eMotion FAROS

90° eMotion FAROS

180° eMotion FAROS

360° eMotion FAROS

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1. Introduction

The eMotion Faros Sensor is a wearable, portable, externally applied electrocardiograph (ECG) recorder and wireless transmitter for ECG measurement, HRV (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 USB connection or with a Bluetooth connection to a wireless device.

The bundled software included with the sensor are the eMotion EDF Viewer for ECG data viewing and Faros Manager software for changing the device settings and updating the device firmware. In-detail analysis can be done by Faros Mobile Event web service, Faros Event Recorder software or with several Holter analysis software solutions, available from Mega. 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 HRV can be measured by using Faros Sensor with Stingray adapter and Textile Belt or Cable Set, Fast-Fix Electrode and commercially available single-use snap on ECG electrodes.

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

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

Before operating the eMotion Faros, please read this manual thoroughly and retain it for future reference.

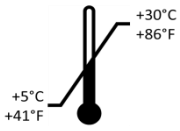
1.1. General Safety Precautions

- eMotion Faros Sensor is not waterproof
- Do not use Sensor in an environment with extreme humidity or temperature (e.g. in bath or while swimming)
- Do not disassemble, try to repair, or modify sensor
- Sensor does not have any electrical stimulation capabilities
- eMotion Faros does not provide diagnosis
- Accelerometer data is not analyzed within the device or differentiated between various physical activities
- Use ECG sampling rate of 500Hz with pediatric patients

1.2. Warnings

- Sensor is not suitable for direct cardiac application
- Do not attempt self-diagnosis or self-treatment based on acquisitioned data
- Not suitable to use in MRI environment
- The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with defibrillator
- Patients, who have active implantable medical device (like heart pacemaker etc.), should consult supervising physician or doctor before use.
- When operating with the eMotion Faros ECG Sensor, do not touch parts of the computer, docking station or any non-medical electrical equipment and the patient at the same time.
- To avoid danger of electrical shock and electromagnetic disturbances the computer and associated equipment used with the eMotion 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 at the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfils the requirements.

1.3. 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.
USE BEFORE	The electrodes shall not be used after the date followed this symbol.
	This symbol, found on some equipment parts, means that additional instructions that further explain use of a particular part or function is found in the Device Manual or Service Manual.
	The Lot number follows this symbol (Electrodes).
	General Warning sign
	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)
	Consult Instruction for use
	Storage: +5°C…+30°C (+41°F…+86°F)
	During transportation: keep package dry, protect from rain
NOTE!	Note text in manual: These statements identify condition or practices that could result in performance loss of the equipment or must be otherwise paid attention to.
	Wireless Transmission Symbol

2. Faros ECG Sensor Overview

2.1. General

There are three different models of the Faros sensor: two one-channel ECG and one three-channel ECG model. The Faros 180 and Faros 360 models are capable of Bluetooth communication. All sensors have the same form and shape, but the colour of the sensor changes by the model.

Technical Specification			
	90° eMotion FAROS	180° eMotion FAROS	360° eMotion FAROS
ECG holter	Yes	Yes	Yes
ECG online	No	Yes	Yes
1-channel ECG	Yes	Yes	Yes
3-channel ECG	No	No	Yes
HRV	Yes	Yes	Yes
Bluetooth	No	Yes	Yes
Accelerometer	Yes	Yes	Yes
HRV Sampling Frequency	1000 Hz	1000 Hz	1000 Hz
ECG Sampling Frequency	125, 250 Hz	125, 250, 500, 1000 Hz	125, 250, 500, 1000 Hz
ADC Precision	24 bits	24 bits	24 bits
3D Accelerometer Precision	14 bits	14 bits	14 bits
3D Accelerometer Sampling Frequency	25 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 13g	48 x 29 x 12 (mm) Weight 13g	48 x 29 x 12 (mm) Weight 13g
Operating time	Up to 7 days ECG 125 Hz	Up to 7 days ECG 125 Hz	Up to 7 days ECG 125 Hz

**Faros Power Source Li-ion battery comply with 62133.*

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2.2. Accessories and Replacement Parts

Cable sets		
 **2-electrodes** 900865	 **3-electrodes** 900866	 **5-electrodes** 900867

Charging Dock and USB cable	
 **Charging dock** VP00516	 **USB Cable** 900826

Stingray adapter and textile belt	
 **Textile belt** 900810	 **Stingray Adapter** 900809

Fast Fix Electrode
 **Fast Fix Electrode** 900811

2.3. Sensor Symbols and Indicators

Sensor Symbols and Indicators provide information of the sensor state. Sensor has four LEDs and Buzzer for audio indications. Indications are presented in tables below.

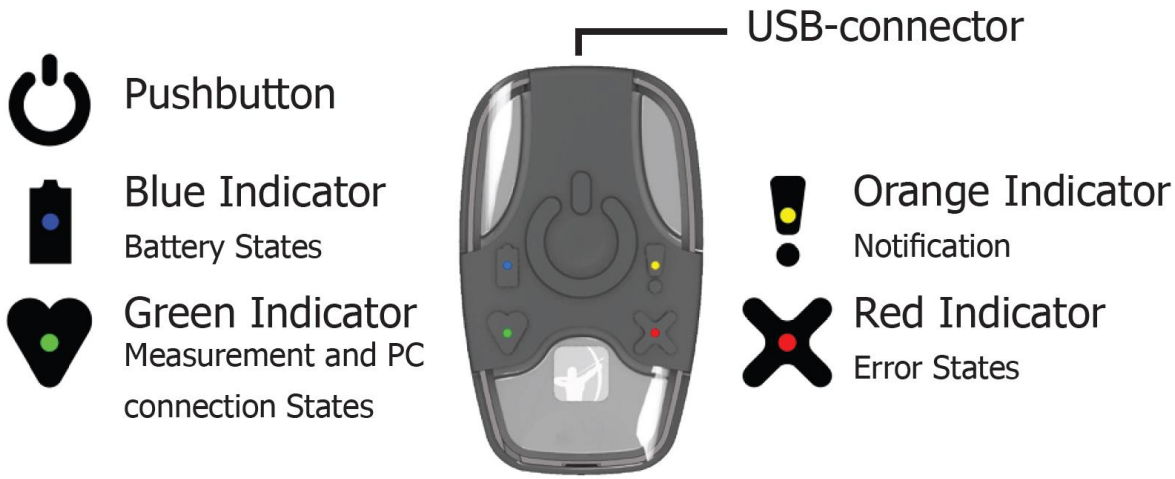


Figure 2.4.1-1: Sensor symbols and indicators

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 is started	**Green** indicator is lit
Measurement is running	**Green*** indicator blinks every five seconds
Measurement is ended	Three ♫ ♫ ♫ beep-sound indications
Pushbutton is pushed during measurement	One ♫ beep-sound indication
Battery is running empty	**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
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

2.4. Recharging the Battery

2.4.1. Charging via USB

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 sensor, let the sensor dry 2 hours on table before you plug it into computer via USB cable for charging.

- Use USB cable delivered with your Faros ECG Sensor to connect sensor to your personal computer
- Plug USB Cable to your computer
- Plug other end to your Faros Sensor
- Blue light indicator starts to blink
- Blue light indicator shine continuously when Sensor's battery is fully charged
- Recommended recharge time is 1.5 hours
- Un-plug USB-Cable from Faros and Computer

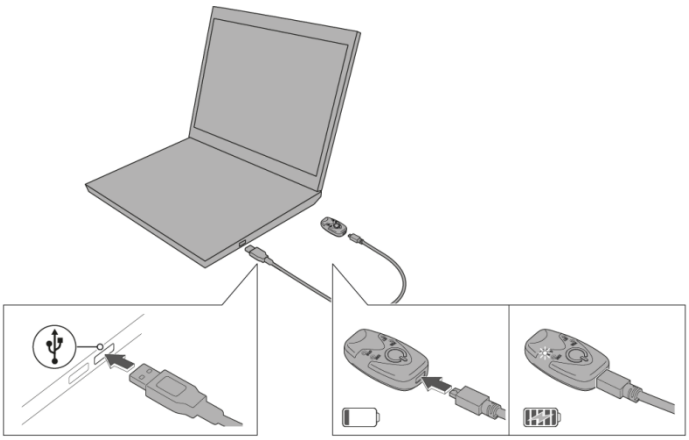


Figure 2.4.1-1: Connecting Faros to computer using USB cable

2.4.2. Charging with Charger Station

Connect Charger Station to PC via USB Cable delivered with Charger Station. Cable is connected correctly when the Charger Station's Green LED indicator is on. Connect sensors to Charger Station. Sensors are being recharged when Battery LED Indicator (Blue LED) of the sensor(s) start to blink.

Please note that Charger Station's battery charges about 15 minutes before sensor recharging starts if station's battery is completely empty.

