Bittium Faros™ Manual

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www.bittium.com

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Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland
Phone: +358 40 344 2000
www.bittium.com

Legal Notice

Notice

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Summary of Changes

Version	Date	Changes Between Releases	Status
3.0.0	2021.03.09	Omega electrode added. Document re-structured.	Approved
4.0.0	2021.03.16	Modifications for Faros Manager version 3.3.0	Approved
5.0.0	2021.11.11	Modifications for OmegaSnap ECG Electrodes and Faros Manager version 3.4.0	Approved
6.0.0	2022.05.03	Modifications for OmegaSnap ECG Electrodes, Bittium Faros 180L, Bittium SafePort for Faros. Added Warranty information	Approved
7.0.0	2023.09.12	Clarifications on device disposal instructions and warranty conditions.	Approved

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1 CONVENTIONS

The following conventions are used in this user guide:

WARNING: Warning statements describe conditions or actions that can result in personal injury or loss of life.

CAUTION: Caution statements describe conditions or actions that can result in damage to the equipment or loss of data. Caution statements alert the user that the clinician has the responsibility of determining significance of results due to actions and varying factors present with each case.

NOTE Notes contain additional information on using this product.

The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Directive 93/42/EEC.

The electrode is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.

1.1 Terminology

Table 1 Terms used in the document

Term	Description
ECG or EKG	Electrocardiogram
EDF	European Data Format
IP	Ingress Protection
SSP	Secure Simple Pairing
MDD	Medical Device Directive
MDR	Medical Device Regulation

2 GENERAL WARNINGS AND CAUTIONS TO REVIEW BEFORE USE

Do not operate Bittium Faros™ device without first reviewing the following notices. See also Appendix 3: Bittium OmegaSnap electrodes supplementary information and Appendix 4: Bittium Faros 180L supplementary information.

WARNING: Do not disassemble, try to repair, or modify device.

WARNING: Device is not suitable for direct cardiac application.

WARNING: Do not touch parts of the computer, docking station or any non-medical electrical equipment and the patient at the same time when operating the Faros ECG device.

WARNING: To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the Faros ECG device should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfils the requirements.

WARNING: Do not attempt self-diagnosis or self-treatment based on acquired data.

CAUTION: Faros device IP classification is IP67.

CAUTION: Operating environments: Professional healthcare facility environment and Home healthcare environment.

CAUTION: Faros does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation.

CAUTION: Use ECG sampling rate of 500Hz with pediatric patients weighing less than 10 kg.

CAUTION: If a patient has been given defibrillation, while Faros ECG device and applied part are connected to the patient, Faros device and applied part must be sent to manufacturer for checking before continuing device use.

CAUTION: Faros device is not suitable to use in MRI environment.

CAUTION: Faros device is not intended to be used at the same time with high frequency (HF) surgical equipment or with defibrillator.

CAUTION: Patients, who have active implantable medical device (like heart pacemaker etc.) should consult supervising physician or doctor before use.

CAUTION: 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 device, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result.

CAUTION: Use Faros ECG device with accessories provided by Bittium Biosignals Ltd. Other cables and accessories may negatively affect device performance.

NOTE EMC disturbances might cause interference and/or noise to measurement data.

NOTE Any incident (serious or non-serious) that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

NOTE Faros device does not have any electrical stimulation capabilities.

NOTE Accelerometer data is not analyzed within the device or differentiated between various

physical activities.

NOTE Always follow instructions for disposable electrodes which are used for recordings

3 INTRODUCTION

The information in this user guide applies to Bittium Faros device revision H or later. The goal of this user guide is to provide an understanding of using Bittium Faros device.

CAUTION: Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

Faros device is a wearable, portable, externally applied electrocardiograph (ECG) recorder and wireless transmitter for ECG measurement, R-R interval data measurement and patient motion capturing.

The device monitors patient ECG and can be set to generate event markers using the built-in arrhythmia detection algorithms. The data recorded by the device can be extracted by either a USB connection or via a Bluetooth connection to a wireless device.

The device comes together with two bundled software: *eMotion EDF Viewer* for ECG data viewing and *Faros Manager software* for changing the device settings and updating the device firmware. Detailed analysis can be executed with *Cardiac Navigator* analysis software, available from Bittium. Also, a Faros Bluetooth protocol is available for third party connectivity and data extraction.

There are several different options for device attachment to human body. ECG and RR can be measured by using Faros device with OmegaSnap electrode or cable set and commercially available single-use snap on ECG electrodes.

Faros device is intended for adult and pediatric patients who require vital sign monitoring be it inside or outside hospital, or healthcare facility environment.

Faros device does not provide interpretive statements. Final interpretation and diagnosis are the responsibility of a physician.

Before operating Faros device, please read this manual thoroughly and keep it for future reference.

NOTE The screenshots shown in the document may not represent the latest software User Interface views.

3.1 Contraindications

- Faros device is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.
- Faros 180L is contraindicated for pediatric patients weighing less than 10 kg.

3.2 Security

System applications are recommended to be used with computers with proper anti-virus protection installed. Use of firewall is also recommended. Faros Bluetooth module uses Secure Simple Pairing (SSP). Online measurements via Bluetooth connection with Faros device is recommended to be done in hidden mode. Hidden mode can be configured using Faros Manager. With any concern related to security please contact medical.support@bittium.com for additional recommendation and support.

3.3 Symbols

Symbol	Description
	The device is CE-marked for the conformity to Council Directive 93/42/EEC regarding medical devices.
	The device is equipped with type BF applied parts fulfilling the EN 60601-1 (IEC60601-1) standard.
	The additional electrodes are disposable.
	Consult Instruction for use.
LOT	The Lot number of the electrodes.
	For EU only: This symbol indicates that this device shall be disposed according to European Union directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).
	During transportation: keep package dry, protect from rain.
NOTE!	Note text in manual: These statements identify conditions or practices that could result in equipment performance loss or must be otherwise observed.
MD	Medical device.
IP67	Faros device is IP67.
	This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Radio Law. Bluetooth module BT121 is certified in Japan with certification number 209-J00171.
	Wireless Transmission Symbol.

	A relative humidity range of 15 % to 90 %, non-condensing.
	Transport and storage conditions -20 °C to + 60 °C (transport) -20 °C to + 60 °C at a relative humidity up to 90 %, non-condensing (storage).
REF	Indicates the catalogue number so that the medical device can be identified.
	Manufacturer.
	Warning: MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment.
	A data matrix (GS1) code is a two-dimensional barcode consisting of GTIN and PI for Faros ECG device.
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed. An atmospheric pressure range of 700 hPa to 1 060 hPa.

3.4 Environmental conditions

3.4.1 Transport and storage conditions

Faros device must be transported and stored in conditions listed below.

- -20 °C to + 60 °C (transport)
- - 20 °C to + 60 °C at a relative humidity up to 90 %, non-condensing (storage)
    - 1 month storage: -20 °C to +60 °C
    - 3 months storage: -20 °C to +45 °C
    - 12 months storage: -20 °C to +25 °C
- Occasional storage and transport: -40°C to+70°C

3.4.2 Continuous operating conditions

Faros device must be used in conditions listed below:

- A temperature range of + 0 °C to + 45 °C
- A relative humidity range of 15 % to 90 %, non-condensing
- An atmospheric pressure range of 700 hPa to 1 060 hPa.

3.5 Bluetooth Protocol

Bittium Biosignals Ltd. will provide “Faros 3.x Bluetooth Protocol” documentation to support Faros ECG device Bluetooth communication integration to 3rd party solutions.

Table 2 Bluetooth Protocol

3rd party interoperability requirements
Bluetooth 2.1

3.6 Warranty

All repairs on products under warranty must be performed or approved by Bittium Biosignals Ltd. Unauthorized repairs will void the warranty. The warranty terms are as follows:

Warranty: 12 months unless otherwise specified herein below.

Coverage: Parts and labor unless otherwise specified herein below.

All warranties will be invalidated if unauthorized repairs are made to any parts of the overall system.

The liability of Bittium Biosignals Ltd is limited to the repair of the product under warranty and specifically excludes consequential loss. The warranty covers all labor and parts associated with normal use. The warranty does not cover travelling expenses in case the repair is needed at end-user's facilities.

Bittium Biosignals Ltd guarantees the spare part supplies for at least 5 years after delivery date of the product.

Installation of additional equipment that is not specified or approved by Bittium, or is such quality to render the unit inoperable, may invalidate the warranty.

This warranty does not cover accidental damage or misuse.

The end-user shall ensure that the environment and electrical supply are suitable for the equipment and are maintained in accordance with the specification of Bittium Biosignals Ltd.

The end-user shall keep and operate the equipment in a proper and prudent manner and ensure that only competent persons are allowed to operate it.

The end-user shall not make any addition, modification or adjustment to the equipment without the prior written consent of Bittium Biosignals Ltd, nor allow persons other than Bittium staff or authorized agents to adjust, repair or maintain it.

Special terms and conditions for parts of the system:

Accessories

- OmegaSnap adapter - 12 months from the delivery date
- Bittium Safeport for Faros - 12 months from the delivery date
- Bittium USB cable - 12 months from the delivery date
- Bittium Cable set - 6 months from the delivery date

The warranty does not cover faults caused by improper handling.

Disposable items

Manufacturing faults of non-expired goods will be replaced.

3.7 Disposal

Please follow your local environment safety regulations when disposing of the system, or any parts of it. In many countries the electronics recycling is possible or even obligatory.

For EU users only: The device shall be disposed according to European Union directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). If the device is contaminated the directive may not apply.

The equipment may contain confidential information. Follow national standards and guidelines regarding secure disposal of waste containing confidential information.

4 FAROS ECG DEVICE OVERVIEW

4.1 General information

There are three models of the Faros device: a 1-channel ECG models (Faros 180 and Faros 180L) and a 3-channel ECG model (Faros 360). All models are capable of Bluetooth communication; have the same form and shape but are differentiated only by the color and device features.

Bittium Faros 180™

9404302

Bittium Faros 180L™

9404659

Bittium Faros 360™

9404300

Table 3 Faros device technical specifications

Technical specification	Bittium Faros 180™	Bittium Faros 180L™	Bittium Faros 360™
ECG Holter	Yes	Yes	Yes
ECG wireless transfer	Yes	Yes	Yes
Waterproof IP67 design	Yes	Yes	Yes
1-channel ECG	Yes	Yes	Yes
3-channel ECG	No	No	Yes
RR intervals	Yes	Yes	Yes
Bluetooth	Yes	Yes	Yes
Accelerometer	Yes	Yes	Yes

RR sampling frequency	1000 Hz	NA	1000 Hz
ECG sampling frequency	125, 250, 500, 1000 Hz	125, 250 Hz	125, 250, 500, 1000 Hz
ADC precision	24 bits	18 bits	24 bits
3D accelerometer precision	14 bits	12 bits	14 bits
3D accelerometer sampling frequency	25, 100 Hz	25, 100 Hz	25, 100 Hz
Datalogger file format	EDF	EDF	EDF
Memory capacity	4 GB	4 GB	4 GB
Power source*	3,7 V Li-ion battery	3,7 V Li-ion battery	3,7 V Li-ion battery
Dimension	48 x 29 x 12 (mm) Weight 18 g	48 x 29 x 12 (mm) Weight 18 g	48 x 29 x 12 (mm) Weight 18 g
Operating time	Up to 7 days ECG 125 Hz	Up to 14 days ECG 250 Hz	Up to 7 days ECG 125 Hz
**Faros power source Li-ion battery complies with IEC 62133.*			

4.2 Device symbols and indicators

Device symbols and indicators provide information of the device state. Device has four LEDs and a buzzer for audio indications. Indications are presented in tables below.

Figure 1 Symbols and indications

Table 4 Device indications

Description	Indications
Device is connected to computer.	**Green** indicator is lit.
Battery is charging.	**Blue** indicator blinks.
Battery is fully charged.	**Blue** indicator is lit.
Unable to start measurement; error.	**Red** indicator is lit.
Measurement has started.	**Green** indicator is lit together with a start sound ♫
Measurement is running.	**Green*** indicator blinks every five seconds.
Measurement has ended.	Three ♫ ♫ ♫ beep-sound indications.
Pushbutton is pushed during measurement.	One ♫ beep-sound indication.
Battery is running low.	**Blue** indicator blinks twice and two ♫ ♫ beep-sound indications every five seconds.
Internal memory is almost full.	**Orange** indicator blinks twice and two ♫ ♫ beep-sound indications every five seconds.
Lead-off alarm (when lead-off detection is active)	Red indicator blinks twice and two ♫ ♫ beep-sound indications every five seconds.
Device is in Bluetooth idle state.	**Green*** indicator blinks every two seconds.
Firmware update.	**Green** indicator blinks during update.
Device reset.	All indicators blink once and one long ♫ beep-sound indication.
Device has halted at internal error handling checkpoint.	All indicators blink.
*Green heart indicator changes colour from green to blue in the following cases: • Measurement is running and Bluetooth is connected. • Device is in Bluetooth idle state and Bluetooth is connected.	

4.3 Accessories and replacement parts

9404644 Bittium OmegaSnap 1-CH ECG Electrode (Applied part)	
9404716 Bittium OmegaSnap 2-CH ECG Electrode (Applied part) **NOTE** OmegaSnap 2-CH ECG Electrode is supported from Faros device firmware version 3.7.2 and Faros Manager version 3.4.0 onwards.	

9404717 Bittium OmegaSnap 3-CH ECG Electrode (Applied part)	
9404718 Bittium MiniSnap Sensitive 1-CH ECG Electrode (Applied part)	
9404719 Bittium OmegaSnap Multi-CH Adapter (Applied part)	

9400147 Bittium OmegaSnap 1-CH Adapter (Applied part)	
9404265 2-electrodes cable set (Applied part)	
9404266 3-electrodes cable set (Applied part)	
9404282 5-electrodes cable set (Applied part)	
5501020 USB Cable	

9404724 Bittium SafePort (a docking station with USB cable)	

4.4 Recharging the battery

It is recommended to recharge the battery to full capacity before use.

NOTE Make sure that the device is completely dry, especially the USB connector, before you start to recharge your Faros device. No moisture is allowed in device's USB connector area. Check the device's USB connector for dust and remove it with paper towel.

If there is moisture on the device, let the device dry for 2 hours before you plug it into a computer via USB cable for charging.

