

Bittium

Bittium Faros Manual



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1 INTRODUCTION

The Faros Sensor 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 sensor 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 Explorer software* or *Cardiac Navigator Holter* analysis software, both available from Bittium. We also offer a Bluetooth API for third party connectivity and data extraction.

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

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

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

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

1.1 Contraindications

- Faros is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

1.2 General safety precautions

- Use ECG sampling rate of 500Hz with pediatric patients weighting less than 10 kg.
- Faros Sensor IP Classification code is 67.
- Do not disassemble, try to repair, or modify sensor.
- Sensor does not have any electrical stimulation capabilities.
- Faros does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation.
- Accelerometer data is not analyzed within the device or differentiated between various physical activities.
- Operating environments: Professional healthcare facility environment and Home healthcare environment.
- If a patient has been given defibrillation, while Faros ECG sensor and applied part are connected to the patient, Faros sensor and applied part must be sent to manufacturer for checking before continuing device use.
- Always follow instructions for disposable electrodes which are used for recordings
-








1.3 Warnings








- Sensor is not suitable for direct cardiac application.
- Do not attempt self-diagnosis or self-treatment based on acquired data.
- Not suitable for use in MRI environment.
- The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.
- Patients who have active implantable medical device (like heart pacemaker and so on), should consult supervising physician or doctor before use.
- 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 Sensor.
- 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.
- EMC disturbances might cause interference and/or noise to data acquisition
- Use Faros ECG sensor with accessories provided by Bittium Biosignals Ltd. Other cables and accessories may negatively affect sensor performance.
- 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 Faros sensor, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result.

1.4 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.

1.5 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
	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.

Symbol	Description
IP67	IP classification for device. Faros device is waterproof while recording is made with cable set fixed to device or with Fast-fix electrode fixed to device.
	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 GTIN and PI for Faros ECG sensor

1.6 Environmental conditions

1.6.1 Transport and storage conditions

Faros shall be transported and storage 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 month storage: -20 °C to +45 °C
 - 12 month storage: -20 °C to +25 °C
- Occasional storage and transport: -40°C to +70°C

1.6.2 Continuous operating conditions

Faros shall 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.

1.7 Bluetooth Protocol

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

3rd party interoperability requirements

Bluetooth 2.1

2 FAROS ECG SENSOR OVERVIEW

2.1 General information

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

Bittium Faros 180™



901158

Bittium Faros 360™



901159

Technical specification	Bittium Faros 180™	Bittium Faros 360™
ECG holter	Yes	Yes
ECG wireless transfer	Yes	Yes
Waterproof IP67 design	Yes	Yes
1-channel ECG	Yes	Yes
3-channel ECG	No	Yes
RR intervals	Yes	Yes
Bluetooth	Yes	Yes
Accelerometer	Yes	Yes
RR sampling frequency	1000 Hz	1000 Hz
ECG sampling frequency	125, 250, 500, 1000 Hz	125, 250, 500, 1000 Hz
ADC precision	24 bits	24 bits
3D accelerometer precision	14 bits	14 bits
3D accelerometer sampling frequency	25, 100 Hz	25, 100 Hz
Datalogger file format	EDF	EDF

Memory capacity	4 GB	4 GB
Power source*	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
Operating time	Up to 7 days ECG 125 Hz	Up to 7 days ECG 125 Hz

*Faros power source Li-ion battery complies with IEC 62133.













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2.2 Sensor symbols and indicators

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



Figure 1 Symbols and indications

Description	Indications
Sensor 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 medium   beep-sound indications every five seconds
Sensor is in Bluetooth idle state.	Green* indicator blinks every two seconds.
Firmware update.	Green indicator blinks during update.
Sensor reset.	All indicators blink once and one long  beep-sound indication.
Sensor has halted at internal error handling checkpoint.	All indicators blink.

*Green heart indicator changes color from green to blue in the following cases:

- 1) Measurement is running and Bluetooth is connected.
- 2) Sensor is in Bluetooth idle state and Bluetooth is connected.

2.3 Accessories and replacement parts

2-electrodes cable set - 901021	 A black cable with two black electrodes at the end, coiled.
3-electrodes cable set - 901022	 A black cable with three electrodes (two yellow, one green) at the end, coiled.
5-electrodes cable set - 901023	 A black cable with five electrodes (two yellow, two green, one red) at the end, coiled.
Fast-Fix ECG Electrode - 901155	 A white, oval-shaped electrode with a black Bittium logo and a black connector.
USB Cable - 900826	 A black USB cable with a standard USB-A connector on one end and a Bittium connector on the other.

2.4 Recharging the battery

It is recommended to recharge the battery to full capacity before conducting operations or performing data acquisition with the device.

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

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

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

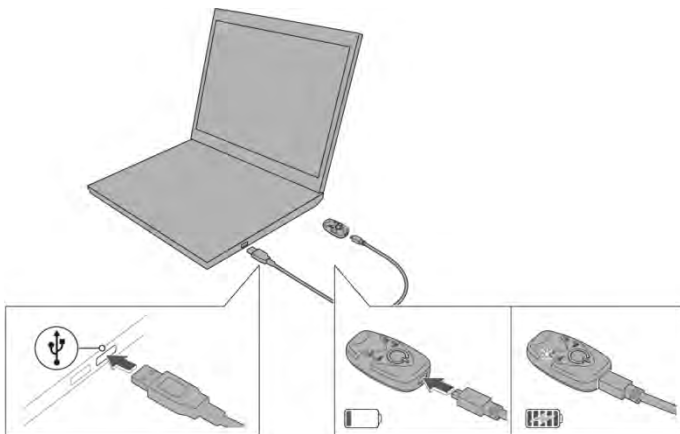


Figure 2 Connecting Faros to computer using USB cable

2.5 Connection to Computer

2.5.1 Make the connection from Faros to computer

1. Use the USB cable delivered with your Faros ECG Sensor to connect the device to your personal computer.
2. Plug the USB cable to your computer.
3. Plug the other end to your Faros Sensor. Blue light indicator starts to blink first, and then green light indicator should start to blink also.

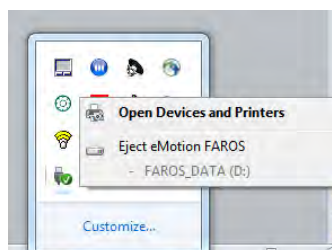
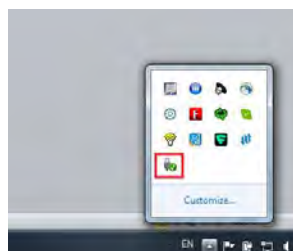
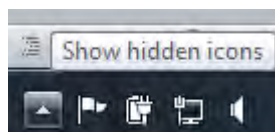
If green light indicator does not blink when device is connected to your computer, there may be a connection issue. In this case, user should disconnect the USB cable connection and reconnect again, also check carefully that the USB connection between device and cable and between cable and your computer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

2.5.2 Disconnect Faros from computer safely

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

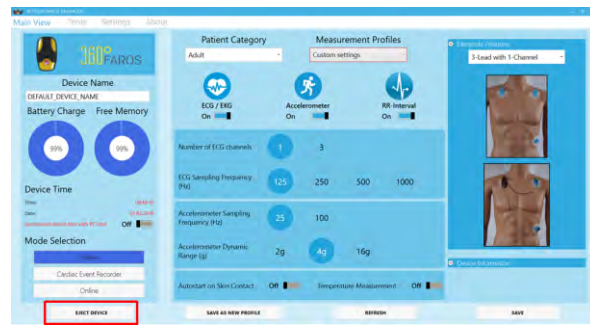
2.5.2.1 Using “Safely Remove Hardware and Eject Media” tool from Windows

1. User opens the hidden icons in Windows taskbar in 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, then user can disconnect the device now.

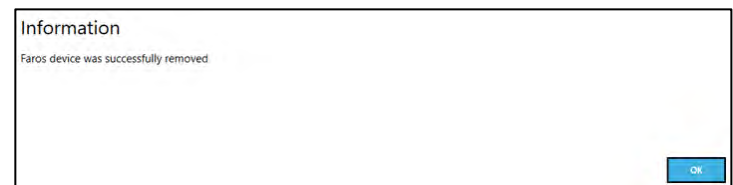


2.5.2.2 Using tool from Faros Manager

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



2. Then a small window 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.

2.6 Troubleshooting

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

Recharge the device

- Follow instruction in chapter 2.4 Recharging the battery.

