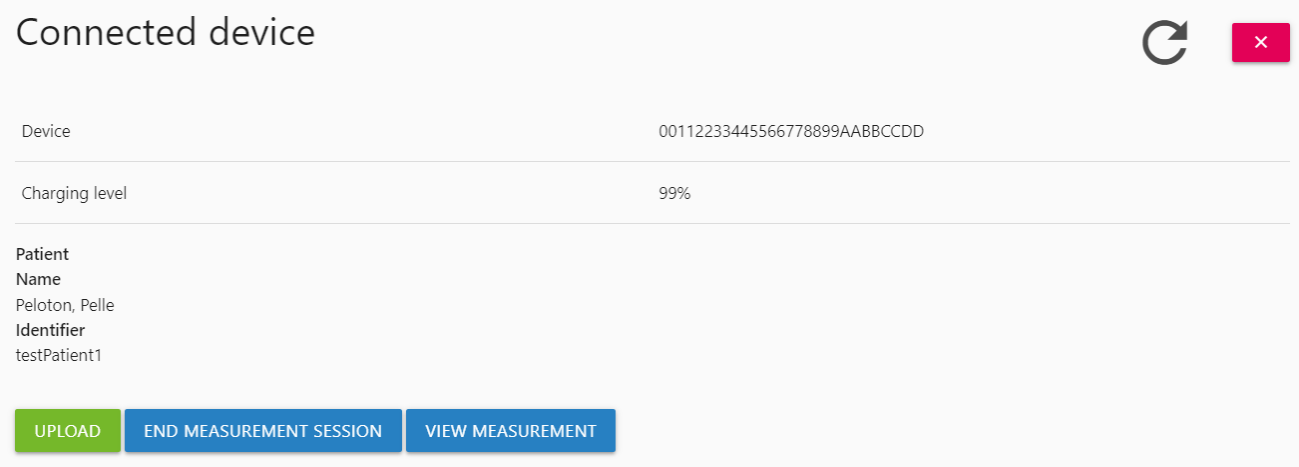


Figure 5-29. Device modal for device with session and files

A measurement session can also be ended via the DTS applications context menu. The User opens the menu by right-clicking the system tray icon and chooses to end the measurement session by clicking the relevant menu item. After confirmation, the DTS should inform the user that the measurement session has ended.

5.6.2.3 Viewing Measurement Session Information

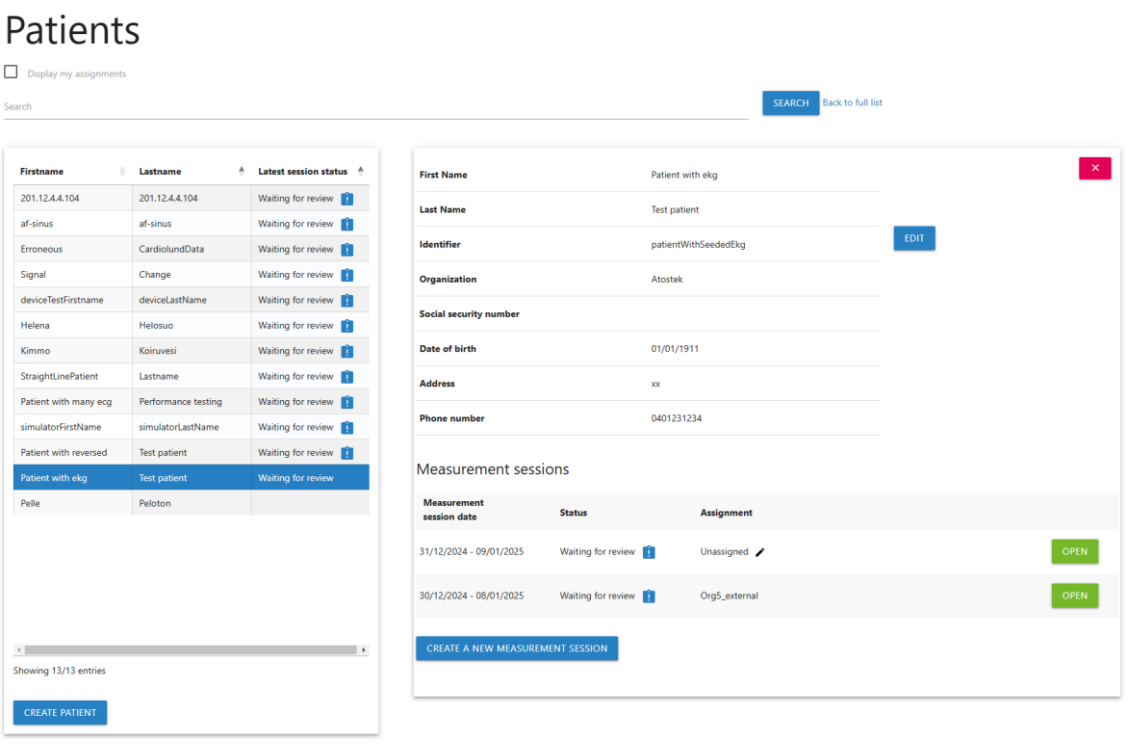
When (i) the Patient has used the device during the measurement session, i.e. ECG measurements have been taken, and (ii) IBI (heart rate) data has been gathered, then the Doctor logs in to view this information. When the device is connected to the computer, DTS will automatically begin transferring the measurement session data to the DMS database. After the transfer is done, the information will be available via the UI.

5.6.2.3.1 Measurement Session Sidebar

On the left side of the month view, week view and day view (i.e. all measurement session specific pages) is the sidebar. Here the user can see the Patient's name and identifier, switch between measurement sessions, and view information related to the current measurement session: start/end time, categorized ECG measurement count, and annotations. The user can add Initial information and Conclusions to the session in the sidebar as described in Annotations.

On the sidebar, the user can also modify the measurement session status. In a regular user's case, the sidebar allows the user to set the session as 'Completed'. For external users, the sidebar allows the user to set the session as 'Reviewed'. In addition, the sidebar allows the user to revert the status changes.

5.6.2.3.2 Measurement Session Week View



After selecting a Patient by clicking on a row in the Patient list, the Doctor can open the measurement session by clicking the green “Open“ button.

Figure 5-30. A screen capture of the Patients page

The user selects a measurement session and is redirected to the Week View of the selected measurement session.

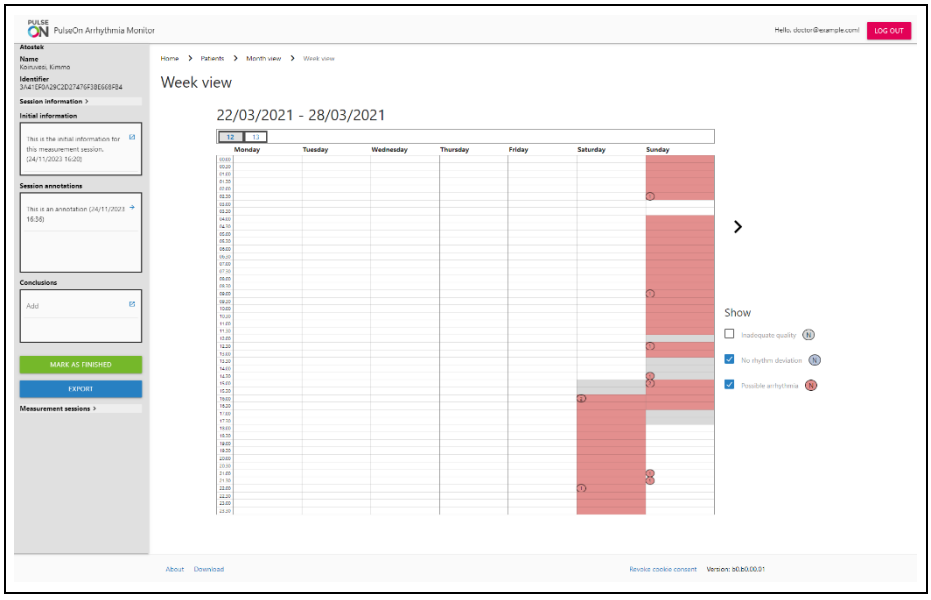


Figure 5-31. A screen capture of the week view

In the week view, each day is coloured according to information gathered by the wrist devices IBI sensor. The background colours of days indicate whether no reliable data exists, or whether analysed heart rate data suggests possible arrhythmia or sinus rhythm during that half-hour segment. The circled numbers indicate ECG measurements of the selected week, which will be displayed as circles, at their appropriate day of the week and time of day. Additionally, the ECG measurements done during the respective day, the number showing the number of measurements. Additionally, the ECG measurement circles are coloured according to input from an ECG analysis algorithm provided by Cardiolund. Annotated ECGs will also be distinguishable. Clicking on a day takes the user to the day view described later.

5.6.2.3.3 Month View

Each segment will be coloured according to the same logic as the days in the week view: whether no reliable data exists, or whether analysed heart rate data suggests possible arrhythmia or sinus rhythm during that day.

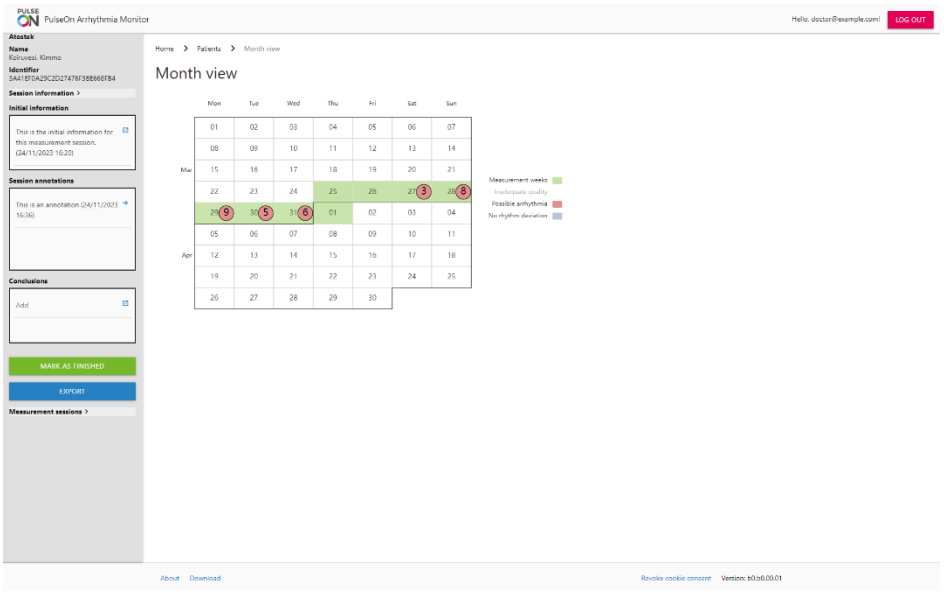


Figure 5-32. A screen capture of the month view

If the User clicks directly on an ECG measurement, the selected ECG measurement is shown to the user. When the User hovers the mouse over a week, that week is highlighted. The User can move to the week view by clicking the week.

5.6.2.3.4 Day View

The measurement session day view will contain all the ECG measurements taken during that day. The ECG measurements will be in a scrollable view. By checking or unchecking the checkboxes under the title “Show” on the right side of the view, the healthcare professional User can choose what categories of data are shown. For example, this filtering can mean only displaying ECG measurements flagged in a certain way by the Cardiolund algorithm or only displaying annotated ECG measurements.

The User can also select which data type to display. The table below describes the datatypes.

Table 7. Data type description

Data type	Description
Smoothed and prefiltered	If this is selected, the data shown is prefiltered and smoothed by the Cardiolund algorithm: prefiltering smoothing performs additional high-pass and low-pass filtering to the signal, thus efficiently removing baseline wandering and high-frequency components from the signal. Clinical interpretation of the ECG report may be affected by the filtering.
Prefiltered	If this selected, the data shown is prefiltered by the Cardiolund algorithm: prefiltering performs additional high-pass filtering on the signal, thus efficiently removing baseline wandering from the signal. Clinical interpretation of the ECG report may be affected by the filtering.
Raw data	Directly from device, not processed for readability. If this selected, the raw data will be displayed.