Use the USB cable delivered with your Faros ECG device to connect the device to your personal computer.

1. Plug the USB cable to your computer.
2. Plug the other end of the USB cable to your Faros device. Blue light indicator starts to blink. Blue light indicator shines continuously when the device's battery is fully charged. Recommended recharge time is 1.5 hours.
3. Unplug the USB cable from the Faros device and the computer.

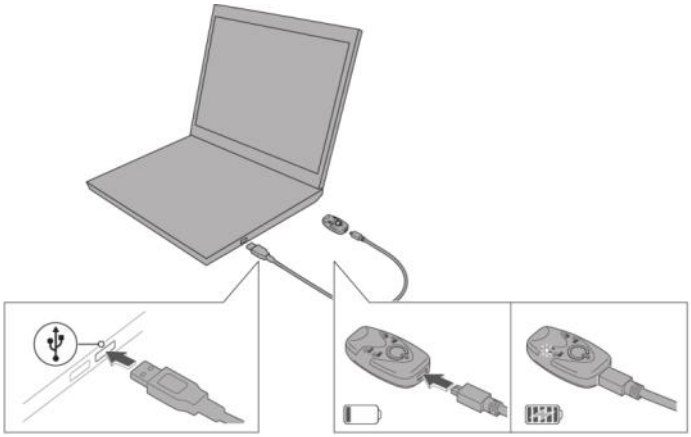


Figure 2 Connecting Faros to computer using USB cable

4.5 Connection to computer

4.5.1 Connecting Faros to a computer

Use the USB cable delivered with your Faros device to connect the device to your personal computer.

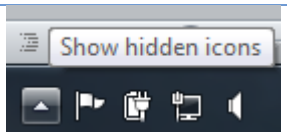
1. Plug the USB cable to your computer.
2. Plug the other end to your Faros device. Blue light indicator starts to blink first, and then green light indicator should start to blink also.

If green light indicator does not blink when device is connected to your computer, there may be a connection issue. In this case, you should disconnect the USB cable connection and reconnect again, also check carefully that the USB connection between the device and the cable and between the cable and your computer is not loose.

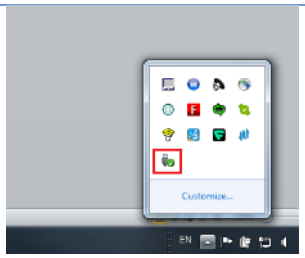
4.5.2 Disconnect Faros from computer safely

Faros device must be safely disconnected from PC to avoid disk error. There are two methods for disconnecting the device safely.

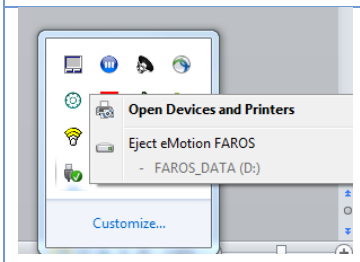
4.5.2.1 Using “Safely Remove Hardware and Eject Media” tool from Windows

1. Open the hidden icons in Windows taskbar at the bottom right corner of Windows.	

2. One of the hidden tools is the “Safely Remove Hardware and Eject Media”

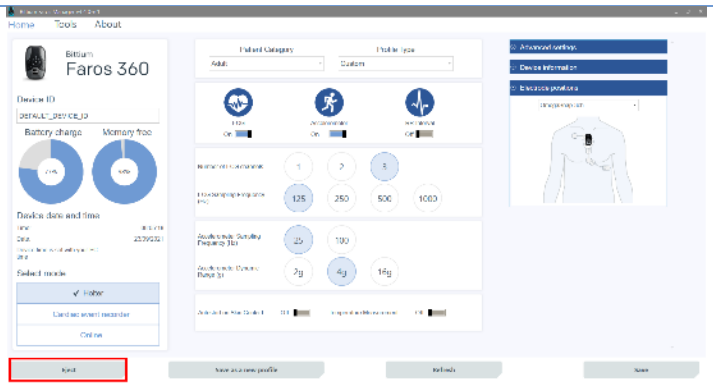


3. Click on the icon of the tool, it should show an option to “Eject FAROS”
4. Choose “Eject FAROS” and wait until Faros device has only blue light indicator turning on. You can disconnect the device now.

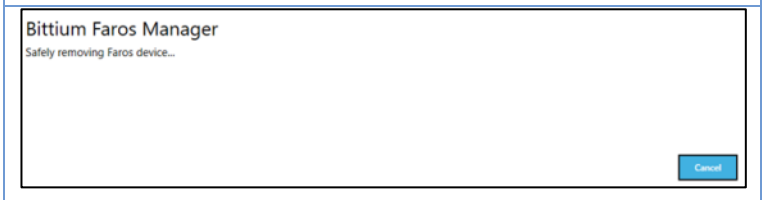


4.5.2.2 Disconnecting from Faros Manager

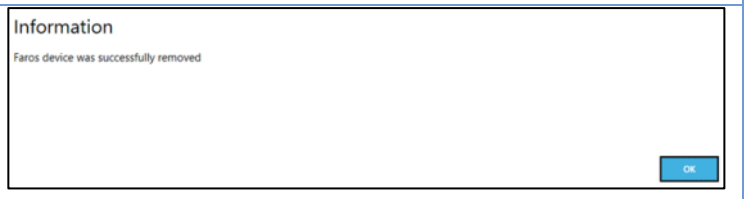
1. When Faros device is already connected to computer and Faros Manager is opened, click on “Eject” button.



2. A dialog opens and informs to wait as software removes Faros device safely.



3. After that, software shows a message to inform whether Faros device was removed successfully or not.



If Faros device could not be removed, please check if there are any measurement files still open on the computer or any program is using Faros device memory card.

4.6 Bittium SafePort

Bittium SafePort is a USB cradle designed to facilitate the daily use of Bittium Faros devices and to protect them from electrical and mechanical failures (E.g., Rough handling of the device. Moisture residue in the connector of a recently cleaned device etc.).

Figure 3 Bittium SafePort

NOTE Bittium SafePort acts only as an extension to USB cable.

Bittium SafePort has a LED indicator that provides information about the operation of SafePort. Indications are presented in tables below.

NOTE The operation and indications of the LED indicator in Bittium SafePort differ from the Bittium Faros device.

Table 5 Bittium SafePort indications

Description	Indications
Bittium SafePort is connected to computer.	**Green** indicator is lit.
Bittium Safeport has detected one of the following error conditions: - overcurrent - overvoltage - undervoltage - critical temperature.	**Red** indicator is lit.

4.6.1 Connecting to computer with the Bittium SafePort

When using a Bittium SafePort device, the Faros device is connected to the computer as follows.

Use the USB cable delivered with your Bittium SafePort USB cradle to connect SafePort to your personal computer.

1. Plug the USB cable delivered with your SafePort USB cradle to connect SafePort to your personal computer.
2. Plug the other end of USB cable to your SafePort USB cradle. Green light indicator in Bittium SafePort is lit.
3. Place the Faros ECG devices in the Bittium SafePort. Blue light indicator on Faros device starts to blink first, and then green light indicator should start to blink also.

If green led indicator in Bittium SafePort USB cradle is not lit when device is connected to your computer, there may be a connection issue. In this case, you should disconnect the USB cable connection and reconnect again, also check carefully that the USB connection between the device and the cable and between the cable and your computer is not loose.

NOTE Do not connect Faros device to Bittium SafePort USB cradle if red LED indicator is lit in Bittium USB cradle.

NOTE Remove Faros Device from Bittum SafePort USB cradle if red LED indicator is lit in Bittium USB cradle when the device is attached to it.

If green light indicator on Faros device does not blink when device is connected to your computer with Bittium SafePort USB cradle, there may be a connection issue. In this case, you should first check that the Faros device is properly attached to Bittium SafePort USB cradle. If this is not the case, then disconnect the USB cable connection and reconnect again, also check carefully that the USB connection between the device and the cable and between the cable and your computer is not loose.

4.6.2 Recharging the battery with the Bittium SafePort

Connect Faros device to computer with Bittium SafePort as described in chapter 4.6.1.

Blue light indicator in Faros device starts to blink when the device is recharging.

Blue light indicator is lit when the battery of Faros device is fully charged.

4.7 Troubleshooting

If the device does not work or operation is unpredictable, try the following:

Recharge the device

- Follow instructions in chapter 4.4.

Device does not start measurement (error light indicator blinks three (3) times)

- Recharge the device.
- Synchronize the device clock via Faros Manager.
- Save settings.

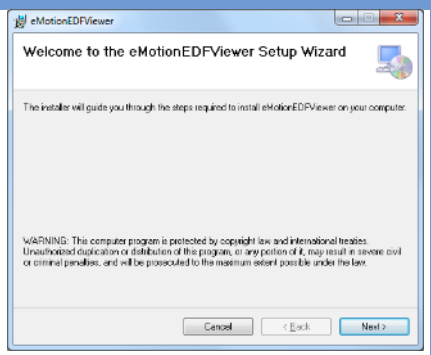
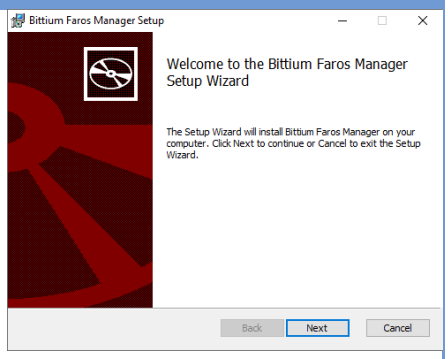
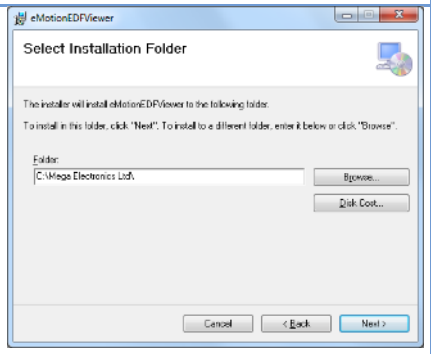
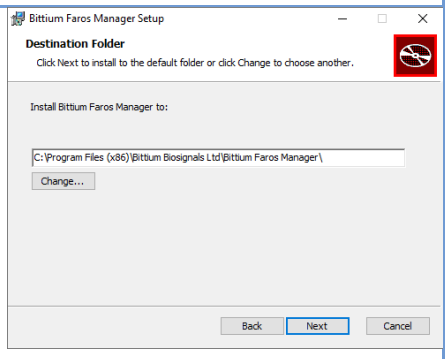
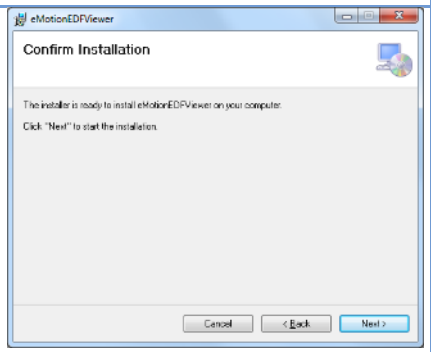
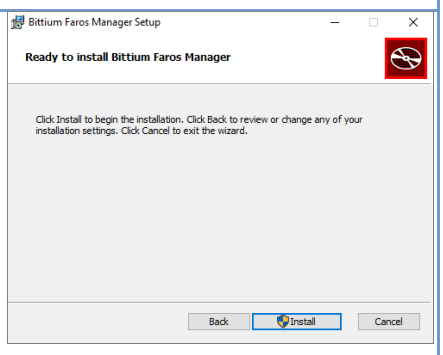
Reset the device

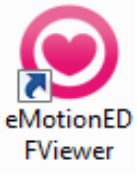
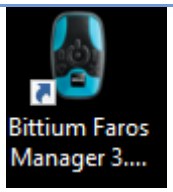
- Push the pushbutton until all light indicators flash.
- Power on the device by pushing the power button.

5 SOFTWARE INSTALLATION

NOTE Use Windows 10 64-bit operating system for installing Faros Manager or EDF Viewer software.

Connect Faros device to your computer via USB and browse to “FAROS_DATA/Software” folder. To install applications, run installer programs from “eMotion EDF Viewer” and “Faros Manager” folders. After this follow the on-screen instructions

Steps	EDF Viewer	Faros Manager
Click “Next” to continue. Accept the License Agreement, if asked.		
Use default or select desired destination folder for installation. Click “Next” to proceed.		
Click “Next” to perform installation. After installation is complete click “Close” or “Finish”.		

Application shortcut icons appear on desktop. Applications are ready to use.		

NOTE Faros Manager icon contains also the current software version number.

6 MEASUREMENT CONFIGURATION

The measurement configuration is managed with Faros Manager software.

1. Connect Faros device to computer and run Faros Manager software from desktop icon.
    a. If Faros Manager software is not installed, browse to “FAROS_DATA/Software” folder on device hard drive and run Faros Manager installer to use the Faros Manager software.
2. Set the desired measurement configuration.
3. Configure desired settings. Click “Save” button to apply the configuration. Click “Close” to exit the application. Remove Faros device safely (see ch. 4.5.2)

Faros Manager recognizes the model of the connected device, and the configuration options are based on the device model. The options are presented in tables below.

Table 6 Faros device options

Device type	Device revision	Firmware version	ECG sampling	ECG channels	ACC sampling	ACC range
180	0H	3.6.x or newer	125, 250, 500, 1000	1	25, 100	2, 4, 16
180L	0I	3.7.1 or newer	125, 250	1	25, 100	2, 4, 16
360	0H	3.6.x or newer	125, 250, 500, 1000	1,3	25, 100	2, 4, 16

Table 7 Other Faros device options

Device type	Bluetooth	Autostart	Ambient temperature	Cardiac events	Pacemaker events	Lead off detection	Configurable measurement time
180	Yes	Yes	**No**	Yes	Yes	Yes	Yes
180L	Yes	Yes	**No**	Yes	Yes	Yes	Yes
360	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 8 Electrode configurations

Number of ECG channels	Supported electrode configurations
1	2 electrodes, 3 electrodes, OmegaSnap, MiniSnap
2	3 electrodes, OmegaSnap-2ch (supported from firmware version 3.7.2)
3	5 electrodes, OmegaSnap-3ch

6.1 Holter measurement configuration

Holter measurements can be performed with every Faros model. The configuration for Holter measurement is set using Faros Manager.

