MedicalSuite™ Platform Holter Service

Clinical Guide

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Date of Issue: May 06, 2025

Published by

Bittium Biosignals Ltd. Pioneerinkatu 6 70800 Kuopio Finland Phone: +358 40 344 2000 www.bittium.com

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Summary of Changes

Version	Date	Changes Between Releases	Status
6.0.0	2024.10.01	Compliance with MDR requirements.	Approved
7.0.0	2025.05.06	CHREP address change.	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: Patients who have an active implantable medical device (e.g., heart pacemaker) should consult supervising physician before use.



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 a	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 Bittium Faros ECG recorder notes and warnings from Bittium Faros[™] Manual.

NOTE Check Bittium Cardiac Navigator software notes and warnings from Cardiac Navigator[™] Software User Guide.

3 GENERAL

Bittium MedicalSuite is a web-based remote monitoring service platform that enables the management and analysis of various data recorded in healthcare. The service platform facilitates secure information and data sharing and allows hospitals, clinics, and healthcare professionals to work together regardless of their locations, permitting faster examination, diagnosis, and treatment of a patient. Bittium MedicalSuite enables wireless data transfer, intelligent data analysis, and handy reporting and management modules that can be optimized individually for each user according to their needs.

These instructions are applicable to MedicalSuite[™] Center v. 3.5.X and MedicalSuite[™] Mobile v.3.2.X.

3.1 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 arrythmias.

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

3.2 Bittium Faros

Faros device is a wearable, portable, externally applied electrocardiograph (ECG) recorder and wireless transmitter for ECG measurement, R-R interval data measurement and patient motion capturing. The device monitors patient ECG and can be set to generate event markers using the built-in arrhythmia detection algorithms.

More information about the Faros ECG recorder can be found from **Bittium Faros™ Manual**.

3.3 Bittium Cardiac Navigator

Bittium Cardiac Navigator software is a flexible and versatile solution for performing clinical Holter ECG analysis when analysing 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 Bittium Cardiac Navigator software can be found from Cardiac Navigator[™] Software User Guide.

3.4 Intended use for MedicalSuite[™] Center

MedicalSuite[™] Center is an independent medical device software intended to be used with Bittium measuring devices. 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. The analysed data can be used for diagnosis, prediction or prognosis.

MedicalSuite[™] Center is suitable for use in healthcare environment. Intended users are healthcare professionals.

3.5 Intended use for MedicalSuite[™] Mobile

MedicalSuite[™] Mobile is an independent medical device software intended to be used for ambulatory recording support and transmission with Bittium Faros Holter ECG device. The recorded data can be used for diagnosis, prediction or prognosis of heart disease. 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.

3.6 Indications

• The device is intended to be used for anybody when the heart function monitoring is required.

More information about the Bittium Faros ECG recorder indications can be found from **Bittium Faros**[™] **Manual**.

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

3.7 Contraindications

• No contraindications are identified.

More information about the Faros ECG recorder contraindications can be found from **Bittium Faros**[™] **Manual**.

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 <u>medical.support@bittium.com</u> for additional recommendation and support.

3.9 Symbols and Labels

Symbol	Description
CE 0537	The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Regulation 2017/745.
CH REP	Swiss authorized representative.
i	Consult Instruction for use.
MD	Medical device.
REF	Product number. Indicates the catalogue number so that the medical device can be identified.
	Manufacturer.
UDI	 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 recorder, 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 recorder, 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 Bittium 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 Bittium 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.

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.

The management of Bittium MedicalSuite accounts of your organization is performed byNOTEadmin 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).

Bittium MedicalSuite	
Sign in with Microsoft	

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.

Microsoft	
Pick an account	
account1@example.com	:
account2@example.com	
+ Use another account	

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

Microsoft		
Sign in		
Email or phone		
Can't access your account	t?	
	Back	Next

Figure 4 Enter account credentials

4 Enter the password.

Enter password	
Forgot my password	
	Sign in

Figure 5 Enter password

- 5 Make sure your phone registered for authentication is nearby and powered on.
- 6 Click on **Sign** 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).

Bittium
Approve sign in request
Open your Authenticator app, and enter the number shown to sign in.
No numbers in your app? Make sure to upgrade to the latest version.
Don't ask again for 7 days
I can't use my Microsoft Authenticator app right now
More information

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

If "We didn't hear from you" view is displayed, select Send another request to myNOTE Microsoft Authenticator app and proceed according to instructions in the application and sign in view.

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

8 MedicalSuite Center Dashboard page opens (Figure 7).

Bittium	Dashboard	Recordings				EN -	Technician Technician	
ashboard Create recording +	J						Edit dashboar	rd -
Created 2		Active	9	• Ended		Closed	3	
Active recordings								
All () Bittium Ho	lter 🔞 Bittium He	olterPlus 🚺		_				^
Test		- Started		Bittium Holter		Duration	0 / 0 day(s)	
 HolterPlus_4 		08.06.2020 16:	07	Bittium HolterPlus		_	2 / 30 day(s)	
Holter_2		14.02.2018 11:	43	Bittium Holter			1 / 1 day(s)	
 HolterTest2 		14.02.2018 11:	43	Bittium Holter			1 / 1 day(s)	
 HolterTest 		14.02.2018 11:	43	Bittium Holter			1 / 1 day(s)	
PID000d3		14.02.2018 11:	43	Bittium Holter			1 / 1 day(s)	
Offline_Test2		14.02.2018 11:	43	Bittium Holter			1 / 1 day(s)	~
Latest reports								
Recording	C	Organization	Added		Approval			
HolterPus_6	D	DemoClinic1	10.08.2020 Diagnostic gro	10:04 up	Approve		B 4.	
HolterPlus_2	۵	DemoClinic2	03.07.2020 Diagnostic gro	16:40 up	Approve		₽ .	
Holter_1	D	DemoClinic1	08.06.2020 Diagnostic gro	09:57 up	Approve		B 4.	
HolterPlus_2 Holter_1	0	DemoClinic2	Diagnostic gro 08.06.2020 Diagnostic gro	up 09:57 up	Approve		e T.	