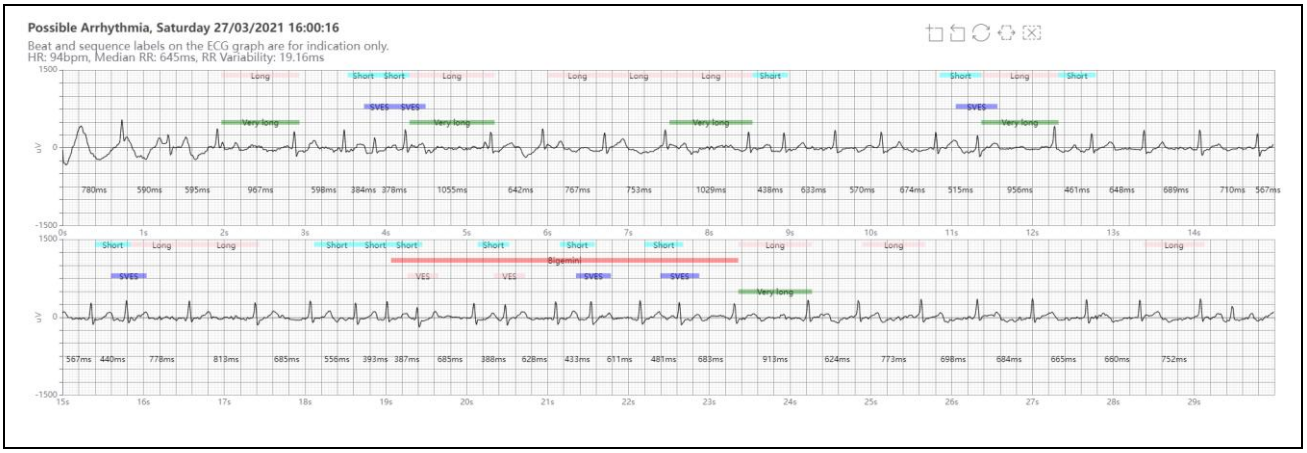
NOTE: If the data type is not raw data, the displayed ECGs are analysed and processed by ECG Parser software provided by Cardiolund. The ECG Parser is advanced ECG analysis software. In addition to the ECG curve, the graphs may contain markings, essentially coloured lines with descriptions, related to beats (e.g. 'Short', 'SVES') and data sequences (e.g. 'Irregular Rhythm'). These are also produced by the ECG Parser. Additionally, the displayed beat lengths are calculated by the ECG Parser.

5.6.2.3.5 ECG Visualization

NOTE: All data should be reviewed by a healthcare professional.

The day view shows the ECG measurements in graphs. The visualization contains the ECG line plotted on a graph with time on the x-axis and microvolts on the y-axis. If the user has not selected “Raw data” as the data type, the graph can also contain additional markings generated by the Cardiolund algorithm. These markings are for indication only. All data should be reviewed by a healthcare professional. For more information, see section 5.6.3 Automated ECG Analysis.

Additionally, the title of the ECG contains a Category, also determined by the Cardiolund algorithm. The possible categories are: Inadequate Quality, No Rhythm Deviation, Possible Arrhythmia, AV Block II, Fast Regular, Fast Regular and Wide QRS, Fast Slow Episode, Bigemini, Trigemini, Wide QRS, SVES5, and VES5. This categorization is not a diagnosis. All patient data should be reviewed by a healthcare professional.



The ECG graph has overlaying colours and markings with descriptions generated by the Cardiolund algorithm. These markings are for indication only. All data should be reviewed by a healthcare professional.

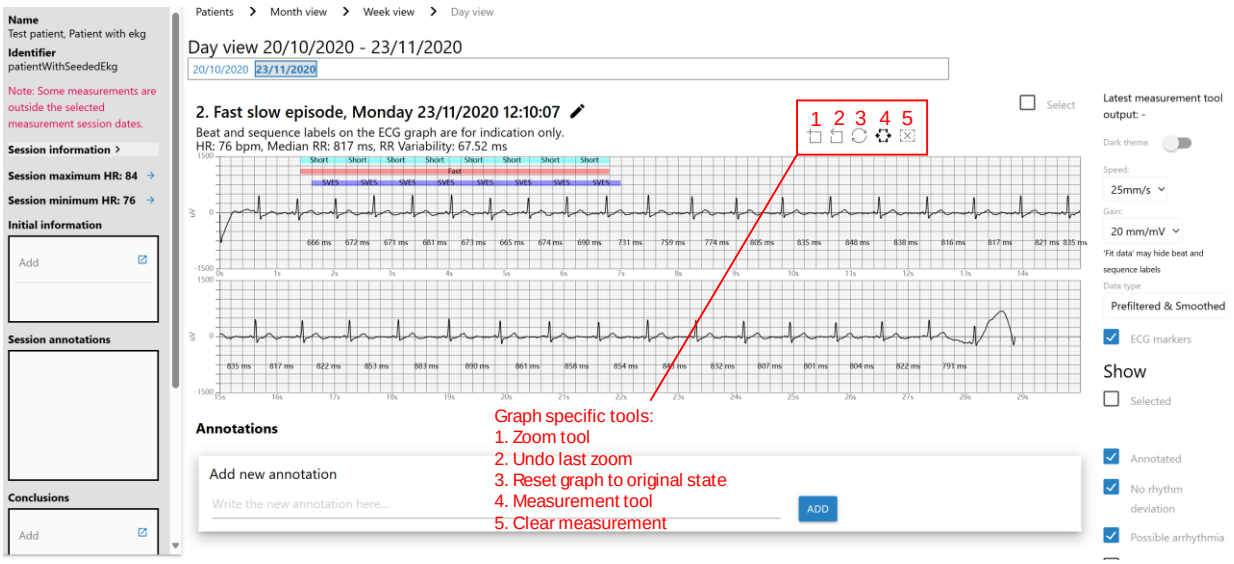
The markings on this ECG include markings related to singular beats: short, long and very long beats, and SVES beats. Additionally, a Bigemini sequence has been proposed by the algorithm. A healthcare professional should use these markings as helpful indicators, not as a basis for a diagnosis.

The title of the ECG contains a categorization generated by the Cardiolund algorithm. This specific ECG is categorized as Possible Arrhythmia by the Algorithm (see the title of the ECG). The subtitle of the chart contains some numeric values, also calculated by the Cardiolund Algorithm: heartbeat information, Median RR and RR variability.

All data should be reviewed by a healthcare professional. The markings or categorizations generated by the Cardiolund algorithm are not a basis for a diagnosis.

Figure 5-33. A screen capture displaying a part of an ECG measurement

The day view includes some configurations and tools related to the ECG measurement graph to which the User has access. The User can change the speed of the paper, essentially how many seconds per row are displayed, by adjusting the selection on the dropdown menu titled “Speed”. If the User selects 25 mm/s, a single row will have 15 seconds of data at most, i.e. a 30 second measurement will be displayed in two rows. If the User selects 50 mm/s, a single row will have 7.5 seconds of data, i.e. a 30 second measurement will be displayed in four rows. The width of each row will remain unchanged, so changing the speed from 25 mm/s to 50 mm/s essentially zooms the data by 100%.

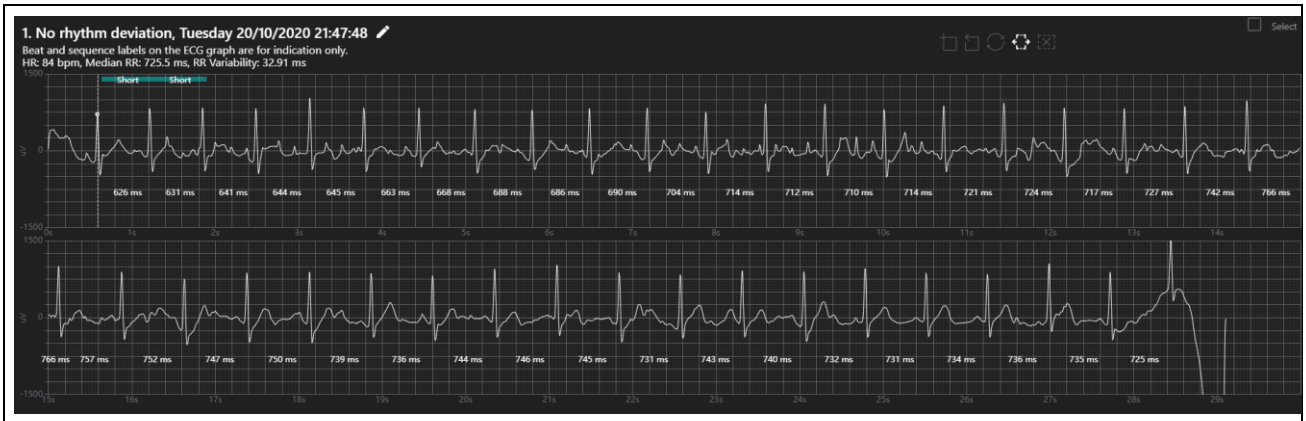


The red markings and text on the image are not part of the product but have been added to describe the view.

Figure 5-34. A screen capture of the day view

The User can adjust the Y-axis zoom by changing the selection of the dropdown menu titled “Gain”. The two settings affect all the ECG measurements in the day view.

The colour scheme can be changed to use a dark background using the “Dark theme” option. The ECG markers can be hidden from the graphs by deselecting the “ECG markers” option.



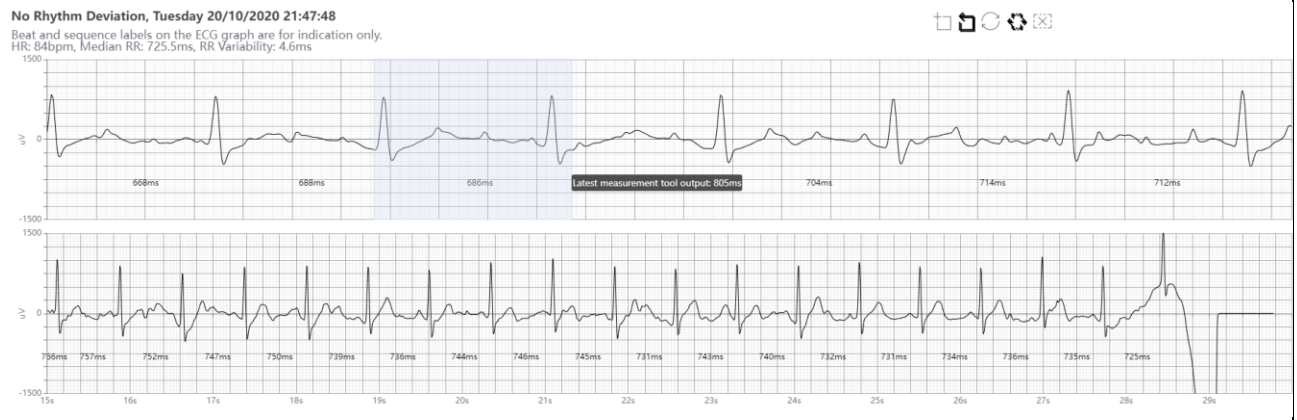
ECG with the dark theme option turned on

Figure 5-35. ECG graph with dark theme

Measurement session minimum and maximum HR is displayed in the panel on the left. The inadequate quality ECGs are excluded when calculating the values. User can navigate to the minimum and maximum HR by clicking the corresponding text.

The zoom tool allows the user to drag an area in the graph and zoom into it. The zoom reset button should undo this action. The measurement tool can be used to create a coloured area by dragging on the graph, which the user can move around. This way the user can reliably compare the intervals between beats, for example. The user can adjust the width of the measurement tool by dragging from either side of the selection and can move it around by dragging within the selection. The interface should clearly display the length of the measured area in milliseconds.

The zoom and measurement tools are accessed via the buttons on top of the ECG graph. They can be activated by clicking on them. For example, the user activates the zoom tool by clicking on the zoom tool button. The zoom tool is highlighted, and the user can drag on the graph to zoom in. If the User wants to use the measurement tool and clicks on the measurement tool button on top of the graph, the measurement tool button is highlighted, and the user can drag an area in the graph and move it around. The User can reset the zoom by clicking on the reset zoom button. The X-axis zoom is reset to its original state.



The top row is zoomed in, and an area is measured using the measurement tool.

Figure 5-36. A screen capture of an ECG measurement

5.6.2.3.6 ECG Category Modification

The system allows for modifying the category of an ECG. This can be done by clicking the ECG title or the pen icon next to the title. After selecting the appropriate category from the list, the changed category can be saved by pressing the “Save” button. Additionally, the history of the ECG category changes is displayed as a list under the ECG.

