Bittium

MedicalSuite™ HSAT Service

Clinical Guide

Table of Content

1 GENERAL

1.1 Bittium Home Sleep Apnea Testing service

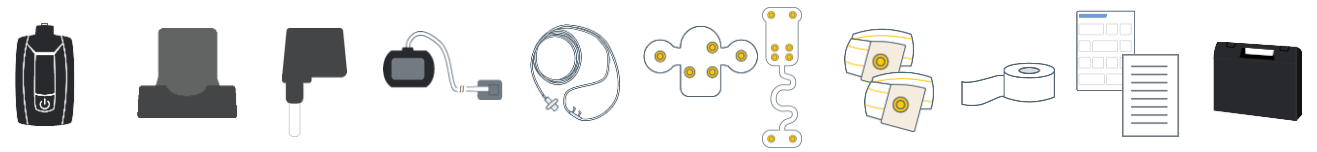
Bittium Home Sleep Apnea Testing (HSAT) service is intended to be used for recording standard polygraphy (PG) level data and analyzing typical sleep-related breathing disorders, such as obstructive sleep apnea, central sleep apnea, mixed sleep apnea, hypopnea, and Cheyne-Stokes breathing.

Bittium HSAT™ service is a combination of recording equipment and Bittium MedicalSuite™ service platform including Bittium Respiro Analyst™ software. **Bittium HSAT** service provides a conventional offline solution to perform and analyze HSAT recordings where recording data is uploaded from Bittium Respiro™ recorder to MedicalSuite service platform for analysis once the recording is completed. (Figure 1)

Figure 1 Bittium Home Sleep Apnea Testing service

1.1.1 Recording equipment and configurations

The recording equipment used in HSAT recordings depends on the recording needs. **Bittium HSAT** recording **always** contains the following equipment (Figure 2):



Bittium Respiro recorder | Charging dock with USB for Respiro | Charger for Respiro | Pulse oximeter with a finger sensor | Nasal cannula | Respiro patch for 1 or 2 RIP belts | 1 or 2 RIP belts | Medical tape | Quick guide, notes, and warnings | Carry case

Figure 2 Bittium HSAT recording equipment

Bittium HSAT recordings **can additionally** contain the following equipment (Figure 3):

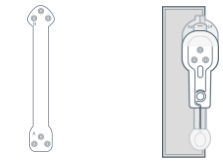
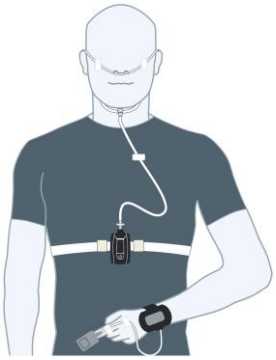


Figure 3 Additional equipment for HSAT recording

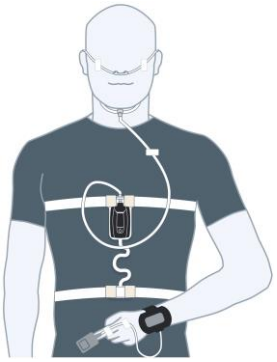
Bittium HSAT service supports different configuration options such as sensor setup, time synchronization, Bluetooth setting and scheduled time for different recording needs. Bittium HSAT recording is configured using **Bittium Respiro™ Device Manager** software (see chapter 3.2.3).

Bittium Respiro Device Manager and Bittium MedicalSuite Center have three **setup options** for sensor configuration. Respiro recorder (integrated accelerometer and microphone), pulse oximeter with a finger sensor and nasal cannula are used in every setup options. Instead, the **number of RIP belts** and the inclusion of **ECG (electrocardiography) electrode** are dependent on the used setup option. All three setup options are illustrated in the Figure 4.



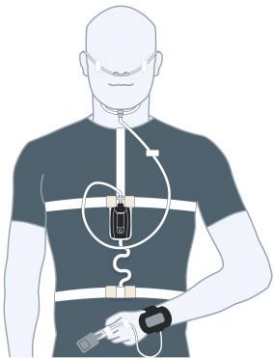
1 RIP belt configuation

- Respiro recorder
- Pulse oximeter with a finger sensor
- Nasal cannula
- **1 RIP belt**



2 RIP belts configuration

- Respiro recorder
- Pulse oximeter with a finger sensor
- Nasal cannula
- **2 RIP belts**



2 RIP belts configuration with ECG

- Respiro recorder
- Pulse oximeter with a finger sensor
- Nasal cannula
- **2 RIP belts**
- **ECG**

Figure 4 Bittium HSAT service setup options

1.1.2 Bittium MedicalSuite service platform

Bittium MedicalSuite is a web-based remote monitoring service platform that combines different medical devices and modules into a single service thus enabling the analysis and management of various recordings performed 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 is a combination of wireless data transfer, intelligent data analysis, and handy reporting and management modules that can be optimized individually for each user according to their needs.

1.1.3 Bittium Respiro Analyst

Bittium Respiro Analyst™ is a web application that enables sleep specialists to make polygraph analyses for Bittium Respiro™ recordings. Respiro Analyst provides accurate medical information on patients (polygraphy signals and preliminary analysis).

Respiro Analyst enables sleep specialists who are working in remote locations to analyze recordings made by the health centers and clinics. For the sleep specialist, the system provides a complete working environment for signal visualization and analysis. The sleep specialist can write a statement based on the analysis using integrated Statement Tool.

1.2 Intended use

Bittium HSAT service is intended to be used for recording standard PG level data and analyzing typical sleep-related breathing disorders, such as obstructive sleep apnea, central sleep apnea, mixed sleep apnea, hypopnea, and Cheyne-Stokes breathing. Several devices and sensors are used to record different biosignals for analysis with Bittium Respiro Analyst software included in Bittium MedicalSuite service platform. See sensor and biosignal details from the Table 1.

Sensor	**Biosignal**
Nasal cannula + air pressure sensor	Airflow
Respiratory Inductance Plethysmography (RIP) for thorax/abdomen	Respiratory effort
Integrated accelerometer	Body position & activity
Integrated microphone	Snoring
1-channel ECG electrode patch	ECG
Pulse oximeter with finger sensor	Blood oxygen saturation & pulse rate

Table 1 Bittium HSAT service sensors and recorded biosignals

1.2.1 Respiro intended use

Respiro is intended to be used as a screening recorder for brief overnight polygraphy, which is always carried out by doctor's prescription. Use of Respiro for any other purpose is prohibited. Respiro is used either in a hospital or at patient's home. The recorder records patient's biosignals. The recorder does not actively monitor the patient's status, make diagnoses, or treat the patient and it cannot be used as a life-sustaining recorder. The recorder does not record EMG, EOG, or EEG signals required in an extensive sleep study (polysomnography). The recorder is not designed to be used with children. The recorder is operated by healthcare professionals (hospital), the patient or another person at the patient's home. A healthcare professional gives instructions to the patient or the recorder operator on using the recorder and starting the recording before using it at home. The patient is provided with an illustrated quick guide for home use.

