Bittium

MEDICAL

Faros Pro

Recording with EasyFlex 1-CH or Cable Sets



Instructions for Use for a Professional User

Read these instructions for use before using Faros Pro and refer to Bittium Device Manager instructions for use (D0000036443) when necessary. The English version is the master version of these instructions for use. If clarification is needed regarding the content, refer to the English version.

Electronic instructions for use are available from www.bittium.com/medical/support

Document code: D0000036441
Version 2.0.0
Latest revision: Aug 07, 2026

Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio, Finland
www.bittium.com
+358 40 344 2000
bbs@bittium.com

MD

CE

CE 0537

EasyFlex 1-CH

Faros Pro

Copyright notice

Copyright 2026 Bittium Biosignals Ltd. All rights reserved. The information contained herein is subject to change without notice. Bittium Biosignals Ltd retains ownership of and all other rights to the material expressed in this document. Any reproduction of the content of this document without prior written permission from Bittium Biosignals Ltd is prohibited.

Disclaimer

Bittium Biosignals Ltd reserves the right to change its products and the information in this document without notice due to continuous improvement and development. Bittium Biosignals Ltd makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability or fitness for a particular purpose. Bittium Biosignals Ltd shall not be liable for errors contained herein or for damages in connection with the furnishing, performance, or use of this material.

Table of Contents

General information **4**
Intended purpose 4
Indications 5
Contraindications 5
Clinical benefit 5
Required equipment 6
Device symbols and indicators 8
Recording status 9
When connected via USB 9
System messages 10
Warnings and precautions **11**
Operating instructions **13**
Operating modes 13
Initial device setup 13
Before each use 13
1. Device configuration 14
2a. Applying Faros Pro using EasyFlex 14
Skin preparation 14
Attaching the devices 15
2b. Applying Faros Pro using cable sets 18
Skin preparation 18
Cable set preparation 18
Apply the recording system 19
3. Start the recording 21
4. During recording 21
Logging symptoms 22
5. After recording 22
When using EasyFlex 23
When using cable set 23
6. Transferring data 24
Maintenance **25**
Service 25
Cleaning 25

Disinfection 25
Compatible disinfectants 25
Disinfection procedure 26
Battery and charging 26
Firmware update 26
Disposal 26
Cybersecurity 27
Operator responsibilities 27
IT operating environment 27
Password protection 27
Secure erasing of the memory card 28
Troubleshooting 29
Recording does not start 29
Alerts during recording 29
Device messages and faults 29
Technical specifications 30
Device specifications 30
Channel configurations 32
Storage, transport and operating conditions 33
Electromagnetic compatibility 33
Symbols 35

GENERAL INFORMATION

The Faros Pro is a reusable ambulatory device for recording electrocardiography (ECG) data. The device supports single- and multichannel ECG recording and R-R interval measurement. The device is designed to be worn on the body during recording. ECG signals are acquired using either disposable EasyFlex patch electrodes or compatible cable sets. When compatible cable sets are used, disposable snap electrodes are required for connection to the patient. A push button is available for marking events during recording. During operation, ECG data is recorded and then stored in the device memory and can be transferred to external systems for analysis.

Intended purpose

Faros Pro is an ambulatory recorder and transmitter for ECG. The Faros Pro device can perform single or multichannel ECG recording and R-R interval measurement. All data is recorded on the Faros Pro's internal memory. Recorded ECG data can be analyzed by other processing systems such as Holter analysis software to provide Holter reports. Recorded ECG data can be transferred via Bluetooth to companion systems for further analysis.

Faros Pro is intended to be used in healthcare facilities and in a home environment for adult and pediatric patients. Faros Pro can be used with active, passive or resting patients. Faros Pro does not provide diagnosis. Interpretation and diagnosis are the responsibility of a physician.

Intended users are the operator and the lay user.

- Operators are healthcare professionals who are familiar with ambulatory ECG recording and who are able to evaluate the recorded data. The Operator is responsible for example including but not limited to; patient data interpretation, analysis, diagnosis, measurement preparation and proper treatment.
- Lay users are patients who require ambulatory ECG recording to be performed in home and hospital environment. Lay user can also be professional or non-professional person assisting the patient.

EasyFlex is a non-sterile single-use patch electrode used to transmit ECG signal from patient skin to Faros Pro ambulatory ECG device. EasyFlex is intended to interact with patient intact skin only.

Intended users of EasyFlex are the operator and the lay person:

- Operators are qualified healthcare personnel who are familiar with ambulatory ECG recording.
- Lay users are patients who require ambulatory ECG recording to be performed in home and hospital environment. Lay user can also be professional or non-professional person assisting the patient.

EasyFlex is intended to be used in healthcare facilities and in a home environment for adult and pediatric patients.

Indications

Faros Pro is indicated for patients with symptoms related to non-life-threatening cardiac arrhythmias.

- Evaluation of patients with symptoms related to rhythm disturbance or symptoms suggesting arrhythmia

Symptoms may include, but are not limited to, dizziness, palpitations, or irregular heartbeats. The device can be used for patients with implanted pacemakers.

EasyFlex is limited by the indications for use of the connected Faros Pro ambulatory ECG device.

Contraindications

- Do not use Faros Pro with pediatric patients weighing less than 10 kg.
- Do not use EasyFlex on patients with open wounds, lesions, infected or inflamed areas of skin.

Clinical benefit

The intended clinical benefit to the patient is reliable and clinically interpretable long term ambulatory ECG recordings, support arrhythmia detection and diagnosis.

Indirect benefit of the devices is that clinically interpretable ECG supports clinical decision-making in the detection and diagnosis of cardiac arrhythmias.