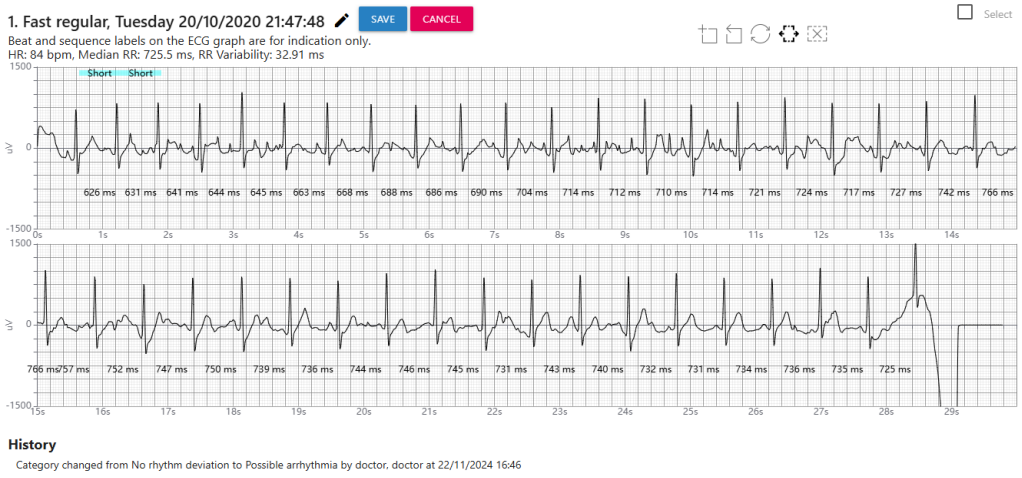


Figure 5-37. ECG graph with history

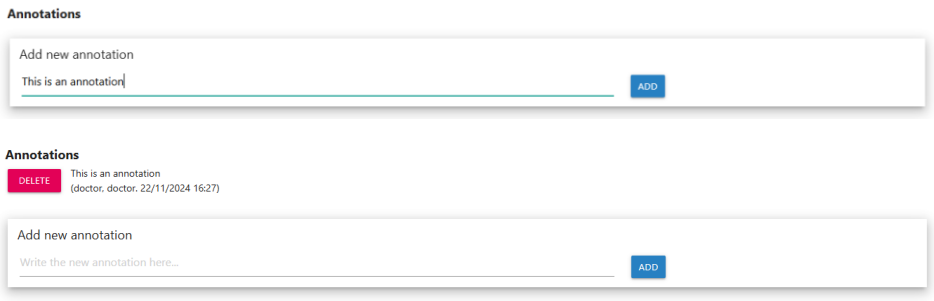
5.6.2.3.7 Method for Calculating Heart Rate

The representative heart rate reading provided for each ECG graph is calculated in the following way. Heart rate in bpm is inverted and scaled from the parameter RRmean (not shown in the user interface), which is calculated as the average of the 90% most central intervals of the selected RR intervals. Selection of which RR intervals to include is based on beat classification and signal quality parameters. For example, if the 30-second recording consists mainly of normal sinus-originated heartbeats and some ectopic beats, the RRmean and thus

the heart rate is calculated by first excluding the RR-intervals that are associated with an ectopic beat and then excluding the 5% longest and 5% shortest of the remaining RR-intervals.

5.6.2.3.8 Annotations

With a single ECG measurement highlighted, the ECG annotation-related functionalities will be available to the User.



In the first screen capture, a user has written an annotation “This is an annotation” in the field under “Add new annotation”. The user may then press the “ADD THE ANNOTATION BUTTON” to add the annotation to the ECG. The Annotation should then be visible to any user viewing the measurement session.

In the second screen capture, a single annotation “This is an annotation” can be seen, with the creator’s “signature”, a user named “doctor doctor”, and the time when the annotation was created.

Each ECG has its own annotations area under the graph itself.

Figure 5-38. Screen captures of the annotations functionality

Annotations are associated with a single ECG measurement. Annotations are displayed under the ECG measurement they are associated with, as well as in the sidebar container titled “Annotations of the measurement session”. As the title indicates, this container displays all the annotations associated with the currently open measurement session.

In addition, the user can add initial information or conclusions for the measurement session in the month, week and day views. The initial information and conclusions are associated with the entire measurement session. The initial information and conclusions for the measurement session can be found in the sidebar containers titled “Initial information” and “Conclusions”. Attachments can be added to initial information and conclusions using the file input.

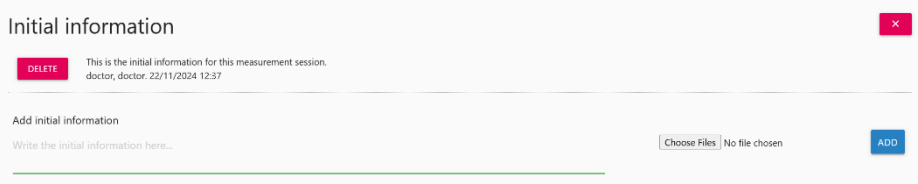
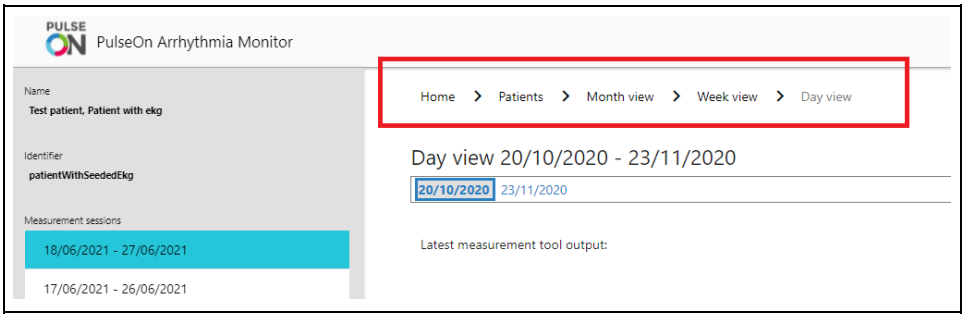


Figure 5-39. Initial information popup

Clicking the initial information box opens a popup which enables the user to read the earlier entries and add new ones. The popup can be closed by clicking the “X” in the upper right corner, pressing the “ESC” key or clicking anywhere outside of the popup.

5.6.2.3.9 Navigation



Breadcrumb navigation is highlighted with a red frame.

Figure 5-40. Breadcrumb navigation

Users can navigate to previous views by clicking items in the breadcrumb navigation.

5.6.3 Automated ECG Analysis

The number of ECG measurements can be very large when using an easy-to-operate wrist device to take ECG measurements in everyday life, thus making it challenging for doctors to manually review all ECG recordings.

The DMS has an automated results analysis algorithm that can be used for prioritizing resources, since it allows doctors to focus on the important cases, i.e. recordings classified as having a rhythm deviation.

This automated analysis is part of the ECG Parser software provided by Cardiolund. The ECG Parser is medical device software classified as Class IIa, and as Class B (non-serious injury possible) on the EN IEC 62304 classification scale.

The performance of the ECG Parser relies on the quality of the recorded signals. Signals with disturbances or lead connection issues may cause problems for the software and may result in miss-detection, mislabelling or non-detection of important events. Depending on the signal quality level, there is a significant over-estimation of the irregular sequence category.

For most errors that are detected by the software, for example “no signal” and “no beats detected”, the only option is to discard the signal, and (if possible) advise the end-user to record a new signal. The same is true if the signal, or dominating segments of the signal, are classified as “poor quality” by the software.

There are known errors related to signal quality that go undetected by the software, including:

- Detection errors, i.e. imperfect detection of events or identification of non-existing events in the signal.
- Classification errors, i.e. wrong classification of a signal. For example, a signal of poor quality is classified as an irregular sequence.

In particular, the software has been tuned not to miss important cases, so there is a significant miss-classification (or over-estimation) of “no rhythm deviation” and “poor quality” signals into other categories.

The definitions of the 12 different deviations and possible arrhythmias are in the table below.

Table 8. Classification of different deviations and possible arrhythmias

#	Category	Deviation
0	Inadequate Quality	Difficult to follow the beat sequence
1	No Rhythm Deviation	Only insignificant irregular beats present
2	Possible Arrhythmia	Unexplained irregularities which may be AF or paroxysmal AF with or without P waves
3	AV Block II	AV block 2 or beats longer than 2.2 s
4	Fast Regular	Fast rhythm without wide QRS complexes, RR interval shorter than 600 ms
5	Fast Regular and Wide QRS	Fast rhythm with wide QRS complexes, RR interval shorter than 600 ms and QRS duration more than 120 ms
6	Fast Slow Episodes	Shorter sequences of faster or slower beats
7	Bigemini	Bigemini patterns with P waves detected
8	Trigemini	Trigemini patterns with P waves detected
9	Wide QRS	QRS duration more than 120 ms in general, but not fast
10	SVES5	More than 5 supraventricular extrasystole detected
11	VES5	More than 5 ventricular extrasystole detected, not all wide beats

The performance of the algorithm creating automated results analysis depends on the ECG measurement quality. Thus it is recommended that the patient stay still during an ECG measurement, as described in ***Taking an ECG Measurement***.

- The automated analysis result is not a diagnosis, and the results should be reviewed by a trained professional (cardio-tech or cardiologist) in order to verify the result. Additional information may be needed before a trained professional can establish a complete diagnosis.

5.6.4 Exporting Measurement Session Data as a PDF

A user viewing a patient's measurement session can decide to export the session's data as a PDF. This functionality is available in the sidebar that is visible in any measurement session view.

After clicking either of the buttons, the user is presented with a popup of three drop-down menus: "Data type", "Speed", "Gain", and "Group of ECG". These are used to select settings for the data and its presentation.

The week view information is included in the PDF export by default. The information can be excluded from the export by unchecking the "Week view" option in the PDF export window.

The ECGs included in the PDF can be adjusted using the "Annotated", "Selected" and "All" filters. The "All" option includes all ECGs of adequate quality. The options can be combined freely.

The ECG markers can be hidden from the graphs by deselecting the "ECG markers" option in the PDF export window.

The "Data type" determines which type of data the graphs in the PDF will display. The user can select between "Prefiltered & Smoothed", "Prefiltered", and "Raw data". "Raw data" is received directly from the device and may not be perfectly visible in the export.

When the measurement session is too large for a single PDF, the user can choose a group of ECGs to be included in the export. The ECGs are grouped by time and a single export can contain up to 100 ECGs.

The following table describes the data types in more depth.

Table 9. Data type description

Data type	**Description**
Prefiltered & Smoothed	Prefiltering and smoothing performs additional high-pass and low-pass filtering on the signal, thus efficiently removing baseline wandering and high-frequency components from the signal. Clinical interpretation of the ECG report may be affected by the filtering.
Prefiltered	Prefiltering performs additional high-pass filtering on the signal, thus efficiently removing baseline wandering from the signal. Clinical interpretation of the ECG report may be affected by the filtering.
Raw data	Directly from the device, not processed for readability.

NOTE: If the data type is not raw data, the ECGs in the PDF export are analysed and processed by ECG Parser software provided by Cardiolund. The ECG Parser is an advanced ECG analysis software. In addition to the ECG curve, the graphs may contain markings, essentially coloured lines with descriptions, related to beats (e.g. 'Short', 'SVES') and data sequences (e.g. 'Irregular Rhythm'). These are also produced by the ECG Parser. Additionally, the displayed beat lengths are calculated by the ECG Parser.

The "Speed" dropdown selects the width of one second in millimetres in the final PDF file. If the user selects 25 mm/s, each second should be 25 millimetres long on a printed version of the PDF. If the user selects 50 mm/s, each second should be 50 millimetres long on a printed version of the PDF. In addition to this, each ECG will be divided into 10 second (for 25mm/s) or 5 second (for 50mm/s) rows, respectively.