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

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

Reset the device

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

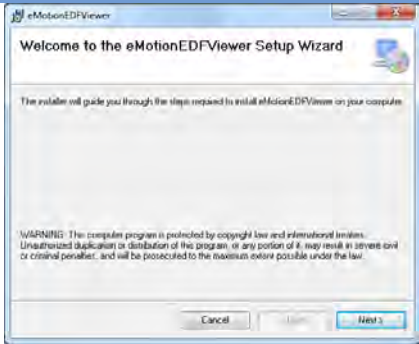

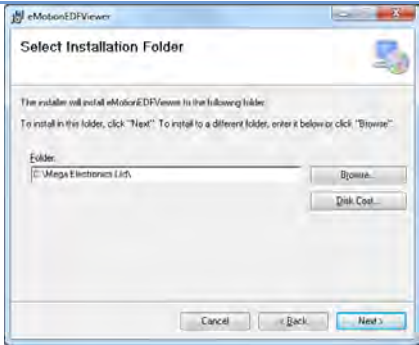
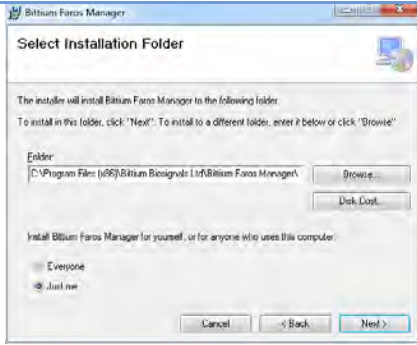
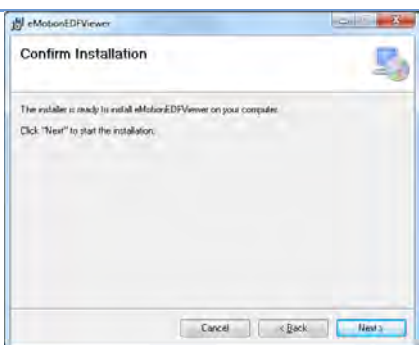
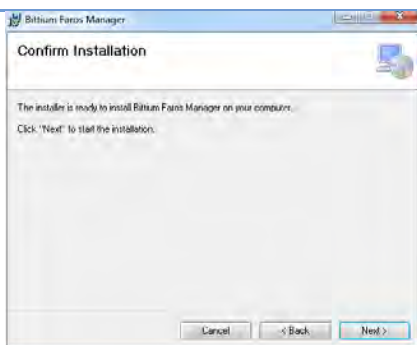
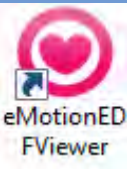
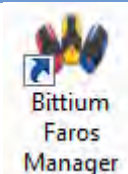
Charging dock will not charge Faros Sensors

- Charging dock's battery might be empty. Connect the Faros sensor to PC or USB power adapter.
- Charging dock's battery charges about 15 minutes before Sensor recharging starts if dock's battery is completely empty.

3 SOFTWARE INSTALLATION

***NOTE! For installation of Faros Manager or EDF Viewer software is required to use PC with Windows 8.1 or Windows 10 64-bit operating system.**

Connect Faros Sensor 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.		
Use default or select desired destination folder for installation. Click “Next” to proceed.		
Click “Next” to perform installation. After installation is complete click “Close”.		
Application shortcut icons appear on desktop. Applications are ready to use.		

***NOTE! Faros Manager icon also contain the current software version number.**

4 MEASUREMENT CONFIGURATION

The measurement configuration is managed with Faros Manager software.

1. Connect Sensor 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 from there to enable yourself to use the Faros Manager software.
2. Synchronize sensor time and set the desired measurement configuration.
 - a. Before first use the device clock must be synchronized.
3. Configure desired settings. Click “Save” button to apply the configuration. Click “Close” to exit the application. Remove Faros device safely (see Section 2.5.2)

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

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

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

4.1 Holter measurement configuration

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



Figure 3 Holter configuration

1. Run Bittium Faros Manager.
2. Select 'Holter' mode from Manager main view.
3. Select 'Custom settings', or desired measurement time (1-7 days) from Measurement Profiles
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 only available with Faros 360).
6. Select values for acquisition parameter:
 - a. ECG - Sampling Frequency
 - b. Accelerometer - Sampling Frequency
 - c. Accelerometer - Dynamic Range
7. Autostart on skin contact, On/Off
8. Temperature measurement On/Off (ONLY with Faros 360).
9. Electrode positions, with graphics to assist with positioning.
10. Synchronize clock.
11. Press 'Save' to apply the configuration.
12. Click "Eject Device" to eject Faros device.

4.2 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 4 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
Atrial fibrillation;	activated

4.3 User customized profiles

In Faros Manager 3.0.0, user can save their current measurement configurations to a profile for later use. User clicks on “Save as new profile” button at the bottom bar of application.



Figure 5 "Save as new profile" button

“Information” –window is shown and user is asked to name the created profile. User enters the new profile name and clicks “OK” button. User’s new profile is now saved.

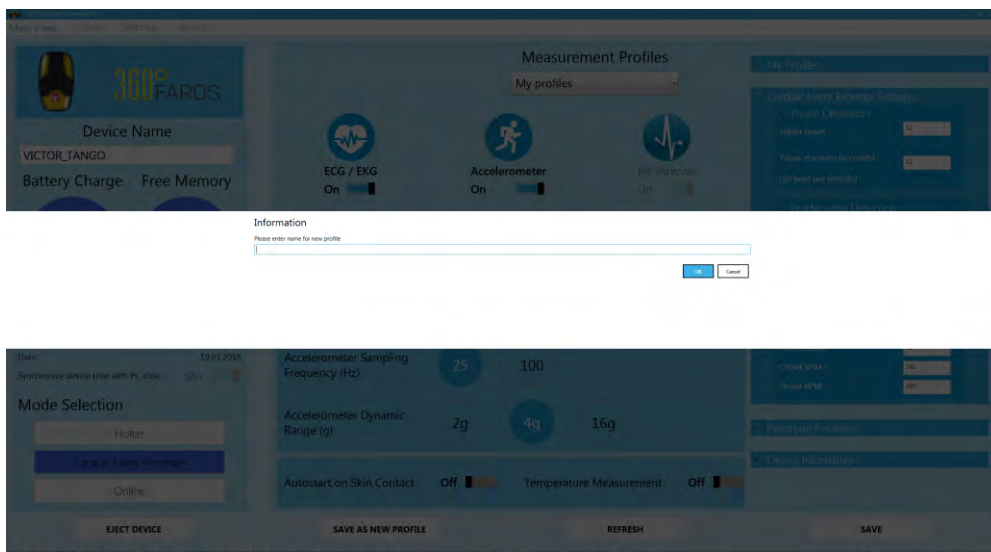


Figure 6 Enter new profile name

By choosing “My Profiles” in Measurement Profiles list, user can find a list of their saved customized profiles on the top right column.

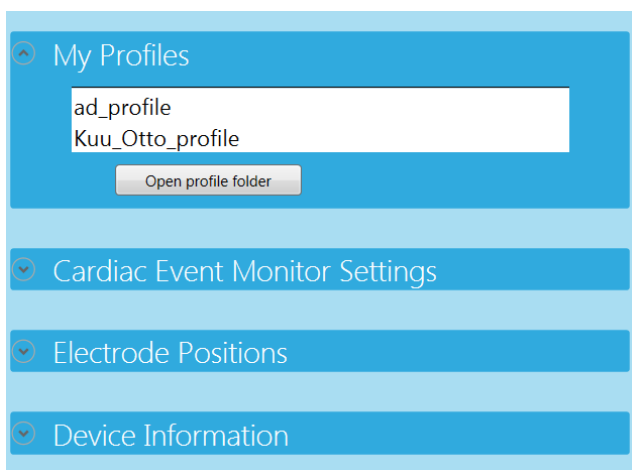


Figure 7 User's profile list

4.4 Online mode

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

1. Run Bittium Faros Manager.
2. Select 'Online Mode' from Manager main view.
3. Press 'Save' to apply configuration.
4. Click "Close".

Sensor is now ready to perform online ECG data monitoring.

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

NOTE! Online mode measurement parameters can be modified via Bluetooth connection.