1.2.2 Respiro Analyst intended use

Respiro Analyst is intended to be used as analysis software in overnight respiratory polygraphy, which is always carried out by a medical doctor's prescription. Use of this software for any other purpose is prohibited. Respiro Analyst is used typically in a hospital or a clinic. Software analyses patient's biosignals that have been recorded with Respiro™. Software does not actively monitor the patient's status or treat the patient and it cannot be used as a life-sustaining application. The annotated episodes should be considered as preliminary and should not be used as such as a basis for diagnosis. The user must be certain of the analyzed signals' purity and quality, and he/she must ensure the correctness of the annotated episodes before making an analysis for a statement. Respiro Analyst is not designed to be used with children. The application is operated by sleep specialists and healthcare professionals (hospital).

1.3 Contraindications

Bittium HSAT service contraindications regards to age, body, and usage of the equipment and they can also be seen from Bittium Respiro operating instructions. Contraindications are listed as follows:

- The product is not intended for pediatric patients. Age limit 18 years.
- Outstandingly big physical size. Sensor adjustment out of control.
- Amputation – missing fingers / both hands (SpO2 measurement not possible)
- Unfeasible to use sensors for any reason (sensitive skin)
- Artificial nails / thick fingernail painting prevents SpO2 measurement
- Person who is not capable to execute self-directed / self-contained measurement at home (even with pre-set recording timing functionality)
- Acute respiratory infection, which might be a confusing factor in symptoms and interpretation

A doctor always assesses the requirement for a night polygraphy and whether the patient is suitable for home recording. Only an expert can interpret and analyze the results of night polygraphy recording and be responsible for the given statements and care. 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.

1.4 Notes and warnings

Bittium HSAT service usage is safe, but there are several notes and warnings which need to be considered for the recording equipment. Before using the services familiarize yourself with notes and warnings which are included in the equipment carry case.

2 GENERAL PREPARATIONS AND INSTRUCTIONS

2.1 Recording equipment preparations

Before creating Bittium HSAT recording, the recording equipment needs to be prepared. The recording equipment is collected (see chapter 1.1.1) and cleaned (see chapter 4.1, Table 2), Respiro is charged, batteries are inserted to the pulse oximeter, and device connections are checked. See more details from the following chapters.

2.1.1 Charging Respiro recorder and inserting batteries to pulse oximeter

Before performing Bittium HSAT recording, Respiro recorder is charged, and batteries are inserted to the pulse oximeter to check the battery state. Connect Respiro to an outlet using the charging dock and the charger to charge Respiro. The LED indicators represent the recorder battery charge state. **If all LEDs are continuously green, the battery is >95% charged** (recommended). Respiro battery life of Bittium HSAT service with the most extent configuration and Bluetooth® use is enough for typical PG level study, and in principle a patient does not need to charge the battery.

NOTE	Connect the charging dock to the charger's USB port only. Do not connect it anywhere else for charging.

NOTE	Respiro is >95% charged when all LED are continuously green and only then is recommended to start a recording.

Contrast to Respiro, a pulse oximeter contains replaceable batteries. After inserting batteries check the state of the battery indicator. The battery indicator shows one of three states: full, half, and low. **Replace batteries to a pulse oximeter when it reaches less than three segments on the screen** (about after 34h / 4 nights). Remove the batteries and disconnect the sensor if the pulse oximeter is to be stored for more than 1 month.

NOTE	Replace batteries to a pulse oximeter when the battery indicator reaches less than three segments.

2.1.2 Checking connection between devices

By default, Respiro and the pulse oximeter are connected by the manufacturer, but the connection between devices is recommended to check before starting a recording using Respiro recorder. To check the connection using Respiro, follow the steps below:

NOTE	Make sure that Respiro is not in the charger dock or connected to a computer when checking the device connections.

NOTE	If the devices are not connected with each other, they need to be connected (see instructions from chapter **Error! Reference source not found.**)

1 **Switch on** Respiro by pressing the power button about 3 seconds. After Respiro has started all 3 indicator LEDs will be lit blue. Press the power button again about 8 seconds until Respiro vibrates once and LEDs will be blinked blue.

2 **Switch on** the pulse oximeter by attaching the sensor to the pulse oximeter first and then inserting your finger in it. Alternatively, you can press the pulse oximeter's power button with your fingernail to start it (finger does not need to be inserted in this case). Bluetooth icon is always shown on the screen (blinking icon = connecting, stable icon = connected) (Figure 5).

Figure 5 Pulse oximeter power button and Bluetooth icon

3 After the pulse oximeter is started, Respiro recorder's **left LED** indicator will be **green**, if the finger is inserted in the sensor and **yellow** if it is not. Respiro is not connected to the pulse oximeter if the **left LED** indicator is **red**.

4 **Switch off** Respiro recorder by pressing the power button. Press the power button for about 3 seconds to stop the activated recording state.

NOTE	It is not necessary to switch off the pulse oximeter separately from its power button. It switches off automatically when the finger is removed from the sensor.

You can also find out the device connections via Bittium Respiro Device Manager by comparing the serial number information in Respiro Device Manager with that shown on the pulse oximeter.

2.2 Using Bittium Respiro Device Manager

2.2.1 Bittium Respiro Device Manager functionalities

Bittium Respiro Device Manager is a software that is used for setting up Respiro recorder in HSAT recordings (Figure 6). Bittium Respiro Device Manager works in Windows 10 operating system, and it includes the following functionalities:

- Updating firmware
- Access to manual
- Synchronizing device time with PC time
- Language selection
- Selecting sensor configuration
- Connecting Respiro and pulse oximeter
- Scheduling recording (start and end times)
- Saving recording files
- Deleting recording files

NOTE Respiro Device Manager functionalities are available mainly for Bittium HSAT service except for connecting Respiro and pulse oximeter, updating firmware, and access to manual, which also are useful in Bittium HSAT service.