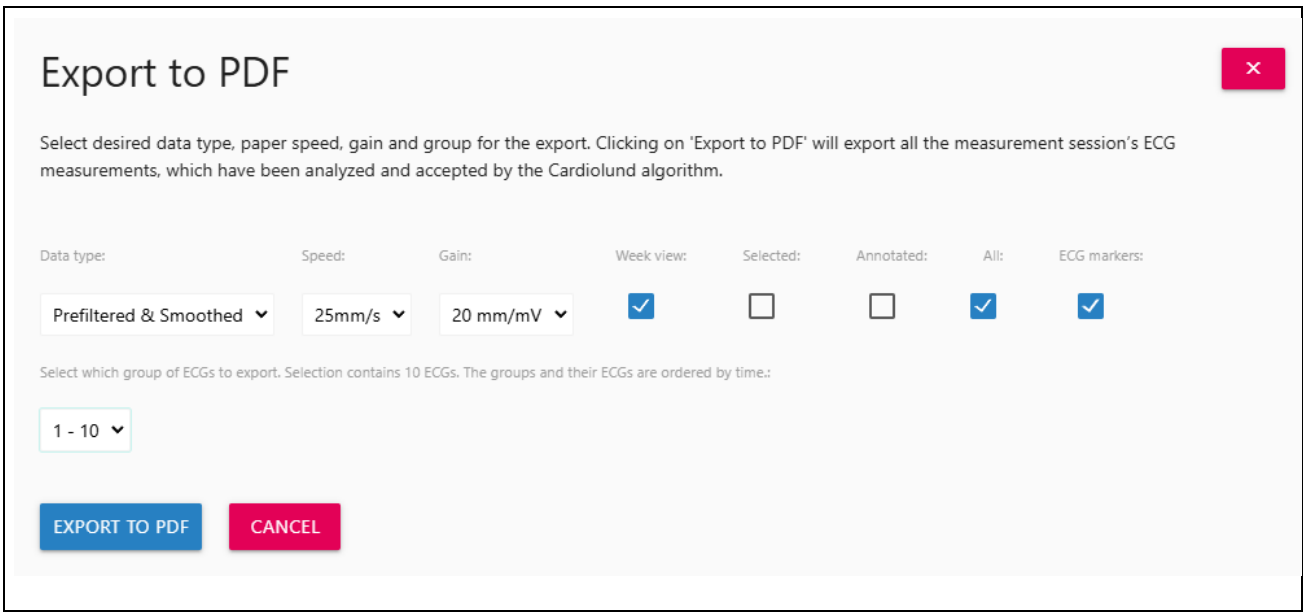


Figure 5-41. Export settings

In addition, the user can export specific data. The “Week view” option enables inclusion of the week view in the PDF or exclusion of it from the PDF. The “Selected”, “Annotated” and “All” options enable inclusion of selected, annotated or all ECGs respectively. The “ECG Markers” option enables inclusion of the ECG markers.

Clicking “Export to PDF” will start PDF generation. The page will keep loading until the PDF is ready and the browser downloads the file. The user cannot navigate around during this time. The user must wait until the process finishes and the file has downloaded. If the user navigates away from this page, the PDF will not be downloaded.

The user can also choose to click “Cancel”, in which case no PDF generation begins and the settings popup closes.

5.7 External Assignment

External Assignments are used to allow organizations other than the Internal Organization responsible for the patient and creation of the measurement session to interpret and annotate the patient’s measurement sessions.

The External Organization’s users do not have access rights directly to Internal Organization patients, but measurement sessions belonging to patients can be assigned to External Organizations and then forwarded to External Organization doctors. This allows the assigned external doctor to view and annotate the measurement session.

5.7.1 Organization Assignments View

When measurement sessions are assigned to External Organizations they are not assigned to any of the External Organization’s doctors by default. To assign external doctors to measurement sessions, a WorkflowManager user exists, which assigns measurement sessions to external doctors through the Organization Assignments View.

The view is similar to Patient List View with the exception that the workflow manager has no access to patient data or to patients' measurement sessions.

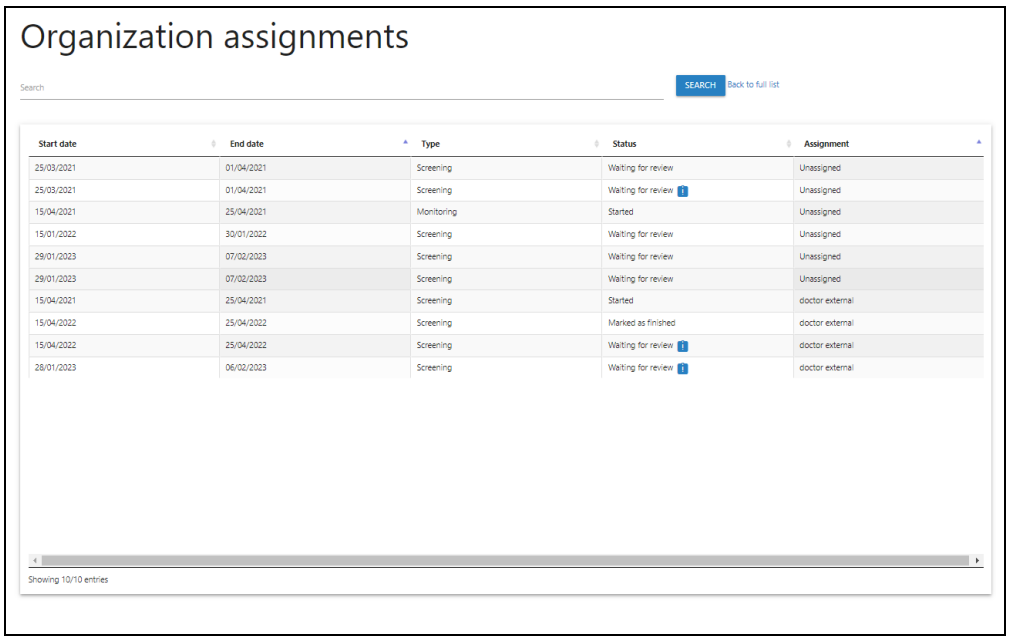


Figure 5-42. Screen capture of the Organization Assignments page

5.7.2 My External Assignments View

Through the External Assignments view, doctors belonging to an External Organization can view and annotate measurement sessions that are assigned to them. Measurement sessions, which are started before the latest assigned measurement session, are also viewable by the external doctor, but the external doctor can only view and not annotate these measurement sessions.

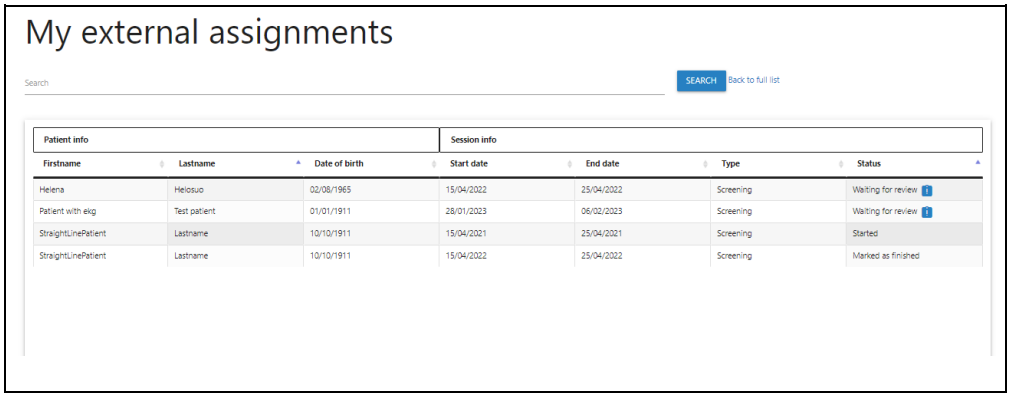


Figure 5-43. Screen capture of My External Assignments page

5.8 GDPR – Downloading User and Patient Data

According to GDPR (General Data Protection Regulation) requirements, a User can request an administrator to download and send a file (.csv) containing information related to the User account. The User can also download this data personally, under the “Personal data” link in user settings (see. “Managing common user settings”).

If a user requests to see this data and they have no ability to log in to their account (e.g. the account has been deactivated or the password forgotten) another user with an administrative role within the same organization as the first user can download the data by navigating to the first user’s account settings PersonalData page.

5.8.1 Downloading User Data

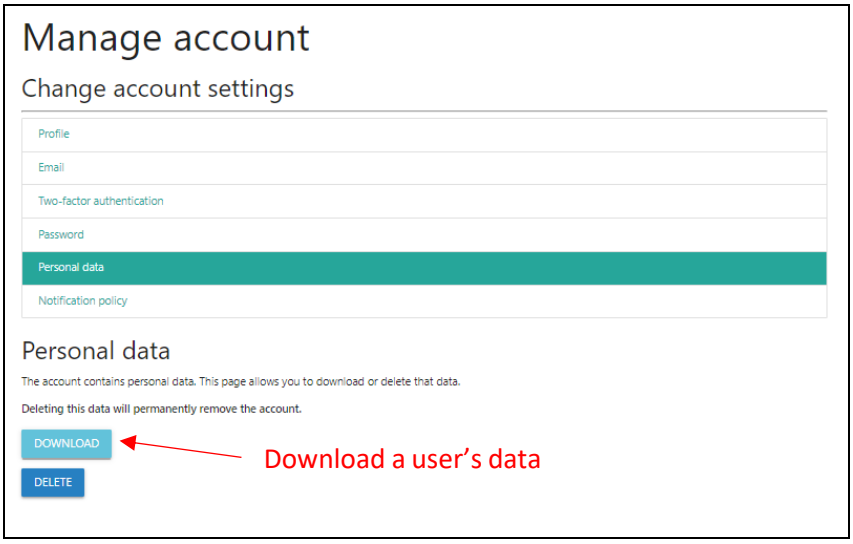
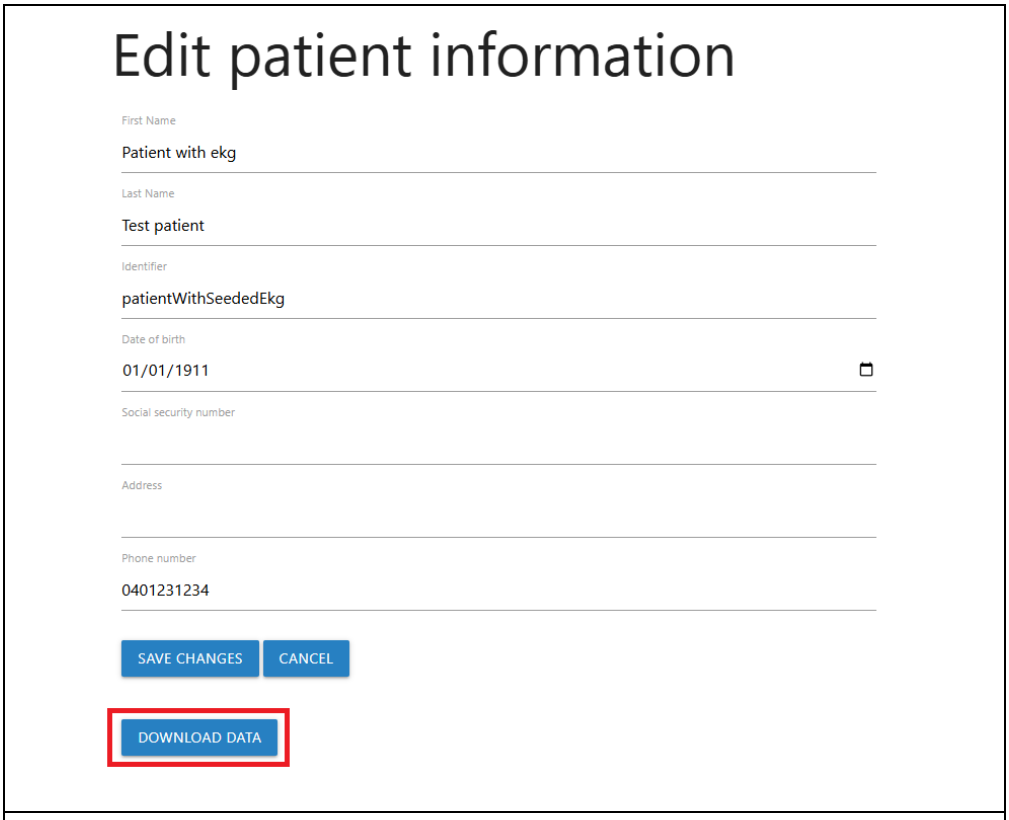


Figure 5-44. Downloading a user’s data

5.8.2 Downloading Patient Data

Healthcare professionals with access to a specific Patient’s data can also download that data by selecting (highlighting) the specific Patient on the PatientList page, navigating to the Patients modification view by pressing “EDIT”, and there pressing the “DOWNLOAD DATA” button at the bottom.



Ensure that the correct Patient's information is displayed.

(In the image, the selected patient has the following info: Firstname: Patient with ekg, Lastname: Test patient, Identifier: patientWithSeededEkg)

Figure 5-45. Downloading patient data

5.9 Cookies

The DMS uses functional cookies for handling language settings (Localization). A user must accept these functional cookies in order to change the language settings in user settings (see "Managing common user settings").

If a user has not accepted cookies in the current browser, the DMS will display a cookie consent popup at the top of the view.