Required equipment

INCLUDED IN THE FAROS PACKAGE

Faros Pro
Prod. no. S0000035721



Cable USB-A to Micro-B 0.5m
Prod. no. S0000036393

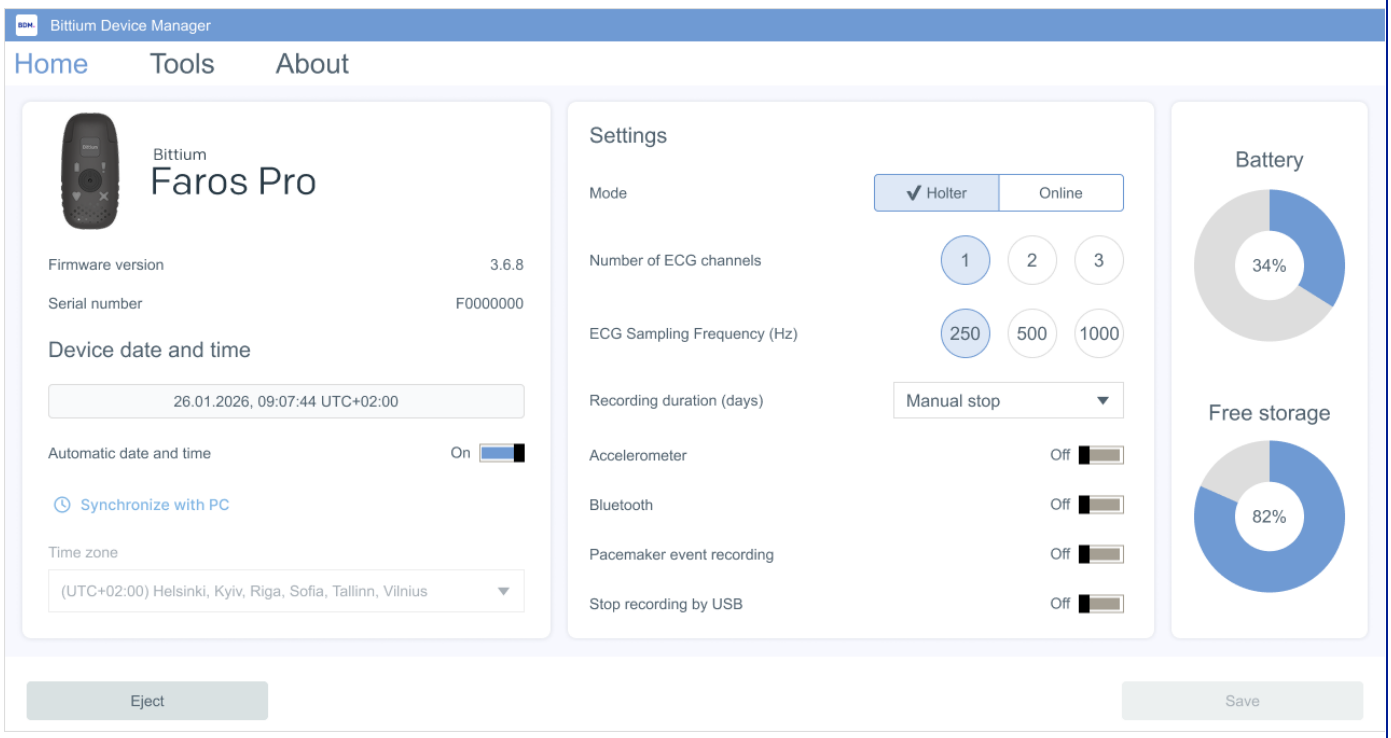


Instructions for use
for lay user
Doc no. D0000036442



REQUIRED SOFTWARE

Bittium Device Manager
Prod. no S0000036109



OPTIONAL EQUIPMENT

Faros Pro is intended for use either with EasyFlex 1-CH patch electrode or cable set (with 3rd party electrodes). Other cables and accessories may negatively affect device performance.

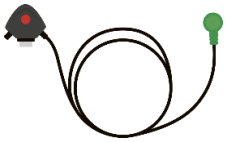
Follow the instructions for the equipment you are using.

ECG cable set types



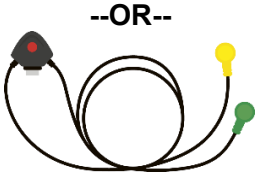
Prod. no S0000022709
IEC 2-electrode 1-CH patient cable 125mm (Short)

--OR--



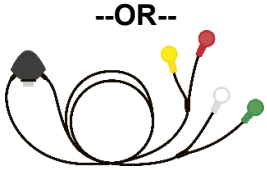
Prod. no 9404265
Faros 2-electrode IEC cable set (Long)

--OR--



Prod. no 9404266
Faros 3-electrode IEC cable set

--OR--

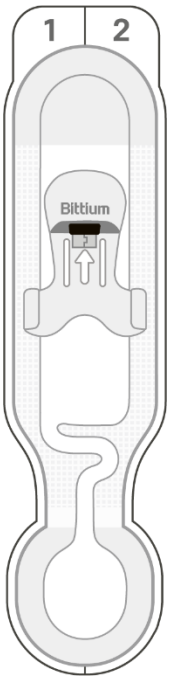


Prod. no 9404282
Faros 5-electrode IEC cable set

In addition, 3rd party ECG electrodes (wet gel only) with snap connectors and maximum impedance of 2000 Ω (Ohms) are required (e.g. Ambu® BlueSensor, Covidien Kendall 450/455 or Stable Base SBW601). Always follow instructions provided for 3rd party electrodes.

EasyFlex 1-CH

Prod. no S0000033817



OTHER COMPATIBLE PRODUCTS
- Analysis software (e.g. Cardiac Navigator) - MedicalSuite Platform Bittium provides interface to enable connectivity with accessories and/or analysis software. Any accessory conforming to the specified interface requirements may be integrated. In this case the customer organization is responsible, as the system producer, for ensuring appropriate verification and validation of the system in accordance with applicable regulatory requirements.

Device symbols and indicators

The Faros Pro provides operational status information through light indicator symbols located on the front cover of the device. An internal sound indicator provides audible feedback to indicate and confirm device operations. The device includes the following controls, indicators, and connectors:



The tables below provide an overview of Faros Pro's light and sound indicators in normal operating situations.

Recording status

	Sound	Light	Meaning
Holter mode	♪♪♪ and		Device powered on in **Holter mode**. Recording starts.
	none	 every 5 sec	Ongoing recording in Holter mode.
Online mode	♪	none	Device powered on in **Online mode**. Waiting for mobile companion to connect.
	none	 every 2 sec	Bluetooth is active, but device is not connected or recording.
	none	 every 2 sec	Bluetooth connected, but device is not recording.
	♪♪♪	 every 5 sec	Measurement started in Online mode
	none	 or  every 5 sec	Ongoing recording in Online mode.
Common	♪	none	Patient marker created. Button pressed less than 7 seconds during recording.
	♪♪♪	none	Recording ended by user or system. If by user button pressed more than 7 seconds during recording.

When connected via USB

Sound	Light	Meaning
none		USB connection established.
none		Device transferring data via USB.
none	 every 1 sec	Device connected to charger and battery is charging.
none		Charging completed. Battery fully charged.

System messages

Sound		Light	Meaning
♪	and		Software reset performed. Device restarted by system
♪	and		Exiting low power shipping mode. USB connected or button pressed while in shipping mode.
none			Firmware update in progress. Do not disconnect power during update.

If any problems occur during the use of the device, refer to the Troubleshooting section for further guidance.

WARNINGS AND PRECAUTIONS

For patient/user/third party in the European Union and in countries with an identical regulatory regime (MDR; 2017/745/EU); if, during use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is stated on the second page of these instructions for use.

Read and follow all **WARNINGS, CAUTIONS and NOTES** provided in this guide. To avoid the possibility of injury, damage to your system or data loss, always observe these safety precautions during system operation.

WARNING: Do not place electrodes on broken, damaged or irritated skin. The use of electrodes on broken, damaged or irritated skin can make the irritation or damage worse. Apply the electrodes only on clean intact skin.

WARNING: If skin irritation such as severe redness, itching or allergic symptoms develop, remove the electrodes from patient. If more significant symptoms develop or persist, contact the manufacturer and inform the lot number/batch code of EasyFlex patch electrode.

WARNING: Improper removal or reuse of electrodes may cause skin irritation, discomfort or redness.

WARNING: Do not use Faros Pro in combination with an external cardiac defibrillator. Remove Faros Pro and related accessories before applying external cardiac defibrillation.

WARNING: Remove the devices before entering areas with strong magnetic fields or imaging equipment (MRI, X-ray, CT), or where high-frequency surgical equipment is in use. This may affect the scanning results, lead to malfunction of the devices, or injure the patient.

WARNING: Keep the device and accessories out of reach of infants, small children and pets due to choking or suffocation risk.