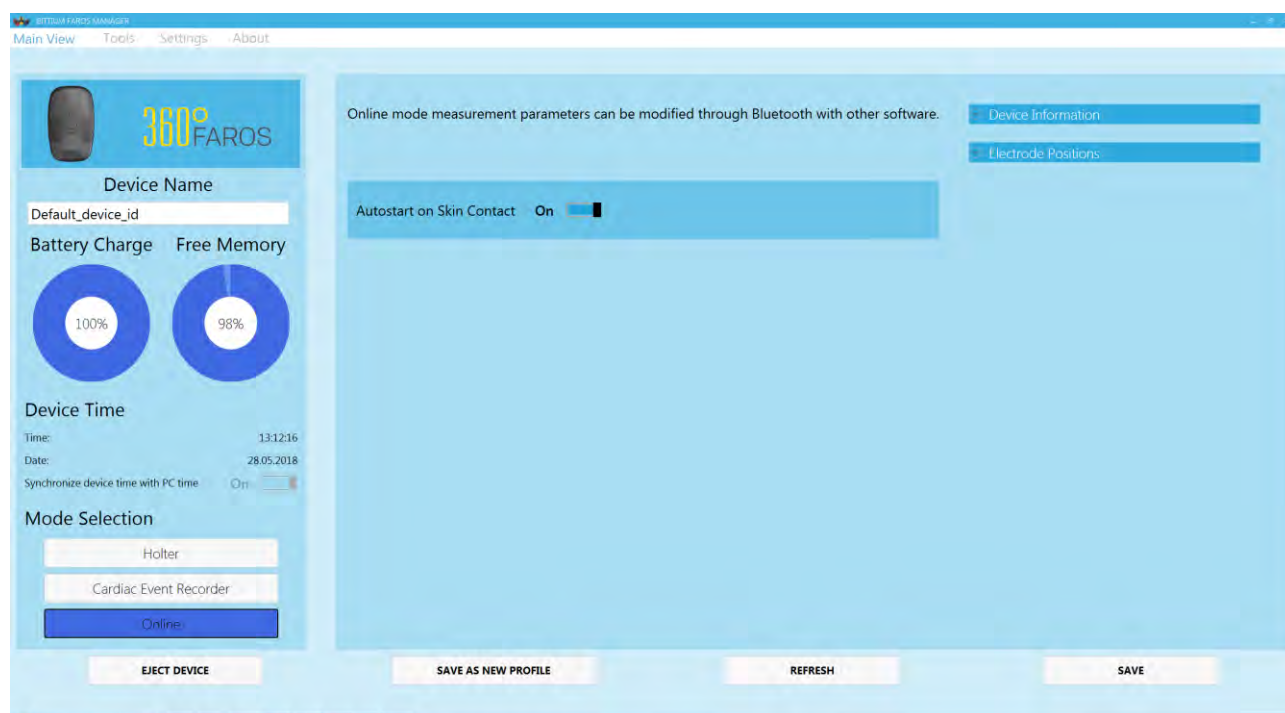


Figure 8 Online configuration

4.5 Settings

Click Settings to open Faros Manager Settings view.



Figure 9 Faros Manager Settings

In Settings view you can configure the following settings:

- 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.
- Measurement duration in minutes.
- Accelerometer based patient activity monitor, On/Off.
- Lead-off Detection, On/Off.
- Pacemaker Event Record, On/Off.
- Stop measurement by USB, On/Off.

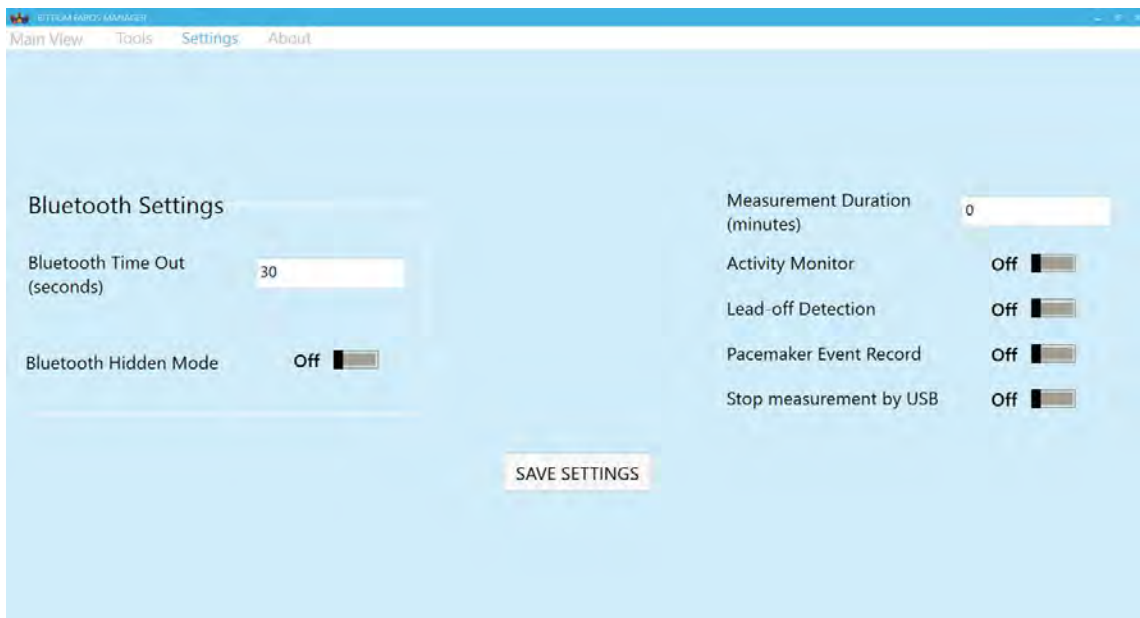


Figure 10 Settings view

4.6 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'.

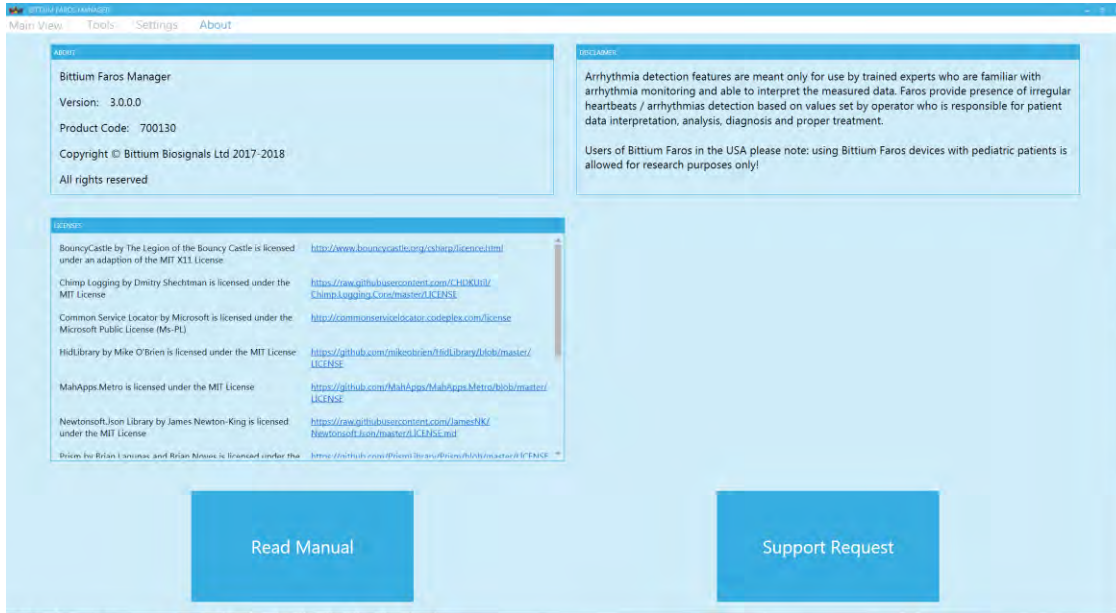


Figure 11 About view

5 HOW TO START NEW RECORDING

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

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

The Faros Sensor has one pushbutton. The device starts when you push the button. The device is shut down when you push the button continuously for 5 seconds.

5.1 Patient preparation

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

1. Shave the hair off from the areas where the electrodes are placed.
2. 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:

3. Electrode placement is instructed in the next chapter.
4. Check that the adhesive sticks properly.
5. Check that there is no air left between the electrode gel and patient's skin.
6. Check that there is no hair left under the adhesive.

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

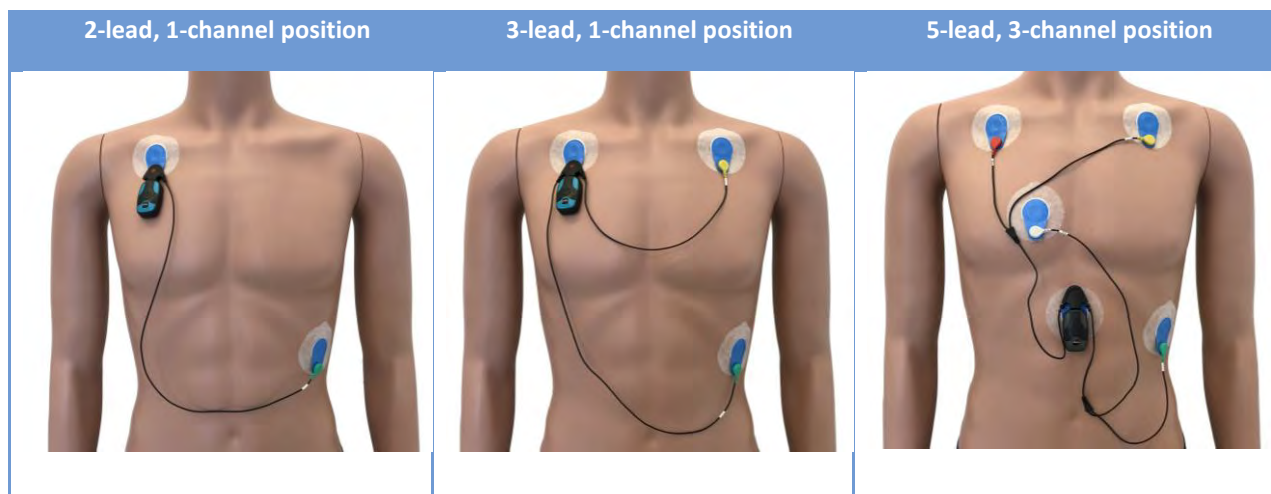
7. Attach the cables to corresponding electrodes (see electrode placement pictures in the next chapter 5.1.1 Electrode position and lead placement)
8. If necessary, the cables can be attached to the skin by tape. Notice that the tape should not touch the electrode.