NOTE Faros 180L requires using Faros Manager version 3.4.1 or later.

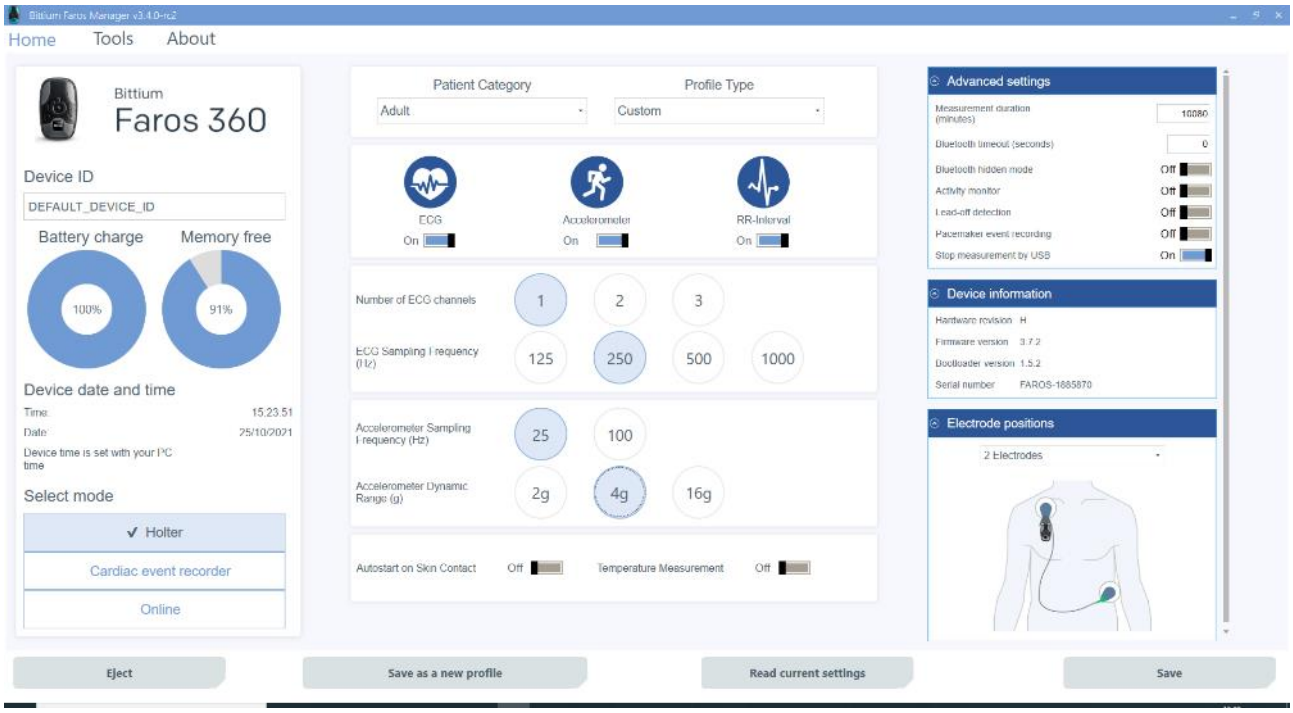


Figure 4 Holter configuration

1. Run Bittium Faros Manager.
2. Select ‘Holter’ mode from Manager main view.
3. Select ‘Custom’, or desired measurement time (Preset recording options, 1-7 days) from Profile Types.
4. When using “Custom settings”, select wanted measurement parameters:
    a. Patient category, Adult/Pediatric
    b. RR Intervals, On/Off
    c. Accelerometer, On/Off
    d. ECG/EKG, On/Off
5. ECG Channel count (3 channels option is only available with Faros 360).
6. Select the electrode positions to match the electrode type and positioning used for the measurement.
7. Select values for acquisition parameter:
    a. ECG - Sampling Frequency
    b. Accelerometer - Sampling Frequency
    c. Accelerometer - Dynamic Range
8. Autostart on skin contact, On/Off
9. Temperature measurement On/Off (ONLY with Faros 360).
10. Press ‘Save’ to apply the configuration.
11. Click “Eject” to eject Faros device.

NOTE The selection of Electrode positions affects the displayed device settings. Set the Electrode positions picture to match the type of electrode used for measurement.

6.2 Cardiac Event Recorder configuration

Cardiac event recordings can be performed with every Faros model. The configuration for Cardiac Event Recorder mode is set using Faros Manager.

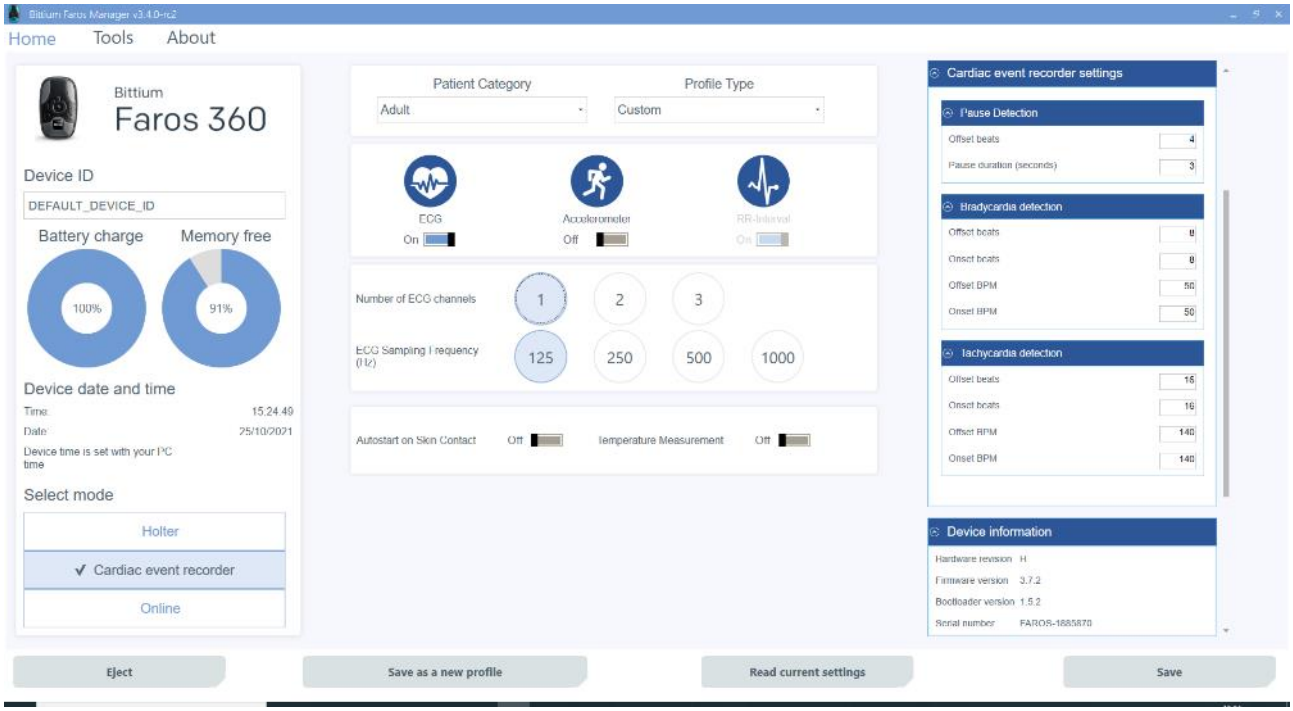


Figure 5 Cardiac Event Recorder configuration

Cardiac event recorder settings (default detection values)
Pause; Offset beats 4, Pause duration (seconds) 3
Bradycardia; Onset / Offset beats 8, Onset / Offset bpm 50
Tachycardia; Onset / Offset beats 16, Onset / Offset bpm 140

6.3 User customized profiles

In Faros Manager 3.4.x, you can save your current measurement configurations to a profile for later use. Click on “Save as new profile” button at the bottom bar of application.

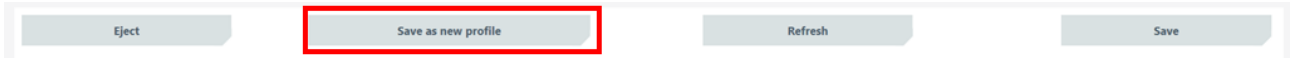


Figure 6 "Save as new profile" button

“Information” –window is shown, and you are asked to name the created profile. Enter the new profile name and click “OK” button. New profile is now saved.

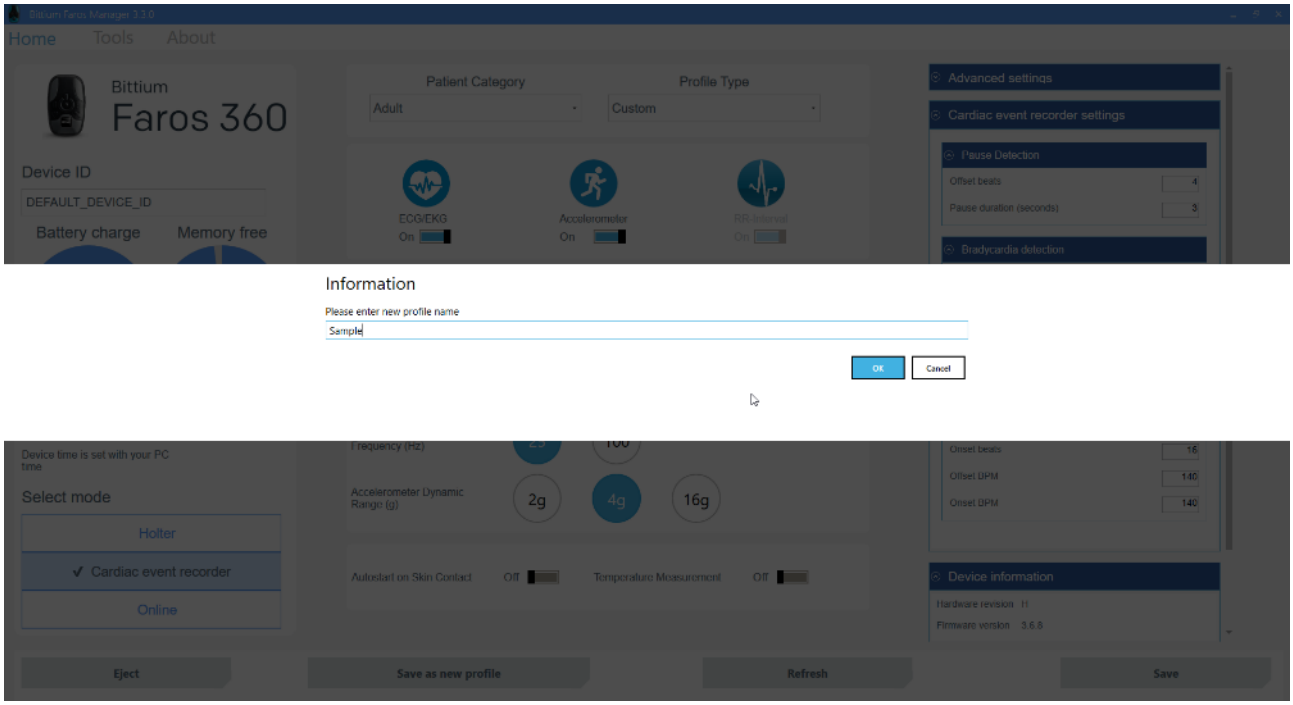


Figure 7 Enter new profile name

By choosing “User” in Profile Type list, you can find a list of your saved customized profiles on the top right column.

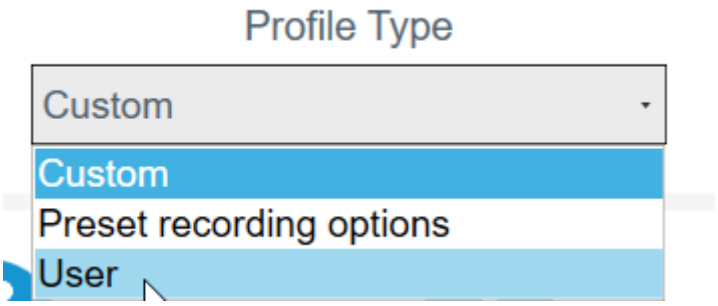


Figure 8 User profile

6.4 Online mode

The online ECG data monitoring is available on Faros 180 and Faros 360 devices. Configuration for online mode is set using the Faros Manager.

1. Run Bittium Faros Manager.
2. Select ‘Online’ from Manager main view.
3. Adjust the settings as desired.

4. Press ‘Save’ to apply configuration.
5. Click “Close”.

Device is now ready to perform online ECG data monitoring.

Contact Bittium to receive further information on using Faros device with a mobile device.

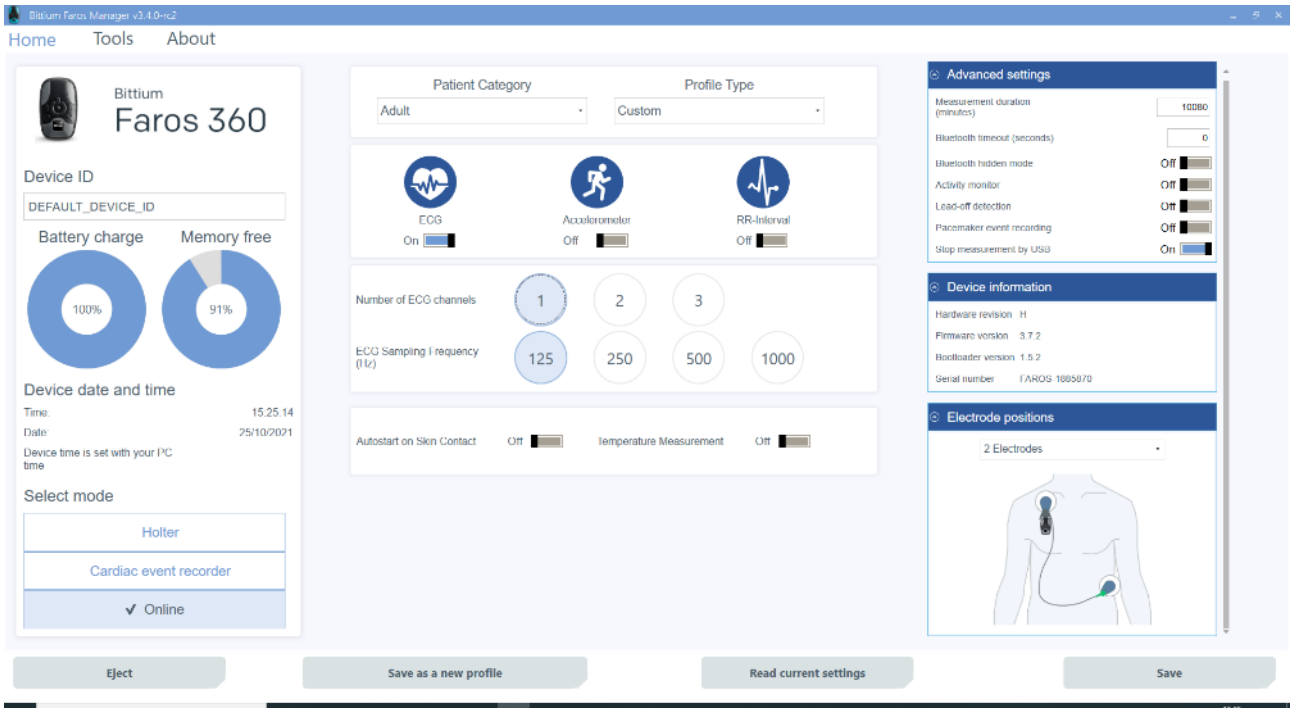


Figure 9 Online configuration

Advanced settings

Select Advanced settings to open Faros Manager settings view.

In Settings view you can configure the following settings:

- Measurement duration in minutes.
- Bluetooth timeout (automatic shutdown of Bluetooth in offline mode after given period when no Bluetooth connection is established with a companion device)
- Bluetooth hidden mode, On/Off
    - Bluetooth Hidden Mode is a cyber-security enhancement which makes Faros device undiscoverable and non-pairable from untrusted devices.
- Accelerometer-based patient activity monitor, On/Off.

- Lead-off detection, On/Off.
- Pacemaker event recording, On/Off.
- Stop measurement by USB, On/Off.

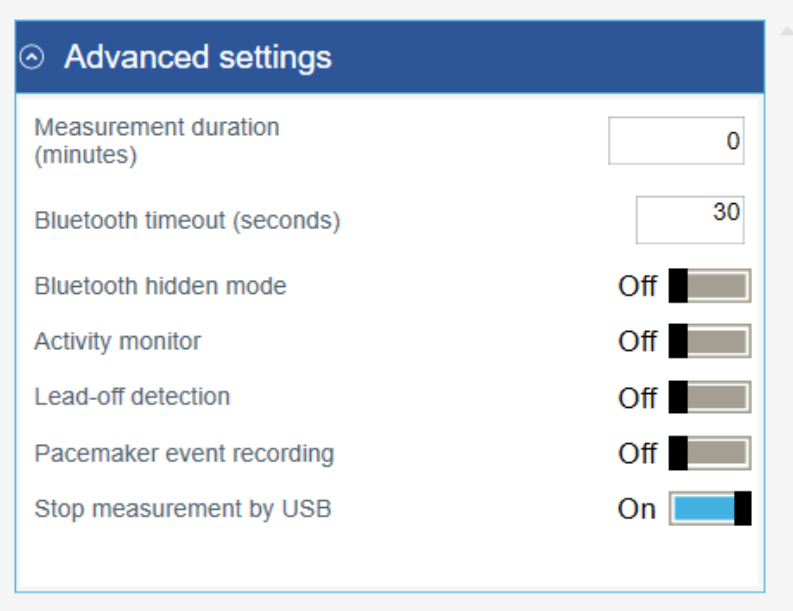


Figure 10 Advanced settings view

6.5 Electrode positions

The selection of Electrode positions affects the displayed device settings. Always set the image to match the type of electrode used for measurement to ensure the optimal measurement results.

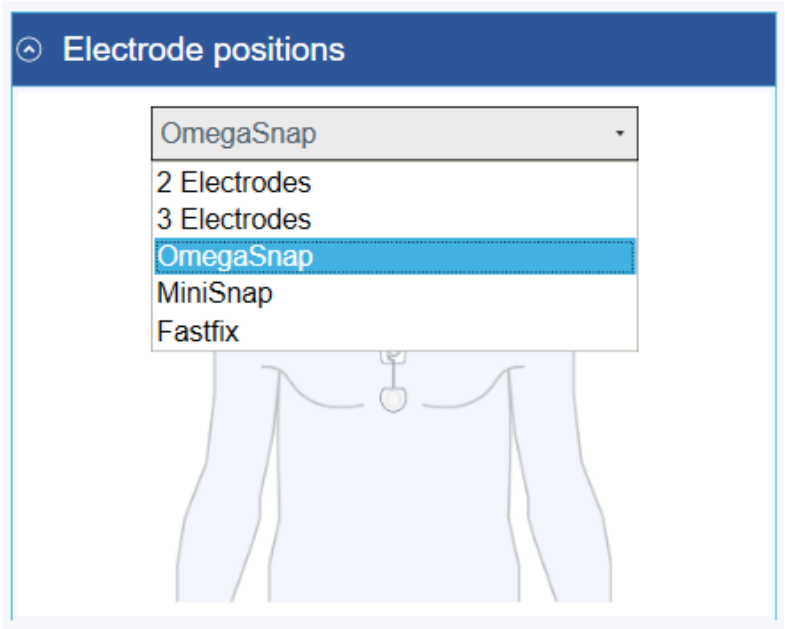


Figure 11 Selection for Electrode positions

6.6 About

About view describes the software version details as well as license information. You can also access the User Manual by clicking 'Read Manual' and send a support request to Bittium Biosignals by clicking 'Support request'.

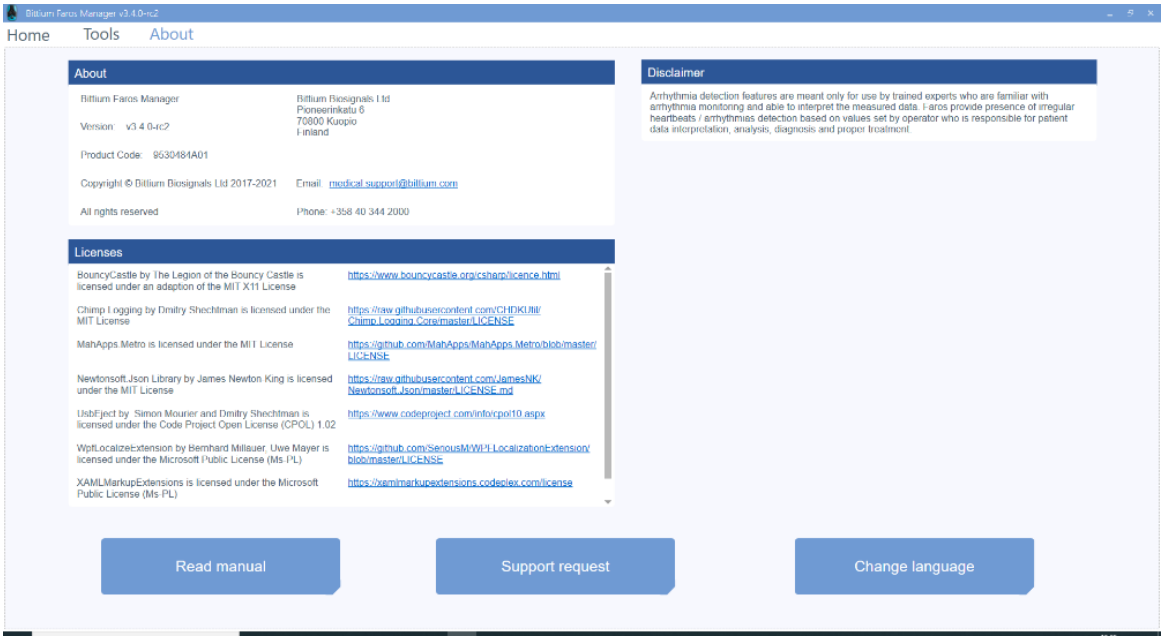


Figure 12 About view

6.6.1 Change language

You can change the language used in Faros Manager by selecting About and then clicking ‘Change language’. The available languages are Finnish, English, Swedish, Danish, German, and French. Once the language is selected clicking Close will set that language in use.

7 HOW TO START AND STOP A RECORDING

Before recording make sure that the device battery is fully charged. The device can be charged with the USB-cable included in the Faros package or with a regular micro-USB charger.

- The blue light indicator is blinking when the battery is charging
- When the battery is full, the blue light indicator shines continuously.

The Faros device has one pushbutton. The device starts when you push the button.

7.1 Patient preparation for OmegaSnap electrodes

Step 1: Prepare the skin of the patient in the area where the electrode is placed:

a) Shave the hair off from the area where the electrode is placed.

b) Clean the skin with appropriate alcohol (for example denat. 80% alcohol), electrode preparation pads or using mild soap and water.

c) Make sure that the skin is dry before applying electrode

Step 2: Attach the electrode to the patient's skin:

d) Electrode placement is instructed in next chapters.

e) Check that the adhesive sticks properly.

f) Check that there is no air between the electrode gel and patient's skin.

g) Check that there is no hair under the adhesive.

Step 3: Attach the device to the electrode:

h) Attach the device to the electrode (see electrode placement pictures in chapter 7.1.1)

Step 4. Start the measurement:

i) Press the Faros device pushbutton once.

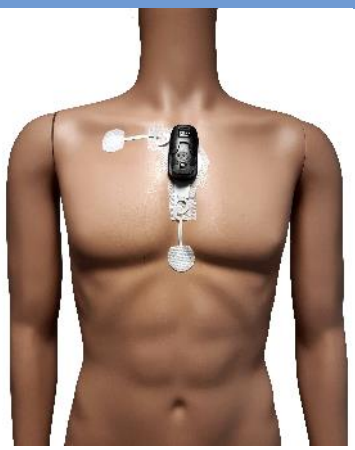
j) Green light indicator starts to blink – the device is now recording.

7.1.1 Positioning of the OmegaSnap electrode

The recommended position for the OmegaSnap electrode is on the middle of the sternum as seen in the pictures. Please refer to following User manuals for more information on how to use OmegaSnap electrodes:

- 5800638 Bittium OmegaSnap 1-CH ECG Electrode Quick Guide
- 5800646 Bittium OmegaSnap 2-CH ECG Electrode Quick Guide
- 5800662 Bittium OmegaSnap 3-CH ECG Electrode Quick Guide

Table 9 OmegaSnap electrode positioning

OmegaSnap 1-CH ECG Electrode	OmegaSnap 2-CH ECG Electrode	OmegaSnap 3-CH ECG Electrode
		

NOTE Optimal signal quality is obtained when the electrode is fully placed on top of the thorax and the bottom of the electrode is clearly above the diaphragm.

7.1.2 Positioning of the MiniSnap electrode

The recommended position for the MiniSnap electrode is on the middle of the sternum as seen in the pictures. Please refer to following User manual for more information on how to use MiniSnap Sensitive electrode:

- 5800647 Bittium MiniSnap Sensitive 1-CH ECG Electrode Quick Guide

Table 10 MiniSnap Sensitive electrode positioning

MiniSnap Sensitive 1-CH Electrode


NOTE Bittium MiniSnap™ Sensitive 1-CH ECG electrode is the most suitable for 24h ECG measurements on small adults and children.

NOTE Optimal signal quality is obtained when the electrode is fully placed on top of the thorax and the bottom of the electrode is clearly above the diaphragm.

7.2 Patient preparation for electrodes and leads

Step 1: Prepare the skin of the patient in areas where the electrodes are placed:

a) Shave the hair off from the areas where the electrodes are placed.

b) Clean the skin with appropriate alcohol (for example denat. 80% alcohol), electrode preparation pads or using mild soap and water.

Step 2: Attach the electrodes to the patient's skin:

c) Electrode placement is instructed in next chapter.

d) Check that the adhesive sticks properly.

e) Check that there is no air between the electrode gel and patient's skin.

f) Check that there is no hair under the adhesive.

Step 3: Attach the device to the cable set and the cable set to the electrodes:

g) Attach the cables to corresponding electrodes (see electrode placement pictures in next chapter)

h) If necessary, the cables can be attached to the skin with tape. Notice that the tape should not touch the electrode.

Step 4. Start the measurement:

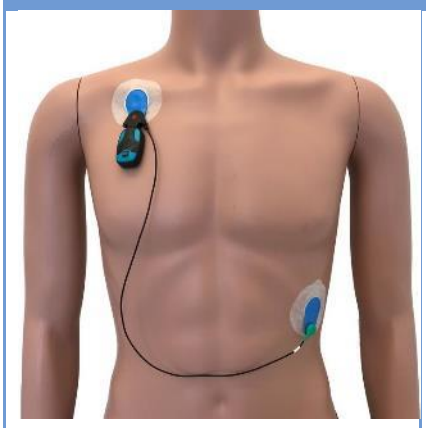
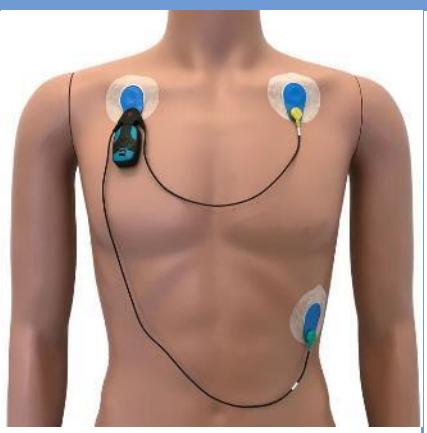
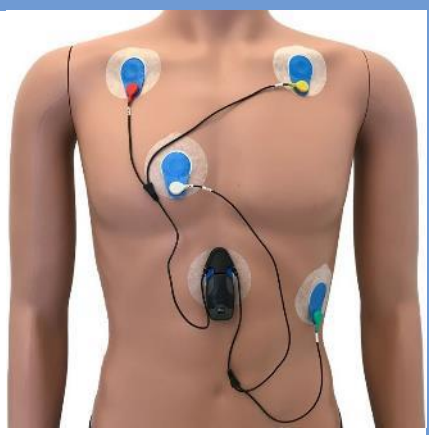
i) Press the Faros device pushbutton once.

j) Green light indicator starts to blink – the device is now recording.

7.2.1 Electrode positioning and lead placement

The operator should be familiar with the correct placement of electrodes. Incorrectly placed electrodes will weaken the reliability of the data. Cable sets are compatible with 4 mm snap connector ECG electrodes.

Table 11 Electrode and lead positioning

2-lead, 1-channel position	3-lead, 1-channel position	5-lead, 3-channel position
		

NOTE It is recommended to use disposable ECG electrodes which has stud connection and Ag/AgCl gel. Electrode must be also suitable for required recording period. For 24–72-hour Holter recordings suitable electrodes are for example Ambu VLC-00-S electrodes or similar. Always check instructions from electrode manufacturer for electrode use.

7.3 Stopping a recording

To end a recording press the pushbutton continuously for 5 seconds.

NOTE	Starting from firmware version 3.6.8 you must press the button for 8 seconds.

7.4 Accelerometer data

The data recorded by the accelerometer can be utilized by the operator to recognize the movement and non-movement periods from the measurement. The reading from the accelerometer is the acceleration induced by the sum of all forces acting on the device, including gravity, movement of the patient and movement caused by the environment, for example vibration of a car.

The total acceleration is represented by the accelerometer vector components (x, y and z). The direction of each acceleration component is represented by the sign of the vector and the amplitude is represented as the absolute value of the vector.

The strong environmental-based vibrations (for example driving a bumpy road) can reflect on accelerometer data when the subject does not move. The accelerometer output is raw data. Accelerometer data is not analyzed within the device or differentiated between various physical activities.

Figure 13 Accelerometer axis directions

8 DATA REVIEW WITH EDF VIEWER

8.1 Measurement data review

Faros EDF data recordings can be reviewed using eMotion EDF Viewer. For installation instructions, see chapter 5.

Open eMotion EDF Viewer from desktop icon or alternatively:

1. Connect your Faros device to computer using USB cable.
2. Browse to FAROS_DATA hard drive.
3. Open 'Software' folder.
4. Double click eMotion EDF Viewer folder and run 'eMotionEDFViewer'.

NOTE To acquire software reviewing cardiac events from measurement data please contact us: medical.support@bittium.com

NOTE It is recommended to install eMotion EDF Viewer to a computer before use. Software installation package is located in Faros device internal memory Software – eMotion EDF Viewer – Installer folder. Click 'Setup' icon and follow the installation instructions on screen.

NOTE It is recommended to move a large data file (<100 MB) to personal computer before reviewing the data. If you are opening large data files directly from Faros device, it will take several minutes to open.

8.1.1 Review

1. Click ‘Open EDF’ in main view (alternatively select ‘File’ and ‘Open’).
2. Select an EDF record file:
    a. Browse FAROS_DATA hard drive and open “DATA” folder.
    b. Folder names indicate the date of performed measurement(s).
    c. Browse file location from your personal computer.
3. Select the wanted folder and the .edf-file and click ‘Open’.

Selected data appears on eMotion EDF Viewer. Data can be reviewed using the scrollbar or arrow keys or page up/down buttons on the keyboard.

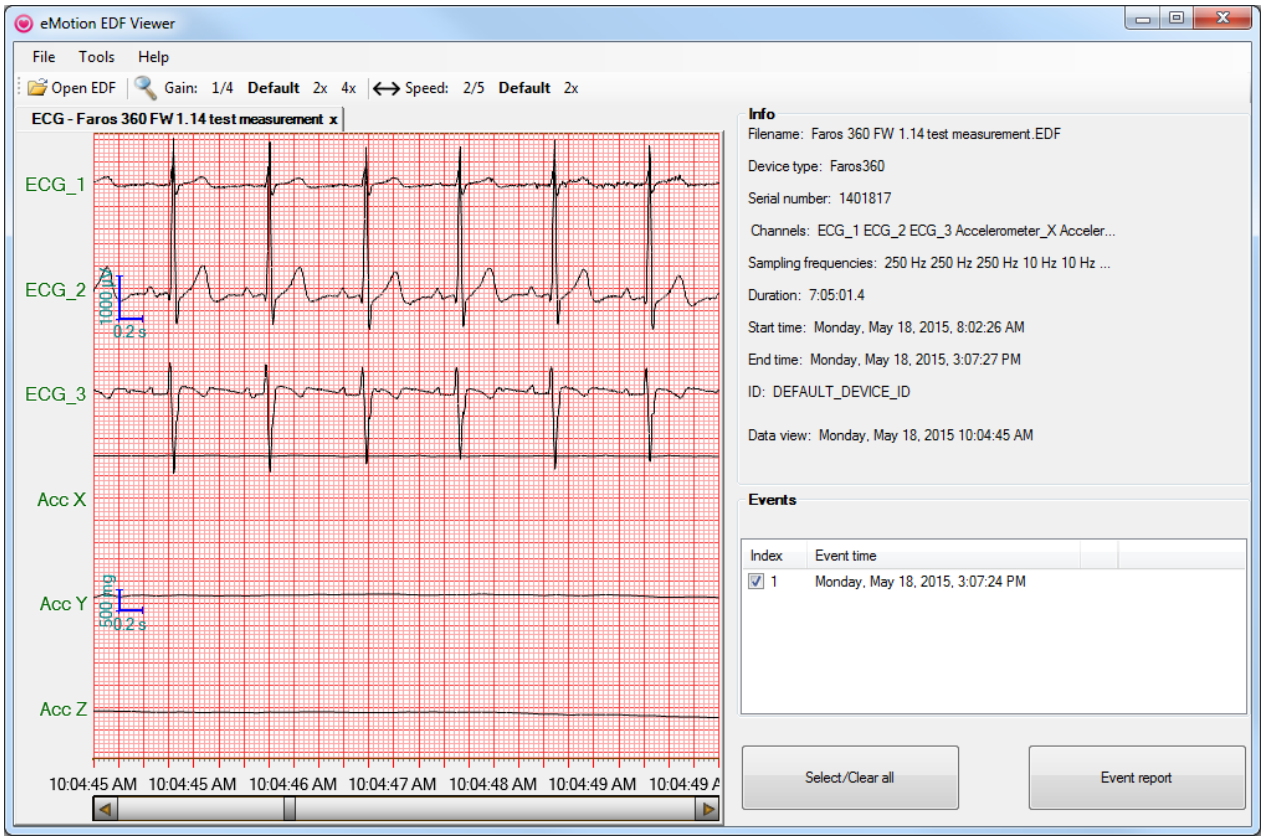


Figure 14 EDF Viewer data view

Table 12 EDF Viewer settings

Gain	mm/mV	Speed	mm/s
¼	5 mm/mV	**2/5**	10 mm/s
default	10 mm/mV	**Default**	25 mm/s
2x	20 mm/mV	**2x**	50 mm/s
4x	40 mm/mV		

8.1.2 Accelerometer data

The physical activity output is raw data from the Faros device's in-built accelerometer. The data recorded by the accelerometer is used to recognize movement (for example sports, walking or other physical activity) from the measurement.

The accelerometer data itself does not have an effect on the ECG measurement data. The difference between ECG data during high physical activity period (for example sports) and low physical activity period (for example lying down) can be seen in figures 15 and 16.

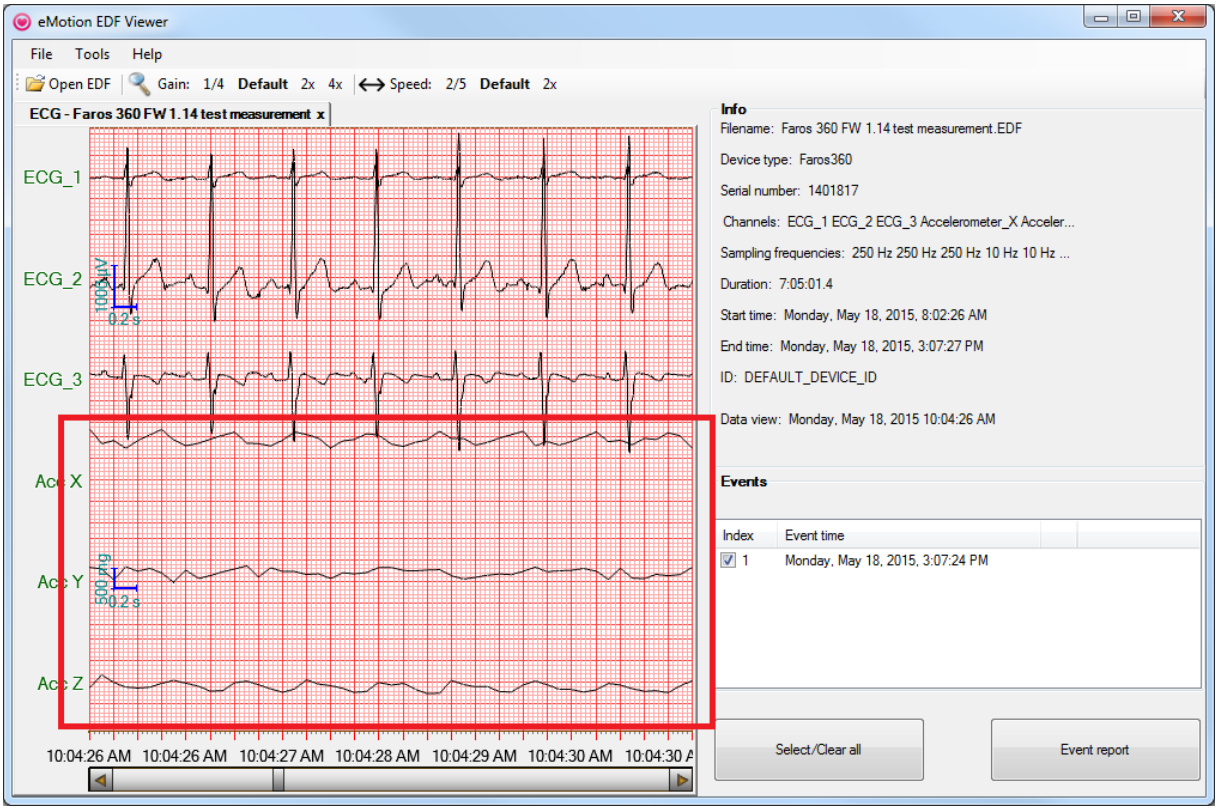


Figure 15 Accelerometer data with physical activity

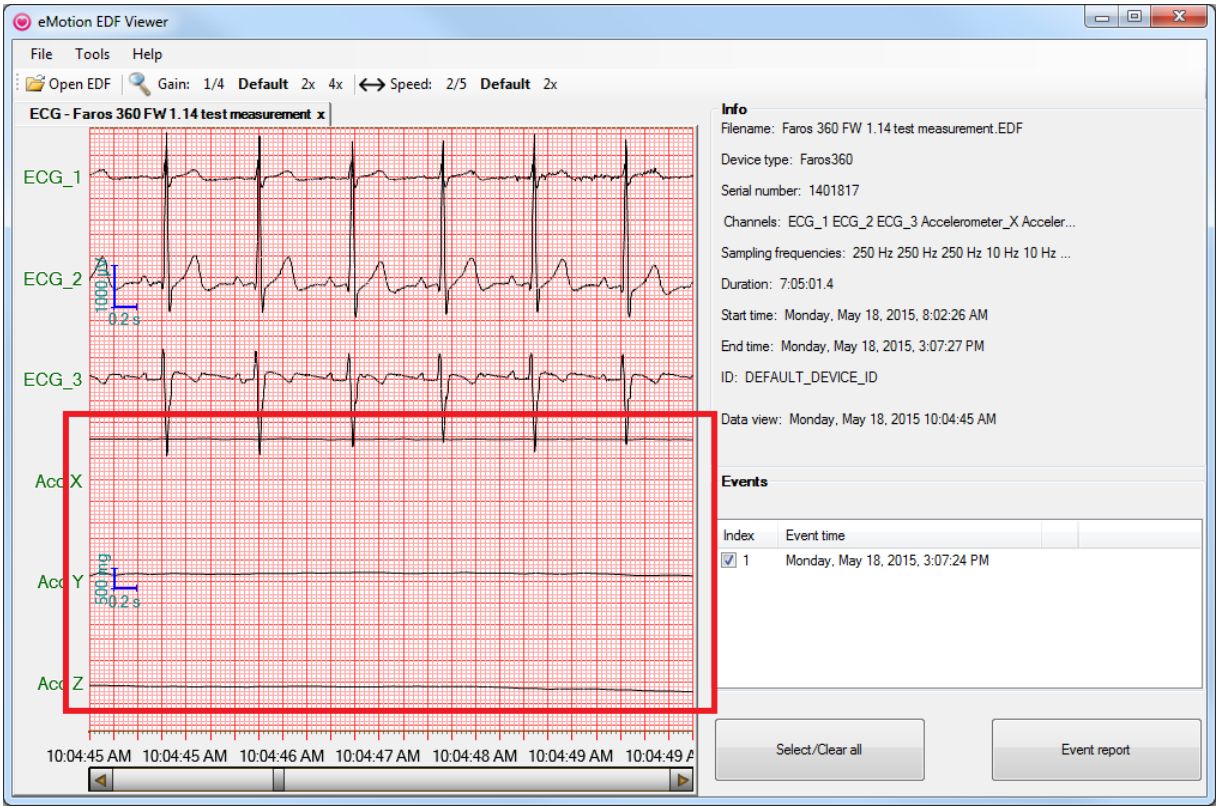
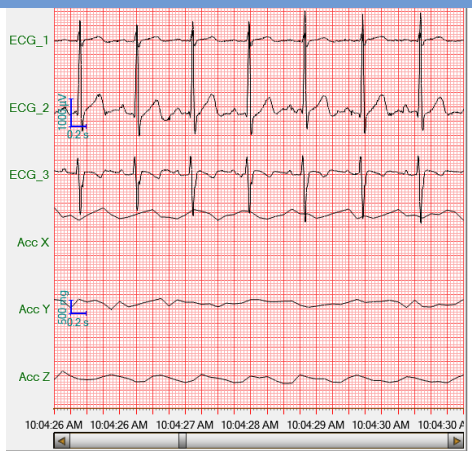
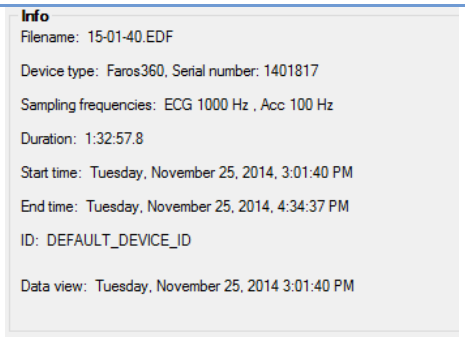


Figure 16 Accelerometer data without physical activity

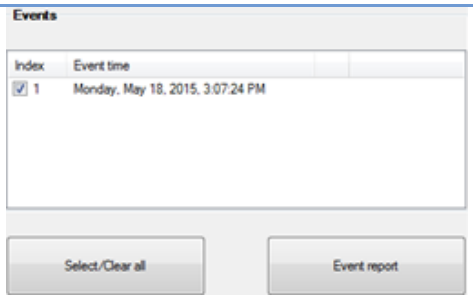
Table 13 User interface description

User interface parts	
Data window shows the measured ECG data. Info window contains Faros device configuration which was used in the measurement. Manually created events are listed in the Event window.	

<table>
<tr>
<td>Info window shows the configuration of the ECG data.
Filename: EDF filename.
Device type: Faros device type.
Serial number: Faros serial number.
Sampling frequencies: Sampling rates of EDF data channels.
Duration: Data length (hh:mm:ss.s).
Start time: Recording start date and time formatted.
End time: Recording end date and time formatted.
ID: ID tag set in Faros device.
Data view: EDF data view pointer, that is the date and time of current data in review window.</td>
<td> 
</td>
</tr>
<tr>
<td>Events window shows the manually created patient markers.

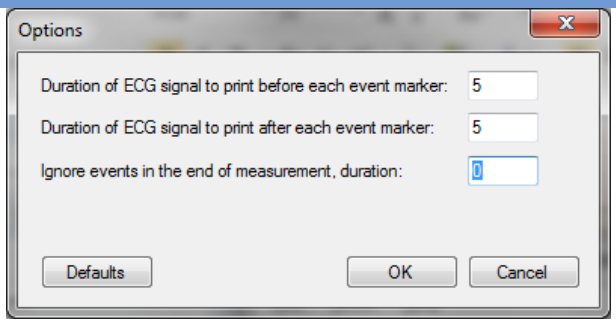
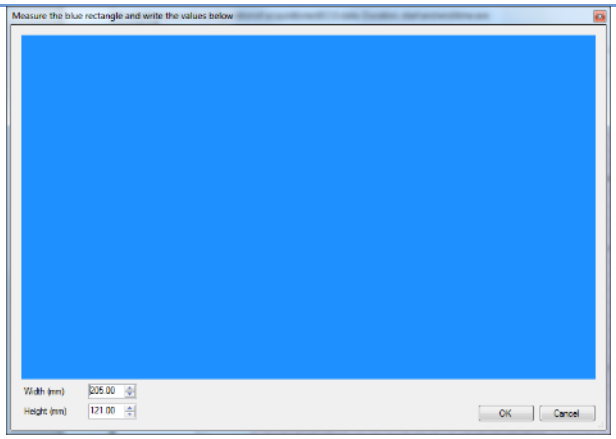
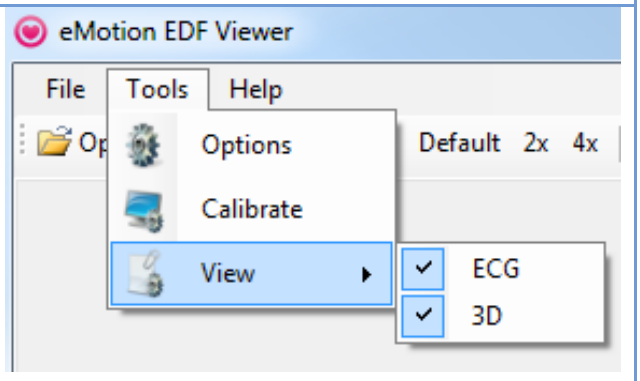
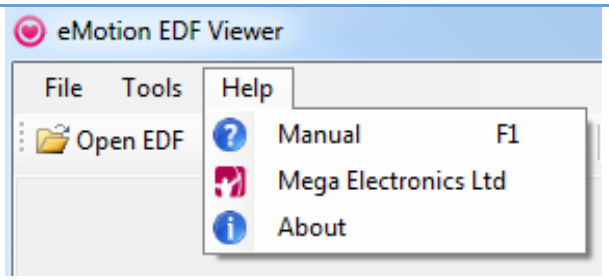
A reporting option is provided for desired events. Checked (with checkboxes) events will be included in the report.

‘Select/Clear all’ will toggle event selection between ‘None selected’ and ‘All selected’.

‘Event report’ will open a PDF report in a separate window with options to print or save.</td>
<td> 
</td>
</tr>
</table>

8.2 eMotion EDF Viewer menus

Table 14 EDF Viewer menus

Menu options	
Tools: Options Event Report layout and parameters can be managed from 'Tools' ⍰ 'Options' menu.	
Calibrate To calibrate 'Data window' mm-grid view select 'Calibrate' from 'Tools'. Measure the blue rectangle and write the values below. Click 'OK'.	
Tools: View Multiple signals (that is ECG and physical activity (3D) can be reviewed if they are recorded. Before opening the .edf-file click 'Tools' and 'View' to select presented signal types.	
Help Help menu contains software-related information, link to manufacturer webpage and the User Manual.	

9 MAINTENANCE AND SERVICE

Faros device does not require any maintenance procedures except recharging the battery. Please follow these simple precautions to ensure correct functioning:

- Handle this device carefully
- Store the device away from dusty or dirty areas
- Keep the device away from moisture or extreme temperatures
- If there is moisture in the device USB connector, let it dry for two hours before recharging
- Disconnect cable set from device when not in use
- Connect cable set only to Faros device
- Do not disassemble this device. If a problem occurs use pushbutton to reset the device.

Do not try to repair or modify the device. If you cannot solve a problem with the device, please contact medical.support@bittium.com for support.

9.1 Tools view in Bittium Faros Manager software

9.1.1 Save measurement files

Measurement files can be saved from the Tools view by selecting ‘Save measurement files’.

1. Select the file(s) you want to save. Multiple files can be saved at the same time.

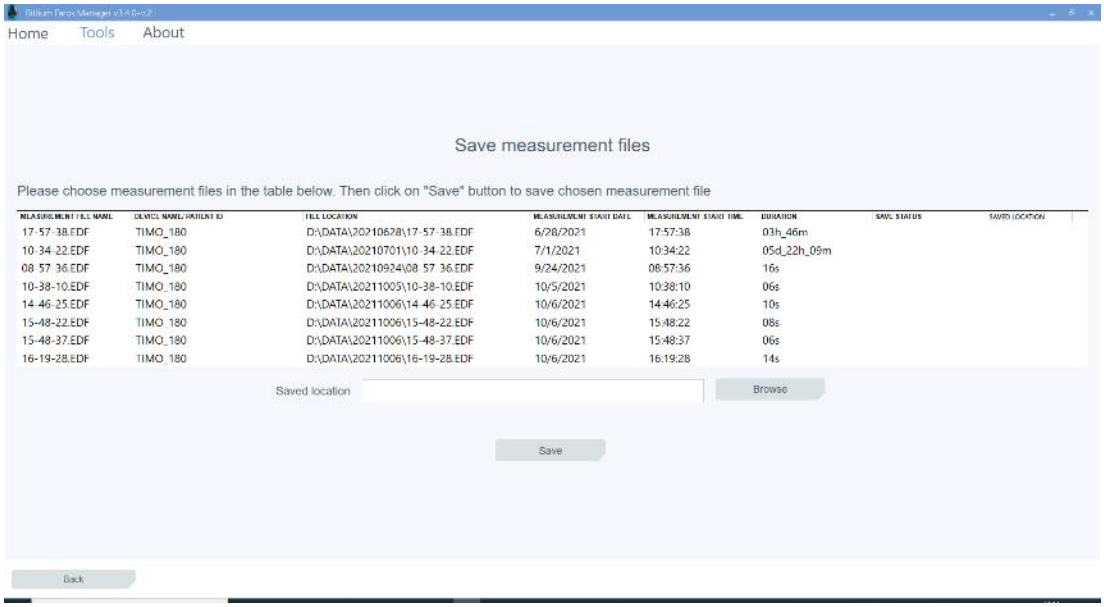


Figure 17 Save Measurement Files

2. Click ‘Save’ to save the files. Saved files will appear at the top of the view.

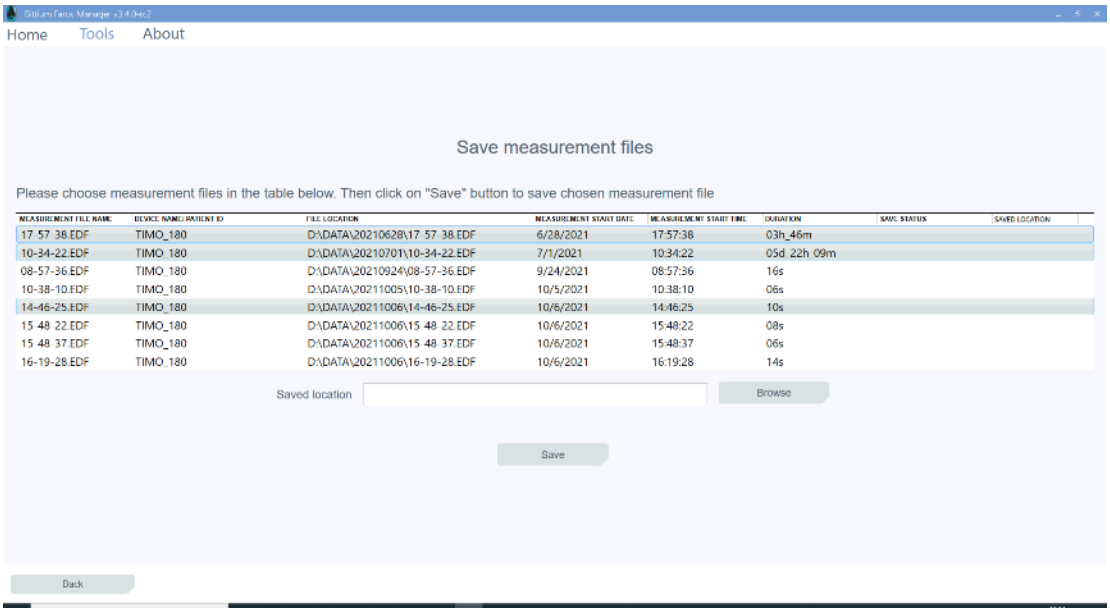


Figure 18 Measurement files are saved

After the files have been saved it is possible to delete them from Faros device:

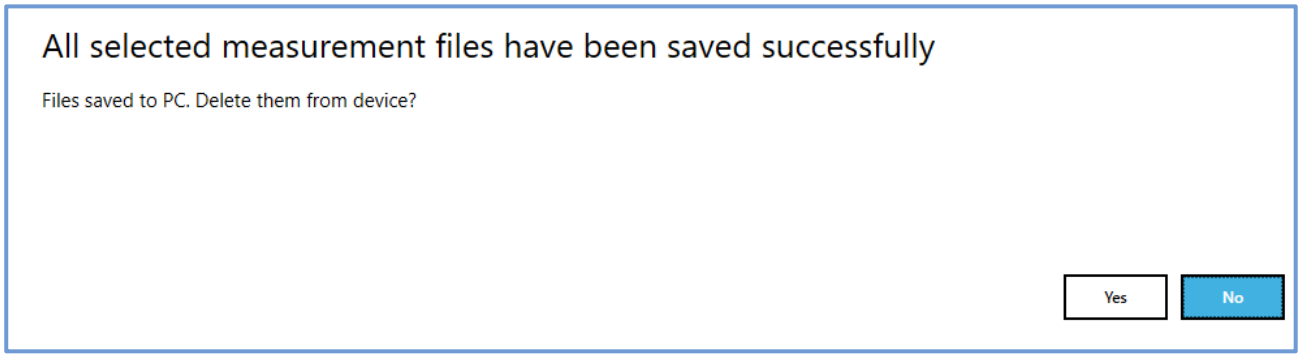


Figure 19 Delete measurement files confirmation dialog

9.1.2 Device firmware update

Automatic update

Faros device firmware update is performed automatically if software detects that a newer firmware is available for the device.

NOTE Latest firmware for Bittium Faros devices is also available for downloads via Bittium web-site: https://www.bittium.com/medical/support

Follow these steps:

1. Click 'Tools' at the top of the main view.
2. Select 'Update firmware'.

Figure 20 Tools view

3. Select the location where the firmware file is with the 'Browse' button. Click the arrow icon if you want to cancel the operation. Note that you must disconnect the Faros device first before clicking this.

