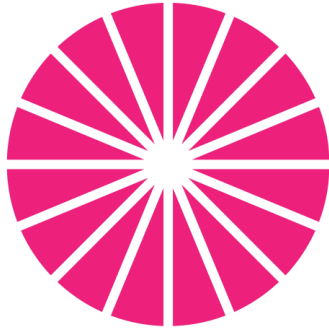




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800778-1.4 eMOTION FAROS SERIES MANUAL
DATE OF ISSUE: JUNE 26, 2015



eMotion FAROS

Leading the way
to wellness

180°
eMotion
FAROS

360°
eMotion
FAROS

90°
eMotion
FAROS



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1. Introduction

The eMotion Faros Sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

Faros sensor is a compact wireless solution for Electrocardiography (ECG) and Heart Rate Variability (HRV) applications. The Sensor records data acquisition or communicates remotely with Bluetooth enable device. ECG and HRV measurements can be done 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. Before operating the eMotion Faros, please read this manual thoroughly and retain it for future reference.

The eMotion Faros Sensor can be used with eMotion EDF Viewer and eMotion Faros ECG Mobile software. Measurement configurations are managed with eMotion Faros Manager.

In addition, the Faros sensors can be integrated to existing systems utilizing the Faros Bluetooth Communication API. Contact us for further information.

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 operates solely on acquisition of Electrocardiograph and Physical Activity data
- ⇒ Sensor does not have any electrical stimulation capabilities
- ⇒ eMotion Faros does not provide any automatic analysis or diagnosis
- ⇒ Accelerometer data is not analyzed within the device or differentiated between various physical activities
- ⇒ **eMotion Faros users in the USA please note: For prescriptions use only**

1.2 Warnings

- ⇒ Sensor is not suitable for direct cardiac application
- ⇒ Do not attempt self-diagnosis or self-treatment based on acquisition 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



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



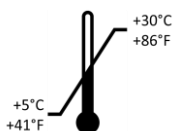
For EU only: This symbol indicates that this device shall be disposed according to European Union directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)



Faros users in the USA please note: For prescriptions use



Consult Instruction for use



Storage: +5°C...+30°C (+41°F...+86°F)



During transportation: keep package dry, protect from rain



Note symbol in manual: These statements identify condition or practices that could result in performance loss of the equipment or must be otherwise paid attention to.

2. Faros ECG Sensor overview

2.1 General

eMotion Faros device series is an innovative tool for monitoring ECG, HRV (Heart Rate Variability), stress, recovery and general well-being. Lightweight (13 grams), smoothly designed (48 x 29 x 12 mm) and easy to use eMotion Faros is ideal for instant measurements and also for long-term follow-up. All eMotion Faros devices and mounting options offer the user friendly technology on Electrocardiography, Heart Rate Variability and physical activity monitoring.

90° eMotion
FAROS



180° eMotion
FAROS



360° eMotion
FAROS



Sensor Specifications

“Simple stress and Recovery Monitoring”

- Heart rate variability
- Physical Activity
- ECG offline (holter)
- 1 GB memory
- Memory capacity up to 2 months measuring
- Rechargeable battery
- USB download
- HRV Sampling rate 1000 Hz
- ECG sampling rate up to 250 Hz

“Advanced well-being measuring system”

- Heart rate variability
- Physical Activity
- ECG online/offline
- 1 GB memory
- Rechargeable battery
- Bluetooth
- USB download
- HRV Sampling rate 1000 Hz
- ECG Sampling rate up to 1000 Hz

“All-inclusive monitoring of mind and body”

- Heart rate variability
- Physical Activity
- ECG online/offline
- Temperature
- Breathing
- 3 channel ECG
- 1 GB memory
- Rechargeable battery
- Bluetooth
- USB download
- HRV Sampling rate 1000 Hz
- ECG Sampling rate up to 1000 Hz

Figure 1: Sensor Specifications

2.2 Accessories and Replacement Parts



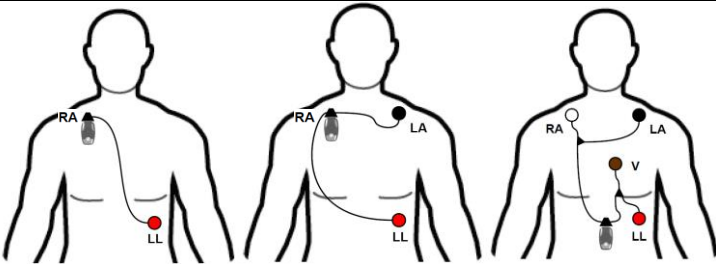

Part		Part number
<p>USB cable is used to data transfer and re-charging the battery. To manage Sensor settings connect eMotion Faros to PC via USB cable.</p>		900826
<p>Stingray Adapter and Textile Belt are used for one channel ECG acquisition. For further information see chapter 4.1.</p>		<p>Textile Belt: 900810</p> <p>Stingray Adapter: 900809</p>
<p>Electrode Leads are connected to electrodes placed on patient skin. Lead transfer acquisition data to ECG sensor. For further information see chapter 4.2.</p>		<p>2-electrodes 900865</p> <p>3-electrodes 900866</p> <p>5-electrodes 900867</p>
<p>The additional 8 slot docking station enables to re-charge 8 devices at the same time. The 8 slot docking station is connected to computer via USB Cable.</p>		VP00489

Figure 2: Accessories and replacement parts

2.3 Faros Technical Specification





Technical Specifications			
			
HRV Sampling Frequency	1000 Hz	1000 Hz	1000 Hz
ECG Sampling Frequency	100, 125, 250 Hz	100, 125, 250, 500, 1000 Hz	100, 125, 250, 500, 1000 Hz
ADC Precision	14 bits	14 bits	24 bits
3D Accelerometer Precision	14 bits	14 bits	14 bits
3D Accelerometer Sampling Frequency	10, 25, 50 Hz	10, 25, 50, 100, 200, 400 Hz	10, 25, 50, 100, 200, 400 Hz
Datalogger File Format	SDF/ASC and EDF	SDF/ASC and EDF	SDF/ASC and EDF
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 three (3) days HRV and Acc datalogging Up to three days (3) ECG: 250 Hz Acc: 10 Hz	Up to three days (3) ECG: 250 Hz Acc: 10 Hz Up to two (2) days ECG: 1000 Hz Acc: 200Hz	Up to three days (3) ECG: 250 Hz Acc: 10 Hz Up to two (2) days ECG: 1000 Hz Acc: 200Hz





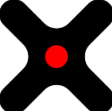
Figure 3: Faros Technical Specification

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

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2.4 Sensor Light Indicators and States

Sensor Light Indicators

	Pushbutton, powers sensor on / off
	Battery Indicator <i>Blue Light</i>
	Measurement and Power on Indicator <i>Green Light</i>
	Caution Indicator <i>Orange Light</i>
	Error Indicator <i>Red Light</i>



Sensor States

State	Light indicator
Battery charging	Battery Indicator light blinks
Battery is full	Battery Indicator light light shine continuously
Measurement, start	Green light until the signal is recognized
Measurement	Measurement and Power on Indicator light blinks
Measurement, battery near empty	Caution Indicator is blinking at the same time with the green light
Shutting down	Caution Indicator blinks 5 seconds and green light shine before shut down
Error	Error Indicator light shine continuously
Reset	All Light Indicators flash (to reset device see chapter 4.2)
Device clock not synchronized	Error Indicator blink three times when trying to switch the device on
Battery running low	Battery indicator starts to blink during measurement session
Buffer memory full (online mode)	Error Indicator blinks during measurement

Figure 4:Sensor state listing

2.5 Recharging the Battery

USB Cable

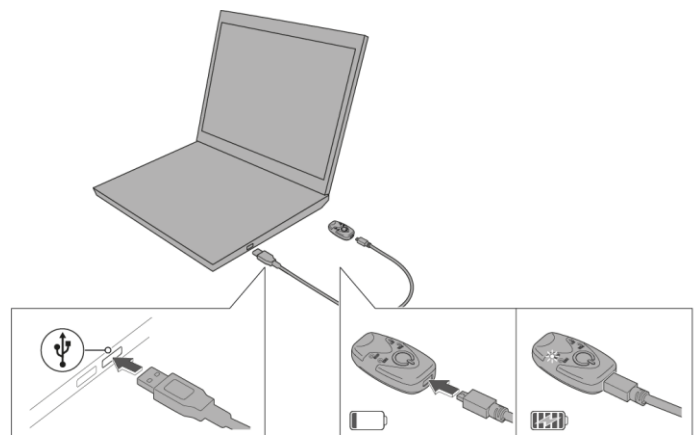
It is recommended to recharge the battery to full capacity before conducting operations or performing data acquisition with the device



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 or scrap paper towel and remove it.