Step 4. Start the measurement:

9. Press the Sensor pushbutton once.
10. Green light indicator starts to blink – the Sensor is now recording.

5.1.1 Electrode positioning and lead placement

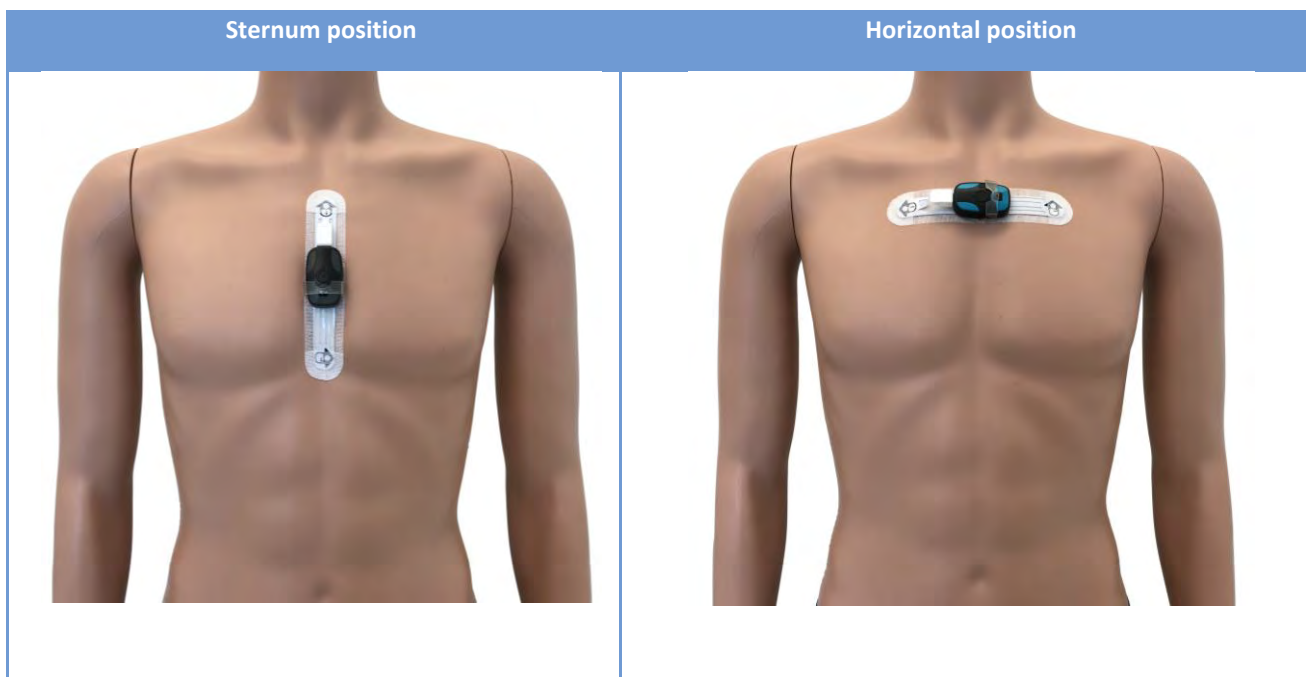
The operator should be familiar with the correct placement of electrodes. Incorrectly placed electrodes will weaken the reliability of the data. Cable sets are compatible with 4 mm snap connector ECG electrodes.



***NOTE:** It is recommended to use disposable ECG electrodes which has stud connection and Ag/AgCl gel. Electrode must be also suitable for wanted recording period. For example 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

5.1.2 Positioning of the FastFix electrode

The recommended position for the FastFix electrode is on the middle of the sternum as seen in the picture. If this positioning is not possible for some reason, the electrode can be placed horizontally above the chest muscles, with the USB connector pointing to right.



5.2 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 12 Accelerometer axis directions

6 DATA REVIEW WITH EDF VIEWER

6.1 Measurement data review

Faros EDF data recordings can be reviewed using eMotion EDF Viewer. For installation instructions, see chapter 3.

Open eMotion EDF Viewer from desktop icon or alternatively;

1. Connect your Faros Sensor 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 Sensor 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 Sensor it will take several minutes to open.

6.1.1 Review

1. Click 'Open EDF' in main view (alternatively select 'File' and 'Open').
2. Select a 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 .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.

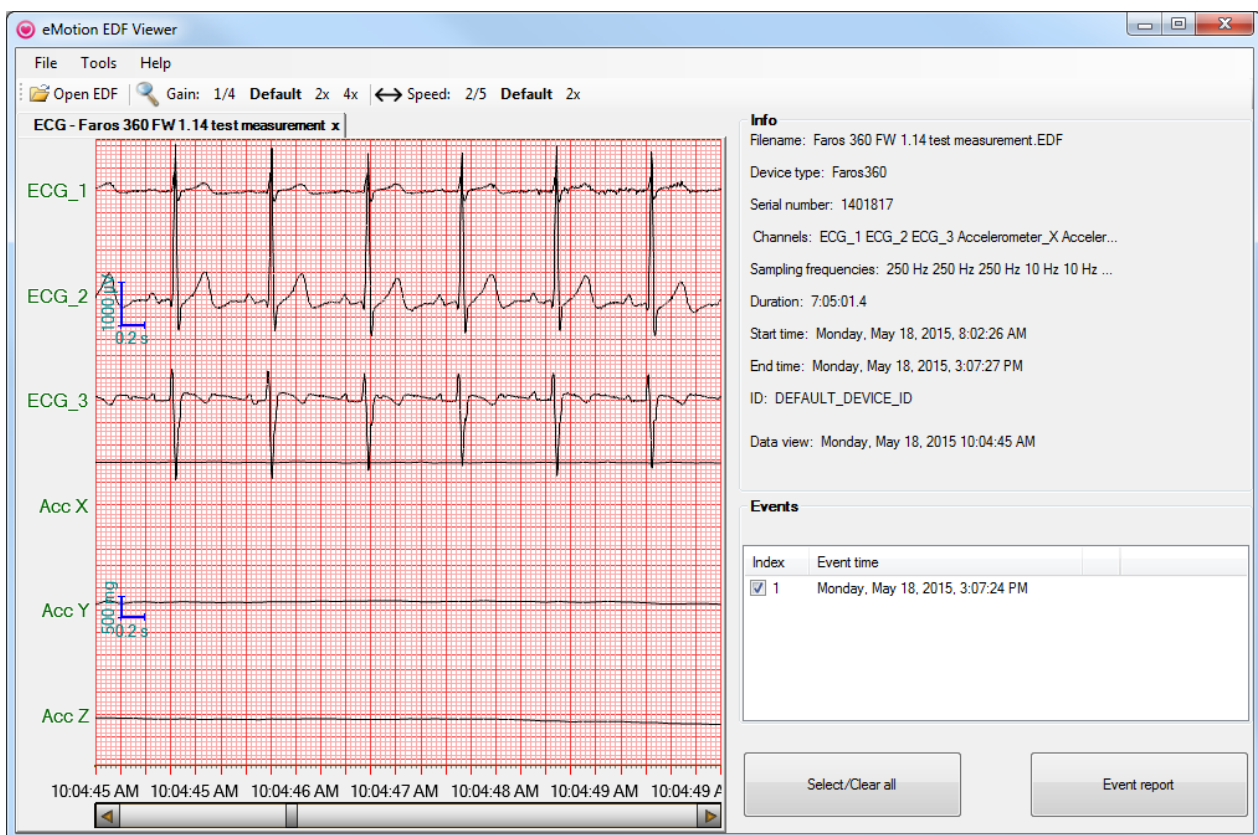


Figure 13 EDF Viewer data view

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		

6.1.2 Accelerometer data

The physical activity output is raw data from the Faros Sensor'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 11 and 12.

