Vital Signs Monitoring System

REF 1200

FastFocus

Contents

1 General information

1.1 About the system

This manual is written and compiled in accordance with the European Medical Device Regulation (EU) 2017/745 and harmonized standards. In this manual, you can find important information about how to operate the FastFocus' Vital Signs Monitoring System (hereafter referred to as 'system' or 'device'). The manual helps you with the operation and the maintenance of the system and its modules, in a safe and responsible manner.
Read this manual carefully before use, and all precautionary information and specifications. The manual which describes the operating procedures should be followed strictly. Perform the procedures in the given sequence. Always keep the manual near the device. Failure to follow the manual may cause measuring abnormality, equipment damage and human injury.

The device has the following modules:

- FastFocus EarSensor (hereafter referred to as 'EarSensor')
- FastFocus Server (hereafter referred to as 'Server')

and the following accessory:

- FastFocus Multi-Docking Station (hereafter referred to as 'Multi-Docking Station')

1.2 Intended Purpose of the device

1.2.1 Intended Use statement

The Vital Signs Monitoring System is intended for frequent non-invasive measurement of functional oxygen saturation of arterial haemoglobin (SpO2), pulse rate, and respiratory rate during no motion conditions and measurement of physical activity, including posture and motion intensity, for the purpose of monitoring rehabilitation and early detection of deterioration of adult patients. The Vital Signs Monitoring System is intended to be used by healthcare professionals in professional healthcare facility environments.

1.2.2 Intended patient population

The Vital Signs Monitoring System is intended to be used on adult patients (>18 years of age) without any of the contraindications (see section 2).

1.2.3 Intended user

The intended users are adult healthcare professionals e.g., clinicians and medically qualified personnel for monitoring of non-invasive pulse rate, non-invasive functional oxygen saturation of arteriolar haemoglobin (SpO2) and respiratory rate during no-motion conditions. They need to be instructed by medical staff and/or acquired information by reading this Instructions for Use (IFU) before using this equipment. The intended users for operating the device have the following characteristics:

- Occupation: healthcare professionals (e.g., clinicians, physicians, medically qualified personnel for monitoring of pulse rate, functional oxygen saturation and respiratory rate such as nurses, and therapists)
- Age: Adult (>18 years of age)
- Education: at least a nursing diploma or equivalent and medically qualified for monitoring of pulse rate, functional oxygen saturation and respiratory rate
- Knowledge: according to education; trained and experienced to be able to handle medical devices
- Language understanding: minimum requirements for a nurse apply, English
- Experience: minimum experience required for a healthcare professional to work in the intended environment
- Permissible impairment: minimum requirements for a nurse apply
- Assigned responsibilities: Allowed to care for patients

Users for installation, maintenance and testing of this equipment need to be technical personnel, trained, and experienced to install, test, and maintain medical equipment. They need to have instruction by medical staff and/or by these instructions for use/manual before using this equipment.

1.2.4 Intended part of the body or tissue type applied to or interact with

The FastFocus' Vital Signs Monitoring System, more specific the module EarSensor, does have direct contact to the patient's intact skin and is intended to be worn on the ear. The housing of the EarSensor is made of biocompatible materials.

The anatomical site for taking the measurement is on the backside of the ear concha. It has other contact points at the frontside and top of the ear. The EarSensor can only be applied to patients with intact skin and is contra-indicated for patients with signs of redness, swelling, infection or skin breakdown at the sensor application site, including the inner aspect of the ear and behind the ear. The sensor cannot be placed on patients with pierced ears at the measuring site.

The EarSensor is not intended for use on a monitoring site for prolonged periods. It is recommended to check the skin every four (4) hours. The sensor must be removed and repositioned to a different monitoring site at least every twelve (12) hours to ensure adequate adhesion, circulation, skin integrity and correct optical alignment. If extended monitoring is required, the sensor must be moved to the opposite ear. It may be necessary to move and reposition the sensor to a different monitoring site more frequently, since individual skin conditions and perfusion levels affect the ability of the site to tolerate sensor placement.

The FastFocus' Server and other accessories to the system (i.e., Multi-Docking Station) have no direct contact with the patient.

1.2.5 Intended environment

The FastFocus' Vital Signs Monitoring System is intended for the use in professional healthcare facility environments. The most likely locations for patients to be monitored are general medical/surgical wards, general hospital and alternate care environments.

The device is not intended for use for continuous surveillance of vital physiological processes in anaesthesia, intensive care, or emergency care, and to monitor vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient. The device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.

The FastFocus' EarSensor is a wireless mobile device that can be used within wireless range of up to 30 m free line of sight to the FastFocus' Local Server. The FastFocus' Server and other accessories to the system (i.e., Multi-Docking Station) are non-mobile parts of the system.

The Vital Signs Monitoring System and all its accessories must be considered all non-sterile. Before use, the system must be cleaned/disinfected following the Instructions for Use (see 7.1). The physical characteristics of use and storage are listed in Table 1.

Table 1 - Physical characteristics of the intended environment of use of the FastFocus' Vital Signs Monitoring System

Characteristic	Conditions of use		Conditions of storage	
	minimum	maximum	minimum	Maximum
EarSensor				
Temperature	15°C	35°C	-20°C	70°C
Relative humidity	10%	95% (non-condensing)	10%	90% (non-condensing)
Atmospheric pressure	50 kPa	106 kPa	50 kPa	106 kPa
Local Server				
Temperature	0°C	40°C	-20°C	60°C
Relative humidity	10%	95% (non-condensing)	10%	90% (non-condensing)
Atmospheric pressure	50 kPa	106 kPa	50 kPa	106 kPa

1.2.6 Indications for Use statement

The Vital Signs Monitoring System is indicated to frequently non-invasively monitor vital signs and physical activity of adult patients by healthcare professionals for which the healthcare professional deems it is of additional value. These patients could be rehabilitating patients that have unstable vital signs, are recovering and getting more active, or need extra attention due to their disease, for example pneumonia or COPD. The system provides the healthcare professionals the ability to access and monitor the patient physiological parameters to support the clinical decision-making process.

Note!
The device is not intended for use for continuous surveillance of vital physiological processes in anaesthesia, intensive care, or emergency care, and to monitor vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient.
The device does not have alarms. In case anomalies are detected in the measurement data, the measurement should be verified with another device first.

1.2.7 Intended clinical benefits

- The device is designed for frequently monitoring the vital physiological parameters of adult patients. With the functions of frequently recording and displaying parameters, such as pulse rate, functional oxygen saturation, respiratory rate, and physical activity, it allows comprehensive analysis of patient's physiological condition.
- The Vital Signs Monitoring System can serve its medical purpose by providing valuable data for diagnosis and ongoing monitoring of patients supporting clinical decision making by the healthcare provider.
- The device benefits patients by helping healthcare professionals setting diagnosis based on the provided data that improve their treatment.

1.2.8 Type of use/reuse

The FastFocus' Vital Signs Monitoring System is intended for continuous use, is reusable, provided that cleaning is performed according to standard hospital procedures and Instructions for Use (see section 7.1). Accessories to be used with the system are re-usable.

1.3 Contact

FastFocus B.V.
Gerverscop 9
3481 LT Harmelen
The Netherlands
Tel: +31 (0)348 443 840
E-mail: info@fastfocus.nl

1.4 Warranty

For the warranty provisions, refer to the website: www.fastfocus.nl.

1.5 Authorization of personnel

Make sure that only authorized personnel use and service the device.

1.6 Warning, caution and note

Warning!
A "warning" tells you that there is a risk of personal injury or death.

Caution!
A "caution" tells you that:

- there is a risk of damage to the system, and/or
- there is a risk of damage to other equipment.

Note!
A "note" gives more information.

1.7 Disclaimer

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless, the manufacturer reserves the right to make alterations and improvements to the device. These may not yet have been described in the instructions. The manufacturer cannot be held liable for the outcome of the patients' treatment.

This document contains proprietary information that may not be disclosed to third parties. This document may not be used without the explicit written consent of the manufacturer.

These instructions are intended for personnel authorized to work with and/or service the medical device described in this manual.

2 Safety precautions

2.1 Contraindications

- The Vital Signs Monitoring System is contraindicated for patients with signs of skin damage on the ear, such as, but not limited to, signs of redness, swelling, infection or skin breakdown at the sensor application site, including the inner aspect of the ear and behind the ear.
- The EarSensor cannot be placed on patients with pierced ears at the sensor application/measurement site.
- The EarSensor shall not be used on patients with skin conditions that could result in permanent harm when using the EarSensor.
- The EarSensor shall not be used on patients with limited blood perfusion through the ear due to medical condition (e.g., cauliflower ears, ischemic ear shells, etc.).
- The EarSensor shall not be used if the patient is unable to sense the device and the associated pressure, friction, and shear on their skin due to sedation, encephalopathy, or neurologic disease.
- The EarSensor shall not be used on patients that are obligated to wear other medical devices for health and/or disability purposes (e.g., hearing aids, oxygen tubes, etc.)
- The sensor should not be used on patients if the inner aspect of the ear (cavum conchae [A]) is not large enough to accommodate the hook of the sensor without touching the tragus and/or crus of helix.

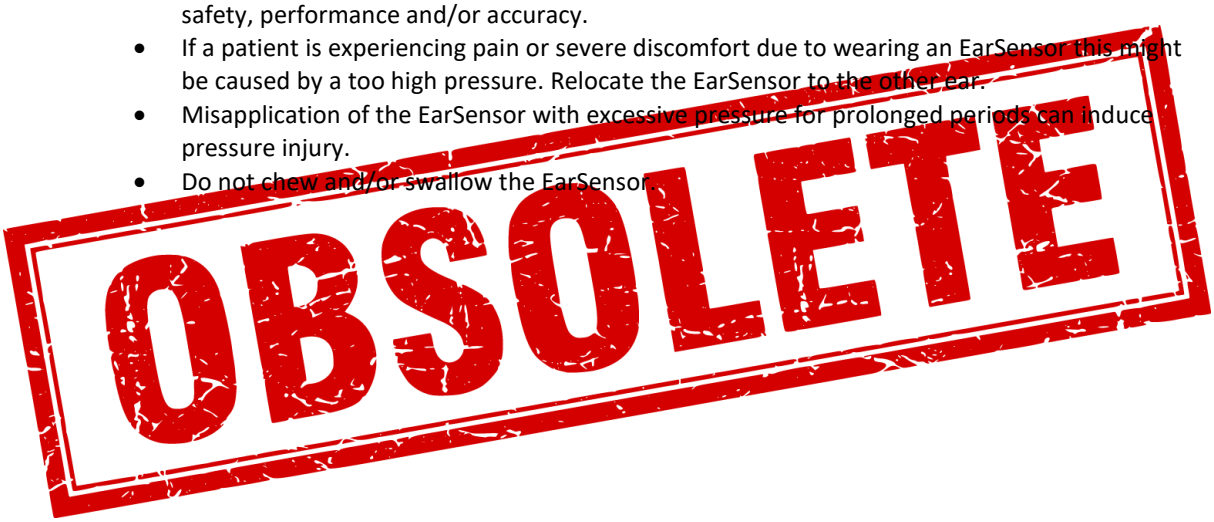
Figure 1 – Ear. A) Cavum conchae, B) tragus, C) ear lobe, D) crus of helix.

2.2 Warnings

Warning!

- Use of accessories, transducers, and cables other than those specified or provided by FastFocus B.V. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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 they are operating normally.
- Do not service or maintain the system while in use with a patient.
- The system is classified class A according to CISPR 11, the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR 11 class B is normally required) this system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- To reduce the possibility of heat-related injuries or of overheating the computer, do not place the computer directly on your lap or obstruct the computer air vents. Use the computer only on a hard, flat surface. Do not allow another hard surface, such as an adjoining optional printer, or a soft surface, such as pillows or rugs or clothing, to block airflow. Also, do not allow the AC adapter contacting the skin or a soft surface, such as pillows, rugs, or clothing, during operation.
- Do not use modules when they are damaged. Injury may result.
- Do not use the modules near flammable anaesthetics and/or in oxygen enriched environment, to avoid the risk of explosion or fire.
- Do a check on the device after a temporary interruption of the mains supply. The device does not have an isolating switch. After an interruption of the supply mains, the device is in standby mode.
- Before you clean the Server or Multi-Docking Station, disconnect the power supply cord to eliminate the risk of electrocution.
- Clean the EarSensor after and prior to each use to reduce the risk of contamination and infection.
- Before performing maintenance, disconnect the power supply cord to eliminate the risk of electrocution. There are electrically live parts within the Server and Multi-Docking Station when they are connected to a power supply.
- Place the Server and Multi-Docking Station in such a way that the mains plug can be disconnected easily in case of emergency. Operator injury may occur.
- Connect the Server and Multi-Docking Station to an adequate reliable grounded receptacle.
- Do not use the EarSensor on another position than the one indicated by this manual, e.g., the inner aspect of the ear (cavum conchae). This may result in inaccurate readings.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- The sensor is not intended for use on a monitoring site for prolonged periods. The sensor must be removed and repositioned to a different monitoring site at least every twelve (12) hours and it is recommended to check the skin every four (4) hours. If extended monitoring is required, the sensor must be moved to the opposite ear. It may be necessary to move the sensor frequently since individual skin conditions and perfusion levels affect the ability of the site to tolerate sensor placement.
- Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the EarSensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the EarSensor if there are signs of tissue ischemia.

- During low perfusion, the EarSensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- Do not use tape to secure the EarSensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the EarSensor.
- EarSensors applied too tightly or that become tight due to oedema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied EarSensors or EarSensors that become partially dislodged may cause incorrect measurements.
- The system is a radio frequency (RF) emission device and should not be used in RF sensitive areas.
- The system is not designed for use near magnetic resonance imaging (MRI) equipment. The EarSensor must be removed from any patient about to undergo an MRI.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the EarSensor.
- To prevent damage, do not soak or immerse the EarSensor in any liquid solution. Do not attempt to sterilize the EarSensor.
- Do not modify or alter the EarSensor in any way. Alteration or modification may affect the safety, performance and/or accuracy.
- If a patient is experiencing pain or severe discomfort due to wearing an EarSensor this might be caused by a too high pressure. Relocate the EarSensor to the other ear.
- Misapplication of the EarSensor with excessive pressure for prolonged periods can induce pressure injury.
- Do not chew and/or swallow the EarSensor.



2.3 Cautions

Caution!

- It is recommended to make regular backups of the content of the system to prevent the total loss of files from physical damage, failure, loss, or theft.
- Avoid strong cleaning solvents that can permanently damage the modules of the system. If you are not sure that a cleaning product is safe, check the product contents to make sure that ingredients such as acetone, ammonium chloride, methylene chloride, and hydrocarbons are not included in the product.
- Do not use abrasive cleaners.
- Remove too much detergent or disinfectant from the device.
- Do not use dripping wet cloth for cleaning of the modules of the system.
- Make sure that liquids cannot come in the electrical areas (sockets) of the modules of the system.
- Let the modules air dry. Do not close the lid of the Server until you have allowed it to completely air-dry.
- Do not use cleaners that contain any petroleum-based materials such as benzene or thinner. These may damage the modules of the system.
- Do not use steam sterilization (autoclave), ethylene oxide (EO) sterilization or dry heat to sterilize the modules of the system.
- The sensor is not considered suitable for use during shower or comparable wet situations.
- The system is not designed for direct X-ray exposure. The EarSensor must be removed from any patient about to undergo an upper torso X-ray.
- The system is not designed for use near X-ray computed tomography (CT) equipment. The EarSensor must be removed from any patient about to undergo a CT scan.
- The system is not designed for use near high frequency (HF) surgical equipment. Do not use the system near HF surgical equipment.

2.4 Notes

Note!

- The Server does not contain an alarm system with an interruption of power supply/supply mains alarm condition. This means that in case of a power failure, there will be no alarm.
- The Server is not equipped with an isolating switch. Temporary interruption of the supply mains will render the device in standby mode and discontinue measurement if the battery is depleted.
- There is no need or requirement for the user to switch the EarSensor on and off. When fully or partially charged, the EarSensor is always activated and ready to be used. The EarSensor will turn off when the battery will be empty and will activate again when it will be connected to the Multi-Docking Station for charging.
- The measurement data shall be accessed from the supplied Server. Accessing the data from a different device may result in incorrect data display.