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



Faros Base Charger Station

Connect Charger Station to PC via USB Cable delivered with Charger Station. Cable is connected correctly when the Base 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.



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 5: Faros 180 sensors placed on Charger Station

2.6 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.Measurement Preparation

With Faros Sensor Manager it is possible to change acquisition configuration. Electrocardiograph data acquisition is possible to perform in offline data logger mode. Data is logged in SDF/ASC or in EDF -format.

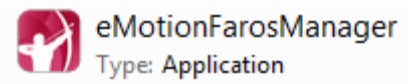
Online data acquisition is possible to perform with Faros 180 and Faros 360 models. Bluetooth data acquisition is supported with eMotion ECG Mobile software (LiveECG application).



User can make markers to measurement by pressing 
Saved file format must be EDF.

eMotion Faros Device Manager Overview

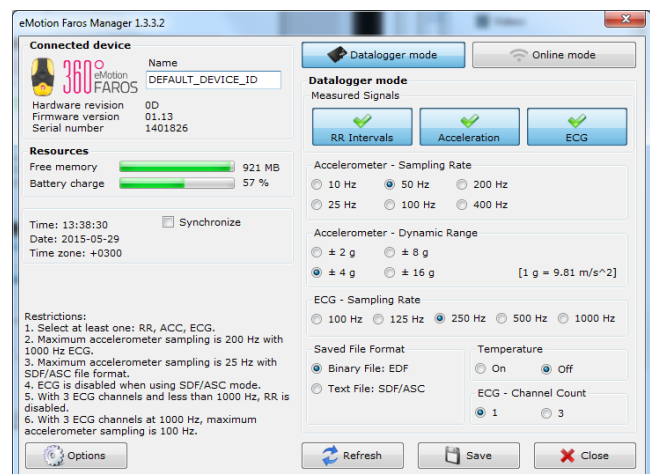
- ⇒ Connect your eMotion Faros Sensor to computer via USB Cable and wait until Windows has finished the installation of the device drivers
- ⇒ Check that 'Measurement and Power on Indicator' shine continuously
- ⇒ Browse to FAROS_xxx hard drive and open the "Software" folder from the hard drive. Open eMotion Faros Manager folder and run 'eMotionFarosManager'.
- ⇒ Set the configuration which you want to use for data acquisition



Example Settings are presented in chapters:
3.1 Offline ECG Data Acquisition
3.2 Online ECG mode
3.3 Heart Rate Variability Acquisition



Faros Manager recognizes the model of connected eMotion Faros sensor and present configuration options based on sensor model.



- ⇒ If you wish to synchronize the clock of the device select 'Synchronize' before saving the settings. **Before first use of the device clock must be synchronized.**

- ⇒ When you are ready press 'Save' button to apply setting



- ⇒ Press 'Close' to exit application



3.1 Offline ECG Data Acquisition

Offline ECG Data Acquisition can be performed with every Faros model. Configuration for ECG data logger mode is set using Faros Device Manager.

1. Open eMotion Faros Manager (eMotion Faros Manager is located on Faros internal memory)
2. Select 'Datalogger mode' from Manager view
3. Select wanted acquisition parameters
 - RR Intervals
 - Accelerometer
 - ECG
4. Select values for acquisition parameter
 - Accelerometer Sampling
 - Accelerometer Dynamic Range
 - ECG Sampling Frequency
5. Select 'Saved File Format'
 - Binary file: EDF (European Data Format)
 - RR-Data: SDF / ASC
- 6. Temperature (ONLY with Faros 360)**
- 7. ECG Channel count (ONLY with Faros 360)**
8. Synchronize clock (if wanted)
9. Press 'Save' to apply the configuration

Now your Faros sensor is ready to perform offline ECG data acquisition.

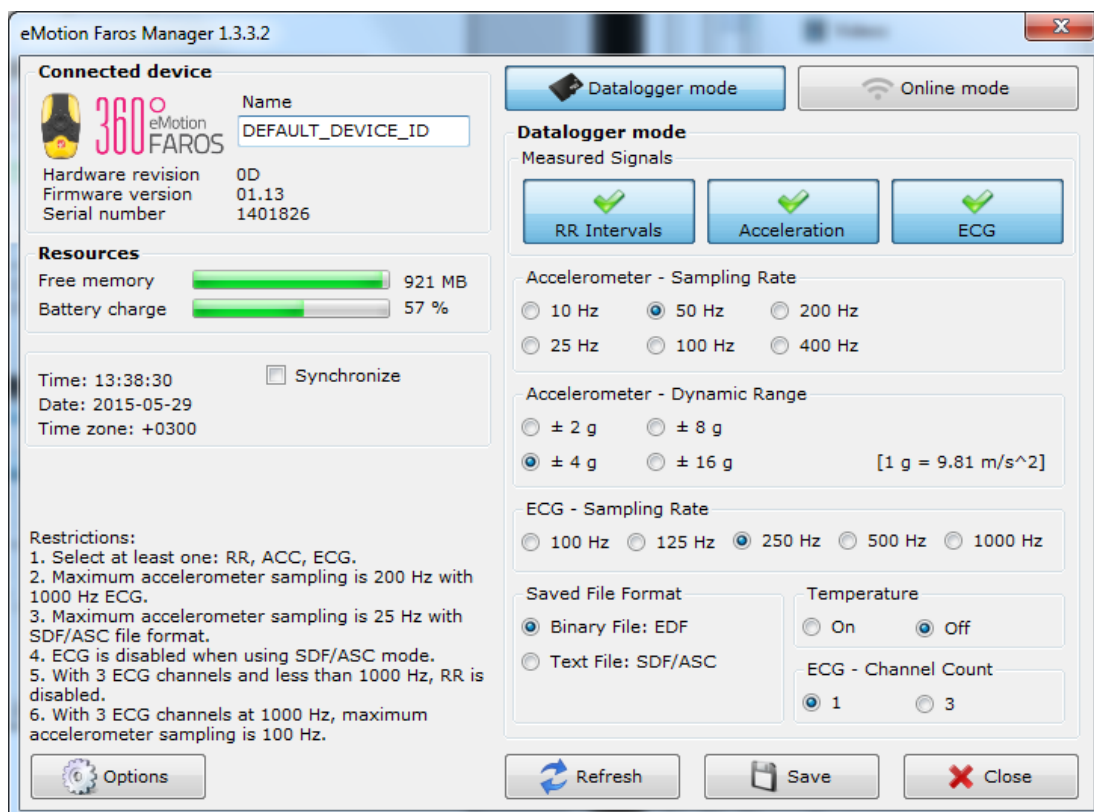


Figure 6: Example Configuration for ECG data logging with Faros 360

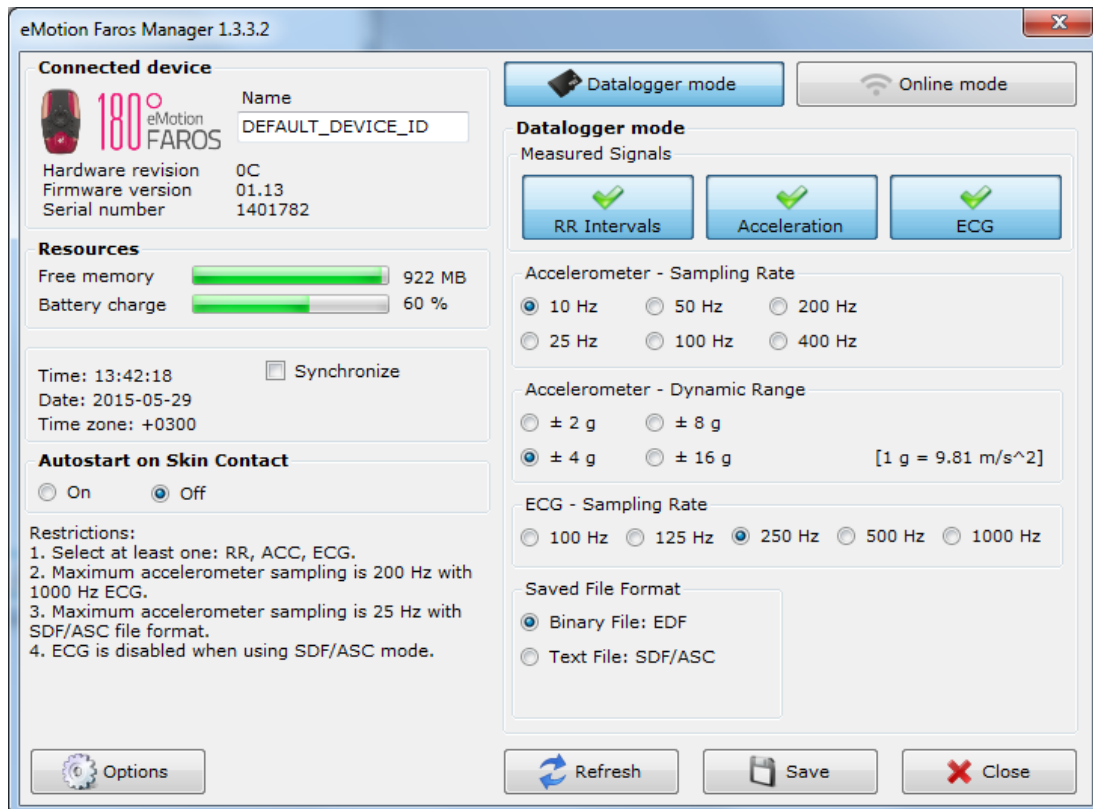


Figure 7: Example Configuration for ECG data logging with Faros 180

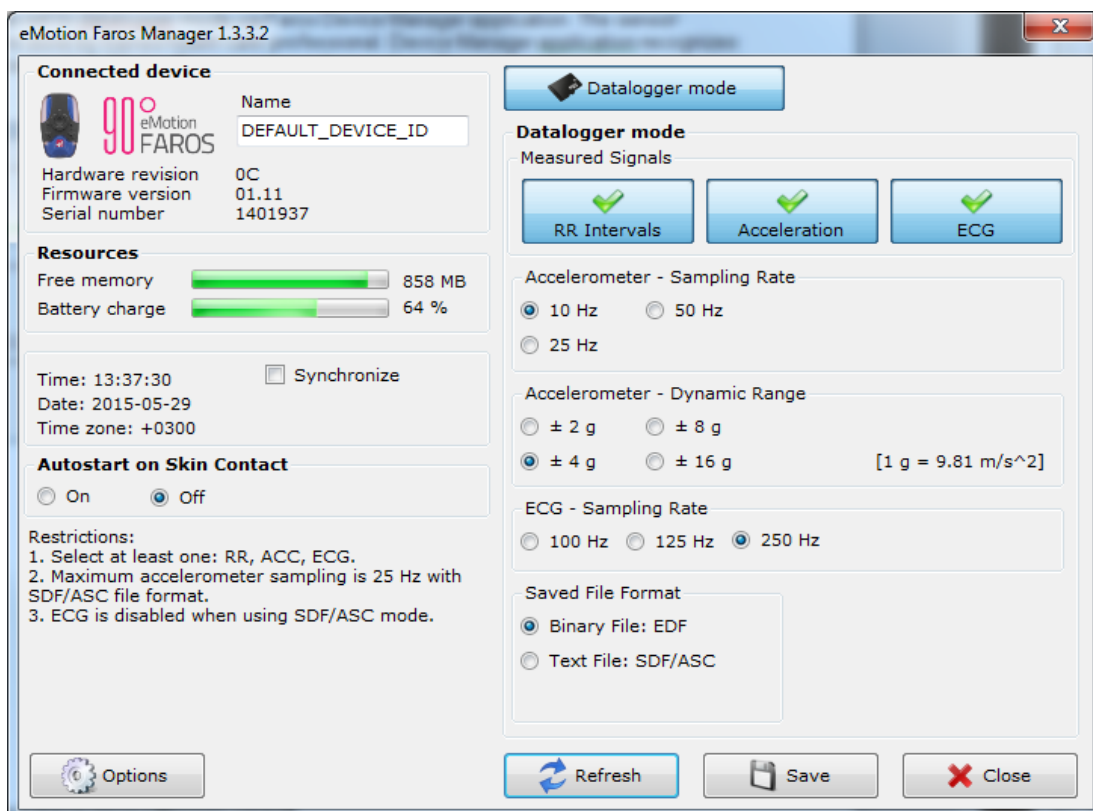


Figure 8: Example Configuration for ECG data logging with Faros 90

3.2 Online ECG Mode

Online ECG Data monitoring can be performed using Faros 180 or Faros 360 Sensor. Configuration for online mode is set using Faros Device Manager.

1. Open Faros Device Manager (eMotion Faros Manager is located on Faros internal memory)
2. Select 'Online Mode' from Manager view
3. Press 'Save' to apply configuration

Now your Faros sensor is ready to perform Online ECG data monitoring.



If you are using Faros sensor with mobile device and LiveECG application refer to 800699 Android LiveECG UserGuide for further information.

NOTE: Online mode measurement parameters can be modified through Bluetooth with the used software.

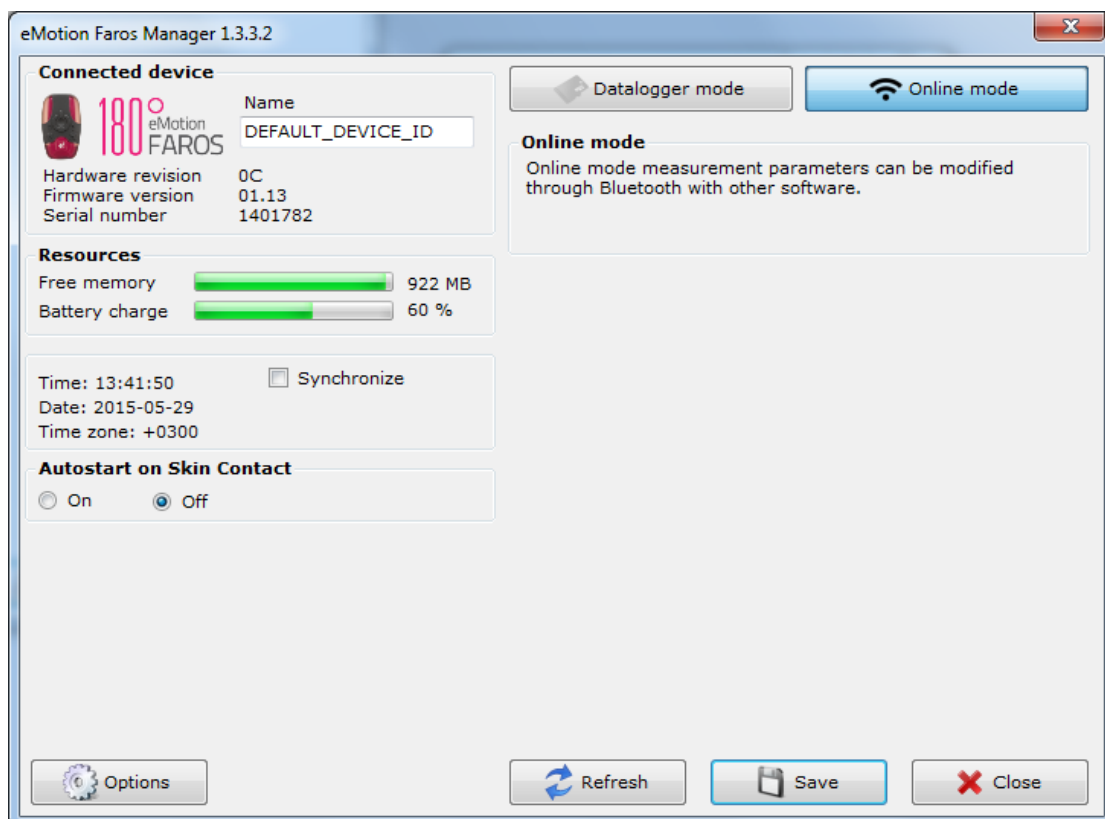


Figure 9: Online ECG monitoring setup

3.3 Heart Rate Variability Acquisition

Heart Rate Variability data acquisition can be performed with every Faros model. Setup for data logger mode for HRV acquisition can be set using Faros Device Manager.

1. Open Faros Device Manager (eMotion Faros Manager is located on Faros internal memory)
2. Select 'Datalogger mode' from Manager view
3. Set wanted acquisition parameters
 - RR Intervals
 - Accelerometer
 - ECG
4. Select values for acquisition parameter
 - Accelerometer Sampling
 - Accelerometer Dynamic Range
 - ECG Sampling Frequency
5. Select 'Saved File Format'
 - Binary file: EDF (European Data Format)
 - Text file: SDF/ASC
6. Synchronize clock (if wanted)
7. Press 'Save' to apply configuration

Now your Faros sensor is ready to perform Heart rate variability data acquisition.

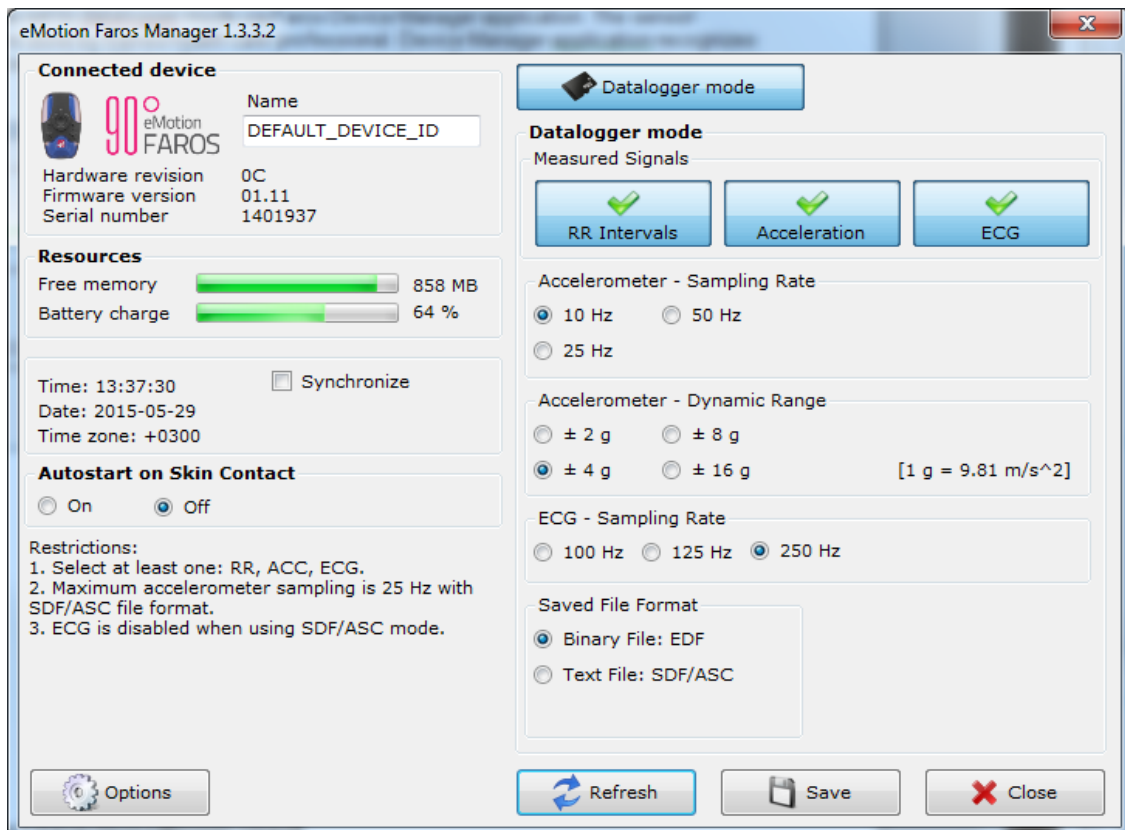


Figure 10: Example of eMotion LAB compatible setup for HRV Acquisition

Note: If you are recording only HRV data, remember to unselect ECG Data



4.Measurement

The eMotion Faros ECG Sensor has one pushbutton.

- The device starts when you push the button.
- The device shutdown when you push the button continuously for 5 sec.

Faros ECG sensor provides several different measurement options. Measurement options and Faros wearing instructions are described below.

- ⇒ If you are using disposable electrodes remember always to place electrodes on intact, clean and dry skin. Shave off excess body hair if needed
- ⇒ Place Cable Set or Stingray Adapter to Faros Sensor connector
- ⇒ Place Cable set or Stingray-Textile Belt on subject's chest
- ⇒ Start data acquisition by pressing pushbutton
- ⇒ Stop data acquisition by pressing pushbutton until green light indicator shine continuously (for 5 sec) then release pushbutton



For further information of using Cable Set and Stingray adapter see chapters 4.1 and 4.2

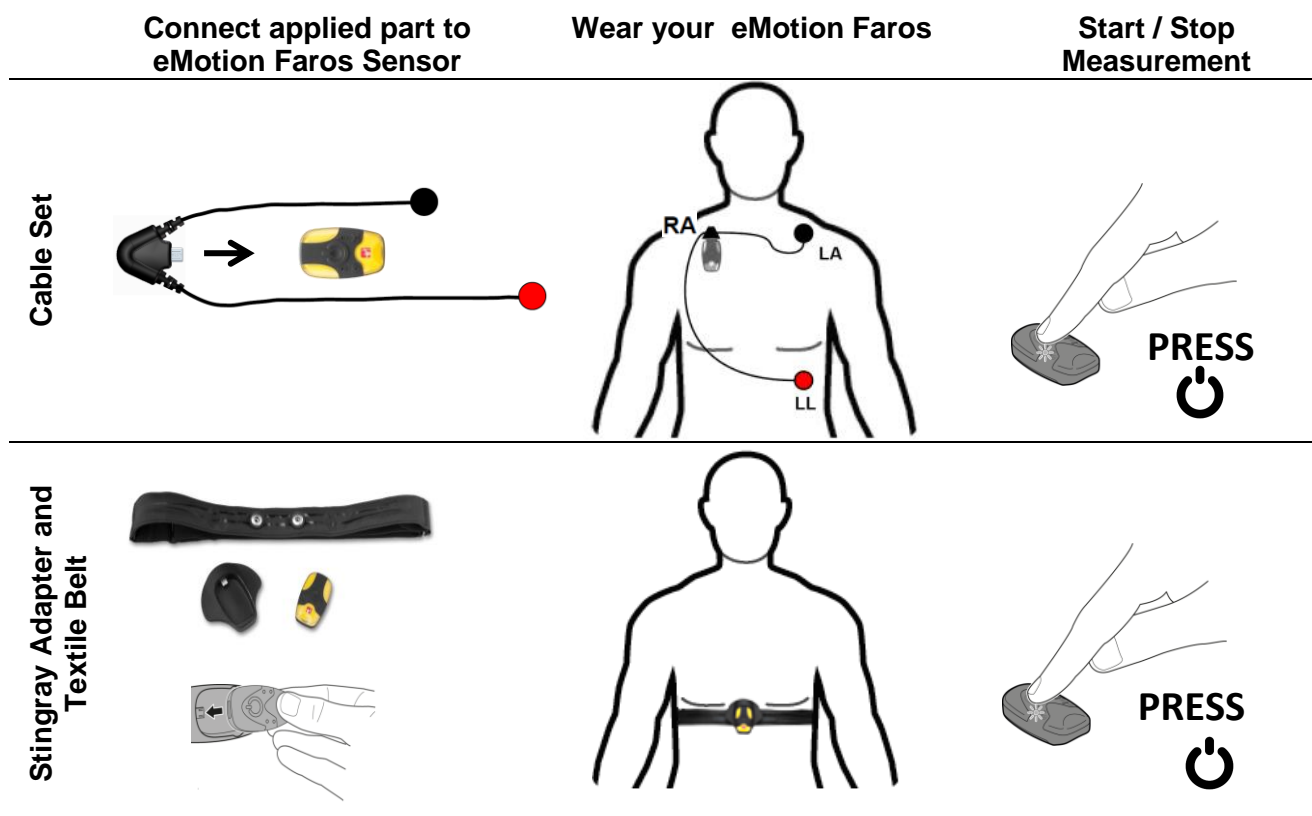


Figure 11: Quick view of ECG sensor placement

4.1 ECG Electrode Placement

The eMotion Faros Sensors are compatible with 4 mm snap connector ECG Electrodes, like Ambu Blue Sensor M-00-S or VLC-00-S. Place the electrodes on the subject according to the instructions illustrated in Figure 12-14 and connect the snap connector electrode wires to the electrodes.



The user should be familiar with correct placement of electrodes. Failure to correctly place the electrodes will weaken the data acquisition reliability.

The quality of an ECG measurement depends on preparation and the skin-electrode resistance value. To ensure quality of ECG and to minimize skin-electrode resistance, follow these casual instructions.

- ⇒ Place electrodes on intact, clean and dry skin. Shave off excess body hair from electrode are, if needed
- ⇒ Thoroughly clean the area with alcohol,
- ⇒ Let area dry before applying electrodes.

- ⇒ Figures 12-14 presents illustrative position of electrode placement
- ⇒ A and B set-up are for 1-channel ECG data acquisition.
- ⇒ C set-up is for 3-channel ECG data acquisition with Faros 360.

ECG Electrode Placements

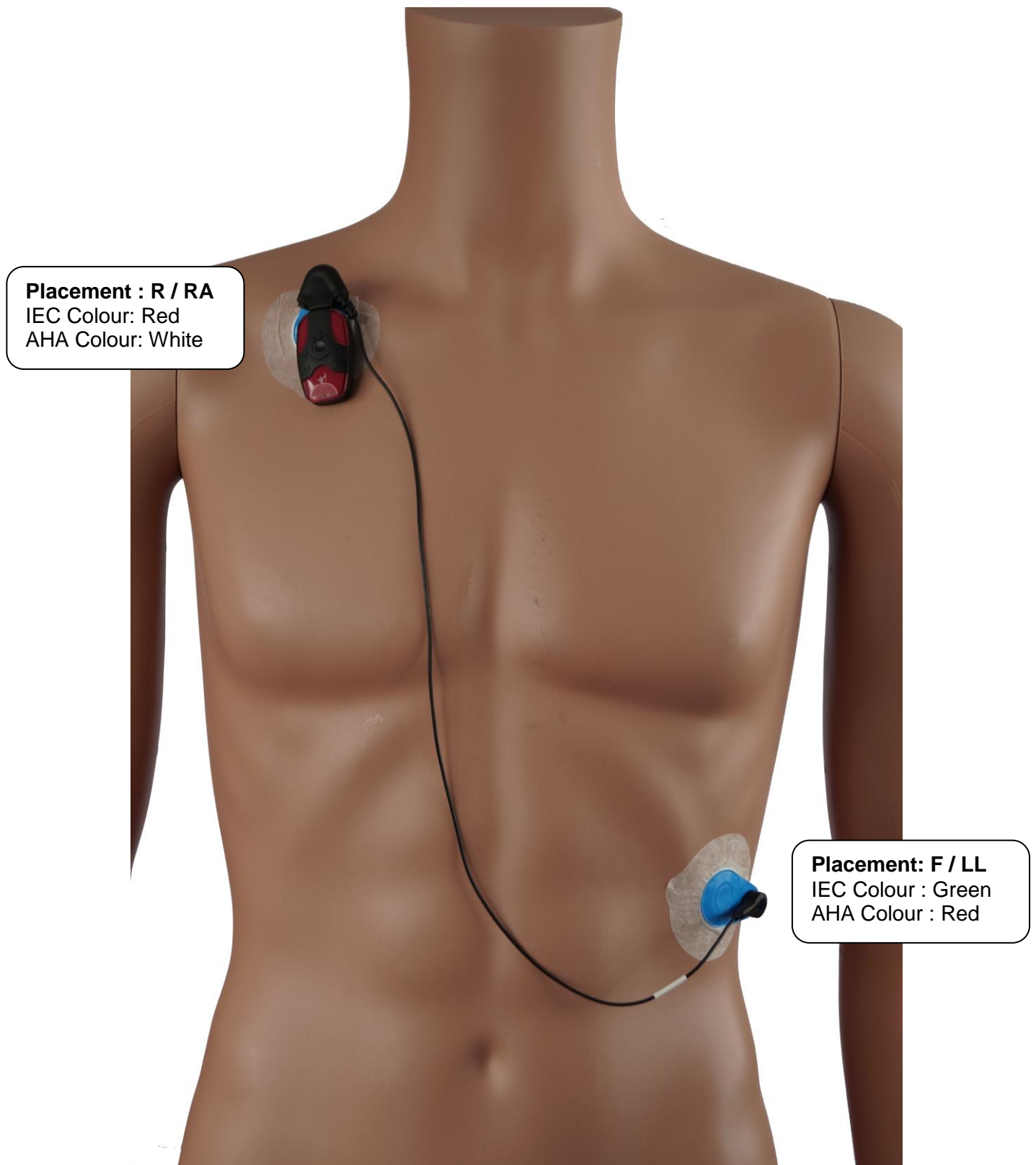


Figure 12: 2-electrode cable set placement

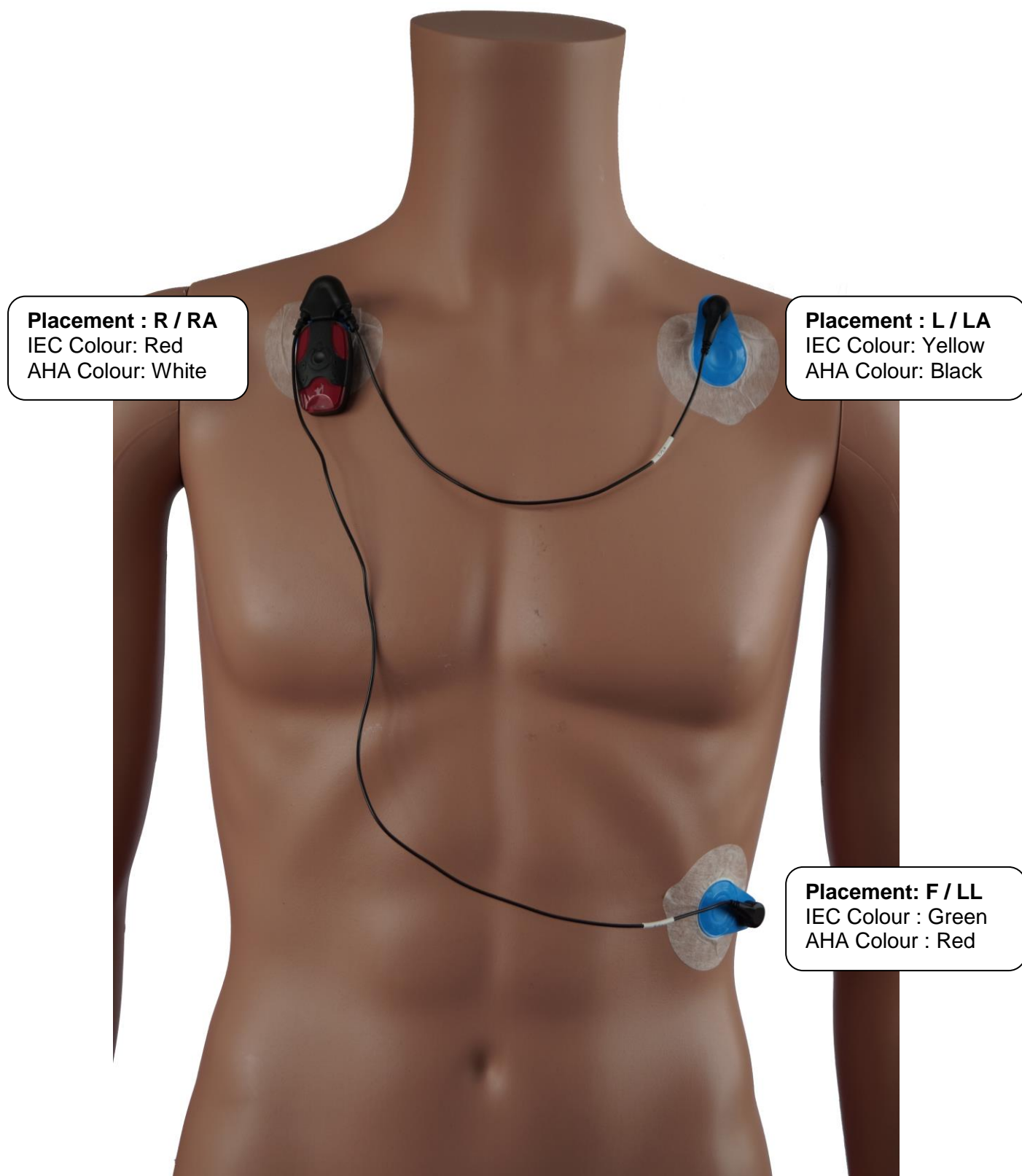


Figure 13: 3-electrode cable set placement

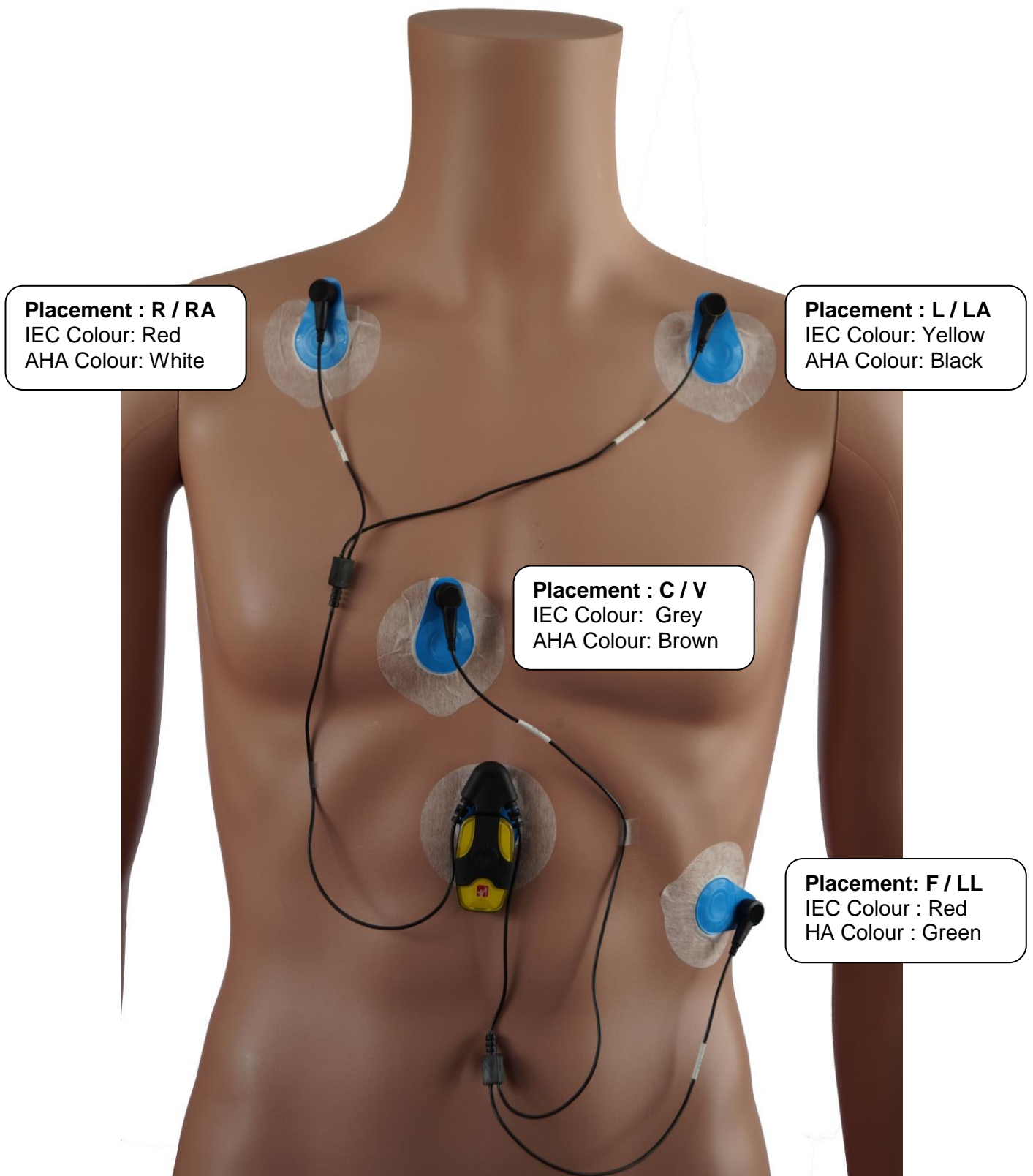


Figure 14: 5-electrode cable set placement

4.2 Stingray adapter and Textile Belt Placement

Faros sensor with Stingray Adapter and Textile Belt can be used to one channel ECG and HRV data acquisition. Connect Faros ECG Sensor to Stingray Adapter. Connect adapter to Textile Belt. Moisten well the belt's electrode areas with water. Wear textile belt under chest muscle line as shown in Figure 17.

Check that the wet electrode areas are against your skin and that the Stingray connector is in a central and upright position as shown in in Figure 15 and 16.



With Faros 360, Stingray adapter and textile belt you can record only one channel ECG. 3-channel ECG can be recorded in datalogger mode using cable set.



Figure 15: Textile Belt and Stingray Adapter



Figure 16: Faros 360 connected to Stingray. Stingray on Textile Belt in upright position



Figure 17: **Correct Placement of Stingray and Textile Belt**

4.3 Fast-Fix Electrode

The Fast-Fix electrode is intended to be used as an adhesive ECG electrode with eMotion Faros Sensor to perform ECG data acquisition. Electrode is applied directly to patient's skin to enable acquisition of ECG.

Follow instructions presented below for proficient use of the Fast-Fix Electrode.

- ⇒ Before measurement, shave off excess body hair if needed and clean skin areas with an antiseptic substance and dry thoroughly. In addition gently abrade the skin to low the impedance
- ⇒ Open the electrode pouch and take out electrode. Connect Sensor to USB connector. Remove liners from contact tapes and place sensor on electrode.



Figure 18: Connecting Sensor to electrode

- ⇒ Peel the adhesive area liner away from the electrode. Do not touch the gel adhesive area
- ⇒ Connect electrode on measurement site. The optional placements of electrode are illustrated below

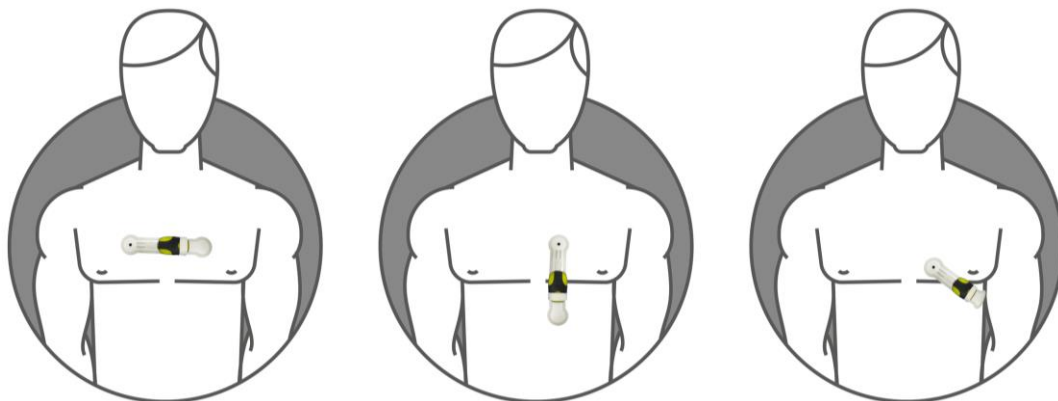


Figure 19: Electrode placement options

- ⇒ Place the electrode on the skin by gently pressing around the electrode
- ⇒ Power on eMotion Faros Sensor to start ECG acquisition
- ⇒ After ECG data acquisition remove the electrode from the skin. Disconnect Sensor from electrode
- ⇒ Electrode residue can be removed using paper towels or water
- ⇒ The electrode is disposable and should be discarded according to local environmental guidelines

Note: Skin contact parts (foam and hydrogel) are biocompatible according to ISO 10993. Even though in some cases the electrode skin contact materials can irritate skin.

4.4 Accelerometer data

The data recorded by the in-built accelerometer can be utilized by the user to recognize the movement and non-movement periods from the data acquisition period. 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, e.g. vibration of a car. The total acceleration is represented in the three accelerometer channels (x, y and z) as vector components. The direction of each acceleration component is represented as the sign of the signal reading of the channel in question and the amplitude represented as the absolute value of the signal reading of the channel in question.



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 analyzed within the device or differentiated between various physical activities.



Figure 20: Faros Sensor Accelerometer axis directions

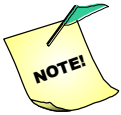
5.eMotion EDF Viewer

5.1 Measurement Data Review

EDF data can be reviewed using eMotion EDF Viewer. Application is located on Faros Sensor internal memory.

Open eMotion EDF Viewer

1. Connect your Faros Sensor to computer using USB Cable
2. Browse to FAROS_XXX hard drive
3. Open 'Software' Folder
4. Double click eMotion EDF Viewer folder and run 'eMotionEDFViewer' application



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.



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.

Review measurement data

1. Click 'Open EDF' in main view (Alternative select 'File' and 'Open')
2. Select desired measurement file
 - a. Browse FAROS_XXX hard drive and open "DATA" folder
Folder names indicate the date of performed measurement(s)
 - b. 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 buttons on keyboard.

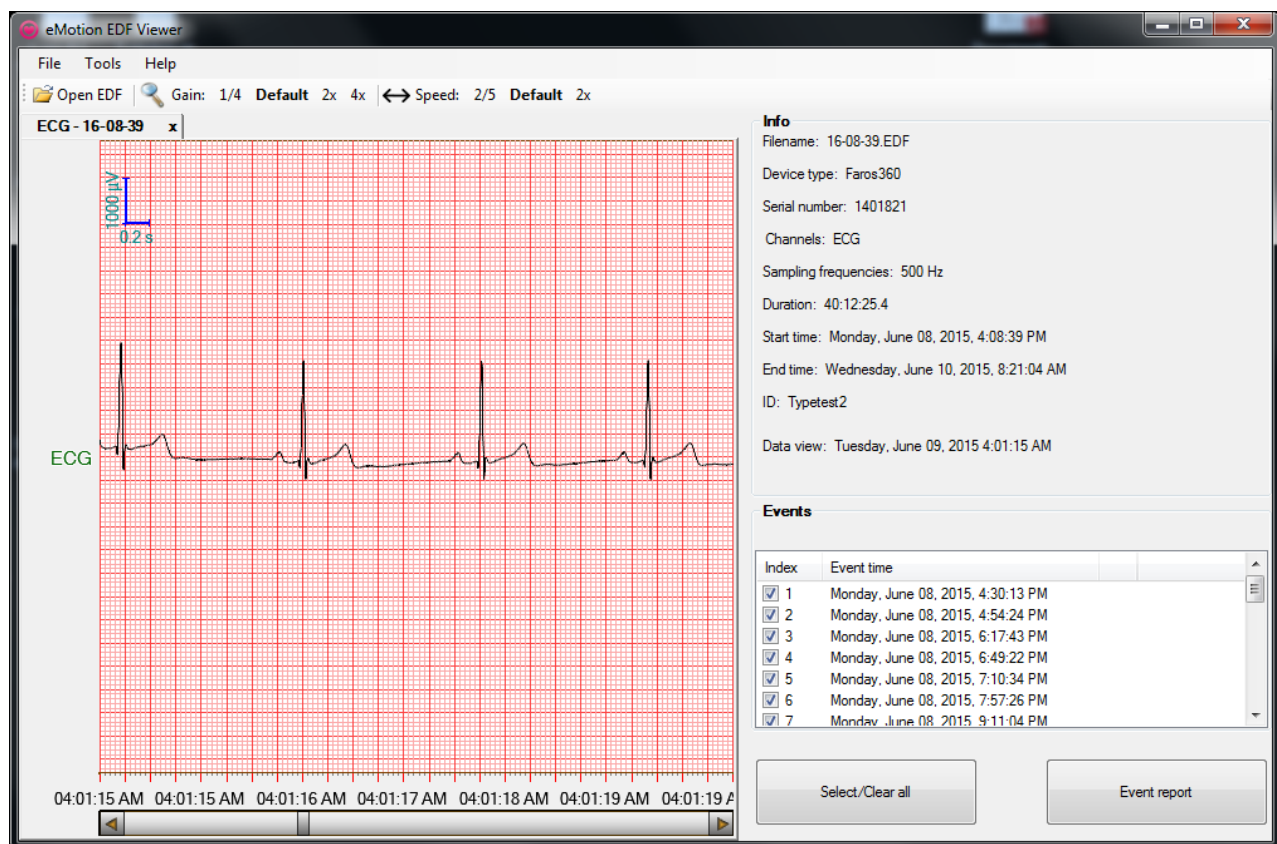


Figure 21: eMotion EDF Viewer application

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 the movement periods (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 18 and 19 can see the difference between ECG data during high physical activity period (e.g. sports) and low physical activity period (e.g. laying down).

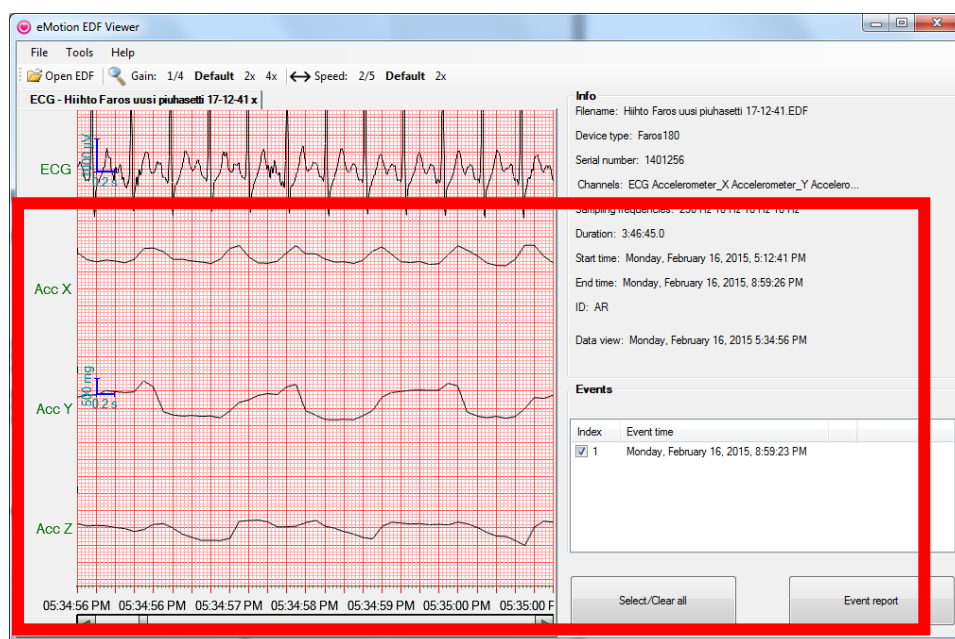


Figure 22: Accelerometer data physical activity

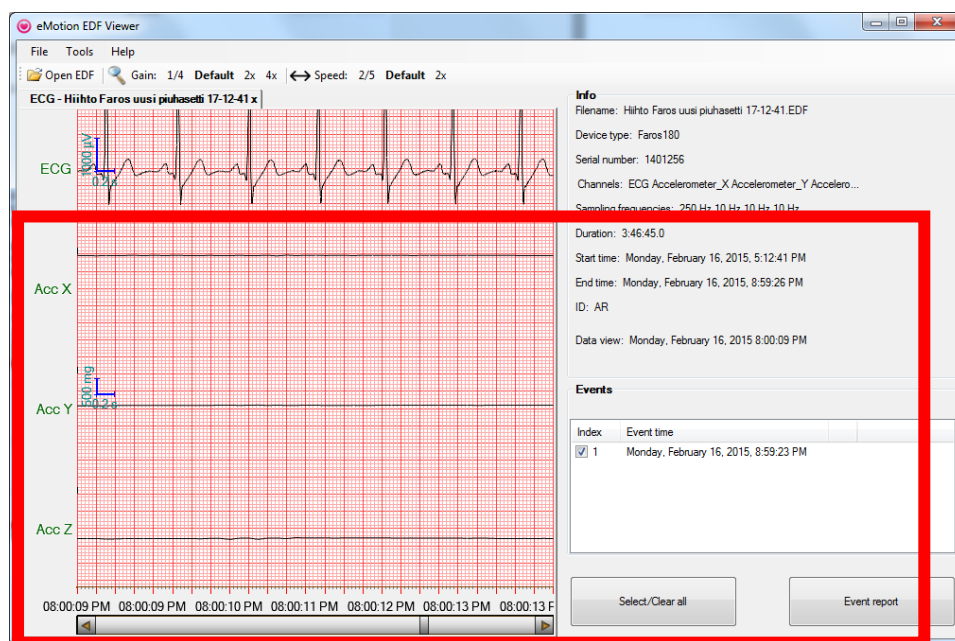


Figure 23: Accelerometer data - laying down

User Interface

Data window presents the acquired ECG data. Possible events are shown in data. Info window contains Faros sensor configuration which was used in measurement. Manually created event(s) are listed to Event window.



Figure 24: Data window

Info window presents configuration of acquisitioned ECG data. Duration, start and end time are presented.

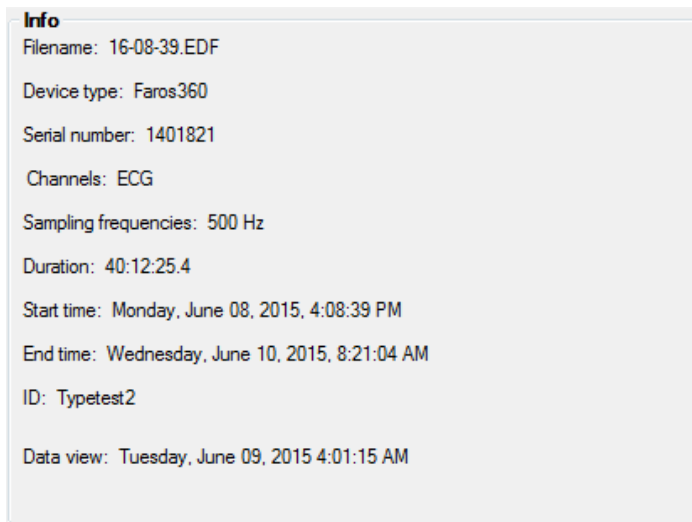
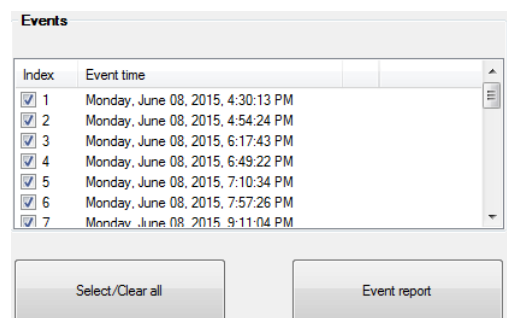


Figure 25: Info window

Events

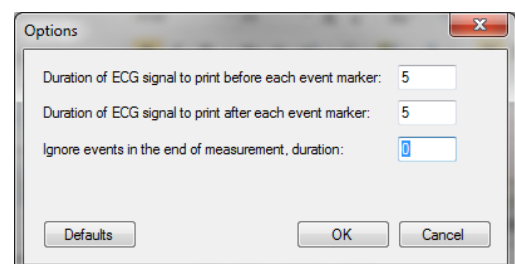
ECG event report is created of inserted events (i.e markers). Click 'Event Report' to generate report of desired events. A PDF report will be open in separate window having options to print or save.



5.2 eMotion EDF Viewer Menus

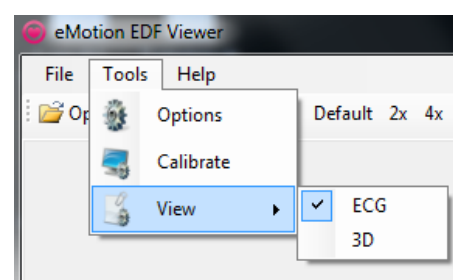
Tools, Options

Event Report layout can be managed from 'Tools' → 'Option' menu.



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..



Calibrate

To calibrate 'Data window' mm-grid view select '**Calibrate**' from 'Tools'. Measure the blue rectangle and write the values below. Click 'OK'.

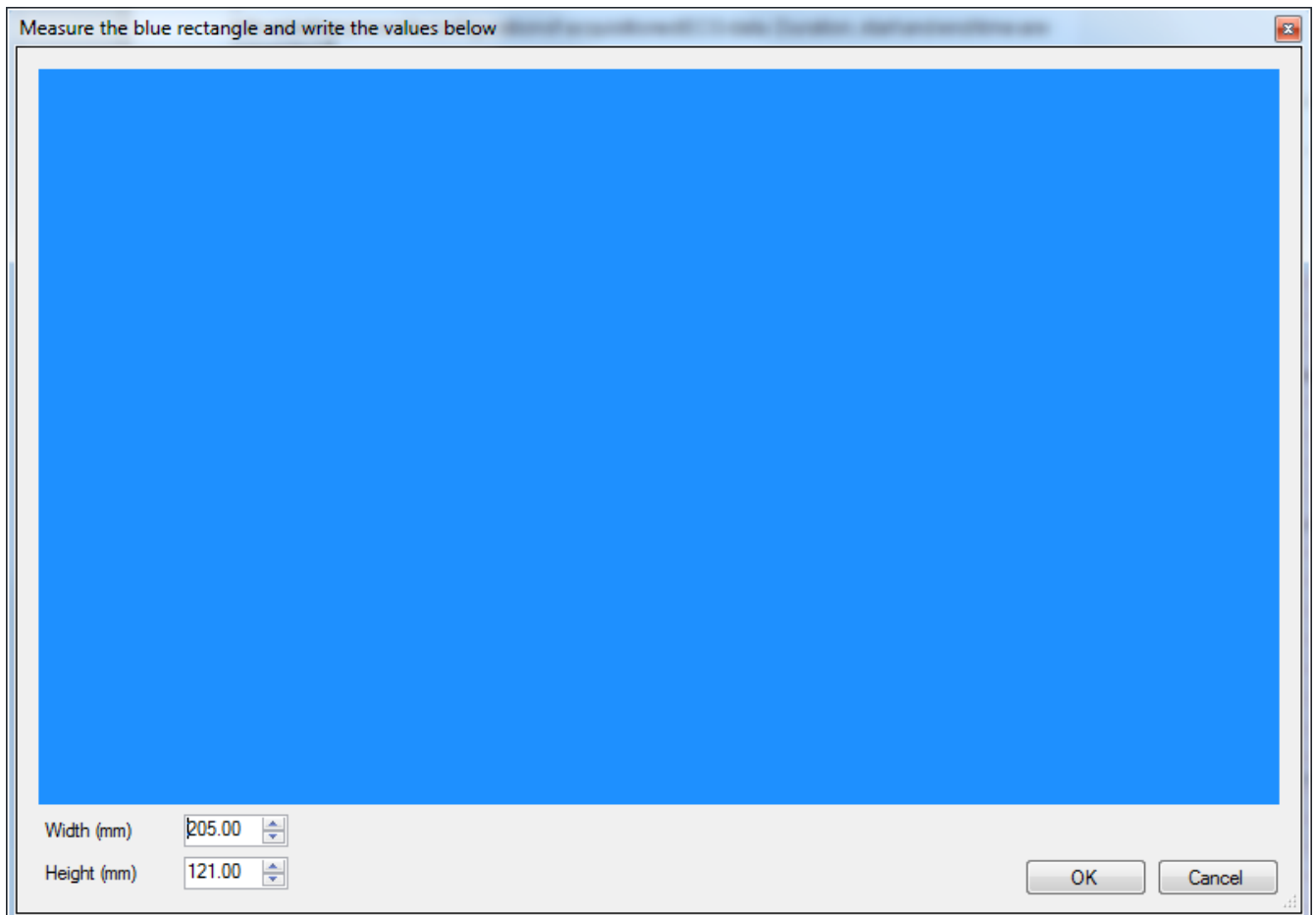


Figure 26: Calibration view

Help

Help menu contains software related information and manual.

6. 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 two hours on table before you plug it into computer via USB cable for charging
- Disconnect Cable Set from Sensor if device is unused
- Connect Cable Set only in 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 mega@megaemg.com for support.

6.1 Cleaning

eMotion Faros ECG Sensor and Stingray Adapter

The eMotion Faros ECG Sensor and Stingray adapter can be cleaned by wiping device with 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.

Do not use cleaning fluid which includes ethers, ketones or partially halogenated or aromatic hydrocarbons!



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!

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
- ⇒ Recommended to use a washing pouch



7. Frequently Asked Questions (FAQ)

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 need 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 a software for downloading measurement data from the sensor?

No, there is no need for a 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_...") 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.

How can I reset my eMotion Faros device?

Start pressing the switch on / off 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 XXX (XXX is model, 90, 180 or 360). 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 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.*

What might be the reason for bad quality measurement data?

If you are using disposable electrodes for measurements, the first thing to do is to check whether the electrodes are dry or not. If the electrodes are dry, the quality of the recorded data will suffer. 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 mega@megaemg.com for support.

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.

8. Regulatory information

8.1 Classification EU

In accordance with MDD 93/42/EEC: Class IIa product
EN60601-1: Internally powered equipment

8.1.1 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 EN60601-2-25 (IEC601-2-25) 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.

8.1.2 Intended Use

The eMotion Faros ECG Sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion Faros is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals, scientists and researchers for monitoring and evaluation.

The eMotion Faros does not provide any automatic analysis or diagnosis.

8.2 Classification U.S

Trade/Proprietary Name:	eMotion Faros ECG Mobile
Regulation Classification:	870.2920
Product Code:	DXH
Class of Device:	Class II
Panel:	Cardiovascular
510(k) Number:	K143032

eMotion Faros ECG Mobile Intended Use in USA

The eMotion Faros ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion Faros ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation.

Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters.

Indicated for adult patients who require clinical or non-clinical ECG monitoring in healthcare facility environment under supervision of a physician or prescript by the supervising physician to supplement data acquisition in home environment.

The eMotion Faros ECG Mobile does not provide any automatic analysis or diagnosis.

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