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).

Bi	ttium	Dashboard	Recording	js			EN -	Te Tec	chnician 1 🖕	
Recordings										
Q Search		Create record	ing -						10 -	O All +
Patient ID 🗸	Status 🗸	Last up	date 🗸 🛛 Or	rganization 🗸	Created 🗸	Recording type \checkmark	Device \checkmark	Ass	ignment 🗸	Action
Test1234	 Created 	22.05.2 14:18	020 Se	erviceProvider	22.05.2020 14:18	Bittium HolterPlus	8 1885069	• Non	в 👻	↓ -
jaakko_demo_test	Active -	22.05.2 12:55	020 Se	erviceProvider	22.05.2020 12:53	Bittium Holter	1724459	Non	e 👻	.↓.+
1234Test	 Created 	22.05.2 09:36	020 De	emoClinic1	22.05.2020 09:36	Bittium HolterPlus	8 1867702	+ Non	e 🔸	↓ -
HolterPlus_ex	 Active - 	20.05.2 13:42	020 De	emoClinic1	20.05.2020 13:41	Bittium Holter	8 1867704	Non	в 👻	¥.+
Test_1234	 Created 	19.05.2 09:29	020 De	emoClinic1	19.05.2020 09:29	Bittium HolterPlus	8 1885161	+ Non	9 +	¥-
Trial554	Active -	26.05.2 14:22	020 De	emoClinic1	18.05.2020 16:20	Bittium Holter	1867703	Card	íiologist 1 🕞	.↓ . -
Trial445	Active •	26.05.2 14:22	020 De	emoClinic1	18.05.2020 16:10	Bittium Holter	8 1867703	Card	iiologist 1 🛛 🚽	↓ +
Trial556	Active -	18.05.2 15:53	020 De	emoClinic1	18.05.2020 15:53	Bittium Holter	8 1867703	Non	9 +	↓ +
HolterPlus_3_1	Active -	22.05.2 14:30	020 De	emoClinic2	15.05.2020 14:03	Bittium HolterPlus	1874602	Diag	nostic group 👻	® 🖵-
jaakko_sstest2	Ended -	15.05.2 22:06	020 Se	erviceProvider	11.05.2020 21·10	Bittium HolterPlus	1885069	Diag	nostic 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 Faros button. The used settings are selected using Bittium Faros Manager 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 **Bittium Faros Manual**. 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.

Bittium	Dashboard	Recordings		EN - 🔒 Tech	hnician 1 🖕
Create recordi	ng: Bittium	Holter			
Patient details*	Anamneses	Recording details* Attachments			
			Next >>	Cancel	Save
Patient details					
Patient ID			Age (years)*		
		Patient ID must be at least 4 characters long and	Height (cm)*		
		lower/uppercase letters, numbers and underscores are allowed. If	Weight (kg)*		
		Patient ID is left blank the system will generate it (for example PID0000A).	Gender*		•

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 Technician
Create recording: Rittium Holton	
create recording: bittium noiter	
Patient details Anamneses Recording details	s* Attachments
	Cancel Sav
8.4	
Medication	
Medication	Medication at time of ECG recording
	O No O Yes
Diseases	
Diagnosed heart disease	Diagnosed arrhythmias and/ or myocardial diseases (e.g. cardiomyopathy) in the family
O No O Yes	O No O Yes
Habits	
Smoking	O No O Yes
Alcohol consumption	O No O Sometimes O Often
Symptoms	-
Cymptonia	
Palpitations	O No O Sometimes O Often
Irregular beat	O No O Sometimes O Often
Slow pulse	O No O Sometimes O Often
Fast pulse	O No O Sometimes O Often
Unpleasant feeling in the chest	O No O Sometimes O Often
Shortness of breath	O No O Sometimes O Often
Dizziness	O No O Sometimes O Often
Weakness	O No O Sometimes O Often
Fainting/ syncope	O No O Sometimes O Often
0	

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

Bittium	Dashboard	Recordings	EN - 🕐 - 💄 Technician 1 - _{Technician}
Create recording Patient details* A	j: Bittium Ho namneses Re	Iter cording details	Attachments
			K Back Next Save
Recording details			
Organization		DemoClinic	c1 Referring physician
Requested re	port language	English	·
Reason for re	ecording		
Device information	1		
Recorder S/N	I	XXXXXXXX	
See back of t	he device.		
		С РАКОВ 386 901150 1837225 1837225 20800 Каоріо	



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).

Bittium	Dashboard	Recordings	EN - A Technician 1 Technician	÷
Create recordi	ng: Bittium H	Holter	Attachments	
			Kack Next >> Cancel Save	
Recording data				
🔁 Add file	e or drag here			
Other documents	S			
(1) Add file	e or drag here			

Figure 14 Create recording – Attachments tab

6 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 recorder settings for the recording need to be configured using Bittium Faros Manager software. Instructions to attach the recorder onto a patient according to the selected electrode setup option can be found from **Bittium Faros Manual**.

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 recorder 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 from **Bittium Faros Manual**.

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 recorder 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.

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)



Figure 16 Add file icon on Recording data tab



Uploading a long duration recording data to Bittium MedicalSuite service platform directly from Faros ECG recorder using a USB cable might take several minutes. It is recommended to first copy the recording data files from the Faros ECG recorder 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).

Measurement data	Patient details Anamneses Measurement details Attachments	
		Cancel Save
Measurement data	3	
+ Add file or dra	ag here 11-18-52.EDF () 12-23-01.EDF () 12-24-21.EDF () 19-28-22.EDF	C
	Figure 17 Data files being verified	
Measurement data	Patient details Anamneses Measurement details Attachments	
		Cancel Save
Measurement data		
+ Add file or dra	ag here	
08-54-59.EDF 🗙	12-23-01.EDF X 12-24-21.EDF X 19-28-22.EDF X 11-18-52.EDF X 10-00-1	5.EDF 🗙 06-26-29.EDF 🗙

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.

4 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).