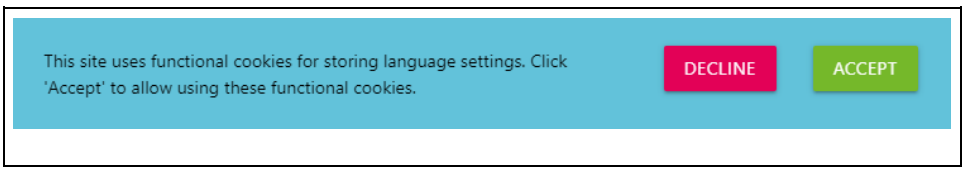


Figure 5-46. Cookie consent popup

The user can choose to DECLINE or ACCEPT the cookies. If the user DECLINES, the popup will be hidden, and the footer (bottom of the page) will display a link button with the text “Show Cookie Consent”. If the user clicks the “Show Cookie Consent” button, the Cookie consent popup will again be displayed at the top of the page.

If the user chooses to click ACCEPT, the Cookie Consent box will disappear. After clicking ACCEPT, the user will be able to change the language settings in their accounts settings (see “Managing common user settings”).

Additionally, after clicking ACCEPT, a link button titled “Revoke Cookie Consent” will appear in the footer (bottom of the page). This button will undo the ACCEPT button’s function, essentially revoking cookie consent and removing the ability to change the system language.

5.10 Notifications

Application users receive email notifications related to assignments. These notifications are created as part of important steps in the assignment workflow and are used to remind the users of important events in the assignment workflow. If notifications are made for the assigned user, but the measurement session is then assigned to another user or to External Organizations, notifications for the original assigned user are removed and not sent.

Table 10. Notification type description

Data type	**Description**
New Assignment	Notifications are made for the user always when the measurement session is assigned to them internally or externally.
Session Ended	Notifications are made for the assigned user always when their assigned measurement session ends.
Not Reviewed Alert (not implemented yet)	Notifications are made for the assigned user if the assigned measurement session is not reviewed in a set time. This review time is set as part of organization settings. Not Reviewed Alert notifications are sent to the user through email and the UI multiple times until the measurement session is reviewed.
Session Marked as Completed	Notifications are always made for the assigned user when their assigned measurement session is marked as completed.
New Annotations	Notifications are made for the assigned user always when a new annotation is made for their assigned measurement session.
Assigned to External	Notifications are made for workflow managers in the external assignment organization always when an internal user has assigned a measurement session to the external organization.

Email notifications are sent to users at times specified by the user notification policy defined in the user settings or, if one does not exist, by the times specified in the organization notification policy. If a notification policy for the user and the user organization does not exist, notifications are still sent to the user using a default notification policy. Default policy means notifications are sent by email Mon-Fri at 6 am Helsinki time (UTC + 2 hours). This means that there is currently no way to opt out of receiving notifications related to assignment events.

By default, notifications are not sent to the user multiple times. An exception to this is when the user has measurement session late notifications; in this case, they are not cleared until the measurement session has been reviewed.

6 Instructions for System Administrators

This part of the user guide is to be read and understood mainly by personnel responsible for system administration.

6.1 Inventory Management System (IMS)

The Inventory Management System (IMS) is the device management system part of the service and can be accessed using a web browser. The system is designed to be used mainly by administrative PulseOn personnel as well as administrative customers. The IMS will provide information about the devices in the field and in stock. The IMS can be also used to perform operations on and management of the devices.

The purpose of this document is to guide a user in executing actions in the IMS. The document describes the common use cases and the workflow related to those actions. Reading this document will help avoid misuse of the software and mitigate any confusion that may arise while using it.

6.1.1 IMS Common Functionalities

User management and access management are described more accurately in the DMS part of this user guide. The user management is similar in IMS, and the DMS user guide should be used as a reference for user management.

Table 11. IMS Roles

Role	Scope	Usage
SuperUser	Whole system	Used by PulseOn personnel. No limitations in access.
SystemAdmin	Customer System specific information	Used by Customer System administration. Limited access to common functionalities and device management.
Admin	Organization-specific information.	Used by organizational administration. Limited access to common functionalities.

6.1.1.1 Security settings

Two-Factor Authentication (2FA) is available for all users. The management of 2FA is similar to DMS. Refer to 5.4.3 Enabling Two-Factor Authentication and subsequent chapters for instructions.

Users are automatically logged out as follows:

1. Inactive sessions are automatically logged off after 15 minutes.
2. Active sessions are automatically logged off after 8 hours.

6.1.1.2 View Device Information

The overall information about devices can be displayed in a device list view. This information depends on the user's role. The devices can be searched for using the search bar. To include past data in the device list, the user should check the “Include history” checkbox. When viewing the historical data as a user who is not a SuperUser, the list also displays devices that have at some point been under the user’s management. Detailed information about the device can be viewed by clicking a device in the table displayed on the left of Figure 6-1.

In addition, a more detailed history of a device can be displayed by clicking the “Display device history” button. The opened view will display information about the version history and measurement session history of a device. Both of the views have limited functionality and limited visibility with regard to history and devices when used by an organization admin. The detailed history is displayed in Figure 6-2.

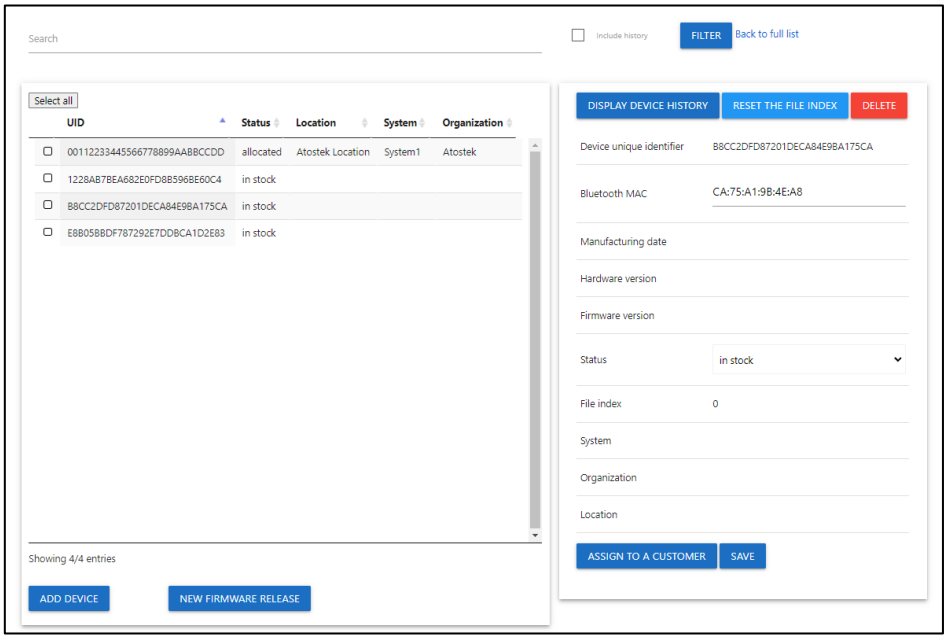


Figure 6-1. Device list

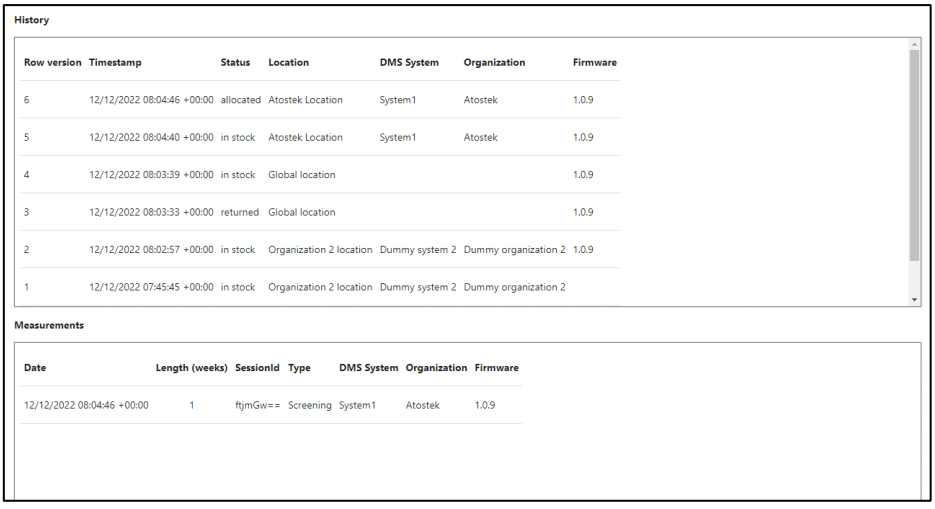


Figure 6-2. Device history

6.1.1.3 View Device Report

Device usage is displayed on the report page. The page lists measurement sessions and devices associated with organizations and systems in the selected period. The report is created by first selecting the appropriate

filters and then clicking the filter button. All ongoing sessions can be included in the report by selecting the “Include ongoing sessions” checkbox. The report can be downloaded in CSV format for post processing.

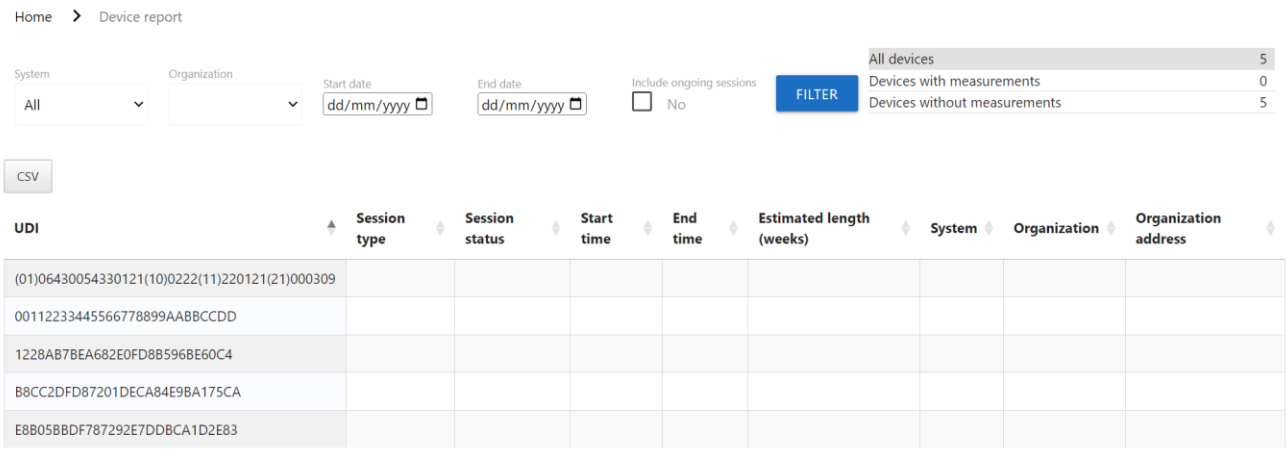


Figure 6-3. Device report page

6.1.1.4 Gateway Management

Gateway management works in the same manner as device management. The user interface for gateway management includes features for adding gateways, searching for gateways, assigning gateways to customers, returning gateways from customers and updating gateway status values.

6.1.1.5 Location Management

Locations are designated to specific Organizations or Systems. Locations can be managed by a PulseOn administrator, i.e. a SuperUser, a Customer System administrator, i.e. SystemAdmin, or an Organization administrator, i.e. Admin. Locations are used to track the current and past location of a device. If the location of a device is set to a system’s location, only organizations under that system can use that device to start measurement sessions, if it is “in stock”. Likewise, if the device’s location is an organization’s location, only that organization can use it to start measurement sessions. In other cases, if the device status is “in stock” it is usable by any organization.