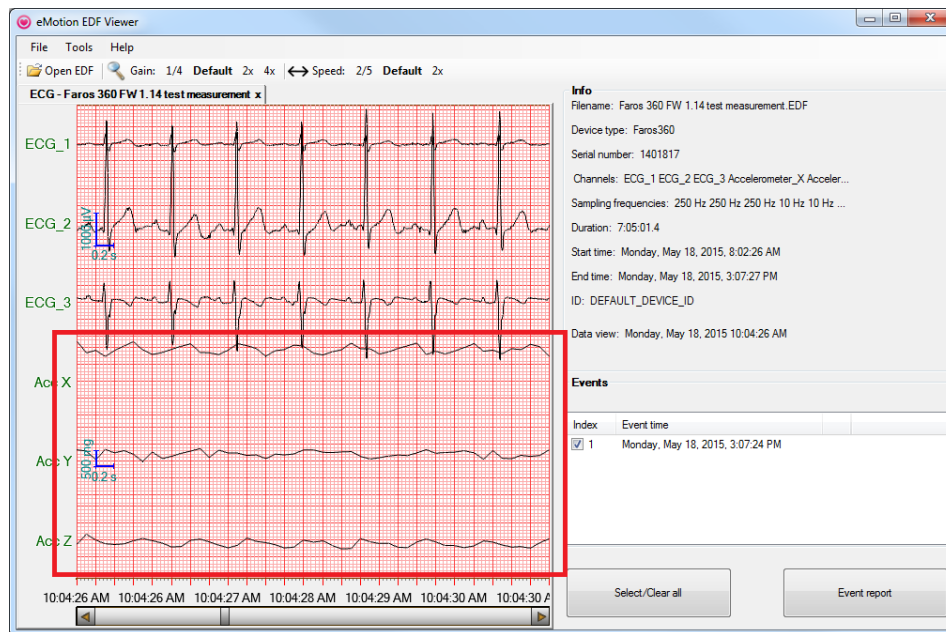


Figure 14 Accelerometer data with physical activity

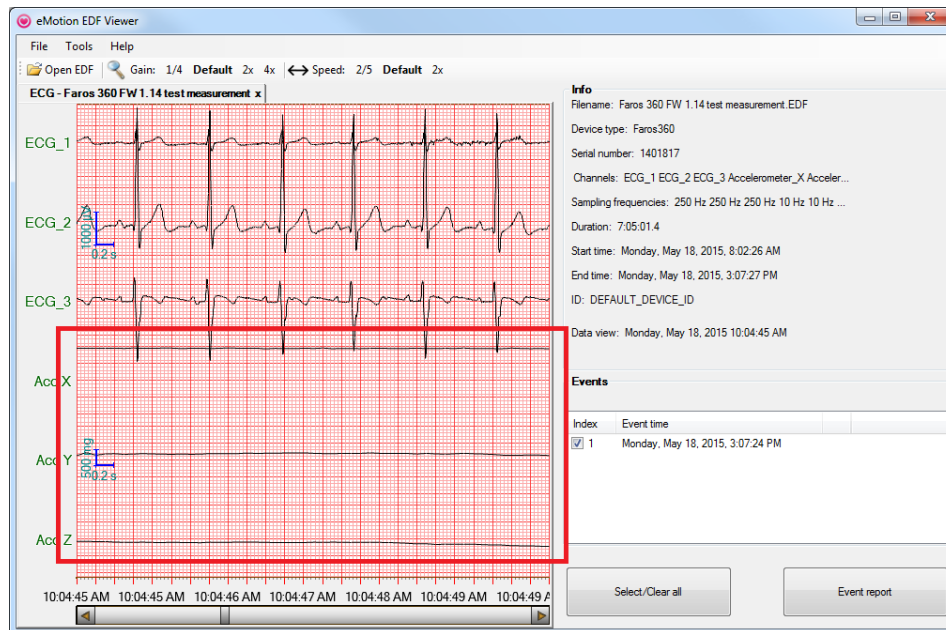

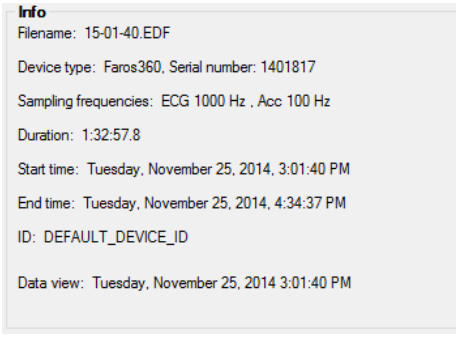
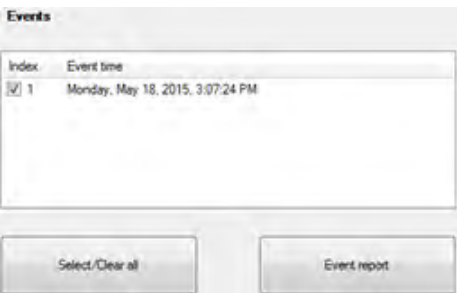
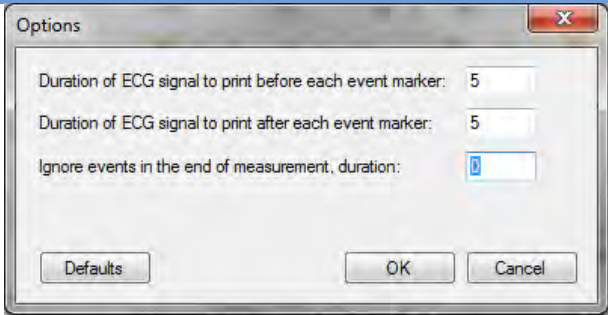
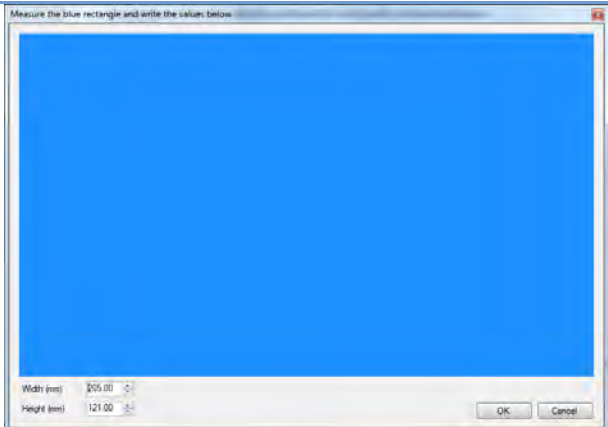
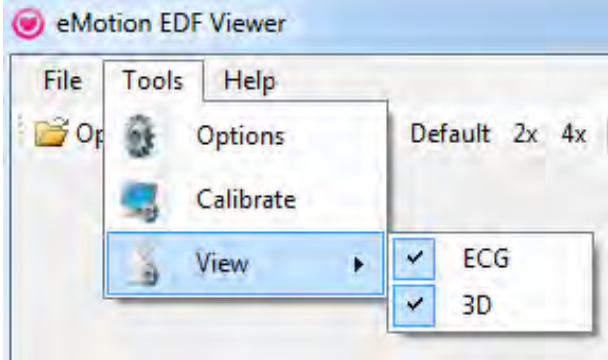
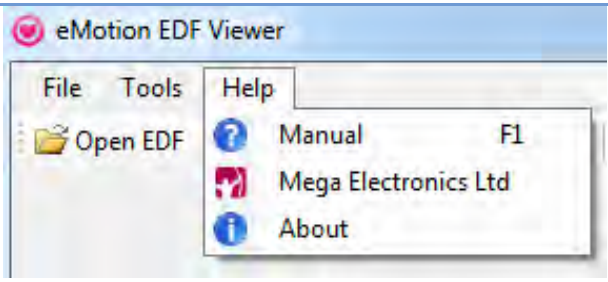


Figure 15 Accelerometer data without physical activity

User interface parts

<p>Data window shows the measured ECG data. Info window contains Faros Sensor configuration which was used in the measurement. Manually created events are listed in the Event window.</p>	
<p>Info window shows the configuration of the ECG data.</p> <ul style="list-style-type: none"> • Filename: EDF filename. • Device type: Faros sensor 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. 	
<p>Events window shows the manually created patient markers.</p> <p>A reporting option is provided for desired events. Checked (with checkboxes) events will be included in the report.</p> <p>‘Select/Clear all’ will toggle event selection between ‘None selected’ and ‘All selected’.</p> <p>‘Event report’ will open a PDF report in a separate window with options to print or save.</p>	

6.2 eMotion 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.	

7 MAINTENANCE AND SERVICE

Faros Sensor does not require any particular maintenance procedure except recharging of 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 Sensor USB connector, let it dry for two hours before you try to recharge
- Disconnect cable set from Sensor when not in use
- Connect cable set only to Faros Sensor
- Do not disassemble this device. If a problem occurs use pushbutton to reset the device.

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

7.1 Tools view in Bittium Faros Manager software

7.1.1 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.