Charger station can also be used to recharge Faros sensors without PC connection. Please make sure that the Charger Station's battery has been fully charged (Yellow charging indication LED turns OFF). Charger Station's internal battery can charge up to 16 Faros sensors without recharging.

NOTE!! Before placing Faros sensors to Charger Station check that sensor connectors are clean and there is no moisture in it (for example water, sweat etc.).

Figure 2.4.2-1: Faros sensor on charger station

2.5. Troubleshooting

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

Recharge the device

- Follow instruction in chapter 2.5 Recharging the Battery

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

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

Reset the device

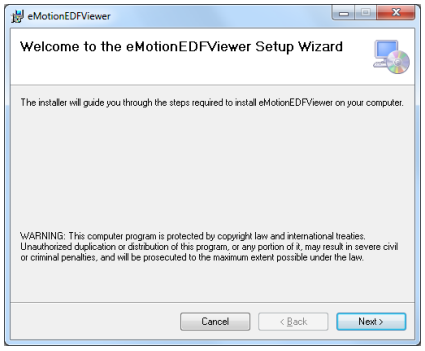
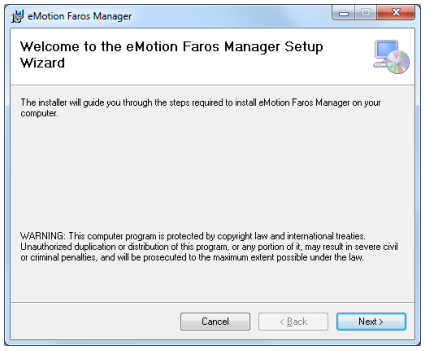
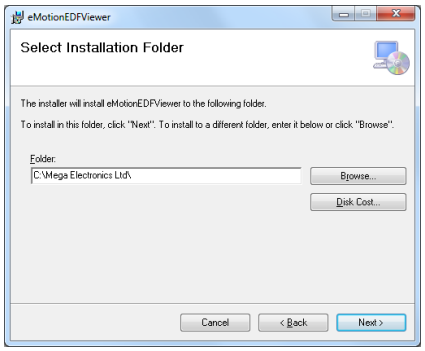
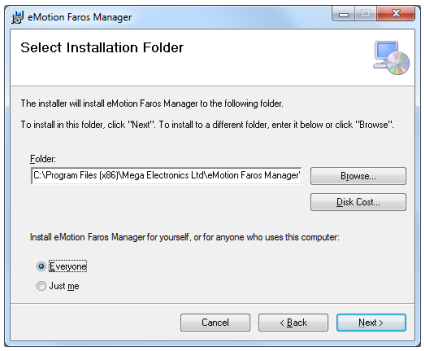
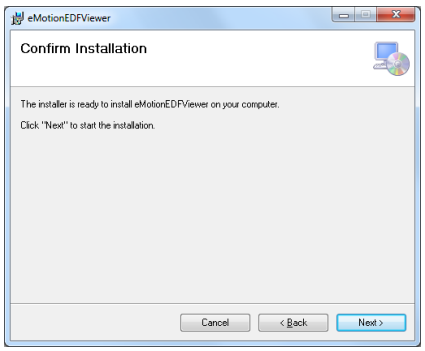
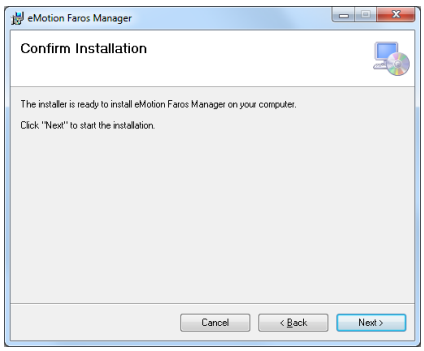
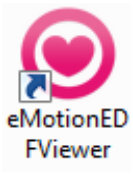
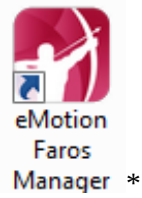
- Push the pushbutton until all light indicators flash
- Power on the device by pushing power button

Charger station won't charge Faros sensors

- Charger station's battery might be empty. Connect the Faros Base to PC or USB Power adapter
- Charger Station's battery charges about 15 minutes before sensor recharging starts if station's battery is completely empty.

3. Software Installation

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 “eMotion Faros Manager” folders. After this follow instructions on screen.

Steps	EDF Viewer	Faros Manager
Click “Next” to proceed installing the software.		
Use default or select desired Destination Folder for installation. Click “Next” to proceed.		
Click “Next” to perform installation. After complete installation click “Close”.		
Application shortcut icons appear on desktop. Applications are ready to use.		 *

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

4. Measurement Configuration

The measurement configuration is managed with eMotion Faros Manager software.

- Connect Sensor to computer and run Faros Manager software from desktop icon
    - Alternatively browse to "FAROS_DATA/Software" folder on device hard drive and run eMotion Faros Manager from there
- Synchronize sensor time and set the desired measurement configuration
- ***Before first use of the device clock must be synchronized***
- Click "Save" button to apply the configuration
- Click "Close" to exit the application

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

Sensor Type	Device Revision	Firmware version	ECG Sampling	ECG Channels	ACC Sampling	ACC Range
90*	0A, 0C, 0E	1.00 - 1.08	No ECG	No ECG	25	2, 4, 16
	0C, 0E	1.09 – 1.nn	125, 250	1	25	
	0G	2.00 - 2.nn 3.n.n -	125, 250	1	25	
180	0A, 0C, 0E,	1.00 - 1.nn	125, 250, 500, 1000	1	25, 100	2, 4, 16
	0G	2.00 - 2.nn 3.n.n -		1	25, 100	
360	0B, 0D	1.09 - 1.nn	125, 250, 500, 1000	1,3	25, 100	2, 4, 16
	0F, 0G	2.00 – 2.nn 3.n.n -				

Note, Faros 90 0A support firmware to 1.08. Faros 0C and 0E support firmware from 1.08 to 1.nn

Sensor Type	Bluetooth	Autostart	RR	SDF/ ASC**	EDF	Temperature
90	No	0C, 0E, 0G	Yes	Yes	Yes	No
180	Yes	0C, 0E, 0G	Yes	Yes	Yes	No
360	Yes	0F, 0G	Yes	Yes	Yes	Yes

Note, Faros firmware 3.x.x onwards does not support SDF/ASC file format

Sensor Type	Combo Restrictions
90	In offline mode select at least one: (ECG, RR, ACC) Maximum accelerometer sampling is 25 Hz with SDF/ASC file format ECG is disabled when using SDF/ASC mode
180	
360	In offline mode select at least one: (ECG, RR, ACC) Maximum accelerometer sampling is 25 Hz with SDF/ASC file format ECG is disabled when using SDF/ASC mode With 3 ECG channels and less than 1000 Hz, RR is disabled

4.1. Holter Measurement Configuration

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

1. Run eMotion Faros Manager
2. Select 'Datalogger mode' from Manager main view
3. Select wanted measurement parameters
    a. RR Intervals
    b. Acceleration
    c. ECG
4. Select values for acquisition parameter
    a. Accelerometer - Sampling Rate
    b. Accelerometer - Dynamic Range
    c. ECG - Sampling Rate
5. Select 'Saved File Format'
    a. Binary File: EDF (European Data Format)
    b. RR-Data: SDF / ASC
6. Temperature (ONLY with Faros 360)
7. ECG Channel count (ONLY with Faros 360)
8. Synchronize clock
9. Press 'Save' to apply the configuration
10. Click "Close" to exit the application

The sensor is now ready to perform Holter measurements with the set configuration.