2.5 Symbols

IPX4	Protected against splashing water - Water spraying at all angles at 10 litres/min at a pressure of 80-100 kN/m2 for 5 min. (According to IEC 60529)
MD	Medical device
SN	Serial number
REF	Catalogue / article number
	Date of manufacture
	Manufacturer
	Keep away from sunlight
	Keep away from rain
	Do not use if packaging is damaged
	AC voltage
	Type BF applied parts (according to IEC 60601-1)
	Refer to instruction manual/booklet
CE	CE-marking conforms EU directive 2014/35/EU

CE 1912	This system is a CE-marked class IIa medical device assessed by Kiwa Dare B.V. conform (EU) Regulation 2017/745 on medical devices
	Dispose according to European Community Directive 2002/96/EC (WEEE)
	Caution. Check the instructions for use for important cautionary
	Class II equipment with functional earthing
	Protection against electrical shock, class II
	Not made with natural rubber latex
	Alarm inhibit. This system does not have alarms

3 Description

3.1 System

The Vital Signs Monitoring System (REF 1200; Basic UDI-DI: **871932658731200V9**) consists of the following elements:

1. EarSensor (REF 1201)
2. Server (REF 1203)

The Multi-Docking Station is an accessory.

3.2 EarSensor

The EarSensor is a module of the system and consists of the following elements:

1. Detection window[1]
2. Hook
3. Charging pins
4. Status indicator (LED can have distinct colours, see *3.2.1 Status indicator*)

Figure 2 – EarSensor

The EarSensor measures acceleration and photoplethysmography. The measurements are sent wirelessly to the Server.

The EarSensor is worn on one of the ears of the patient (*see 5.3 Attaching the EarSensor to the patient*).

[1] LED Emission Aperture (NEN-EN-IEC 60601-2-57(2011)).

3.2.1 Status indicator EarSensor

The status indicator is a multi-colour LED (cyan, green, yellow). The colour and blinking behaviour indicate the status of the EarSensor. The EarSensor can show the following statuses:

Table 1 – Status indicator (LED) combinations and meaning.

EarSensor location	LED Configuration		Meaning
EarSensor on multi-docking station (charging mode)	Cyan LED blinking		Battery charging; EarSensor is between 0% and 90% full
	Cyan LED continuously on		Battery fully charged; Ear Sensor above 90% full
EarSensor out of multi-docking station	Green LED blinking		The EarSensor is performing a tissue check to verify that the sensor is on the ear.
	Green LED continuous for five (5) seconds		The EarSensor is correctly positioned on the ear and in measuring mode.
Other	Yellow LED continuously on		EarSensor is not functional due to software or hardware error.

3.3 Server

The Server is a module of the system and consists of the following elements:

1. Laptop
2. Coordinator
3. Power supply

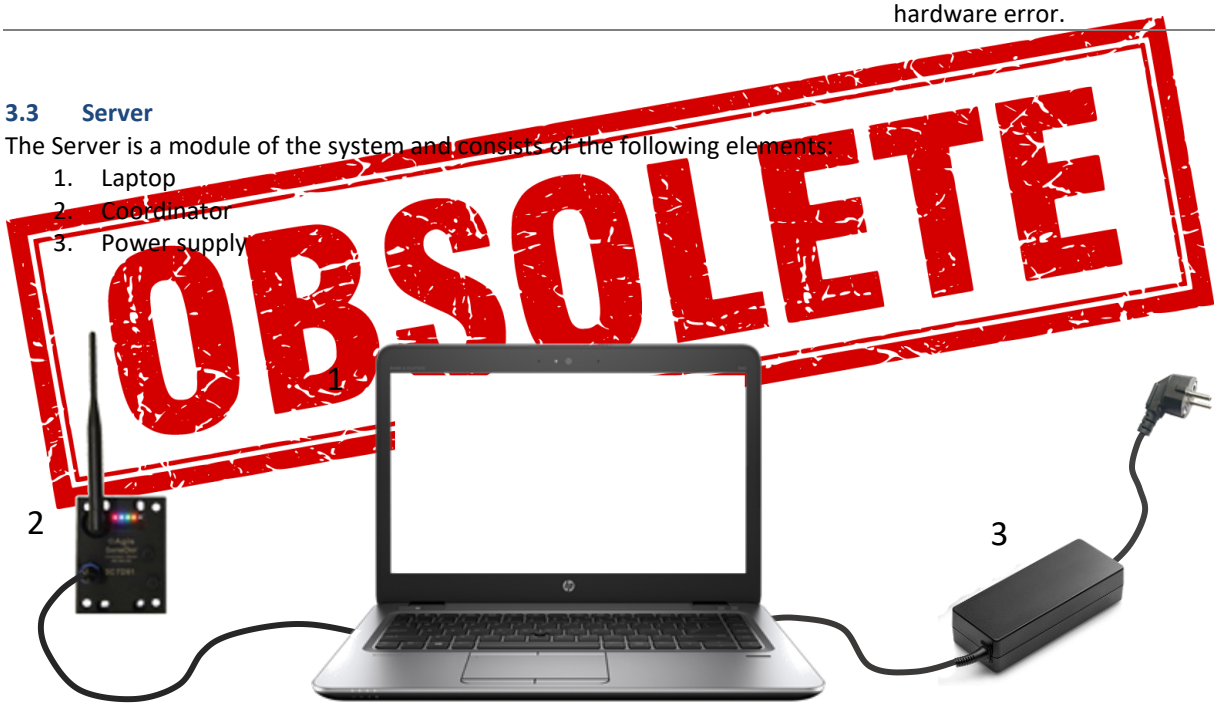


Figure 3 – Server module including laptop, Coordinator and power supply.

The Server receives data and status related information from 1 and up to 25 EarSensors. Measurement data is stored in a database and pulse rate, oxygen saturation, and respiratory rate are calculated based on the received measurement data. The intended user can view and export the data measured.

3.4 Multi-Docking Station

The Multi-Docking Station (REF 1102) is intended for docking and charging the EarSensors. The Multi-Docking Station is suitable for charging a maximum of ten (10) EarSensors at the same time.

The following elements of the multiple docking station are presented on Figure 4:

1. Charging pins

2. 5V power input
3. External power supply

Figure 4 - Multi-Docking Station

4 Installation

Warning!

- Do not use modules when they are damaged. Injury may result.
- Do not use the modules near flammable anaesthetics and/or in oxygen enriched environment, to avoid the risk of explosion or fire.
- Use of accessories, transducers, and cables other than those specified or provided by FastFocus for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Place the Server and Multi-Docking Station in such a way that the mains plug can be disconnected easily in case of emergency. Operator injury may occur.
- Connect the Server and Multi-Docking Station to an adequate reliable grounded receptacle. Operator injury may result.

Note!

- The Server must be located within 30 meters distance from all EarSensors of the system.

4.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See specifications on page 61.

4.2 First installation and configuration

Upon first use, FastFocus will perform the configuration and installation of the system. Please contact FastFocus if for some reason it is needed to configure the system again. After first installation, the modules can be re-installed by following the steps depicted in the following paragraphs.

4.3 Install the modules

Perform the following steps prior to the first use of the system:

- First check if all components of the system are available and not damaged.
- Clean all modules according to the cleaning instructions on page 50.

4.3.1 Install Server

- Place the Server on a table or another smooth horizontal surface at a comfortable working height.
- Connect the power supply to the laptop. Before connecting the power supply to a grounded receptacle first connect the power supply connector (power jack) to the laptop as shown in Figure 5. The input power port of the laptop can be found on the right side indicating by a lightning sign: ϟ.

Figure 5 – Connect the power supply to the laptop.

Connect the power supply to a grounded receptacle. The AC plug as shown in Figure 6 may now be inserted into a grounded receptacle. Make sure that the AC plug is fully inserted and not loosely connected. Note that the power adapter might get warm over time.

Figure 6 – Power mains.

- Assemble the Coordinator; Screw the antenna firmly on the coordinator with pointed pliers.

Figure 7 – Connecting antenna on coordinator.

- Assemble the Coordinator; Connect the USB cable with the blue screw cap to the coordinator.

Figure 8 - Connect USB cable to Coordinator

- Connect the Coordinator via the USB cable to the laptop. The Coordinator comes with a standard USB connector. Insert the USB connector to the port on the left side of the Laptop.

Figure 9 – Connect the Coordinator to the laptop.

- Turn on the Server using the Laptop power button located on the top left.

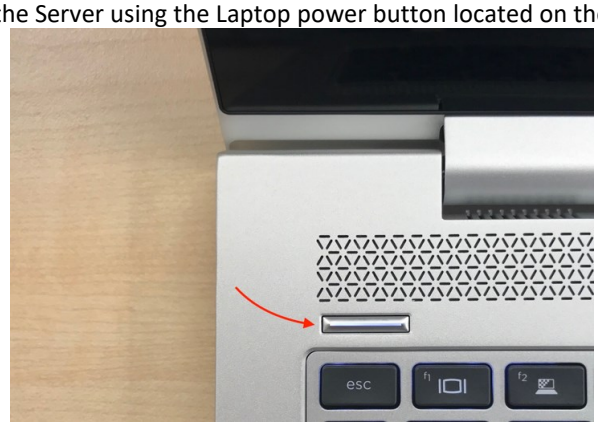


Figure 10 – Turn on the Server using the Laptop power button

- Login to the Windows environment with your Windows credentials. When it is the first time you login to the system refer to section 4.3.1.1: 'Logging in for the first time to the Server'.
- Open the FastFocus interface via the 'short cut'-icon on the desktop.

- Login to the FastFocus Server software with your FastFocus credentials. When the FastFocus software is used for the first time the administrator user can login using the default account as described in section: 'Logging in for the first time to the Server'.
- Once you are logged in, you will be redirected to the labels overview and ready to use the system.

4.3.1.1 Logging in for the first time to the Server

The FastFocus Vital Signs Monitoring System comes with a default Windows user. Besides the Windows login the FastFocus Server software has a separate login as well.

Default Windows credentials

When the system is used for the first time the default Windows login credentials can be used to login:

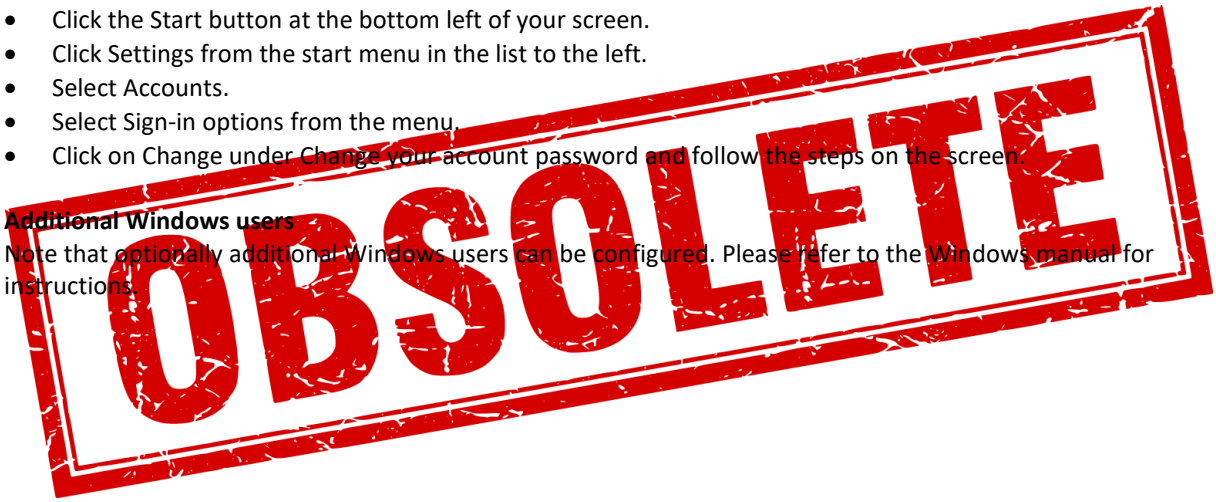
Username:	superuser@fastfocus.nl
Password:	FFVSMS_1o

Change the default Windows credentials

It is highly recommended to change the default password after the first login. See below explanation on how the default Windows user login credentials can be changed.

To change / set a password follow the following steps:

- Click the Start button at the bottom left of your screen.
- Click Settings from the start menu in the list to the left.
- Select Accounts.
- Select Sign-in options from the menu.
- Click on Change under Change your account password and follow the steps on the screen.



Additional Windows users

Note that optionally additional Windows users can be configured. Please refer to the Windows manual for instructions.

First time login to the FastFocus interface

- Login with the Username and Password below.

Username: superuser@fastfocus.nl
Password: FFVSMS_1o

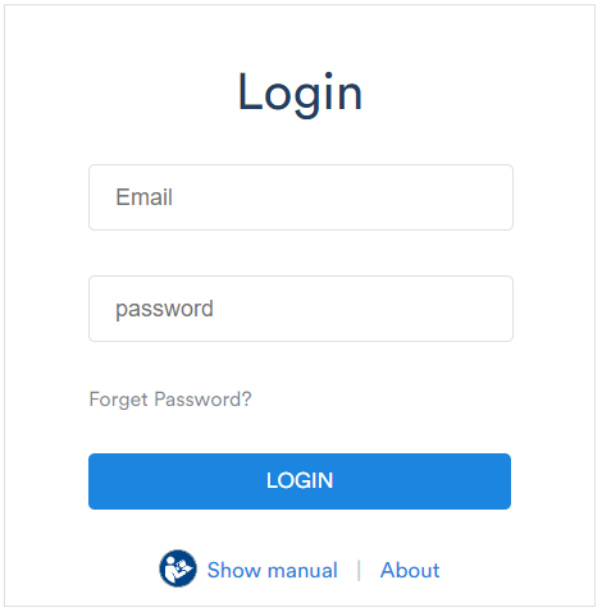


Figure 11 - Login Window

- You will now be asked to change the default password. Make sure to remember your password and store it safely as you cannot recover the password afterwards. A complete reinstall will be required.

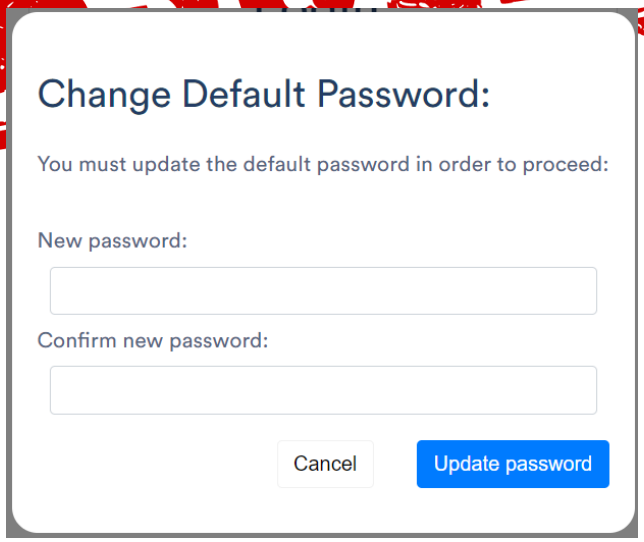


Figure 12 - Change Default Password Window

- Once you are logged in you will be redirected to the labels overview.

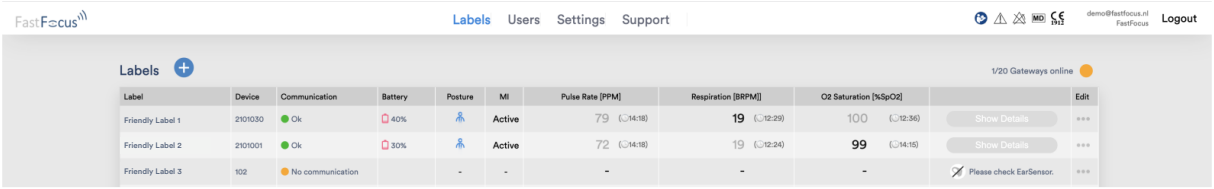


Figure 13 - Labels Overview Screen – list view

4.3.1.2 Managing user access

At the first login we used the default "superuser" to login to the system. Additional users may be configured with different rights. Below a concise overview of the user rights:

Superuser	The FastFocus Server comes with one predefined user who has all rights to create additional users. The superuser cannot be removed and or adjusted. Generally, the superuser is only used by system administrators.
Administrator	Users who will get the role administrator have all rights the superuser has. It has the rights to create new users.
View & Edit	These users are allowed to add Labels and link EarSensors to a label. They won't have access to create new users.
View	Users with view right may only look at the data but may not change anything. The creation of labels, linking EarSensors or creating users are all not allowed.

Adding users

- Press the "Add user" button to add a new user.

- A new popup will appear where additional user information needs to be filled in. The user's email, First Name and Last Name are all required. It is recommended to let the user fill in his / her personal password. By default, users will get "view" rights. Press "Create" to add a new user.