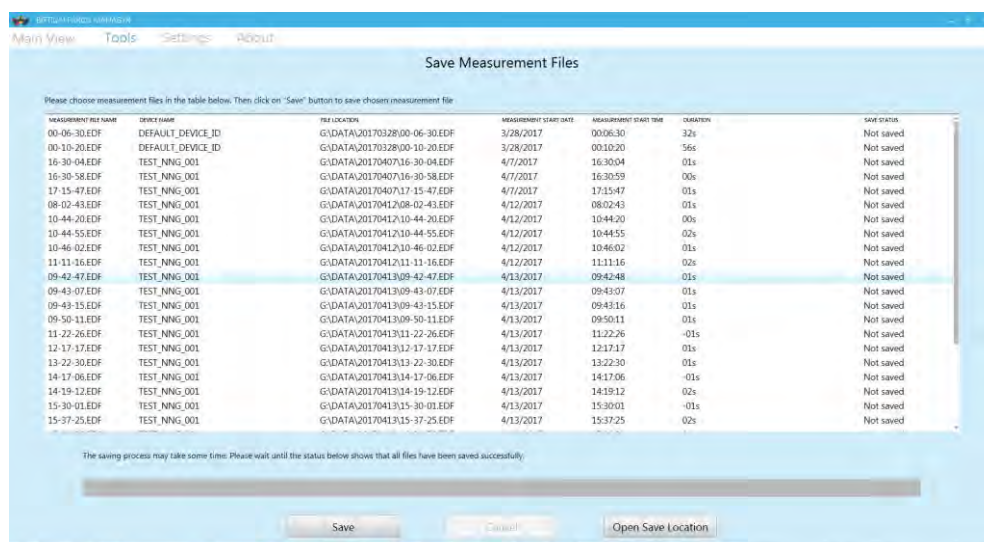


Figure 16 Save Measurement Files

- Click 'Save' to save the files. Once saving process is completed, a message dialog shows up and asks users if they want to delete chosen measurement files on device SD card after saved them.

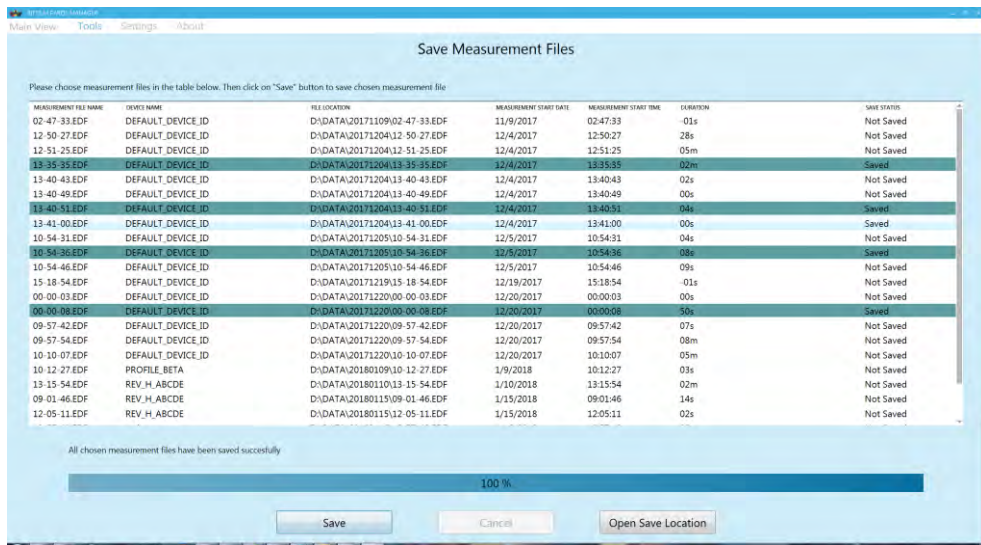


Figure 17 Measurement files are saved

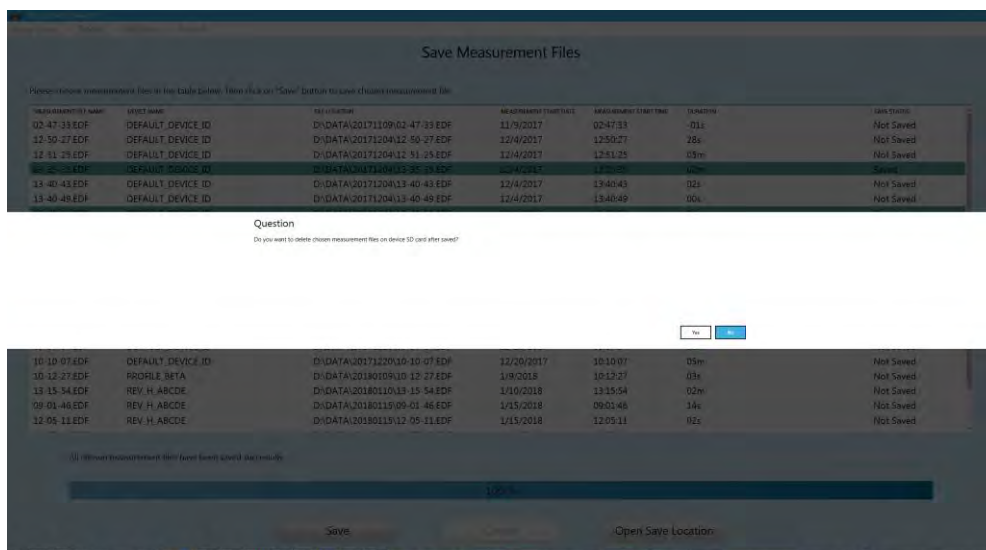


Figure 18 User can choose whether to delete saved measurement files on device SD card

If you need to open the file save folder click 'Open Save Location'.

7.1.2 Sensor firmware update

Automatic update

Faros Sensor firmware update is performed automatically if software detects that a newer firmware is available for the device. In this case the following screen will be shown:

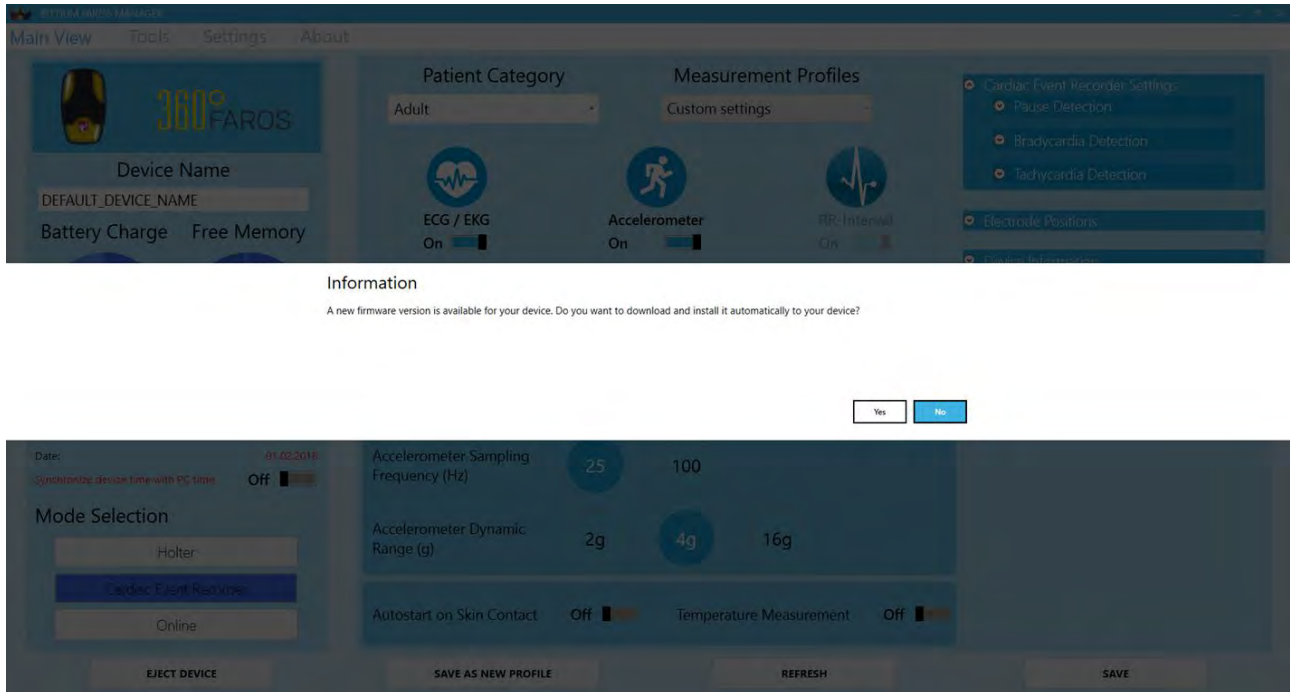


Figure 19 Automatic firmware update

Click 'Yes' to start the update process. Clicking 'No' will cancel the operation.