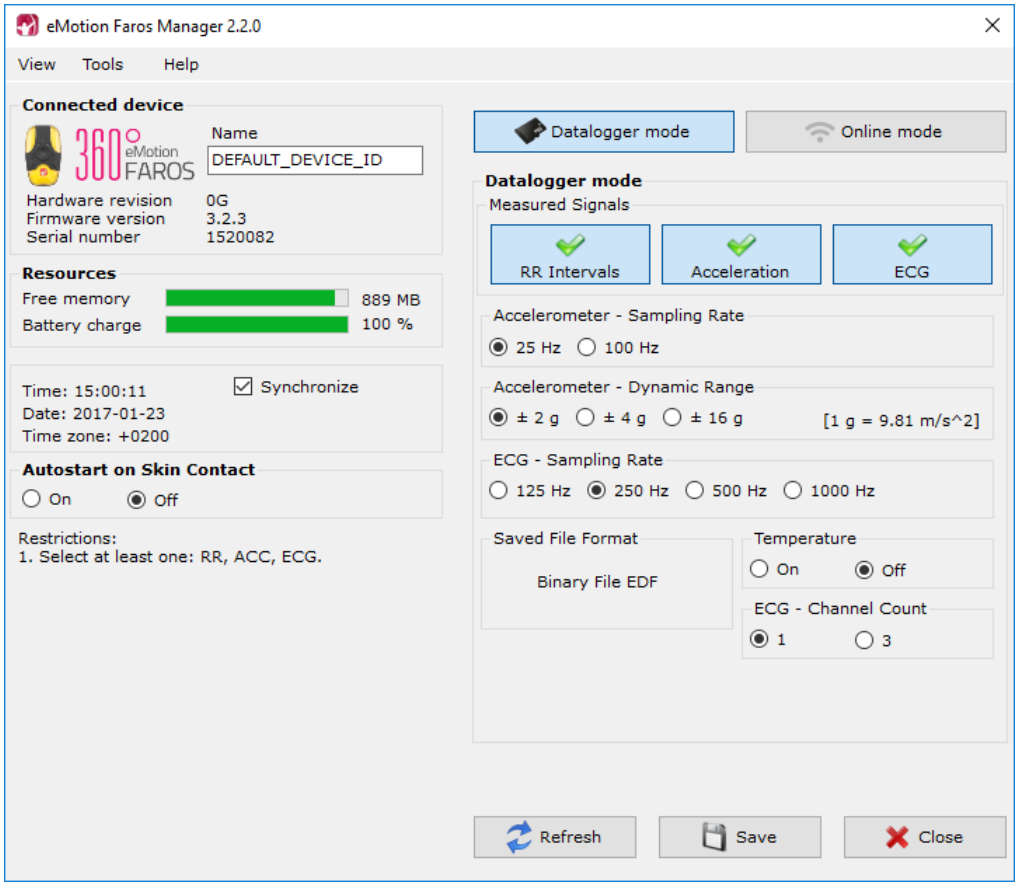


Figure 2.4.2-1: Holter configuration

NOTE! With pediatric patients, ECG sampling rate shall be 500Hz

4.2. Advanced Settings

The access to advanced settings is protected by a PIN code. The default PIN-code is 70800.

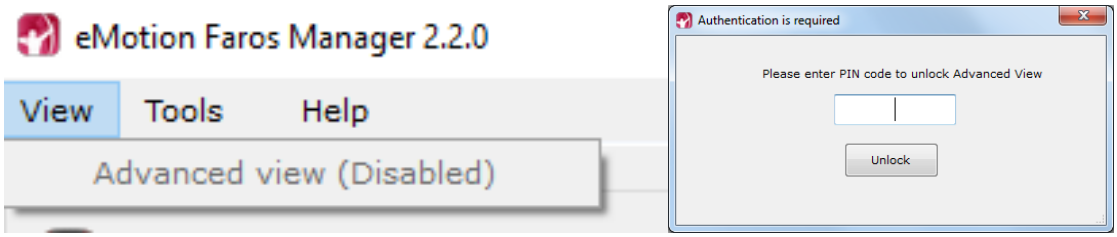


Figure 2: Advanced settings PIN code

Advanced Settings configures following features:

- Measurement duration (e.g. automatic stop after 24h)
- Bluetooth timeout (automatic shutdown of Bluetooth in offline mode after given period)
- Bluetooth Hidden Mode
    - Bluetooth Hidden Mode is a cyber-security enhancement which makes Faros device undiscoverable and non-pairable from untrusted devices
- Pacemaker Event Recording
- RR-based nonlethal arrhythmia detection (AF, pause, bradycardia, tachycardia)
    - Enable / disable arrhythmia detection
    - Tachycardia (high heart rate) detection onset and offset values
    - Bradycardia (low heart rate) detection onset and offset values
    - Pause detection onset and offset values
- Enable / disable accelerometer based patient activity monitor

Advanced Setting appears on right side.

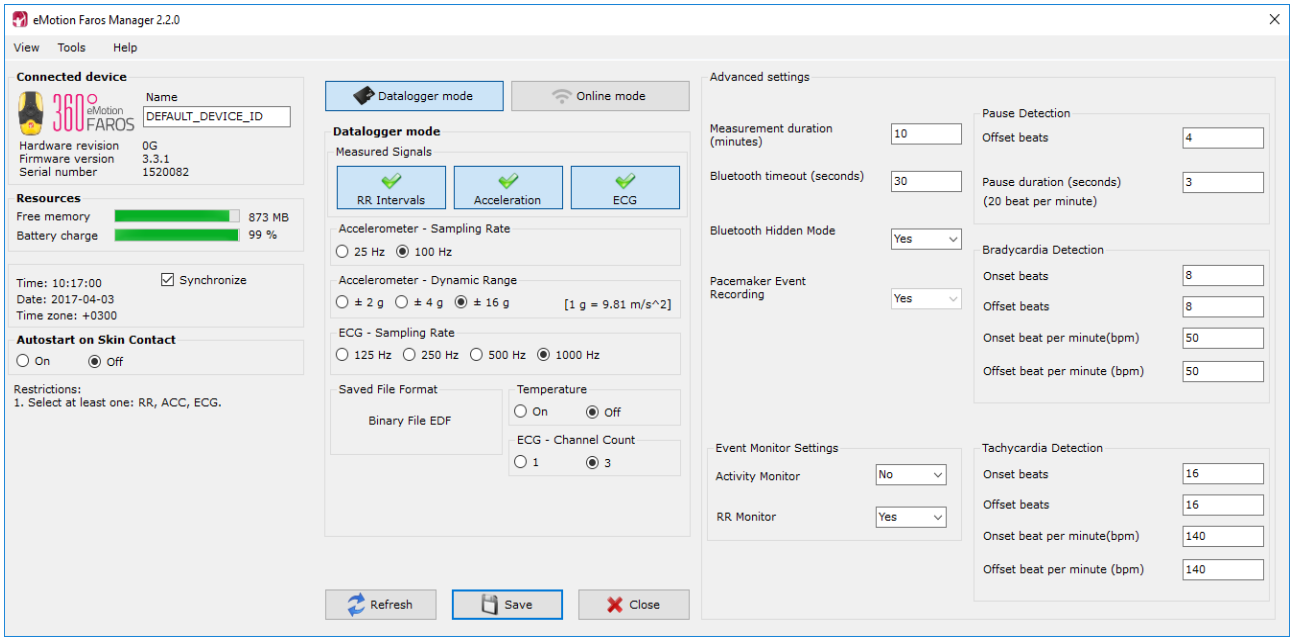


Figure 3: Advanced settings view

Advanced 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

***Note, arrhythmia detection is supported from Faros firmware v3.3.x onwards. Feature is not available for firmware version 1.xx or 2.xx.**

4.3. Online Mode

The Online ECG Data monitoring is available on Faros 180 or Faros 360 sensors. Configuration for online mode is set using Faros Manager.

1. Run eMotion 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.

For further information on using Faros sensor with mobile device and LiveECG application refer to document “800699 Android LiveECG UserGuide”.

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

NOTE! With pediatric patients, ECG sampling rate shall be 500Hz

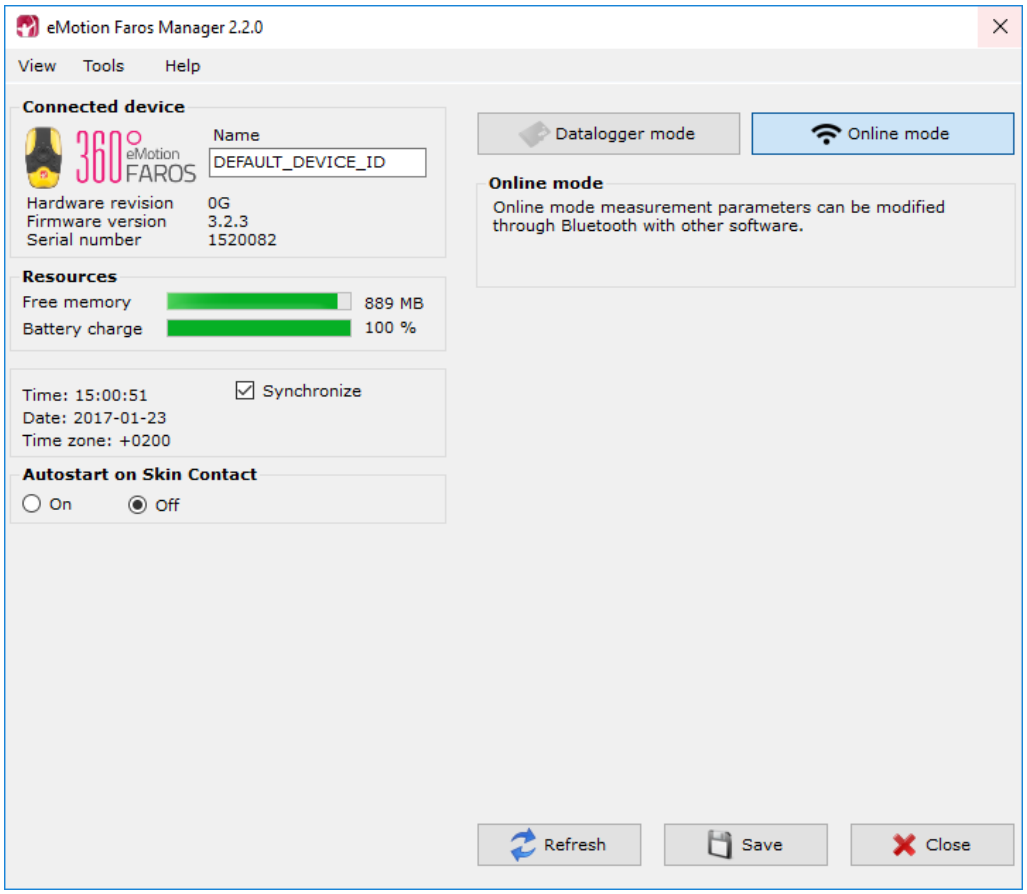


Figure 2.4.2-1: Online configuration

4.4. Heart Rate Variability Measurement

Heart Rate Variability data measurement can be performed with every Faros model. Configuration for HRV measurement is set using Faros Manager software.