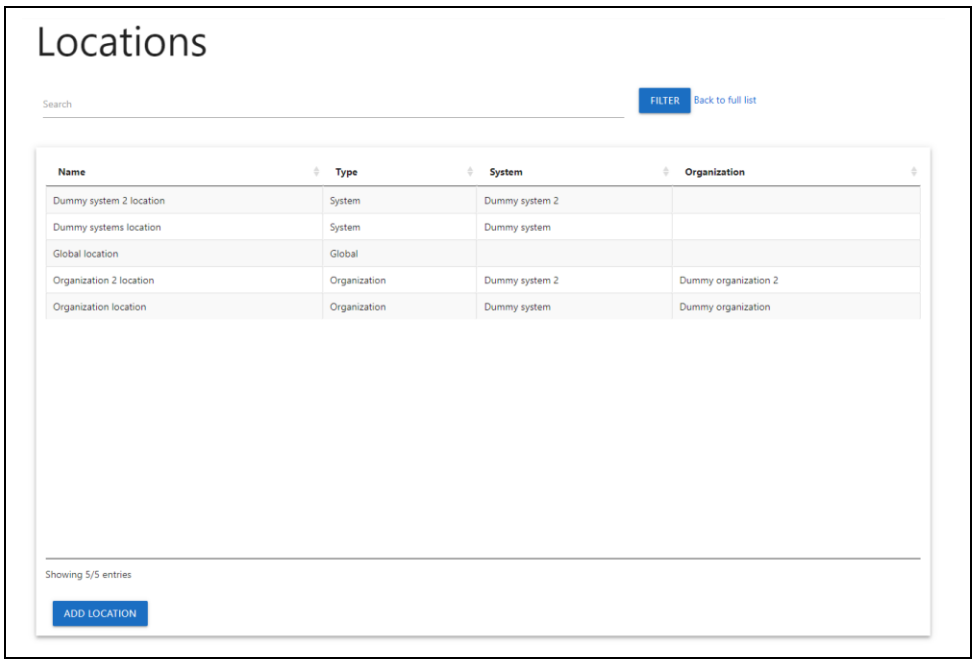


Figure 6-4. Location listing

6.1.1.5.1 Creating a Location

To add a new Organization, an authorized user first needs to be logged in.

The user navigates to the page listing Locations, clicks on the link titled “ADD LOCATION” (or similar). After clicking the link, the CreateLocation page will be displayed. There the user should input the data of the Location that is being created. The user selects the desired type and then depending on the type, Customer System and Organization.

Figure 6-5. The CreateLocation page

To create the Location, the user clicks on a button titled “CREATE LOCATION”.

6.1.1.5.2 Viewing and Editing a Location

To view or edit an existing Location's information, an authorized user of the specific Location first needs to be logged in. In addition, the Location the user wants to edit should exist within the system.

The user navigates to the page listing Locations, selects the desired Location from the list of Locations and clicks on a link to edit its information, i.e. "EDIT". On the EditLocation page, the user makes changes.

After making the changes, the user can choose to click "SAVE CHANGES", saving the changes to the database. Alternatively, the user can click "CANCEL" to return to the Location list page and omit the changes made.

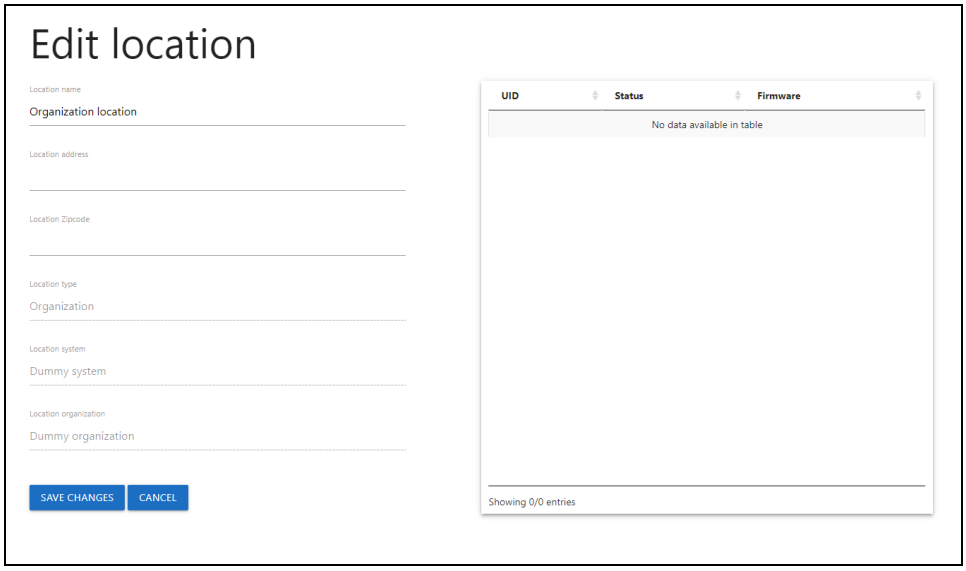


Figure 6-6. Editing a Location

6.1.2 IMS Device Management Functionalities

Device management functionalities are functionalities used by PulseOn personnel and Customer System administrators to manage the state of the devices. The following table defines the roles which can access these functionalities:

Table 12. Roles that can access Device Management Functionalities

Role	Scope	Usage
SuperUser	Whole system	Used by PulseOn personnel. No limitations in access.
SystemAdmin	Customer System specific information	Used by Customer System administration. Limited access to common functionalities and device management.

6.1.2.1 Assign a Device to a Customer

Devices can be assigned to a customer location. The device can be assigned by clicking the “Assign to customer” button and filling in the location information (Figure 6-8). The view has a search bar to help with finding the right location from the dropdown.

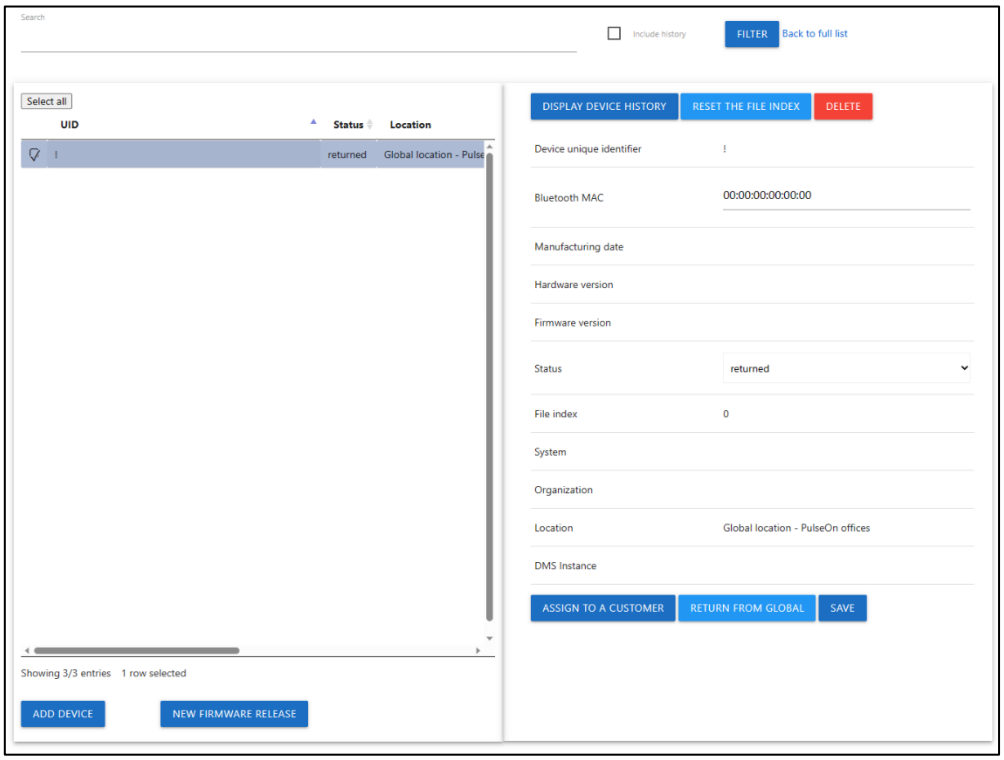


Figure 6-7. Selected device without a customer

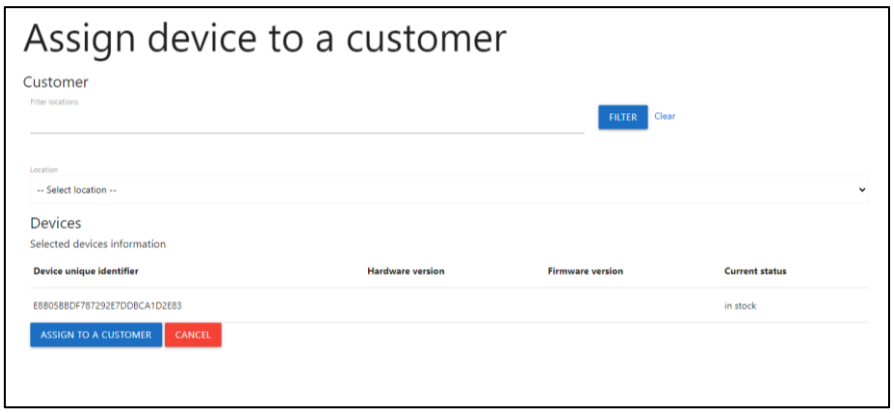


Figure 6-8. Assigning the device to a customer

6.1.2.2 Return of Device from a Customer

The device can be returned from a customer by selecting a device from the device list which is currently assigned to a customer (Figure 6-9). A confirmation dialogue will be displayed. The returned location depends on the roles of the returning user. SystemAdmin can return a device from an organization’s location

to the system's location, and from a system's location to a global location. The confirmation dialogue will display information of the current and return locations.

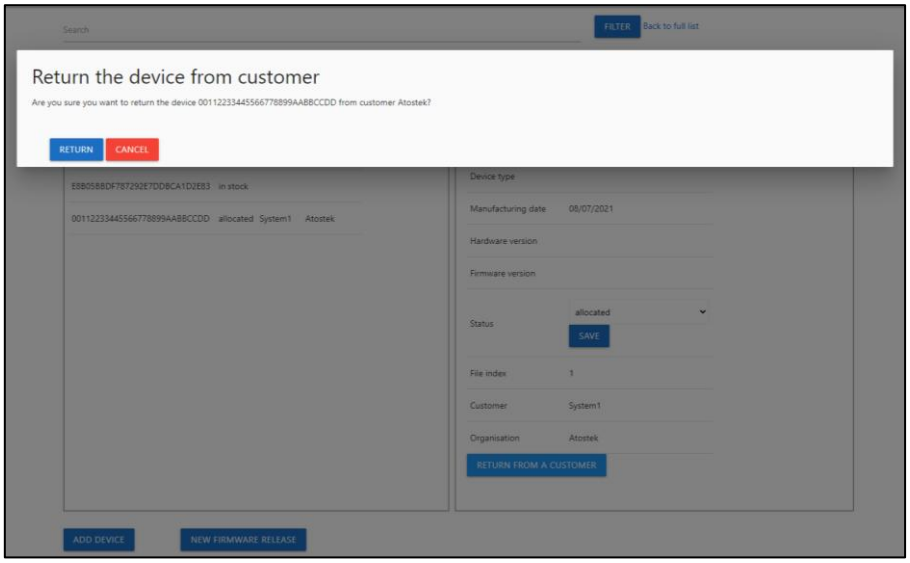


Figure 6-9. Return device from a customer confirmation dialogue

6.2 Data Transfer Software (DTS)

DTS Version	Applicability
01.07.00 and newer	Fully applicable
01.06.01 and older	Partly applicable.

Data Transfer Software (DTS) is a windows application that is used to achieve communication between the DMS and IMS systems. The common functionalities are described from the point of view of a user. Some parts of the operations may be related to functionalities of the IMS or DMS systems. DTS is a tray application that is displayed in the taskbar.

6.2.1 DTS Communication

The software connects to the wrist device using a USB connection. The software uses two methods for communication between the systems:

1. Direct PUSH communication to the DMS and IMS systems.
2. Communication between the systems using users' web browsers.

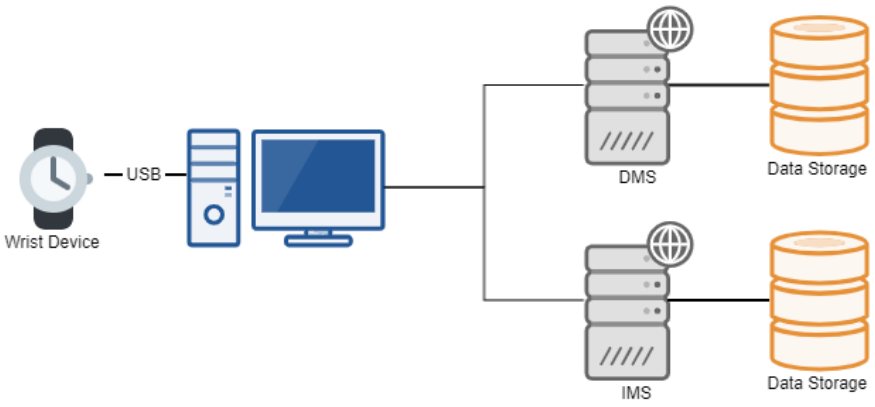


Figure 6-10. Communication principles

6.2.2 DTS Installation Requirements

The software is intended to be used with a Windows operating system. The software will install and launch a webserver on the user's computer. The application uses the 5001 port as a default port for the server. Thus, the port should not be in use by the user's computer. The following table defines the supported versions:

Table 13. Supported Windows versions

Operating system	Version
Windows 10	All
Windows 11	All

6.2.3 Installing and Updating DTS

The PulseOn DTS installer is distributed as a Windows installer (msi) packet. A User with credentials for DMS can download the DTS installer from the DMS website.