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

WARNING: Do not use devices if mechanically damaged. Devices may not perform as intended.

WARNING: To avoid the risk of electric shock, disconnect the device from the charger or computer before cleaning.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Faros Pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with Faros Pro should comply with IEC 62368 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply

with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be connected to electrical power using an isolation transformer that fulfills the requirements.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION: Faros Pro contains a battery. Properly dispose of device in accordance with local regulations.

CAUTION: Do not use EasyFlex patch electrode if the package is tampered with, defective, opened or past its expiry date.

CAUTION: Faros Pro includes an anti-tampering seal located on the bottom of the device, covering the enclosure fixing screws. If the seal is not intact, do not use the device.

CAUTION: The supervising healthcare professional must check whether the patient has an active implantable medical device (e.g. Implantable pacemaker) before using the device. This may affect the configuration of the device.

CAUTION: To avoid premature detachment leading to loss of recording data, avoid excess sweating during first 24 hours of use.

NOTE: The strong vibrations can reflect on accelerometer data when the subject does not move (e.g. while in a moving car). Accelerometer data is not differentiated for various physical activities.

OPERATING INSTRUCTIONS

Operating modes

The device supports three operating modes: Holter, Online, and Event. Available modes depend on the applied configuration. In all modes, the device continuously records ECG signals and optional acceleration data according to configured settings. All data is stored in the device memory for later clinical review. Recorded ECG data must be interpreted by qualified healthcare professionals.

In **Holter mode**, the device is operated manually using the power button. Wireless or remote-control functions are not available in this mode.

Online mode allows remote control of the device for ECG recording, using compatible external software provided by Bittium. Recording is started and stopped remotely, and the device button cannot be used to start recording. Bluetooth communication performance depends on environmental conditions and compatible system integration.

NOTE	For information on Event mode and its configuration, please contact medical.support@bittium.com

Initial device setup

The device is delivered in shipping mode and must be prepared for use before the first recording. To disable shipping mode, connect the device to a computer using a USB cable or press and hold the device button for more than 3 seconds.

After disabling shipping mode, synchronize the device clock to the desired date and time. For instructions on synchronizing the device clock, refer to the Bittium Device Manager Instructions for Use.

Before each use

The device can be used with either an EasyFlex patch electrode for one-channel (1-CH) ECG recording or a cable set for one-, two-, or three-channel (1-, 2-, or 3-CH) ECG recordings, depending on the intended recording configuration.

Before each use, verify that:

1. the device is properly cleaned (chapter *Maintenance*)
2. the device is fully charged (chapter *Battery and charging*)
3. the device has been configured for the intended recording (chapter *Device configuration)*
4. the appropriate ECG recording accessory is selected and available (EasyFlex patch electrode or cable set with electrodes)

NOTE	Always verify the electrode expiration date before use. Expired electrodes may result in poor adhesion and reduced signal quality.

NOTE	When using EasyFlex patch electrode, use it immediately after opening the pouch, otherwise the electrode may dry out due to ambient conditions.

1. Device configuration

Before applying the device to the patient, configure the device using the **Bittium Device Manager software**. Configuration includes settings such as recording mode, duration, and signal parameters. Incorrect configuration may affect recording behavior, battery operating time, or wireless functionality.

NOTE	Refer to the Bittium Device Manager Instructions for Use for instructions on how to configure the device. The specific configuration settings depend on the intended measurement and are determined by the user according to clinical practice.

NOTE!
Preparation differs depending on whether EasyFlex patch electrode or cable sets are used to connect the Faros Pro to the patient.
If using the device with **EasyFlex patch electrode**, follow **Section 2a**
If using the device **with cable sets**, follow **Section 2b**

After completing the applicable section, continue common instructions with **Sections 3–6**.

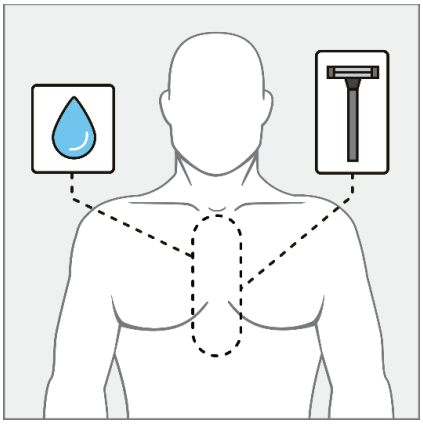
2a. Applying Faros Pro using EasyFlex

The EasyFlex patch electrode is attached to the body with the adhesive surface of the patch. It is placed in the chest area (thorax) and is worn up to 7 days at a time. Always ensure that the skin is intact and free from irritation before applying the electrode.

Before applying the electrode, read chapter Warnings and precautions to ensure safe and correct use of the device.

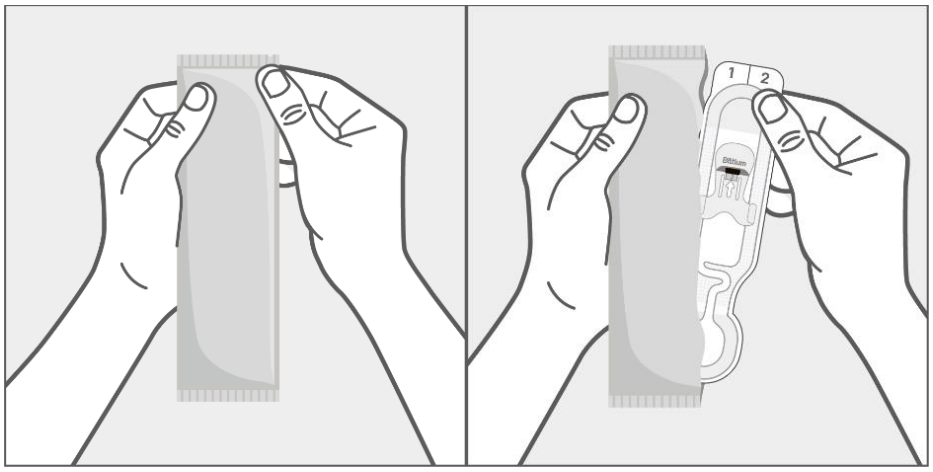
Skin preparation

Prepare the skin from the area where the EasyFlex patch electrode will be placed.



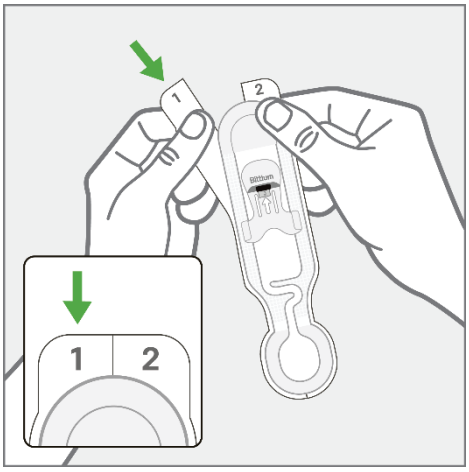
1. Remove excess body hair using a razor or an electric shaver.
2. Use soap and water to clean the area.
3. Dry the area completely.
4. Do not apply lotions, oils, or perfumes. Do not use alcohol.

Attaching the devices

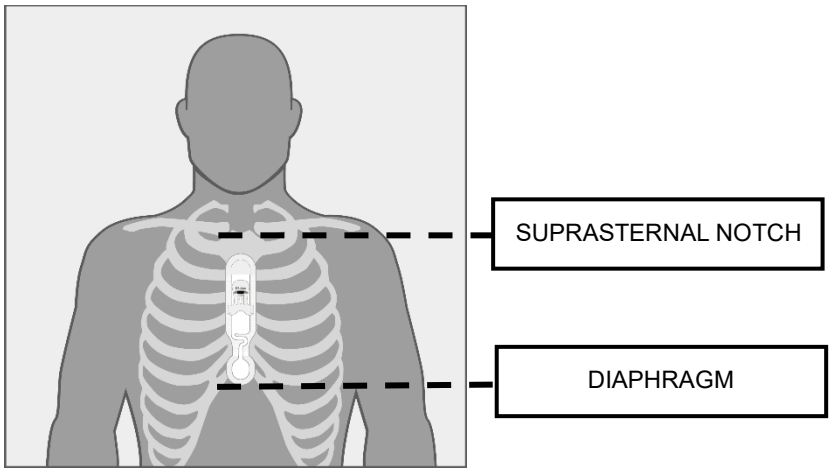


1. Make sure the patch electrode pouch is unopened and check the expiration date before use.
2. Tear open the pouch and remove the patch electrode from the pouch.

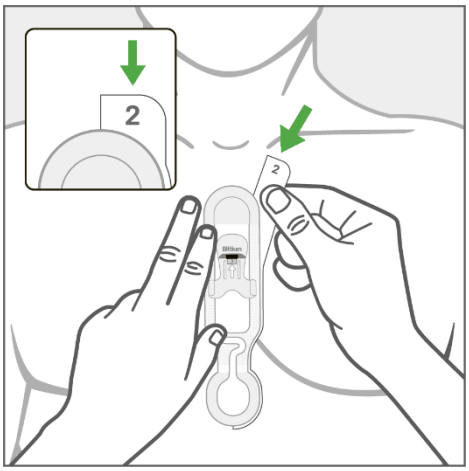
NOTE Do not use sharp items to open the pouch.



3. Remove liner **1** from the patch electrode. Do not touch the adhesive surface.



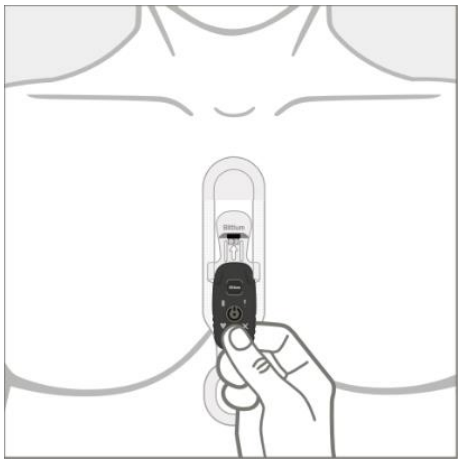
4. Place the EasyFlex onto the skin
    a. Position the patch electrode flat on the thorax with top of the patch electrode approximately two finger-widths below the suprasternal notch and the bottom above the diaphragm.
    b. Make sure the electrode does not crease during placement.



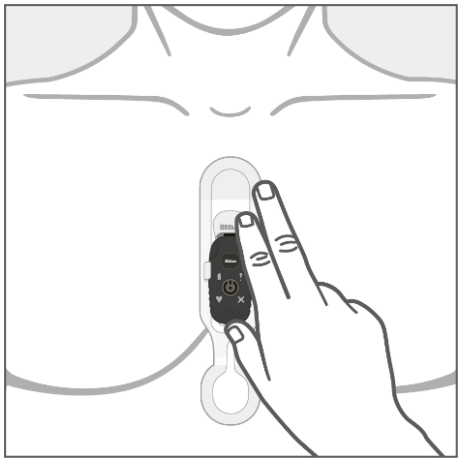
5. Once positioned on the thorax, remove liner **2**.
6. Press the patch electrode firmly onto the skin to ensure secure attachment.

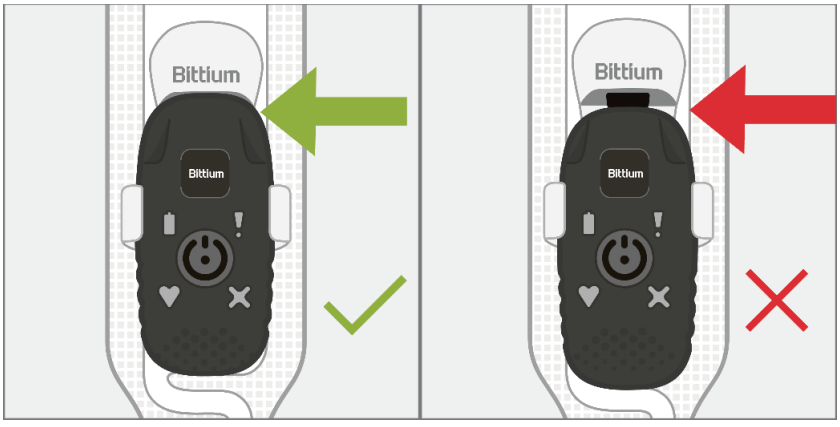
NOTE Poor electrode contact due to creasing or loose attachment may result in loss or distortion of ECG data.

NOTE Do not reposition or reapply an electrode after it has contacted the skin. If repositioning is required or an electrode becomes detached, discard the electrode and apply a new one.



7. Slide Faros Pro into the white holder on EasyFlex and fully insert the connector into the device.





8. Firmly pinch the device into the white holder using thumb and index finger until the connector is fully seated to ensure a secure connection.

NOTE!

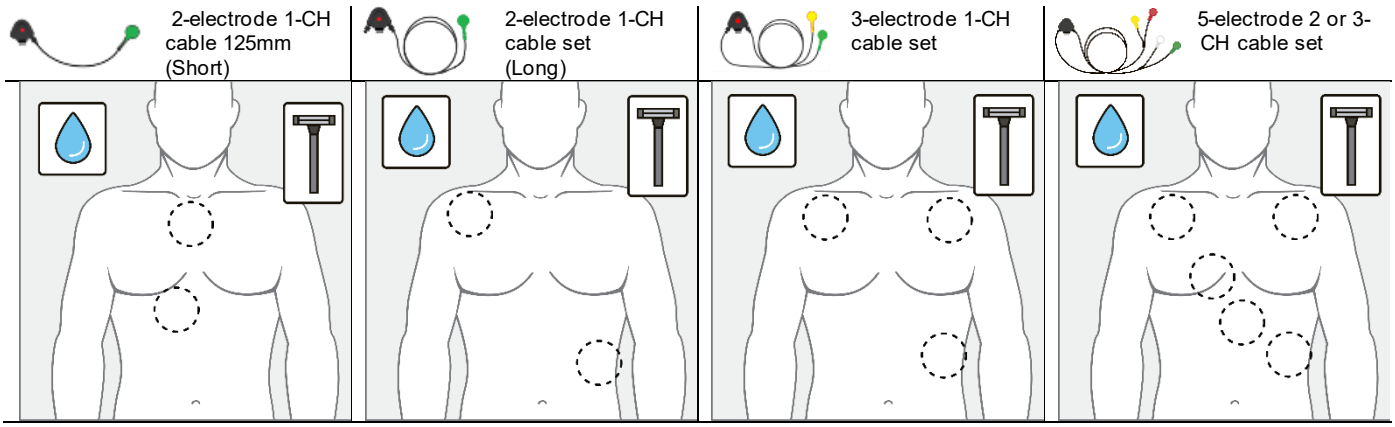
After completing this section, continue common instructions with **Sections 3–6**.

2b. Applying Faros Pro using cable sets

Each cable set name includes (see package label) the number of supported recording channels (1-CH, 2-CH, or 3-CH). Choose the cable set that matches the required recording type.

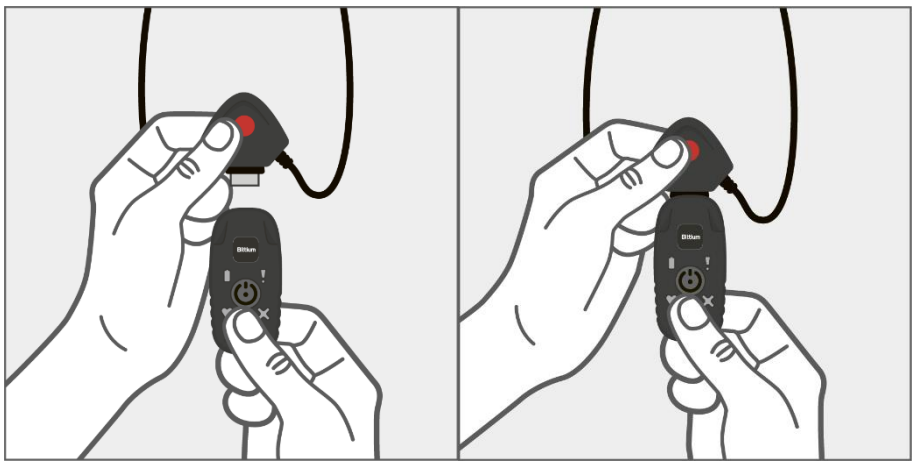
Skin preparation

Prepare the skin according to the selected cable set. The preparation areas vary depending on the chosen configuration and corresponding electrode placements.

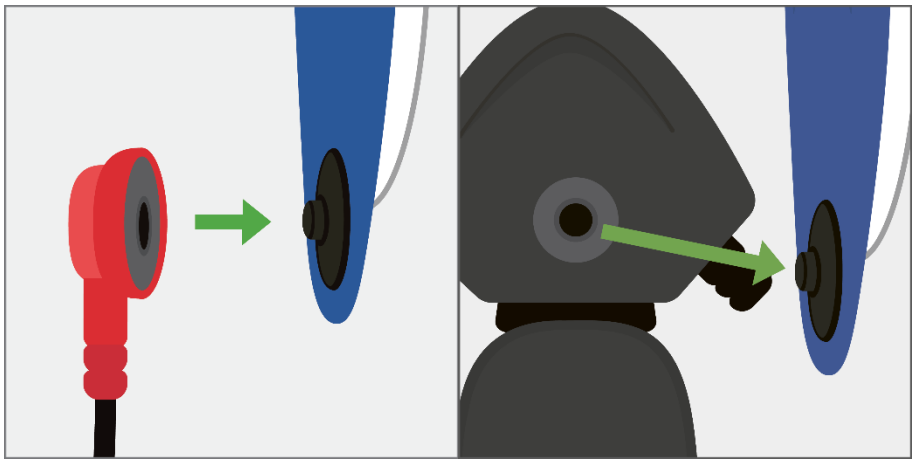


1. Remove excess body hair using a razor or an electric shaver.
2. Use soap and water to clean the area.
3. Dry the area completely.
4. Do not apply lotions, oils, or perfumes. Do not use alcohol. Only gently abrade if skin impedance is too high.

Cable set preparation

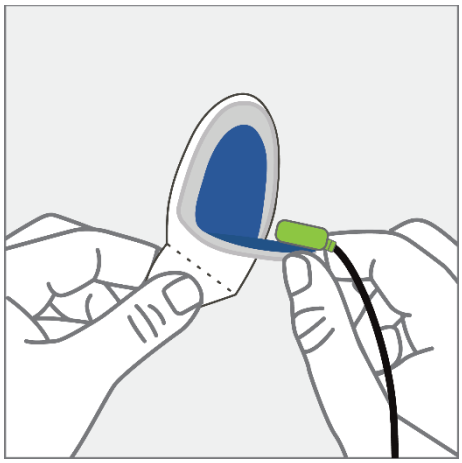


1. Connect Faros Pro to the center connector of the selected cable set. Ensure that there is no gap between the device and the center connector.

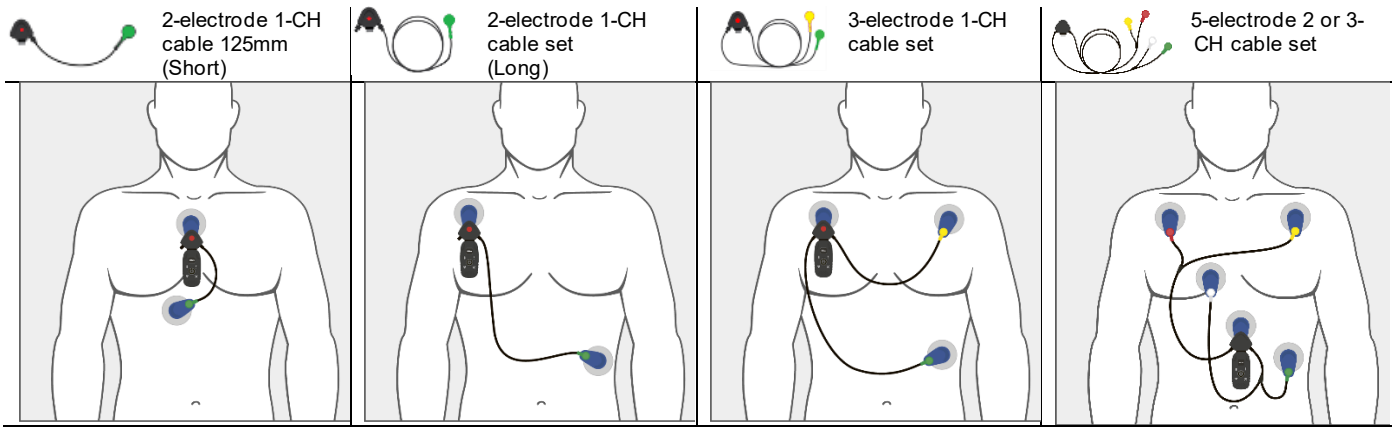


2. Snap one ECG electrode onto each cable lead and one onto the center connector.

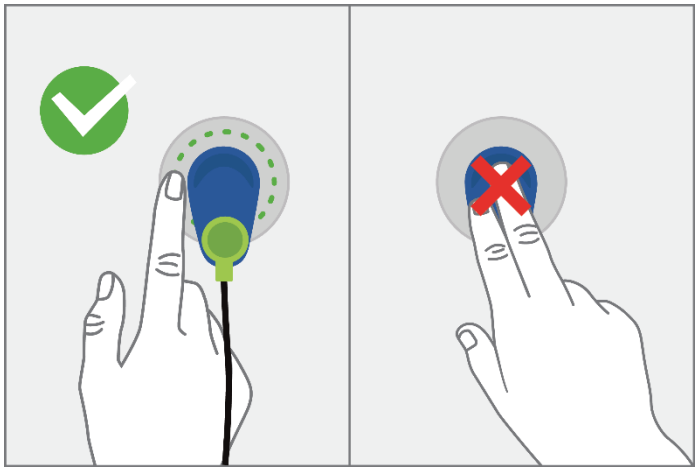
Apply the recording system



1. Peel the electrode away from the protective liner and dispose of the protective liner immediately after removal. Protective liners may have sharp edges.