2.2.2 Starting Bittium Respiro Device Manager

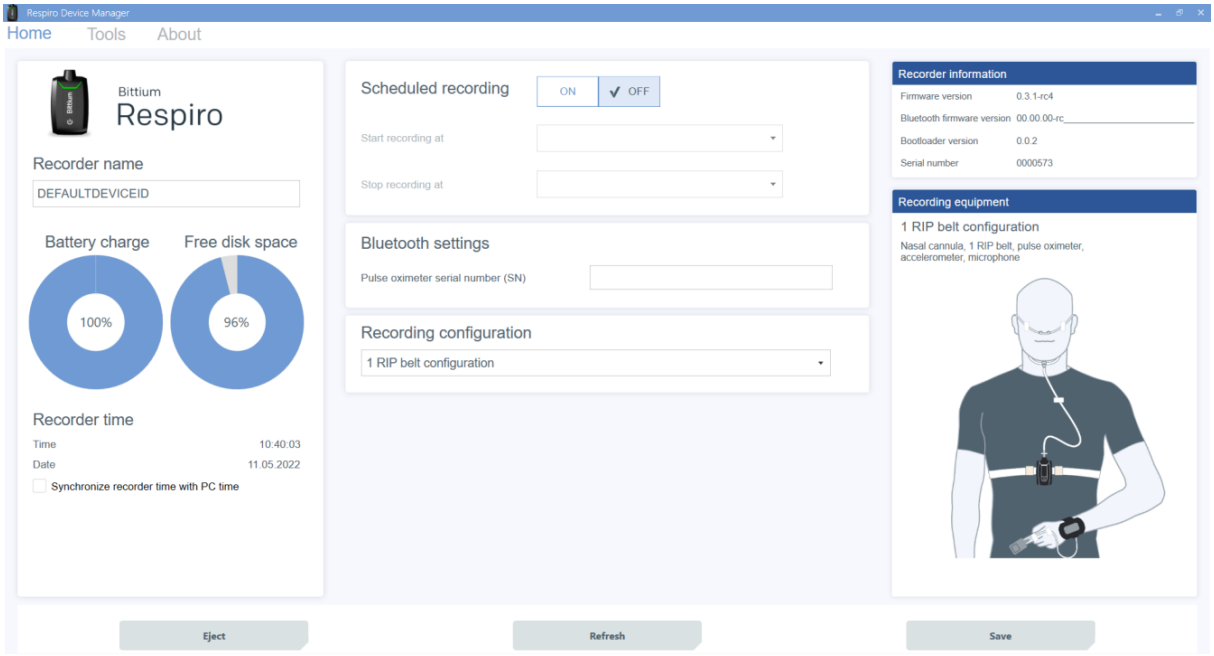


Figure 6 Bittium Respiro Device Manager - main view

Bittium Respiro Device Manager is a software that has many functionalities (see chapter 2.2.1). If you want to start Respiro Device Manager, you need to open it first from Respiro's internal memory by following next steps:

1 Connect the Respiro's charging dock to a computer with the USB cable.
2 Set Respiro in the charging dock.
3 Start Respiro Device Manager via Windows File Explorer by double-clicking **Respiro Device Manager** file (Figure 7). You can find it by following next steps.
   a) Double-click Respiro icon from Windows File Explorer.
   b) Double-click Respiro Device Manager folder.
   c) Double-click Respiro Manager execution file.

NOTE Bittium Respiro Device Manager folder can be saved to a computer and the software then run directly from there.

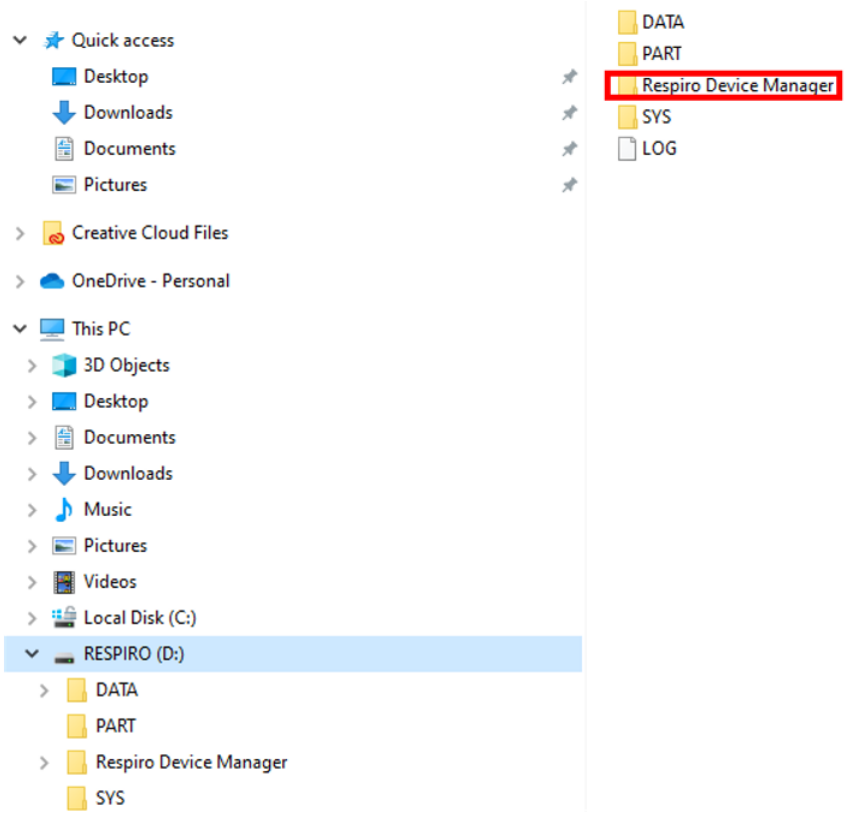


Figure 7 Clicking Respiro Device Manager file

4 Wait for the application to detect Respiro. Respiro Device Manager main view opens (Figure 6, chapter 2.2.1).

NOTE You can also request Bittium Respiro Device Manager software from Bittium technical support (MedicalSuite.support@bittium.com).

2.3 Using Bittium MedicalSuite service platform

2.3.1 MedicalSuite accounts

Each unit offering a particular type of healthcare services relate to a separate organization entity belonging in a tree type organization structure on Bittium MedicalSuite service platform (Figure 8).

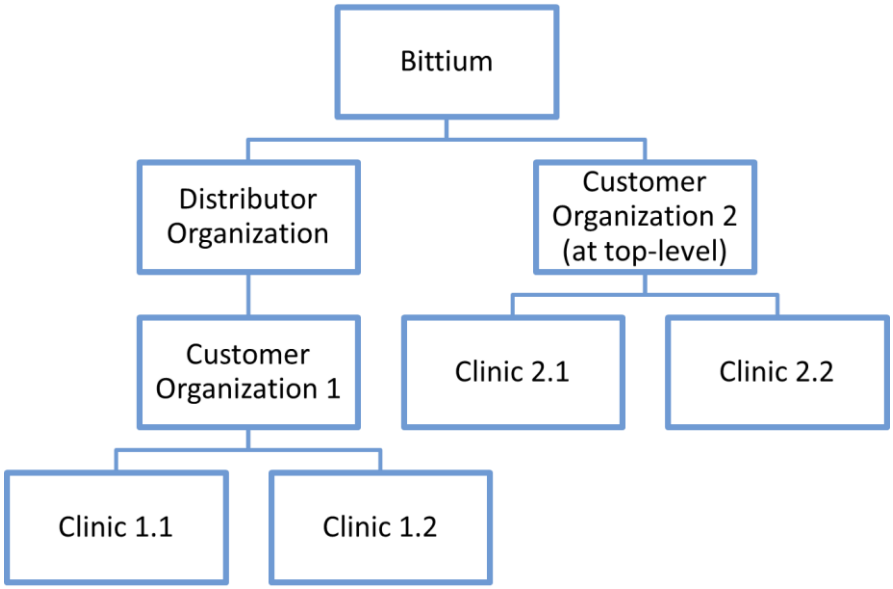


Figure 8 Tree type organization structure

Furthermore, each organization on Bittium MedicalSuite may include multiple users with different functionality access. The structure of MedicalSuite organizations, their users and tasks can vary based on the organization process and their 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 recorders/devices
- Has access to service platform usage statistics of his/ her own organization and its lower-level organizations

Clinic

- Prepares a recording with patient details according to service type and prescription of the physician
- Attaches Respiro recorder, pulse oximeter, sensors, electrode, and cables if necessary
- Uploads (Bittium HSAT) and validates the recording data
- May end (set ready for analysis) recording
- 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 Respiro recorder, sensors, and cables if necessary
- May upload and validate the recording data
- Assigns the recording to a diagnostic user or diagnostic group for analysis and interpretation
- May end (set ready for analysis) the recording
- May perform the data clean-up using Bittium Respiro Analyst analysis software
- Approves a diagnostic report and thus provides the report with interpretation notes to the lower-level organization

Diagnostic

- Analyzes the HSAT data with Bittium Respiro Analyst
- 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.

2.3.2 Login to Bittium MedicalSuite Center

Management of Bittium HSAT recordings throughout the whole workflow is performed using **Bittium MedicalSuite Center** (see also chapter 2.3.3) that is a part of Bittium MedicalSuite service platform. 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. See chapter 2.3.1 for more information about the different user roles.

To create and manage Bittium HSAT recordings, login to Bittium MedicalSuite Center by following the steps below:

1 Go to Bittium MedicalSuite Center **login page** (https://medicalsuite.bittium.com/center/login)

NOTE	To access Bittium MedicalSuite, each user needs to have an organization-specific secure certificate imported to a computer. Contact your Bittium MedicalSuite organization admin user to get a secure certificate for Bittium MedicalSuite.

NOTE	The recommended browsers for using Bittium MedicalSuite service platform are the latest versions of Google Chrome and Mozilla Firefox.

2 Enter the user credentials.

NOTE	The management of your organization's Bittium MedicalSuite accounts 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.

3 Click **Login** button.

4 MedicalSuite Center Dashboard view opens (Figure 9**Error! Reference source not found.**).

2.3.3 Using Bittium MedicalSuite Center

Bittium MedicalSuite service platform consists of **Bittium MedicalSuite Center** that enables effective recording management for hospitals, clinics, and health care professionals. MedicalSuite Center allows organization and role-based configurations that makes possible to easily tailor the service for different kind of organizations. It consists of personalized dashboards for a clinic user (nurse), technician and specialists that help medical professionals to view only the issues they need. MedicalSuite Center has three main views: **Dashboard**, **Recordings** and **Single recording views**. See more details for using MedicalSuite Center from the next chapters.

2.3.3.1 Dashboard view

MedicalSuite Center Dashboard view presents the statistics and highlights the most recent activity on the Bittium MedicalSuite service platform (Figure 9). It adapts to the current user role.

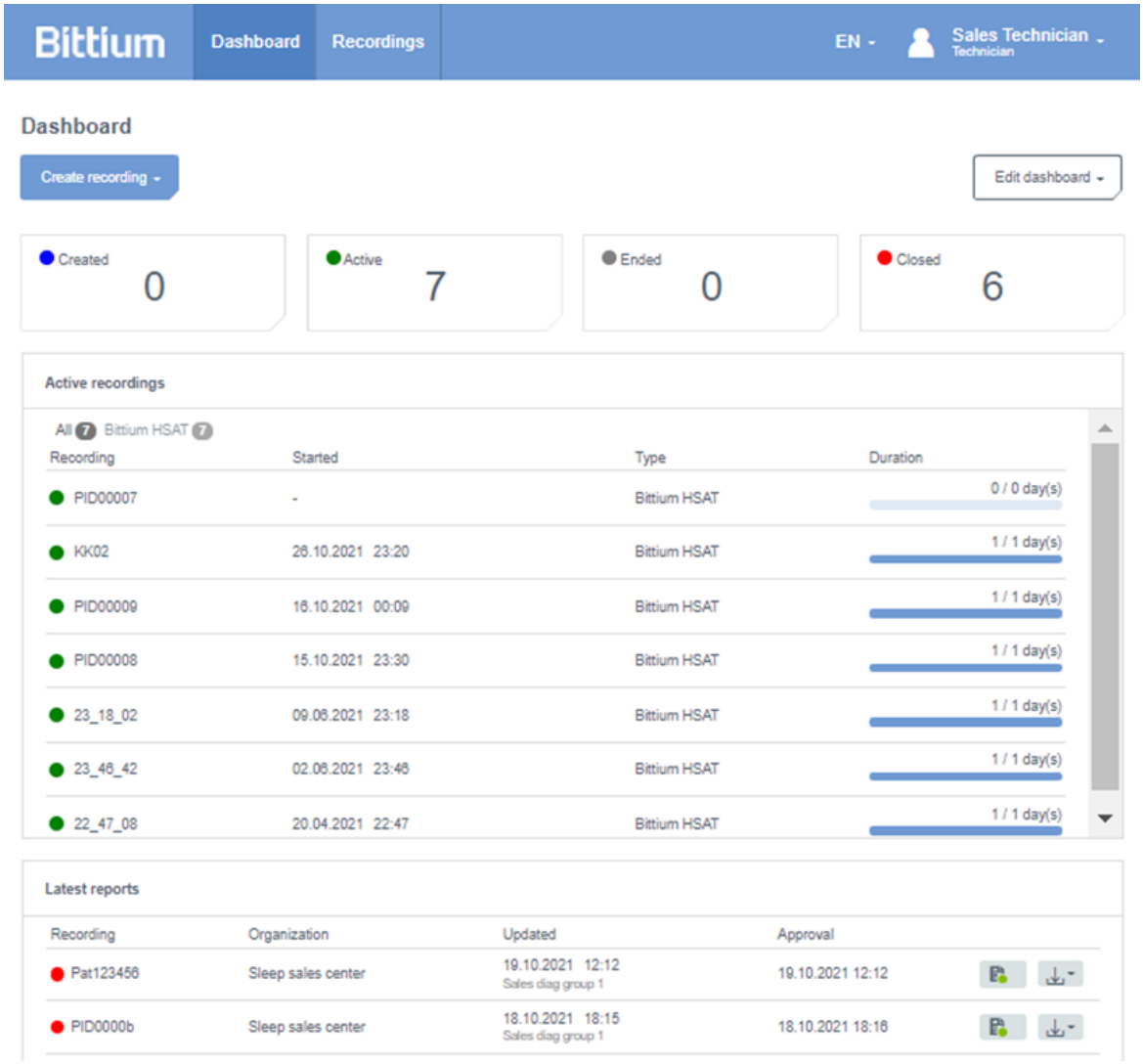


Figure 9 MedicalSuite Center Dashboard view

You can select a **language** (English, German, French) you want to use in Dashboard view (Figure 10).

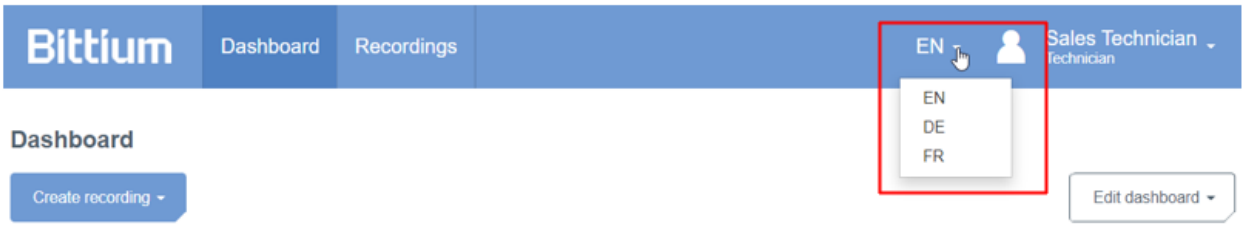


Figure 10 Selecting language in Dashboard view

You can see the current **user role** in the top-right corner of the view. By clicking the **role name** (Sales Technician 1 in Figure 11) you can see the **organizations** to whose data you have an access. You can also **log out** from the service platform when needed (Figure 11).

Figure 11 Viewing user account details and logging out in Dashboard view

A recording is created in **Dashboard** view or **Recordings** view. Select **Bittium HSAT** recording (Figure 12).

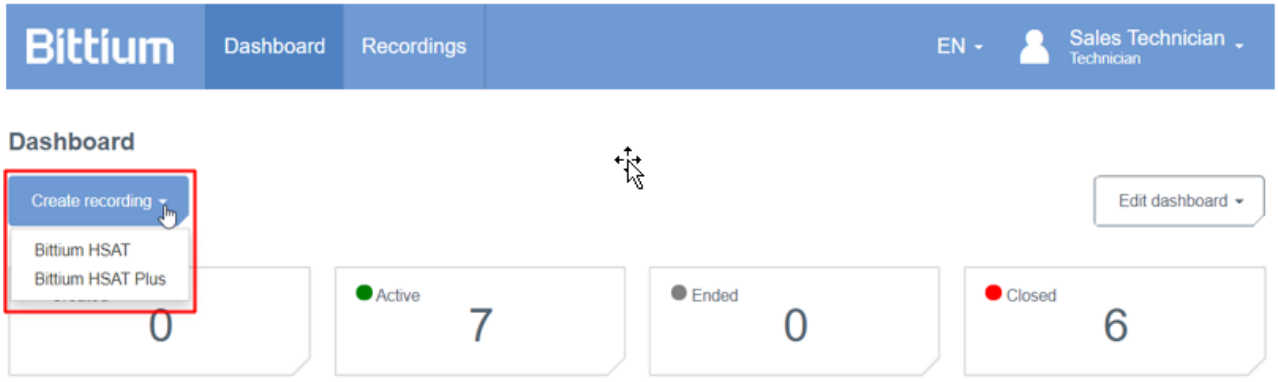


Figure 12 Starting to create a recording in Dashboard view

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 (Figure 13).

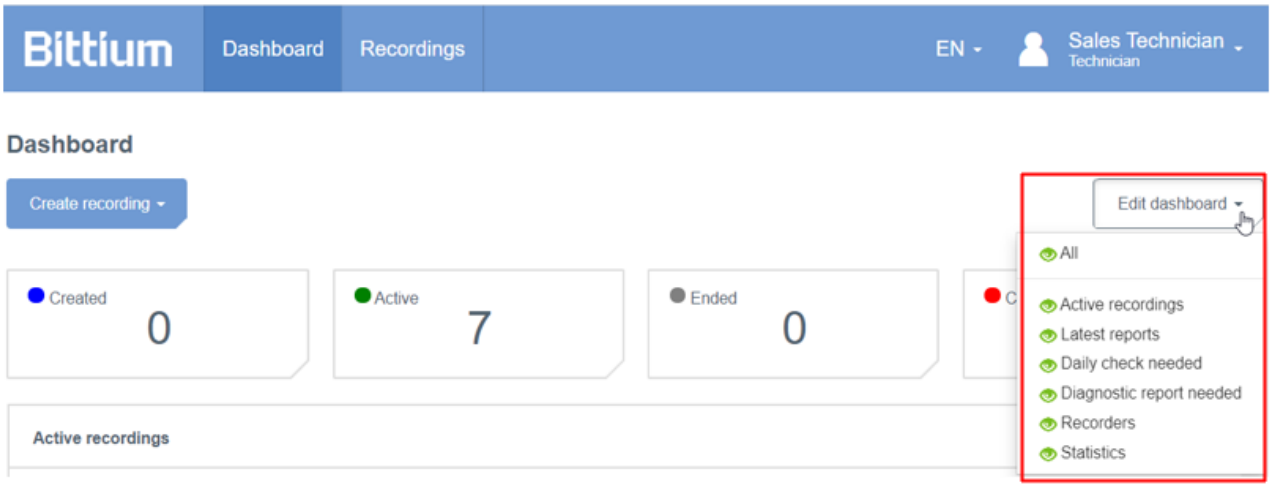
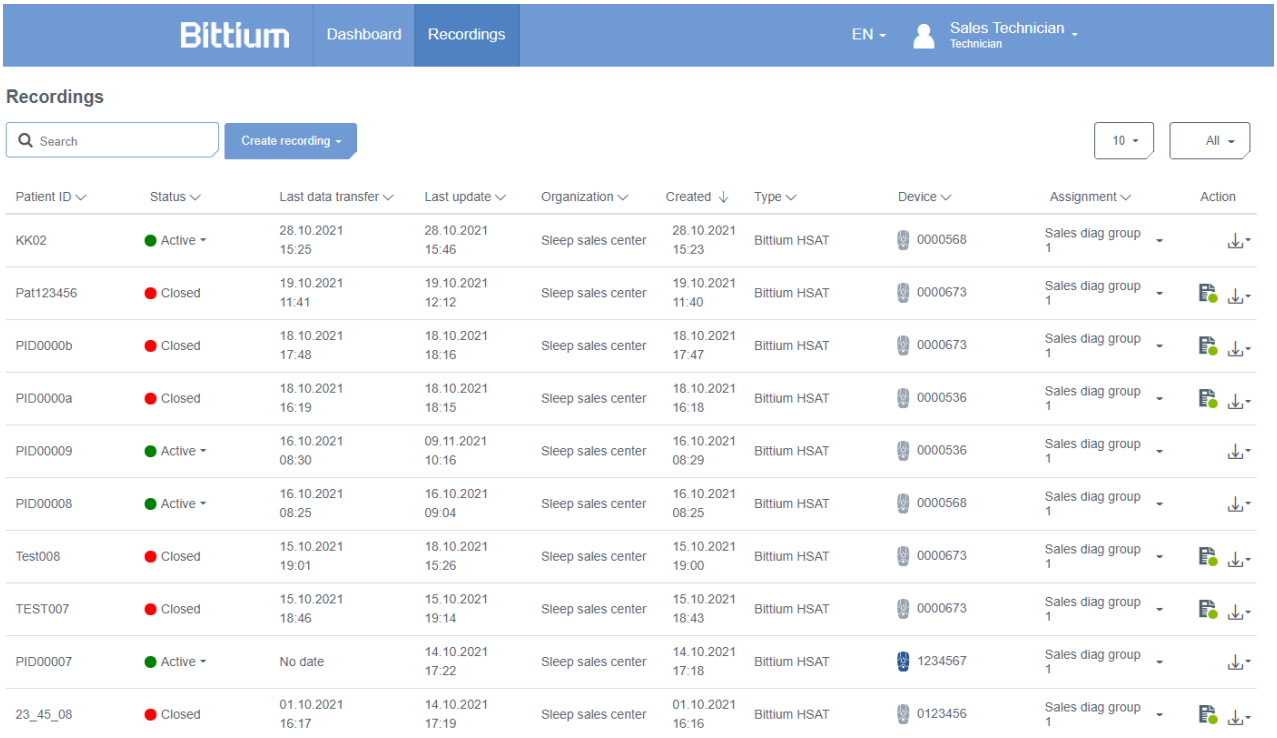


Figure 13 Editing dashboard in Dashboard view

2.3.3.2 Recordings view

The Recordings view shows recordings with details such as patient ID, status, last data transfer, last update, organization, created recording time, service type, device serial number, assignment, and action. If you are logged in as an admin, technician or clinic user, the Recordings view contains a list of all recordings created for your own organization and its lower-level organizations. 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 view (Figure 14)



Patient ID	Status	Last data transfer	Last update	Organization	Created	Type	Device	Assignment	Action
KK02	Active	28.10.2021 15:25	28.10.2021 15:46	Sleep sales center	28.10.2021 15:23	Bittium HSAT	0000568	Sales diag group 1	
Pat123456	Closed	19.10.2021 11:41	19.10.2021 12:12	Sleep sales center	19.10.2021 11:40	Bittium HSAT	0000673	Sales diag group 1	
PID0000b	Closed	18.10.2021 17:48	18.10.2021 18:16	Sleep sales center	18.10.2021 17:47	Bittium HSAT	0000673	Sales diag group 1	
PID0000a	Closed	18.10.2021 16:19	18.10.2021 18:15	Sleep sales center	18.10.2021 16:18	Bittium HSAT	0000536	Sales diag group 1	
PID00009	Active	16.10.2021 08:30	09.11.2021 10:16	Sleep sales center	16.10.2021 08:29	Bittium HSAT	0000536	Sales diag group 1	
PID00008	Active	16.10.2021 08:25	16.10.2021 09:04	Sleep sales center	16.10.2021 08:25	Bittium HSAT	0000568	Sales diag group 1	
Test008	Closed	15.10.2021 19:01	18.10.2021 15:26	Sleep sales center	15.10.2021 19:00	Bittium HSAT	0000673	Sales diag group 1	
TEST007	Closed	15.10.2021 18:46	15.10.2021 19:14	Sleep sales center	15.10.2021 18:43	Bittium HSAT	0000673	Sales diag group 1	
PID00007	Active	No date	14.10.2021 17:22	Sleep sales center	14.10.2021 17:18	Bittium HSAT	1234567	Sales diag group 1	
23_45_08	Closed	01.10.2021 16:17	14.10.2021 17:19	Sleep sales center	01.10.2021 16:16	Bittium HSAT	0123456	Sales diag group 1	

Figure 14 MedicalSuite Center Recordings view

The **Search** field helps you to find recordings from MedicalSuite Center. You can use for example **patient ID** or **device serial number** to find the recording you want. (Figure 15)

Figure 15 Searching recording in Recordings view

From the menu of the right corner, you can select the number of **visible recordings** at a time (10, 50 or 100) (Figure 16).

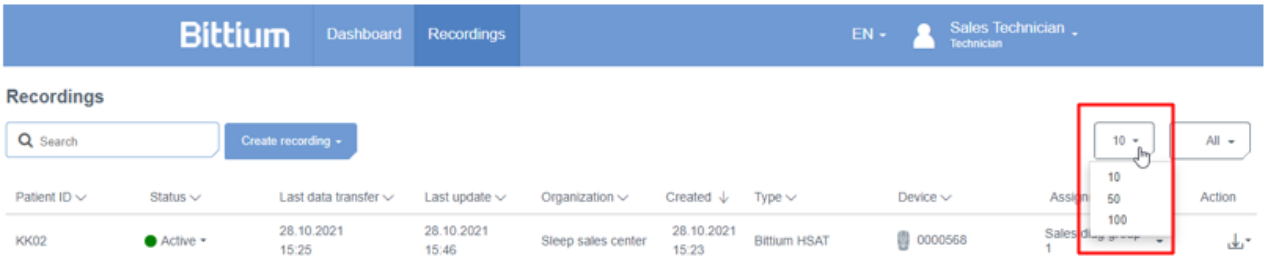


Figure 16 Selecting visible recordings in Recordings view

From the menu of the right corner, you can also select the recordings with the desired **status** (all, active, ended, closed, error) (Figure 17).

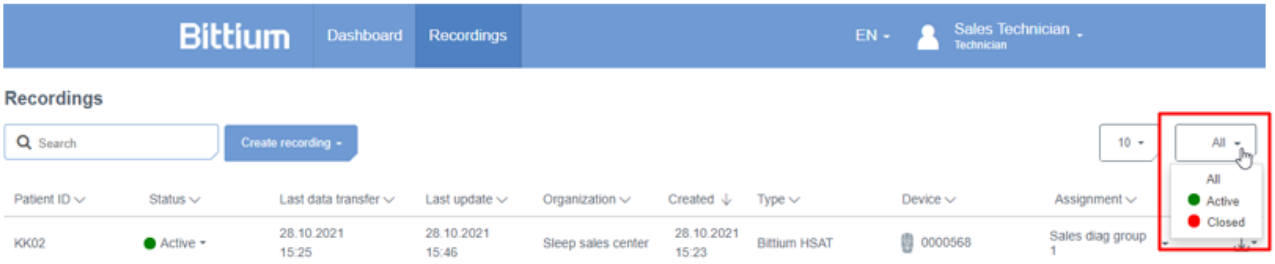


Figure 17 Selecting recordings with desired status in Recordings view

Clicking the **icon** beside **Patient ID** means that you can order patient IDs alphabetically. When you click the **icon** next to **Created** or **Last update**, you can see the oldest or the newest recordings the first (Figure 18).

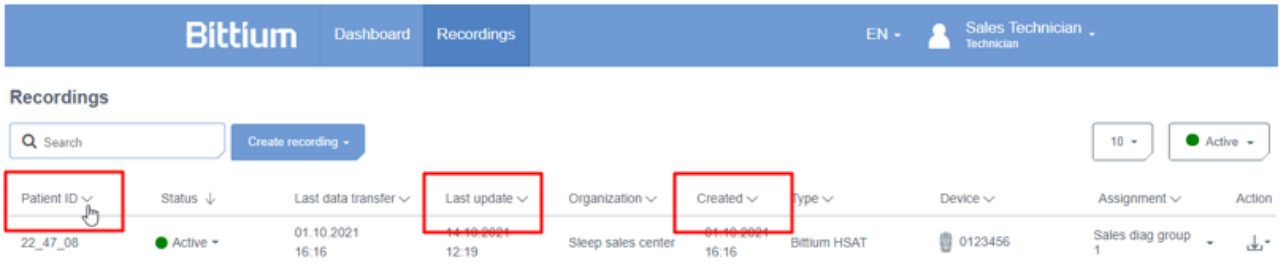


Figure 18 Sorting recordings in Recordings view

A recording can be assigned to diagnostic user or diagnostic group from assignment list (Figure 19). When a recording is assigned for the user or group, the user or group can see a recording in the own dashboard view after a recording is set ready for analysis. If there are many users or groups in the list, you can also search the user or group using a search field of the assignment list.

Figure 19 Recording assignment in Recordings view

If there are recording data, reports, or other documents in a recording, they can be downloaded from the **action** menu by clicking on the item (e.g., recording-information.pdf) (Figure 20). The **report symbol** beside the action menu indicates if approved report is viewable.

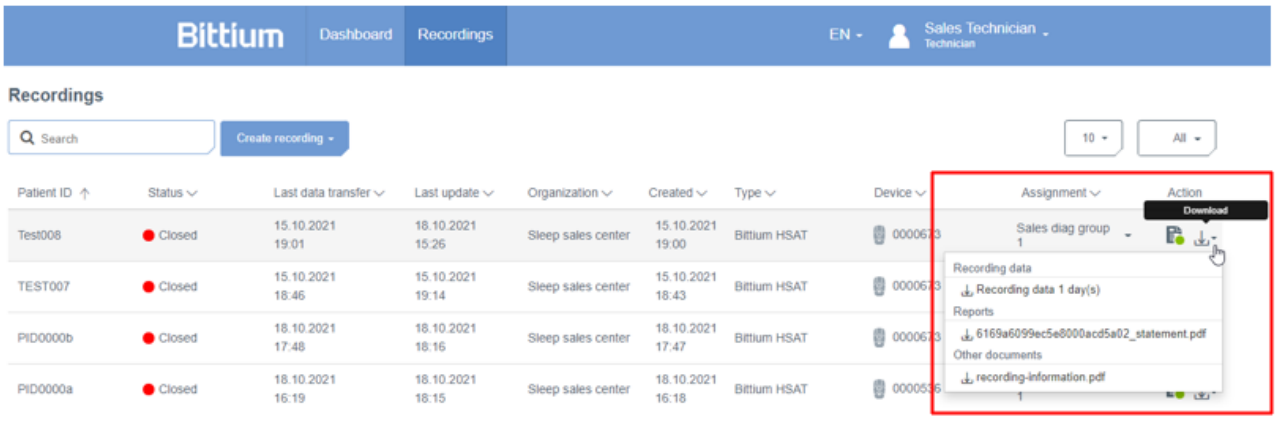


Figure 20 Downloading recording data and documents in Recordings view

2.3.3.3 Single recording view

The Single recording view presents recordings details such as recording data, patient details, anamnesis, patient diary, recording details and attachments on own tabs. You can find a single recording view for example by clicking a single recording in Dashboard view or Recordings view (Figure 21).