1. Navigate to the DMS website (https://prod.pulseon-ecg.com or, for the UK, https://prod.pulseon-ecg.uk)
2. Log in with existing credentials
3. At the bottom of the page, click “Download”

Figure 6-11. Bottom of the page of logged in user

4. On the Download page, click “Download” in the Data Transfer Software section.

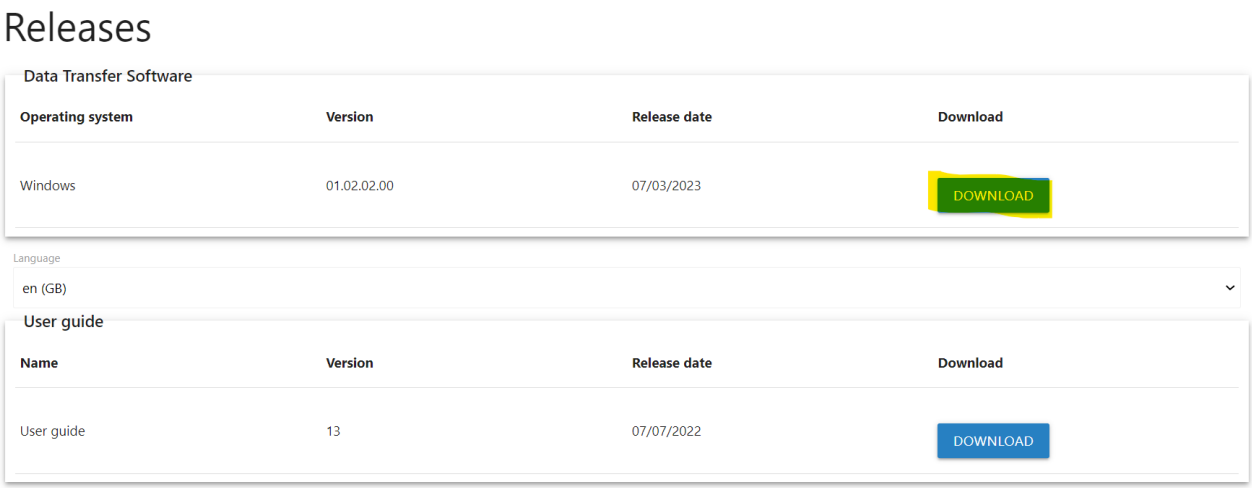


Figure 6-12. Content on the Download page

The software is installed by double-clicking the installer and allowing the installer to modify the computer files.

Updating the PulseOn DTS application is done by executing a newer version of the application installer when the PulseOn DTS application is closed. To close the application, open the PulseOn DTS context menu and click "Exit". Updating is done in the same way as installation, by running a newer version of the installer. The installer will automatically update the required files.

6.2.4 Uninstalling DTS

Uninstallation of the PulseOn DTS can be done from the add or remove programs menu of Windows. Locate the PulseOn DTS application and perform the uninstallation. The PulseOn DTS application should be closed when performing the uninstallation.

In addition, the certificates should be cleared from the certificate store. The certificates are issued by PulseOn DTS Local CA, and they are stored in the Trusted Root Certificate Authorities store. Locate the certificates using the Windows certificate manager and remove the certificates from the store. The certificates are only created by DTS version 01.06.01 and older versions.

6.2.5 DTS Installation Verification

After installation of the DTS, the installation should be verified. Verification of the installation should be done by using the intended end-user:

1. Start the DTS application by using the shortcut in the Desktop or by searching for the application PulseOn DTS.
    a. A shortcut can be created manually, if required, from the application installation location (C:\Program Files (x86)\PulseOn DTS\PulseOn DTS.exe)
2. Approve the initial certificate installation request. The initial startup can take several seconds while the certificate is created.
3. Verify that the DTS is started by locating the PulseOn DTS system tray icon.
    a. If the system tray icon does not appear, refer to chapter 6.2.7.5 Startup issues
4. Verify that the DTS can communicate with the wrist device by attaching a PulseOn Wrist Device to the computer using a dock. The system tray icon should turn green.

6.2.6 DTS Common Functionalities

6.2.6.1 Opening Menu and Verifying Device Connection

Before performing any functions, the user should verify that the software is running. The software should appear on the taskbar as a small icon. Hovering a mouse pointer over the icon should display *PulseOn Arrhythmia Monitor*. The menu is opened by right clicking the icon.

The menu displays the connected device identifier in the first row in the context menu. When the device is connected for the first time, there might be some delay until the device is displayed in the menu. When identifying connection problems, the user should always first verify that the device is properly connected to the computer with a USB cable and that the application displays the device information in the context menu.

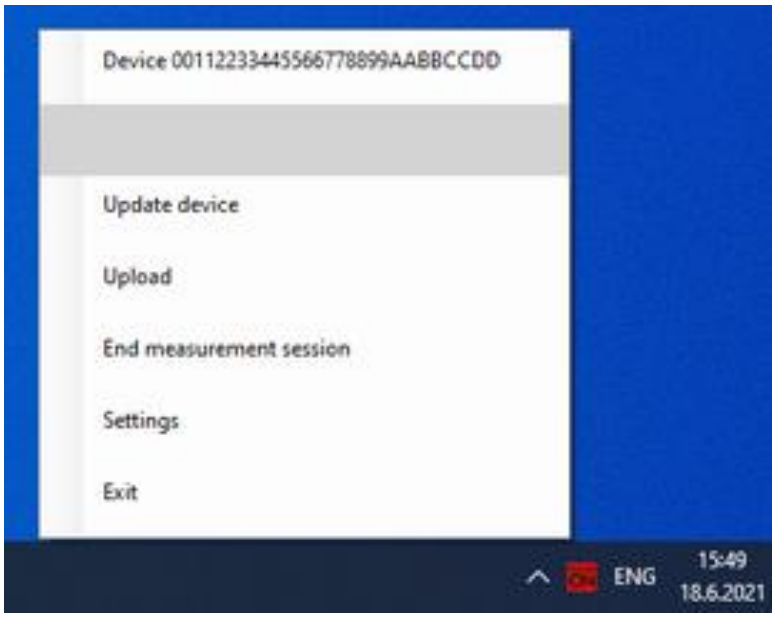


Figure 6-13. DTS menu showing the connected wrist device ID

6.2.6.2 Save Information

The device information should frequently be sent to the IMS and DMS services. This information includes the measurement data (ECG, IBI), device metadata and debug data. At minimum, the device should be cleared after every measurement session and before creating a new measurement session.

The process can be started in two ways:

1. By connecting the device to the user's computer.
2. By clicking the Upload action on the context menu (Figure 6-13).

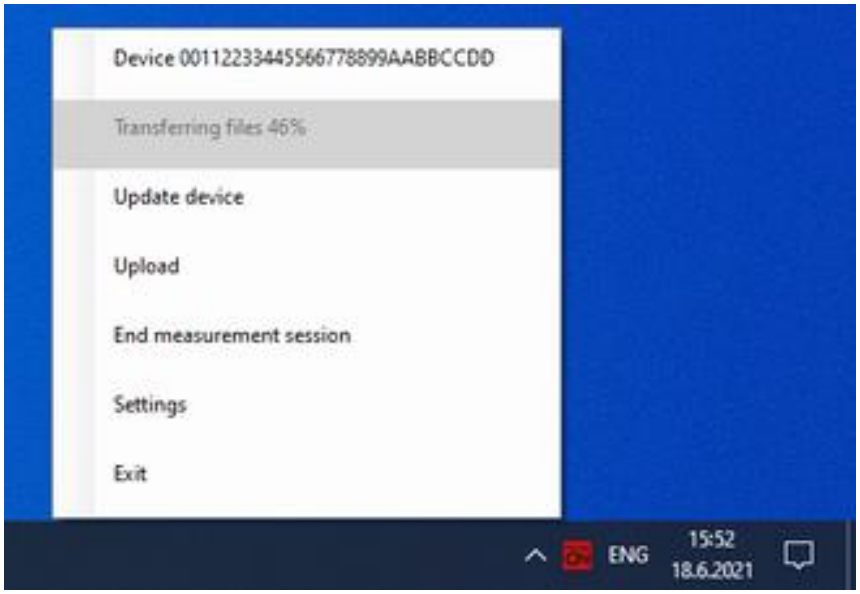


Figure 6-14. The progress of the save process can be viewed from the DTS menu

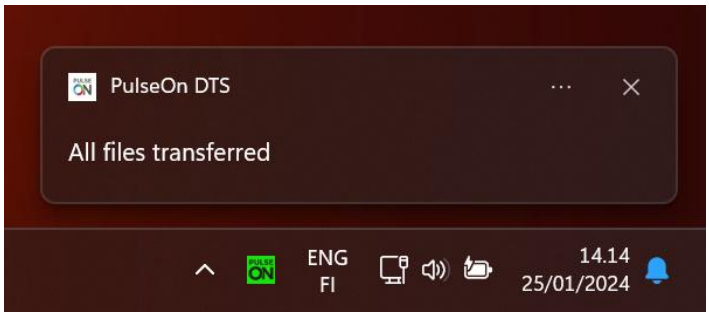


Figure 6-15. The save process has been completed successfully

6.2.6.3 End Measurement Session

Upon receiving the wrist device from a patient, the measurement session should be closed. The user interface will display the option to end the measurement session even when there is no active measurement session for the device. Thus, the user is only required to perform this function once and to verify that the application informs the user that the operation was successful (Figure 6-17).

The measurement session can be closed before or after the file transfer. The measurement session can be closed from the DTS menu (Figure 6-16). The user is asked to verify the closing of the measurement session.

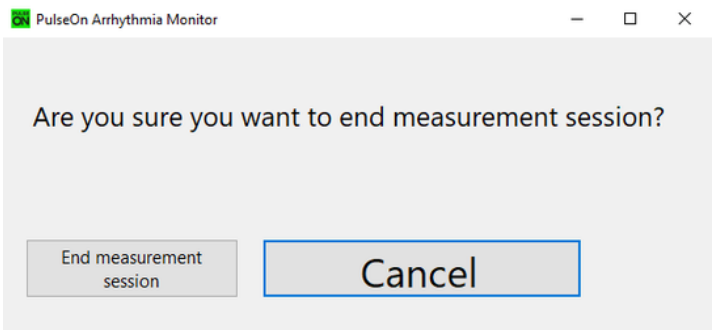


Figure 6-16. Confirmation dialogue for ending the measurement session

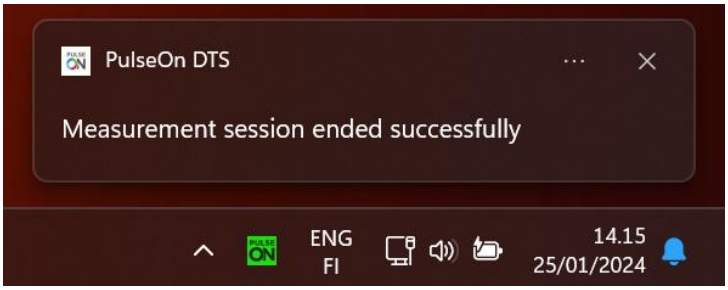


Figure 6-17. The measurement session has been ended and requires no further action from the user

6.2.6.4 Wrist Device Update

The DTS application will automatically try to update the wrist device upon connection. Additionally, the update can be launched from the context menu (Figure 6-13). When the device update is started, the user should not unplug the device from the computer. After a successful update, the device will reboot. Thus, the user should patiently wait until the device is back online.

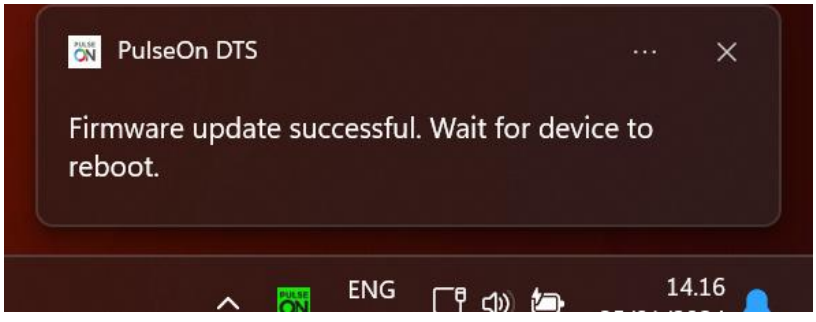


Figure 6-18. Device update in progress. Do not remove the device.