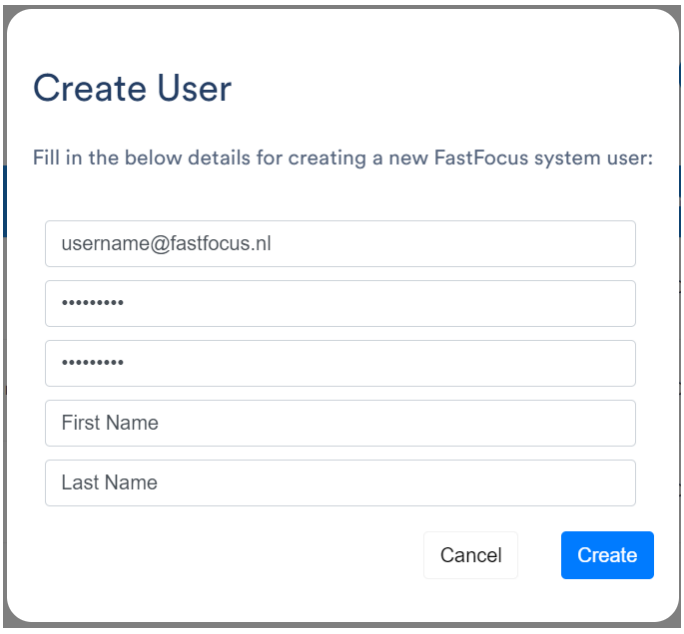
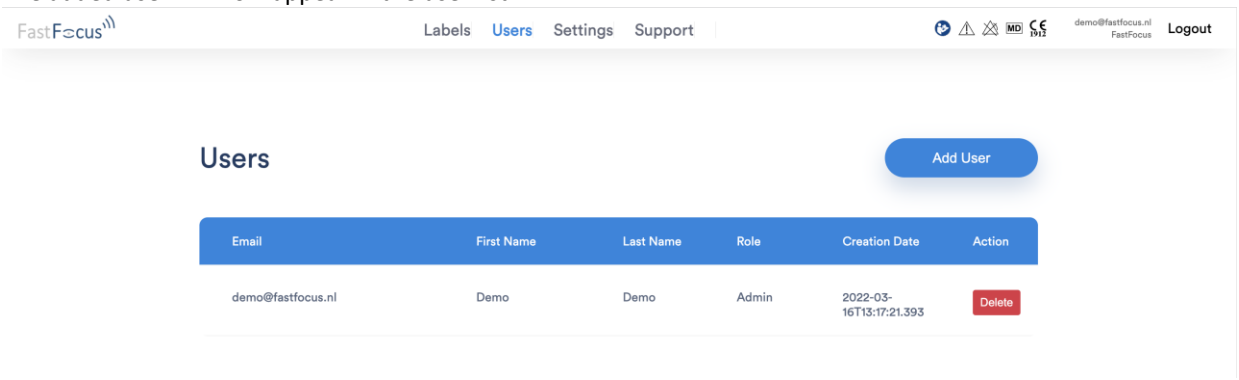


Figure 14 - Create User Window

The added user will now appear in the user list:



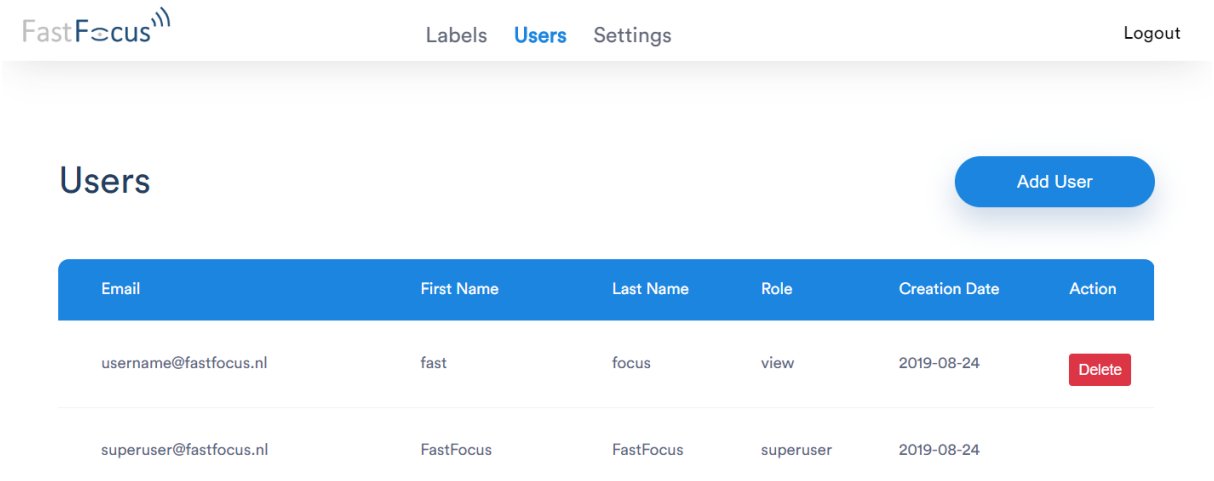


Figure 15 - Users List

By clicking on a user in the users list, the appropriate user rights can be set for the given user.

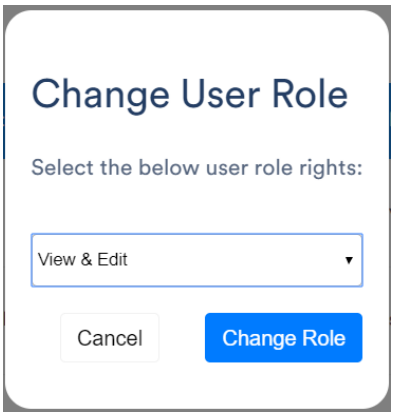


Figure 16 - Change User Role Window

Note!

- It is not possible to change a user password. However, it is possible to delete the user and re-add the user again.

Deleting users

When user leaves the company or does not need access to the system anymore the user can be removed from the system. Simply press the “delete” button and confirm the removal:

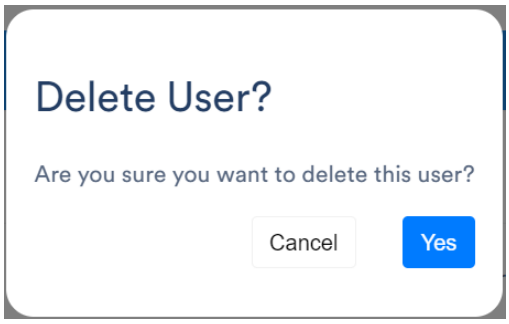
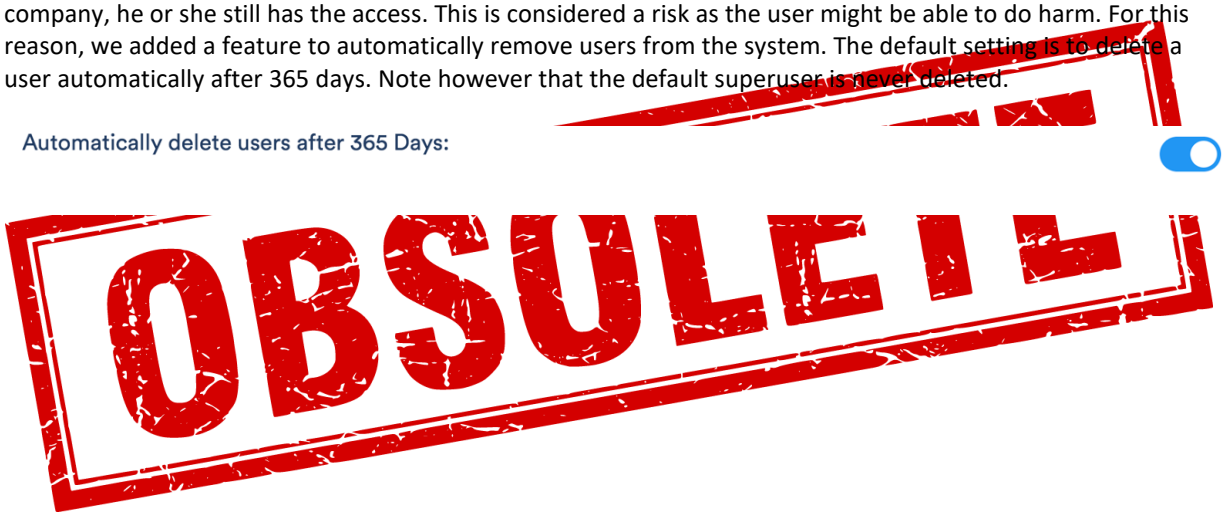


Figure 17 - Delete User Window

Automatically delete users

In practice it happens often that user accounts are created but are forgotten. Long after a colleague has left the company, he or she still has the access. This is considered a risk as the user might be able to do harm. For this reason, we added a feature to automatically remove users from the system. The default setting is to delete a user automatically after 365 days. Note however that the default superuser is never deleted.



4.3.2 Install Multi-Docking Station

- Place the Multi-Docking Station on a table or another smooth horizontal surface at a comfortable working height.
- Connect the power supply to the Multi-Docking Station. Before connecting the power supply in the receptacle first connect the power supply connector (power jack).
- Connect the power supply to the receptacle. The AC plug as shown in Figure 4 may now be inserted into a grounded receptacle. Make sure that the AC plug fully inserted and not loosely connected.

4.3.3 Install EarSensor for charging and storing

Perform the steps as described in §6.10 'Dock the EarSensor in the Multi-Docking Station' to install an EarSensor in the Multi-Docking Station. Repeat this for all EarSensors.

4.4 Installation verification

After installation, verify if the system is installed correctly and functioning properly by following the instructions of chapter 5.

5 Verification

The instructions in this chapter are for verification of proper functioning of the system and its modules.

5.1 EarSensor

Perform the following checks on all EarSensors of the system.

5.1.1 Visual Inspection

Required means

- EarSensor

Procedure

1. Check if the EarSensor is physically intact and has no damages (cracks, scratches, fractures, holes, or other damaged parts).
2. Check if the printed information on the housing is properly readable.

Criteria

If the EarSensor is damaged or if the information on the housing is not properly readable, do not use the EarSensor. Contact FastFocus for assistance.

5.1.2 Functional test

Required means

- EarSensor
- Server
- Multi-Docking Station
- Reference pulse-oximeter (calibrated)

Procedure

1. Place the EarSensor in the Multi-Docking Station (refer to §6.10).
2. Check if the LED on top of the EarSensor lights up cyan, blinking or continuously (refer to §3.2.1).
3. Take the EarSensor out of the Multi-Docking Station (refer to §6.1).
4. Check if the LED on top of the EarSensor blinks green (refer to §3.2.1).
5. Turn on the installed Server using the Laptop power button located on the top left (refer to §6.2).
6. Login to the Windows environment with your Windows credentials.
7. Login to the FastFocus Server software with your FastFocus credentials (superuser, administrator or view & edit user).
8. Create a new label (refer to §6.2.2).
9. Read the serial number on the housing of the EarSensor.
10. Link the EarSensor to the label (refer to §6.2.3).
11. Check if the status of the EarSensor is being displayed.
12. Clean the EarSensor. See instructions in §7.1.
13. Make sure that the measurement location of both the EarSensor and the reference pulse-oximeter (see Figure 18) is suitable for photoplethysmography measurements:
    - Intact skin without signs of redness, swelling, infection, breakdown or other deviations from normal skin;
    - Free from debris;
    - Sufficiently warm (≥ 33˚C) to prevent low perfusion due to vasoconstriction and poor measurement quality because of that.
14. Place the EarSensor on your index finger (see Figure 18).
15. Check if the LED on top of the EarSensor is green for 5 seconds (refer to §3.2.1).
16. Place a pulse-oximeter with finger sensor on your middle finger of the same hand as the EarSensor (according to the instructions of the manufacturer) (see Figure 18).
17. Sit still during the measurements.
18. Wait until the pulse rate and the oxygen saturation levels appear on both the server and the reference pulse-oximeter (this can take several minutes).
19. The saturation level measured with the EarSensor should lay within 4% O2 Saturation of the value measured with the reference pulse-oximeter.

20. Remove the EarSensor and reference pulse-oximeter from your fingers.
21. Unlink the EarSensor (refer to §6.2.4).
22. Repeat steps 1-4 and 9-21 if multiple EarSensors need to be verified.
23. Delete the label when all sensors are verified (refer to §6.2.4).
24. Logout from the Server software and shut down the Laptop.

Figure 18 – EarSensor verification setup.

Criteria

If all the above steps could be performed successfully, the EarSensor passes the test. If one or more steps could not be performed successfully, contact FastFocus for assistance.

5.2 Server

5.2.1 Visual Inspection

Required means

- Server

Procedure

1. Check if all Server elements are available (i.e. Laptop, Coordinator and power supply) (see Figure 3 in §3.3).
2. Check the modules of the Server on damages.
3. Check if the printed information on the unit label is properly readable.

Criteria

If one or more modules of the Server are damaged or if the information on the unit label is not properly readable, do not use the Server. Contact FastFocus for assistance.

5.2.2 Functional test

Required means

- Server
- EarSensor

Procedure

1. Turn on the installed Server using the Laptop power button located on the top left (refer to §6.2).
2. Login to the Windows environment with your Windows credentials.
3. Login to the FastFocus Server software with your FastFocus credentials.
4. Create a label (refer to §6.2.2).
5. Read the serial number on the housing of the EarSensor.
6. Link the EarSensor to the label (refer to §6.2.3).
7. Check if the status of the EarSensor is being displayed.
8. Unlink the EarSensor and delete the label (refer to §6.2.4).
9. Logout from the Server software and shut down the Laptop.

Criteria

If all the above steps could be performed successfully, the Server passes the test. If one or more steps could not be performed successfully, contact FastFocus for assistance.

5.3 Multi-Docking Station

5.3.1 Visual Inspection

Required means

- Multi-Docking Station

Procedure

1. Check if all Multi-Docking Station elements are available (docking station and power supply).
2. Check the Multi-Docking Station on damages (cracks, holes, wear, missing charging pins).
3. Check if the printed information on the unit label is properly readable.

Criteria

If the Multi-Docking Station is damaged or if the information on the unit label is not properly readable, do not use the Multi-Docking Station. Contact FastFocus for assistance.

5.3.2 Functional test

Required means

- Multi-Docking Station
- EarSensor
- Wall mains supply (100-240V)

Procedure

1. Install the Multi-Docking Station (refer to §4.3.2).
2. Place the EarSensor in the Multi-Docking Station (refer to §6.10).
3. Verify if the EarSensor is properly docked.
4. Verify if the EarSensor receives power by checking if the LED on top of the EarSensor lights up cyan, blinking or continuously (refer to §3.2.1).
5. Take the EarSensor out of the Multi-Docking Station (refer to §6.1).
6. Repeat steps 2 – 5 for all ten (10) docking positions.

Criteria

If all the above steps could be performed successfully, the Multi-Docking Station passes the test. If one or more steps could not be performed successfully, contact FastFocus for assistance.

6 Operation

Warning!

- Do not use modules when they are damaged. Injury may result.
- Do not use the modules near flammable anaesthetics and/or in oxygen enriched environment, to avoid the risk of explosion or fire.
- Do a check on the device after a temporary interruption of the mains supply. The device does not have an isolating switch. After an interruption of the supply mains, the device is in standby mode.
- Clean the EarSensor after and prior to each use to reduce the risk of infection.
- Do not use the EarSensor on any site other than the inner aspect of the ear (cavum conchae). This may result in inaccurate readings.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- The sensor is not intended for use on a monitoring site for prolonged periods. The sensor must be removed and repositioned to a different monitoring site at least every twelve (12) hours and it is recommended to check the skin every four (4) hours. If extended monitoring is required, the sensor must be moved to the opposite ear. It may be necessary to move the sensor frequently since individual skin conditions and perfusion levels affect the ability of the site to tolerate sensor placement.
- Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the EarSensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the EarSensor if there are signs of tissue ischemia.
- During low perfusion, the EarSensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- Do not use tape to secure the EarSensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the EarSensor.
- Sensors applied too tightly or that become tight due to oedema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- The system is a radio frequency (RF) emission device and should not be used in RF sensitive areas.
- The system is not designed for use near magnetic resonance imaging (MRI) equipment. The EarSensor must be removed from any patient about to undergo an MRI.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the EarSensor.
- To prevent damage, do not soak or immerse the EarSensor in any liquid solution. Do not attempt to sterilize the EarSensor.
- Do not modify or alter the EarSensor in any way. Alteration or modification may affect the safety, performance and/or accuracy.
- If a patient is experiencing pain or severe discomfort due to wearing an EarSensor this might be caused by a too high pressure. Relocate the EarSensor to the other ear.

Caution!