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)

Recording data	Patient details	Anamneses	Recording details	Attachments			
↓ Download						Cancel	Save
Reports							0 file(s)
Other documen	ts						1 file(s)
Add file or dra	ag here						
Filenam	e				Added		
recordin	g-information.pdf					È	i 🕹

Figure 22 Add file icon on Attachments tab

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

Recordi	ng data Patient details	Anamneses	Recording details	Attachments				
上 Dowr	nload					Cancel		Save
Reports							0	file(s)
A	Report can be added after the	e recording is clo	sed.					
Other do	ocuments						2	file(s)
🕂 Add	l file or drag here							
	Filename				Added			
	recording-information.pdf						6	⊥
	SAMPLE-HOLTER-MONITO	OR-DIARY-Holter	_jpg.pdf		27.10.2020 18:19	Đ	Î	⊥

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 Recording	s	EN +	Clinic Demo 🖕
Patient ID: BittiumHolter_		Ready for analysis		
Status Active -	Create	d 27.10.2020 15:51	Last update	28.10.2020 09:31
Lineu	Starte	d 14.02.2018 11:43	Duration	1/1 day(s)
Recording data Patient details	Anamneses Recordir	g details Attachments		Cancel Save
Recording data				
Add file or drag here				
Day No. Start date	e of file Status N	otes		
□ 1/1 14.02.201 11:43	18 <mark>-</mark> Open - A	ld notes		

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

Bitti	um	Dashboard	Recordings			EN - Clinic Dem	
Recordings							
Q Search		Create recording	•			10	• O All •
Patient ID \checkmark	State	us ↓	Last update 🗸	Created 🗸	Recording type \checkmark	Device 🗸	Action
BittiumHolter_1	• Ac	tive -	28.10.2020 09:31	27.10.2020 15:51	Bittium Holter	1750044	ب
			28.10.2020	28.10.2020		# 1000000	

Figure 25 Changing recording status to "Ended" on Recordings view

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



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 Bittium Cardiac Navigator integration is in use, the complete recording data gets automatically transferred to the related Bittium 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 recorder 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).

R	ecording da	ata Patient	details Anamne	eses Recordin	g details Attachments	
	Download Include all a	attachments				Cancel Save
Re	cording c	lata				
		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 recorder 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)

< Back Bit	tium	Dashboard	Recordings		EN - ? -	Technician 1 - Technician
Patient ID: Bit	ttiumHolter_	1 Bittium Holt	er		Re	eady for analysis
Organization Status Assignment	DemoClinic1 Active Diagnostic groups	► Dup ►	Created Started Ready for analysi	04.07.2024 12:49 19.12.2023 15:21 s No date	Last data transfer Last update Duration	04.07.2024 12:49 04.07.2024 12:53 3 / 3 day(s)
Recording data	Patient detail	s Anamnese	s Recording deta	ils Attachments		Cancel Save
Add file or dra	ng here ay No. Start da	te of file	Status	To be checked	Notes	
▼ □ 1/3 Quick Preview	3 19.12.20	023 15:21	Pending	✓ 1d	Add notes	
16:00 18:00 1 √ 2	20:00	22:00 channel	00:00 02:00 5 10 15 1	04:00 06:00 ines 15 √ 30	08:00 10:00 -	12:00 14:00
19:17:46 mm	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	└╍┟╍┥╍╋╍╋╍╋╍╋╍╋╍╋ ┟╍╋╍╍╋╍╋╋╋╋╋╋╋╋╋	\cdot
19:18:16						
19:18:46	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	γ	+-+-+-+-+-+-+-+-+-+++++++	*****	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium Cardiac Navigator MedicalSuite edition 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).

	< Back Bitt	:íum	Dashboard	Recordings		EN - ? -	Technician 1 _ Technician
	Patient ID: Bitt	iumHolter <u></u>	_ 1 Bittium Holte	er		Rea	dy for analysis
	Organization Status	DemoClinic1	÷	Created	04.07.2024 12:49 19.12.2023 15:21	Last data transfer Last update	04.07.2024 12:49 04.07.2024 15:58
C	Assignment	None	~	Ready for analysis	No date	Duration	3 / 3 day(s)
G	roups Cardiscope Group Diagnostic group Diagnostic group (autor HRV group (autoreports HSAT Analysis	reports) 3)	ımr eses	Recording details	Attachments		Cancel Save
U	Carla Cardiologist Diagnostic group	1010	v				

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.

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

< Ba	ack	Bitti	um	Dashboard	Recordings				EN • 🥐 •	Technician 1 - Technician
Pat	ient	ID: Bittiur	mHolter_	1 Bittium Holte	er				R	eady for analysis
Orga	nizatio	on [DemoClinic1		Created	(03.07.2024 11:01		Last data transfer	03.07.2024 12:48
Statu	IS	•	Active	*	Started		1.10.2019 11:43		Last update	03.07.2024 12:49
Assig	Inmen	t N	lone	•	Ready for analys	is I	lo date		Duration	29 / 29 day(s)
Re	Recording data Patient details Anamneses Recording details Attachments									
.↓.[L Download Cancel Save									
	nclude	all attachments	s							
Rec	ordin	n data								
	orun	ig data								
•	Add fi	ile or drag he	re							
		Day No	. Start da	te of file	Status		To be checked	No	tes	
		1/29	11.10.20	019 11:43	Open	•	1d	Ad	d notes	
►		2/29	12.10.20	019 11:43	– Open	•	1d	Ad	d notes	
•		3/29	13.10.2	019 11:43	Open	•	1d	Ad	d notes	
►	✓	4/29	14.10.20	019 11:43	Open	•	1d	Ad	d 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 Bittium 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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium Cardiac Navigator database. When a recording is finished, the complete recorded ECG data appears in one instance in Bittium Cardiac Navigator MedicalSuite edition marked with an indication of "Ended". Final analysis of a recording is performed to this "Ended" data instance in Bittium Cardiac Navigator MedicalSuite edition. 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 Bittium Cardiac Navigator MedicalSuite edition to Bittium MedicalSuite Center once the recording is closed.

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

To perform final analysis of a recording and to create a diagnostic report in Bittium Cardiac Navigator MedicalSuite edition, 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 MedicalSuite edition 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).