6.2.6.5 Display Device Information

The device will start charging automatically when connected to the computer. The user can view the device battery level by clicking the device identifier in the DTS menu (Figure 6-13). However, the charge level will not update automatically. Thus, the user should not leave the window open and expect to see the live progress of the device charge state.

Figure 6-19. Device information

6.2.7 DTS Reacting to Erroneous Situations

6.2.7.1 Data is not successfully transferred

1. Verify that the device can be found by opening the context menu. The application should display the device unique identifier.
2. Retry the data transfer
3. Use a different computer to transfer data

6.2.7.2 Viewing the error log and reporting a problem

If any of the measures do not help fix the problem, an error log can be sent to PulseOn. The error log is created in the PulseOn folder under local application data. The shorthand for finding the log folder is *%localappdata%/PulseOn DTS*. The error log should be sent as a part of the error report.

6.2.7.3 Device is reported not found in data management service

1. Verify that the device is found by opening the context menu and waiting for a couple of seconds. The application should display the device unique identifier. If the device unique identifier is not displayed, try plugging in the wrist device again. If this does not help see the chapter: Viewing the error log and reporting a problem
2. Verify that the browser can connect to DTS by visiting the following address with a browser: http://127.0.0.1:5001/api/device/versioninformation. The response should be in JSON format and provide information about the connected device. Update to the latest version of DTS if a connection cannot be established: 6.2.3 Installing and Updating DTS.

6.2.7.4 Verifying that DTS points to the correct environment

View the DTS version by opening the settings page. Verify that the last two numbers of the version are 01. The last two numbers in the version specify the environment and 01 confirms that the DTS version is targeted to production environments.

6.2.7.5 Startup issues

6.2.7.5.1 Making sure the system tray icon is not hidden

Make sure that the system tray icon is not hidden in the expandable context.

6.2.7.5.2 Missing user permissions for the file system

The PulseOn DTS application creates two certificates on initial startup. The application will not start if the user does not have permissions to read and write to the intended folder and its content. Verify that all users have read and write access to the C:\ProgramData\PulseOn folder and its content. If the folder is not created, the PulseOn DTS can be started with elevated permissions (Administrator) or the folder can be manually created.

6.2.7.5.3 Missing user permissions for certificate storage

The PulseOn DTS application tries to add the locally created CA certificate to the users Windows certificate storage on initial startup. In case of a group policy preventing users from adding CA certificates to their store, the certificate can be manually added to the system or user certificate storage. Add C:\ProgramData\PulseOn\ca.cer to the certificate store as a trusted root certificate authority on the computer. If the certificate cannot be located in the file system, check that the permissions are configured correctly as mentioned in chapter 6.2.7.5.2 Missing user permissions for the file system.

6.2.7.5.4 Required port already in use by different program

The PulseOn DTS application uses port 5001 and the application cannot start if the port is being used by different software. Find the program using port 5001 and close it.

7 Technical Support and Maintenance

In case of a need for technical support or assistance in maintaining or setting up the equipment or the cloud service, please contact PulseOn support.

7.1 Support Contacts

Address : PulseOn Oy, Tekniikantie 12, 02150 Espoo, Finland
Telephone : +358 44 554 0811
Email : support@pulseon.com
Website : https://www.pulseon.com/support

7.2 Recycling Information

Electrical and electronic equipment (WEEE) contains materials, parts and substances that can be dangerous to the environment and harmful to human health if the electrical waste and electronic equipment (WEEE) is not disposed of correctly.

Equipment that is marked with the WEEE logo should not be thrown away with your household waste. The product should be handed over to the applicable collection point for the recycling of electrical and electronic equipment, for proper treatment, recovery and recycling in accordance with your national legislation.

Contact your local authority waste disposal department, as they will be able to provide details of the recycling options available in your area.

7.3 Troubleshooting

Wrist device does not work

If the yellow LED lights on the bottom of the device are off, recharge the device. The wrist device will automatically turn off (LEDs on the bottom turn off) if the battery level gets too low.

Red LED is on, but the wrist device does not react to anything

If the red LED on top of the wrist device is continuously on, the device is in unrecoverable error mode. Please contact the personnel that provided you with 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.

How to force reset the device

The wrist device can be reset when it is in its charging dock. Resetting does not clear the device memory.

1. Connect the charging dock to the mains.
2. Place the wrist device in the charging dock.
3. Reset is done by holding down a button (in small hole at the bottom of the charging dock). A pin or a needle is needed to press the button.
4. Hold the button down for 12–15 seconds.
5. Remove the wrist device from the dock
6. Put it back into the dock. If it starts recharging, the reset was successful.

Cannot take an ECG measurement

A moist or wet hand can prevent the initiation of an ECG measurement. Take the device off to clean and dry both the wrist and the bottom of the device.

Gateway is not working

Please ensure that the gateway is correctly connected to the mains. The status light indicator should be lit.

Computer does not recognize the device

If you receive a notification stating "*USB device was not recognized*", please ensure that the contacts on the wrist device and charging dock are clean.

Service error codes

Identifier	Code	Description	Resolution
GeneralError	0000	Unhandled exception	
PatientDidNotMatch	0001	Authorization failure	
OrganizationDidNotMatch	0002	Authorization failure	
EntityNotFound	0003	Invalid request – the resource could not be found	
CanNotConnectToDts	0004	DMS UI cannot connect to DTS	*Verify:* DTS is running. Ref: 6.2.7.5 Opening Menu and Verifying Device Connection DTS installation points to correct environment. Ref: 6.2.7.4 Verifying that DTS points to the correct environment
NoAnnotationsForReviewedSession	0007	Cannot mark session as reviewed without adding an annotation	Add an annotation to the measurement session before marking it as reviewed
MultipleIdpsRegisteredForUser	0010	Found multiple possible organizations for using "Organization login"	Ask an administrator to update the account roles so

			that they only have one “Organization login”
LoginOptionsDidNotMatch	0013	Found organizations both using and not using “Organization login”	Ask an administrator to update the account roles so that they only have either/or
SsoIdentityAlreadyInUse	0014	“Organization login” account already tied to another DMS account	Contact support
OrganizationIsReadOnly	0020	Modified patient or session belongs to a read-only organization	*Verify:* You are modifying the correct patient or session
ImsDeviceNotFound	1000	Device not registered to IMS	
ImsInvalidMacAddress	1001	Device not registered to IMS	
ImsInvalidFileIndex	1002	Device file cannot be processed – the file is not expected by DMS	
ImsDeviceRecalled	1003	Device cannot be used – it is recalled	
ImsMeasurementSessionNotFound	1004	Measurement session cannot be found – the information is not available	
CardiolundVersionNotSupported	2000	Cardiolund version not supported	
WebRendererGeneralError	3000	General error	
PdfServiceS3UploadFailed	3001	Storing of PDF data failed.	
PdfServiceS3ReadFailed	3002	Reading of PDF data failed.	
PdfServiceLambdaInvokeFailed	3003	Creation of PDF failed.	
DtsGeneralError	4000	General DTS error	
DtsGeneralDeviceNoResponse	4001	DTS did not get response from WD.	
DtsGeneralDeviceNotFound	4002	DTS could not connect to device.	*Verify:* Device is connected to computer. Ref: 6.2.6.1
DtsGeneralDeviceBusy	4003	DTS could not communicate with WD.	
DtsGeneralInvalidSequenceNumber	4004	DTS and WD communication exception.	
DtsGeneralMultipleDevicesConnected	4005	DTS cannot fulfil the request – multiple devices connected.	
DtsGeneralInvalidDeviceIdentifier	4006	Authorization failure.	
DtsTimeSetFailed	4007	DTS could not set the time to WD.	
DtsTimeFetchFailed	4008	DTS cannot connect to the configured timeserver.	
DtsFtsInvalidCrc32	4009	DTS binary cannot be processed – the CRC32 checksum failed.	
DtsDeviceFileRemoveFailed	4010	DTS cannot remove file in device.	

DtsDeviceFileGetFailed	4011	DTS cannot get a file from device.	
DtsServiceCodeMismatch	4012	DTS communication error.	
DtsFirmwareUnsupported	4013	DTS does not support the device version.	
DtsDeviceConnectionFailed	4014	DTS could not open connection to the device.	
DtsServiceVersionGetFailed	4015	DTS could not get the version information from WD.	
DtsSessionIdGetFailed	4016	DTS could not get the session id from WD	
DtsParallelFileTransfer	4017	File transfer is already ongoing.	Wait until file transfer is completed. Check progress from DTS.
DtsDeviceLowBattery	4018	Low battery on wrist device.	Recharge the wrist device.
DtsDeviceChargingStatusInvalid	4019	Wrist device charging status is invalid.	Try to disconnect and connect the wrist device again.

Appendix A – Electromagnetic Compatibility (EMC)

Electromagnetic Emissions

Manufacturer's Declaration – Electromagnetic Emissions	
The PulseOn Arrhythmia Monitor is suitable for use in an electromagnetic environment as described below. The user should ensure that the device is used in such an environment.	
Emission Tests	Compliance
RF emissions CISPR11:2009 + A1:2010	Group 1
RF emissions CISPR11: 2009 + A1:2010	Class B
Voltage fluctuations and flicker IEC 61000-3-3	Complies

Electromagnetic Immunity

Manufacturer's Declaration – Electromagnetic Immunity	
The PulseOn Arrhythmia Monitor is suitable for use in an electromagnetic environment as described below. The user should ensure that the device is used in such an environment.	
Interference Resistance Test	IEC 60601 – Testing Level
Electrostatic discharge (ESD) acc. to IEC 61000-4-2:2008	± 8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ± 15 kV air discharge
Fast transient electric disturbances / bursts acc. to IEC 61000-4-4:2012	±2 kV for Input a.c. power port 100 kHz repetition frequency
Surge voltage acc. to IEC 61000-4-5:2005	±0.5 kV, ±1 kV for Input a.c. power port
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11:2004	0% UT ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for Input a.c. power port 0% UT ; 1 cycle and 70% UT ; 25/30 cycles single phase: at 0° for Input a.c. power port 0% UT ; 250/300 cycle for Input a.c. power port
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8:2009	30 A/m 50Hz and 60Hz

Manufacturer's Declaration – Electromagnetic Interference Resistance		
The PulseOn Arrhythmia Monitor is suitable for use in an electromagnetic environment as described below. The user should ensure that the device is used in such an environment.		
Interference Resistance Test	IEC 60601 – Testing Level	Accordance Level

Conducted HF disturbances acc. to IEC 61000-4-6:2013 Radiated HF disturbances acc. to IEC 61000-4-3:2006 +A1:2007 +2:2010	3 Vrms 150 KHz to 80 Mhz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz for Input a.c. power port 3 V/m 80 MHz to 6 GHz	See test specifications table below

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Appendix B – Regulations, Directives and Standards

Medical Device Regulation (MDR) Classification

Wrist device	Class IIa
Charging dock	Class I (accessory to the wrist device)

Regulations and Directives

(EU) 2017/745	Medical Device Regulation (MDR)
2014/53/EU	Radio Equipment Directive (RED)
2014/35/EU	Low Voltage Directive (LVD)
2014/30/EU	Electromagnetic Compliance Directive (EMC)
2011/65/EU	RoHS Directive & (EU) 2017/2102 RoHS 2 Directive
2012/19/EU	WEEE Directive

Standards

ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
ISO 13485:2016	Medical devices – Quality Management Systems –- Requirements for Regulatory Purpose
ISO 14155:2020	Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 20417:2021	Medical Devices. Information to be Supplied by the Manufacturer
ISO 15223-1:2021 /AMD1:2025	Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
IEC 60601-1:2005 /AMD1:2012 /AMD2:2020	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
ISO 17664-2:2021	Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices – Part 2: Non-Critical Medical Devices
IEC 60601-1-2:2014 /AMD1:2020	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 /AMD2:2020	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC 60601-1-11:2015 /AMD1:2020	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
IEC 60601-2-47:2012 (Ed. 2.0) EN 60601-2-47:2015	Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

IEC 62304:2006 /A1:2015	Medical Device Software – Software Life-Cycle Processes
IEC 62366-1:2015/A1:2020	Medical devices – Part 1: Application of Usability Engineering to Medical Devices
EN 50566:2017 /A1:2023	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: handheld and body-mounted devices in close proximity to the human body
EN 300 328 v2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide-band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
IEC 63000:2016 /AMD1:2022	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances