



MedicalSuite™ Platform Holter Service

Clinical Guide

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Version	Date	Changes Between Releases	Status
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7.0.0	2025.05.06	CHREP address change.	Approved
8.0.0	2026.03.27	Updates for MedicalSuite Center v. 3.6.0 release.	Approved
9.0.0	2026.04.06	General updates.	Approved
10.0.0	2026.08.24	Faros Pro compatibility changes	Approved

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1 CONVENTIONS

The following conventions are used in these user instructions:



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



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

NOTE

Notes contain additional information on using this product.



The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Regulation 2017/745.

2 GENERAL WARNINGS AND CAUTIONS TO REVIEW BEFORE USE



CAUTION: Do not enter any patient delicate information (e.g., use the patient's name or social security number as a patient ID) to the Bittium MedicalSuite service platform.



CAUTION: Quick Preview feature is used only for checking the quality of the acquired ECG signal. Any determination of cardiac event occurrences should not be made using the Quick Preview feature. Always use proper cardiac analysis software to analyze ECG data.

NOTE

Contact healthcare professional if you are unsure about the usage of the device.

NOTE

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the country in which the user and/or patient is established.

NOTE

Check ECG device notes and warnings from applicable instructions for use.

NOTE

Check Cardiac Navigator software notes and warnings from **Cardiac Navigator™ Software User Guide**.

3 GENERAL

Bittium MedicalSuite is a web-based remote service platform designed for the management, transmission, storage, and analysis of data recorded with compatible Bittium medical devices. The platform supports secure data handling and controlled information sharing between hospitals, clinics, and healthcare professionals. The system provides wireless data transfer, automated data processing, configurable reporting and management functionalities.

These instructions are applicable to MedicalSuite™ Center v. 3.7.X and MedicalSuite™ Mobile v.3.2.X.

3.1 MedicalSuite™ Center

MedicalSuite™ Center is software intended to be used as an accessory for Bittium measuring devices to support electrocardiographic (ECG) recording procedures. MedicalSuite™ Center is used to create a measurement, including adding patient details, selecting the measurement type, and selecting the prespecified features of Bittium Faros device; to manage the measurement, and to assign the measurement result to a healthcare professional for analysis which is completed in separate analysis program. The prespecified features impact on the collected data and the length of recordings. MedicalSuite™ Center is suitable for use in healthcare environment. Intended users are healthcare professionals.

3.1.1 Clinical benefits

MedicalSuite Center provides indirect clinical benefit only, arising from its role as an accessory medical device software that supports the correct configuration, management, and controlled use of compatible ECG measuring devices and supports the reliable handling, availability, and transfer of measurement data generated by those devices. Through these functions, MedicalSuite Center contributes to the clinical workflow without independently generating clinical outcomes.

3.1.2 Performance

The performance of MedicalSuite Center is defined as non-clinical, functional performance, focusing on whether the software performs its intended functions correctly, reliably, and safely when used as intended. Functional performance characteristics relevant from a clinical perspective include, but are not limited to:

- reliable configuration and management of compatible measuring devices
- integrity, availability, and controlled handling of measurement data
- support of intended clinical workflows without introducing additional risks
- mitigation of use-related and system-related risks through usability and cybersecurity controls

3.2 MedicalSuite™ Mobile

MedicalSuite™ Mobile is a software intended to be used as an accessory for ambulatory recording support and transmission with Bittium Faros Holter ECG device. MedicalSuite™ Mobile is used for controlling, i.e. starting and ending the recording on Bittium Faros. MedicalSuite™ Mobile instructs lay users to attach the device correctly. MedicalSuite™ Mobile can transfer the ECG and patient



motion data generated by Bittium Faros. MedicalSuite™ Mobile can also be used to select prespecified features of Bittium Faros, which defines the configuration for data recording. During ECG recording, MedicalSuite™ Mobile will collect a patient-generated digital diary and can show the live-ECG.

MedicalSuite™ Mobile is suitable for use both in healthcare and home environments. Intended users are healthcare professionals and lay users.

3.3 Bittium Holter service

Bittium MedicalSuite platform Holter service is used for managing and visualizing standard ECG data typical for cardiac-related disorders, such as various arrhythmias.

Bittium Holter service provides a conventional offline solution to manage data from ECG recording where recording data is uploaded from Faros ECG device to MedicalSuite service platform for analysis with Cardiac Navigator™ software.

Bittium HolterPlus is a flexible, online solution to manage data from ECG recording whose duration can be adjusted according to the case specific needs to optimize the amount of acquired ECG data and required time resources. The acquired recording data from Faros ECG device together with digital patient diary markings are automatically transferred to Bittium MedicalSuite service platform using mobile device with Bittium MedicalSuite mobile application periodically. Digital diary and recorded data are available in Bittium MedicalSuite service platform for signal quality verification, daily symptoms and arrhythmia events check and, eventually, for the complete ECG data analysis with Cardiac Navigator™ software.

3.4 Compatible ECG devices

MedicalSuite Center shall be used in combination with the following devices

- Faros 180 - 9404302
- Faros 180L - 9404659
- Faros 360 - 9404300
- Faros Pro - S0000035721

3.4.1 Faros ECG devices

The Faros ECG devices are wearable, portable, externally applied electrocardiograph (ECG) recorders and wireless transmitters for ECG measurement, R-R interval data measurement, and patient motion capture. The devices monitor patient ECG and can be configured to generate event markers using built-in arrhythmia detection algorithms.

More information about the Faros 180, 180L and 360 ECG devices can be found from **Bittium Faros Manual**.

More information about the Faros Pro ECG devices can be found from **Faros Pro Instructions for use**.

The **Bittium Faros Manual** and **Faros Pro Instructions for Use** are hereinafter collectively referred to as the applicable Instructions for Use (IFU).

3.5 Cardiac Navigator

Cardiac Navigator software is a flexible and versatile solution for performing clinical Holter ECG analysis when analyzing recordings with multiple days of ECG data efficiently, thereby speeding up the diagnosis. Cardiac Navigator integrated to MedicalSuite platform enables specialists who are working in remote locations to analyze recordings made by the health centers and clinics. For the specialist, the system provides a complete working environment for signal visualization and analysis.

More information about the Cardiac Navigator software can be found from **Cardiac Navigator Software User Guide**.

3.6 Indications

More information about the indications for the Faros ECG devices can be found in the applicable Instructions for Use (IFU).

More information about the Cardiac Navigator indications can be found from Cardiac Navigator Software User Guide.

More information about the patient target group for the Faros ECG devices can be found in the applicable Instructions for Use (IFU).

3.7 Contraindications

- No contraindications are identified.

More information about the contraindications for the Faros ECG devices can be found in the applicable Instructions for Use (IFU)

More information about the Cardiac Navigator contraindications can be found from Cardiac Navigator Software User Guide.

3.8 Security

System applications are recommended to be used with computers with proper anti-virus protection installed. Use of firewall is also recommended. With any concern related to security please contact medical.support@bittium.com for additional recommendation and support.

3.9 Symbols and Labels

Symbol	Description
	The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Regulation 2017/745.
	Swiss authorized representative.

	Consult Instruction for use.
	Medical device.
REF	Product number. Indicates the catalogue number so that the medical device can be identified.
	Manufacturer.
	UDI code in human readable and machine-readable format, accompanied with symbol “Unique Device Identifier” • UDI code shall consist of the following attribute: ○ UDI-DI AI(01) GS1 GTIN ○ UDI-PI AI(8012) software version no. 0000
	Data matrix (GS1) is a two-dimensional barcode consisting of black and white modules arranged in either a square or rectangular pattern, also known as a matrix. The data to be encoded can be text or numeric data. GS1 data matrix includes GTIN and production identifier (PI). • GTIN (01) • Version no. 0000 (8012)

4 USING MEDICALSUITE CENTER

MedicalSuite Center supports following Web-browsers:

- Google Chrome
- Mozilla Firefox
- Microsoft Edge (chromium based)

4.1 Bittium MedicalSuite accounts

Each unit offering a particular type of healthcare services relates to a separate organization entity belonging in a tree type organization structure in Bittium MedicalSuite service platform (Figure 1).

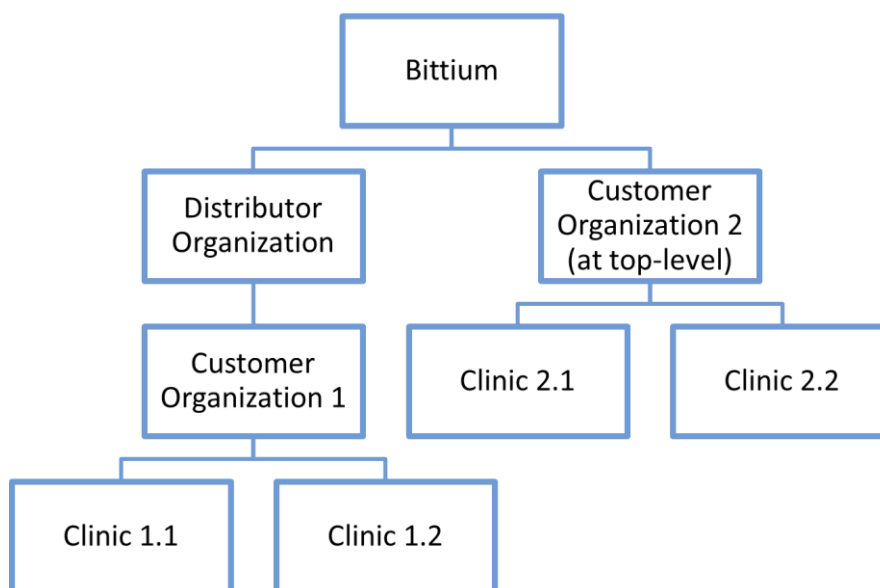


Figure 1 Tree type organization structure

Furthermore, each organization on Bittium MedicalSuite may include multiple users with different functionality access. The structure of MedicalSuite organizations and its' users and their tasks can vary based on the organization process and needs. To access the data of the organization on Bittium MedicalSuite service platform, each user needs to log in with their personal user account. According to the required user functionality access, a role (admin, clinic, technician or diagnostic) is set for each user account. In addition to user role, each user has its own customizable dashboard that includes task list of the user and can be configured based on the user's needs. The following user roles are available.



Admin

- Manages the organization structure, its users, diagnostic groups and devices.
- Has access to web service usage statistics of his/ her own organization and its lower-level organizations.



Clinic

- Prepares a recording with patient details according to the study prescription of the physician.
- Attaches the ECG device, electrodes and cables if necessary.
- Gets the diagnostic report when it is approved.



Technician

- May prepare a recording with patient details according to the study prescription of the physician.
- May attach the ECG device, electrodes and cables if necessary.
- Verifies the acquired signal quality using **Quick Preview** feature on Bittium MedicalSuite Center.
- Assigns the recording to a diagnostic user or diagnostic group for analysis and interpretation.
- May perform the ECG data clean-up using Cardiac Navigator™ analysis software or other relevant analysis software.
- Approves a diagnostic report and thus provides the report with interpretation notes to the lower-level organization.



Diagnostic

- Analyzes the ECG data with Cardiac Navigator or other relevant analysis software.
- Interprets the analysis results and creates a diagnostic report.

Management of Bittium MedicalSuite accounts of your organization is performed by admin user(s) using Bittium MedicalSuite BackOffice. Contact your Bittium MedicalSuite organization admin user to get user credentials for Bittium MedicalSuite service platform. No specific training is required to use MedicalSuite Center. If you encounter any issues while using the product, please contact medical.support@bittium.com.

5 SIGNING IN BITTIUM MEDICALSUITE SERVICE PLATFORM

Management of Bittium Holter recordings throughout the whole study workflow is performed using Bittium MedicalSuite Center. Users can create and manage recordings of their own organization or its lower-level organizations according to the functionality access of the user role (admin, clinic, technician or diagnostic) of their user account.

NOTE

The management of Bittium MedicalSuite accounts of your organization is performed by admin user(s) using Bittium MedicalSuite BackOffice. Contact your Bittium MedicalSuite organization admin user to get user credentials for Bittium MedicalSuite service platform.

To create and manage Bittium Holter recordings, sign in Bittium MedicalSuite Center by following the steps described below:

- 1 Go to Bittium MedicalSuite Center sign in page.
- 2 Click **Sign in with Microsoft** button (Figure 2).

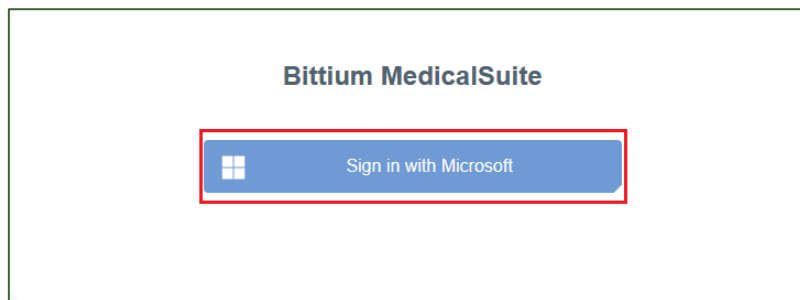


Figure 2 Sign in with Microsoft view

- 3 Pick the wanted account from the list OR click **Use another account** option and enter the user credentials.

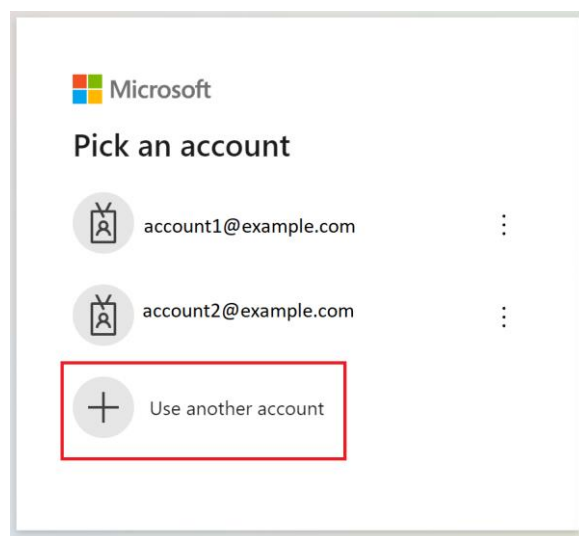


Figure 3 Select earlier saved account or use another account to sign in

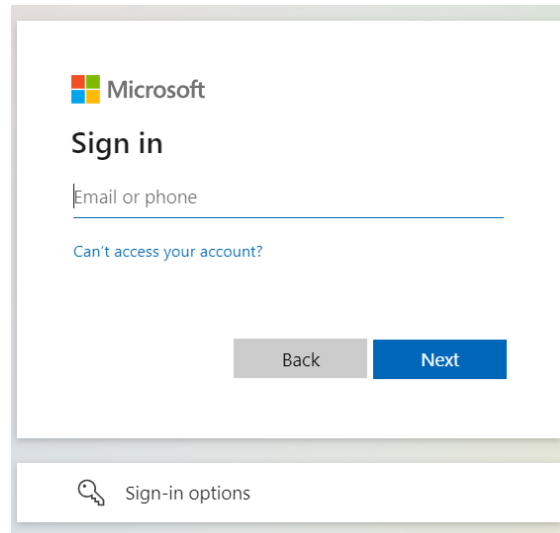


Figure 4 Enter account credentials

- 4 Enter the password.

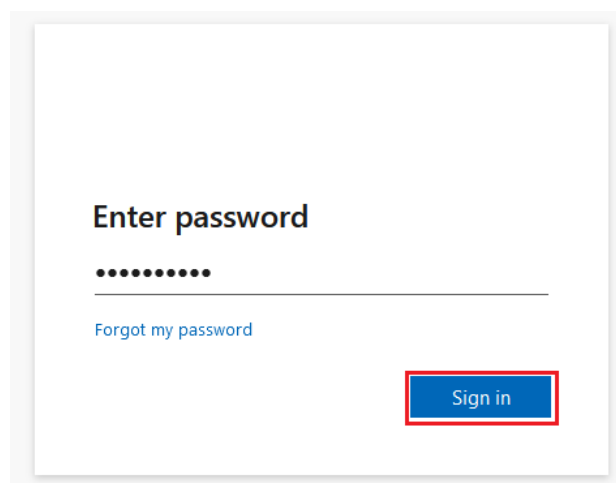


Figure 5 Enter password

- 5 Make sure your phone registered for authentication is nearby and powered on.
- 6 Click on **Sign in** button (Figure 5).
- 7 Enter the numbers shown in the Approve sign in request view to the Microsoft Authenticator application. Confirm the sign in request by selecting **Yes** from the Microsoft Authenticator application (Figure 6).

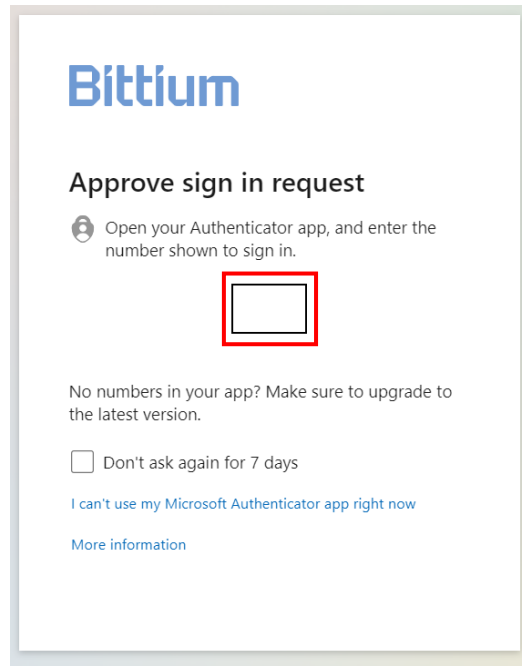


Figure 6 Approve sign in by entering shown number to prompt in Authenticator application

NOTE If “We didn’t hear from you” view is displayed, select **Send another request to my Microsoft Authenticator app** and proceed according to instructions in the application and sign in view.

NOTE Depending on your Microsoft Authenticator application settings, your personal verification code may be requested by the application. If requested, enter your personal verification code.

8 MedicalSuite Center Dashboard page opens (Figure 7).

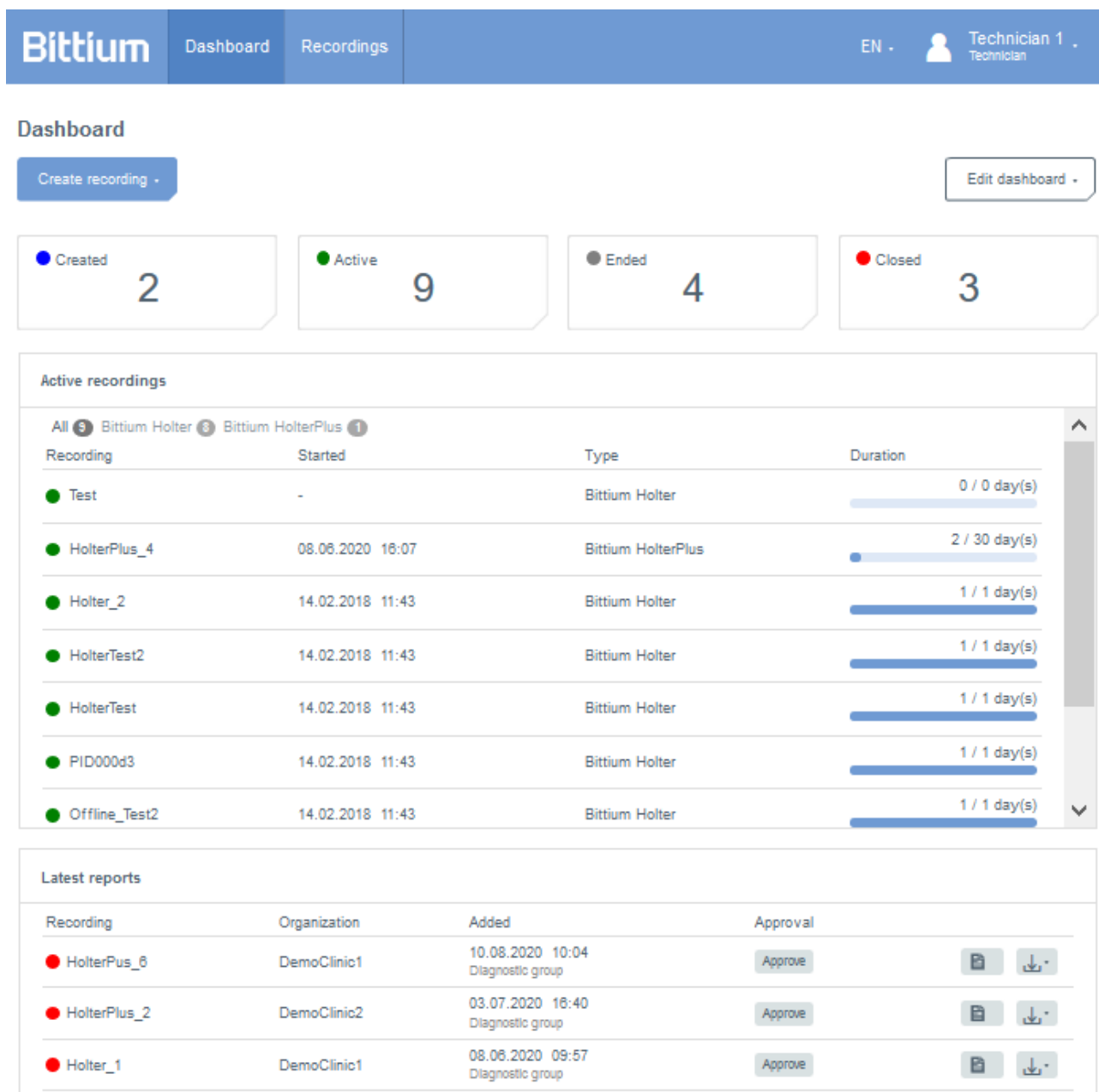


Figure 7 MedicalSuite Center Dashboard page

The MedicalSuite Center Dashboard page presents the statistics and highlights the most recent activity on the Bittium MedicalSuite service platform. It adapts to the current user role logged in. You can see the current user role in the top-right corner of the page. Using **Edit dashboard button**, you can select the dashboard cards that are presented and change their order by dragging and dropping them in the drop-down menu.

9 Select **Recordings tab** from the top bar and the Recordings page opens (Figure 8).

Bittium

Dashboard

Recordings

EN

Technician 1

Recordings

Q Search

Create recording

10

All

Patient ID	Status	Last update	Organization	Created	Recording type	Device	Assignment	Action
Test1234	Created	22.05.2020 14:18	ServiceProvider	22.05.2020 14:18	Bittium HolterPlus	1885069	None	
jaakko_demo_test	Active	22.05.2020 12:55	ServiceProvider	22.05.2020 12:53	Bittium Holter	1724459	None	
1234Test	Created	22.05.2020 09:36	DemoClinic1	22.05.2020 09:36	Bittium HolterPlus	1867702	None	
HolterPlus_ex...	Active	20.05.2020 13:42	DemoClinic1	20.05.2020 13:41	Bittium Holter	1867704	None	
Test_1234	Created	19.05.2020 09:29	DemoClinic1	19.05.2020 09:29	Bittium HolterPlus	1885161	None	
Trial554	Active	26.05.2020 14:22	DemoClinic1	18.05.2020 16:20	Bittium Holter	1867703	Cardiologist 1	
Trial445	Active	26.05.2020 14:22	DemoClinic1	18.05.2020 16:10	Bittium Holter	1867703	Cardiologist 1	
Trial556	Active	18.05.2020 15:53	DemoClinic1	18.05.2020 15:53	Bittium Holter	1867703	None	
HolterPlus_3_1	Active	22.05.2020 14:30	DemoClinic2	15.05.2020 14:03	Bittium HolterPlus	1874602	Diagnostic group	
jaakko_sstest2	Ended	15.05.2020 22:06	ServiceProvider	11.05.2020 21:10	Bittium HolterPlus	1885069	Diagnostic group	

<<

1/5

>>

Figure 8 Recordings page

If you are logged in as an admin, technician or clinic user, the Recordings page contains a list of all recordings created for your own organization and its lower-level organizations. Respectively, if you are logged in as a diagnostic user, a list of recordings that are assigned to you or your diagnostic group is shown on the Recordings page.

6 BITTIUM HOLTER RECORDINGS

Bittium Holter is a regular, offline ECG recording, in which the cardiac activity of a patient is recorded for a predetermined time period. Once the recording has been completed, the acquired ECG data is manually uploaded to Bittium MedicalSuite service platform for the complete ECG data analysis.

6.1 Introduction to Bittium Holter workflow

Bittium Holter recording workflow is visualized in Figure 9. Bittium Holter is an ambulatory offline recording that is used to record ECG data. Bittium Holter recording can be manually started and stopped by pressing the ECG device button. The used settings are selected using applicable configuration software. Once the recording has been completed, the recording data is manually uploaded to MedicalSuite Center for the complete data analysis.

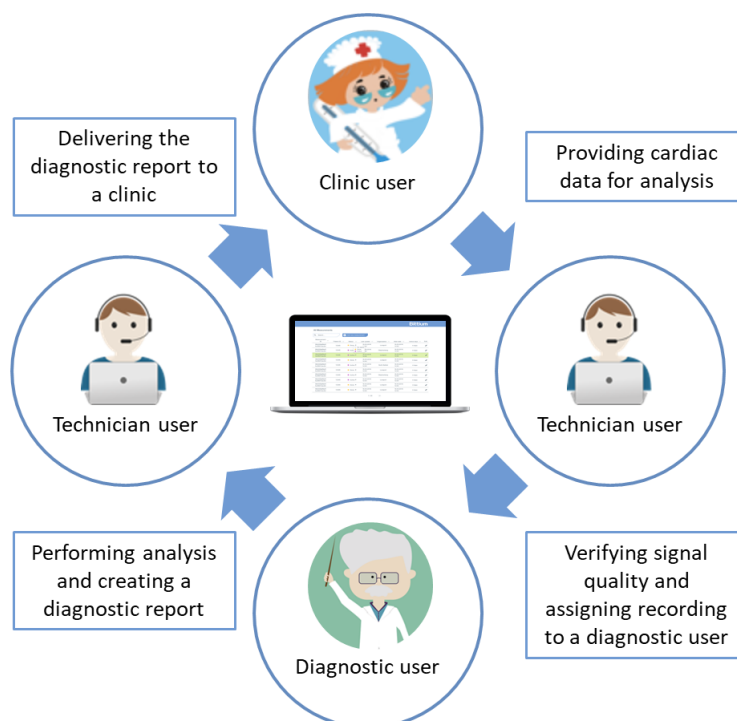


Figure 9 Bittium Holter workflow

Detailed instructions for performing Bittium Holter recording workflow steps are described in the following chapters.

6.2 Preparing Bittium Holter recording

The recording equipment needs to be prepared for Holter recording based on the recording needs as instructed in applicable ECG device instructions for use. Bittium Holter recording is created on MedicalSuite Center.

6.3 Creating Bittium Holter recording

To create a Bittium Holter recording on Bittium MedicalSuite Center, follow the steps described below:

- 1 Click **Create recording button** either on the Dashboard or the Recordings view on Bittium MedicalSuite Center. A drop-down menu is presented (Figure 10). Select **Bittium Holter**. Create recording view opens.

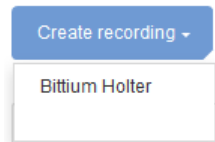


Figure 10 Create recording drop-down menu

- 2 Enter information to all the required fields (*) on the Patient details tab (Figure 11). If desired, other fields can be left unfilled. Note the following:
 - a Patient ID is for identifying the patient. If this field is left blank, the system will generate it.
 - b Do not use the patient's name or social security number as a patient ID!**



CAUTION: Do not enter any patient delicate information (e.g., use the patient's name or social security number as a patient ID) to the Bittium MedicalSuite service platform.

Figure 11 Create recording – Patient details tab

- 3 Click **Next** and enter patient anamneses information on the Anamnesis tab, if necessary (Figure 12, optional step).

Bittium

Dashboard

Recordings

EN  Technician 1
Technician

Create recording: Bittium Holter

Patient details

Anamneses

Recording details*

Attachments

<< Back

Next >>

Cancel

Save

Medication

Medication

Medication at time of ECG recording

☐ No ☐ Yes

Diseases

Diagnosed heart disease

Diagnosed arrhythmias and/ or myocardial diseases (e.g. cardiomyopathy) in the family

☐ No ☐ Yes

☐ No ☐ Yes

Habits

Smoking

Alcohol consumption

☐ No ☐ Yes

☐ No ☐ Sometimes ☐ Often

Symptoms

Palpitations	☐ No	☐ Sometimes	☐ Often
Irregular beat	☐ No	☐ Sometimes	☐ Often
Slow pulse	☐ No	☐ Sometimes	☐ Often
Fast pulse	☐ No	☐ Sometimes	☐ Often
Unpleasant feeling in the chest	☐ No	☐ Sometimes	☐ Often
Shortness of breath	☐ No	☐ Sometimes	☐ Often
Dizziness	☐ No	☐ Sometimes	☐ Often
Weakness	☐ No	☐ Sometimes	☐ Often
Fainting/ syncope	☐ No	☐ Sometimes	☐ Often

Comments

Figure 12 Create recording – Anamnesis tab

- 4 Click **Next** and enter recording details and device information (if necessary) on the Recording details tab (Figure 13). The required information includes:
 - a Organization arranging the recording
 - b Requested report language

Device information

Recorder S/N

Type or select a serial number

Faros 180 / 180L / 360

See back of the recorder.



Faros Pro

See back of the recorder. Please add characters after "SN".



Figure 13 Create recording – Recording details tab

- 5 Click **Next** and attach the recording data file (if already available) and additional documents (if necessary) on the Attachments tab (Figure 14 Figure 13, optional step).

Create recording: Bittium Holter

[Patient details](#)
[Anamneses](#)
[Recording details](#)
[Attachments](#)

<< Back
Next >>

Cancel

Save

Recording data

+ Add file or drag here

Other documents

+ Add file or drag here

Figure 14 Create recording – Attachments tab

- Click **Save** and a confirmation notification will open (Figure 15). Click **Create** to confirm the creation of a new recording.

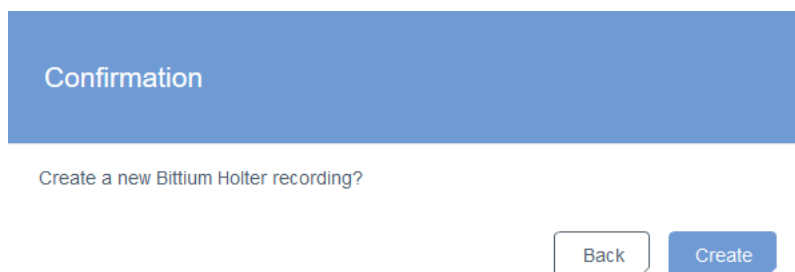


Figure 15 Create recording – Confirmation notification

NOTE

If recording data file was not attached to the created Bittium Holter recording at step 5, the recording status will be **Active**, and the recording will appear in the **Active recordings** card on the Bittium MedicalSuite Center dashboard. This indicates that the recording is still ongoing, and the recording data file will be uploaded later.

6.4 Setting up a Bittium Holter recording

After a recording is created on Bittium MedicalSuite Center, desired Faros ECG device settings for the recording need to be configured using applicable configuring software. Instructions to attach the ECG device onto a patient according to the selected electrode setup option can be found in the applicable Instructions for Use (IFU).

6.5 Ending Bittium Holter recording

Ending Bittium Holter recording consists of four separate phases that are stopping the data acquisition, uploading recording data from Faros ECG device to Bittium MedicalSuite service platform, uploading other documents to the recording and setting the recording to **Ready for analysis**. Detailed instructions for performing these phases are described in the following chapters.

6.5.1 Stopping the data acquisition

When the predetermined recording time has elapsed and sufficient amount of ECG data has been acquired for the analysis, data acquisition can be stopped. Instructions to stop the data acquisition can be found in the applicable Instructions for Use (IFU).

6.5.2 Uploading recording data to Bittium Holter recording

Before Bittium Holter recording can be ended on Bittium MedicalSuite Center, the recording data needs to be uploaded to the recording. Complete recording data can be added in multiple files provided that the files are from the same Faros ECG device and acquired using the same electrode setup option. In addition, files uploaded are required to be not more than 31 days apart from one another.

NOTE Recording status must be **Active** to be able to upload recording data to it.

After a successful data upload, remove the data from the Faros ECG device according to the device instructions.

More detailed instructions for the use of Faros ECG devices can be found in the applicable Instructions for Use (IFU).

To upload recording data to a recording, follow the steps described below:

- 1 Open the recording either from the **Active recordings** card on the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Select **Recording data** tab.
- 3 Click **Add file** and select a file or multiple files to be added. Click **Open**. Alternatively, you can drag the file to the prompted area. (Figure 16)

Recording data
Patient details
Anamneses
Recording details
Attachments

Cancel
Save

Recording data

+ Add file or drag here

	Day No.	Start date of file	Status	Notes
☐				

Figure 16 Add file icon on Recording data tab



CAUTION: Uploading a long duration recording data to Bittium MedicalSuite service platform directly from Faros ECG device using a USB cable might take several minutes. It is recommended to first copy the recording data files from the Faros ECG device to a computer local drive, and then upload the files to Bittium MedicalSuite service platform from the computer local drive.

After the files have been selected, the files will be verified. Please wait for the verification spinners (Figure 17) to change to remove icons (Figure 18).

Recording data

+ Add file or drag here

24h_3ch_FUIAF_00C21E...

	Day No.	Start date of file	Status	To be checked	Notes
☐					

Figure 17 Data files being verified

Recording data

+ Add file or drag here

24h_3ch_FullAF_00C21.E... 

☐	Day No.	Start date of file	Status	To be checked	Notes
--------------------------	---------	--------------------	--------	---------------	-------

Figure 18 Data files verified for upload

If the files are found to be non-compatible, an error showing which files are non-compatible and for what cause will be displayed.

You can add more files to be uploaded if needed. This will start a re-verification of the given files.

- When all data files to be uploaded are selected and verified, click **Save** (Figure 18) and a confirmation notification will open (Figure 19). Click **Yes** to confirm the uploading of the recording data files.

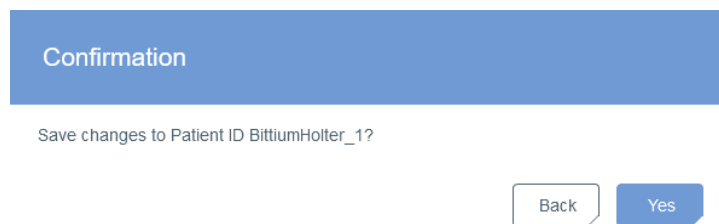


Figure 19 Uploading of recording data files – Confirmation notification

An upload widget will open indicating the progressing of the upload (Figure 20 Figure 19). Do not close or refresh the browser tab while the upload process is running.

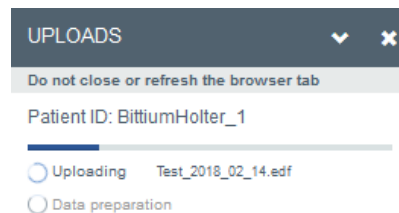


Figure 20 Upload widget indicating the progressing of the upload

While the upload is running, recording status is **Preparing** (Figure 21).

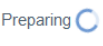
BittiumHolter_1		03.07.2024 12:48	03.07.2024 12:48	DemoClinic1	03.07.2024 11:01	Bittium Holter	1724459
-----------------	---	---------------------	---------------------	-------------	---------------------	----------------	---------

Figure 21 Recording in Processing state on Recordings view

Depending on the size of the uploaded recording data, the processing may take a while. Once the process is done, the status of the recording will change back to **Active**. This indicates that new data files can still be uploaded to the recording by repeating the previous steps.

6.5.3 Uploading other documents to Bittium Holter recording

Along with the recording data, additional patient background information can be uploaded as other documents to Bittium Holter recording. For example, to keep a track of any events occurring during a recording and to help the analysis and interpretation of the acquired ECG data, patients are commonly asked to mark down any felt symptoms and other diary notes that can affect the acquired signal and be important for proper analysis of the ECG data. Such documents can be attached to a recording on Bittium MedicalSuite Center to make them available for the diagnostic user when the ECG data is analyzed.

To add a document to a recording, follow the steps described below:

- 1 Open the recording either from the **Active recordings** card on the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Select **Attachments** tab.
- 3 Click **Add file** and select a file or multiple files to be added. Click **Open**. Alternatively, you can drag the file to the prompted area. (Figure 22)

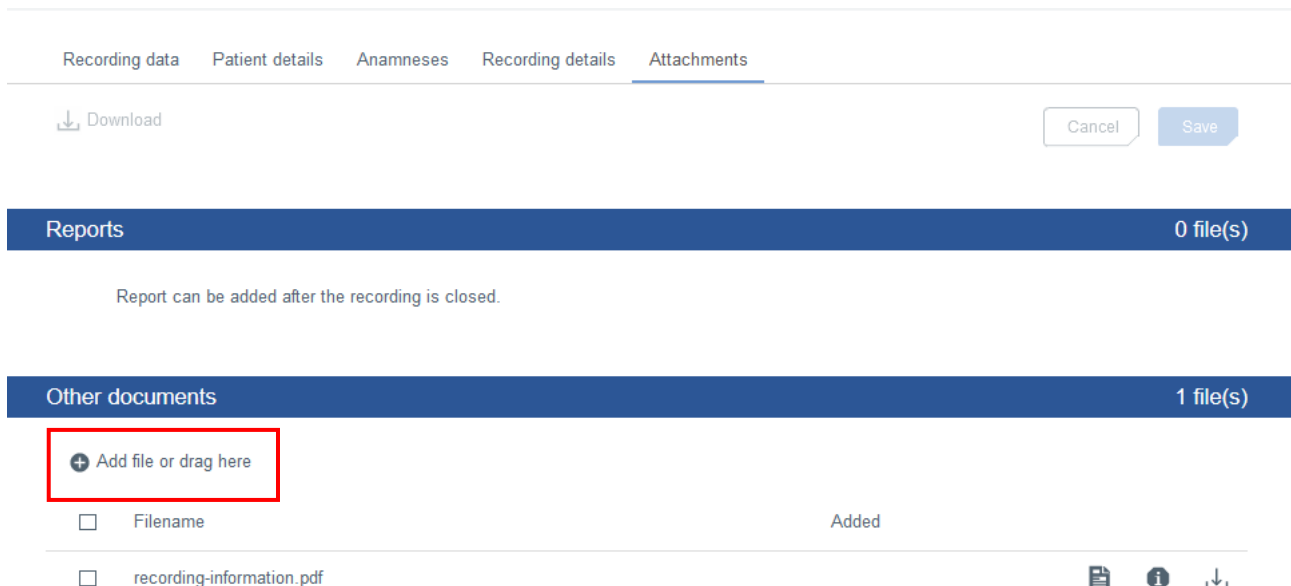


Figure 22 Add file icon on Attachments tab

The uploaded document will appear in the Other documents section on the **Attachments** tab (Figure 23).

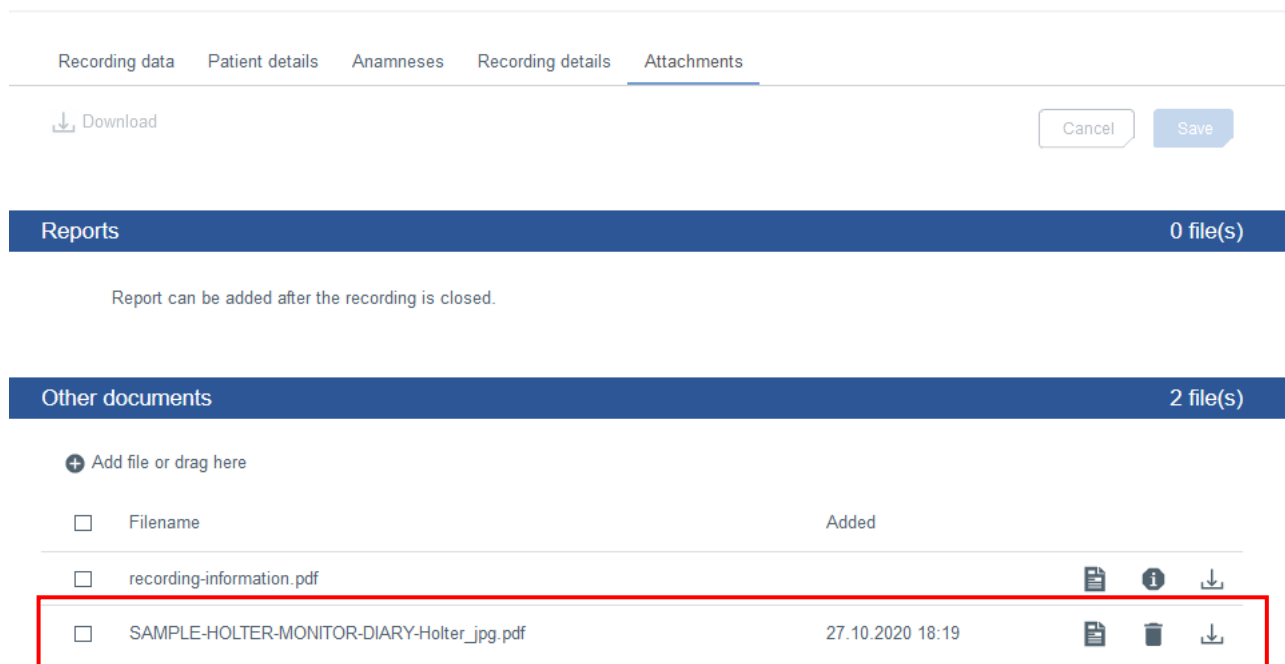


Figure 23 Uploaded document on Attachments tab

NOTE You can only add files of following filetypes to Reports and Other documents sections: .txt, .pdf, .png, .gif, .rtf, .bmp, .jpg, .xml and .edf.

6.5.4 Setting Bittium Holter recording to “Ready for analysis”

When the complete recording data has been uploaded to a recording, the Bittium Holter recording can be ended to indicate that final analysis can be performed for the recording.

NOTE Bittium Holter recording must have a recording data uploaded as described in chapter 6.5.2 before it can be ended.

To end a recording, set the recording to **Ready for analysis** or change the recording status from **Active** to **Ended** by following the steps described below:

- 1 Open the recording e.g., from the **Active recordings** card on the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Click **Ready for analysis button** on the single recording top bar (Figure 24). The same action can also be made by changing the recording status from **Active** to **Ended** either on the single recording top bar (Figure 24), or directly on the Recordings view (Figure 25).

< Back **Bittium** Dashboard Recordings EN Clinic Demo

Patient ID: **BittiumHolter_1** Bittium Holter Ready for analysis

Status	● Active ▾ Ended	Created	27.10.2020 15:51	Last update	28.10.2020 09:31
		Started	14.02.2018 11:43	Duration	1 / 1 day(s)

Recording data Patient details Anamneses Recording details Attachments

Download ☐ Include all attachments Cancel Save

Recording data

+ Add file or drag here

☐	Day No.	Start date of file	Status	Notes
☐	1/1	14.02.2018 11:43	● Open ▾	Add notes

Figure 24 Setting recording to “Ready for analysis” on the single recording top bar

Bittium Dashboard Recordings EN Clinic Demo

Recordings

Create recording ▾ 10 ▾ ☐ All ▾

Patient ID ▾	Status ▾	Last update ▾	Created ▾	Recording type ▾	Device ▾	Action
BittiumHolter_1	● Active ▾ Ended	28.10.2020 09:31	27.10.2020 15:51	Bittium Holter	1750044	
...	...	28.10.2020	28.10.2020	...	...	...

Figure 25 Changing recording status to “Ended” on Recordings view

- Confirm the ending by clicking **Ready for analysis** (Figure 26).

Ready for analysis

Patient ID BittiumHolter_1

Are you sure this recording is ready for analysis? You will no longer be able to upload new recording data to it.

Cancel

Ready for analysis

Figure 26 Confirming ending of a recording

The complete recording data is now available on Bittium MedicalSuite service platform for detailed ECG analysis, and the recording appears in **Diagnostic report needed** dashboard card (Figure 27). If Cardiac Navigator integration is in use, the complete recording data gets automatically transferred to the related Cardiac Navigator database for further analysis once the recording is assigned to a diagnostic user or diagnostic group. The complete data can also be manually downloaded from Bittium MedicalSuite service platform in EDF format (see chapter 6.8).

Diagnostic report needed				
All Not assigned				
Recording	Assignment	End time	Duration	
● BittiumHolter_1	None	15.02.2018 11:43	1 day(s)	Close Analyze 

Figure 27 “Diagnostic report needed” dashboard card

6.6 Verifying signal quality using Quick Preview

The ECG data that has been transferred from Faros ECG device to Bittium MedicalSuite service platform can be previewed in Bittium MedicalSuite Center using the **Quick Preview** feature. The feature is available for users to whom the feature has been enabled in MedicalSuite BackOffice. In **Quick Preview**, users can preview and check the quality of the acquired ECG signal.

NOTE

This feature is available only for users to whom it has been enabled in MedicalSuite BackOffice.



CAUTION: This feature is used only for checking the quality of the acquired ECG signal. Any determination of cardiac event occurrences should not be made using the **Quick Preview** feature. Always use proper cardiac analysis software to analyze ECG data.

To check the quality of the acquired ECG signal using **Quick Preview** feature, follow the steps described below:

- 1 Open the recording either from the Dashboard or the Recordings page on Bittium MedicalSuite Center by clicking on the recording.

- 2 Select **Recording data** tab.
- 3 Open **Quick Preview** by clicking the right arrow related to the daily signal data you want to preview (Figure 28).

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
☐ Include all attachments
Cancel
Save

Recording data

	☐	Day No.	Start date of file	Status	Notes
▶	☐	1/7	22.05.2021 12:07	● Pending ▾	Add notes
▶	☐	2/7	23.05.2021 12:07	● Pending ▾	Add notes
▶	☐	3/7	24.05.2021 12:07	● Pending ▾	Add notes

Figure 28 Right arrow that opens the Quick Preview of the signal

- 4 The ECG signal of the related day is presented on **Quick Preview**. The digital diary markings as well as the Faros ECG device button presses are shown on the timeline. You can navigate to the desired time using the timeline on top of the graph. You can also choose the length of the presented signal time range using the related buttons. (Figure 29)

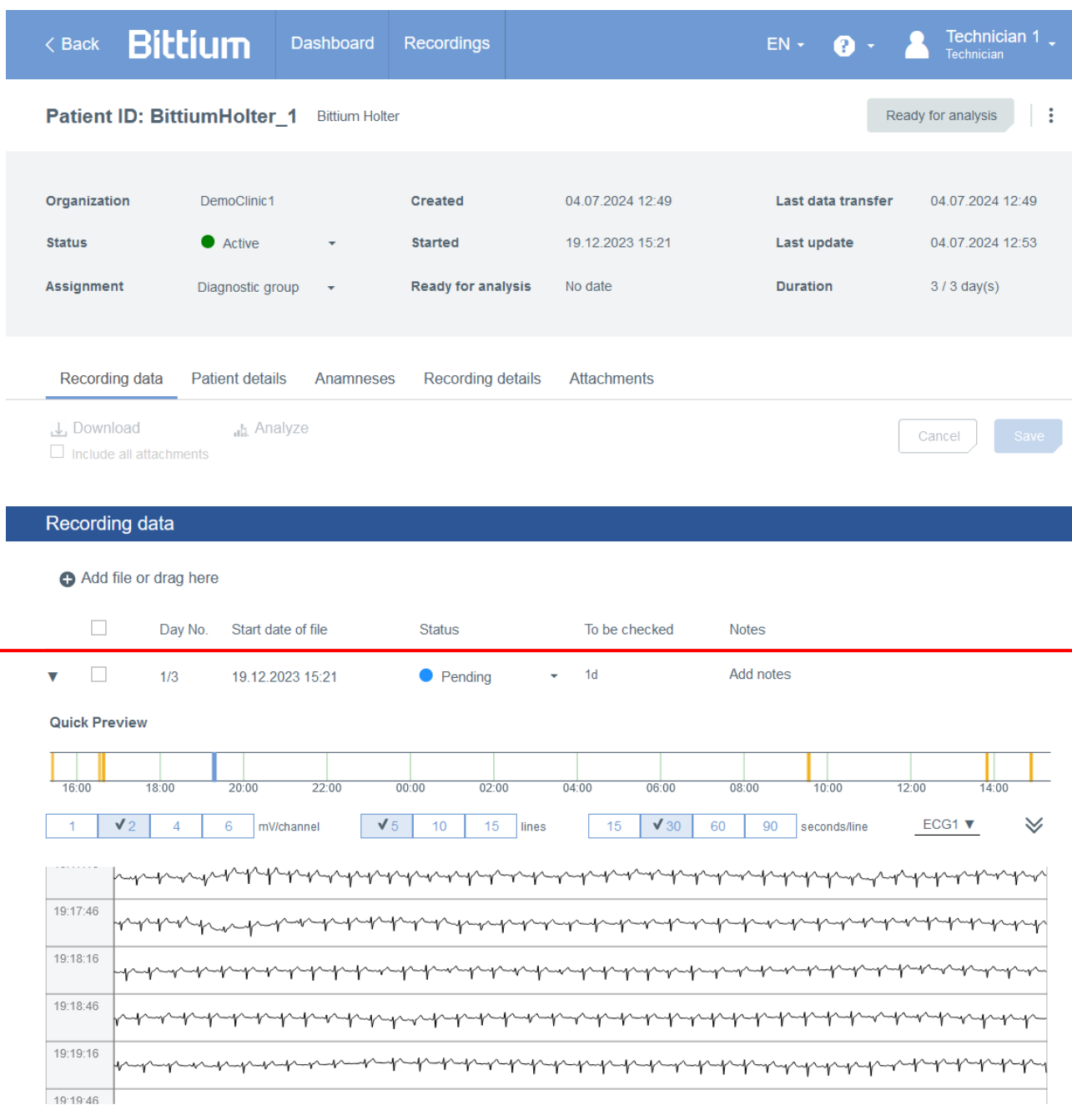


Figure 29 Quick Preview of the ECG data of the selected day

6.7 Assigning recording to a specific diagnostic user or diagnostic group

For final analysis purposes the recording is assigned either to a specific diagnostic user or diagnostic group responsible for the analysis of the patient recording. If Cardiac Navigator is in use and a database is set up for the selected diagnostic user or diagnostic group, the assignment triggers an automatic data transfer from Bittium MedicalSuite service platform to the related Cardiac Navigator database. At first place, assigning a recording to a specific diagnostic user or

diagnostic group can be made by a technician user by selecting the desired diagnostic user or diagnostic group from the drop-down list of the recording assignment field (Figure 30).

The screenshot shows the Bittium MedicalSuite interface. At the top, there is a navigation bar with 'Back', 'Bittium', 'Dashboard', and 'Recordings'. The user is logged in as 'Technician 1'. The main area displays a recording card for 'Patient ID: BittiumHolter_1'. The card includes fields for 'Organization' (DemoClinic1), 'Status' (Active), 'Created' (04.07.2024 12:49), 'Started' (19.12.2023 15:21), 'Ready for analysis' (No date), 'Last data transfer' (04.07.2024 12:49), 'Last update' (04.07.2024 15:58), and 'Duration' (3 / 3 day(s)). A red box highlights the 'Assignment' dropdown menu, which is open and shows a list of diagnostic groups and users. The 'Groups' section includes 'Cardioscope Group', 'Diagnostic group', 'Diagnostic group (autoreports)', 'HRV group (autoreports)', and 'HSAT Analysis'. The 'Users' section includes 'Carla Cardiologist' and 'Diagnostic group'. The background shows a recording card for 'Patient ID: BittiumHolter_1' with fields for 'Organization', 'Status', 'Created', 'Started', 'Ready for analysis', 'Last data transfer', 'Last update', and 'Duration'.

Figure 30 Assigning a recording

Assignment can also be made on the Recordings view by selecting the desired diagnostic user or diagnostic group from the drop-down list of the related field on the assignment column. In addition, the **Diagnostic report needed** card on the Dashboard includes assignment feature.

NOTE This feature is available only for technician and diagnostic users.

NOTE This feature is fully available only for technician users. For diagnostic users the feature is limited such that a diagnostic user can only change the assignment inside the diagnostic group or, alternatively, remove the whole assignment from the recording.

6.8 Downloading data from Bittium MedicalSuite service platform

For storing the recorded data or further analyzing it with non-integrated analysis software, the recorded ECG data can be manually downloaded from Bittium MedicalSuite service platform in EDF format.

To download data from Bittium MedicalSuite service platform, follow the steps described below:

- 1 Open the recording either from the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Select **Recording data** tab.
- 3 Select the days you want to download the data of. To download the complete ECG recording as one file, place a checkmark on the top box as shown in the Figure 31. If you wish to

download also the related attachments e.g., the recording information PDF file that contains patient details, check also the box of “Include all attachments” (Figure 31).

Patient ID: BittiumHolter_1 Bittium Holter

Ready for analysis

Organization	DemoClinic1	Created	03.07.2024 11:01	Last data transfer	03.07.2024 12:48
Status	Active	Started	11.10.2019 11:43	Last update	03.07.2024 12:49
Assignment	None	Ready for analysis	No date	Duration	29 / 29 day(s)

Recording data Patient details Anamneses Recording details Attachments

Download
☐ Include all attachments

Cancel Save

Recording data

+ Add file or drag here

☒	Day No.	Start date of file	Status	To be checked	Notes
☒	1/29	11.10.2019 11:43	Open	1d	Add notes
☒	2/29	12.10.2019 11:43	Open	1d	Add notes
☒	3/29	13.10.2019 11:43	Open	1d	Add notes
☒	4/29	14.10.2019 11:43	Open	1d	Add notes

Figure 31 Selecting the days for download

4 Click **Download** (Figure 31).

The recorded data of the selected days is downloaded as a zip file that contains the recording ECG data file in EDF format and the attachments if selected to be included. Store the downloaded data to the desired location or extract the recording data file and import it to ECG analysis software for further analysis.

6.9 Analyzing ECG data in Cardiac Navigator and creating a diagnostic report

Final analysis of the acquired ECG data is performed by a specific diagnostic user or a member of the diagnostic group to whom the recording is assigned. Evaluation of cardiac event occurrences is performed using proper cardiac analysis software. If Cardiac Navigator is in use and a database is set up for the diagnostic user or diagnostic group who is responsible for the analysis of the patient recording, changing the recording status to **Ended** triggers an automatic complete data transfer from Bittium MedicalSuite service platform to the related Cardiac Navigator database. When a recording is finished, the complete recorded ECG data appears in one instance in Cardiac

Navigator marked with an indication of “Ended”. Final analysis of a recording is performed to this “Ended” data instance in Cardiac Navigator. Also, the diagnostic report including interpretation notes written using the narrative tool is added to this “Ended” data instance to get the report automatically transferred from Cardiac Navigator to Bittium MedicalSuite Center once the recording is closed.

NOTE

This feature is available only for technician and diagnostic users who are linked to the related Cardiac Navigator™ user account in MedicalSuite BackOffice.

To perform final analysis of a recording and to create a diagnostic report in Cardiac Navigator, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard.
- 2 Open the complete recorded ECG data in Cardiac Navigator by clicking **Analyze** (Figure 32). The same icon can also be found from the Recording data tab on a single recording view in MedicalSuite Center (Figure 33).

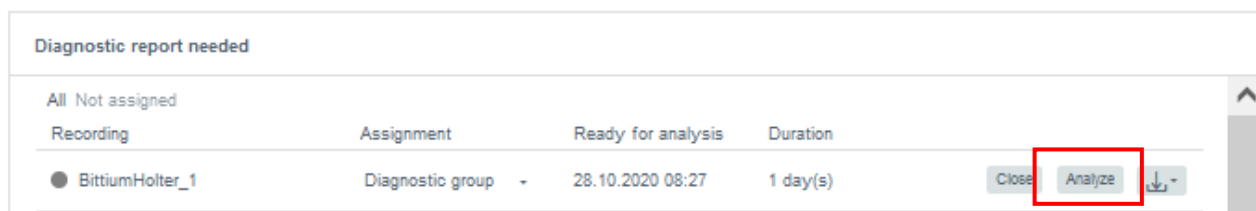


Figure 32 Navigation to the complete recorded ECG data in Cardiac Navigator

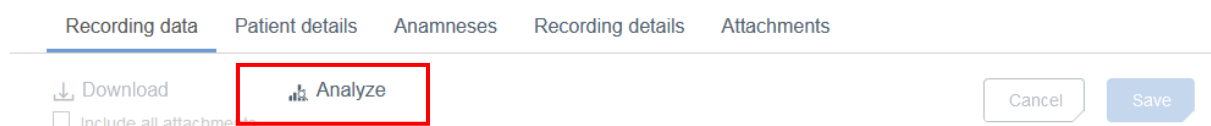


Figure 33 Navigation to the complete recorded ECG data in Cardiac Navigator from the single recording view

When using Cardiac Navigator Online, click **Analyze button** to open a new window for logging in to Cardiac Navigator with your user credentials. The related recording data opens in Cardiac Navigator.

Analyze the complete recording for cardiac event occurrences using different data tabs in Cardiac Navigator. When creating a diagnostic report in Cardiac Navigator, select **Add to record** to transfer the report to the MedicalSuite service platform (Figure 34).

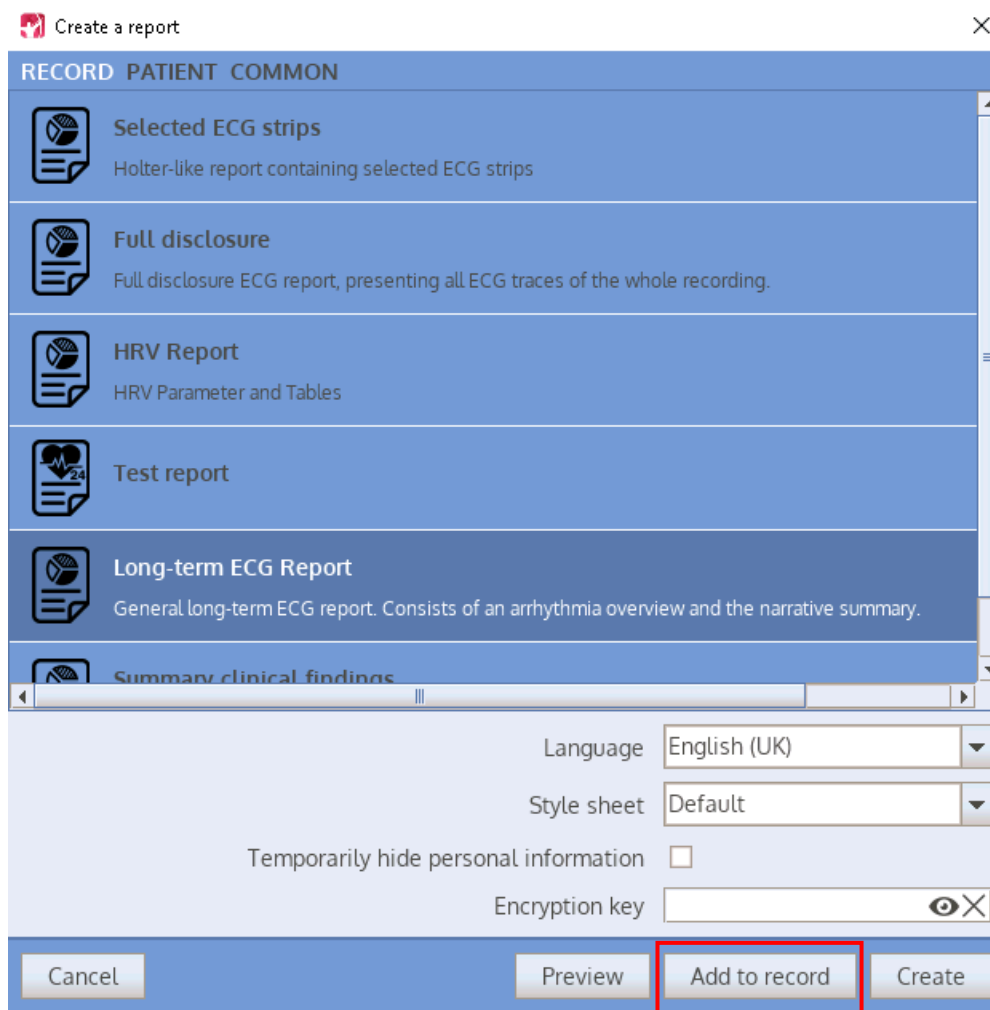


Figure 34 Adding report to a recording in Cardiac Navigator database

More detailed instructions for the use of Cardiac Navigator can be found on separate Cardiac Navigator user manual.

6.10 Closing Bittium Holter recording and attaching diagnostic report

When final analysis of a recording is performed, the recording can be closed. Attaching a diagnostic report to a recording removes the recording from the **Diagnostic report needed** dashboard card. If Cardiac Navigator is in use and a database is set up for the diagnostic user or diagnostic group to whom the recording is assigned, changing the recording status to **Closed** triggers an automatic report transfer from the related Cardiac Navigator database to Bittium MedicalSuite service platform. After the diagnostic report is attached to the recording in Bittium MedicalSuite service platform, the recording will appear on the Latest reports dashboard card.

NOTE

This feature is available only for technician and diagnostic users who are linked to the related Cardiac Navigator™ user account in MedicalSuite BackOffice.

To close a recording, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **Close button** related to the recording that you want to close either directly from the **Diagnostic report needed** card on the Dashboard (Figure 35) or on the single recording top bar (Figure 36, open first the recording by clicking it). The same action can also be made by changing the recording status from **Ended** to **Closed** either on the single recording top bar (Figure 36), or directly on the Recordings view (Figure 37).

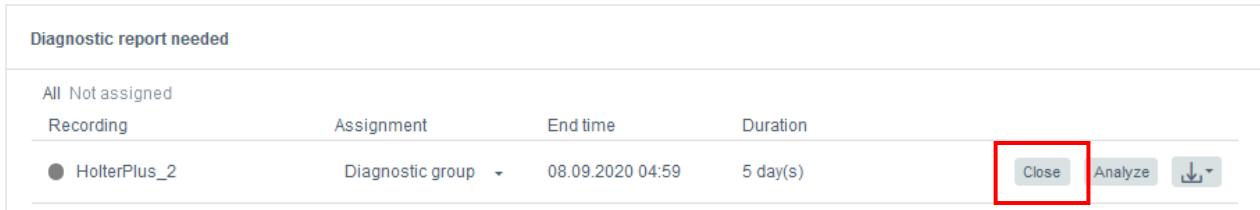


Figure 35 Close button on “Diagnostic report needed” dashboard card

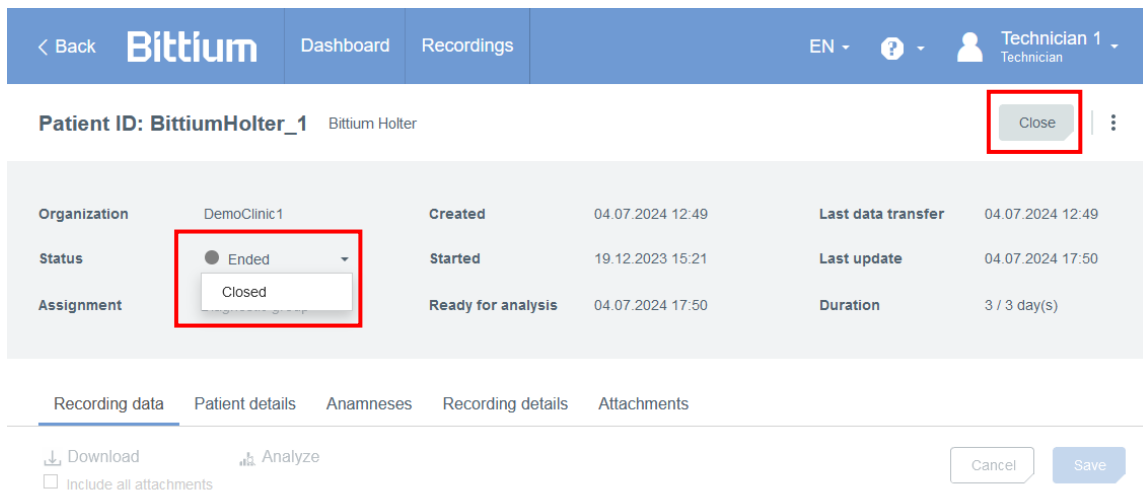


Figure 36 Closing recording on single recording top bar

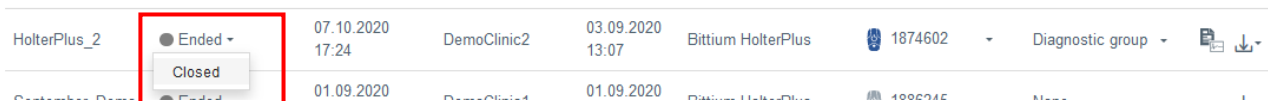


Figure 37 Changing recording status to “Closed” on Recordings view

- 3 Confirm the closing by clicking **Close** (Figure 38).

Close recording

If a report is attached to the recording in Cardiac Navigator, it will be imported to the recording. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider.

Cancel

Close

Figure 38 Confirming closing of a recording

If Cardiac Navigator is in use, all diagnostic reports saved to the recording in the related Cardiac Navigator database get automatically transferred to Bittium MedicalSuite service platform when the recording is closed. You can trigger the report transfer also manually by clicking **Import reports icon** on the **Attachments** tab of the recording (Figure 39).

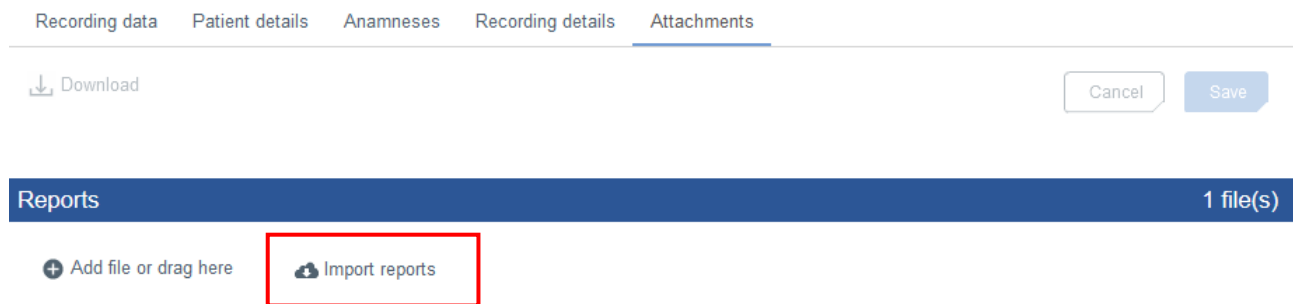


Figure 39 Import reports icon on Attachments tab

A diagnostic report can also be uploaded manually to a recording on Bittium MedicalSuite Center.

To manually upload a diagnostic report to a recording, follow the steps described below:

- 1 Click **Add report button** related to the recording that you want to upload a diagnostic report to, from the **Diagnostic report needed** card on the Dashboard (Figure 40) and click **Add file icon** (Figure 41).

Diagnostic report needed				
All	Not assigned			
Recording	Assignment	End time	Duration	
● HolterPlus_2	Diagnostic group ▾	08.09.2020 04:59	5 day(s)	Add report Analyze ⬇ ▾

Figure 40 Add report button on “Diagnostic report needed” dashboard card

Add report

New reports created in Cardiac Navigator will be imported to the recording by clicking the “Import” button. Already imported reports will not be updated. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider. If you want to add a report manually, click “Add file”.

+ Add file or drag here

Cancel

Import

Figure 41 Adding report manually to recording from “Diagnostic report needed” dashboard card

- 2 Select a file or multiple files to be added. Click **Open**. Alternatively, you can drag the file to the prompted area.
- 3 Click **Upload** to perform the uploading of the selected file(s) (Figure 42).

Add report

New reports created in Cardiac Navigator will be imported to the recording by clicking the “Import” button. Already imported reports will not be updated. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider. If you want to add a report manually, click “Add file”.

+ Add file or drag here

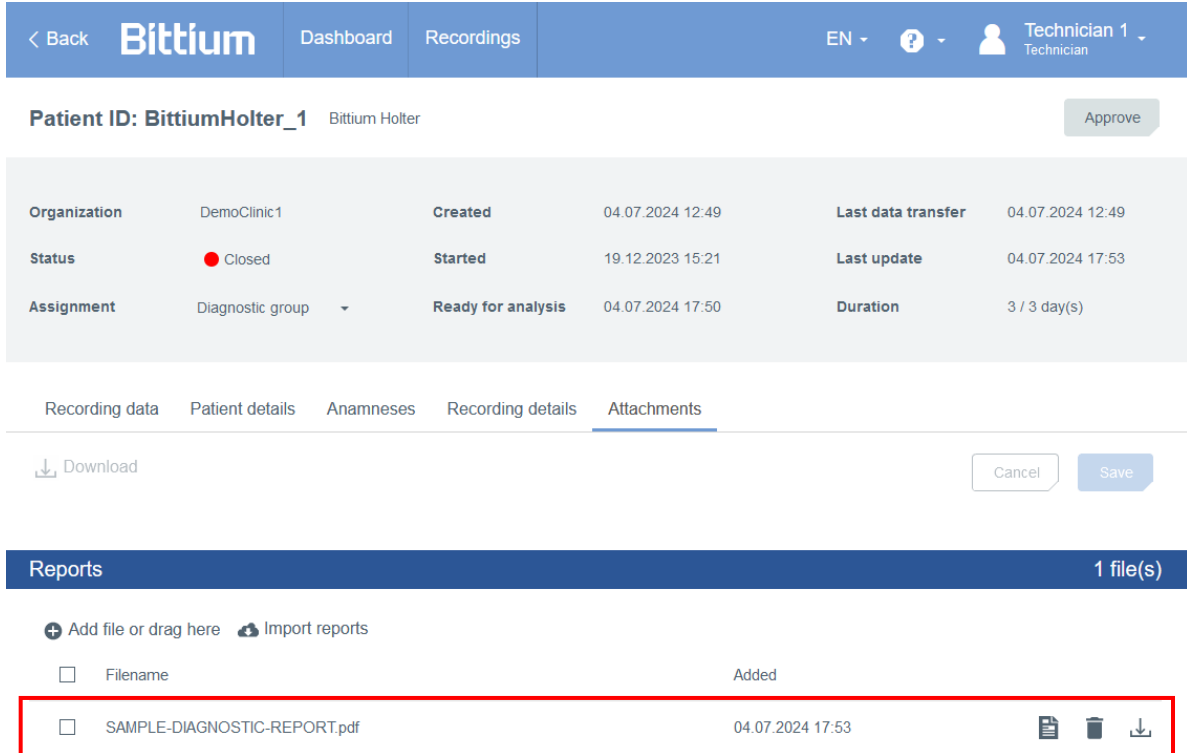
SAMPLE-HOLTER-MONITO... ✖

Cancel

Upload

Figure 42 Uploading report manually to recording from “Diagnostic report needed” dashboard card

The same action can also be made by clicking **Add file icon** under Reports section on the **Attachments** tab of the recording (Figure 43, open first the recording by clicking it).



6.11 Approving recording and delivering diagnostic reports to lower-level organization

Recording needs to be approved by a technician user of the upper-level organization on Bittium MedicalSuite Center to get the diagnostic report(s) delivered to the associated lower-level organization. When a report is attached to a recording on Bittium MedicalSuite service platform, a technician user of the upper-level organization first previews it and verifies that the report contains all the necessary information. After previewing, the technician user finally approves the recording to deliver the diagnostic report(s) to the associated lower-level organization.

NOTE This feature is available only for technician users.

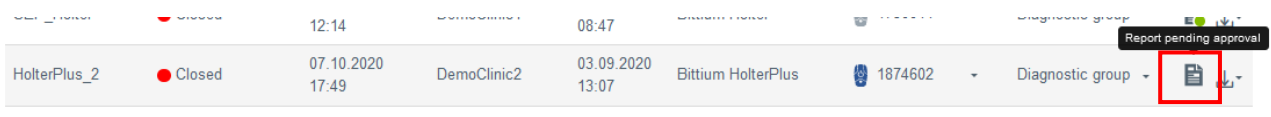
To preview a diagnostic report, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Latest reports** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **preview icon** related to the recording whose report you want to preview either directly from the **Latest reports** card on the Dashboard (Figure 45) or on the Recordings view (Figure 46).



Recording	Organization	Added	Approval	
HolterPlus_2	DemoClinic2	07.10.2020 21:02 Diagnostic group	Approve	

Figure 45 Preview icon on “Latest reports” dashboard card



Recording	Status	Added	Organization	Date	Recorder	Diagnostic group	
HolterPlus_2	Closed	07.10.2020 17:49	DemoClinic2	03.09.2020 13:07	Bittium HolterPlus	1874602	

Figure 46 Preview icon on Recordings view

If you clicked the preview icon on the Recordings view (Figure 46), the **Attachments** tab of the recording will open. Click **preview icon** related to the report you want to preview.

To approve a recording to deliver the diagnostic report(s) to the associated lower-level organization, follow the steps described below:

- 1 Click **Approve button** related to the recording whose report(s) you want to deliver to the associated lower-level organization either directly from the **Latest reports** card on the Dashboard (Figure 47) or on the single recording top bar (Figure 48, open first the recording by clicking it).

Recording	Organization	Added	Approval
 HolterPlus_2	DemoClinic2	07.10.2020 17:49 Diagnostic group	Approve  

Figure 47 Approve button on “Latest reports” dashboard card

[< Back](#)

Bittium

Dashboard
Recordings

EN
?
Technician 1
Technician

Patient ID: BittiumHolter_1
Bittium Holter

Approve

Organization	DemoClinic1	Created	04.07.2024 12:49	Last data transfer	04.07.2024 12:49
Status	● Closed	Started	19.12.2023 15:21	Last update	04.07.2024 17:53
Assignment	Diagnostic group ▾	Ready for analysis	04.07.2024 17:50	Duration	3 / 3 day(s)

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports
1 file(s)

+ Add file or drag here
Import reports

☐ Filename	Added
☐ SAMPLE-DIAGNOSTIC-REPORT.pdf	04.07.2024 17:53

Figure 48 Approve button on single recording top bar

- 2 Confirm approving by clicking **Approve** (Figure 49).

Confirmation

Are you sure you want to approve the reports of Patient ID: HolterPlus_2? After approval, reports will be visible for the clinic.

CancelApprove

Figure 49 Confirming approving of a recording

When a recording is approved (Figure 50), the related diagnostic reports imported to Bittium MedicalSuite service platform are delivered to the associated lower-level organization, and the related preview icons have a green dot indicating the delivery (Figure 51).

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Bittium

Dashboard

Recordings

EN

?

Technician 1

Technician

Patient ID: BittiumHolter_1

Bittium Holter

Approved

Organization	DemoClinic1	Created	04.07.2024 12:49	Last data transfer	04.07.2024 12:49
Status	● Closed	Started	19.12.2023 15:21	Last update	04.07.2024 17:58
Assignment	Diagnostic group	Ready for analysis	04.07.2024 17:50	Duration	3 / 3 day(s)

Figure 50 Recording approved

Latest reports					
Recording	Type	Organization	Updated	Approval	
● BittiumHolter_1	Bittium Holter	DemoClinic1	04.07.2024 17:53 Diagnostic group	04.07.2024 17:58	

Figure 51 Preview icon with a green dot indicating report delivery

6.12 Previewing and downloading diagnostic reports and other documents

When a recording is approved by a technician user of the upper-level organization, the related diagnostic report(s) transferred to Bittium MedicalSuite service platform are available also for the associated lower-level organization users. Previewing and downloading a diagnostic report or some other attached document (e.g., recording information PDF file) from Bittium MedicalSuite Center can be done directly from the **Latest reports** card on the Dashboard or from the **Attachments** tab of the recording.

To preview a diagnostic report or some other document, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Latest reports** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **preview icon** related to the recording whose report or some other document you want to preview either directly from the **Latest reports** card on the Dashboard (Figure 52) or on the Recordings view (Figure 53).

Latest reports				
Recording	Organization	Added		Approval
● HolterPlus_2	DemoClinic2	07.10.2020	17:49	07.10.2020 17:54

Figure 52 Preview icon on “Latest reports” dashboard card

Bittium

Dashboard

Recordings

EN

Clinic Demo 2

Clinic

Recordings

Q Search

Create recording

10

All

Patient ID	Status	Last update	Created	Recording type	Device	Action
HolterPlus_2	Closed	07.10.2020 18:31	03.09.2020 13:07	Bittium HolterPlus	1874602	

Figure 53 Preview icon on Recordings view

If you clicked the preview icon on the Recordings view (Figure 53), the **Attachments** tab of the recording will open. Click **preview icon** related to the report you want to preview.

NOTE Microsoft Edge users may experience problems opening PDF reports. This inconvenience is caused by Microsoft Edge privacy settings, including the Microsoft Edge-specific PDF handling option. In case previewing the report in medical suite is not possible, download the file.

To download a diagnostic report or some other document, follow the steps described below:

- Click **download icon** related to the recording whose report or some other document you want to download either directly from the **Latest reports** card on the Dashboard (Figure 54) or on the Recordings view (Figure 55) and select the document you want to download.

Latest reports				
Recording	Organization	Added		Approval
● HolterPlus_2	DemoClinic2	07.10.2020	17:49	07.10.2020 17:54

Download

- Recording data
 - Recording data 5 day(s)
- Reports
 - HOLTERPLUS_2_HolterPlus_2_01-01-1993_26-06-2020-2_-_General_long-term_ECG_report.pdf
- Other documents
 - recording-information.pdf

Figure 54 Download icon on “Latest reports” dashboard card

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports
1 file(s)

☐	Filename	Added		
☐	HOLTERPLUS_2__HolterPlus_2_01-01-1993_26-06-2020-2_-_General_long-term_ECG_report.pdf	07.10.2020 17:49		

Other documents
1 file(s)

+ Add file or drag here

☐	Filename	Added		
☐	recording-information.pdf			

Figure 55 Download icons on Attachments tab of a recording

Store the downloaded document(s) to the desired location.

7 BITTIUM HOLTERPLUS RECORDINGS

Bittium HolterPlus is a flexible, online ECG recording whose duration can be adjusted according to the case specific needs to optimize the amount of acquired ECG data and required time resources. The acquired cardiac signal together with digital patient diary markings are automatically transferred to Bittium MedicalSuite service platform periodically and are available there for signal quality verification, daily symptoms and arrhythmia events check and, eventually, for the complete ECG data analysis.

More detailed requirements concerning IT networks characteristics and IT security measures contact Bittium customer support: medical.support@bittium.com

7.1 Introduction to Bittium HolterPlus workflow

Bittium HolterPlus recording workflow consists of steps listed below. Bittium HolterPlus is an ambulatory online recording that is used to record ECG data. Bittium HolterPlus recording is automatically started, and data transferred to Bittium MedicalSuite service platform using Bittium MedicalSuite Mobile application. The used settings are selected using Bittium MedicalSuite Center application when creating recording to service. Once the recording is completed, the recording data is available in Cardiac Navigator analysis software for the complete data analysis.

- Clinic user creates Bittium HolterPlus recording either on Bittium MedicalSuite Center or using the MedicalSuite Mobile application, attaches electrodes to patient and checks signal quality using Live ECG feature on the MedicalSuite Mobile application.
- Patient is filling digital diary during recording period using MedicalSuite Mobile application.
- Technician user assigns recording for diagnostic user/group for daily analysis
- Diagnostic user performs daily analysis every day and decides if recording can be ended before scheduled ending
- Diagnostic user performs final analysis and reporting when recording is ended
- Technician user accepts final report before delivering to clinic

Detailed instructions for performing Bittium HolterPlus recording workflow steps are described in the following chapters.

7.2 Creating Bittium HolterPlus recording

Bittium HolterPlus recordings can be created either on Bittium MedicalSuite Center or using Bittium MedicalSuite Mobile application.

7.2.1 Creating Bittium HolterPlus recording on Bittium MedicalSuite Center

To create a Bittium HolterPlus recording on Bittium MedicalSuite Center, follow the steps described below:

1. Click **Create recording button** either on the Dashboard or the Recordings page on Bittium MedicalSuite Center. A drop-down menu is presented (Figure 56). Select **Bittium HolterPlus**. Create recording page opens.

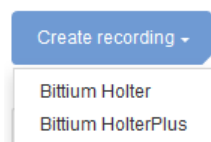


Figure 56 Create recording drop-down menu

2. Enter information to all the required fields (*) on the Patient details tab (Figure 57). If desired, other fields can be left unfilled. Note the following:
 - a Patient ID is for identifying the patient. If this field is left blank, the system will generate it.
 - b Do not use the patient's name or social security number as a patient ID!**



CAUTION: Do not enter any patient delicate information (e.g., use the patient's name or social security number as a patient ID) to the Bittium MedicalSuite service platform.

Bittium

Dashboard

Recordings

EN  Technician 1
Technician

Create recording: Bittium HolterPlus

Patient details*

Anamneses

Recording details*

Attachments

<< Back

Next >>

Cancel

Save

Patient details

Patient ID

Patient ID must be at least 4 characters long and lower/uppercase letters, numbers and underscores are allowed. If Patient ID is left blank the system will generate it (for example PID0000A).

Age (years)*

Height (cm)*

Weight (kg)*

Gender*

Figure 57 Create recording – Patient details tab

3. Click **Next** and enter patient anamneses information on the Anamnesis tab, if necessary (Figure 58, optional step).

Bittium

Dashboard

Recordings

EN  Technician 1

Create recording: Bittium HolterPlus

Patient details

Anamneses

Recording details*

Attachments

<< Back

Next >>

Cancel

Save

Medication

Medication

Medication at time of ECG recording

☐ No
 ☐ Yes

Diseases

Diagnosed heart disease

Diagnosed arrhythmias and/ or myocardial diseases (e.g. cardiomyopathy) in the family

☐ No
 ☐ Yes

☐ No
 ☐ Yes

Habits

Smoking

Alcohol consumption

☐ No
 ☐ Yes

☐ No
 ☐ Sometimes
 ☐ Often

Symptoms

Palpitations	☐ No	☐ Sometimes	☐ Often
Irregular beat	☐ No	☐ Sometimes	☐ Often
Slow pulse	☐ No	☐ Sometimes	☐ Often
Fast pulse	☐ No	☐ Sometimes	☐ Often
Unpleasant feeling in the chest	☐ No	☐ Sometimes	☐ Often
Shortness of breath	☐ No	☐ Sometimes	☐ Often
Dizziness	☐ No	☐ Sometimes	☐ Often
Weakness	☐ No	☐ Sometimes	☐ Often
Fainting/ syncope	☐ No	☐ Sometimes	☐ Often

Comments

Figure 58 Create recording – Anamnesis tab

- Click **Next** and enter recording details and device information on the Recording details tab. (Figure 59)

The required information includes:

- a. Organization arranging the recording
- b. Maximum recording duration in days
- c. Referring physician
- d. Requested report language
- e. Recorder S/N (Faros serial number, e.g., 1857243) that can be found from the back of the device
- f. Setup option based on the number and type of electrodes used
- g. The use of an accelerometer and desired ECG sampling rate. Use defaults if unsure.
- h. Confirm whether the patient has an implanted pacemaker and, if applicable, select the pacemaker event ON/OFF option accordingly.

NOTE The selected ECG device type determines the available setup options and sampling rates. If the ECG device type is changed, all device-specific settings are reset to their default values.

NOTE Faros Pro devices are currently not supported for Online Holter measurements.

Device information

Recorder S/N

9173546 (Faros 360) ▼

Type or select a serial number

Faros 180 / 180L / 360

See back of the recorder.



Faros Pro

See back of the recorder. Please add characters after "SN".



These are the default settings. Use default settings if not instructed otherwise.

Accelerometer

On Off

ECG sampling rate (Hz)

125 250 500 1000

Pacemaker event detection

On Off

Setup options

OmegaSnap 1-CH ECG Electrode ▼



Figure 59 Create recording – Recording details tab

- Click **Next** and attach additional documents on the Attachments tab, if necessary (Figure 60, optional step).

Bittium

Dashboard Recordings

EN Technician 1 Technician

Create recording: Bittium HolterPlus

Patient details

Anamneses

Recording details

Attachments

<< Back

Next >>

Cancel

Save

Other documents

+ Add file or drag here

Figure 60 Create recording – Attachments tab

- Click **Save** and a confirmation notification will open (Figure 61). Click **Create** to confirm the creation of a new recording.

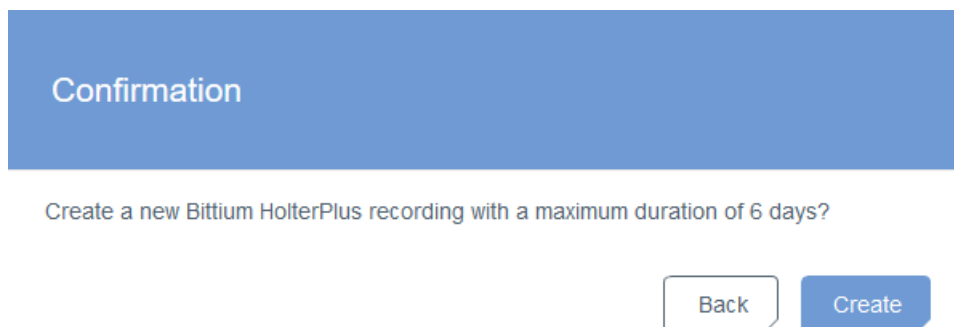


Figure 61 Create recording – Confirmation notification

7.2.2 Creating Bittium HolterPlus recording using Bittium MedicalSuite Mobile application

To create a Bittium HolterPlus recording using Bittium MedicalSuite Mobile application, follow the steps described below:

- Go to the administrator view by tapping **Bittium logo** five times on the top right of the Bittium MedicalSuite Mobile application main view.
- Tap **Create recording** on the Device setup view (Figure 62). Create recording view opens (Figure 63).
- Enter information to all the required fields (*) on the Patient details view (Figure 63). If desired, other fields can be left unfilled. Note the following:
 - Patient ID is for identifying the patient. If this field is left blank, the system will generate it.
 - Do not use the patient's name or social security number as a patient ID!**



CAUTION: Do not enter any patient delicate information (e.g., use the patient's name or social security number as a patient ID) to the Bittium MedicalSuite service platform.

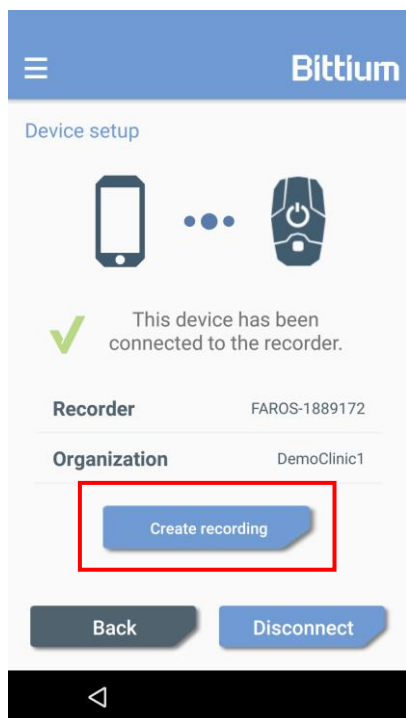


Figure 62 Device setup view

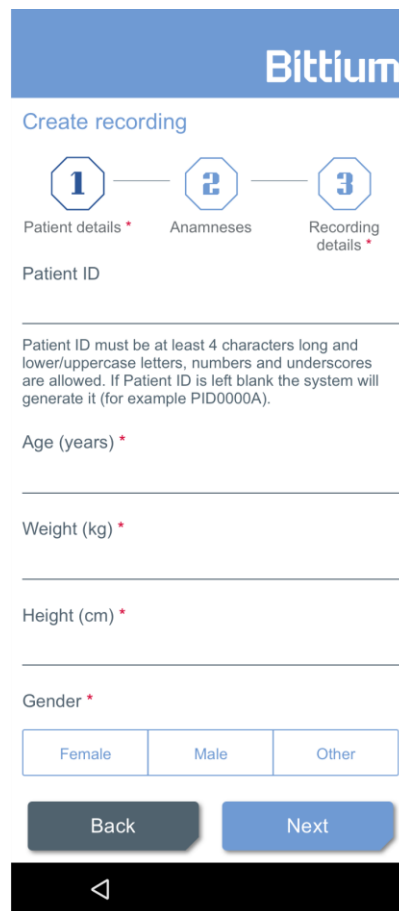


Figure 63 Create recording – Patient details view

- 4 Tap **Next** and enter patient anamneses information on the Anamnesis view, if necessary (Figure 64, optional step).

Bittium

Create recording

1

2

3

Patient details *

Anamneses

Recording details *

Thses questions are optional. You can also fill in the form later from MedicalSuite Center.

Medication

Medication

Medication at the time of ECG recording

No

Yes

Diseases

Diagnosed heart disease

No

Yes

Diagnosed arrhythmias and / or myocardial diseases (e.g., cardiomyopathy) in the family

No

Yes

Habits

Smoker

No

Yes

Alcohol consumption

No

Sometimes

Often

Symptoms

Palpitations

No

Sometimes

Often

Irregular pulse

No

Sometimes

Often

Slow pulse

No

Sometimes

Often

Fast pulse

No

Sometimes

Often

Unpleasant feeling in the chest

No

Sometimes

Often

Shortness of breath

No

Sometimes

Often

Dizziness

No

Sometimes

Often

Weakness

No

Sometimes

Often

Fainting / syncope

No

Sometimes

Often

Comment

Back

Next

Figure 64 Create recording – Anamnesis view

- 5 Tap **Next** and enter recording details on the Recording details view (Figure 65). The required information includes:
 - a Maximum recording duration in days
 - b Setup option based on the number and type of electrodes used
 - c The use of an accelerometer and desired ECG sampling rate. Use defaults if unsure.
- 6 Tap **Save** and a confirmation notification will open (Figure 66). Tap **Create** to confirm the creation of a new recording.

Bittium

Create recording

1 — 2 — 3
Patient details * Anamneses Recording details *

Max duration (days) *

1 - 30 days

Setup option

OmegaSnap electrode

These are the default settings. Use default settings if not instructed otherwise.

Accelerometer

☒ On ☐ Off

Sampling rate (Hz)

☒ 125 ☐ 250 ☐ 500 ☐ 1000

Pacemaker event record

☐ On ☒ Off

Please fill in required * fields before saving.

Figure 65 Create recording – Recording details view

Bittium

Create recording

Confirmation

Are you sure you want to create the recording?

Max. duration 30 days

Device setup FastFix patch

Accelerometer On

ECG sampling rate (Hz) 125 Hz

Figure 66 Create recording – Confirmation notification

7 Return to MedicalSuite Mobile application main view.

7.3 Attaching Faros ECG device and starting Bittium HolterPlus recording

After a recording is created either on Bittium MedicalSuite Center or using Bittium MedicalSuite Mobile application, the mobile device connected to the corresponding Faros ECG device gets the related recording information and provides instructions to attach the ECG device onto a patient according to the selected electrode setup option.

To attach a Faros ECG device onto a patient, follow the instructions shown on the mobile device screen:

- 1 Open the instructions to attach the ECG device by tapping **Tap here for instructions** on Bittium MedicalSuite Mobile application welcome view (Figure 67).
- 2 Browse through the step-by-step instructions by tapping **Next** and **Back** buttons on the mobile device screen (Figure 68) and attach the Faros ECG device according to the given instructions. Note that there are separate instructions for Bittium FastFix electrode, Bittium OmegaSnap electrode, 1-channel and 3-channel recordings, and only the instructions related to the electrode setup option selected during the recording creation are shown. Finally, close the instructions view by tapping **Finish**.

See separate patient instruction documents for more detailed information on the different electrode setup options.

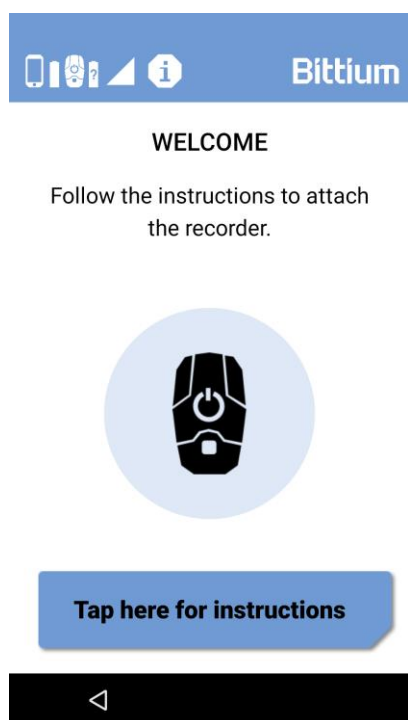


Figure 67 Welcome view

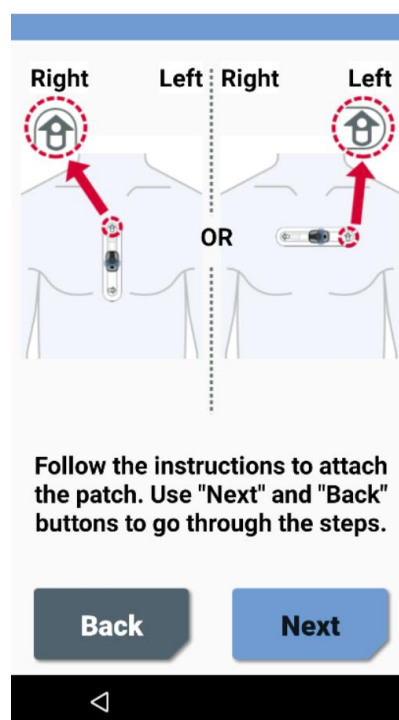


Figure 68 Instructions view for ECG device attachment

After the Faros ECG device is attached properly onto the patient, MedicalSuite Mobile application will detect a heartbeat (Figure 69). Once a heartbeat is successfully found, the recording starts and the text **Recording ongoing** is showed on the MedicalSuite Mobile application main view (Figure 70).



CAUTION: Data of the previous recording is automatically deleted from the Faros ECG device when a new HolterPlus recording is started.

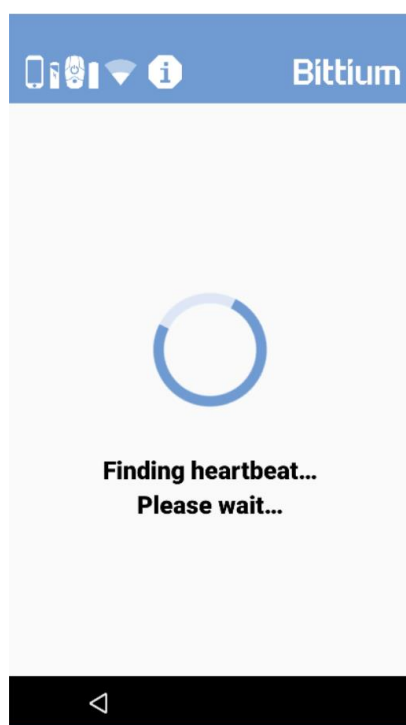


Figure 69 Finding heartbeat view

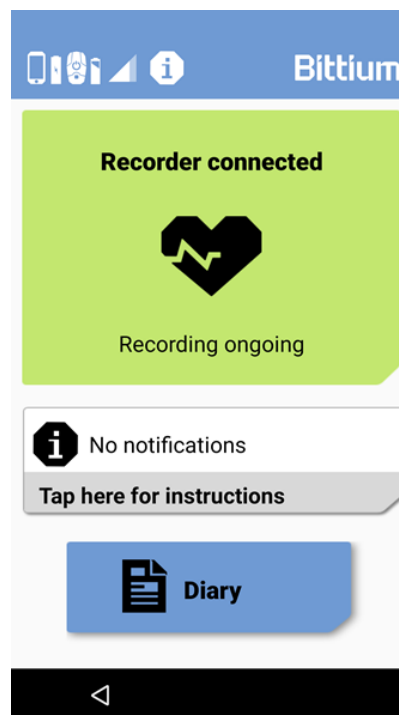


Figure 70 Main view showing “Recording ongoing”

The icons indicating the battery charge levels of the Bittium The mobile device and the Faros ECG device as well as the strength of the current network connection are displayed on the top left of Bittium MedicalSuite Mobile application views.

- 3 To verify the proper attachment of electrode(s) and the quality of the acquired ECG signal, use **Live ECG** feature on the Bittium MedicalSuite Mobile application. See chapter 7.11 for instructions.

When recording has started, its status will change from **Created** to **Active**, and the recording will appear in the **Active recordings** card on the Bittium MedicalSuite Center dashboard.

- 4 Find the created recording from Bittium MedicalSuite Center and verify that the related recording status is **Active**.
- 5 If **Quick Preview** feature is enabled to your user account, you can verify the quality of the acquired ECG signal on Bittium MedicalSuite Center using the **Quick Preview** feature. View the initial seconds of the acquired ECG signal on the Recording data tab. See chapter 7.12 for instructions.

7.4 Live ECG feature on Bittium MedicalSuite Mobile application

When Faros ECG device is attached onto a patient, it is possible to view the acquired real-time ECG and heart rate using the **Live ECG** feature on the Bittium MedicalSuite Mobile application. The feature is used for verifying the proper functioning of attached electrodes and checking the quality of the acquired ECG signal.

NOTE This feature is available only in the administrator view on MedicalSuite Mobile application.

To check the quality of the acquired ECG signal using **Live ECG** feature, follow the steps described below:

- 1 Go to the administrator view by tapping **Bittium logo** five times on the top right of the Bittium MedicalSuite Mobile application main view.
- 2 Tap **Menu icon** (3 lines) from the top left.
- 3 Tap **Live ECG** (Figure 71).
- 4 Press the Faros ECG device button (Figure 72) to activate Bluetooth. The activation is indicated by one beep-sound.
- 5 The acquired ECG signal is presented real-time with the heart rate information (Figure 73).

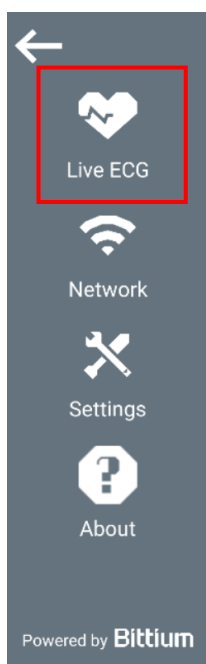


Figure 71 Live ECG on menu

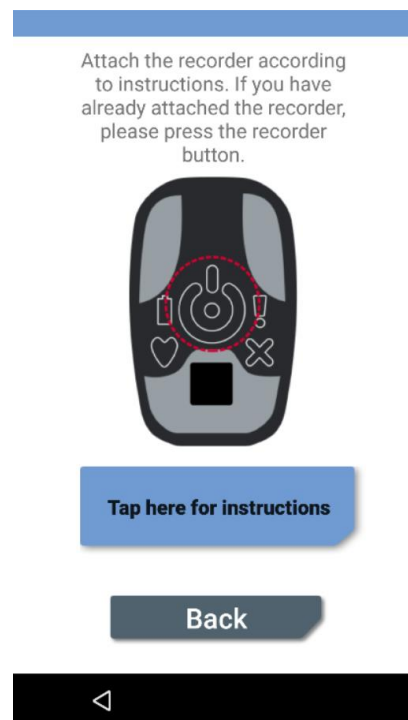


Figure 72 Faros ECG device button

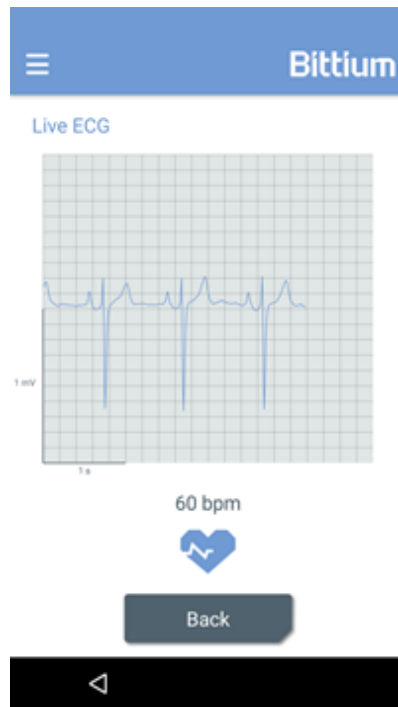


Figure 73 Live ECG view

7.5 Quick Preview feature on Bittium MedicalSuite Center

The ECG data that has been transferred from Faros ECG device to Bittium MedicalSuite service platform can be previewed in Bittium MedicalSuite Center using the **Quick Preview** feature. The feature is available for users to whom the feature has been enabled in MedicalSuite BackOffice. In **Quick Preview**, users can preview and check the quality of the acquired ECG signal.

NOTE

This feature is available only for users to whom it has been enabled in MedicalSuite BackOffice.



CAUTION: This feature is used only for checking the quality of the acquired ECG signal. Any determination of cardiac event occurrences should not be made using the **Quick Preview** feature. Always use proper cardiac analysis software to analyze ECG data.

To check the quality of the acquired ECG signal using **Quick Preview** feature, follow the steps described below:

- 5 Open the recording either from the Dashboard or the Recordings page on Bittium MedicalSuite Center by clicking on the recording.
- 6 Select **Recording data** tab.
- 7 Open **Quick Preview** by clicking the right arrow related to the daily signal data you want to preview (Figure 74).

Recording data

Patient details

Anamneses

Recording details

Attachments

Download

☐ Include all attachments

Cancel

Save

Recording data

☐	Day No.	Start date of file	Status	Notes
▶ ☐	1/7	22.05.2021 12:07	● Pending ▾	Add notes
▶ ☐	2/7	23.05.2021 12:07	● Pending ▾	Add notes
▶ ☐	3/7	24.05.2021 12:07	● Pending ▾	Add notes

Figure 74 Right arrow that opens the Quick Preview of the signal

The ECG signal of the related day is presented on **Quick Preview**. The digital diary markings as well as the Faros ECG device button presses are shown on the timeline. You can navigate to the desired time using the timeline on top of the graph and using the left and right arrow buttons. You can also choose the length of the presented signal time range using the related buttons (Figure 75).

Patient ID: HolterPlus_2 Bittium HolterPlus

Ready for analysis ⋮

Organization	DemoClinic2	Created	22.05.2021 13:07	Last data transfer	No date
Status	● Active ▼	Started	22.05.2021 12:07	Last update	27.05.2021 15:45
Assignment	Diagnostic group ▼	Ready for analysis	25.05.2021 09:47	Duration	5 / 7 day(s)

[Recording data](#)
[Patient details](#)
[Anamneses](#)
[Recording details](#)
[Attachments](#)

Download
 Analyze

☐ Include all attachments

Cancel

Save

Recording data



Figure 75 Quick Preview of the ECG data of the selected day

7.6 Creating digital diary markings

To keep a track of any events occurring during a recording and to help the analysis and interpretation of the acquired ECG data, patients are commonly asked to mark down any felt symptoms and other diary notes that can affect the acquired signal and be important for proper analysis of the ECG data. Instead of using a conventional method of a paper and pen, patient can mark the diary events to a digital diary on Bittium MedicalSuite Mobile application. These diary markings are automatically merged with the acquired ECG data and are available for the diagnostic user when the ECG data is analyzed.

7.6.1 Marking symptoms to digital diary

- 1 Activate the mobile device display.
- 2 Tap **Diary** (Figure 76).
- 3 Tap **Symptoms** on the following view (Figure 77).
- 4 Tap the appropriate symptom from the symptoms view (Figure 78).
- 5 Enter the date and time when the symptom occurred.
- 6 Tap **Save** to confirm the saving of the symptom to the diary.

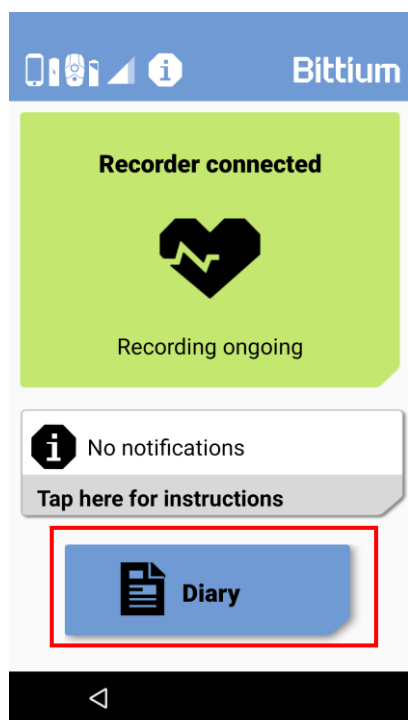


Figure 76 Diary button

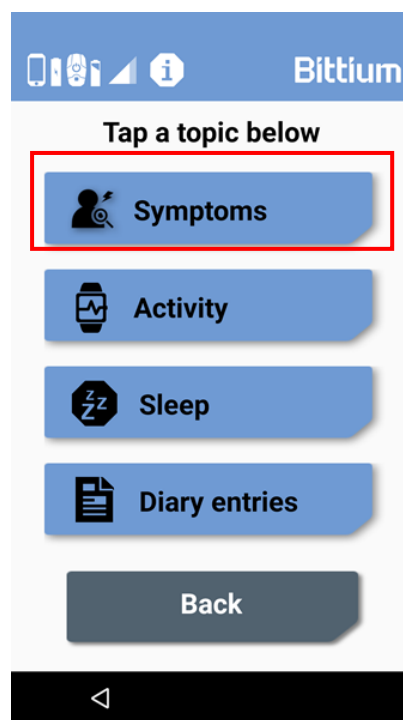


Figure 77 Symptoms button

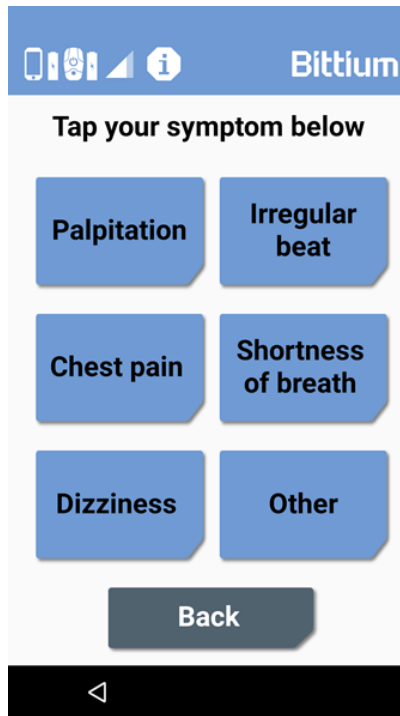


Figure 78 Symptoms view

7.6.2 Marking activity to digital diary

- 1 Activate the mobile device display.
- 2 Tap **Diary**.
- 3 Tap **Activity** on the following view.
- 4 If you are about to start an activity, tap **Start activity** (Figure 79).
- 5 While activity time is being recorded, it is indicated in the mobile application main view (Figure 80).
- 6 When you finish your activity, tap **Tap here to stop** below the indication of an ongoing activity time recording on the mobile application main view. The same action can also be made by first tapping **Diary**, then tapping **Activity** and finally tapping **Finish activity** (Figure 81).
- 7 Confirm or adjust your activity time (Figure 82).
- 8 Write an optional comment (Figure 83).
- 9 Tap **Save** button. A confirmation dialog opens asking you to confirm the information you have entered.
- 10 Tap **OK** button. Diary entry is automatically created.

You can also enter an activity marking in the past by tapping **Add activity time** (Figure 79) and entering the details for the activity marking. Confirm the action by tapping **Save**. Tap **OK** to confirm the saving of the activity marking to the diary.

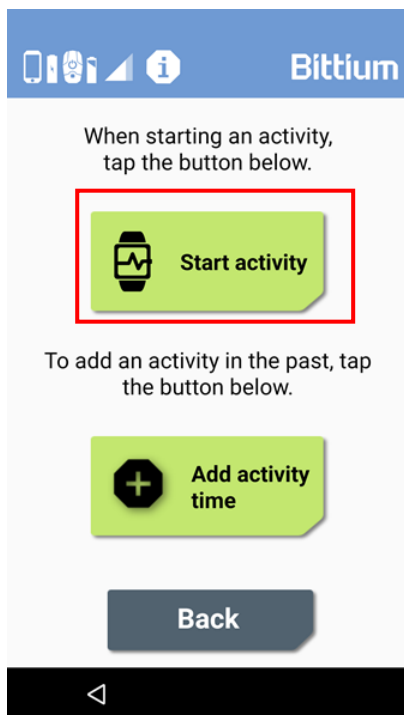


Figure 79 Start activity button

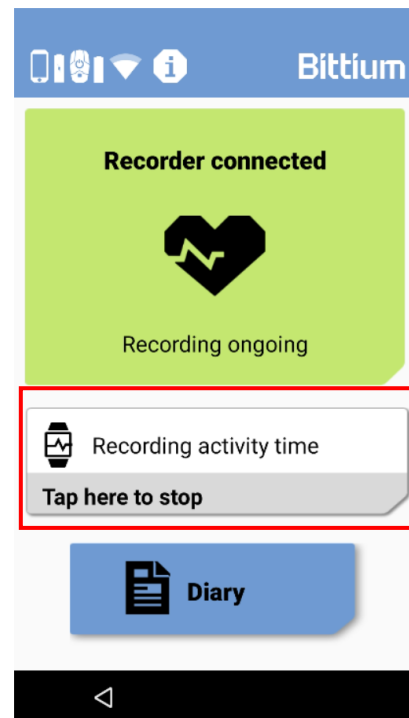


Figure 80 Main view showing "Recording activity time"



Figure 81 Finish activity button

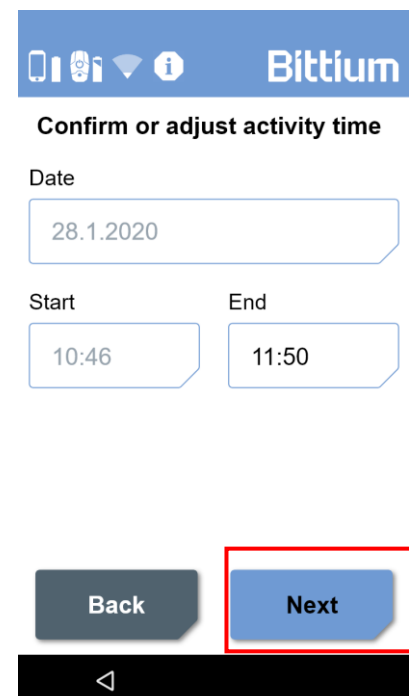


Figure 82 Confirming or adjusting activity time

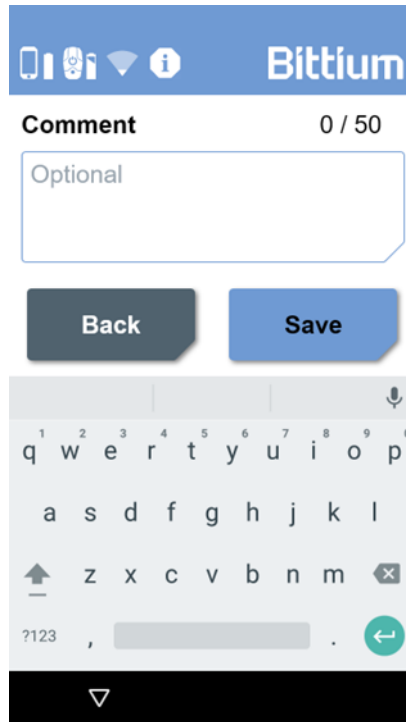


Figure 83 Writing optional comment

7.6.3 Marking sleep to digital diary

- 1 Activate the mobile device display.
- 2 Tap **Diary**.
- 3 Tap **Sleep** on the following view.
- 4 If you are about to go to sleep, tap **Go to bed** (Figure 84).
- 5 While sleep time is being recorded, it is indicated in the mobile application main view (Figure 85).
- 6 When you wake up, tap **Tap here to stop** below the indication of an ongoing sleep time recording on the mobile application main view. The same action can also be made by first tapping **Diary**, then tapping **Sleep** and finally tapping **Wake up** (Figure 86).
- 7 Confirm or adjust your sleep time. (Figure 87).
- 8 Write an optional comment (Figure 88).
- 9 Tap **Save** button. A confirmation dialog opens asking you to confirm the information you have entered.
- 10 Tap **OK** button. Diary entry is automatically created.

You can also enter a sleep marking in the past by tapping **Add sleep time** (Figure 84) and entering the details for the sleep marking. Confirm the action by tapping **Save**. Tap **OK** to confirm the saving of the sleep marking to the diary.

Bittium

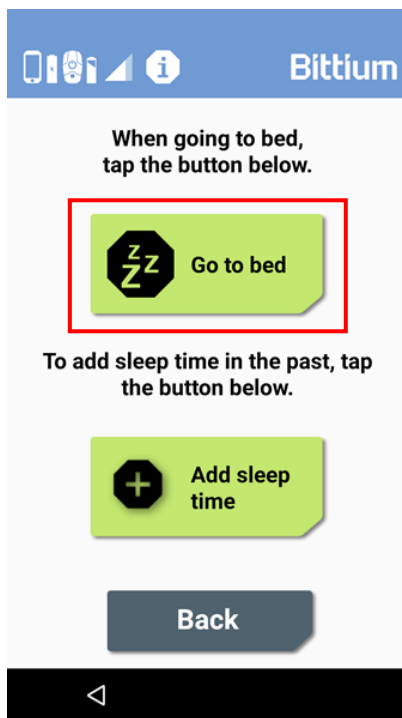


Figure 84 Go to bed button

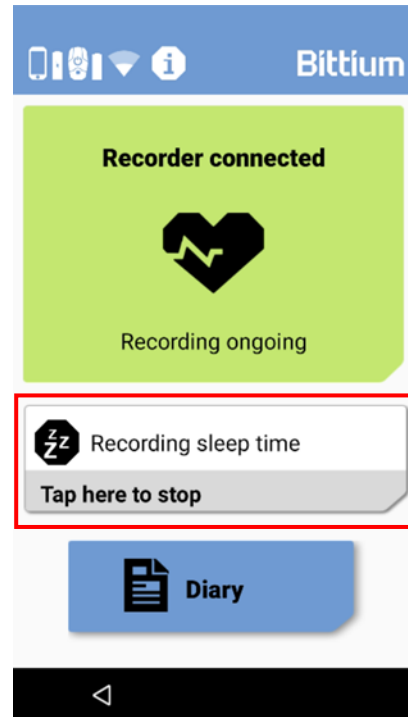


Figure 85 Main view showing "Recording sleep time"



Figure 86 Wake up button

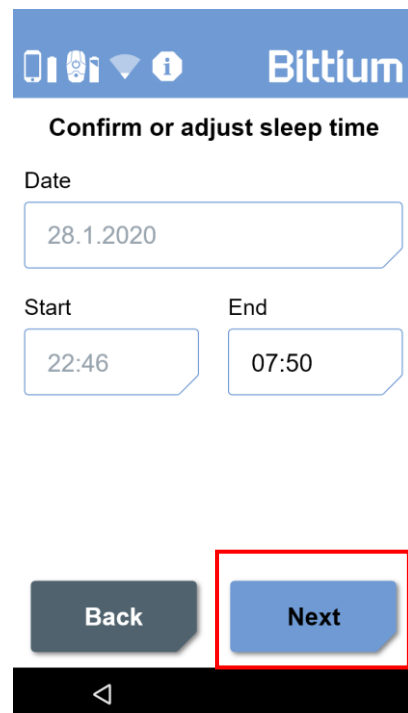


Figure 87 Confirming or adjusting sleep time

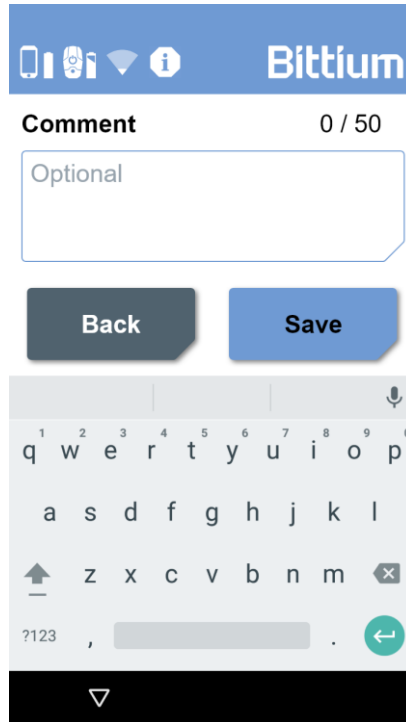


Figure 88 Writing optional comment

7.7 Assigning recording to a specific diagnostic user or diagnostic group

For daily data check and final analysis purposes the recording is assigned either to a specific diagnostic user or diagnostic group responsible for the analysis of the patient recording. If Cardiac Navigator is in use and a database is set up for the selected diagnostic user or diagnostic group, the assignment triggers an automatic data transfer from Bittium MedicalSuite service platform to the related Cardiac Navigator database. At first place, assigning a recording to a specific diagnostic user or diagnostic group can be made by a technician user by selecting the desired diagnostic user or diagnostic group from the drop-down list of the recording assignment field (Figure 89).

Figure 89 Assigning recording

Assignment can also be made on the Recordings page by selecting the desired diagnostic user or diagnostic group from the drop-down list of the related field on the assignment column. In addition, the **Daily check needed**, and **Diagnostic report needed** cards on the Dashboard include assignment feature.

NOTE This feature is available only for technician and diagnostic users.

NOTE This feature is fully available only for technician users. For diagnostic users the feature is limited such that a diagnostic user can only change the assignment inside the diagnostic group or, alternatively, remove the whole assignment from the recording.

7.8 Daily check and report

Recorded ECG data of an ongoing recording is transferred to Bittium MedicalSuite service platform every 30 minutes when the mobile connectivity between the Faros ECG device, the mobile device and Bittium MedicalSuite service platform is working properly.

On Bittium MedicalSuite service platform the recorded ECG data is divided into 24-hour signal periods that can be previewed using **Quick Preview** feature in MedicalSuite Center by users to whom the feature has been enabled in BackOffice (Figure 75 in chapter 7.5).

NOTE **Quick Preview** feature is available only for users to whom it has been enabled in MedicalSuite BackOffice.

When a full 24-hour period ECG data is available on Bittium MedicalSuite service platform, it is noted in the **Daily check needed** dashboard card (Figure 90), and the status of the daily data changes from **Ongoing** to either **Open** (when the recording has not been assigned to a diagnostic user or diagnostic group) or **Pending** (if the recording assignment has already been made) to indicate the need for a daily check.

Daily check needed					
All	Not assigned				
Recording	Assignment	Day No.	Status	Start date of file	
● HolterPlus_2	None	1 / 7	● Pending	26.08.2020 13:07	
				Preview	↓

Figure 90 “Daily check needed” dashboard card

Daily signal quality check can be performed using **Quick Preview** feature on Bittium MedicalSuite Center as described in chapter 7.5. Any determination of cardiac event occurrences should not be made using the **Quick Preview** feature.



CAUTION: **Quick Preview** feature is used only for checking the quality of the acquired ECG signal. Any determination of cardiac event occurrences should not be made using the **Quick Preview** feature. Always use proper cardiac analysis software to analyze ECG data.

When Cardiac Navigator is used, the daily data gets automatically transferred from Bittium MedicalSuite service platform to the related Cardiac Navigator database according to the recording assignment. The data can also be manually downloaded from Bittium MedicalSuite Center in EDF format (see chapter 7.11). Always use proper cardiac analysis software to analyze ECG data.

To perform a daily check for cardiac event occurrences, open the daily data in Cardiac Navigator and evaluate it for meaningful events by following the steps described below:

NOTE

This feature is available only for technician and diagnostic users who are linked to the related Cardiac Navigator™ user account in MedicalSuite BackOffice.

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Daily check needed** card on the Dashboard.
- 2 Navigate to the daily data by clicking **Preview** (Figure 91).

Daily check needed					
All	Not assigned				
Recording	Assignment	Day No.	Status	Start date of file	
● HolterPlus_2	Diagnostic group ▾	2 / 7	● Pending	26.02.2021 12:07	Preview 

Figure 91 Navigation to the daily recording data

- Open the daily data in Cardiac Navigator by clicking the related daily data icon on Recording data tab on a single recording view in MedicalSuite Center (Figure 92).

< Back

Bittium

Dashboard

Recordings

EN ▾



Technician 1 ▾

Technician

Patient ID: HolterPlus_2

Bittium HolterPlus

Ready for analysis

⋮

Status

● Active ▾

Created

25.02.2021 12:07

Last data transfer

No date

Assignment

Diagnostic group ▾

Started

25.02.2021 12:07

Duration

5 / 7 day(s)

Recording data

Patient details

Anamneses

Recording details

Attachments

 Download

 Analyze

☐ Include all attachments

Cancel

Save

Recording data

	☐	Day No.	Start date of file	Status	Notes	
▶	☐	1/7	25.02.2021 12:07	● Done ▾	Pause detected	
▶	☐	2/7	26.02.2021 12:07	● Pending ▾	Add notes	

Figure 92 Opening the daily recording data in Cardiac Navigator

If you want to evaluate data of an ongoing day (which does not yet include full 24-hour period ECG data) in Cardiac Navigator, you can manually trigger the data transfer of it on MedicalSuite Center. To trigger the data transfer of an ongoing day from MedicalSuite service platform to Cardiac Navigator, click the synchronization icon of the ongoing daily data on the Recording data tab on a single recording view in MedicalSuite Center (Figure 93).

Recording data Patient details Anamneses Recording details Attachments

Download

☐ Include all attachments

Analyze

Cancel

Save

Recording data

☐	Day No.	Start date of file	Status	Notes	
▶ ☐	1/7	03.09.2020 12:07	● Done -	daily check done	
▶ ☐	2/7	04.09.2020 12:07	● Done -	daily check done	
▶ ☐	3/7	05.09.2020 12:07	● Done -	daily check done	
▶ ☐	4/7	06.09.2020 12:07	● Done -	daily check done	
▶ ☐	5/7	07.09.2020 12:07	● Ongoing	Add notes	

Figure 93 Synchronizing the data of an ongoing day to Cardiac Navigator

When the synchronization is finished, you can open the data of an ongoing day in Cardiac Navigator by clicking the related daily data icon (Figure 92).

- Evaluate the daily recording data (X/Y) or synced data of an ongoing day (Active) for cardiac event occurrences. Please note that any markings and analysis made on daily data can only be used in daily reporting and will not be transferred automatically to the final report. **More detailed instructions for the use of Cardiac Navigator can be found on separate Cardiac Navigator User Guide.**



CAUTION: Markings made to daily data in Cardiac Navigator will not be transferred to the complete recording data which is finally analyzed.

When the daily check is performed, the status of the daily data needs to be changed to **Done** to remove the notification of a needed daily data check from the **Daily check needed** dashboard card. If desired, user can add notes to the related field of a daily data. In case of checking daily data of an ongoing day several times a day, the notes field can be used to mark down the time until which the ECG data has already been checked.

To mark a daily check as completed, follow the steps described below:

- Open the recording either from the Dashboard or the Recordings page on the Bittium MedicalSuite Center by clicking on the recording.
- Select **Recording data** tab.
- Change the related daily data status to **Done** (Figure 94).
- If desired, write notes about the daily check results to the related field.

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Open Cardiac Navigator
☐ Include all attachments
Cancel
Save

Recording data

☐	Day No.	Start date of file	Status	Notes
▼ ☐	1/7	25.08.2020 14:07	Done	Good quality signal. No meaningful events found on signal analysis performed using a proper cardiac analysis software.

Quick Preview

Figure 94 Marking results of the daily check on Bittium MedicalSuite Center

If meaningful cardiac events were found during the daily check of the recording, and the diagnostic user determines that sufficient amount of ECG data has already been acquired for the complete analysis, the recording can be finished either by setting the recording to **Ready for analysis** or by changing the recording status from **Active** to **Ended** on Bittium MedicalSuite Center (see chapter 7.10).

7.9 Uploading other documents to Bittium HolterPlus recording

Additional patient background information and more extent recording notes can be uploaded as other documents to Bittium HolterPlus recording. For example, if you are using a desktop version of Cardiac Navigator and have created an interim report of the evaluated daily recording data, such documents can be attached to a recording on Bittium MedicalSuite Center to make them available for the diagnostic user when the ECG data is analyzed.

To add a document to a recording, follow the steps described below:

- Open the recording either from the **Active recordings** card on the Dashboard or the Recordings page on the Bittium MedicalSuite Center by clicking on the recording.
- Select **Attachments** tab.
- Click **Add file** and select a file or multiple files to be added. Click **Open**. Alternatively, you can drag the file to the prompted area. (Figure 95)

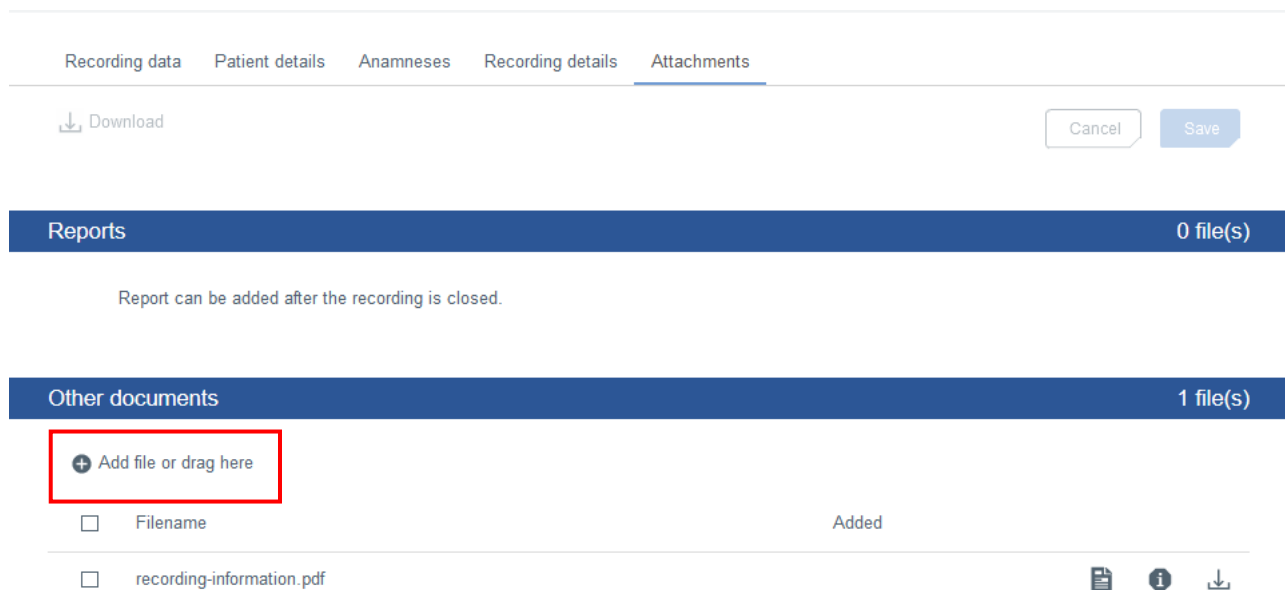


Figure 95 Add file icon on Attachments tab

The uploaded document will appear in the Other documents section on the **Attachments** tab (Figure 96).

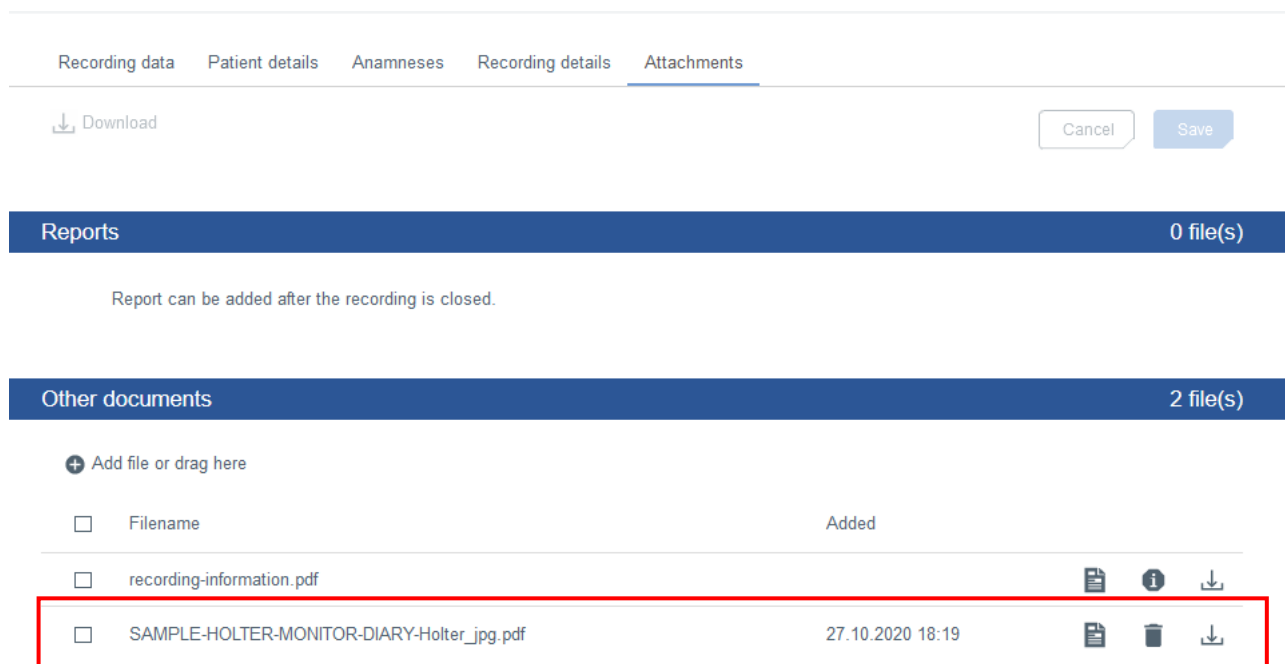


Figure 96 Uploaded document on Attachments tab

7.10 Ending Bittium HolterPlus recording

When the maximum recording duration selected when the recording was created has elapsed, the recording will end automatically. However, the recording can be manually ended when the diagnostic user determines that enough ECG data has been acquired for the complete analysis even though the maximum duration has not yet been reached.

To end a recording manually, set the recording to **Ready for analysis** or change the recording status from **Active** to **Ended** by following the steps described below:

- 1 Open the recording e.g., from the **Active recordings** card on the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Click **Ready for analysis** button on the single recording top bar (Figure 97). The same action can also be made by changing the recording status from **Active** to **Ended** either on the single recording top bar (Figure 97), or directly on the Recordings view (Figure 98).

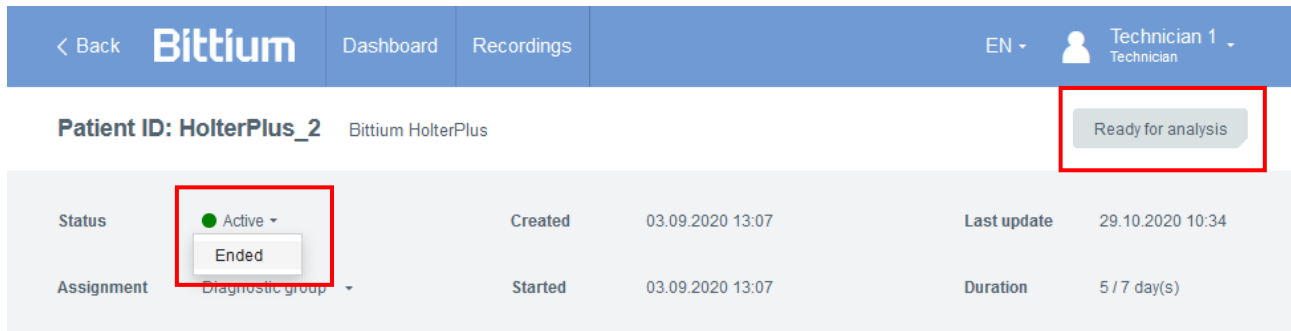


Figure 97 Setting recording to “Ready for analysis” on the single recording top bar

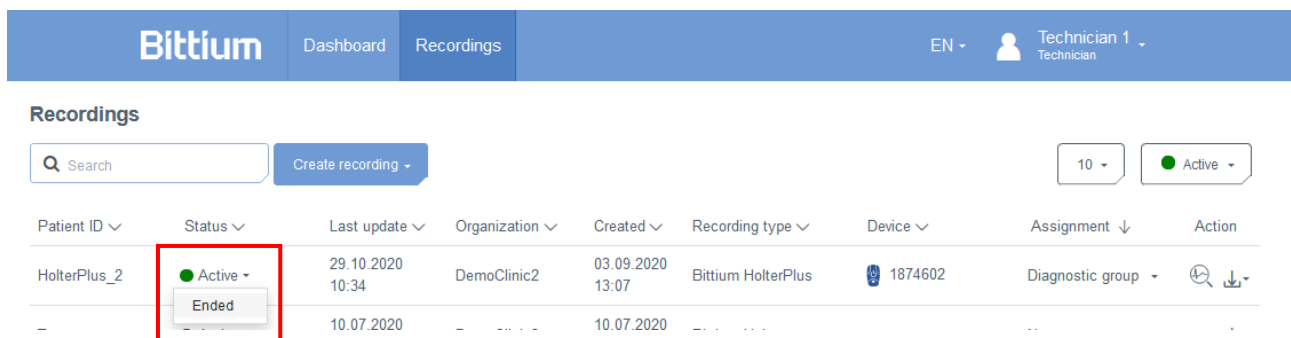


Figure 98 Changing recording status to “Ended” on Recordings view

- 3 Confirm the ending by clicking **Ready for analysis** (Figure 99).

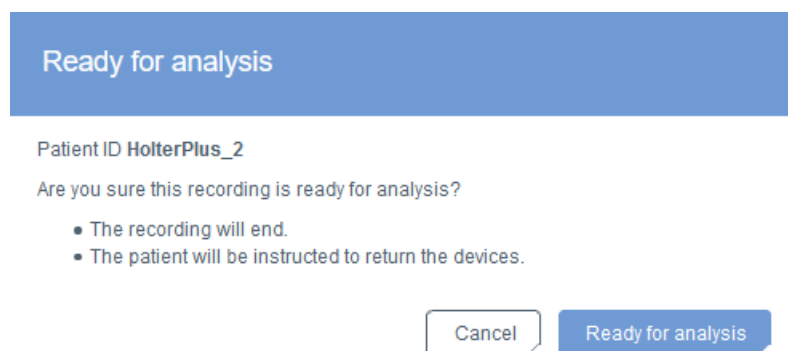


Figure 99 Confirming ending of a recording

After ending the recording, Bittium MedicalSuite Mobile application will shortly update the recording status view to state that the recording has been completed (Figure 100).

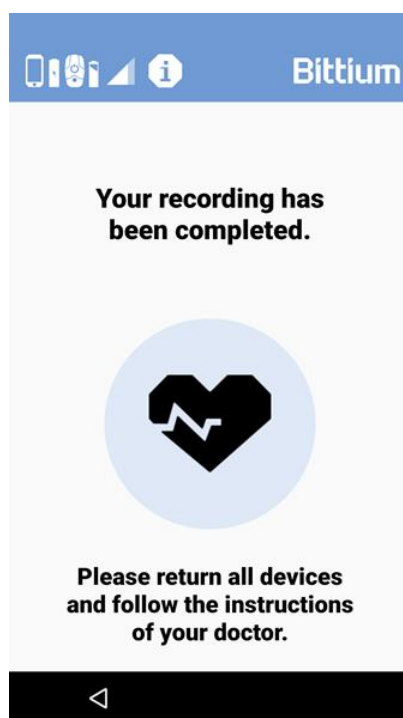


Figure 100 MedicalSuite Mobile application showing recording completion

The complete recording data is now available on Bittium MedicalSuite service platform for detailed ECG analysis, and the recording appears in **Diagnostic report needed** dashboard card (Figure 101). If Cardiac Navigator is in use, the complete recording data gets automatically transferred to the related Cardiac Navigator database for further analysis. The complete data can also be manually downloaded from Bittium MedicalSuite service platform in EDF format (see chapter 7.11).

Diagnostic report needed				
All My Assignments				
Recording	Assignment	End time	Duration	
● HolterPlus_2	Cardiologist 1 ▾	08.09.2020 04:59	5 day(s)	Close Analyze ↓ ▾

Figure 101 “Diagnostic report needed” dashboard card

7.11 Downloading data from Bittium MedicalSuite service platform

For storing the recorded data or further analyzing it with non-integrated analysis software, the recorded ECG data can be manually downloaded from Bittium MedicalSuite service platform in EDF format.

To download data from Bittium MedicalSuite service platform, follow the steps described below:

- 1 Open the recording either from the Dashboard or the Recordings view on the Bittium MedicalSuite Center by clicking on the recording.
- 2 Select **Recording data** tab.
- 3 Select the days that you want to download the data of. To download the complete ECG recording as one file, place a checkmark on the top box as shown in the Figure 102. If you wish to download also the related attachments e.g., the recording information PDF file that contains patient details and digital diary markings, check also the box of “Include all attachments”. (Figure 102)

Patient ID: **HolterPlus_2** Bittium HolterPlus

Close

Status	● Ended ▾	Created	03.09.2020 13:07	Last update	06.10.2020 11:26
Assignment	None ▾	Started	03.09.2020 13:07	Duration	5 / 7 day(s)

[Recording data](#)
[Patient details](#)
[Anamneses](#)
[Recording details](#)
[Attachments](#)

Download

☒ Include all attachments

Open Cardiac Navigator

Cancel

Save

Recording data

☒	Day No.	Start date of file	Status	Notes
☒	1/7	03.09.2020 13:07	● Open ▾	Add notes
☒	2/7	04.09.2020 13:07	● Open ▾	Add notes
☒	3/7	05.09.2020 13:07	● Open ▾	Add notes
☒	4/7	06.09.2020 13:07	● Open ▾	Add notes
☒	5/7	07.09.2020 13:07	● Open ▾	Add notes

Figure 102 Selecting the days for download

4 Click **Download** (Figure 102).

The recorded data of the selected days is downloaded as a zip file that contains the recording ECG data file in EDF format and the attachments if selected to be included. Store the downloaded data to the desired location or extract the recording data file and import it to ECG analysis software for further analysis.

7.12 Analyzing ECG data in Cardiac Navigator and creating a diagnostic report

Final analysis of the acquired ECG data is performed by a specific diagnostic user or a member of the diagnostic group to whom the recording is assigned. Evaluation of cardiac event occurrences is performed using proper cardiac analysis software. If Cardiac Navigator is in use and a database is set up for the diagnostic user or diagnostic group who is responsible for the analysis of the patient recording, changing the recording status to **Ended** triggers an automatic complete data transfer from Bittium MedicalSuite service platform to the related Cardiac Navigator database. When a

recording is finished, the complete recorded ECG data appears in one instance in Cardiac Navigator marked with an indication of “Ended”. Final analysis of a recording is performed to this “Ended” data instance in Cardiac Navigator. Also, the diagnostic report including interpretation notes written using the narrative tool is added to this “Ended” data instance to get the report automatically transferred from Cardiac Navigator to Bittium MedicalSuite Center once the recording is closed.

NOTE

This feature is available only for technician and diagnostic users who are linked to the related Cardiac Navigator™ user account in MedicalSuite BackOffice.

To perform final analysis of a recording and to create a diagnostic report in Cardiac Navigator, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard.
- 2 Open the complete recorded ECG data in Cardiac Navigator by clicking **Analyze** (Figure 103). The same icon can also be found from the Recording data tab on a single recording view in MedicalSuite Center (Figure 104).

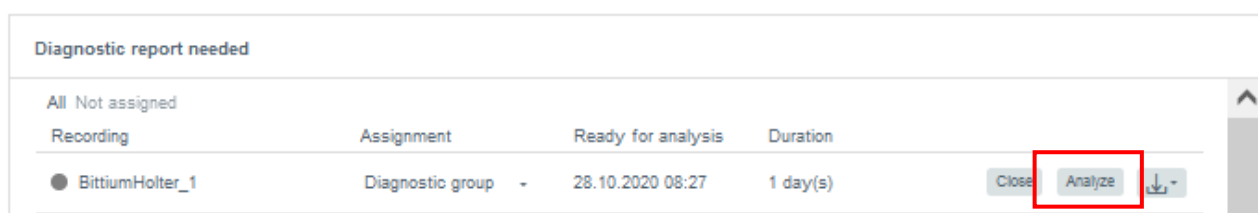


Figure 103 Navigation to the complete recorded ECG data in Cardiac Navigator

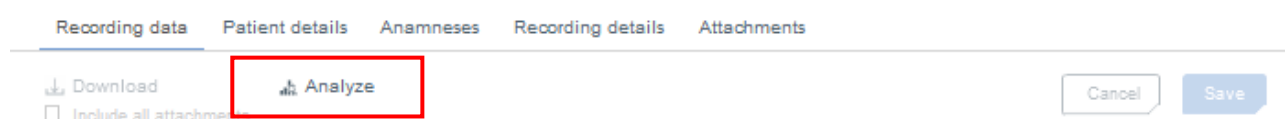


Figure 104 Navigation to the complete recorded ECG data in Cardiac Navigator from the single recording view

When using Cardiac Navigator Online, click **Analyze button** to open a new window for logging in to Cardiac Navigator with your user credentials. The related recording data opens in Cardiac Navigator.

Analyze the complete recording for cardiac event occurrences using different data tabs in Cardiac Navigator. When creating a diagnostic report in Cardiac Navigator, select **Add to record** to transfer the report to the MedicalSuite service platform (Figure 105).

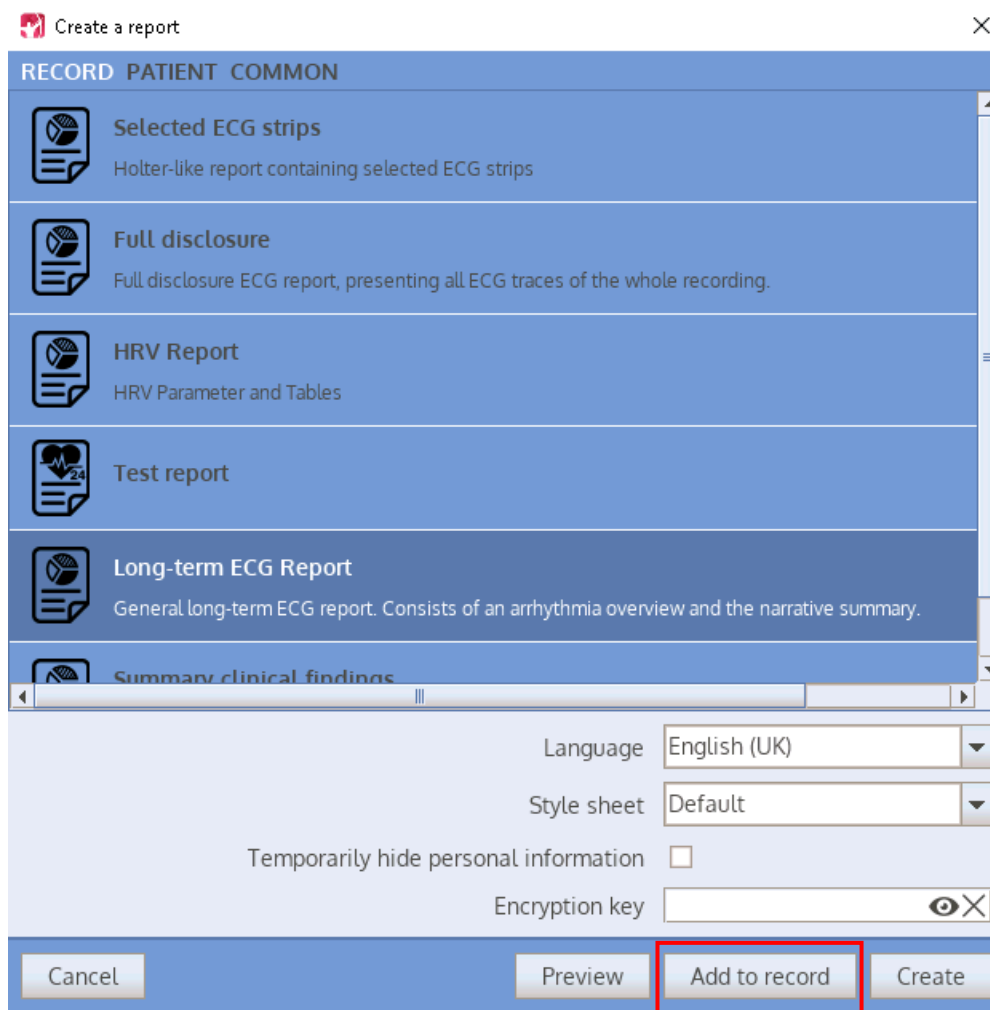


Figure 105 Adding report to a recording in Cardiac Navigator database

More detailed instructions for the use of Cardiac Navigator can be found on separate Cardiac Navigator user manual.

7.13 Closing Bittium HolterPlus recording and attaching diagnostic report

When final analysis of a recording is performed, the recording can be closed. Attaching a diagnostic report to a recording removes the recording from the **Diagnostic report needed** dashboard card. If Cardiac Navigator is in use and a database is set up for the diagnostic user or diagnostic group to whom the recording is assigned, changing the recording status to **Closed** triggers an automatic report transfer from the related Cardiac Navigator database to Bittium MedicalSuite service platform. After the diagnostic report is attached to the recording in Bittium MedicalSuite service platform, the recording will appear on the Latest reports dashboard card.

NOTE

This feature is available only for technician and diagnostic users who are linked to the related Cardiac Navigator™ user account in MedicalSuite BackOffice.

To close a recording, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **Close button** related to the recording that you want to close either directly from the **Diagnostic report needed** card on the Dashboard (Figure 106) or on the single recording top bar (Figure 107), open first the recording by clicking it). The same action can also be made by changing the recording status from **Ended** to **Closed** either on the single recording top bar (Figure 107), or directly on the Recordings view (Figure 108).

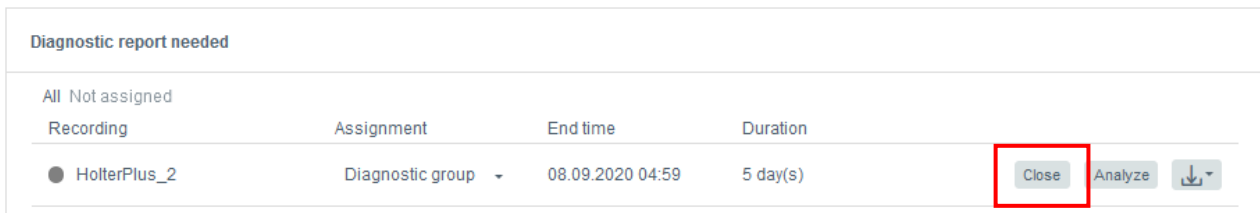


Figure 106 Close button on “Diagnostic report needed” dashboard card

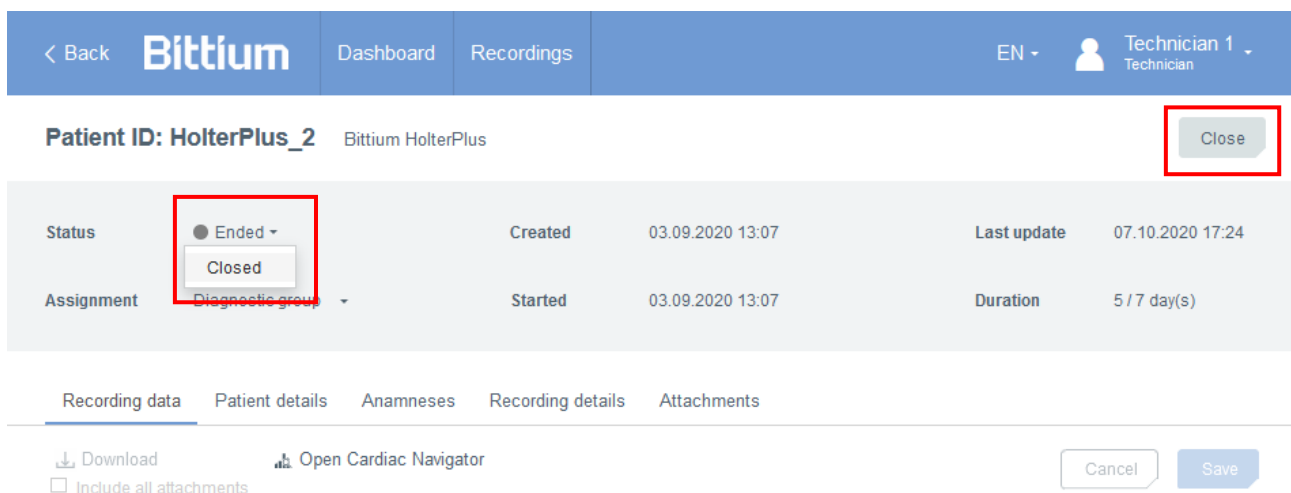


Figure 107 Closing recording on single recording top bar

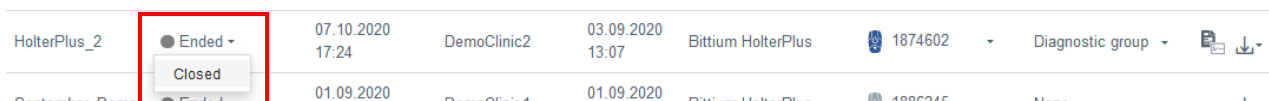


Figure 108 Changing recording status to “Closed” on Recordings view

- 1 Confirm closing by clicking **Close** (Figure 109).

Close recording

If a report is attached to the recording in Cardiac Navigator, it will be imported to the recording. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider.

Cancel

Close

Figure 109 Confirming closing of a recording

If Cardiac Navigator is in use, all diagnostic reports saved to the recording in the related Cardiac Navigator database get automatically transferred to Bittium MedicalSuite service platform when the recording is closed. You can trigger the report transfer also manually by clicking **Import reports icon** on the **Attachments** tab of the recording (Figure 110).

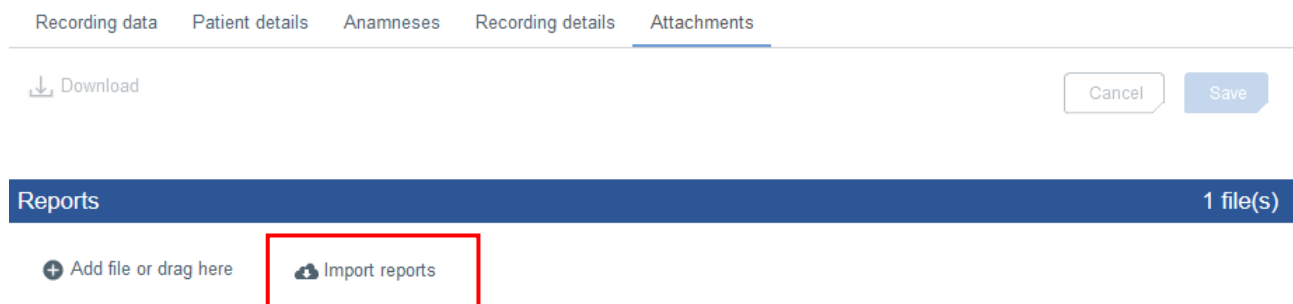


Figure 110 Import reports icon on Attachments tab

A diagnostic report can also be uploaded manually to a recording on Bittium MedicalSuite Center.

To manually upload a diagnostic report to a recording, follow the steps described below:

- 1 Click **Add report button** related to the recording that you want to upload a diagnostic report to, from the **Diagnostic report needed** card on the Dashboard (Figure 111) and click **Add file icon** (Figure 112).

Diagnostic report needed				
All	Not assigned			
Recording	Assignment	End time	Duration	
● HolterPlus_2	Diagnostic group ▾	08.09.2020 04:59	5 day(s)	Add report Analyze ⬇ ▾

Figure 111 Add report button on “Diagnostic report needed” dashboard card

Add report

New reports created in Cardiac Navigator will be imported to the recording by clicking the “Import” button. Already imported reports will not be updated. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider. If you want to add a report manually, click “Add file”.

+ Add file or drag here

Cancel

Import

Figure 112 Adding report manually to recording from “Diagnostic report needed” dashboard card

- 2 Select a file or multiple files to be added. Click **Open**. Alternatively, you can drag the file to the prompted area.
- 3 Click **Upload** to perform the uploading of the selected file(s) (Figure 113).

Add report

New reports created in Cardiac Navigator will be imported to the recording by clicking the “Import” button. Already imported reports will not be updated. Please verify that you created a report in Cardiac Navigator according to the instructions provided by your service provider. If you want to add a report manually, click “Add file”.

+ Add file or drag here

SAMPLE-HOLTER-MONITO... ✕

Cancel

Upload

Figure 113 Uploading report manually to recording from “Diagnostic report needed” dashboard card

The same action can also be made by clicking **Add file icon** under Reports section on the **Attachments** tab of the recording (Figure 114, open first the recording by clicking it).

< Back
Bittium
Dashboard
Recordings
EN
Technician 1
Technician

Patient ID: HolterPlus_2
Bittium HolterPlus
Approve

Status	● Closed	Created	03.09.2020 13:07	Last update	29.10.2020 13:31
Assignment	Diagnostic group ▾	Started	03.09.2020 13:07	Duration	5 / 7 day(s)

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports
0 file(s)

+ Add file or drag here
Import reports

No report available.

Figure 114 Add file icon on Attachments tab

The uploaded report(s) will appear in the Reports section on the **Attachments** tab (Figure 115).

< Back
Bittium
Dashboard
Recordings
EN
Technician 1
Technician

Patient ID: HolterPlus_2
Bittium HolterPlus
Approve

Status	● Closed	Created	03.09.2020 13:07	Last update	29.10.2020 14:37
Assignment	Diagnostic group ▾	Started	03.09.2020 13:07	Duration	5 / 7 day(s)

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports
1 file(s)

+ Add file or drag here
Import reports

☐	Filename	Added	
☐	SAMPLE-DIAGNOSTIC-REPORT.pdf	29.10.2020 14:37	

Figure 115 Uploaded diagnostic report on Attachments tab

When a diagnostic report is attached to the recording on Bittium MedicalSuite service platform, the recording appears on the **Latest reports** card on the Bittium MedicalSuite Center dashboard.

7.14 Approving recording and delivering diagnostic reports to lower-level organization

Recording needs to be approved by a technician user of the upper-level organization on Bittium MedicalSuite Center to get the diagnostic report(s) delivered to the associated lower-level organization. When a report is attached to a recording on Bittium MedicalSuite service platform, a technician user of the upper-level organization first previews it and verifies that the report contains all the necessary information. After previewing, the technician user finally approves the recording to deliver the diagnostic report(s) to the associated lower-level organization.

NOTE This feature is available only for technician users.

To preview a diagnostic report, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Latest reports** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **preview icon** related to the recording whose report you want to preview either directly from the **Latest reports** card on the Dashboard (Figure 116) or on the Recordings view (Figure 117).

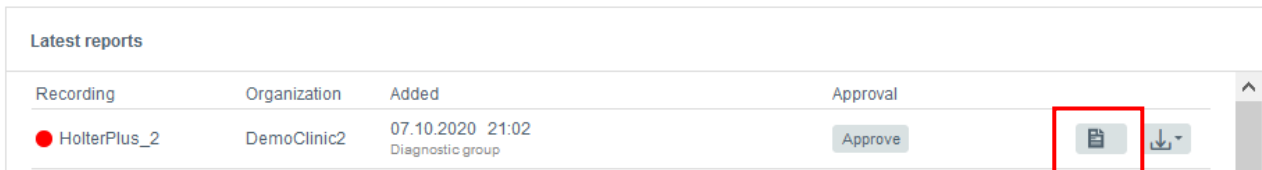


Figure 116 Preview icon on “Latest reports” dashboard card

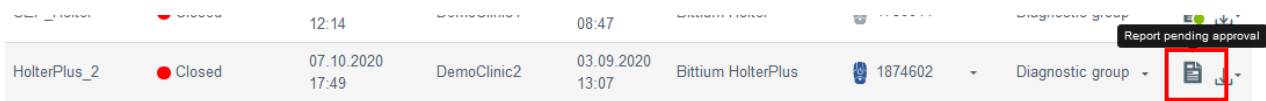


Figure 117 Preview icon on Recordings view

If you clicked the preview icon on the Recordings view (Figure 117), the **Attachments** tab of the recording will open. Click **preview icon** related to the report you want to preview.

To approve a recording to deliver the diagnostic report(s) to the associated lower-level organization, follow the steps described below:

- 3 Click **Approve button** related to the recording whose report(s) you want to deliver to the associated lower-level organization either directly from the **Latest reports** card on the Dashboard (Figure 118 Figure 119) or on the single recording top bar (Figure 119, open first the recording by clicking it).

Latest reports				
Recording	Organization	Added	Approval	
● HolterPlus_2	DemoClinic2	07.10.2020 17:49 Diagnostic group	Approve	 

Figure 118 Approve button on “Latest reports” dashboard card

< Back
Bittium
Dashboard
Recordings
EN
Technician 1
Technician

Patient ID: HolterPlus_2
Bittium HolterPlus
Approve

Status	● Closed	Created	03.09.2020 13:07	Last update	07.10.2020 17:06
Assignment	Cardiologist 1	Started	03.09.2020 13:07	Duration	5 / 7 day(s)

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports
1 file(s)

+ Add file or drag here
Import reports

☐	Filename	Added	
☐	HOLTERPLUS_2__HolterPlus_2_01-01-1993_26-06-2020-1_-_General_long-term_ECG_report.pdf	07.10.2020 17:06	  

Figure 119 Approve button on single recording top bar

4 Confirm approving by clicking **Approve** (Figure 120).

Confirmation

Are you sure you want to approve the reports of Patient ID: HolterPlus_2? After approval, reports will be visible for the clinic.

Cancel
Approve

Figure 120 Confirming approving of a recording

When a recording is approved (Figure 121), the related diagnostic reports transferred to Bittium MedicalSuite service platform are delivered to the associated lower-level organization, and the related preview icons have a green dot indicating the delivery (Figure 122).

< Back
Bittium
Dashboard
Recordings
EN
Technician 1
Technician

Patient ID: HolterPlus_2
Bittium HolterPlus
Approved

Status	● Closed	Created	03.09.2020 13:07	Last update	07.10.2020 17:08
Assignment	Cardiologist 1	Started	03.09.2020 13:07	Duration	5 / 7 day(s)

Figure 121 Recording approved

Latest reports				
Recording	Organization	Added	Approval	
● HolterPlus_2	DemoClinic2	07.10.2020 17:06 Cardiologist 1	07.10.2020 17:08	 

Figure 122 Preview icon with a green dot indicating report delivery

7.15 Previewing and downloading diagnostic reports and other documents

When a recording is approved by a technician user of the upper-level organization, the related diagnostic report(s) transferred to Bittium MedicalSuite service platform are available also for the associated lower-level organization users. Previewing and downloading a diagnostic report or some other attached document (e.g., recording information PDF file) from Bittium MedicalSuite Center can be done directly from the **Latest reports** card on the Dashboard or from the **Attachments** tab of the recording.

To preview a diagnostic report or some other document, follow the steps described below:

- 1 Find the recording from Bittium MedicalSuite Center e.g., from the **Latest reports** card on the Dashboard or by searching by the patient ID or the recorder S/N on the Recordings view.
- 2 Click **preview icon** related to the recording whose report or some other document you want to preview either directly from the **Latest reports** card on the Dashboard (Figure 123) or on the Recordings view (Figure 124).

Latest reports				
Recording	Organization	Added		Approval
● HolterPlus_2	DemoClinic2	07.10.2020	17:49	07.10.2020 17:54

Figure 123 Preview icon on “Latest reports” dashboard card

Bittium

Dashboard

Recordings

EN

 Clinic Demo 2

Clinic

Recordings

Q Search

Create recording

10

All

Patient ID	Status	Last update	Created	Recording type	Device	Action
HolterPlus_2	Closed	07.10.2020 18:31	03.09.2020 13:07	Bittium HolterPlus	1874602	

Figure 124 Preview icon on Recordings view

If you clicked the preview icon on the Recordings view (Figure 124), the **Attachments** tab of the recording will open. Click **preview icon** related to the report you want to preview.

NOTE Microsoft Edge users may experience problems opening PDF reports. This inconvenience is caused by Microsoft Edge privacy settings, including the Microsoft Edge-specific PDF handling option. In case previewing the report in medical suite is not possible, download the file.

To download a diagnostic report or some other document, follow the steps described below:

- 3 Click **download icon** related to the recording whose report or some other document you want to download either directly from the **Latest reports** card on the Dashboard (Figure 125) or on the Recordings view (Figure 126) and select the document you want to download.

Latest reports				
Recording	Organization	Added		Approval
● HolterPlus_2	DemoClinic2	07.10.2020	17:49	07.10.2020 17:54

Download

Recording data

↓ Recording data 5 day(s)

Reports

↓ HOLTERPLUS_2__HolterPlus_2_01-01-1993_26-06-2020-2_-_General_long-term_ECG_report.pdf

Other documents

↓ recording-information.pdf

Figure 125 Download icon on “Latest reports” dashboard card

Recording data
Patient details
Anamneses
Recording details
Attachments

Download
Cancel
Save

Reports 1 file(s)

☐	Filename	Added		
☐	HOLTERPLUS_2__HolterPlus_2_01-01-1993_26-06-2020-2_-_General_long-term_ECG_report.pdf	07.10.2020 17:49		

Other documents 1 file(s)

+ Add file or drag here

☐	Filename	Added		
☐	recording-information.pdf			

Figure 126 Download icons on Attachments tab of a recording

Store the downloaded document(s) to the desired location.

7.16 Releasing devices

After finishing a Bittium HolterPlus recording, the used Faros ECG device needs to be released from the recording on Bittium MedicalSuite Center to be able to use it in another Bittium HolterPlus recording later.

To release a Faros ECG device from a finished recording, follow the steps described below:

- 1 Find the recording where the Faros ECG device was previously used from Bittium MedicalSuite Center e.g., by searching by the recorder S/N on the Recordings view.
- 2 Release the Faros ECG device from the recording by first clicking the **blue recorder icon** and then clicking **Release device** (Figure 127).

Bittium

Dashboard

Recordings

EN

Technician 1
Technician

Recordings

Create recording

10

All

Patient ID	Status	Last update	Organization	Created	Recording type	Device	Assignment	Action
HolterPlus_3	Ended	09.06.2020 10:31	DemoClinic2	08.06.2020 10:00	Bittium HolterPlus	In use: 1871773 1871773 Release device	None	↓

<< 1/1 >>

Figure 127 Releasing Faros ECG device

After releasing the device, the previously blue Faros ECG device icon turns to grey and the Faros device can be used again in another recording. Bittium MedicalSuite Mobile application, to which the Faros ECG device is connected, starts to wait for information about a new recording (Figure 128).

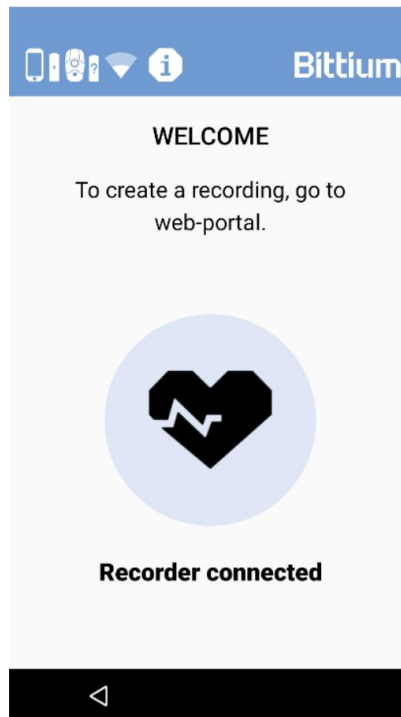


Figure 128 Bittium MedicalSuite Mobile application waiting for recording configuration

7.17 Deleting recording data from Faros ECG device

When a new Bittium HolterPlus recording is created, data of the previous recording is automatically deleted from the Faros ECG device. However, old recording data can also be deleted manually from the Faros ECG device to free disk space if needed.



CAUTION: Data of the previous recording is automatically deleted from the Faros ECG device when a new HolterPlus recording is started.

To delete old data from a Faros ECG device, follow the steps described below:

- 1 Connect Faros ECG device to a computer with a USB cable. Faros ECG device will appear as a disk drive in Windows File Explorer.
- 2 Click **FAROS_DATA** on Windows File Explorer (Figure 129).

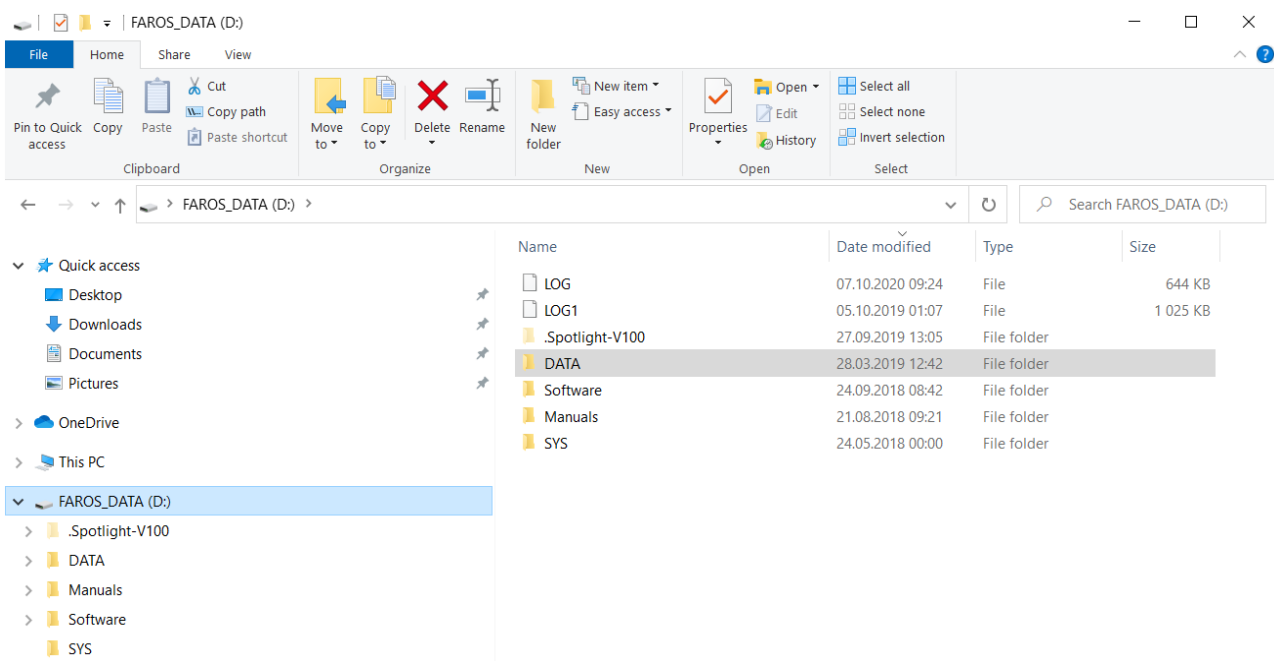


Figure 129 Faros ECG device appearing as a disk drive in Windows File Explorer

- 3 Double click **DATA**.
- 4 Select the recording data folder(s) to delete. The folders are named according to the recording date in format yyyy.mm.dd.
- 5 Delete the selected folders.
- 6 Disconnect the Faros ECG device from the computer.

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WEBSITE

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SERVICE DESK

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