Diagnostic report needed							
All Not assigned							^
Recording	Assignment	Ready for analysis	Duration				
BittiumHolter_1	Diagnostic group 🕞	28.10.2020 08:27	1 day(s)	Close	Analyze	- بل	

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

Recording data	Patient details	Anamneses	Recording details	Attachments	
	ាង Analyz	e			Cancel Save

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

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

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

👩 Create	e a report		×					
RECORI	PATIENT COMMON							
	Selected ECG strips Holter-like report containing selected ECG strips		<u> </u>					
	Full disclosure Full disclosure ECG report, presenting all ECG traces of the who	ole recording.						
	HRV Report HRV Parameter and Tables							
	Test report							
	Long-term ECG Report General long-term ECG report. Consists of an arrhythmia overv	iew and the narrative sur	mmary.					
	Summany clinical findings		▼					
	Language	English (UK)	-					
	Style sheet	Default	-					
	Temporarily hide personal information							
	Encryption key		øΧ					
Cance	el Preview	Add to record	Create					

Figure 34 Adding report to a recording in Bittium Cardiac Navigator database

More detailed instructions for the use of Bittium Cardiac Navigator can be found on separate Bittium 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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium 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.

This feature is available only for technician and diagnostic users who are linked to the related Bittium Cardiac Navigator™ MedicalSuite Edition 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).

Diagnostic report needed										
All Not assigned Recording	Assignment	End time	Duration							
HolterPlus_2	Diagnostic group 🕞	08.09.2020 04:59	5 day(s)	Close Analyze						

Figure 35 Close button on "Diagnostic report needed" dashboard card

< Back Bit	tium "	Dashboard	Recordings		EN - ? -	Technician 1
Patient ID: Bit	ttiumHolter_1	Bittium Holte	r			Close
Organization Status Assignment	DemoClinic1 Ended Closed	•	Created Started Ready for analysis	04.07.2024 12:49 19.12.2023 15:21 04.07.2024 17:50	Last data transfer Last update Duration	04.07.2024 12:49 04.07.2024 17:50 3 / 3 day(s)
Recording data	Patient details	Anamneses	Recording details	Attachments		

Figure 36 Closing recording on single recording top bar

HolterPlus_2	● Ended +	07.10.2020 17:24	DemoClinic2	03.09.2020 13:07	Bittium HolterPlus	8 1874602	Ŧ	Diagnostic group 🕞	₽ <u>_</u>
0	Closed	01.09.2020	D014	01.09.2020		M 1000010		NI	

Figure 37 Changing recording status to "Closed" on Recordings view

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



Figure 38 Confirming closing of a recording

If Bittium Cardiac Navigator MedicalSuite edition is in use, all diagnostic reports saved to the recording in the related Bittium 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

New reports created in Card	iac Navigator will be imported to the recording by clicking
the "Import" button. Already i you created a report in Cardi your service provider. If you v	mported reports will not be updated. Please verify that ac Navigator according to the instructions provided by vant to add a report manually, click "Add file".

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 in the "Import" button. Already imported reports will no you created a report in Cardiac Navigator according your service provider. If you want to add a report ma	nported to the recording by clicking ot be updated. Please verify that g to the instructions provided by nually, click "Add file".
SAMPLE-HOLTER-MONITO X	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).

< Back Bit	tium	Dashboard	Recordings		EN - ? -	Technician 1
Patient ID: Bit	tiumHolter_1	Bittium Holter	r			Approve
Organization	DemoClinic1		Created	03.07.2024 11:01	Last data transfer Last update	03.07.2024 12:48
Assignment	Diagnostic group) +	Ready for analysis	04.07.2024 17:49	Duration	29 / 29 day(s)
Recording data	Patient details	Anamneses	Recording details	Attachments		
J. Download						Cancel Save
Reports						0 file(s)
Add file or dra No report available	g here 🔥 Impor	t reports				

Figure 43 Add file icon on Attachments tab

The uploaded report(s) will appear in the Reports section on the Attachments tab (Figure 44).

< Back Bit	tium	Dashboard	Recordings		EN • 💡 •	Technician 1 - Technician					
Patient ID: Bit	Patient ID: BittiumHolter_1 Bittium Holter Approve										
Organization	DemoClinic1		Created	04.07.2024 12:49	Last data transf	er 04.07.2024 12:49					
Status Assignment	Closed Diagnostic group	p 👻	Started Ready for analysis	19.12.2023 15:21 04.07.2024 17:50	Last update Duration	04.07.2024 17:53 3 / 3 day(s)					
Decording data	Datiant dataila	Anomnooco	Decording details	Attachmonto							
J. Download	Patient details	Anamneses	Recording details	Allachments		Cancel Save					
Doporto											
Reports						T file(S)					
Add file or drag	j here 🔥 Impo	rt reports									
Filename					Added						
SAMPLE-	AGNOSTIC-REP	ORT.pdf			04.07.2024 17:53	🖹 🔋 🕹					

Figure 44 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.

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).



Latest reports										
Recording		Organization	Added			Approval			_	^
HolterPlus	_2	DemoClinic2	07.10.2020 21:02 Diagnostic group			Approve		Ē	₩.	
		Figure	45 Preview icor	n on "Late	st reports" da	ashboard co	ard			
	- 0.0004	12:14		08:47	Data in Fiore	U			eport pendin	. vy.* ng approva
HolterPlus_2	Closed	07.10.20 17:49	DemoClinic2	03.09.2020 13:07	Bittium HolterPlus	874602	•	Diagnostic group	• 🗈	Ì, <u>L</u> +
		07.00.07								

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).



Latest reports				
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 Bit	tíum	Dashboard	Recordings		EN • 💡 •	Technician 1
Patient ID: Bit	tiumHolter_	1 Bittium Holte	r			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 grou	ib 🔺	Ready for analysis	o4.07.2024 17:50	Duration	3 / 3 day(s)
Recording data	Patient details	Anamneses	Recording detai	ils Attachments		
,↓ Download						Cancel
Reports						1 file(s)
Add file or drag	g here 🛛 🔥 Impo	ort reports				
Filename					Added	
SAMPLE-	AGNOSTIC-REF	PORT.pdf			04.07.2024 17:53	

Figure 48 Approve button on single recording top bar

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



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).

< Back Bit	tium Dashboard	d Recordings		EN • ? •	Technician 1
Patient ID: Bit	tiumHolter_1 Bittium F	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 Reco	ording approved		
itest reports					
Recording	Туре	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 - A Clinic I	Demo 2 🛫
Recordings						
Q Search	Create recording					10 • O All •
Patient ID ↓ S	tatus 🗸	Last update 🗸	✓ Created ∨	Recording type \checkmark	Device \checkmark	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.

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 54) or on the Recordings view (Figure 55) and select the document you want to download.

Latest reports				
Recording	Organization	Added	Approval	Download
HolterPlus_2	DemoClinic2	07.10.2020 17:49	07.10.2020 17:54	
	Record یا Re Report: بط HC Other d	ing data cording data 5 day(s) s LTERPLUS_2HolterPlus_2_01-01- locuments cording-information.pdf	-1993_26-06-2020-2General_long-tr	erm_ECG_report.pdf

Figure 54 Download icon on "Latest reports" dashboard card

Recordi	ing data Patient details	Anamneses	Recording details	Attachments				
J. Dow	nload					Cancel)	ave
Reports	;						1	file(s)
	Filename				Added			
	HOLTERPLUS_2Holterf term_ECG_report.pdf	Plus_2_01-01-199	3_26-06-2020-2Ge	eneral_long-	07.10.2020 17:49		F.	⊥
Other d	ocuments						1	file(s)
🖨 Ade	d file or drag here							
	Filename				Added			
	recording-information.pdf						6	⊥

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 Bittium 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 recordi	ng: Bittium	HolterPlus		
Patient details*	Anamneses	Recording details* Attachments		
			k 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 •	E Technic Technician	cian 1 .
Caracter and all	D:#!	U a léa a Dhua							
Create record	пд: ышит	nonerPlus							
Patient details	Anamneses	Recording deta	ils* At	tachments					
				<< Back	Ne	ext >>		Cancel	Save
Medication									
Medicatio	n					Medication at time of ECG	recording	9	
]		O No O Yes			
Diseases									
Discuses									
Diagnosed	d heart disease					(e.g. cardiomyopathy) in th	e family	cardial diseases	
O No	O Yes					O No O Yes			
Habits									
Smoking				0	No	O Ves			
Alcohol co	onsumption			0	No		. 0	Often	
						0 0000000000000000000000000000000000000	- 0		
Symptoms									
Palpitatio	ns			0	No	O Sometime:	• 0	Often	
Irregular b	eat			0	No	O Sometime	• 0	Often	
Slow pulse	e			0	No	O Sometime	• 0	Often	
Fast pulse				0	No	O Sometime	• 0	Often	
Unpleasar	nt feeling in the	chest		0	No	O Sometime	• 0	Often	
Shortness	of breath			0	No	O Sometime	• 0	Often	
Dizziness				0	No	O Sometime	• 0	Often	
Weakness				0	No	Sometimes	• 0	Often	
Fainting/s	syncope			0	No	O Sometimes	0	Often	
Comments									

Figure 58 Create recording – Anamnesis tab

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

Bittium	Dashboard	Recordings	EN + 🕜 - 💄 Technician 1 -
Create recording	: Bittium Ho	IterPlus	
Patient details An	amneses Rec	ording details	Attachments
Recording details			
Organization			Max. duration (days) * 1-30 day(s)
Referring phy	sician		Requested report language English 🔻
Reason for re	cording		
Device information	1		
Setup options	OmegaSna	o 1-CH ECG Elec	trode These are the default settings. Use default settings if not instructed otherwise.
	_		Accelerometer On Off
			ECG sampling rate (Hz) 125 250 500 1000
	$\left \right $		Pacemaker event detection On Off
Recorder S/N	•	X000000X	
		Select organi	ization
See back of t	he device.		_
		FARCE DES COLLEGE HISTPER JUNE COLLEGE	

Figure 59 Create recording – Recording details tab

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

Bittium	Dashboard	Recordings		EN - 🙎 Technicia	in 1 .
Create recordi	ing: Bittium	HolterPlus			
Patient details	Anamneses	Recording details	Attachments		
			<< Back	Cancel	Save
Other documen	ts				
🕀 Add fi	le or drag here				

Figure 60 Create recording – Attachments tab

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

Confirmation	
Create a new Bittium HolterPlus recording with a maximum	duration of 6 days? Back Create

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:

- 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 **Create recording** on the Device setup view (Figure 62). Create recording view opens (Figure 63).
- 3 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:
 - 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.

		Bittiu
	Bittium	Create recording
ce setup		(1) - (2) - (3)
	. 0	Patient details Anamneses Record details Patient ID
This dev connected	rice has been to the recorder.	Patient ID must be at least 4 characters long and lower/uppercase letters, numbers and underscorr are allowed. If Patient ID is left blank the system generate it (for example PID0000A).
ecorder	FAROS-1889172	Age (years) *
Organization	DemoClinic1	Weight (kg) *
Create r	recording	Height (cm) *
Back	Disconnect	Gender *
\bigtriangledown		Female Male Other
igure 62 Dev	vice setup view	Back Next
		\triangleleft

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).

	F	Riffirum
Create recording		JICCIGIT
	n	
Patient details * Anam	ineses	Recording
Thses questions are option	al. You car	details * n also fill in the
form later from MedicalSuit	e Center.	
Medication	cation	
Medication at the time o	of ECG re	cording
No		Yes
Dise	ases	
Diagnosed heart diseas	e	
No		Yes
Diagnosed arrhythmias diseases (e.g., cardiomy	and / or r yopathy)	nyocardial in the family
No		Yes
На	bits	
Smoker		
No		Yes
Alcohol consumption		
No Some	etimes	Often

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										
Patient details * Anamneses Recording details *										
Max duration	Max duration (days) *									
1 - 30 days										
Setup option OmegaSna	n ap electrode									
These are the not instructed Accelerome	default settin otherwise.	gs. Use defau	It settings if							
√ 0	n	0	ff							
Sampling ra	te (Hz)									
√ 125	250	500	1000							
Pacemaker	event record	i								
0	On 🗸 Off									
Please fill in	required * fiel	ds before sav	ing.							
Ba	Back Save									



Figure 66 Create recording – Confirmation notification

Figure 65 Create recording – Recording details view

7 Return to MedicalSuite Mobile application main view.

7.3 Attaching Faros ECG recorder 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 recorder gets the related recording information and provides instructions to attach the recorder onto a patient according to the selected electrode setup option.

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

- 1 Open the instructions to attach the recorder 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 recorder 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.



After the Faros ECG recorder 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).



NOTE

Data of the previous recording is automatically deleted from the Faros ECG recorder 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 recorder 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 recorder 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 recorder button (Figure 72) to activate Faros 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 recorder 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 recorder 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.



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).

Re	cording da	ata Patient	t details Anamne	eses Recordir	ng details	Attachments			
	Download nclude all a	attachments						Cancel	Save
Rec	cording	data							
		Day No.	Start date of file	Status	Notes				
Þ		1/7	22.05.2021 12:07	● Pending +	Add note	es			
•		2/7	23.05.2021 12:07	● Pending +	Add note	es			
Þ		3/7	24.05.2021 12:07	● Pending -	Add note	es			

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 recorder 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).

< Back Bittie	JIM Dashboard I	Recordings		EN - 🙎 Technician 1 - Technician
Patient ID: Holter	Plus_2 Bittium HolterPlus			Ready for analysis
Organization Den	toClinic2	Created	22.05.2021 13:07	Last data transfer No date
Status 🕒 A	ctive *	Started	22.05.2021 12:07	Last update 27.05.2021 15:45
Assignment Diag	nostic group -	Ready for analysis	25.05.2021 09:47	Duration 5 / 7 day(s)
Recording data P	atient details Anamnese	s Recording de	tails Attachments	
🚽 Download	<u>"b.</u> Analyze ts			Cancel Save
□ Day No.	Start date of file Status 22.05.2021 12:07	s Notes Iding - Add note	5	
Quick Preview				
77 14:00 16 12:07:12 - 13:07:12 Renge: 01:00	∞ 18:00 20:00 ∞ 【 ▶ 1 h	22:00 30 min 1 min	00:00 02:00 04:00 30 s 10 s 5 s	06:00 06:00 10:00 12:0
5 min Grid				
5 5 5 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	······		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	maliter for a narrier of the annual stage
▶ □ 2/7	23.05.2021 12:07	nding - Add note	5	ali.
► 3/7	24.05.2021	nding - Add note	5	di.





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 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 82 Confirming or adjusting activity time

	<u>.</u>		i			Bíl	:tíu	IIII
Con	nme	nt					0/	50
Opt	iona	al						
	Ba	ck				Sa	ve	
								Ŷ
q ¹ v	v ² 6	5	r ·	t s	/ l	7	i°c	° p°
а	s	d	f	g	h	j	k	I.
±	Z	х	С	v	b	n	m	×
?123	,							e
	∇							

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.



Figure 84 Go to bed button



Figure 86 Wake up button



Figure 85 Main view showing "Recording sleep time"

0 🖗 🔻 🛈	Bittium								
Confirm or adjust sleep time									
Date									
28.1.2020									
Start	End								
22:46	07:50								
Back	Next								
\bigtriangledown									

Figure 87 Confirming or adjusting sleep time

			i	Bittium				
Con	nme	nt				0 /	50	
Opt	iona	al						
	Ba	ck			Sa	ave		
								Ŷ
q ¹ v	v ² 6	5	r	t	у ⁶	u ⁷	i [®] (o [°] p [°]
а	S	d	f	g	h	j	k	I.
	Z	Х	С	V	b	n	m	×
?123	,							e
	∇							

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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium Cardiac Navigator MedicalSuite edition 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).

< Back Bittium	Dashboard	Recordings		EN •	Technician 1 . Technician
Patient ID: HolterPlus_2	Bittium Holter	Plus			Ready for analysis
Status • Active -		Created	24.09.2020 13:07	Last update	29.09.2020 15:04
Assignment None	•	Started	24.09.2020 13:07	Duration	5/7 day(s)
Recordir Diagnostic group	Anamneses	Recording detail	ls Attachments		
Down Degreetic group Include Cardiologist 1 Degreetic group Cardiologist 1 Diagneetic group	Cardiac Navig	gator			Cancel Save
Recording data					

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 recorder, 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 Bittium Cardiac Navigator MedicalSuite edition is used, the daily data gets automatically transferred from Bittium MedicalSuite service platform to the related Bittium Cardiac Navigator MedicalSuite edition 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 Bittium Cardiac Navigator MedicalSuite edition and evaluate it for meaningful events by following the steps described below:

- This feature is available only for technician and diagnostic users who are linked to theNOTErelated Bittium Cardiac Navigator™ MedicalSuite Edition user account in MedicalSuiteBackOffice.
- 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

3 Open the daily data in Bittium Cardiac Navigator MedicalSuite edition 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					
Patient ID: HolterPlus_2	Patient ID: HolterPlus_2 Bittium HolterPlus									
Status • Active -		Created	25.02.2021 12:07	Last data transfer	No date					
Assignment Diagnostic group	Ŧ	Started	25.02.2021 12:07	Duration	5 / 7 day(s)					
Recording data Patient deta	Recording data Patient details Anamneses Recording details Attachments									
Day No. St	art date of file S	tatus N	otes							
► 1/7 25 12	5.02.2021 2:07	Done • P	ause detected		du					
► 2/7 26 12	3.02.2021 2:07	Pending - A	dd notes		ah					

Figure 92 Opening the daily recording data in Bittium Cardiac Navigator MedicalSuite edition

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



Reco	rding o	data Patie	ent details Ana	mneses Re	ecording details Attachments					
Download Analyze Cancel Save Cancel Save										
Recording data										
		Day No.	Start date of file	Status	Notes					
► C		1/7	03.09.2020 12:07	🔴 Done -	daily check done	al.				
► □		2/7	04.09.2020 12:07	😑 Done -	daily check done	4				
•		3/7	05.09.2020 12:07	😑 Done -	daily check done	A.				
•		4/7	08.09.2020 12:07	Oone -	daily check done	da.				
► C]	5/7	07.09.2020	Ongoing	Add notes	۵ <u>۵</u>				

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

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

4 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 Bittium Cardiac Navigator can be found on separate Cardiac Navigator User Guide.



CAUTION: Markings made to daily data in Bittium Cardiac Navigator MedicalSuite edition 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:

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



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 Bittium Cardiac Navigator MedicalSuite edition 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:

- 4 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.
- 5 Select Attachments tab.
- 6 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)

Recording data	Patient details	Anamneses	Recording details	Attachments			
J. Download						Cancel	Save
Reports							0 file(s)
Other documer	nts						1 file(s)
Add file or dr	rag here						
Filenam	ie				Added		
recordin	ig-information.pdf						0 🕹

Figure 95 Add file icon on Attachments tab

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

Recor	ding data	Patient details	Anamneses	Recording details	Attachments					
J Do	wnload						Cancel		Save	
Repor	ts							C) file(s)	
	Report can be added after the recording is closed.									
Other	documen	ts						2	? file(s)	
e A	dd file or dra	ag here								
	Filenam	e				Added				
	recording	g-information.pdf						6	⊥	
	SAMPLI	E-HOLTER-MONIT	OR-DIARY-Holte	r_jpg.pdf		27.10.2020 18:19		Î	⊥	

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).

< Back Bittium	Dashboard	Recordings		EN •	Technician 1 - Technician
Patient ID: HolterPlus_2	Bittium Holter	Plus			Ready for analysis
Status Active -]	Created	03.09.2020 13:07	Last update	29.10.2020 10:34
Assignment Diagnostic group		Started	03.09.2020 13:07	Duration	5/7 day(s)

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

E	Bittium	Dashboard	Recordings				Echnician 1 . Technician			
Recordings	tecordings									
Q Search		Create recording -					10 •	Active 👻		
Patient ID \checkmark	Status 🗸	Last update	 Organizat 	tion V Created V	Recording type \checkmark	Device 🗸	Assignment \downarrow	Action		
HolterPlus_2	Active -	29.10.2020 10:34	DemoClin	nic2 03.09.2020 13:07	Bittium HolterPlus	1874602	Diagnostic group 🕞	€. ±-		
-	Ended	10.07.2020		10.07.2020						

Figure 98 Changing recording status to "Ended" on Recordings view

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

Ready for analysis	
Patient ID HolterPlus_2	
Are you sure this recording is ready fo	r analysis?
 The recording will end. The patient will be instructed to 	return the devices.
	Cancel Ready for analysis

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 Bittium Cardiac Navigator MedicalSuite edition is in use, the complete recording data gets automatically transferred to the related Bittium Cardiac Navigator MedicalSuite edition 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)

< Ba	ck 📕	ittium	Dashboard	Recordings		EN •	Technician 1
Pati	ent ID: I	HolterPlus_2	Bittium Holter	Plus			Close
Status	3	● Ended -		Created	03.09.2020 13:07	Last update	06.10.2020 11:26
Assig	nment	None	-	Started	03.09.2020 13:07	Duration	5/7 day(s)
Rec	ording data	a Patient deta	ils Anamneses	Recording d	letails Attachments		
.⊎, C ⊮r In	L Download A Open Cardiac Navigator Cancel Save						
Reco	ording da	ata					
		Day No.	Start date of file	Status	Notes		
•		1/7	03.09.2020 13:07	<mark>●</mark> Open •	Add notes		
•		2/7	04.09.2020 13:07	😑 Open 🗸	Add notes		
•		3/7	05.09.2020 13:07	<mark>●</mark> Open •	Add notes		
•		4/7	06.09.2020 13:07	<mark>●</mark> Open •	Add notes		
		5/7	07.09.2020 13 [.] 07	<mark>●</mark> 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 Bittium 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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium Cardiac Navigator database. When a recording is finished, the complete recorded ECG data appears in one instance in Bittium Cardiac Navigator MedicalSuite edition marked with an indication of "Ended". Final analysis of a recording is performed to this "Ended" data instance in Bittium Cardiac Navigator MedicalSuite edition. 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 Bittium Cardiac Navigator MedicalSuite edition to Bittium MedicalSuite Center once the recording is closed.

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

To perform final analysis of a recording and to create a diagnostic report in Bittium Cardiac Navigator MedicalSuite edition, 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 MedicalSuite edition 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).

Diagnostic report needed					
All Not assigned					^
Recording	Assignment	Ready for analysis	Duration		
BittiumHolter_1	Diagnostic group -	28.10.2020 08:27	1 day(s)	Close Analyze 👃 -	

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

Recording data	Patient details	Anamneses	Recording details	Attachments	
	"九 Analyz mente	e			Cancel Save

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

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

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

👩 Create	e a report			×
RECORI	D PATIENT COMMON			
	Selected ECG strips			^
Eø	Holter-like report containing selected ECG strips			
	Full disclosure			
	Full disclosure ECG report, presenting all ECG traces	of the who	ole recording.	
8	HRV Report			=
F	HRV Parameter and Tables			
1	Test report			
E				
	Long-term ECG Report			
E	General long-term ECG report. Consists of an arrhyth	nmia overvi	iew and the narrative su	mmary.
	Summary clinical findings			•
•				
	La	nguage	English (UK)	-
	Styl	e sheet	Default	-
	Temporarily hide personal info	rmation		
	Encryp	tion key		øΧ
Cance	el Pri	eview	Add to record	Create

Figure 105 Adding report to a recording in Bittium Cardiac Navigator database

More detailed instructions for the use of Bittium Cardiac Navigator can be found on separate Bittium 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 Bittium Cardiac Navigator MedicalSuite edition 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 Bittium 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.

This feature is available only for technician and diagnostic users who are linked to the **NOTE** related Bittium Cardiac Navigator[™] MedicalSuite Edition 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).

Diagnostic report needed				
All Not assigned Recording	Assignment	End time	Duration	
HolterPlus_2	Diagnostic group 🕞	08.09.2020 04:59	5 day(s)	Close Analyze 🕁 🗸

Figure 106 Close button on "Diagnostic report needed" dashboard card

< Back Bitt	íum	Dashboard	Recordings		en •	Technician 1
Patient ID: Holt	erPlus_2	Bittium Holter	Plus			Close
Status Assignment	Ended - Closed ognostic group	•	Created Started	03.09.2020 13:07 03.09.2020 13:07	Last update	07.10.2020 17:24 5/7 day(s)
Recording data	Patient details ab Ope	Anamneses n Cardiac Navig	Recording detail	s Attachments	C:	ancel Save

Figure 107 Closing recording on single recording top bar

HolterPlus_2	Ended	07.10.2020 17:24	DemoClinic2	03.09.2020 13:07	Bittium HolterPlus	874602	•	Diagnostic group 👻	₽.↓.
	Closed	04.00.0000							
0	A 7-4-4	01.09.2020	D004	01.09.2020	maximum () also imitia	M 100CD/C		M	

Figure 108 Changing recording status to "Closed" on Recordings view

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



Figure 109 Confirming closing of a recording

If Bittium Cardiac Navigator MedicalSuite edition is in use, all diagnostic reports saved to the recording in the related Bittium 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).



Recording data	Patient details	Anamneses	Recording details	Attachments	
, J Download					Cancel Save
Reports					1 file(s)
Add file or dra	ag here 🔥 I	mport reports			

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



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).



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 Holter	Plus			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	s Anamneses	Recording deta	ails Attachments		
, ↓, Download				C	ancel 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
Patient ID: HolterPlus_2	Bittium HolterPl	lus			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 detail	s Attachments		
🕁 Download					Cancel Save
Reports					1 file(s)
Add file or drag here	Import reports				
Filename				Added	
SAMPLE-DIAGNOSTIC-R	EPORT.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).

Latest reports	s						
Recording		Organization	Added			Approval	
 HolterPlus 	3_2	DemoClinic2	07.10.2020 21:02 Diagnostic group			Approve	
		Figure	116 Preview icc	on on "Late	est reports" d	lashboard card	d
	- 0.0004	12:14	Domoonno.	08:47	Data in Fisico	u	Report pending appr
HolterPlus_2	Closed	07.10.20 17:49	DemoClinic2	03.09.2020 13:07	Bittium HolterPlus	🍓 1874602 🛛 🗕	Diagnostic group 👻 📔 🚽

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 Holter	Plus			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 detail	ls Anamneses	Recording de	tails Attachments		
🕁 Download					Cancel Save
Reports					1 file(s)
Add file or drag here	🔥 Import reports				
Filename				Added	
HOLTERPLUS_2_Holt term_ECG_report.pdf	erPlus_2_01-01-1	1993_26-06-2020-1	IGeneral_long-	07.10.2020 17:06	

Figure 119 Approve button on single recording top bar

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



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
Patient	D: HolterPlus_2	Bittium Holter	Plus			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 - A Clinic I Clinic	Demo 2 🛫
Recordings						
Q Search	Create recording	-				10 • O All •
Patient ID \downarrow	Status 🗸	Last update 🗸	✓ Created ✓	Recording type \checkmark	Device \checkmark	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.

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	Download	
HolterPlus_2	DemoClinic2	07.10.2020 17:49	07.10.2020 17:54		
	۲ ۲ ۲	Recording data ل Recording data 5 day(s) Reports ل HOLTERPLUS_2_HolterPlus_2_01-01-1993_26-06-2020-2General_long-term_ECG_repo Other documents ل recording-information.pdf			

Figure 125 Download icon on "Latest reports" dashboard card

Recordi	ing data Patient details	Anamneses	Recording details	Attachments				
J. Dow	nload					Cancel	Save	
Reports	;						1 file(s)
	Filename				Added			
	HOLTERPLUS_2HolterF term_ECG_report.pdf	Plus_2_01-01-199	3_26-06-2020-2Ge	eneral_long-	07.10.2020 17:49		₽.]
Other d	ocuments						1 file(s	s)
🕀 Ado	d file or drag here							
	Filename				Added			
	recording-information.pdf					È	6 ⊥]

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 recorder 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 recorder from a finished recording, follow the steps described below:

- 1 Find the recording where the Faros recorder 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 recorder from the recording by first clicking the **blue recorder icon** and then clicking **Release device** (Figure 127).

Bittium	Dashboard Recor	dings			en • 🔒	Technician 1 _ Technician
Recordings						
Q 1871773	Create recording -					10 • O All •
Patient ID V Status V	Last update \checkmark	Organization \checkmark	Created \checkmark	Recording type \checkmark	Device	Assignment 🗸 Action
HolterPlus_3	09.06.2020 10:31	DemoClinic2	08.06.2020 10:00	Bittium HolterPlus	Balassa davisa	None - 🕁 -
		~~	1/1	>>		

Figure 127 Releasing Faros ECG recorder

After releasing the device, the previously blue Faros ECG recorder icon turns to grey and the Faros recorder can be used again in another recording. Bittium MedicalSuite Mobile application, to which the Faros ECG recorder 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 recorder

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

NOTE Data of the previous recording is automatically deleted from the Faros ECG recorder when a new HolterPlus recording is started.

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

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



Figure 129 Faros recorder 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 recorder from the computer.

MANUFACTURER

Bittium MedicalSuite[™] Center



Bittium MedicalSuite[™] Center is medical device.

Bittium MedicalSuite[™] Mobile





Bittium MedicalSuite[™] Mobile is medical device.

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WEBSITE

You can find up-to-date product information, documents, and updates by visiting the Bittium website at <u>www.bittium.com</u>

SALES

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Finland	

SERVICE DESK

If you encounter any issues with Bittium medical products, please contact our technical support at

medical.support@bittium.com