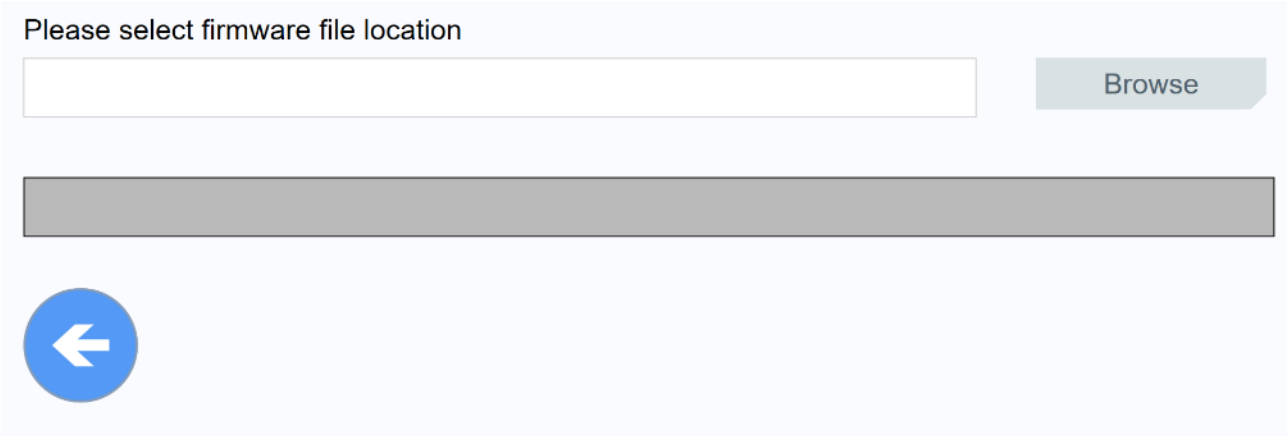


Figure 21 Manual firmware update

4. Select the file. Firmware update will start.

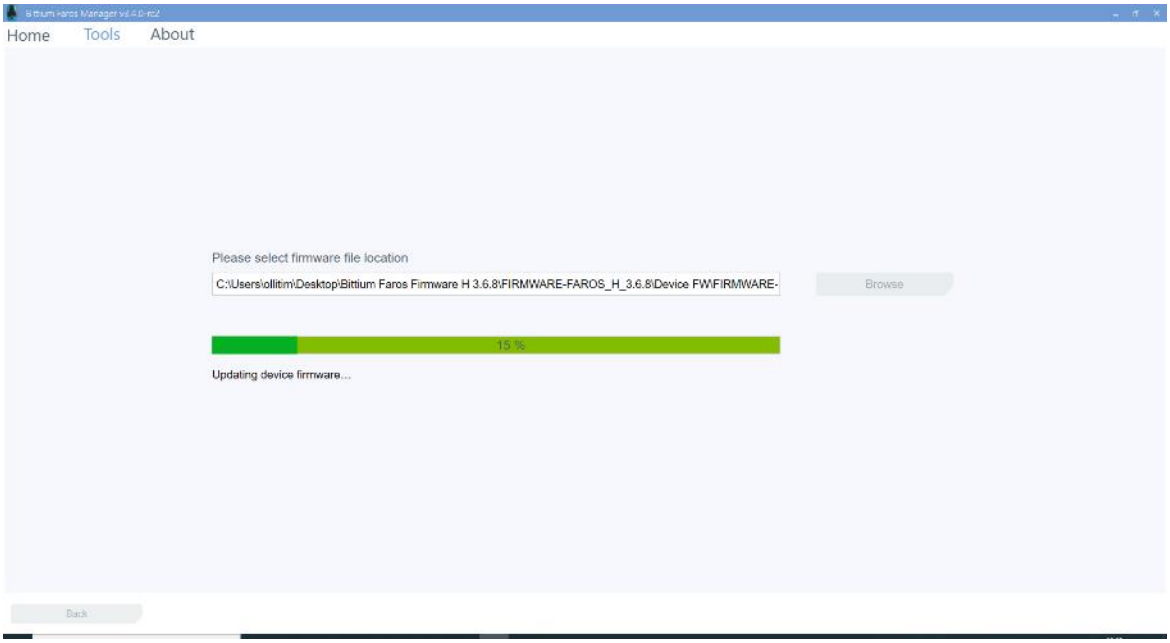


Figure 22 Firmware update ongoing

In case Faros device is not recognized at all after the update it must be reset.

1. Close the Faros Manager and open it again.
2. Press and hold the Pushbutton on the Faros device for 10-12 seconds.
3. Faros Manager will search for the device and open the update view again.

Attentions with firmware update process

- During this process, please note that you MUST NOT disconnect the updating device with PC as it will fail the update process.
- Also, the procedure may not run successfully the first time and it will automatically try to run two times more. This happens when you see the green progress bar run to 50 %, then drop to 0 % and run again. Please keep the device connected to the PC and let the software run normally. If there is an error with the process, it will show at the end of the process.
- After update firmware recovery, there is a possibility that the device name before the update will be lost.

9.1.3 Convert EDF file to Suunto SDF or ASCII file format

Faros device stops supporting measurement in SDF/ASC format from firmware version 3.2.x onwards. Instead, Faros Manager provides users with a new tool called “Convert EDF to SDF/ASC” which helps in choosing and converting an EDF file to SDF file format (HRV signal) and ASC (ASCII format for accelerometer

data). For more information about SDF and ASC file specifications, please refer to this document: 800608 eMotion LAB User Manual.

1. Select ‘Tools’ in the main view and then ‘Convert EDF file to SDF/ASC file’.
2. Select the EDF file to convert by clicking ‘Browse EDF file’.
3. Click ‘Open’ to convert the file. File conversion starts.

If you want to view the save location of the converted file, click ‘Open Output Folder’.

NOTE	Files including just raw ECG data (no R-R, no ACC) cannot be converted to SDF/ASC.

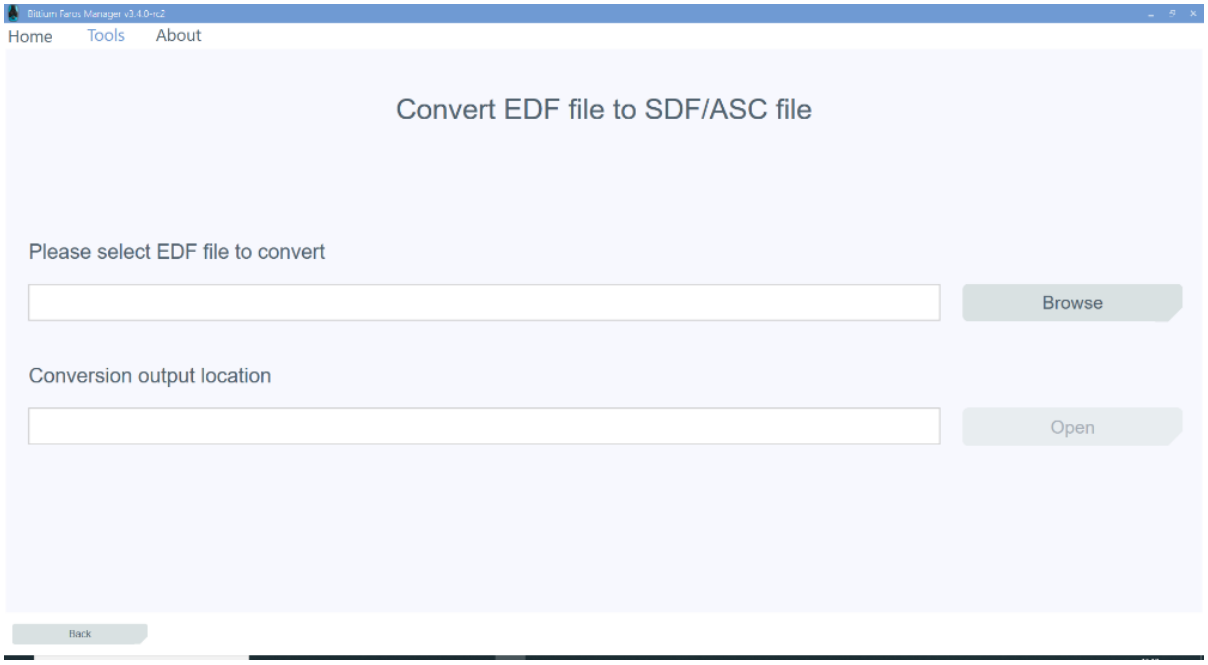


Figure 23 Convert EDF file

9.1.4 Support Request

If you encounter any issues or you would like to give us some feedback, you can easily send a support request to us by using “Support Request” tool in “About”.

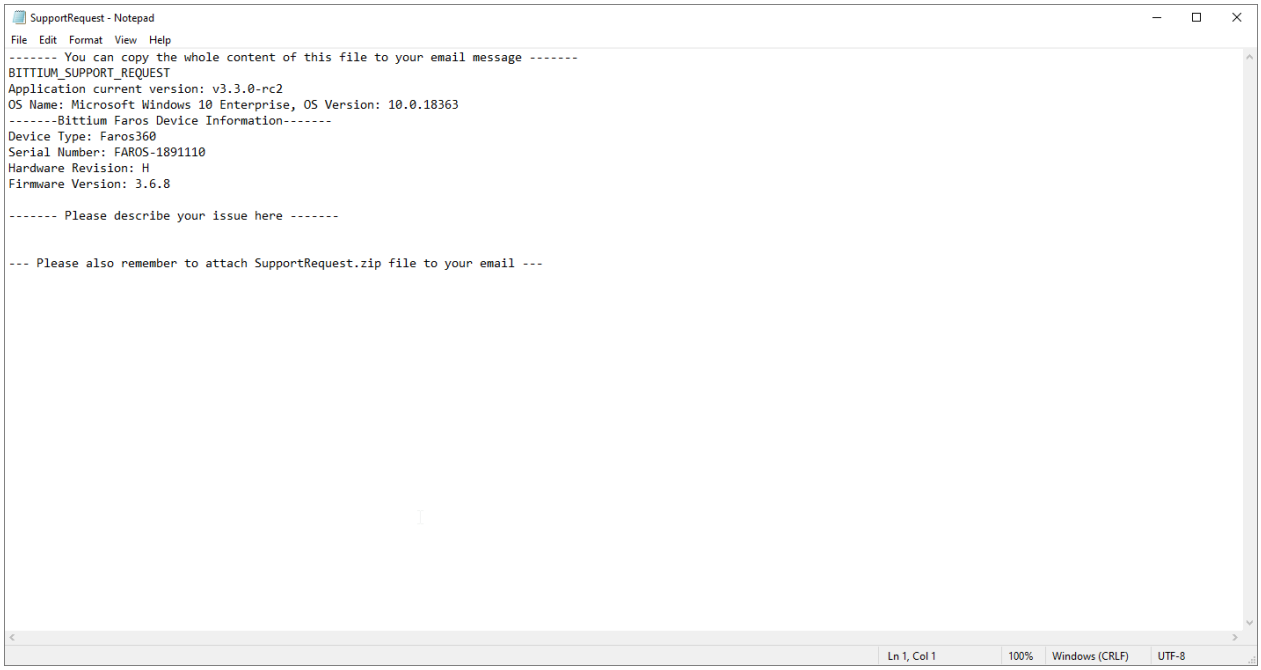


Figure 24 Support Request view

This will create a SupportRequest Note pad file in which you can enter details of your issue and which you can then copy/paste as your e-mail message content. Also, a File Explorer location will be opened with a SupportRequest zip file which automatically contains the relevant data from the software at the time the request was made. By default, the location of this file is:

C:\Users\yourusername\AppData\Roaming\Bittium Biosignals Ltd\Bittium Faros Manager\Support

Remember to add the SupportRequest zip file to your request and send the e-mail to medical.support@bittium.com

9.2 Cleaning

9.2.1 Faros device, Bittium Safeport and cable sets

The Faros device, Safeport and cable sets can be cleaned by wiping the device using a non-fluffing cloth dampened with cleaning fluid such as mild hand soap solution, or water. A non-fluffing cloth dampened with non-alcoholic disinfection fluid can be used for disinfection. Recommended way of cleaning: non-alcoholic cleaning and disinfection wipes for medical devices, for example mikrozid® sensitive wipes.

NOTE Do not use cleaning fluid which includes ethers, ketones or partially halogenated or aromatic hydrocarbons! Make sure that USB connectors are dry before use!

NOTE Be careful not to rub too forcefully. Do not use alcohol-based fluids or corrosive chemicals! Do not sink any cables in water! Do not rinse any cables or measurement devices with cleaning fluid!

9.2.2 OmegaSnap adapter

OmegaSnap adapter can be cleaned by wiping it using a non-fluffing cloth dampened with cleaning fluid such as mild hand soap solution, or water. A non-fluffing cloth dampened with non-alcoholic disinfection fluid can be used for disinfection. Recommended way of cleaning: non-alcoholic cleaning and disinfection wipes for medical devices, for example mikrozid® sensitive wipes.

NOTE Do not use cleaning fluid which includes ethers, ketones or partially halogenated or aromatic hydrocarbons! Make sure that the USB connector is dry before use!

NOTE Be careful not to rub too forcefully. Do not use alcohol-based fluids or corrosive chemicals! Do not rinse measurement devices with cleaning fluid!

9.3 Device battery replacement

Faros device battery is an in-built part of the device and can be changed only by Bittium Biosignals Ltd. Battery lifetime depends on device usage modes and recharging cycles. It is recommended to replace the battery after 300 cycles and in normal use scenarios this is in about 2,5 – 3 years.

When battery replacement is needed, please contact your local distributor or Bittium Biosignals Ltd.

10 FREQUENTLY ASKED QUESTIONS (FAQ)

What can I do if I am experiencing difficulties with my Faros device?

Start by going through the user manual and the Frequently Asked Questions listed below to see if these provide a solution to your question. If you cannot find the solution from the user manual, please contact us through our service portal:

1) Go to: https://dojo.bittium.com/medical
2) Create an account for logging into the portal
3) Send your support request to Bittium through the portal

Alternatively sent your support request via email to: medical.support@bittium.com

How can I review recorded cardiac events?

Cardiac events recorded by Faros can be reviewed with software which needs to be purchased separately. To get quotation and more information, please contact us at medical.support@bittium.com

How do I know that the battery of the device is fully charged?

When the battery is fully charged, the blue LED lights stays on continuously when the device is connected to a computer with micro-USB cable. Please remember to fully charge your Faros devices before the first use.

In my last measurement the time and date of the measurement were totally wrong. Why is that? How can I fix this problem?

When the device is delivered, the device clock is synchronized to the Finnish time (UTC +2, EET). This is why the clock needs to be synchronized before the first use. Also, if the battery of the device has run out, the clock of the device may change. This is why we recommend to synchronize the clock of the device every time you connect the device with your PC (either when recharging or when downloading data from the device).

Do I need software for downloading measurement data from the device?

No, there is no need for software in this case. Once you connect the device to PC via USB, you can browse to the hard drive of the device (named “FAROS_DATA”) and copy/cut and paste the needed files to your computer. If you wish, you can also open the measurement files directly with software from the device’s memory. Alternatively, you can use Faros Manager to save measurement files.

How can I reset my Faros device?

Start pressing the push button. Press and hold the button until all the LED lights blink once (approximately 10 seconds).

How can I change the measurement modes of the device?

Go to the device hard drive Faros Data. From this hard drive you can find the FarosManager.exe with which you can change the measurement settings. See chapter 6 for further information on how to use Faros Manager.

Which data format should I choose for my measurement, SDF (Suunto Data Format) or EDF (European Data Format)?

If you wish to measure ECG or make event markers to the measurement data, you always need to use EDF as saved data format. If you are interested in measuring only R-R intervals and physical activity, you can choose between EDF and SDF. If you wish to save the RR and acceleration data to a text file format, then SDF is more appropriate. Both data formats are rather global, which is why there are a variety of software that can open these files. Note that SDF is not supported from Faros 3.2.x onwards.

Firmware update is not working properly, or device is not responsive after failed firmware update?

If firmware update process is finished ok but firmware is not upgraded, try again using another USB port on your computer. Please follow instructions in chapter 9.1.2.

What might be the reason for bad quality measurement data?

If you are using disposable electrodes, the first thing to do is to check whether the electrodes are dry or not. The quality of the recorded data will suffer with dry electrodes. Once you open the bag of electrodes remember to close it tightly and firmly to avoid drying the electrodes.

If you are using a heart rate belt, you should moisten its electrode surface with water before putting on the belt to ensure better contact and signal quality.

If the two reasons presented above have not caused the problem, you can try to reset the device. If resetting the device does not help, please contact medical.support@bittium.com for assistance.

What is the suitable sampling frequency when measuring ECG?

This depends significantly on the purpose of use for the device. For most measurements and analysis, 250Hz or 125Hz is a suitable sampling frequency. If more accurate ECG data is needed for making ECG or HRV analysis and diagnosis it is recommended to use sampling rate that is 500Hz or higher.

My Faros device does not start, what might cause this problem?

It is important to remember that Faros device uses the energy of the battery also when it is on standby mode (“power off” mode). For example, the device’s inner clock uses the battery also when it is turned off to keep the time. This is why we recommend to recharge the device before every measurement, or at least when the device has been on standby mode for several days.

Why does Windows show a message indicating that device disk has errors, and it should be scanned?

Disk error may occur when the device is not disconnected safely from computer. Please follow instructions in section 4.5.2.

How long is the Faros device lifetime?

Device lifetime depends on device use. Estimated device lifetime is 5 years. For cable sets recommendation is to change to new ones if there is any damage on cables or on connectors.

11 REGULATORY INFORMATION

11.1 Classification EU

In accordance with MDD 93/42/EEC: Class IIa medical device

EN60601-1: Internally powered equipment

11.1.1 Declaration of Conformity

We herewith declare under our sole responsibility that the product listed below is in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 (and the Finnish national laws 1505/94 and 1506/94) concerning medical devices. When used with external evaluation software this declaration of conformity is valid for the Faros hardware.

Trade Name: Faros Product Family

Model(s): Faros 180

Faros 360

MDD Classification: Class IIa

Following standards were used to meet requirements:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2: 2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-2-47:2012, Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 60601-1-11:2015+AMD1:2020, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62366-1:2015+AMD1:2020, Medical devices -- Application of usability engineering to medical devices.
- IEC 62304:2006, Medical device software -- Software lifecycle processes.
- According to the manufacturer of the Bluetooth modules: The Bluetooth modules meet the requirements of the EMC Directive 89/336/EEC as amended by Directives 92/31/EEC and 93/68/EEC within CE marking requirement.

11.2 Intended Use

Faros device is an ambulatory recorder and transmitter for ECG and motion (accelerometer) data. Faros can perform ECG measurement, R-R interval data measurement and capture patient motion. All data is recorded to device internal memory.

Faros device monitors patient ECG and generates event markers using the in-built arrhythmia detection algorithms. Data recorded by the device can be analyzed by other processing systems to provide reports or transferred via Bluetooth to companion systems for further analysis. These systems can be either third party systems or designed, maintained and/or owned by Bittium.

Faros device is intended for adult and pediatric patients who require vital sign monitoring inside or outside hospital or healthcare facility environment.

Faros device does not provide interpretive statements. Final interpretation and diagnosis is the responsibility of a physician.

Appendix 1. Electromagnetic emission

Manufacturer's Declaration - Electromagnetic Emissions		
Faros device is suitable for use in an electromagnetic environment as described below. The users should ensure that the device is used in such an environment.		
Emission Tests	Compliance	Electromagnetic Environment
RF emissions CISPR11	Group 1	Faros device uses RF energy exclusively for its internal function. Thus, the RF emission is very low, and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

Appendix 2. Immunity test levels

Phenomenon	Basic EMC standard or test method	Immunity test levels	
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Appendix 2	
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Conducted disturbances induced by RF fields	EC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	Not applicable	
Voltage interruptions	IEC 61000-4-11	Not applicable	
Surges Line-to-line	IEC 61000-4-5	Not applicable	
Surges Line-to-ground	IEC 61000-4-5	Not applicable	
Electrical fast transients / bursts	IEC 61000-4-4	Not applicable	

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

Appendix 3. Bittium OmegaSnap electrodes supplementary information

Do not operate Bittium OmegaSnap™ electrodes without first reviewing the following notices.

General Warnings, Cautions and safety precautions

WARNING: Do not disassemble, try to repair, or modify the electrode.

WARNING: Choking hazard! Keep away from small children and pets.

CAUTION: OmegaSnap adapter IP classification is 67 when connected to Faros device. IP67 level protection means that the device is built to be protected from dust and can be submerged in 1 meter of water for 30 minutes. Both the Faros device and the OmegaSnap adapter can be used in shower when connected to each other.

CAUTION: Operating environments: Professional healthcare facility environment and Home healthcare environment.

CAUTION: Handle the OmegaSnap™ electrode carefully.

CAUTION: OmegaSnap electrode is not suitable for use in MRI environment.

CAUTION: OmegaSnap electrode is not intended to be used at the same time with high frequency (HF) surgical equipment or with defibrillator.

CAUTION: Patients, who have active implantable medical device (like heart pacemaker etc.) should consult supervising physician or doctor before use.

CAUTION: Use of non-authorized accessories may break the OmegaSnap electrode.

CAUTION: Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.

CAUTION: 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 device, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result.

NOTE Leakage currents on patient connections are limited under acceptable levels if there are short circuit in the OmegaSnap electrode input/output parts.

NOTE EMC disturbances might cause interference and/or noise to measurement data.

NOTE OmegaSnap electrode is not reusable. Electrode performance degradation or contamination may occur with a used OmegaSnap electrode.

NOTE Always follow instructions for disposable electrodes which are used for recordings.

NOTE Any incident (serious or non-serious) that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Symbols

Symbol	Description
	The electrode is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.
	Manufacturing date.

	Manufacturer.
	Use by date.
	Electrodes are disposable.
	Consult Instructions for use.
	Lot number.
	Medical device.

Contraindications

OmegaSnap electrode is not intended for neonatal patients or children weighing less than 10 kilograms. OmegaSnap electrode is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Adverse events

OmegaSnap electrode might irritate skin but there are no other known adverse events due to the use of OmegaSnap electrode. Please, report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the country in which the user and/or patient is established.

Intended use

Omega ECG electrode is an electrocardiograph (ECG) electrode which is applied to the surface of the human body to transmit the ECG signal at the body surface to an ambulatory ECG device. Bittium OmegaSnap electrode is intended for use with Bittium Faros device.

Classification EU

In accordance with MDR 2017/745: Class I medical device

User responsibility

This product shall be assembled, operated, maintained, and repaired in accordance with the instructions provided.

A defective product should not be used. Parts that are broken, worn, missing, incomplete, distorted, or contaminated should be replaced immediately. Should any repair or replacement become necessary, we recommend that the device is delivered to your local distributor or Bittium Biosignals Ltd for service.

The user of the product is solely responsible for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Bittium Biosignals Ltd or their authorized service personnel.

Environmental conditions

Transport and storage conditions

OmegaSnap electrode must be transported and stored in conditions listed below.

- -20 °C to + 60 °C (transport)
- - 20 °C to + 60 °C at a relative humidity up to 90 %, non-condensing (storage)
    - 1 month storage: -20 °C to +60 °C
    - 3 months storage: -20 °C to +45 °C
    - 12 months storage: -20 °C to +25 °C
- Occasional storage and transport: -40°C to+70°C

Continuous operating conditions

OmegaSnap electrode must be used in conditions listed below:

- A temperature range of + 0 °C to + 45 °C
- A relative humidity range of 15 % to 90 %, non-condensing
- An atmospheric pressure range of 700 hPa to 1 060 hPa.

Technical specifications and performance

Table 15 OmegaSnap 1-CH ECG Electrode specifications

Technical specification	Value
Dimensions	170 x 54 mm, without liner
Wear time	7 days
IP classification	IP67 (Faros device with OmegaSnap 1-CH Adapter)
Skin contact type	Non-invasive
Sterility	Non-sterile
Skin contact duration	7 days
Purpose	Ambulatory ECG
Single use	Yes
Recording standard	Holter
Recording type	Continuous

Table 16 OmegaSnap 2-CH ECG Electrode specifications

Technical specification	Value
Dimensions	183,1 x 130,2 mm, without liner
Wear time	7 days
IP classification	IP67 (Faros device with OmegaSnap Multi-CH Adapter)
Skin contact type	Non-invasive
Sterility	Non-sterile
Skin contact duration	7 days

Purpose	Ambulatory ECG
Single use	Yes
Recording standard	Holter
Recording type	Continuous

Table 17 OmegaSnap 3-CH ECG Electrode specifications

Technical specification	Value
Dimensions	265,4 x 227,5 mm, without liner
Wear time	7 days
IP classification	IP67 (Faros device with OmegaSnap Multi-CH Adapter)
Skin contact type	Non-invasive
Sterility	Non-sterile
Skin contact duration	7 days
Purpose	Ambulatory ECG
Single use	Yes
Recording standard	Holter
Recording type	Continuous

Table 18 MiniSnap 1-CH ECG Electrode specifications

Technical specification	Value
Dimensions	115 x 38 mm, without liner
Wear time	24 hours
IP classification	IP67 (Faros device with OmegaSnap 1-CH Adapter)

Skin contact type	Non-invasive
Sterility	Non-sterile
Skin contact duration	24 hours
Purpose	Ambulatory ECG
Single use	Yes
Recording standard	Holter
Recording type	Continuous

Appendix 4. Bittium Faros 180L supplementary information

General Warnings, Cautions and safety precautions

Do not operate Bittium Faros 180 L™ device without first reviewing the following notices.

WARNING: Do not disassemble, try to repair, or modify device.

WARNING: Bittium Faros 180L is not suitable for direct cardiac application.

WARNING: Do not touch parts of the computer, docking station or any non-medical electrical equipment and the patient at the same time when operating the Bittium Faros 180L device.

WARNING: To avoid danger of electrical shock and electromagnetic disturbances the computer and associated equipment used with the Faros ECG Sensor should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfils the requirements.

WARNING: Do not attempt self-diagnosis or self-treatment based on acquired data.

CAUTION: Bittium Faros 180L device IP classification is IP67.

CAUTION: Operating environments: Professional healthcare facility environment and Home healthcare environment.

CAUTION: Bittium Faros 180L does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation.

CAUTION: If a patient has been given defibrillation, while Faros ECG device and applied part are connected to the patient, Faros device and applied part must be sent to manufacturer for checking before continuing device use.

CAUTION: Bittium Faros 180L device is not suitable to use in MRI environment.

CAUTION: Bittium Faros 180L device is not intended to be used at the same time with high frequency (HF) surgical equipment or with defibrillator.

CAUTION: Patients, who have active implantable medical device (like heart pacemaker etc.) should consult supervising physician or doctor before use.

CAUTION: 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 device, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result.

CAUTION: Use Faros ECG device with accessories provided by Bittium Biosignals Ltd. Other cables and accessories may negatively affect device performance.

NOTE EMC disturbances might cause interference and/or noise to measurement data.

NOTE	Any incident (serious or non-serious) that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

NOTE	Bittium Faros 180 L does not have any electrical stimulation capabilities.

NOTE	Accelerometer data is not analyzed within the device or differentiated between various physical activities.

NOTE	Bittium Faros 180L device should be kept closer than 10 meters to the Bluetooth companion device for wireless communication.

NOTE	Faros ECG sensor housing materials are tested and comply with ISO 10993 biocompatibility requirements. **Stop using the device if housing or cable set causes adverse reactions such as blisters and burning.**

NOTE	Bittium recommends using CE marked AMBU disposable ECG electrodes with Faros sensor when measurement is performed using cable sets. Operator shall consult patient's allergies prior to electrode selection. ECG electrodes might cause mild skin irritation, red dots or rash. **Stop using the device and remove ECG electrode from skin if electrode causes adverse reactions such as blisters and burning**.

NOTE	Even though materials used in Faros ECG sensor and cables and ECG electrodes are biocompatible it might cause mild skin irritation or rash. Check for secure absence of skin reaction on a daily basis.

Declaration of Conformity

We herewith declare under our sole responsibility that the product listed below is in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 (and the Finnish national laws 1505/94 and 1506/94) concerning medical devices. When used with external evaluation software this declaration of conformity is valid for the Faros hardware.

Trade Name: Faros Product Family

Model(s): Faros 180L

MDD Classification: Class IIa

Following standards were used to meet requirements:

- IEC 60601-1:2005+AMD1:2012, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: 2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-47:2012, Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 60601-1-11:2015, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015, Medical devices -- Application of usability engineering to medical devices
- IEC 62304:2006, Medical device software -- Software life cycle processes
- According to the manufacturer of the Bluetooth modules: The Bluetooth modules meet the requirements of the EMC Directive 89/336/EEC as amended by Directives 92/31/EEC and 93/68/EEC within CE marking requirement.

MANUFACTURER

Bittium Faros 180, Faros 180L and Faros 360 comply with the requirements of the Medical Device Directive 93/42/EEC and carry the CE 0537 mark accordingly. Bittium OmegaSnap comply with requirements of the Medical Device Regulation 2017/745 and carry the CE mark accordingly.

Manufactured for:

Bittium Biosignals Ltd.

Pioneerinkatu 6

70800 Kuopio

Finland

Tel.: +358 40 344 2000

Email: bbs@bittium.com

Web: https://www.bittium.com

MDD marketing authorization holder in Europe:

Bittium Biosignals Ltd.

Pioneerinkatu 6

70800 Kuopio

Finland

Tel.: +358 40 344 2000

Email: bbs@bittium.com

Web: https://www.bittium.com

WEBSITE

You can find up-to-date product information, documents, and updates by visiting the Bittium website at www.bittium.com

SALES

Please contact your sales representative for any questions that you may have about Bittium products.

Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland

Tel.: +358 40 344 2000
Email: bbs@bittium.com
Web: https://www.bittium.com

SERVICE DESK

If you encounter any issues with Bittium medical products, please contact our technical support at

medical.support@bittium.com