1. Run eMotion Faros Manager
2. Select 'Datalogger mode' from Manager view
3. Set measurement parameters
    a. RR Intervals
    b. Accelerometer
4. Select values for acquisition parameter
    a. Accelerometer Sampling
    b. Accelerometer Dynamic Range
5. Select 'Saved File Format'
    a. Binary file: EDF (European Data Format)
    b. Text file: SDF/ASC
6. Synchronize clock
7. Press 'Save' to apply configuration
8. Click "Close" to exit application

Faros sensor is now ready to perform Heart rate variability data acquisition. Note: If you are recording only HRV data, remember to unselect ECG Data.

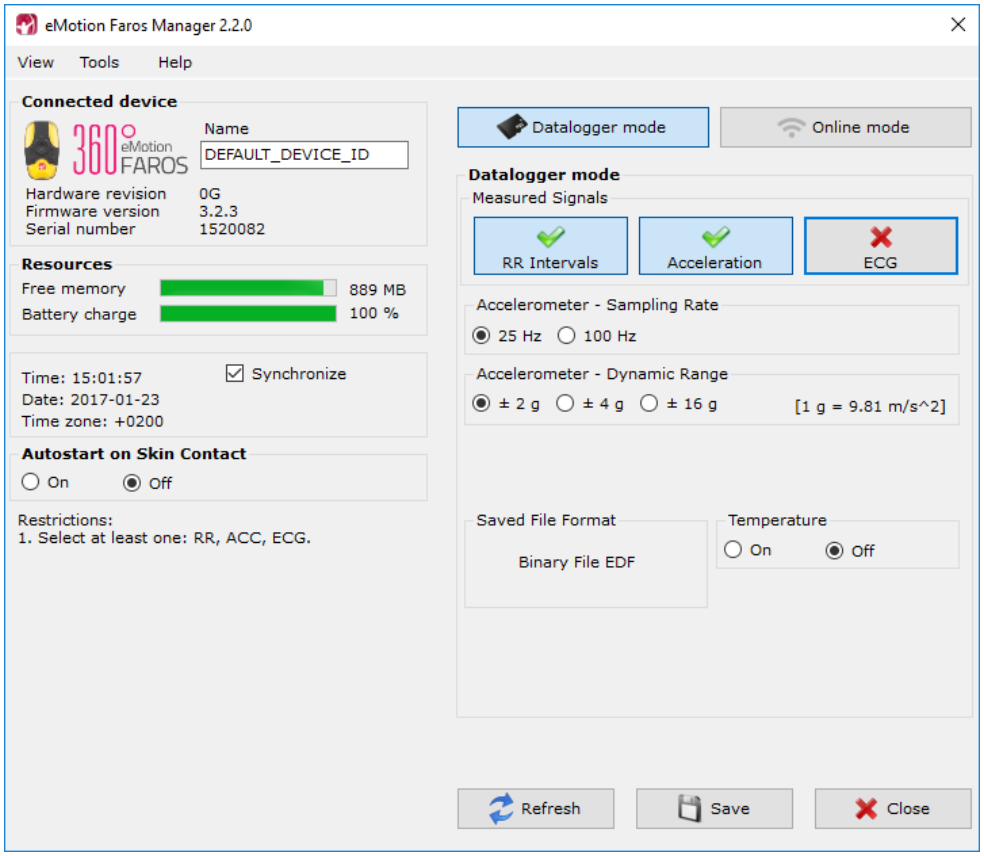


Figure 2.4.2-1: HRV configuration

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 eMotion Faros ECG Sensor has one pushbutton. The device starts when you push the button. The device is shutdown 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 (e.g. denat. 80% alcohol) or electrode preparation pads

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

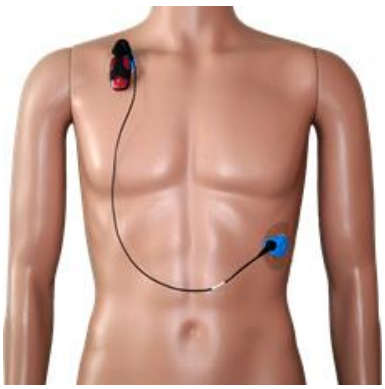
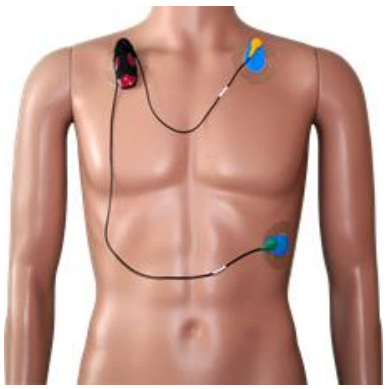
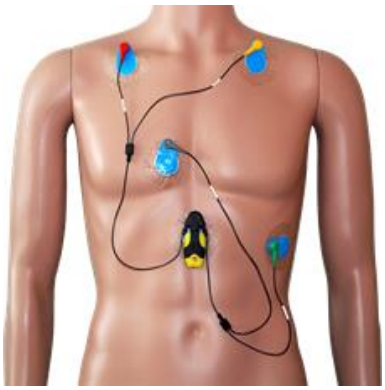
7. Attach the cables to corresponding electrodes (see electrode placement pictures in the next chapter 5.1.1 electrode position)
8. If necessary, the cables can be attached to the skin by tape. Notice that the tape should not touch the electrode

Step 4. Start the measurement:

9. Press the sensor button once
10. Green light indicator starts to blink – the sensors is now recording

5.1.1. Electrode Position and Lead Placement

The operator should be familiar with 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.

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

5.1.2. Positioning of the Fast-Fix electrode

The recommended position for the FastFix electrode is on the left border of the sternum as seen in the left side of the picture. If this positioning is not possible for some reason, the electrode can be placed diagonally on the left side of the chest, seen in the picture on the right.

Sternum position	Diagonally on chest position
	

5.1.3. Stingray and textile belt position

The heart rate belt is positioned under the chest muscle line as illustrated in the picture below

Belt position


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 of the device, including gravity, movement of the patient and movement caused by the environment, e.g. 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 (e.g. driving a bumpy road) can reflect on Accelerometer data when subject does not move. The accelerometer output is raw data. Accelerometer data is not analysed within the device or differentiated between various physical activities.

Figure 5.1.3-1: Accelerometer axis directions

6. Data Review with eMotion 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's recommended to install eMotion EDF Viewer to computer before use. Software installation package is located in Faros sensor internal memory Software – eMotion EDF Viewer – Installer folder. Run 'Setup' icon and follow installation instruction on screen.

NOTE! It's recommended to move 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 (Alternative 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 wanted folder and .edf-file and click ‘Open’

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

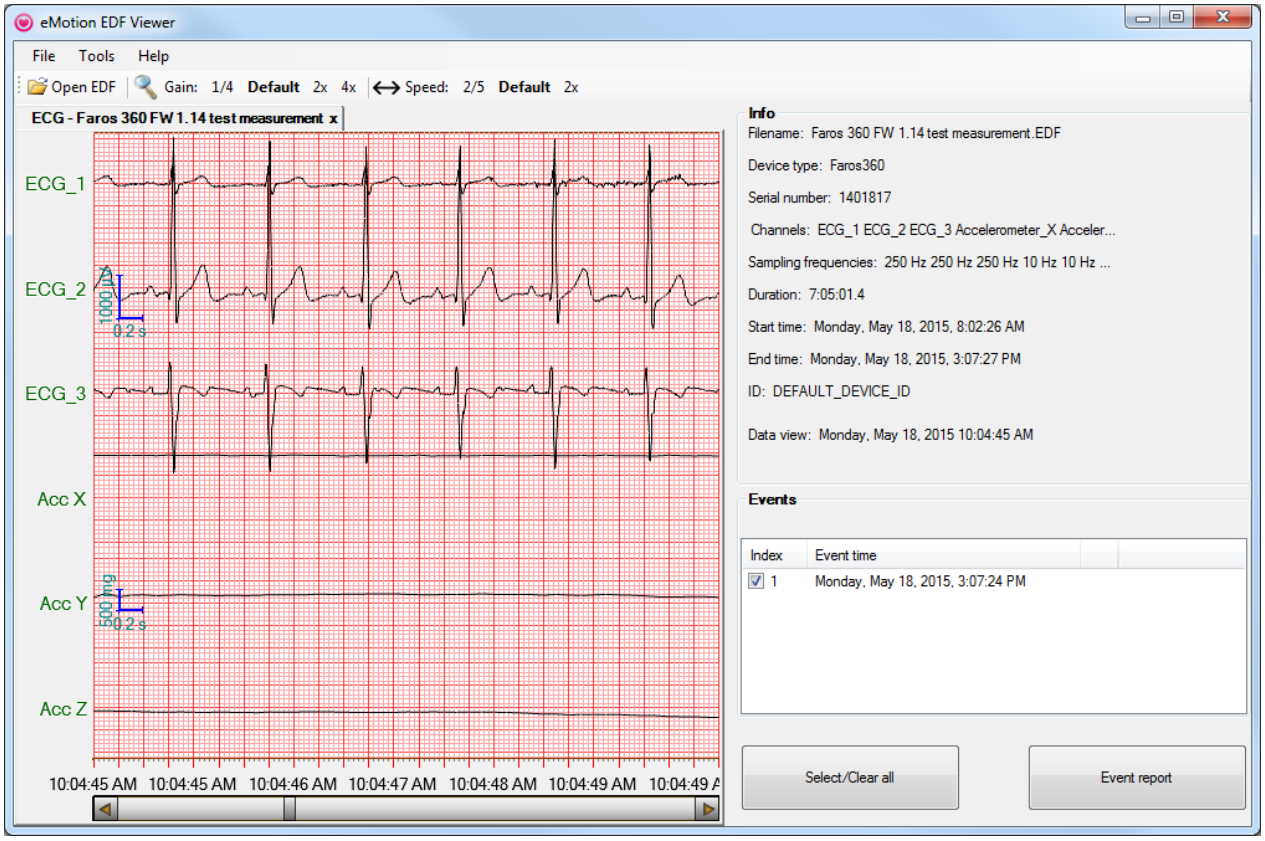


Figure 6.1.1-1: EDF Viewer data view

6.1.2. Accelerometer Data

The physical activity output is raw data from the in-built accelerometer of the Faros sensor. The data recorded by the accelerometer is used to recognize movement (e.g. sports, walking or other physical activity) from the measurement.

The accelerometer data itself does not have an effect on the ECG measurement data. In figure 6.1.2-1 and 6.1.2-2 can be seen the difference between ECG data during high physical activity period (e.g. sports) and low physical activity period (e.g. lying down).

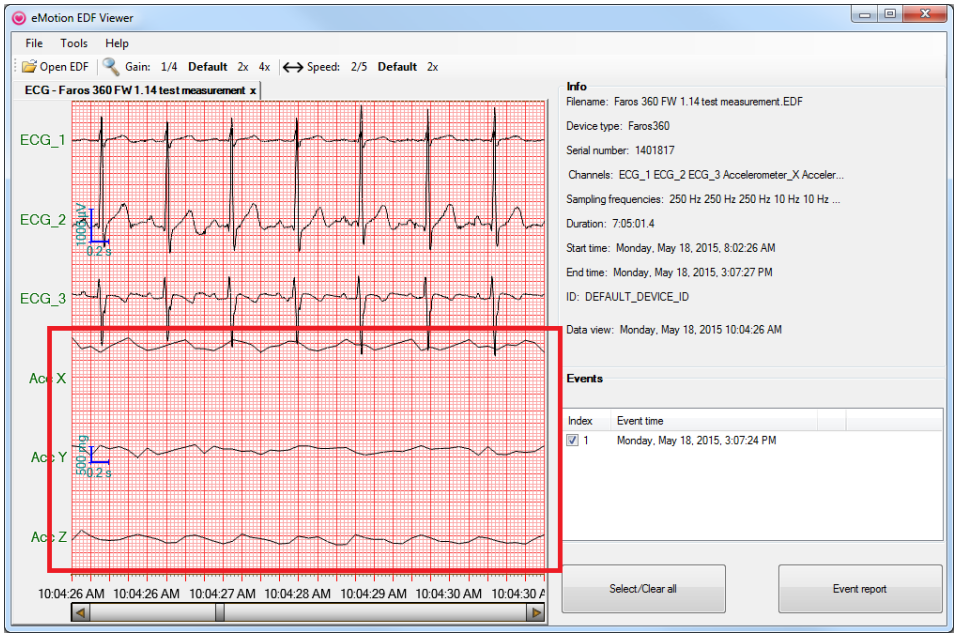


Figure 6.1.2-1: Accelerometer data with physical activity

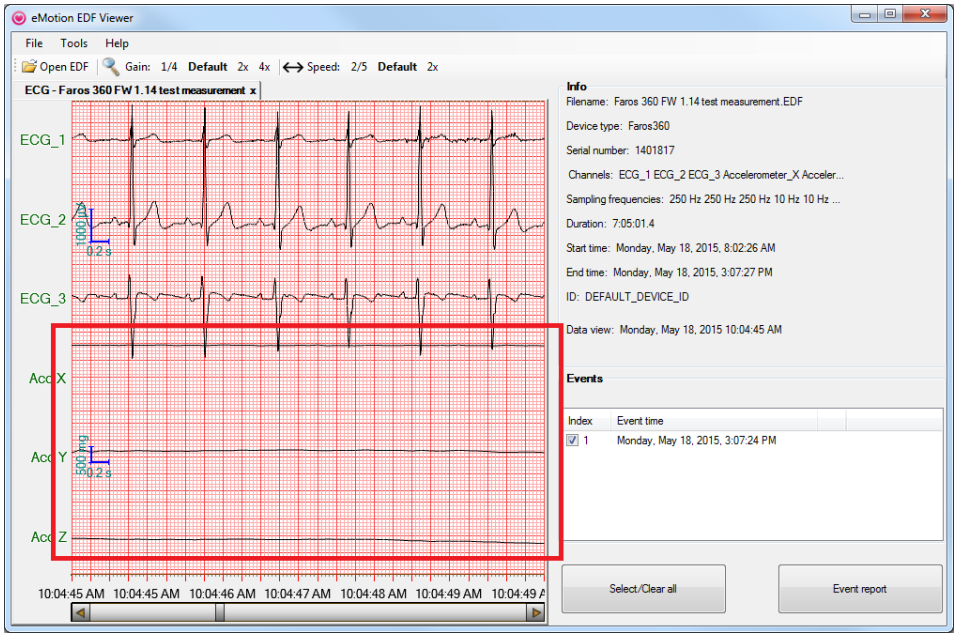
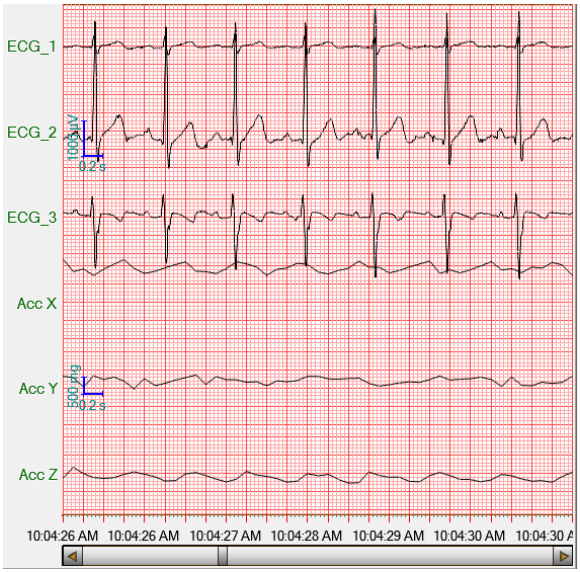
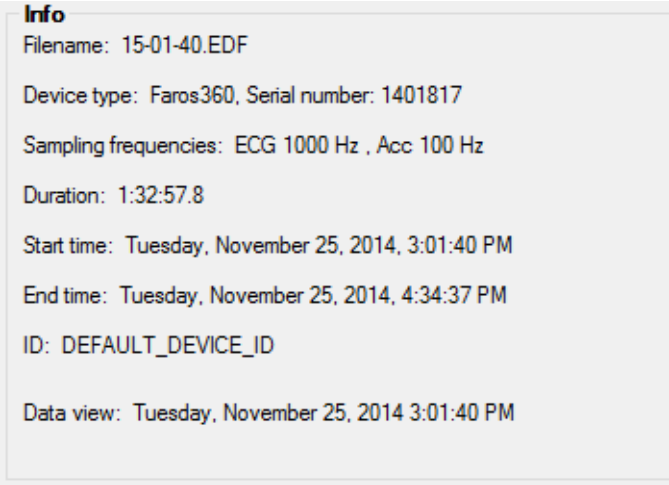
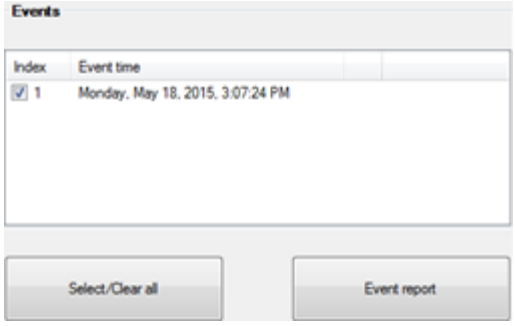
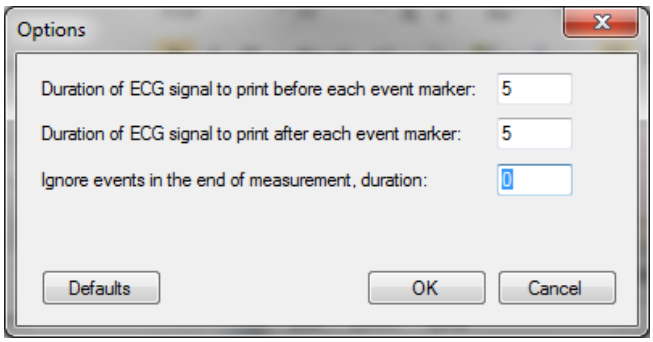
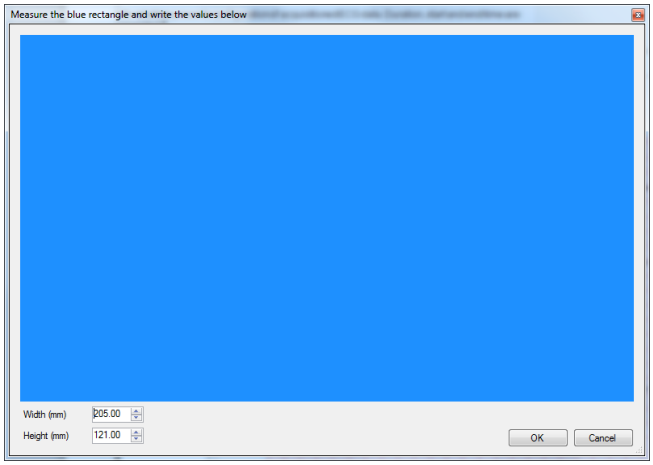
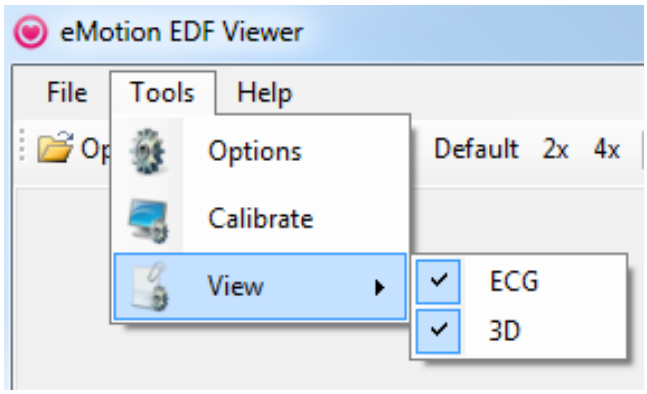
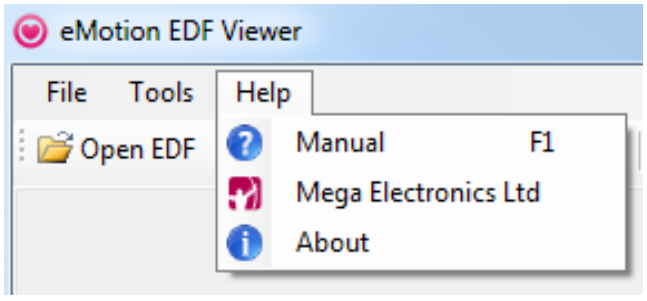


Figure 6.1.2-2: Accelerometer data without physical activity

User interface parts	
Data window presents the measured ECG data. Info window contains Faros sensor configuration which was used in measurement. Manually created events are listed in Event window.	
Info window presents configuration of acquisitioned ECG data. • 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 i.e. the date and time of current data in review window.	
Events window presents 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 separate window having options to print or save.	

6.2. eMotion EDF Viewer Menus

Menu options	
Tools, Options Event Report layout and parameters can be managed from 'Tools' → 'Option' 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 (i.e. ECG and physical activity (3D) can be reviewed if they are recorded. Before opening .edf-file press 'Tools' and 'View' to select presented signal types.	
Help Help menu contains software related information, link to manufacturer webpage and user manual.	

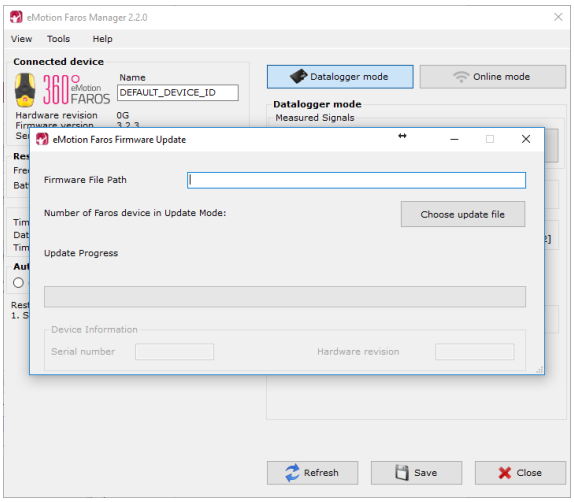
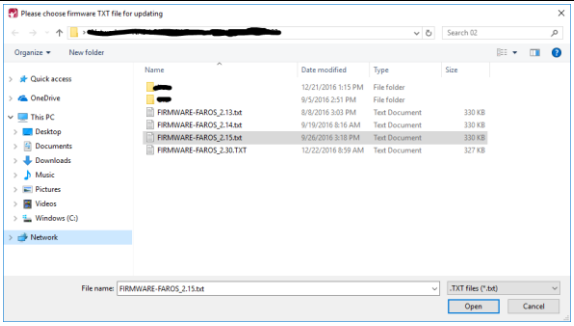
7. Maintenance and Service

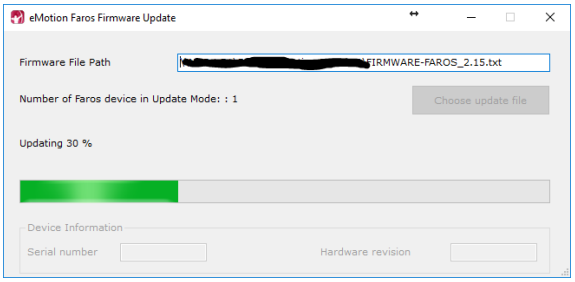
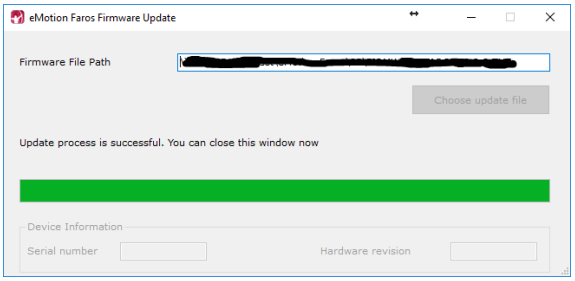
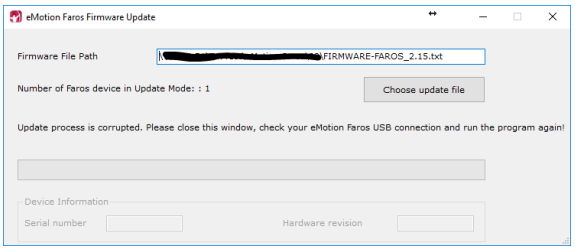
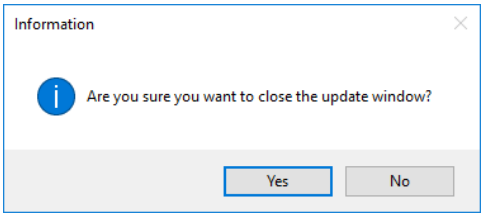
eMotion Faros ECG sensor doesn't require any particular maintenance procedure except recharging of the battery. For a correct functioning please follow these simple precautions:

- Handle this device carefully
- Store the device away from dusty or dirty areas
- Keep the device away from moisture or extreme temperature
- If there is moisture on sensor, let the sensor 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.

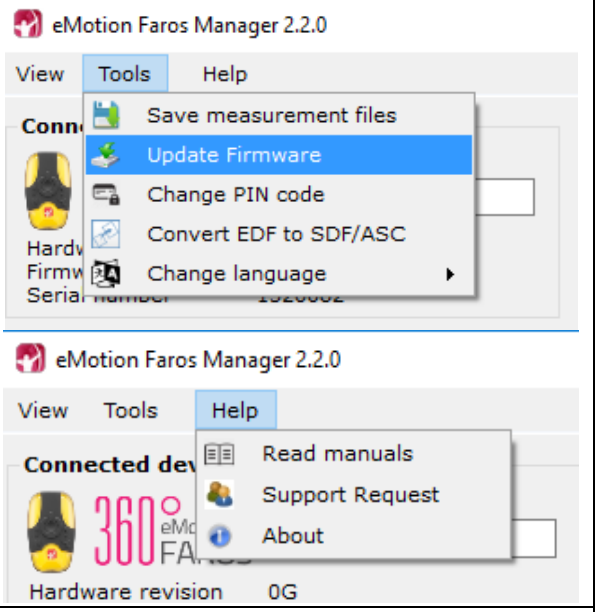
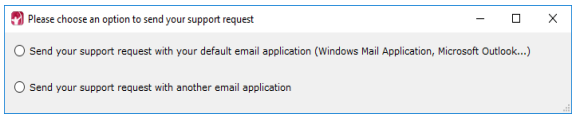
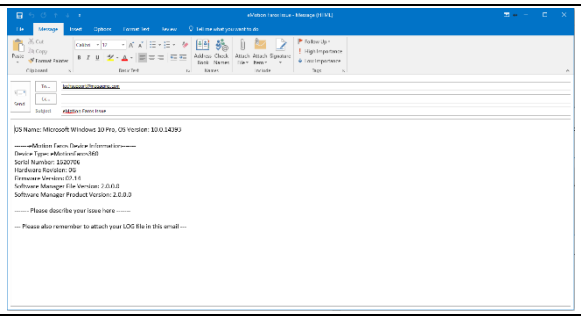
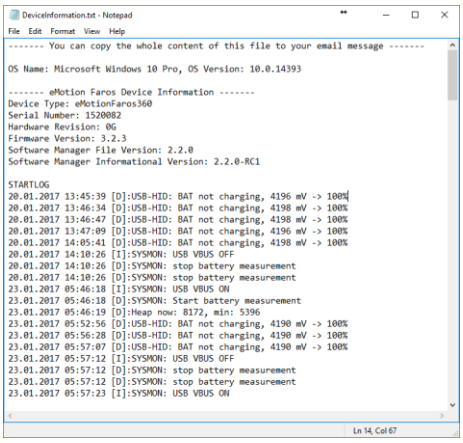
Do not try repair or modify the sensor. If you cannot solve the problem with the device, please contact medical.support@bittium.com for support.

7.1. Sensor firmware update

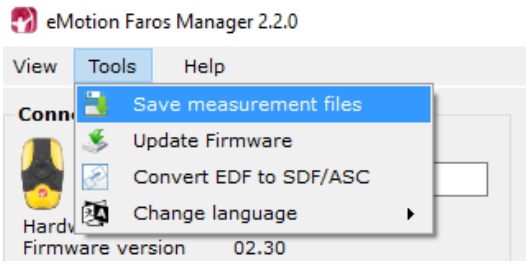
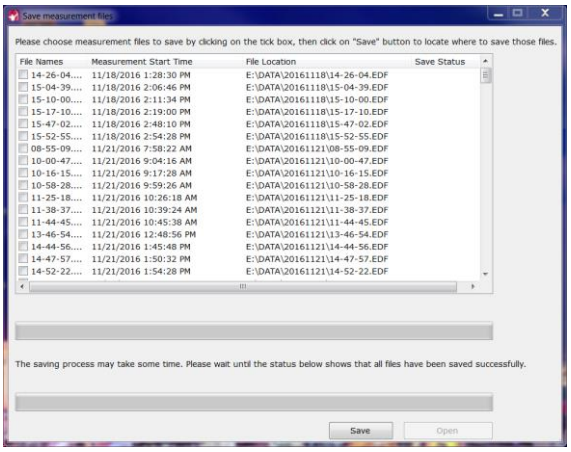
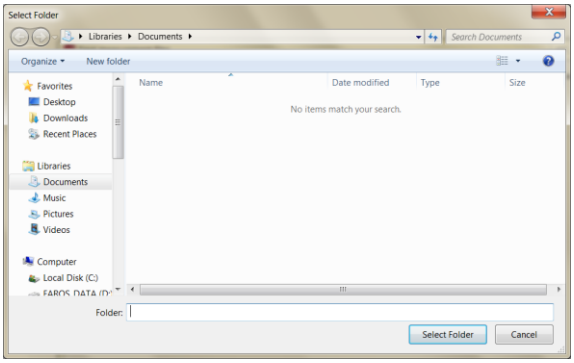
Actions to update sensor firmware	
Click 'Tools' on left top corner on Faros Manager main view Select 'Update Firmware' If device firmware version is not greater or equal to 3.x.x (for example: 1.x.x, 2.x.x), device will be automatically set to update state. In this state, only the red LED is on. If device firmware version is from version 3.x.x to later, the update firmware form will open without showing number of Faros device in Update Mode. In this case, red LED is NOT on until user have chosen firmware file. Click 'Choose update file'	
Choose the firmware file and click on "Open" button. The dialog is closed and the update process will start.	

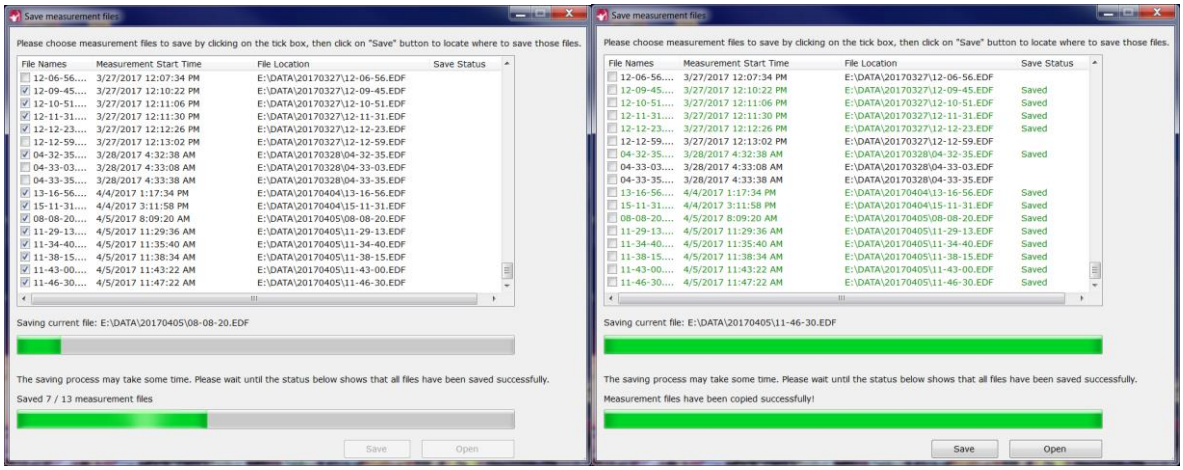
Device update process is illustrated by progress bar running from 0 % to 100 %. When device is updated at 100 % state, the software has to wait until it detects Faros connection and it may take 4-6 seconds for this step	
If the device is updated successfully, it will say that "Update process is successful. You can close this window now".	
If the update process IS NOT successful, it will show this line "Update process is corrupted. Please close this window, check your eMotion Faros USB connection and run the program again!"	
Close update window (choose the X icon at the top right side). Click on "Yes" button and the update process windows is closed and software goes back to the main interface.	