2. Apply the connected electrodes to the patient's skin according to the selected cable set configuration shown above.



3. Press firmly around the adhesive edge of each electrode to ensure secure attachment.

NOTE Poor electrode contact due to creasing or loose attachment may result in loss or distortion of ECG data.

NOTE Do not reposition or reapply an electrode after it has contacted the skin. If repositioning is required or an electrode becomes detached, discard the electrode and apply a new one.

3. Start the recording



Holter mode:

1. Press and release the power button on the device.
2. Three rising beeps confirm that the device has powered on and recording has started.
3. During active recording, the heart indicator blinks green.

Online mode:

1. Press and release the power button on the device.
2. One beep confirms that the device has powered on. Bluetooth is activated automatically, and the device enters connection mode. The device is not recording at this stage.
3. While the device is waiting to connect to the companion device, the heart indicator blinks green.
4. Once the Bluetooth connection is established, the heart indicator blinks blue.
5. Recording is initiated from the companion device. Three rising beeps confirm that recording has started.
6. During active recording, the heart indicator blinks at a slower rate and alternates between blue and green.

If the device does not operate as expected, check the light indicators and audible signals described in chapter Device symbols and indicators, before proceeding with Troubleshooting.

4. During recording

The devices shall remain attached throughout the recording period unless removal is required for safety reasons (e.g., magnetic resonance imaging [MRI]) or due to persistent skin irritation, an allergic reaction, or another clinically relevant issue. Mild skin irritation may occur at the beginning of the recording period and does not normally require device removal.

Avoid pulling, twisting, or otherwise placing mechanical strain on the electrodes, lead wires, or connectors.

Normal daily activities, including showering and light exercise, may be performed. During showering, keep the Faros Pro device connected to the EasyFlex or cable set, and avoid applying soap, shower gel, shampoo, or other cleansing products directly to the patch area. Swimming, bathing, sauna use, and submersion of the device in water are not permitted.

Logging symptoms

If the patient experiences symptoms such as dizziness, chest pain, or shortness of breath, the patient can manually record these events. Symptoms can be recorded by pressing the device's button. The button should not be held down. The device makes a single beep on a successful button push.

5. After recording



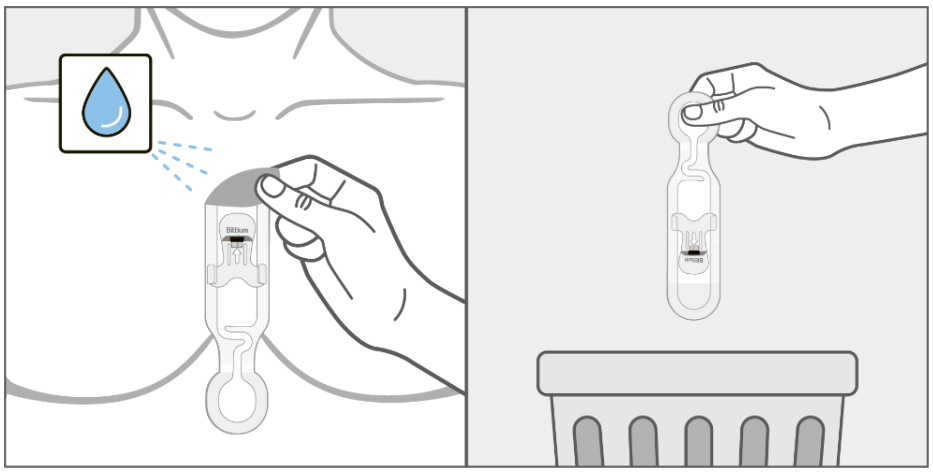
1. Press and hold the button on the device to stop the recording. The device beeps once when the button is pressed. Continue holding the button until the device beeps three times (approximately 7 seconds after the button is pressed). The recording stops, the device powers off, and the heart indicator light turns off.

NOTE	Release the button immediately after the three beeps. Continuing to hold the button for more than 9 seconds initiates a device reset.

NOTE	The recording can also be configured to end automatically after a specified time or when charging is detected.

When using EasyFlex

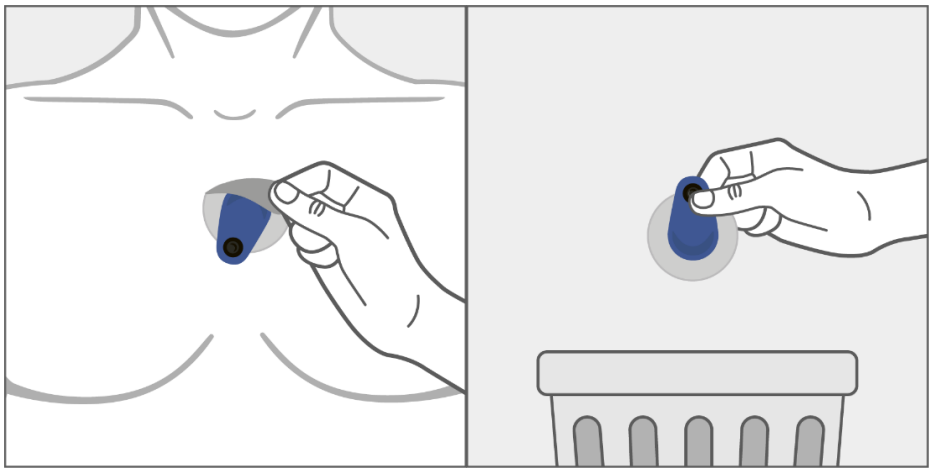
1. Remove the device by sliding it out of the white holder. Do not dispose of the device.



2. Remove the electrode from the skin by gently lifting one edge of the patch and slowly peeling it off. To ease electrode removal or remove any adhesive residue, use mild soapy water or a medical adhesive remover according to its instructions.
3. Dispose of the used electrode in accordance with local waste management practices.

When using cable set

1. Remove the device from the cable set. Do not dispose of the device.



2. Detach the connectors from the electrodes. Do not dispose of the cable set.
3. Remove the electrode from the skin by gently lifting one edge of the electrode and slowly peeling it off. To ease electrode removal or remove any adhesive residue, use mild soapy water or a medical adhesive remover according to its instructions.
4. Dispose of the used electrodes in accordance with local waste management practices.

6. Transferring data

The Faros Pro stores recorded ECG data in its internal memory. After the recording has ended, the data must be transferred to a computer for review and analysis. Data transfer is supported via USB interface or, if enabled, Bluetooth® interface. Do not delete data from the device until successful transfer and verification have been confirmed.