Manual update

Follow these steps in case the firmware update must be performed manually:

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

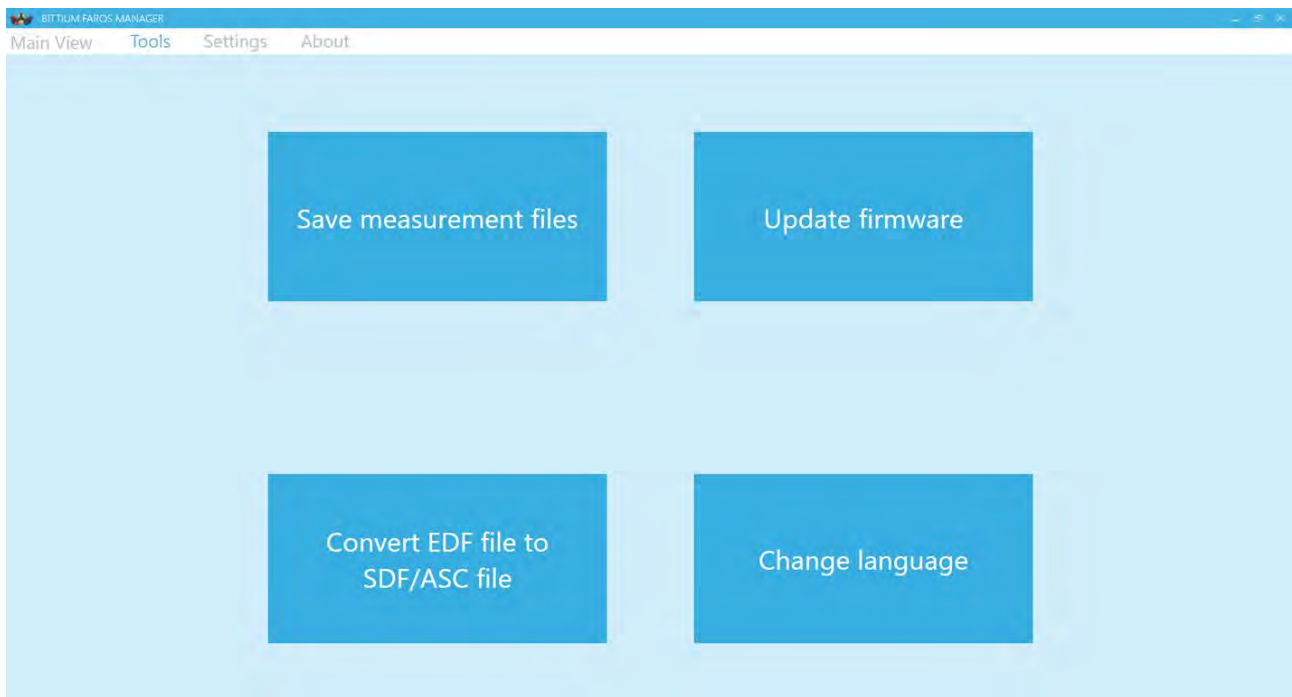


Figure 20 Tools view

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

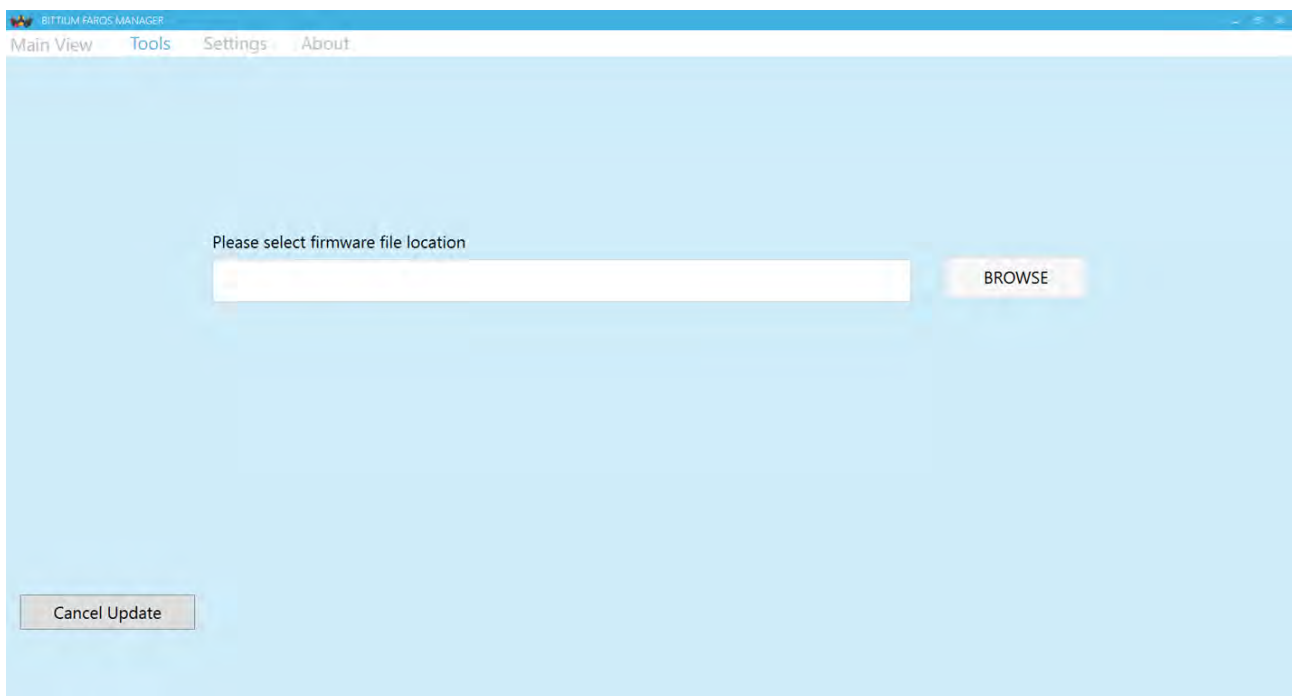


Figure 21 Manual firmware update

4. Select the file and click 'Open'. Firmware update will start.

In case the update fails for some reason Faros Manager opens a view in which the Faros Sensor hardware revision must be selected.

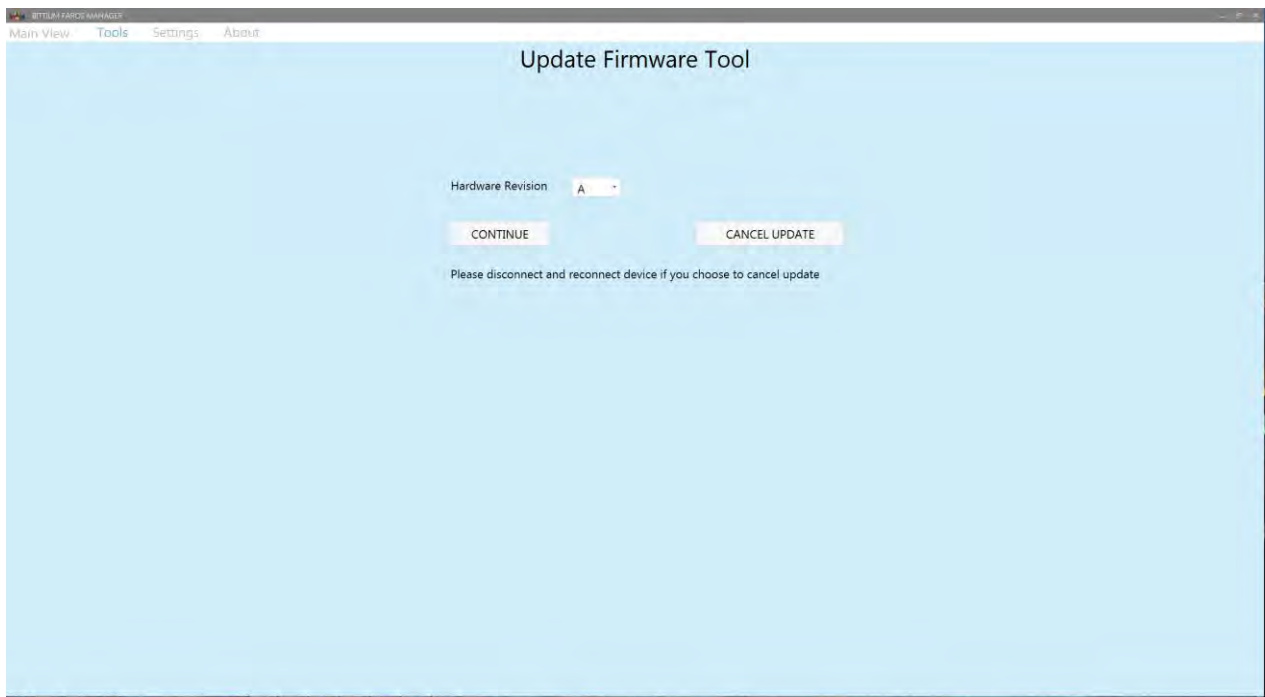


Figure 22 Update firmware tool

1. Select the hardware revision of your Faros Sensor. This information is visible in the Device Information view on the main page.
2. Click 'Continue'.
3. Select the firmware file and click 'Open'. Update process will start.

In case Faros Sensor 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 Sensor for 10-12 seconds.
3. Faros Manager will search for the Sensor and open the update view again.

Attentions with firmware update process

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

7.1.3 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.