7.2. Options View

Actions to update sensor firmware	
The menu contains standard menu structure for manager view settings, tools and help. **Tools menu contain items:** Save measurement files Update firmware Change PIN code Convert EDF to SDF/ASC Change language **Help menu contains items:** Read manual Support request About	
In Customer Support section, when “Support Request” button is clicked, a form including two options appears. 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 user’s computer.	
For example, if Microsoft Outlook was installed in user’s computer then the software would show the message like this	
	

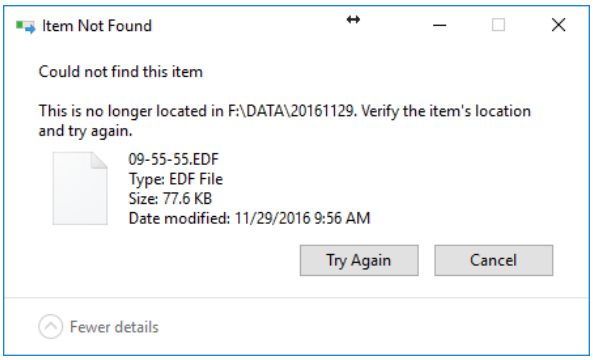
7.2.1. Save Measurement Files

Actions to Save Measurement Files	
This section provides users with instruction to choose and save measurement files from eMotion Faros device to their PC in a convenient way by using eMotion Faros Manager. First, click on "Tools" and choose "Save measurement files".	
Measurement files stored on Faros sensor memory are presented as shown in Figure 7.2.1-2. Click on checkbox with the files you want to save on your computer or local network. Then click "Save" button.	
Choose Save Location in computer or local network. Click "Select Folder" to save selected measurement files.	



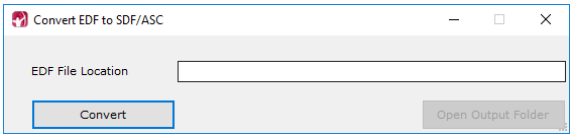
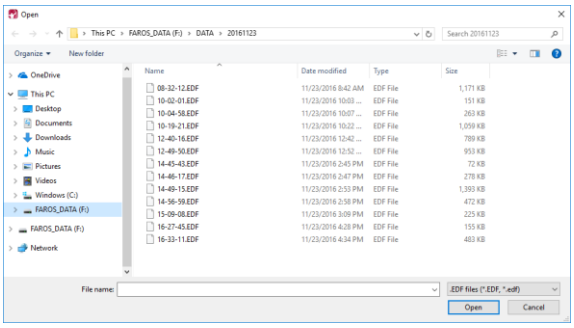
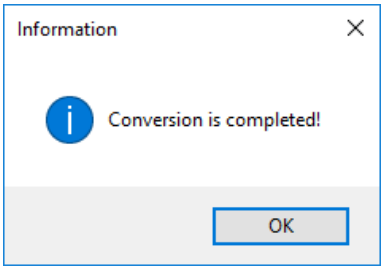
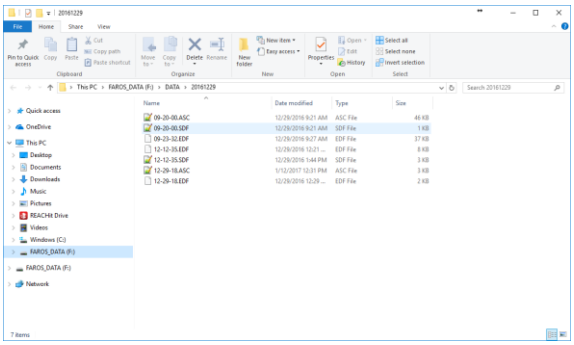
Copying process is presented file-by-file. If all measurement files are copied successfully, a message will be shown. You can click on "Open" button to open folder where files are saved.

During the copying process, if the USB connection between eMotion Faros device and PC corrupts and measurement files cannot continue to copy, a message may appear. In this case, you should check the connection, click on "Cancel" button, close "Save measurement files" form and do it again.



7.2.2. Convert EDF File Format to Suunto SDF file or ASCII File Format

eMotion Faros device stops supporting measurement in SDF/ASC format from firmware version 3.2.x. Instead, eMotion Faros Manager provides users with a new tool “Convert EDF to SDF/ASC” which helps in choosing and converting 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.

Actions to convert files	
First, click on “Tools” and choose “Convert EDF to SDF/ASC”. A small Windows form opens: Click on “Convert” button and a Windows dialog appears waiting for user to choose EDF files.	 
After choosing the EDF file, software starts to convert and save the converted file in the same folder as the EDF source file. If the conversion process is successful, a following message is shown:	
After this you can click on “Open Output Folder” for quick view of output SDF/ASC file location.	

7.3. Cleaning

7.3.1. eMotion Faros sensor, Stingray Adapter and Cable sets

The eMotion Faros ECG Sensor, Stingray adapter and cable sets can be cleaned by wiping device using a non-fluffing cloth dampened in cleaning fluid, such as mild hand soap solution, or in water. For disinfection can be used non-fluffing cloth dampened non-alcoholic disinfection fluid. Recommended way of cleaning: non-alcoholic cleaning and disinfection wipes for medical devices, such as 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!

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

7.3.2. Textile belt

When cleaning Textile Belt make sure that Stingray Adapter is detached. The Textile Belt can be cleaned in fresh water. It is recommended to hand wash textile belt in water after use.

Textile Belt can also be washed according to instructions on belt label!

- Maximum recommended wash temperature: 40°C / 104°F
- Do not bleach
- Do not spin or tumble dry
- Do not iron
- Do not dry clean
- Using a washing pouch is recommended

Figure 7.3.2-1: Belt washing instructions

8. Frequently asked questions (FAQ)

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 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 eMotion 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 with 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 a software from the device's hard drive. Alternatively you can use Faros Manager to save measurement files.

How can I reset my eMotion Faros device?

Start pressing the switch push button. Keep pushing 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. For further information on how to use Faros Manager, please see chapter 3.

Which data format I should 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 (HRV) and physical activity, you can choose between EDF and SDF. If you wish to save the HRV + 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 variety of software that can open these files. **SDF is not supported from Faros 3.2.x onwards.**

Firmware update is not working properly?

If firmware update process is normally finished but firmware is not upgraded, try again using another USB-port on your computer. Alternatively create a folder named SYS on Faros Data hard drive. Copy firmware file to SYS-folder. Disconnect sensor from computer and press push button until sensor resets. Update process is indicated with blinking green led.

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 heart rate belt, you should water the electrode surface of the heart rate belt 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 of the device. If you are making Heart Rate Variability (HRV) measurements and analysis, 250Hz or 125Hz is suitable sampling frequency for these measurements. If more accurate ECG data is needed for making ECG analysis and diagnosis, then it would be recommendable 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 eMotion 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 sensor before every measurement, or at least when the sensor has been on standby mode for several days.

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):	eMotion Faros 90
	eMotion Faros 180
	eMotion Faros 360
MDD Classification:	Class IIa

Following standards were used to meet requirements:

- EN60601-1 3rd edition (IEC601-1 3rd ed.) Medical electrical equipment. Part 1: General requirements for safety
- EN60601-1-2 3rd edition (IEC601-1-2 3rd ed.) Medical electrical equipment. General requirements for safety. 2. Collateral Standard. Electromagnetic compatibility - Requirements and safety
- ECG functions are evaluated using relevant parts of the EN60601-2-47:2012 standard, taking into account the intended use of the device.
- 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.

9.1.2. Intended Use

The eMotion 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.

eMotion 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 Mega.

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

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

Appendix 1. Electromagnetic Emissions

Manufacturer's Declaration - Electromagnetic Emissions		
The eMotion 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 eMotion Faros uses HF energy exclusively for its internal function. Thus the HF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

Appendix 2. Electromagnetic Immunity

Manufacturer's Declaration – Electromagnetic Immunity			
The eMotion 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.			
Interference Resistance Test	IEC 60601- Testing Level	Accordance Level	Electromagnetic Environment – Guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. The use of antistatic materials or higher relative humidity is recommended.
Fast transient electric disturbances / bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	Not applicable	
Surge voltage acc. to IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	Not applicable	
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11	< 5 % UT (>95 % break of UT for 0,5 period 40 % UT (60% break of UT) for 5 periods 70 % UT (30% break of UT) for 25 periods < 5 % UT (>95 % break of UT for 5 seconds	Not applicable	
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	Not applicable	

Manufacturer's Declaration - Electromagnetic Interference Resistance			
The eMotion 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.			
Interference Resistance Test	IEC 60601-Testing Level	Accordance Level	Electromagnetic Environment - Guidelines
			Portable and mobile radio sets should be used in a no less distances to the device including the cables than it is recommended by the equation for the frequency. Recommended safety distance:
Conducted HF disturbances acc. toIEC61000-4-6	3 Vrms 150 KHz to 80 Mhz	Not applicable	
Radiated HF disturbances acc. to IEC61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=1.2 800 MHz to 2.5 GHz P is the nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer; d is the recommended safety distance in meters (m). (a)The field strength of stationary transmitters should be lower than the accordance level for all frequencies according to a testing on location. (b)Disturbances are possible near devices with the following symbol: 
NOTE 1: For 80 Hz and 800 MHz the higher frequency range is valid. NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.			
a) The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. To detect the electromagnetic environment in regard to stationary transmitters a study of the location should be considered. If the measured field strength at the location where the device is being used exceeds the accordance level above the device should be watched to verify the proper functions. If unusual features are watched additional actions might be necessary such as a modified orientation or another location of the device. b) For the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.			

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