NOTE	Do not disconnect the device or otherwise interrupt the data transfer while data is being transferred. This may result in incomplete or corrupt data.

Transferring data via USB

Data can be transferred via the USB interface only after the recording period has ended. Connect the device to a computer via USB and open the Bittium Device Manager software to initiate transfer.

Refer to the Bittium Device Manager Instructions for Use for detailed data transfer and safe device removal instructions.

Transferring data via Bluetooth

If enabled in the configuration (Online mode), data can be transferred using the device's Bluetooth interface. Data transfer via the Bluetooth interface can take place after or during the recording period.

MAINTENANCE

Faros Pro and cable sets have no user-serviceable parts and do not require calibration. Routine maintenance consists of cleaning, disinfection, and battery charging of Faros Pro. EasyFlex patch electrode is intended for a single recording session on one patient. Do not clean, disinfect, or reuse the patch or 3rd party electrodes.

Service

Remove the devices from use and contact the manufacturer or authorized service personnel, if they are damaged, malfunctions, or do not operate as intended. Inspect the devices after cleaning and before each use. The expected service life of Faros Pro is three (3) years or approximately 500 charging cycles, whichever occurs first, when used, cleaned, and stored according to these instructions for use.

Cleaning

Faros Pro and cable sets must be cleaned and disinfected between each patient use to reduce the risk of cross-contamination.

NOTE	Always disconnect the device and any external equipment from the patient before cleaning and disinfection.

- Wipe the exterior surfaces of the device and cable sets using a soft, non-fluffing cloth moistened with a mild detergent solution with near-neutral pH, such as liquid soap diluted in water.
- Prevent liquids from entering connectors or openings. Do not immerse the device in liquid.
- Repeat the procedure if visible soil remains.

If the USB port becomes soiled, clean it using high-purity isopropyl alcohol (IPA) and a small swab with a soft foam tip. Allow the port to dry completely before use.

Disinfection

Compatible disinfectants

The following disinfectants may be used on the exterior surfaces of the device and cable sets:

- Medical alcohol
  - 70 % isopropyl alcohol (IPA)
  - 70 % ethyl alcohol
- Sodium hypochlorite 5.25 % diluted 1:10
- Disinfectant wipes intended for medical devices:
  - PDI Sani-Cloth® AF3 Germicidal Disposable Wipes
  - Mikrozid® sensitive wipes

Disinfection procedure

- Disinfect the device and cable sets using a disinfectant wipe or a soft, non-fluffing cloth moistened with the disinfectant solution.
- Wipe external surfaces of the device and cable sets, including connector areas, and follow the disinfectant manufacturer's required contact time.
- Do not allow liquid to enter connectors or openings and do not immerse the devices.
- Allow the devices to dry completely and inspect for visible damage before next use. Do not use the devices if any defect is observed.

Battery and charging

The Faros Pro contains an integrated rechargeable lithium-ion battery. Before use, ensure that the battery has sufficient charge. The device is not supplied with a dedicated charger. Use the USB cable supplied by Bittium for charging. Use an IEC 62368-1 or EN 60601-1 compliant USB charger with a USB Type-A connector that provides a 5 V DC output with a current capability of at least 500 mA, or use a computer USB port for charging. Faros Pro includes protection against incorrectly connected power sources.

To charge:

1. Connect the USB-A end of the cable to a computer or wall charger.
2. Connect the Micro-USB end to the device.
3. The blue battery indicator blinks during charging and remains steady when fully charged.
4. Disconnect the cable once charging is complete.

Battery replacement must be performed only by the manufacturer or authorized service personnel.

Firmware update

Firmware updates are performed using Bittium Device Manager software. Refer to the Bittium Device Manager Instructions for Use for detailed firmware update instructions.

Disposal

Dispose of the device and accessories according to local regulations. The device contains electronic components and may need to be collected as electronic waste. For users in the EU, dispose of the device in accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).

CYBERSECURITY

The operator is responsible for maintaining the cybersecurity of the device and its operating environment throughout the device lifecycle. This includes implementing and maintaining appropriate organizational, technical, and procedural security measures.

Operator responsibilities

The operator must:

- Ensure that the device is used in accordance with the manufacturer's instructions.
- Restrict physical and logical access to authorized personnel only.
- Follow secure password management practices.
- Install manufacturer-provided updates and security patches as instructed.
- Ensure that personnel are trained to use medical devices securely.
- Notify the manufacturer without delay if a cybersecurity incident or suspected security issue involving the device is identified
- Not to add or store any patient-identifiable data on the device

IT operating environment

To reduce the risk of malware infection and propagation via USB or connected systems, the user organization must ensure that the operating environment and any computers connected to the device implement appropriate IT security controls.

These controls include:

- Use of antivirus or anti-malware software and firewall protection on connected computers.
- Restricting access to authorized users only and using strong passwords.
- Installing only necessary and trusted software from legitimate sources.
- Keeping operating systems and software up to date with the latest security patches.
- Implementing appropriate network security measures, such as network segmentation and traffic control, where applicable.
- Ensuring that connections to the device are implemented according to the manufacturer's specifications.

The user organization is responsible for maintaining a secure operating environment in accordance with applicable regulations and organizational IT security policies.

Password protection

The device uses password-based security mechanisms to prevent unauthorized access to memory card and Bluetooth connection. Devices are shipped with integrated password protection. A custom password can be set using Bittium Device Manager software. Refer to the Bittium Device Manager Instructions for Use for detailed configuration instructions. Strong password policies and password security standards should be followed when managing device passwords.

Secure erasing of the memory card

It is possible to restore recording files deleted from the Faros Pro's memory card by using data recovery software tools. Thus, it is recommended to securely erase the device's memory by using a secure formatting method, before disposing it. This process will make the extracted data not retrievable, and disposed device remain secure.

NOTE	Repeated secure erasing shortens the service life of the Faros Pro’s memory card.

TROUBLESHOOTING

The following indicators signal conditions that prevent recording, require user action, or indicate a device malfunction. If the problem cannot be resolved using the actions described below, contact technical support

Recording does not start

Sound	Light	Meaning	Action
none		Battery too low to perform a recording.	Charge the device before starting recording.
none		USB cable connected	Disconnect the USB cable before starting recording.
none		Memory full or device clock reset detected	1. Connect the device to computer and open Bittium Device Manager 2. Check if device's memory is full. If yes, transfer and delete data. 3. If memory is not full, synchronize device clock using Bittium Device Manager.

Alerts during recording

Sound	Light	Meaning	Action
♪♪ and	 every 5 sec	Battery is running low	Charge the device as soon as possible.
♪♪ and	 every 5 sec	Memory is running low	End recording and transfer data.

Device messages and faults

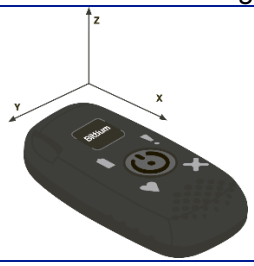
Sound	Light	Meaning	Action
none		Battery charging problem.	Contact customer support for help.
none		Internal system error. Repeats until device exits error state.	Contact customer support for help.
none		Software reset performed and file system corrupted.	Format device memory. If problem persists, customer support for help.
		Firmware update failed	Contact customer support for help.