- Do not use a sharp object to press the buttons on the Server.
- The system is not designed for direct X-ray exposure. The EarSensor must be removed from any patient about to undergo an upper torso X-ray.
- The system is not designed for use near X-ray computed tomography (CT) equipment. The EarSensor must be removed from any patient about to undergo a CT scan.
- The system is not designed for use near HF surgical equipment. Do not use the system near HF surgical equipment.

Note!

- For the EarSensors to be able to send data, the EarSensors and Server must be located within 30 meters distance from each other.
- Do a check on the device after a temporary interruption of the mains supply. The device does not have an isolating switch. After an interruption of the supply mains, the device is in standby mode.
- There is no need or requirement for the user to switch the EarSensor on and off. When fully or partially charged, the EarSensor is always activated and ready to be used. The device will turn off when the battery will be empty and will activate again when it will be connected to the Multi-Docking Station for charging.
- Please report any serious incident that has occurred in relation to the Vital Signs Monitoring System to FastFocus and your local authority.

6.1 Prepare EarSensor

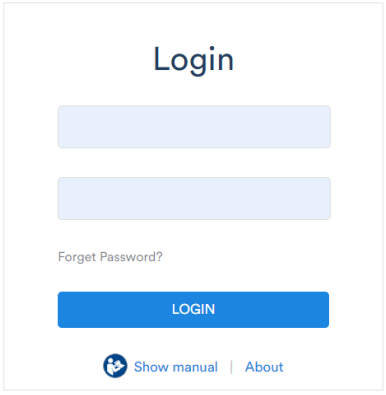
1. Select a fully charged EarSensor from the Multi-Docking Station. The status indicator should be cyan and on (fully charged) continuously when sensor positioned in Multi-Docking Station.
2. Take an EarSensor out of the Multi-Docking Station by performing the movements as shown in the picture below (Figure 19).

Figure 19 – Disconnecting the EarSensor from the Multi-Docking Station.

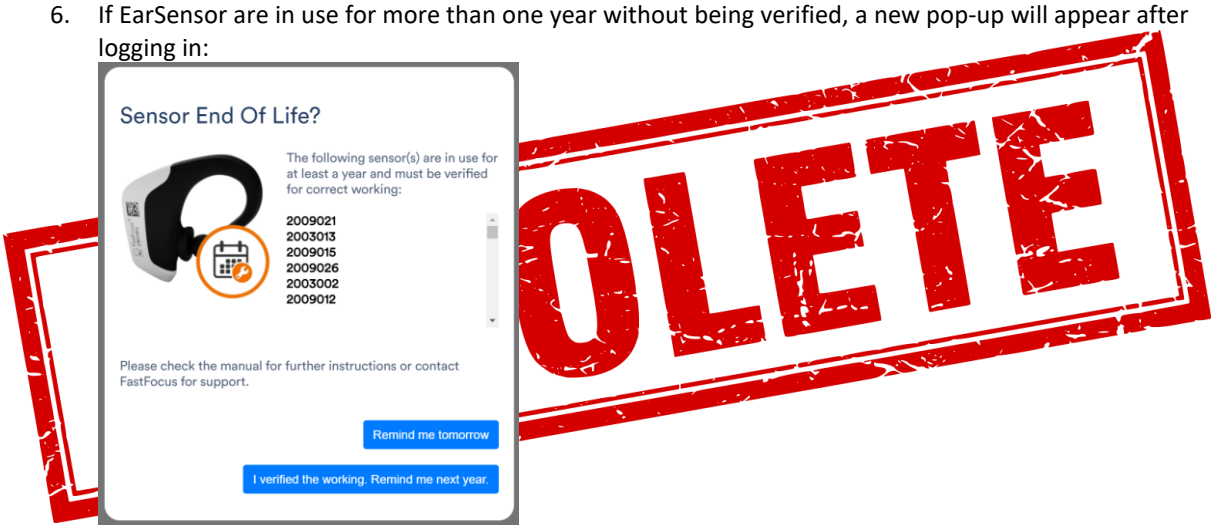
3. Check the EarSensor number and continue with the preparation of the Server.

6.2 Prepare Server

1. Turn on the installed Server using the Laptop power button located on the top left. For installation of the Server see §4.3.1.
2. Login to the Windows environment with your Windows credentials.
3. Open the FastFocus interface via the short cut on the desktop.
4. A login pop-up will appear:



5. Login to the FastFocus Server software with your FastFocus credentials. When the FastFocus software is used for the first time the administrator user can create new user credentials.
6. If EarSensor are in use for more than one year without being verified, a new pop-up will appear after logging in:



7. Once you are logged in you will be redirected to the labels overview and ready to use the system.
8. Add labels to EarSensors as described in the section below.

6.2.1 Labels

Each EarSensor that will be used needs to be labelled. Examples of labels are bed number, patient number or patient name. Labels are stored in the database of the system.

Note!

- To protect personal information (according to GDPR), it is recommended not to use the patient's name. If the system is left unattended and unlocked, unauthorized people could access privacy sensitive data.

The labels page shows all user created labels.

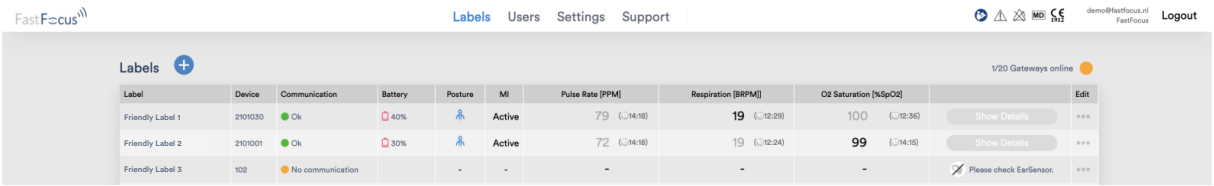


Figure 20 - Labels Page view

The following is shown in the columns:

A. The label names
B. The serial number of the EarSensor added to the label
C. The status of the connection between the EarSensor and the Server
D. Battery level
E. Current posture/activity of the patient
F. Current activity level
G. Pulse rate of the patient; the time of the last measurement is shown right from it
H. Respiratory rate of the patient; the time of the last measurement is shown right from it
I. Blood oxygen level of the patient; the time of the last measurement is shown right from it
J. Information messages
K. Label Edit menu

6.2.2 Adding a new label

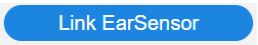
- Press the plus (+) button icon to create a new Label entity:

- A new popup will appear where you can fill in the label name. E.g., "Subject 1":

Figure 21 - Add Label Window

The newly added label will now be added to the overview. By pressing the three dots in most right column of the label (•••, column K in Figure 20), the label can be removed in case it's not needed anymore.

6.2.3 Linking an EarSensor to a label

After creating a new Label, the first step is to assign an EarSensor to it. After selecting 

in the information column of the label (column J in Figure 20), a new popup will appear where you can select the EarSensor number from the list. Note that the EarSensor number can be found on the shell of the EarSensor.

When an EarSensor is already linked to a label it will not be shown in the list. In this case an EarSensor must first be unlinked before it can be linked to a different label.
See for more information section “Unlinking an EarSensor”.

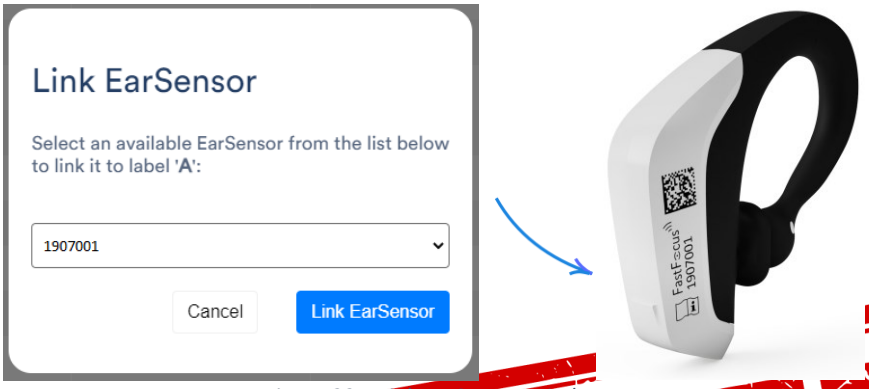


Figure 22 – Link EarSensor Window

After pressing Link EarSensor the user will see instructions for placing the EarSensor:

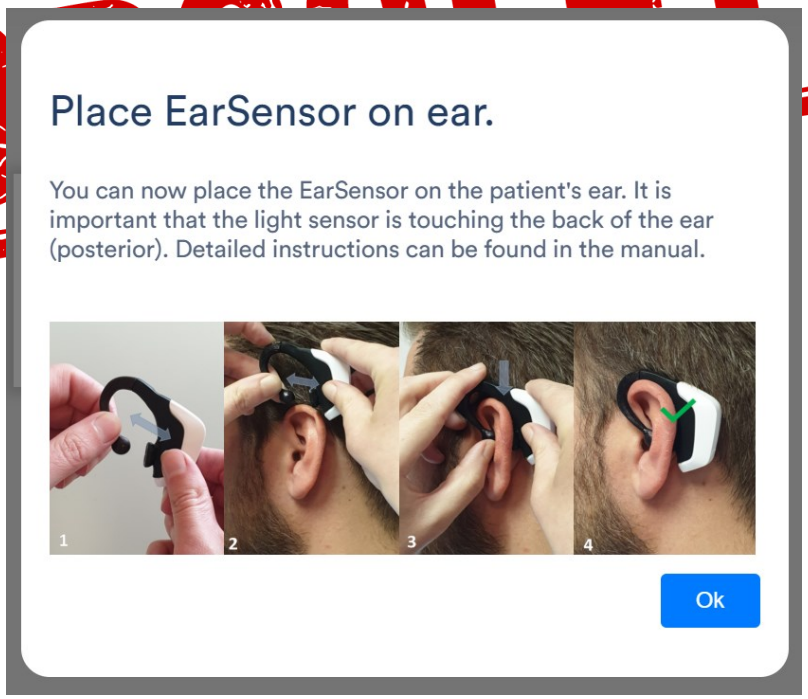


Figure 23 – Placing the EarSensor on the ear.

After linking an EarSensor the measurements will be linked to the label the measuring data will be collected. Note that this might take a minute.

Once measurements are received a concise summary of latest measurements will be visible in the labels overview:

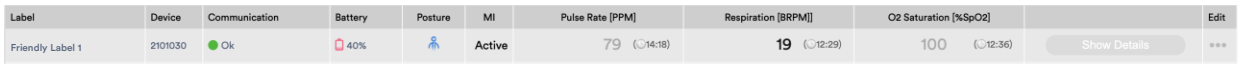


Figure 24 – Label with latest measurements

6.2.4 Unlinking and Changing an EarSensor

After an EarSensor is linked it can be unlinked again by simply pressing the 

button which can be found in the edit menu, the three dots in the rightest column of the label (●●●, column K in Figure 20).

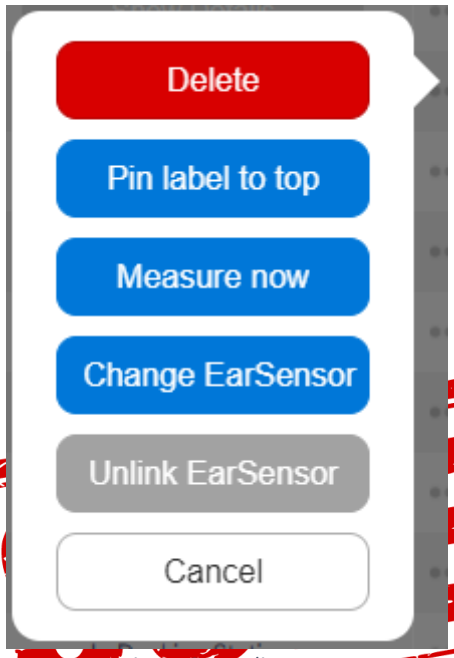


Figure 25 – Edit Menu

A label can be assigned to another EarSensor by pressing the 

button. The previously assigned EarSensor will be unlinked automatically.

6.3 Attaching the EarSensor to the patient

1. Before using the EarSensor, ensure that the sensor is physically intact, without cracks, scratches, fractures, or other damaged parts. In case of doubt do not use the EarSensor.
2. Use a fully charged EarSensor.
3. Clean the EarSensor. See instructions in chapter 7.1.
4. The EarSensor shall be used on intact skin that is free from debris. Prior to sensor placement, the site should be checked to ensure that it is intact and clean, without signs of redness, swelling, infection, breakdown, or other deviations from normal ear skin.
5. Place the EarSensor on the right or left ear. If one ear is damaged, place the EarSensor on the other side.
6. Refer to Figure 26. Orient the sensor to ensure that the hook is in front of the patient's ear. Create an opening between the hook and the detection window by pulling on the hook and main body of the EarSensor.
7. Slide the sensor gently over the ear shell. Place the hook inside the ear so that it rests on the inner aspect of the ear (cavum conchae).
8. Place the detection window on the back of the ear. The detection window should have full contact with the skin on the back of the ear. Make sure the optical sensor is positioned properly and touches the skin. Always choose a site that is well perfused and will completely cover the detector's window. Verify the absence of an eventual airgap or hair between the detector's window and the skin.
9. Position the top of the sensor notch that it fits over the upper part of the ear (pinna) (Figure 26).
10. If the EarSensor does not fit properly on the ear, consider using an alternative monitoring system for the patient.
11. Make sure that the black mushroom shaped part of the EarSensor is contacting the skin without gaps (Figure 27).

Figure 26 - Attaching the EarSensor to the patient.

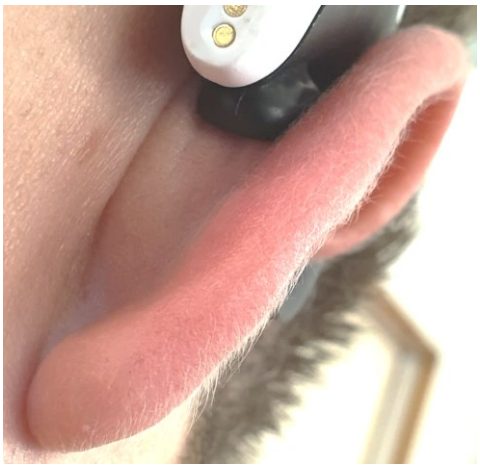


Figure 27 - Proper connection with ear

6.4 Instructions to be communicated to the patient

After placing the EarSensor on the patient's ear, the following information should be given:

- The device measures physical activity and vital signs.
- The patient is free to walk.
- The patient should not wet the device or take a shower with the device.
- The patient should let the medical personnel know if the device is dropped or suffers any kind of damage while being used.
- The patient should let the medical personnel know if the sensor becomes very uncomfortable.

6.5 Realtime monitoring

- Wait 30 seconds and check if the EarSensor is working correctly and that the measurements are received by the Server in the Label screen.
- The next section, "6.8 Analysing stored measurements", explains how the measurement data can be visualized on the Server.
- Pulse rate and oxygen saturation are determined every two minutes over eight seconds measurements.
- Respiration is determined every five minutes over twenty seconds measurements.
- The sensor must be removed and repositioned to a different monitoring site at least every twelve (12) hours (see section 6.8 and 6.9). It may be necessary to move the sensor more frequently, because individual skin conditions and perfusion levels affect the ability of the site to tolerate sensor placement.

6.6 Confidence level

If the raw measurements pass the quality criteria, they are shown on the dashboard and in the graphs. Standard, the measurement values are shown in black. It could be that (external) factors are detected, for example motion or a certain posture, that could lead to a displayed value that isn't correct. In that case, the displayed value is grey instead of black indicating that the confidence level is medium or even low. When the cursor is place on the value the confidence level is shown.

If a measurement is shown in grey, it might be that the shown value is not correct.

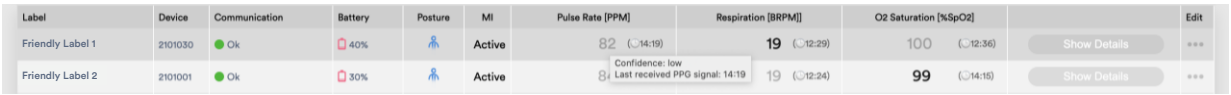


Figure 28 - Low confidence level on respiratory rate

6.7 Vital sign trends

If a measured vital sign is outside the normal range, if the confidence level of at least three measurements over the last 30 minutes is medium or high an upward or downward indicator will be shown for the following conditions:

Pulse rate

If the measured value is below 51 or above 90 pulses per minute and if it differs 10% or more compared with the average value over 30 minutes.

Respiration

If the measured value is below 12 or above 20 breaths per minute and if it differs 10% or more compared with the average value over 30 minutes.