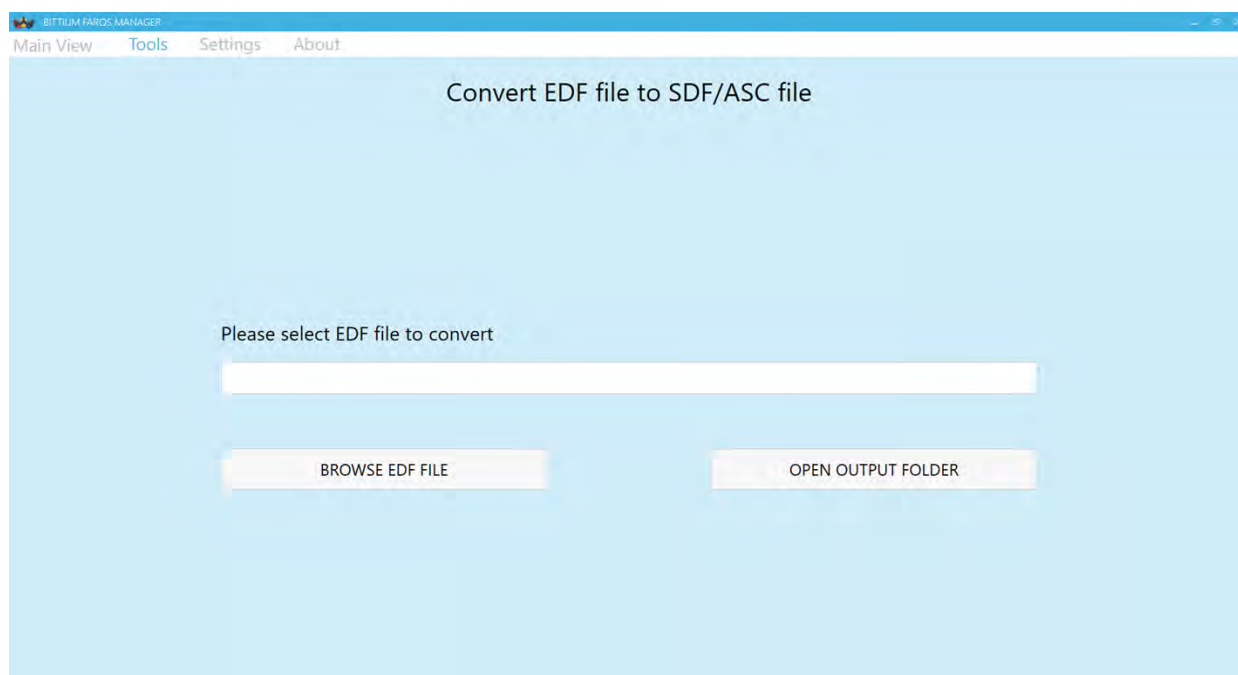


Figure 23 Convert EDF file

7.1.4 Change language

You can change the language used in Faros Manager by selecting Tools and then clicking 'Change language'. The available languages are Finnish and English. Once the language is selected, a small window appears and informs user that application is going to restart to apply language change.

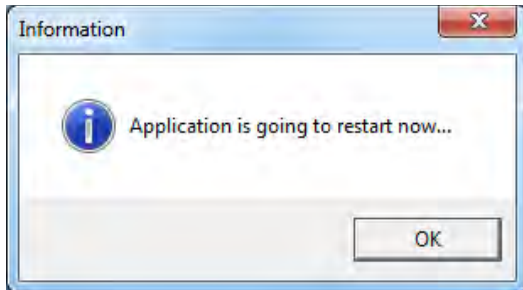


Figure 24 "Change Language" information message box

After user clicked on 'OK' button, application is closed and opened again with chosen language.

7.1.5 Support Request

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

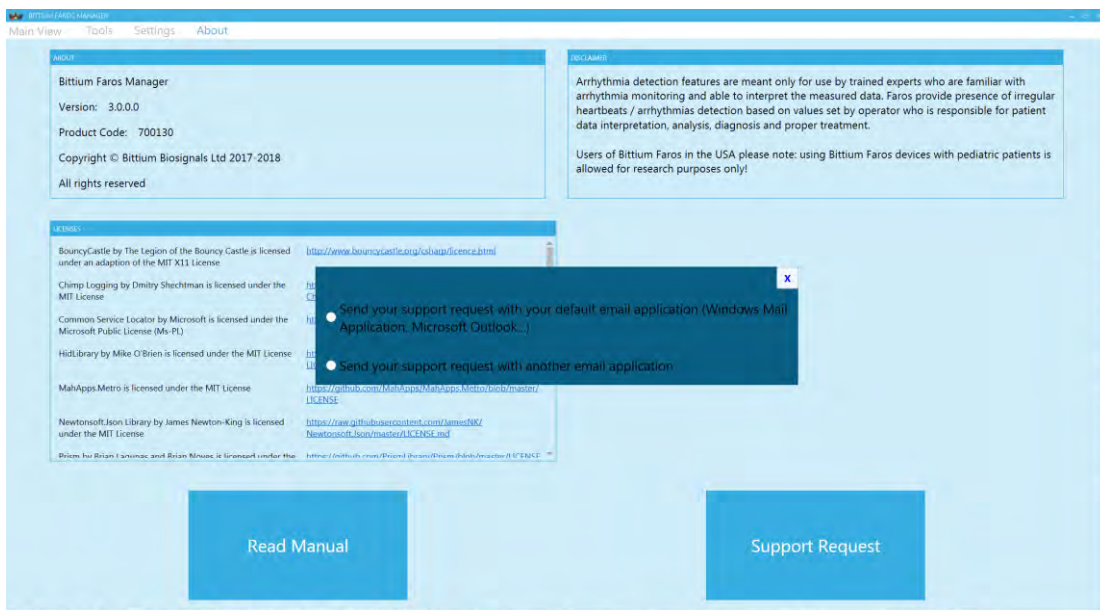
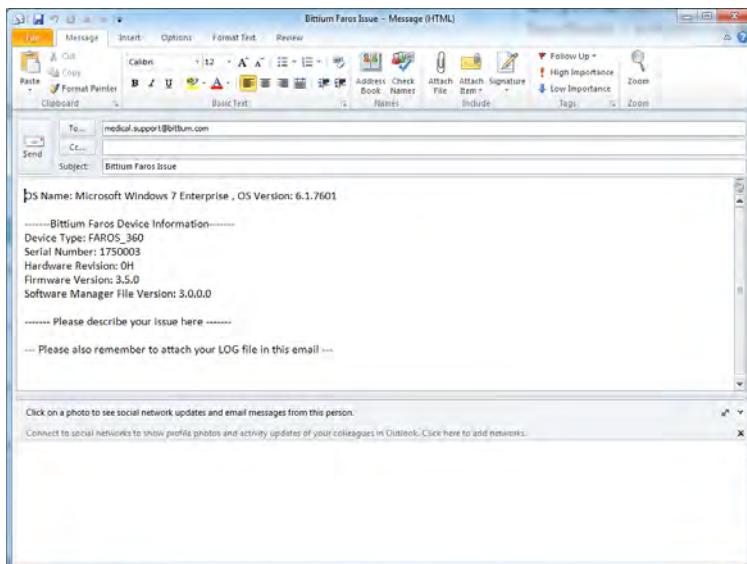


Figure 25 Support Request options

The first option is "Send your support request with your default email application (Windows Mail Application, Microsoft Outlook...", which means it will open an email application installed on your computer. For example, if Microsoft Outlook was installed in your computer then the software would open a Windows form as shown in Figure 22. In this option, you can describe the issues of the device by typing after the line "Please describe your issue here". Also, it is recommended that you attach the LOG file of the device to the email.



The second option is “Send your support request with another email application”. You can choose this option if there is no available email application installed. This tool will create and show a text file including necessary information as same as in Figure 22. But it can also copy the most recent content of eMotion Faros device LOG file (please remember to keep connecting device to PC, otherwise no LOG file is found). Issue description can be typed at the end of the file. You can copy the content the whole content of this file and paste it in user’s email application.

Figure 27 Support Request in text form

7.2 Cleaning

The Faros Sensor 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 mikrozyd® 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!

7.3 Sensor battery replacement

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

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

8 FREQUENTLY ASKED QUESTIONS (FAQ)

What shall 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 in the following way:

- 1) Go to: <https://dojo.bittium.com/jira/servicedesk/customer/portal/7>
- 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 I can 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 sensor is delivered, the device clock is synchronized to the Finnish time. This is why the clock needs to be synchronized before the first use. Also, if the battery of the device has ran out, the clock of the device may change. This is why we recommend you 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 sensor).

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

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 of 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 are able to change the measurement settings. Please see chapter 4 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 of these data formats are rather global, which is why there are a variety of software that can open these files. 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 section 7.1.2.

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 of 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 Sensor does not start, what might cause this problem?

It is important to remember that Faros Sensor 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 up with the time. This is why we recommend you 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 happen when user does not disconnect the device safely from computer. Please follow instructions in section 2.5.2.

How long time Faros sensor is designed for operation?

Device life time is much depending on device use. Estimated device life time is 5 years. For cable sets recommendation is to change to new ones if there are seen damages on cables or on connectors.

9 REGULATORY INFORMATION

9.1 Classification EU

In accordance with MDD 93/42/EEC: Class IIa product

EN60601-1: Internally powered equipment

9.1.1 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, 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.

9.2 Intended Use

The Faros 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 sensor internal memory.

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

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

Appendix 1. Electromagnetic Emission

Manufacturer's Declaration - Electromagnetic Emissions		
The Faros 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	The Faros 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	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
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						

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