TECHNICAL SPECIFICATIONS

Device specifications

Physical characteristics	
Dimensions	62 x 31 x 14 (mm)
Weight	25 g
Performance characteristics	
Memory capacity	4 GB ~ 90 days of recording data (1-CH 250 Hz) ~ 30 days of recording data (3-CH 250 Hz)
ECG file format	EDF, European Data Format
Recording format	Continuous
Number of Channels	1, 2 or 3
Operating time	Holter mode (1-CH, 250 Hz) ~ 21 days Holter mode (3-CH, 250 Hz) ~ 11 days Online mode (1-CH, 250 Hz) ~ 10 days Online mode (3-CH, 250 Hz) ~ 5 days
Communication characteristics	
USB Interface	Hi-Speed USB, 7 MB/s, Micro-B receptacle
Bluetooth	Bluetooth Classic BR/EDR, Bluetooth 4.2
Battery	
Type	3.85 V Rechargeable Li-ion Battery
Battery capacity	560 mAh / 2,156 Wh
Battery life	After 500 cycles charge/discharge the battery can recover 80 % of its initial capacity
Electrical performance	
Classification	Type BF applied part, internally powered, IP67
Sampling rate	250 Hz, 500 Hz or 1000 Hz
Bandwidth	0.05 Hz – 40 Hz
Dynamic range	10 mVp-p with DC offset ±300 mV (1)
ECG Input impedance	> 10 MΩ
R-R Intervals	R-R Intervals are measured with following intervals depending on sample rate: 250 Hz = 4 ms, 500 Hz = 2 ms, 1000 Hz = 1 ms

(1) Dynamic range is better than 60601-2-47 requirement for Digital AMBULATORY RECORDER

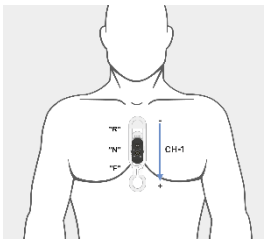
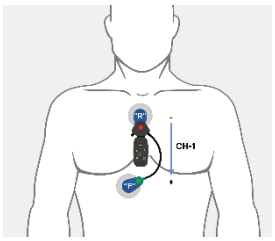
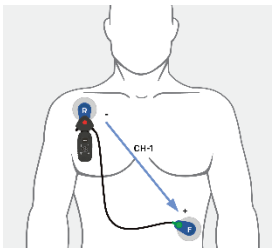
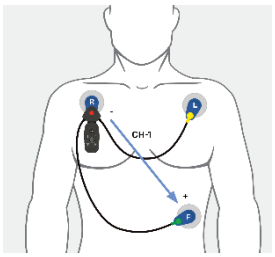
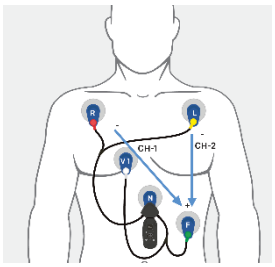
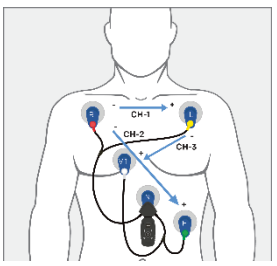
Acceleration measurement	
Output data rate	25 Hz or 100 Hz
Measurement range	±2g, ±4g, ±16g
Bandwidth	Accelerometer bandwidth depends on output data rate and used measurement range.
Axis directions	
Operation	The data recorded by the accelerometer can be utilized by the operator to recognize the movement and non-movement periods from the recording. The reading from the accelerometer is the acceleration induced by the sum of all forces acting on the device, including gravity, movement of the patient and movement caused by the environment, for example vibration of a car. The total acceleration is represented by the accelerometer vector components (x, y and z). The direction of each acceleration component is represented by the sign of the vector and the amplitude is represented as the absolute value of the vector.

Pacemaker	
Detection performance	Faros Pro can record the activity of an implanted pacemaker according to 60601-2-47:2012 201.12.4.4.109, and report dual chamber pacing (double pacing) with heart rate of 200 BPM and 150ms interval between the pacemaker pulses. Performance is verified with 2mV pacemaker signal having pulse widths 0.1 ms, 0.5 ms, 1ms and 2 ms.
ECG recording performance	Faros Pro can record ECG signal in the presence of implanted pacemaker pulses according to 60601-2-47:2012 201.12.4.4.109.
Recording pacemaker event data	Pacemaker events are stored in the EDF file. Please refer to Faros Pro EDF File Specification (Document code 121754EEC0097) for more information.

NOTE

The Faros Pro is capable of filtering pacemaker pulses with certain limitations related to pulse amplitude and duration. Pulses are rejected only from the QRS algorithm input signal but preserved in the recorded ECG data. Please contact Bittium Biosignals for more detailed information about pacemaker rejection performance.

Channel configurations

ECG Configuration	Available ECG channels	Channel configuration
EasyFlex 1-CH	1	
IEC 2-electrode 1-CH patient cable 125mm	1	
Faros 2-electrode IEC cable set	1	
Faros 3-electrode IEC cable set	1	
Faros 5-electrode IEC cable set	2	
	3	 * CH3 - = WCT ((R + L + F) / 3)

Storage, transport and operating conditions

Store and transport all devices within specified environmental conditions. Avoid exposure to extreme temperatures, humidity, or mechanical stress.

	Temperature		Relative humidity	Atmospheric pressure
	Faros Pro	EasyFlex		
Storage conditions	+ 0 °C to + 25 °C (32 °F to 77 °F)	+ 10 °C to + 25 °C (50 °F to 77 °F)	10 % to 95 %, non-condensing	700 hPa to 1 060 hPa
Transport conditions	- 20 °C to + 60 °C (-4 °F to 140 °F)	+ 0 °C to + 45 °C (32 °F to 113 °F)		
Continuous operating conditions	+ 0 °C to + 45 °C (32 °F to 113 °F)			

Electromagnetic compatibility

Manufacturer's Declaration - Electromagnetic Emissions		
Emission test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 1	Faros Pro uses RF energy exclusively for its internal function. Thus, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Faros Pro is suitable for use in all establishments, including domestic establishments.

Immunity test	Basic EMC standards or test method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Conducted disturbances induced by RF fields	EC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

Basic EMC standard or test method: IEC 61000-4-3 Immunity test levels for Proximity fields from RF wireless communications equipment				
Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity level (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

SYMBOLS

CE	CE marking of conformity. May include Notified Body reference number
	Manufacturer
MD	Medical device
UDI	Unique device identifier
REF	Catalogue number
SN	Serial number
LOT	Batch code
	Do not re-use
	Use-by date
	Keep dry
	Keep away from sunlight
	Refer to instruction manual
	Consult instructions for use
	Magnetic Resonance (MR) unsafe
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Type BF applied part
	For EU only: Symbol indicates that device shall be disposed according to EU directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)
	Non-ionizing electromagnetic radiation
	FCC compliant radio frequency equipment
IP67	Ingress protection rating. Device is dust-protected and protected against the effects of immersion in water between 15 cm and 1 m for 30 minutes.
	A data matric (GS1) code is a two-dimensional barcode consisting of GTIN (UDI-DI) and PI(s)