Oxygen saturation

If the measured value is below 96 %SpO2 and if it differs 2% or more compared with the average value over 30 minutes.

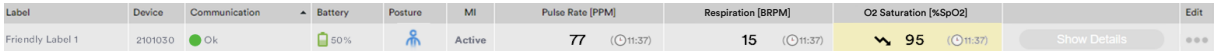


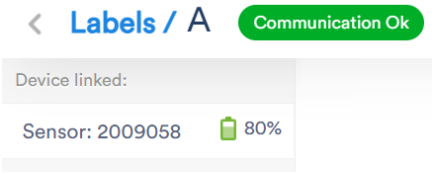
Figure 29 - Downward trend on oxygen saturation

6.8 Analysing stored measurements

6.8.1 Label Measurement Details

After creating a Label entity and linking an EarSensor, the measurement data is recorded and assigned to a label in the database. Select a Label in the overview to show the measurement details by clicking on the label name.

On top of the screen, it is shown which Label is selected and which EarSensor is linked to it.



Different status indicators can be shown next to the label name. These are:

Communication Ok	The status “Communication Ok” is shown when the linked EarSensor is measuring correctly and the communication to the Server is ok.
No Communication	In case the EarSensor didn’t communicate with the Server for the last 3 minutes. E.g., out of range or empty battery.
Reposition EarSensor	The EarSensor should be repositioned. The EarSensor is not correctly placed on the ear. Correct measurements cannot be performed.
EarSensor not worn	The EarSensor is not worn. Place the EarSensor on the ear to resume measuring.
EarSensor in Docking Station	The EarSensor is placed in the Docking Station.

Next to the linked EarSensor the battery status is shown together with the battery percentage:

	Battery empty. The device needs to be recharged and replaced.
	Battery low. It is recommended to replace the EarSensor.
	Battery level is ok.

6.8.1.1 Multigraph (All)

By selecting ‘All’ in the left menu, the graphs of all measured parameters are shown above each other. The vital signs graphs have different colour zones that correspond with the NEWS2 early warning score.
By moving the mouse over the graphs, a popup is shown with the value of the measured parameter.
It is possible to zoom in on the graphs by using the scroll wheel of the mouse. By clicking and holding the left mouse button, the graphs can be moved in time.
The view is per day. On the top right of the screen other days can be selected.

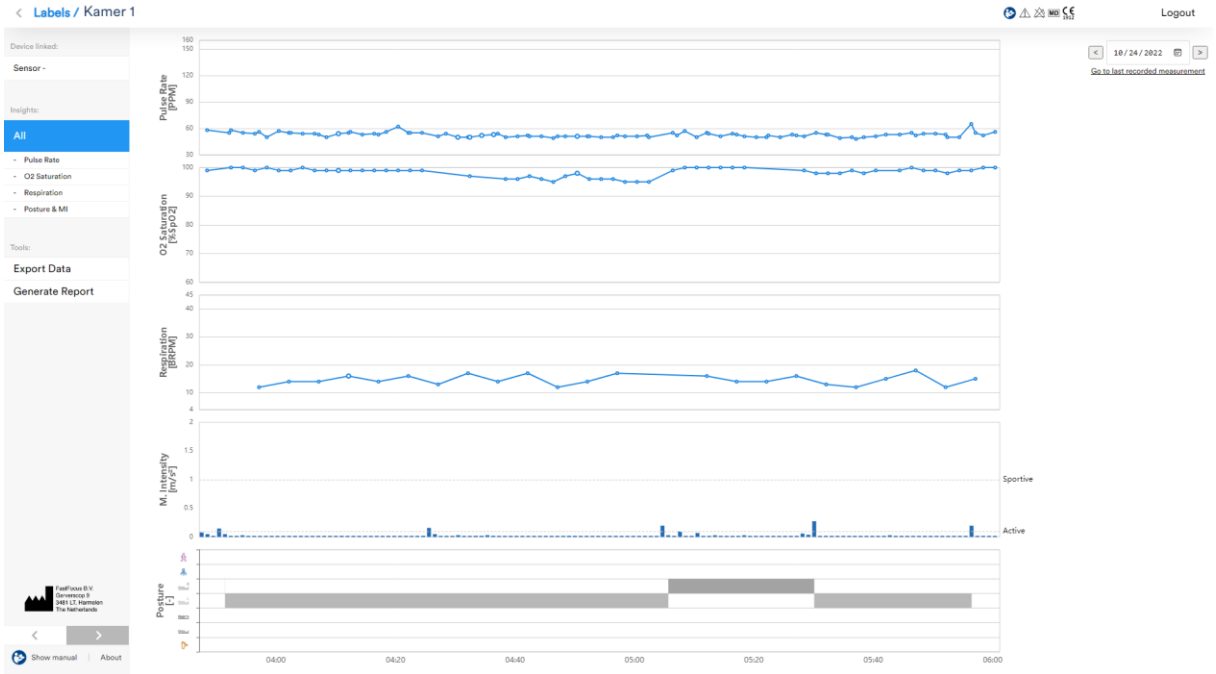


Figure 30 – Multigraph

6.8.1.1.1 Browsing through recorded data

The view is per day. On the top right of the screen other days can be selected. You can browse through the recorded data by using the arrows next of the date or by clicking on the calendar symbol right of the date.

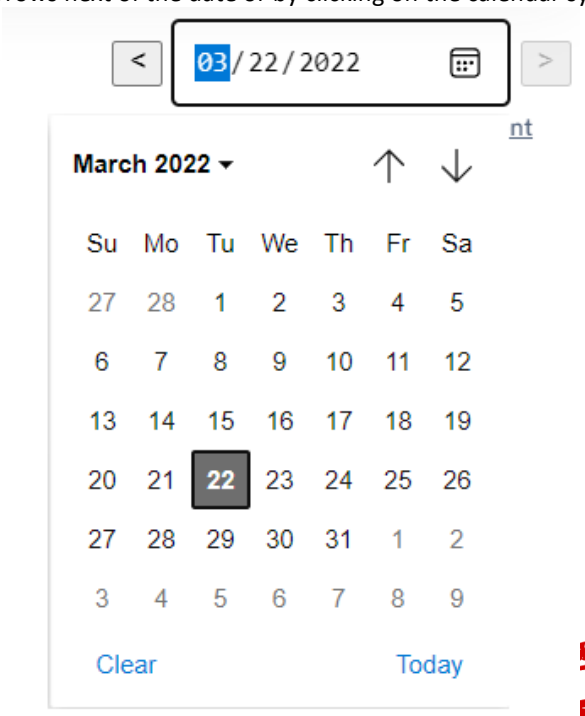


Figure 31 - browse through recorded data.

Furthermore, you can jump to the day with the last recorded measurement by clicking on 'Go to last recorded measurement'.

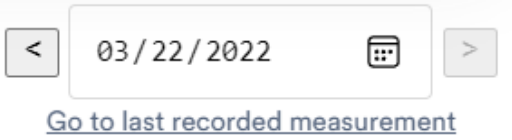


Figure 32 - Go to last recorded measurement.

6.8.1.2 Pulse Rate

By selecting ‘Pulse Rate’ in the left menu, a single graph of the pulse rate is shown.

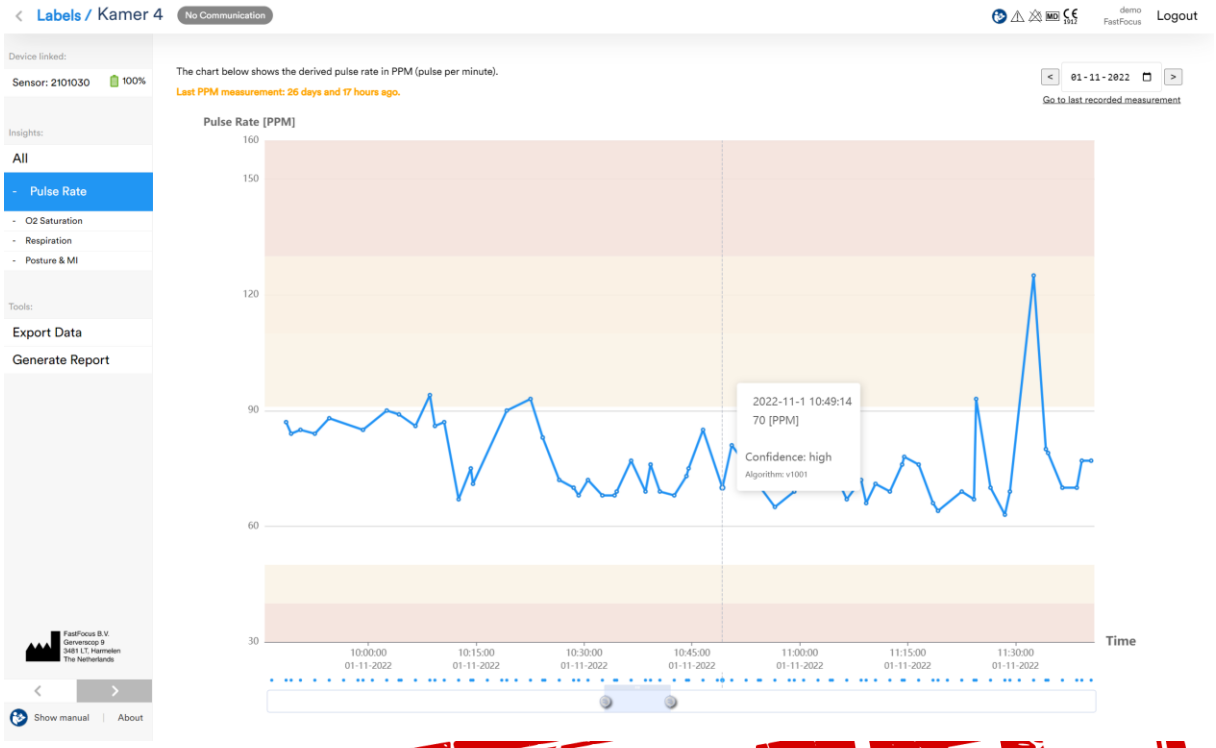


Figure 33 – Pulse Rate Graph

By moving the mouse over the measurement dots in the graph, a popup is shown with the pulse rate. If a measurement dot is selected by clicking on the left mouse button, a popup is shown with the non-normalized source signals for that measurement.

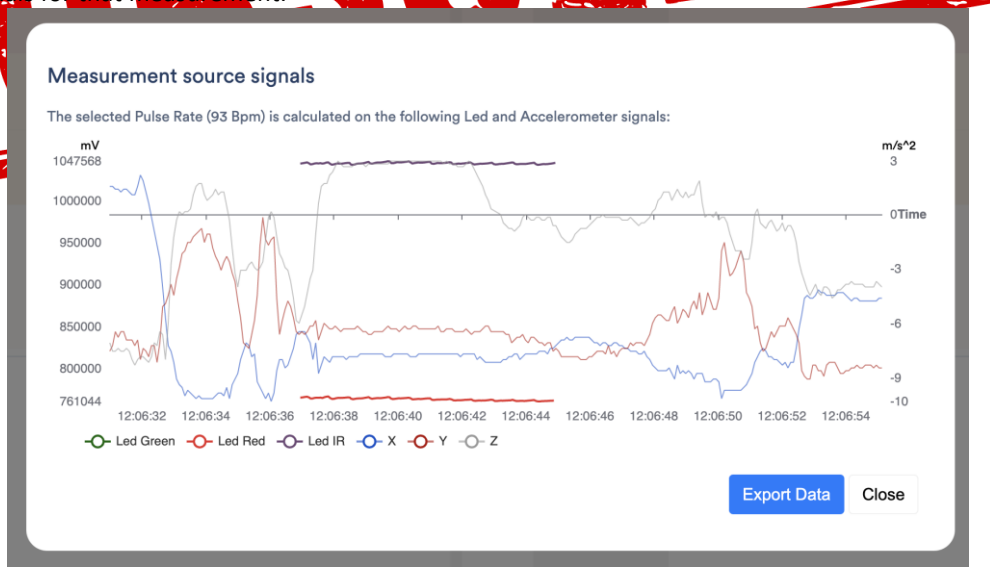


Figure 34 – Pulse Rate Source Signals Pop-Up

It is possible to zoom in on the graphs by using the scroll wheel of the mouse. By clicking and holding the left mouse button, the graphs can be moved in time.
The view is per day. On the top right of the screen other days can be selected.

6.8.1.3 Blood Oxygen Saturation

By selecting ‘O2 Saturation’ in the left menu, a single graph of the blood oxygen saturation is shown.

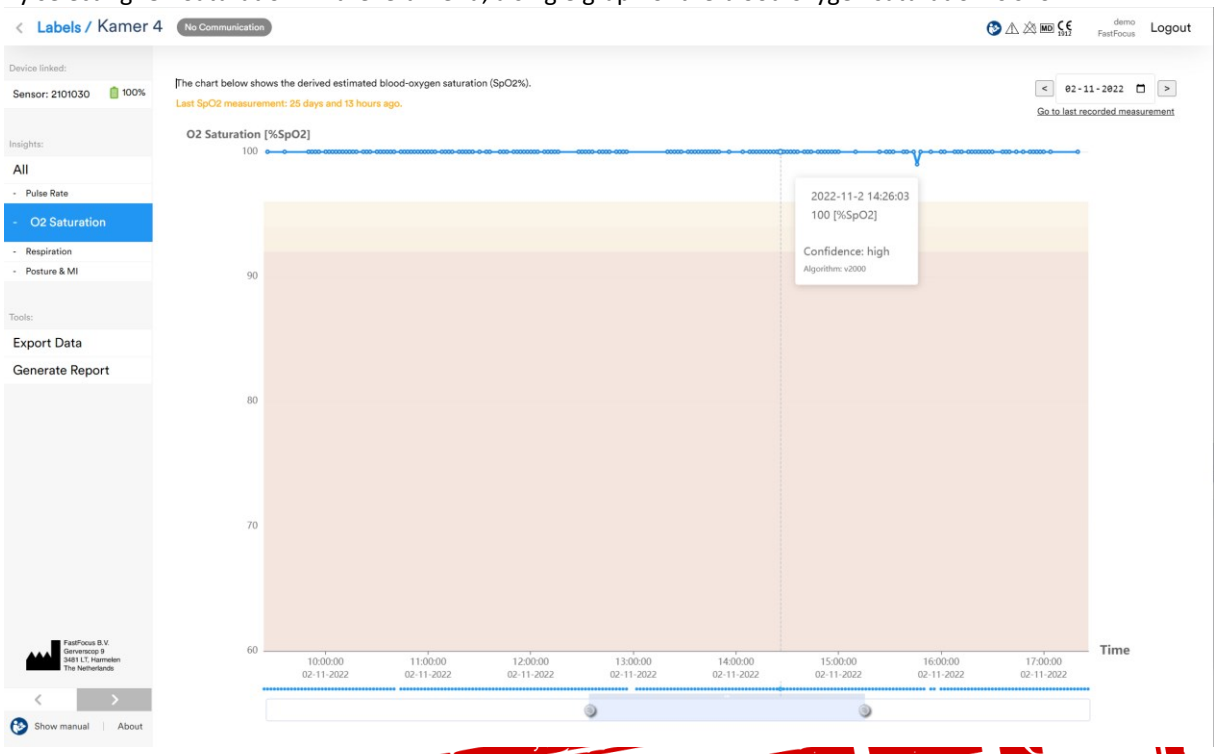


Figure 35 – Blood Oxygen Saturation Graph

By moving the mouse over the measurement dots in the graph, a popup is shown with the blood oxygen saturation. If a measurement dot is selected by clicking on the left mouse button, a popup is shown with the non-normalized source signals for that measurement.

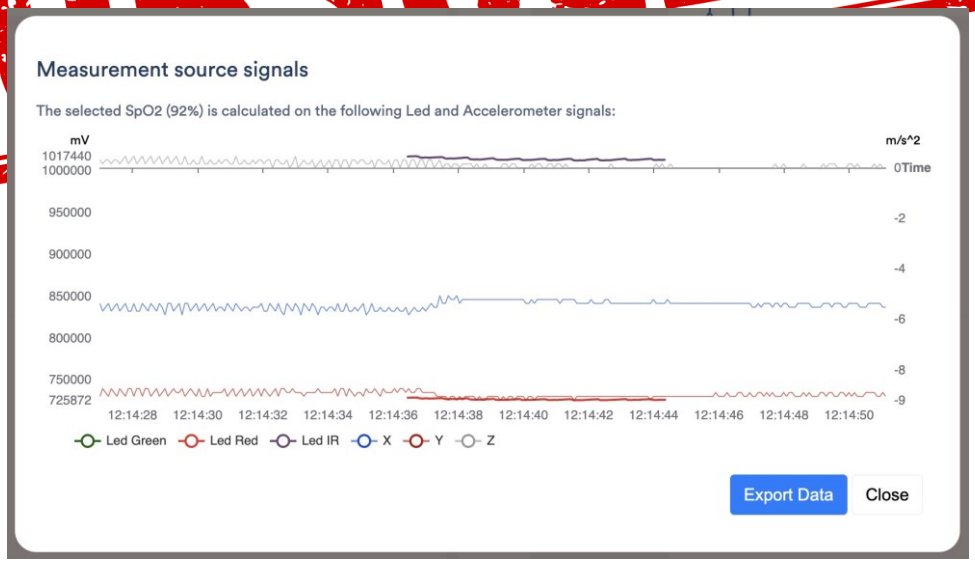


Figure 36 – Blood Oxygen Saturation Source Signals Pop-Up

It is possible to zoom in on the graphs by using the scroll wheel of the mouse. By clicking and holding the left mouse button, the graphs can be moved in time.
The view is per day. On the top right of the screen other days can be selected.

6.8.1.4 Respiration

By selecting ‘Respiration’ in the left menu, a single graph of the respiratory rate is shown.

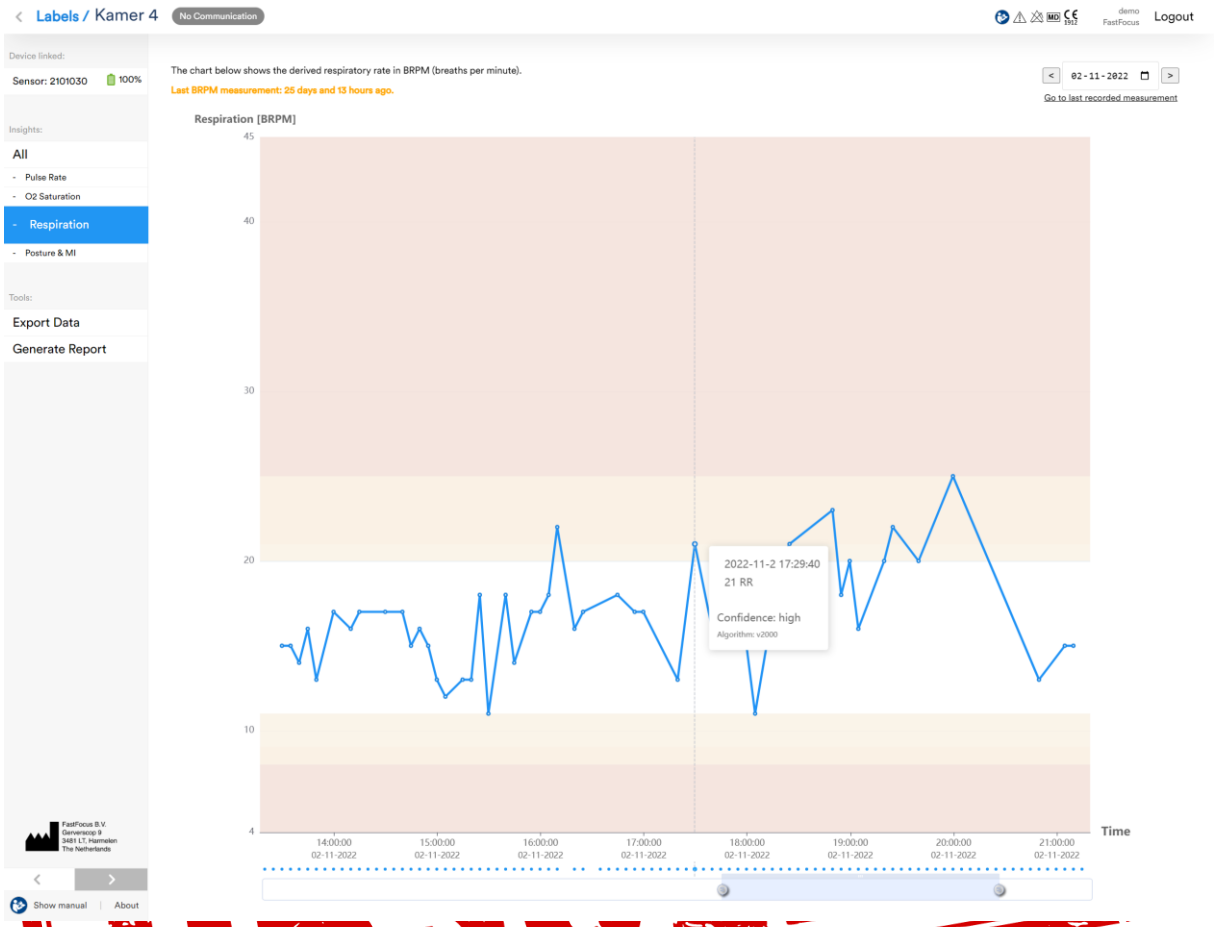


Figure 37 – Respiratory Rate Graph

By moving the mouse over the measurement dots in the graph, a popup is shown with the respiratory rate. If a measurement dot is selected by clicking on the left mouse button, a popup is shown with the non-normalized source signals for that measurement.

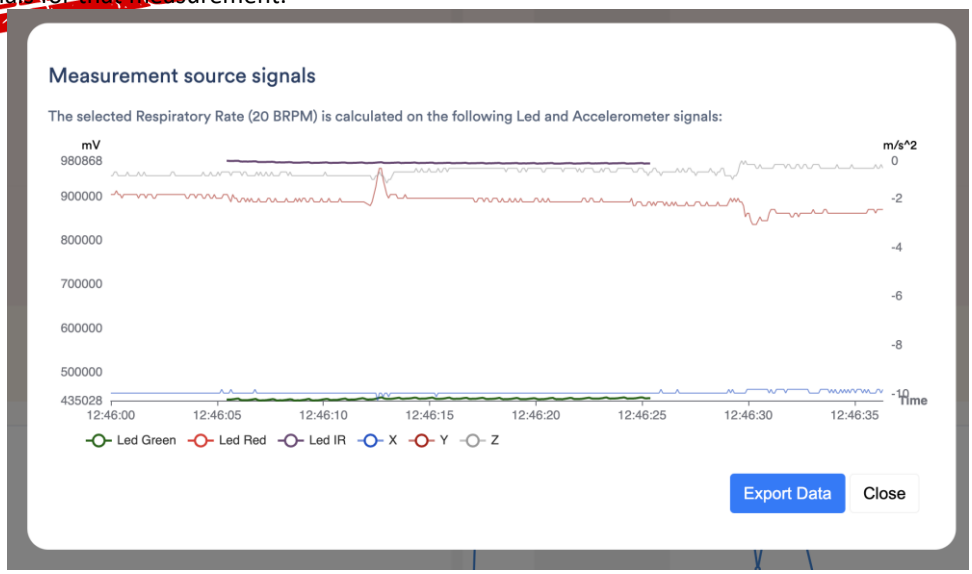


Figure 38 – Pulse Rate Source Signals Pop-Up

It is possible to zoom in on the graphs by using the scroll wheel of the mouse. By clicking and holding the left mouse button, the graphs can be moved in time.
The view is per day. On the top right of the screen other days can be selected.

6.8.1.5 Physical Activity

By selecting 'Posture & MI' in the left menu, a single graph of the physical activity is shown.

The motion intensity and posture/activity are shown in two separate graphs. In the posture/motion graph, posture and motion is shown on a different row. By moving the mouse over the measurements in the graph, a popup is shown with the motion intensity value and posture.

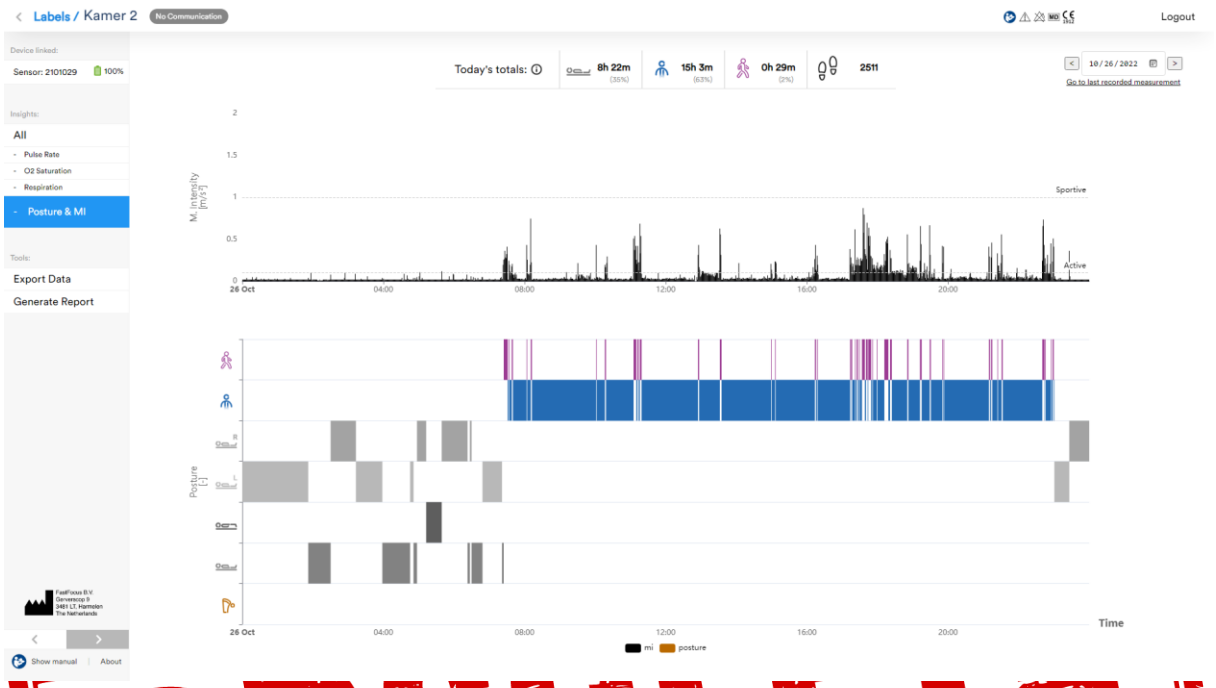


Figure 39 – Physical Activity Graph

It is possible to zoom in on the graphs by using the scroll wheel of the mouse. By clicking and holding the left mouse button, the graphs can be moved in time.
The view is per day. On the top right of the screen other days can be selected.

Note!

- The posture/activity graph is indicative.
- The posture/activity graph shows per minute the dominant posture.
- In case walking is detected in a minute block, the whole block is assigned to walking if the patient has walked for 2 seconds or more.
- Accurate date on posture and activity is shown in the report (see 6.8.1.8).

6.8.1.6 Algorithm tasks

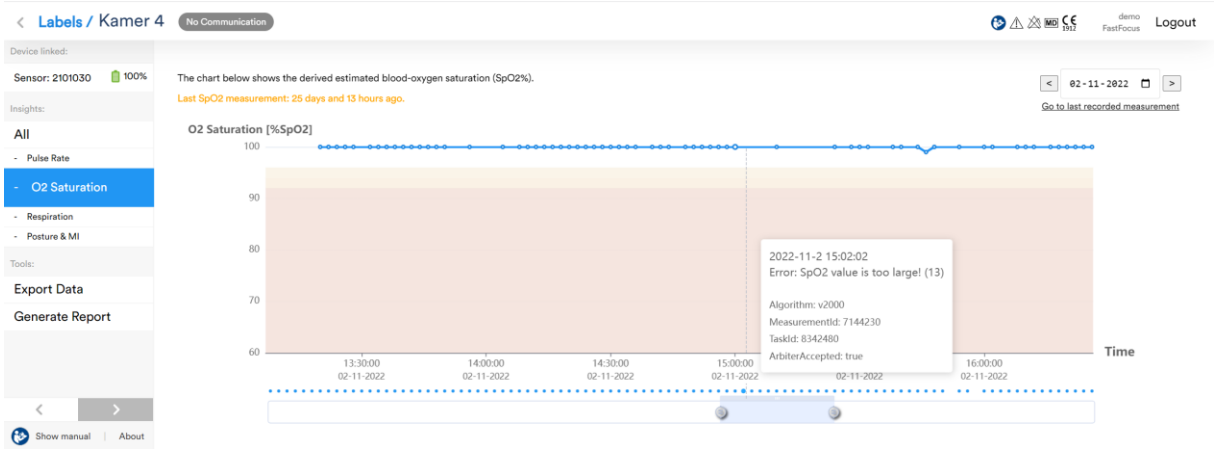


Figure 40 - Algorithm tasks

When the sensor is not positioned correctly on the ear it could happen that no vital sign could be determined. The dots under the pulse rate, blood oxygen saturation and respiration graphs show the algorithm tasks / attempts performed. An indicative reason is shown in the error description that will appear when the mouse cursor is placed above a dot.

6.8.1.7 Export Measurement data

All the label collected measurement data can be exported to .CSV file. Several data Exports can be made. The calculated SpO2, pulse rate, respiratory rate, and motion intensity & posture data can be exported.

To export the data to a .CSV file, press the "Export Data" button in the left menu. The following window will pop up:

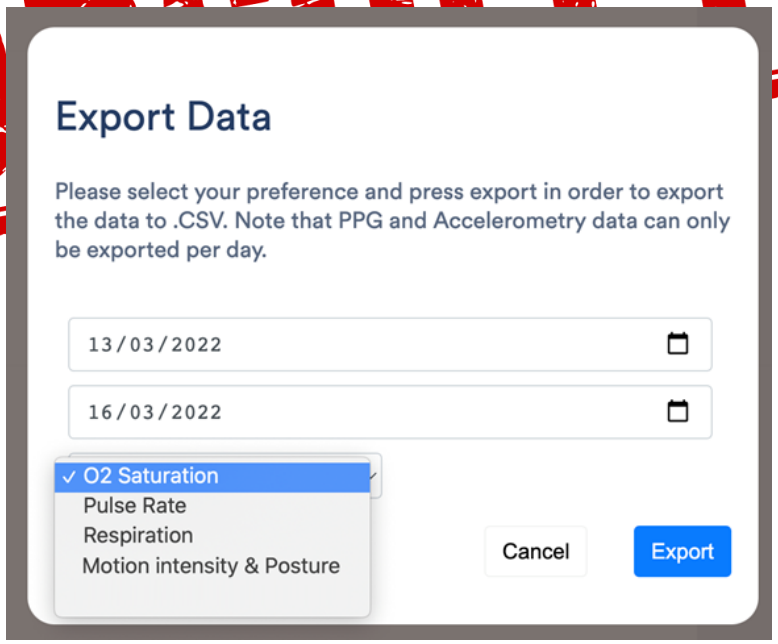


Figure 41 - Export Data Window

Select the start date, end date and the data you want to export. Press Export to export the selected measurement data.

6.8.1.8 Create Report

A report can be created on the label collected measurement data. To generate a report, press the “Generate Report” button in the left menu.

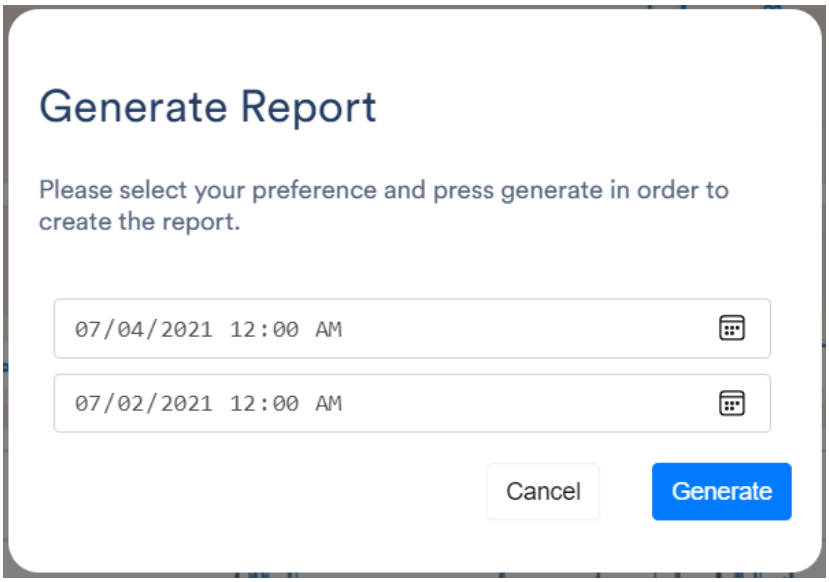


Figure 42 - Generate Report

Select the start date and time, end date and time, and press Generate to generate the report (see Figure 42).

The report includes lists per day with details on posture, physical activity and average motion intensity derived on the acceleration data of the selected time range Figure 43. It also shows the average of the vital signs per day.

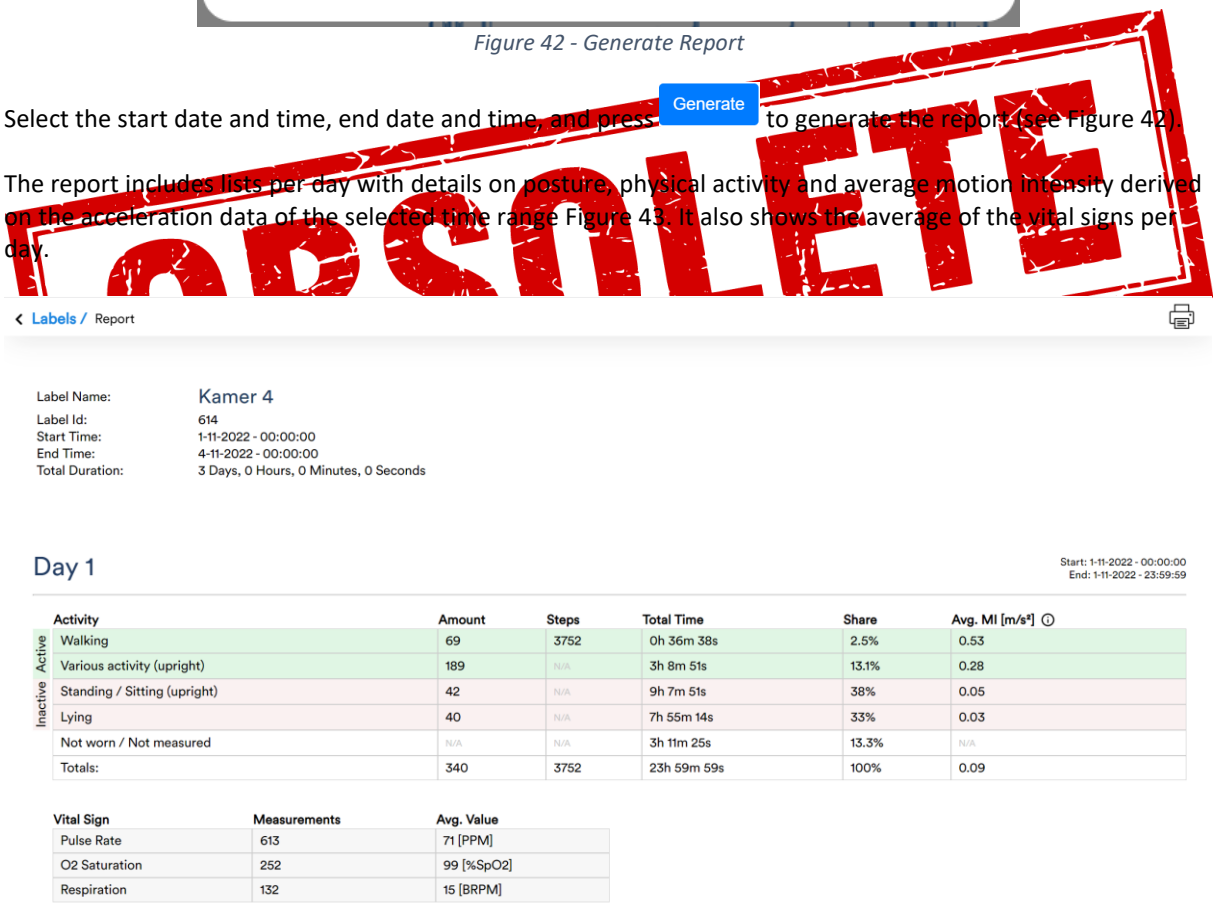


Figure 43 – Day to Day Averages

The average motion intensity (Avg. MI) is derived via Mean Amplitude Deviation (MAD) and represents how intense the physical activity was on average. If the motion intensity is above 0.1 m/s² and if the detected posture is classified as standing/sitting, it is considered that the patient is active. If from the acceleration patterns it is recognized that the patient is walking, the activity is classified as such. Otherwise, the activity is classified as other activity.

If the motion intensity is below 0.1 m/s² and if the detected posture is classified as standing/sitting, it is considered that the patient is sitting or standing and being inactive. If it is detected that the patient is lying, this is also classified as being inactive.

The report includes graphs that show the day-to-day total active time (left Y axis) and the average motion intensity (right Y axis) of the activities.
In addition, the report shows the daily averages of the vital signs. This allows for trend monitoring.

Figure 44 – Daily Averages

The report can be printed or saved as a PDF-file by pressing the printer symbol on the top right of the screen.

Note!

- When the user was inactive for 60 minutes the user is automatically logged out.

6.9 Disconnecting the EarSensor from the patient

1. Create an opening between the hook and the detection window by pulling on the hook and main body of the EarSensor (Figure 26 picture 2).
2. Slide the sensor gently over the ear shell.

6.10 Dock the EarSensor in the Multi-Docking Station

1. Clean the EarSensor. See cleaning instructions in chapter 7.1.
2. Perform the steps shown in the pictures below to install an EarSensor in the Multi-Docking Station.

Figure 45 – Placing the EarSensor in the Multi-docking station.

The status indicator LED on top of the EarSensor (as shown in Figure 2 – EarSensor) will turn cyan, blinking or continuously, if the EarSensor is installed correctly.

6.11 Unlink EarSensor from patient

Please refer to 6.2.4.

7 Maintenance

If you contact the hospital service department or the local supplier for technical support, make sure that you have the serial number of the module at hand depending on which device support is needed.

You can find the serial number on the side of the EarSensor, on the bottom of the Server and on the bottom of the Multi-Docking Station.

Note!

- The EarSensor has an expected service life of one year. After one year, you are informed via a pop-up screen that the service life is exceeded. You can verify the functioning of the EarSensor following the instructions in 5.1.

7.1 Cleaning

7.1.1 General

The system and all its accessories have been cleaned before shipment but must be considered all non-sterile.

Warning!

- Before you clean the Multi-Docking Station or Server, disconnect the power supply cord.

Caution!

- Avoid strong cleaning solvents that can permanently damage the modules of the system. If you are not sure that a cleaning product is safe, check the product contents to make sure that ingredients such as acetone, ammonium chloride, methylene chloride, and hydrocarbons are not included in the product.
- Do not use abrasive cleaners.
- Remove too much detergent or disinfectant from the modules.
- Do not use dripping wet cloth for cleaning of the modules of the system.
- Make sure that liquids cannot come in the electrical areas (sockets) of the Multi-Docking Station and Server.
- Let the modules air dry. Do not close the lid of the Server until you have allowed it to completely air-dry.
- Do not use cleaners that contain any petroleum-based materials such as benzene or thinner. These may damage the modules of the system.
- Do not use steam sterilization (autoclave), EO sterilization or dry heat to sterilize the modules of the system.

7.1.2 EarSensor

Caution!

- Use one of the following (based) cleaning solutions:
  - isopropyl alcohol (≤ 99,9%)
  - ethanol (≤ 99%)
  - diluted chlorine bleach (≤ 30 ml/l water)
  - hydrogen peroxide (≤ 3%)

Perform the following steps:

- Gently wipe the EarSensor with a wet cloth to remove surface dirt. Carefully clean all parts of the device that come in contact with the skin.
- Wipe the EarSensor with a disinfectant wipe to clean it. Do not use cleaning agents other than those described above without explicit written instructions from FastFocus support.
- Air dry or dry it with a dry cloth.

Figure 46 Cleaning the EarSensor

7.1.3 Server

Caution!

- Use any of the following germicidal wipe formulations to safely disinfect all exposed surfaces of the Server, including the keyboard, display, Touchpad, and case. (Refer to the directions for use provided by the manufacturer of the wipes):
  - Formula 1
    - Benzyl-C12-18-alkyldimethyl ammonium chlorides: 0.070%
    - Quaternary ammonium compounds, C12-14-alkyl[(ethylphenyl) methyl] dimethyl, chlorides: 0.070%
  - Formula 2
    - Isopropanol: 14.850%
    - Benzyl-C12-18-alkyldimethyl ammonium chlorides: 0.125%
    - Quaternary ammonium compounds, C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides: 0.125%
  - Formula 3
    - Quaternary ammonium compounds, C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides: <0.5%
    - Benzyl-C12-18-alkyldimethyl ammonium chlorides: <0.5%
  - Formula 4
    - Isopropyl alcohol: 55.0%
    - Benzyl-C12-18-alkyldimethyl ammonium chlorides: 0.250%
    - Quaternary ammonium compounds, C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides: 0.250%
  - Formula 5
    - Isopropanol: 17.2%
    - Ethylene Glycol Monobutyl Ether (2-Butoxyethanol): 1-5%
    - Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride: 0.280%
  - Formula 6
    - Sodium hypochlorite
    - Sodium hydroxide
  - Formula 7
    - Cellulose: 10-30%
    - Ethyl alcohol: 0.10-1.00%
  - Formula 8
    - Isopropanol: 60-70%

Note!

- When cleaning the cover of the laptop, use a circular motion to aid in removing dirt and debris.

Perform the following steps:

- Wipe the exterior of the Server with a soft, water-dampened cloth to remove the soil as needed.
- The cloth should be of dry microfiber or a chamois (static-free cloth without oil), or static-free cloth wipes.
- The cloth should be moist but not wet. Water dripping into the ventilation or other points of ingress can cause damage.
- Do not use fibrous materials, such as paper towels, which can scratch the computer. Over time, dirt and cleaning agents can get trapped in the scratches.
- Allow the unit to air-dry before use or before additional cleaning with germicidal wipes. To prevent keys from sticking and to remove dust, lint, and particles from the keyboard, use a can of compressed air with a straw extension.

7.1.4 Multi-Docking Station

Caution!

- Use one of the following (based) cleaning solutions:
  - isopropyl alcohol (≤ 99.9%)
  - ethanol (≤ 99%)
  - diluted chlorine bleach (≤ 30 ml/l water)
  - hydrogen peroxide (≤ 3%)

Perform the following steps:

- Unplug the Multi-Docking Station from its power supply.
- Gently wipe the Multi-Docking Station with a wet cloth to remove surface dirt.
- Wipe the Multi-Docking Station with a disinfectant wipe to clean it.
- Air dry or dry it with a dry cloth.

Note!

- The golden pins can be touched and pressed while cleaning.

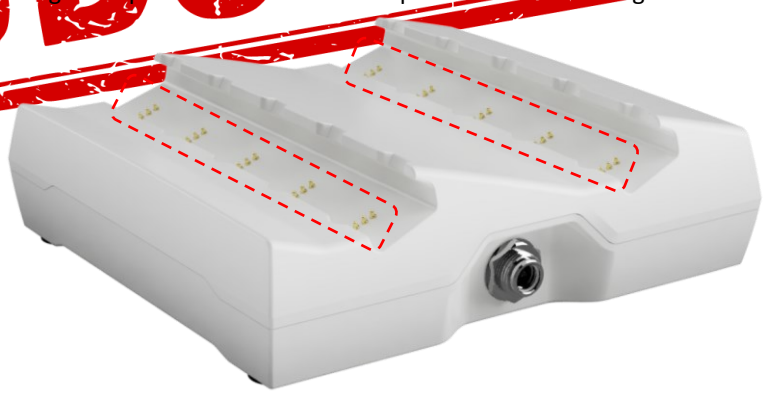


Figure 47 - Position of golden pins

7.2 Corrective maintenance

7.2.1 EarSensor

The EarSensor does not contain serviceable parts. Please contact the hospital service department or the local supplier for technical support in case the EarSensor is malfunctioning.

7.2.2 Server

The Server does not contain serviceable parts. Please contact the hospital service department or the local supplier for technical support in case the Server is malfunctioning.

7.2.3 Multi-docking station

The Multi-Docking Station does not contain serviceable parts. Please contact the hospital service department or the local supplier for technical support in case the Multi-Docking Station is malfunctioning.

8 Troubleshooting

This chapter summarizes the most common problems you could encounter with the FastFocus Vital Signs Monitoring System.

Table 2 - Troubleshooting

#	Problem	Solution
1	The EarSensor measurements seem to be wrong.	If no measurements can be done or the measurement results seem to be wrong, please check if the EarSensor sensor is correctly placed on the ear and no hairs or gap is existing between the detection window and the ear. If deemed that the EarSensor is placed correctly but there is strong believe that the measurement is wrong, please contact FastFocus for further assistance.
2	The EarSensor does not seem to work.	Please check if the EarSensor has been charged correctly and has been activated. This can be done by the following steps: - Place the EarSensor in the docking station and wait ten (10) seconds. - Undock the EarSensor from the Multi-Docking Station again. - After a few seconds the EarSensor status indicator should show a green continue LED, indicating that the device starts measuring. If other behaviour is shown, please refer to Table 1 for understanding the LED status messages. If no LED is shown on the EarSensor please check if the docking station is powered and if the EarSensor LED blinks or is shown continuously when placing the EarSensor in the docking station. Contact FastFocus for further support.
3	When undocking the EarSensor from the docking station no led feedback is given.	If no LED feedback is given at all, please check if the docking station is powered. Also verify if any LED feedback is shown when placing the EarSensor back in the docking station. If LED feedback is shown the time of charging might be too short. We recommend letting the EarSensor in the docking station for at least two (2) hours. If the EarSensor still shows no LED feedback after charging for a minimum of two (2) hours the EarSensor might be damaged. We kindly ask you note down the time and date and contact FastFocus for a replacement.

#	Problem	Solution
4	When docking the EarSensor, no led feedback is given.	If no LED feedback is given at all, please check if the docking station is powered as shown in page 17. Also verify if other EarSensors can be charged. If the EarSensor still cannot be charged and doesn't show any LED feedback the EarSensor might be damaged. We kindly ask you note down the time and date and contact FastFocus for a replacement.
5	The docking station fell on the ground or is damaged.	First remove any charging cables from the power if they are still in. Check carefully for any lose or broken parts. Note that these parts could be of sharp material and must be picked up carefully. Even if no damage can be seen from the outside, please contact FastFocus for further inspection and replacement. If EarSensors were positioned in the docking station check point 6 as well.
6	The EarSensor fell on the ground and may be damaged.	Although the device is tested for certain occurrences it's recommended to not use the EarSensor again. We kindly ask you note down the time and date and contact FastFocus for a replacement.
7	Water or fluid is spilled on the EarSensor or docking station.	First carefully and safely unplug the power cable from the docking station. The EarSensor and docking station are both certified IPX4 which means vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position. If more water is spilled or a different (chemical) fluid, please contact FastFocus first for further advice before using the EarSensors or docking station again.
8	An EarSensor is lost.	Please report the EarSensor number, time and date to the administrator. Note that no patient data or other personal identifiable information is stored on the device itself. Contact FastFocus for further assistance.
9	The EarSensor cannot be 'clicked' correctly in the docking station (loose connection).	Please refer to the paragraph "(Dis)connecting the EarSensor with the docking station" for instructions on how to connect the EarSensor in the docking station. If the EarSensor still cannot be connected please contact FastFocus for further assistance.
10	The EarSensor hook feels too loose.	The end of the hook of the EarSensor doesn't have to touch the detection window. The hook itself should give gentle resistance to keep the EarSensor attached to the ear. Please compare the EarSensor's hook with other EarSensors. If the EarSensor hook still feels too loose it might be damaged, please contact FastFocus for a replacement.

#	Problem	Solution
11	The EarSensor detection window (Figure 2) is damaged or feels loose.	The EarSensor detection window (Figure 2) is designed to gently bend and follow the human ear for an optimal fit and connection. If the detection window is damaged, please let FastFocus know about the possible cause (when know), and contact FastFocus for a replacement.
12	The charging pins seems damaged.	If the charging pins from a docking station are damaged, make sure to unplug the power cable carefully and safely. Contact FastFocus for a replacement. If the charging pins from the EarSensor are damaged the EarSensor may not be used. Contact FastFocus for further instructions and replacement.

8.1 Messages

The Server displays important information about the status of the EarSensors linked to a Label e.g., communication and battery status.

8.1.1 Server has no connection/communication with the EarSensor

It could be that the EarSensor is from time to time out of range of the FastFocus Server. For example, when a patient went for an outside walk. Another example would be that the battery went empty. In case the EarSensor cannot communicate with the Server for more than 5 minutes a message is shown:

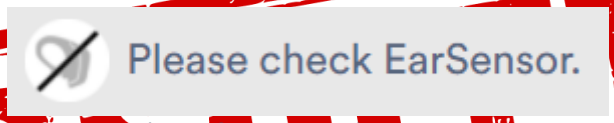


Figure 48 - No connection Message

If the EarSensor is within the proximity (≤ 30 m) of the Server and the no connection message does not disappear, please replace the EarSensor. Refer to 6.2.4 Unlinking and Changing an EarSensor.

8.1.2 Battery status

When the battery of the EarSensor is low or empty the following icons will be shown:

Battery empty.

Battery low.

If the battery of an EarSensor is empty it needs to be replaced and recharged. If the battery is low, it is recommended to replace the EarSensor. Please refer to 6.2.4 Unlinking and Changing an EarSensor.

8.2 EarSensor details

If you are unable to resolve the issue you have, you can contact FastFocus for help. It could be that our service engineer requests you to share details of the EarSensor.

Under each label on the labels page, the current linked **EarSensor ID** is presented.

Figure 49 - EarSensor ID

When clicking on the EarSensor ID, a screen opens to show more EarSensor details.

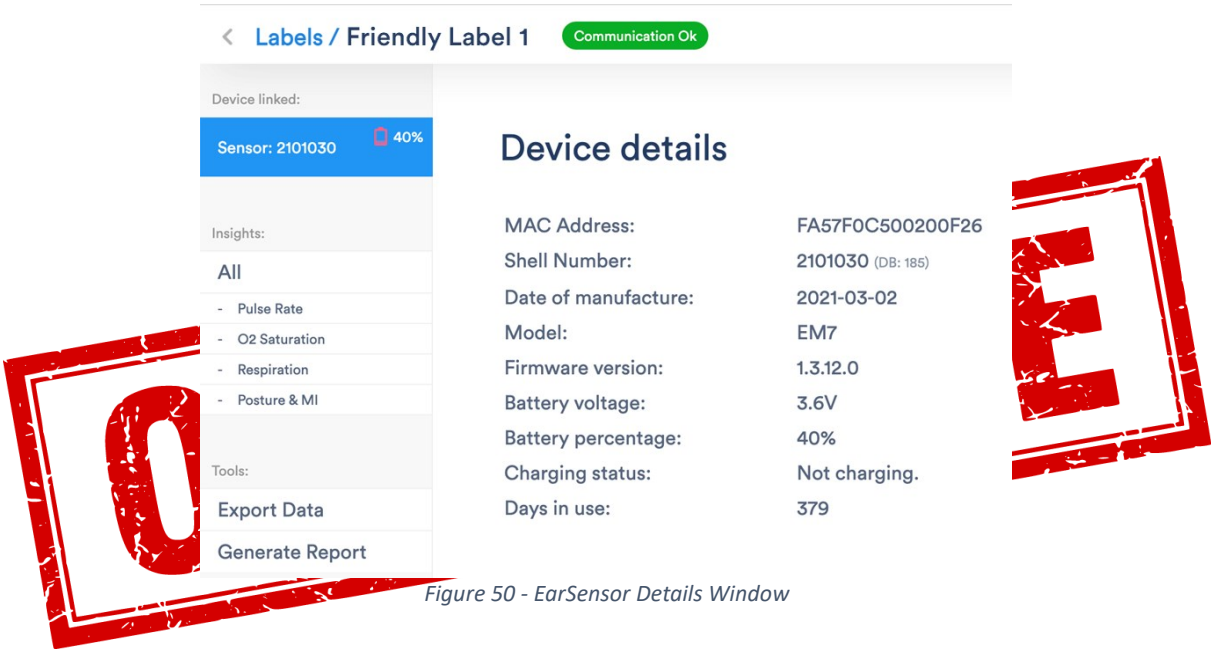


Figure 50 - EarSensor Details Window

8.3 Status indicator Coordinator Server

If you are unable to resolve the issue you have, you can contact FastFocus for help. It could be that our service engineer requests you to share the status of the Coordinator.

Figure 51 - Location of the status LEDs of the Coordinator

On the top side of the Coordinator you will find the status LEDs as shown in Table 3. Note that the following LED patterns will only be shown when the laptop is on, and the software is running.

LED configuration		Meaning
	All LEDs are off	Power off
	First LED is green and continuously on	Power on
	First LED is green, and fourth LED is orange and continuously on	Power on with active connection with laptop
	First LED is green, second LED is blue, and fourth LED is orange and continuously on	Power on with active connection with laptop and registering sensors
	First LED is green, and fourth LED is orange and continuously on, second LED is blue and blinking	Power on with active connection with laptop and registering sensors with too much data received, possible data loss.
	First LED is green, and fifth LED is white and continuously on	Power on without active connection
	First LED is green, and fourth LED is orange and continuously on. Fifth LED is white and blinking	Power on with active connection with laptop and sending data

Table 3 - LED combinations of the Coordinator and meaning.

9 Service life and disposal

The EarSensor has an expected service life of 1 year and the Server 4 years. The actual lifetime depends on the frequency and intensity of use. If one of the modules of the system is malfunctioning, please contact the hospital service department or the local supplier for technical support.

The EarSensor may be a potential biohazard during and after use. Handle and dispose in accordance with acceptable medical practice and applicable regulations.

Dispose according to European Community Directive 2002/96/EC (WEEE).

10 Specifications

10.1.1 General

Part No. device (EarSensor(s) + Server)	1200
Class (MDR (EU) 2017/745)	Class IIa
EN IEC 60601-1 (2006/A1:2013)	Pass
EN IEC 60601-1-2 (2015)	Group 1, Class B, Pass
ETSI EN 301 489-17 V3.1.1 (2017-02)	Pass
ETSI EN 300 328 V2.1.1 (2016-11)	Pass
ETSI EN 300 328 V2.2.2 (2019-07)	Pass
EN IEC 60601-2-57 (2011); Exempt group	Pass

10.1.2 Operating environmental conditions

Temperature	15°C to 35°C
Relative humidity	30% to 90%
Atmospheric pressure	70 kPa to 106 kPa

10.1.3 Transport and storage conditions

Temperature	-20°C to 70°C
Relative humidity	30% to 90% (non-condensing)
Atmospheric pressure	70 kPa to 106 kPa

10.1.4 Measurement accuracy

Note!
The accuracy of the measured vital signs can be influenced by physical movement, low perfusion, or inappropriate positioning of the EarSensor.

10.1.4.1 Pulse rate

Pulses per minute, verified accuracy range[1,2,3]	40 to 240 ± 1 pulse per minute

10.1.4.2 Blood oxygen saturation

Saturation accuracy, verified accuracy range[1,**2**,**3**]	70 to 100 ± 1% SpO2
Saturation accuracy, validated accuracy range[1,**2**,4,5]	80 to 100 ± 4% SpO2

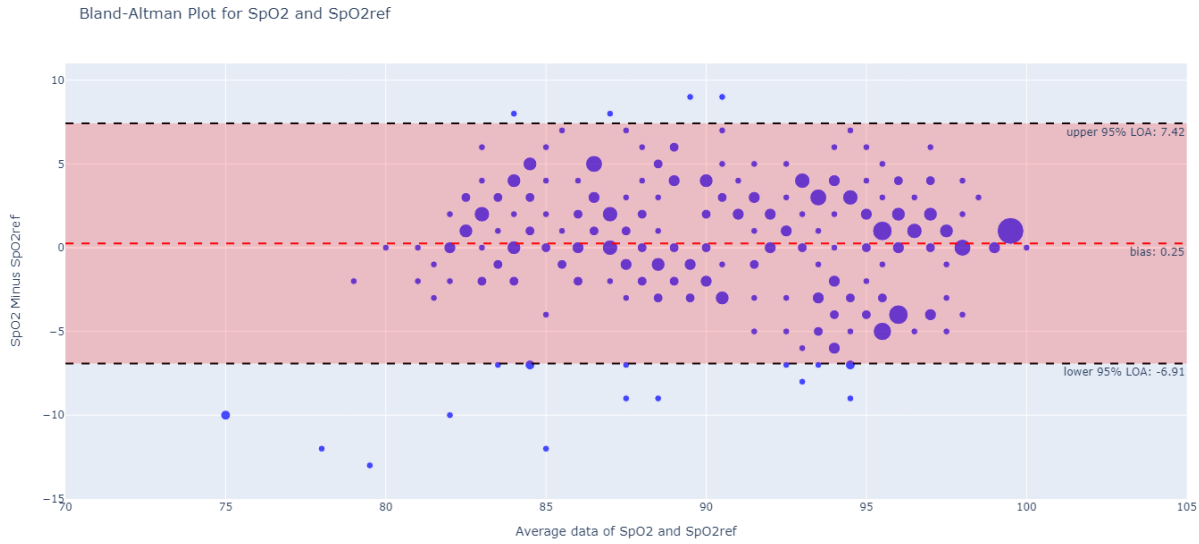


Figure 5-1 Bland-Altman plot of oxygen saturation for the system compared with a finger pulse-oximeter. The mean difference equals 0.25% with levels of agreement from -6.91% to 7.42%[4]

10.1.4.3 Respiratory rate

Breaths per minute, verified accuracy range[1,**2**,**3**]	5 to 42 ± 1 breath per minute
Breaths per minute, validated accuracy range[1,**2**,**6**]	5 to 30 ± 3 breaths per minute

[1] Verified and validated without motion.
[2] Accuracy is indicated by root-mean-square (A_{RMS}) difference. Note that measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ±Arms of the value measured by the reference method.
[3] Verified on test bench (simulated signal)
[4] Limits of agreement are 1.96 times the standard deviation.
[5] Total of 28 healthy subjects participated in the controlled desaturation study with a mean age of 28.2±8.6. The subject group had a 50 to 50% female to male ratio and subject were categorized in Fitzpatrick skin tone 1 to 4. With most categorized in class 3. No subjects belonged to class 5.
[6] Total of 19 healthy subjects participated in the controlled desaturation study with a mean age of 26.4±6.0. The subject group had a 47 to 53% female to male ratio and subject were categorized in Fitzpatrick skin tone 1 to 4. With most categorized in class 3. No subjects belonged to class 5.

10.1.5 EarSensor

Part No.	**1201**
Voltage	5 Vdc (battery powered)
Maximum power	< 1W
Dimensions (bounding box)	L: 55mm, W: 11mm, H: 49mm
Weight	12 grams
Class IEC 60529	IPX4
Class IEC 60601-1	Class II, Body Floating
Class IEC 62471(2008)	Exempt
3-Axis accelerometer	• Sampling frequency: 90 ± 5 Hz (non-customizable). • Interval: 10 seconds continuous each 10 seconds • High sensitivity motion detection across 3 axes: X, Y, and Z. • Range: ±2G. • Accuracy: ±0.15G • Precision: ± 0.005G • Resolution: 0.016G/LSB
Photoplethysmography (PPG)	• Spectral irradiance: RED 1.35 W/m²/nm, GREEN 1.33 W/m²/nm, IR 0.71 W/m²/nm. • Max output of optical radiation for all intended configurations: RED 550-750nm, GREEN 450-650nm, IR 800-1025. • Max variation of the output: RED 105nm, GREEN 120nm, IR 140nm. • Repetition rate: 65 Hz (Non customizable).

10.1.6 Server

Part No.	**1203**
Voltage	100 – 240V~ (50/60 Hz)
Maximum power	65W
Dimensions (bounding box)	L: 326mm, W: 234mm, H: 19 mm
Weight	1.8 Kg
Class IEC 60601-1	Class II, Body Floating The third conductor in the power supply cord is only a functional earth.

10.1.7 Multi-Docking Station

Part No.	**1102**
Voltage	100 – 240V~ (50/60 Hz)
Maximum power	21VA
Dimensions (bounding box)	L: 146 mm, W: 138 mm, H: 41,5 mm
Weight	1 Kg
Class IEC 60601-1	Class II, Body Floating

11 Electromagnetic compatibility

Warning!

- Use of accessories, transducers and cables other than those specified or provided by FastFocus for this system could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Use of this system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this system and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

Note!

- The Emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the device.
- It is possible that an information signal is triggered at a 30% dip. Degradation does not affect ESSENTIAL PERFORMANCE and BASIC SAFETY and is therefore compliant. Refer to Troubleshooting in chapter 8 and Specifications of the device in chapter 10 for a solution.
- This system complies with IEC 60601-1-2:2014 for electromagnetic compatibility. However, if electromagnetic interference with nearby devices is experienced, the user is encouraged to take one or more of the following measures:
  - Isolate the offending device.
  - Reorient or relocate this device.
  - Increase the distance between the interfering device and this device.
  - Use another mains socket.
  - If electromagnetic incompatibility is still experienced, please contact your distributor.

11.1 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000- 4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000- 4-4*	±2 kV for power supply lines ±1 kV for input/out - put lines	Electrical power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000- 4-5*	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Electrical power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000- 4-11*	0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Electrical power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 - Hz) magnetic field IEC 61000- 4-8	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Radiated RF IEC 61000-4-3	3V/m 80Mhz to 2.7GHz	3V/m 80Mhz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the system than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance D = 1.17 SQRT(p) 80MHz to 800 MHz D = 1.23 SQRT(p) 800MHz to 2.5 GHz Where p is the maximum output power rating the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by and electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80Mhz and 800Mhz, the higher frequency range applies**.**

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.

[b] Over the frequency range 150kHz to 80Mhz, field strengths should be less than 3V/m.

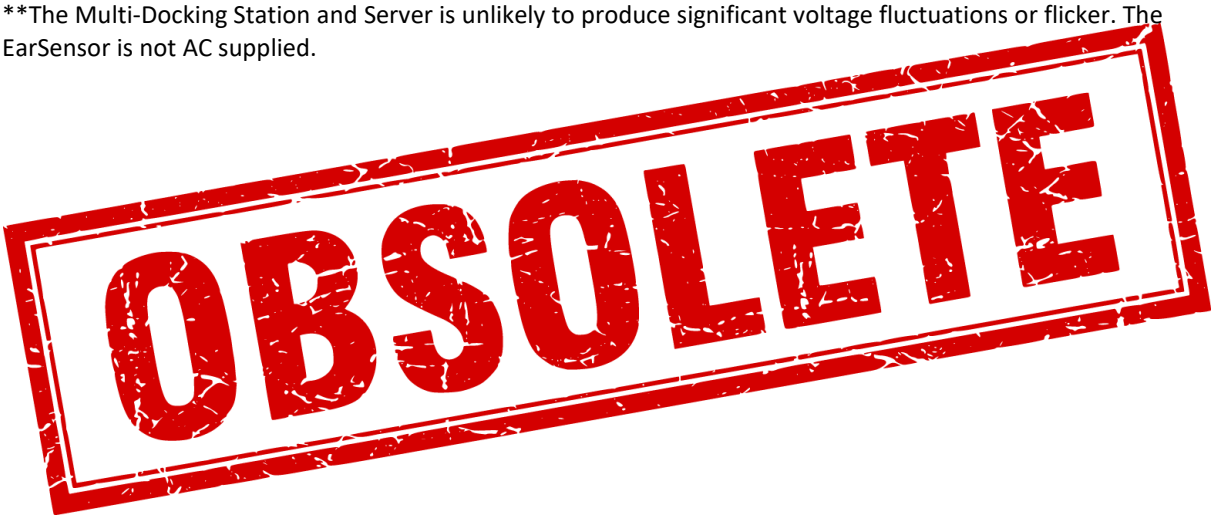
11.2 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Electromagnetic Emission Declaration	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emission test	Compliance
RF emissions CISPR 11 (2015)	Group 1
RF emissions CISPR 11 (2015)	Class B
Harmonic emissions IEC 61000-3-2	Not applicable (the device is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes)
Voltage fluctuations/flicker emissions IEC 61000-3-3	

*The rated power of the Multi-Docking Station and Server is 75W or less. The EarSensor is not AC supplied.
**The Multi-Docking Station and Server is unlikely to produce significant voltage fluctuations or flicker. The EarSensor is not AC supplied.



11.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distance between portable and mobile RF communications equipment and the product.
(For ME equipment ME systems that are not life-supporting)

The product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.

	Frequency Band (MHz)						
Power (W)	**380-390**	**430-470**	**704-787**	**800-960**	**1700-1990**	**2400-2570**	**5100-5800**
0.01	0.03	0.02	0.07	0.02	0.02	0.02	0.07
0.1	0.07	0.07	0.20	0.07	0.07	0.07	0.20
1	0.21	0.20	0.61	0.20	0.20	0.20	0.61
10	0.65	0.62	1.93	0.62	0.62	0.62	1.93
100	2.03	1.96	6.09	1.96	1.96	1.96	6.09

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

The product complies with the applicable requirements and relevant provisions of the Radio Equipment Directive 2014/53/EU (RED)

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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