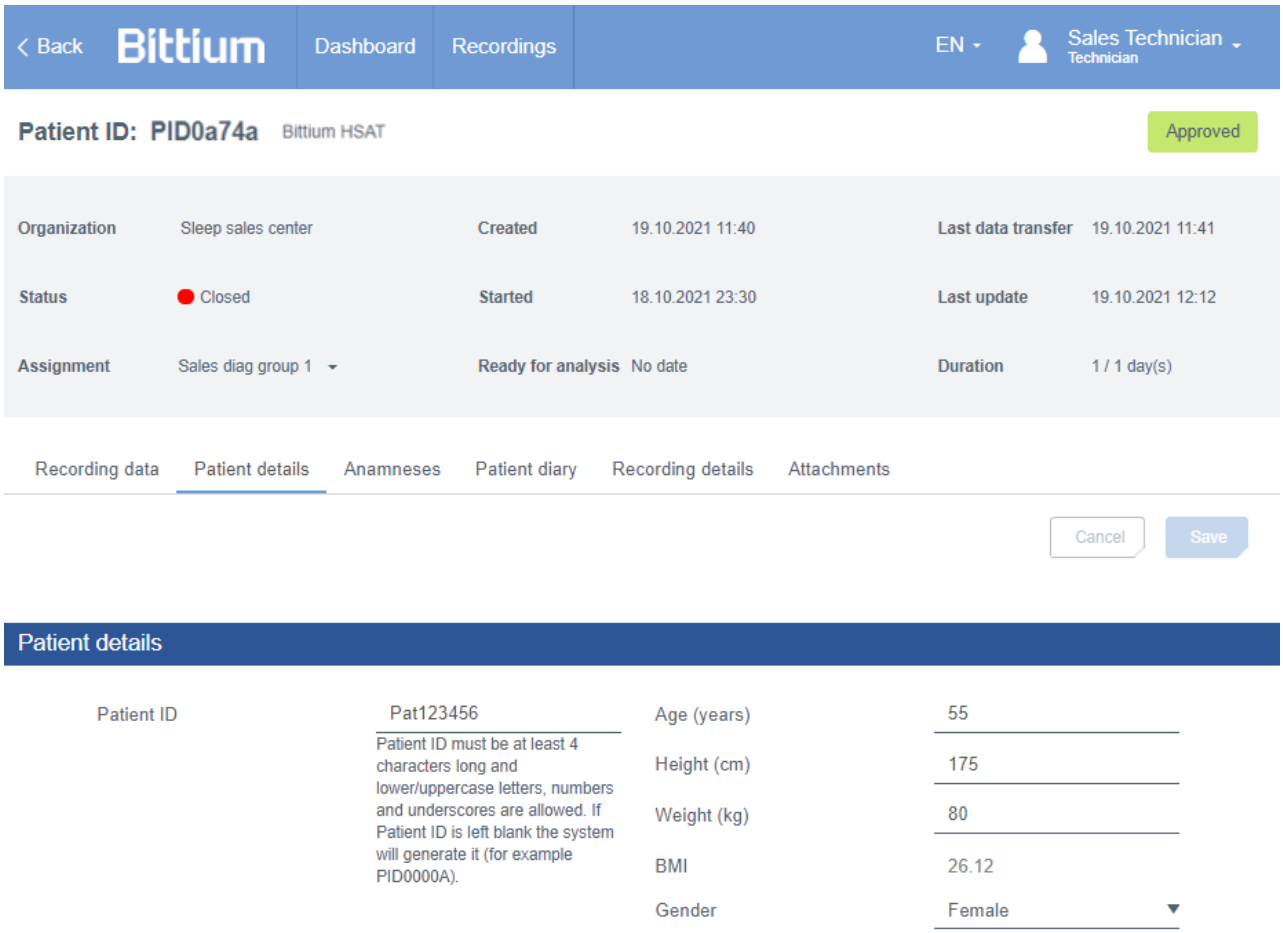


Figure 21 MedicalSuite Center Single recording view

3 BITTIUM HSAT SERVICE

Bittium HSAT is an ambulatory offline recording that is intended to record standard PG level data. Bittium HSAT recording can be set to automatically start and stop at a predefined time, or the recording can be manually started and stopped by pressing the Respiro button. The used operating mode is selected using Bittium Respiro Device Manager software. Once the recording has been completed, the recording data is manually uploaded to Bittium MedicalSuite Center for the complete data analysis.

3.1 Introduction to Bittium HSAT service workflow

Bittium HSAT service workflow is visualized in Figure 22 and includes the steps below.

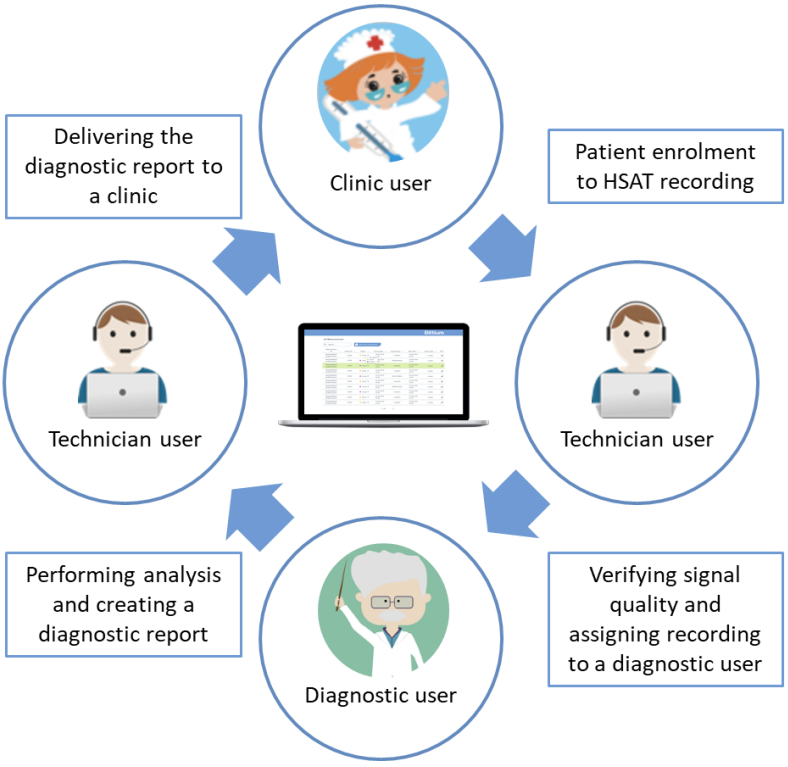


Figure 22 Bittium HSAT service workflow

Preparing Bittium HSAT recording

1 Preparing Respiro, pulse oximeter, sensors and carry case for a patient (cleaning, battery status check and instructions).
2 Creating Bittium HSAT recording in Bittium MedicalSuite Center.
3 Setting up Bittium Respiro recorder including selecting the used recording configuration using Bittium Respiro Device Manager software.

Performing Bittium HSAT recording

4 Attaching Respiro, pulse oximeter and sensors according to instructions and switching the devices on. The recording equipment is attached by the patient at home.
5 Verifying the device connectivity and sensor functionality using Respiro LED indicators.
6 In case of a scheduled recording, the recording starts automatically at the predefined time. Otherwise, the patient starts the recording manually by pressing the Respiro button twice when going to bed: first shortly, less than 3 seconds, to wake up the device and then a longer 8 seconds press to start the recording. Recording start is indicated by a short vibration. The pulse oximeter switches on automatically when a finger is put into the finger sensor.

   The recorded data is automatically stored to the internal memory of Respiro HSAT recorder.

   During a recording, the patient may make patient event markings on the recorded data by pressing the Respiro button less than 3 seconds e.g., to indicate visiting a toilet.

   Patient may fill a paper diary to write down sleep details about e.g., bedtime and perceived quality of sleep.

7 In case of a scheduled recording, a recording stops automatically at the predefined time. Otherwise, the patient stops the recording manually by pressing the Respiro button continuously about 3 seconds when waking up.

   After a recording is completed, a patient may detach the devices and sensors from the body and returns the equipment and possible diary markings to the clinic.

   Uploading and validating the recorded HSAT data on MedicalSuite service platform. If the recorded data is not valid for some reason, the recording can be repeated for example next night.

8 Discussing with a patient about the recording and entering possible missing patient diary markings to the recording in MedicalSuite Center. In case a patient has marked patient events manually by pressing Respiro button during the recording, the events and diary are synchronized during the discussion.
9 Attaching a scanned patient diary to other documents of the recording in MedicalSuite Center if needed.
10 Setting a recording “Ready for analysis” in MedicalSuite Center.
11 Assigning a recording to a diagnostic user (e.g., sleep specialist) or diagnostic group. Note that recording can also be assigned already before or during the recording period.

Processing Bittium HSAT recording

12 Analyzing the complete recorded data and creating a diagnostic report in Respiro Analyst.
13 Accepting the report in Respiro Analyst which causes recording to close, and the accepted report will be available in MedicalSuite Center.

14 Previewing the diagnostic report in MedicalSuite Center and approving the report to deliver it to the lower-level organization if needed.
15 Deleting the previous recording data from Respiro.

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

3.2 Preparing Bittium HSAT recording

Before performing Bittium HSAT recording, the recording equipment needs to be prepared carefully for a new recording. Bittium HSAT recording is created on Bittium MedicalSuite Center and Respiro is set up using Bittium Respiro Device Manager software.

3.2.1 Preparing recording equipment

The recording equipment needs to be prepared for HSAT recording based on the recording needs as instructed in chapter 2.1. The patient instructions related to the used recording configuration are reviewed with the patient and the recording equipment handed to a patient in a carry case, so that the patient can attach the recording equipment at home.

3.2.2 Creating recording on Bittium MedicalSuite Center

To create a Bittium HSAT recording on Bittium MedicalSuite Center, follow the steps 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 23). Select **Bittium HSAT**. Create recording page opens.

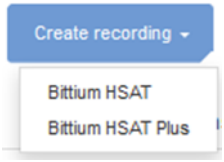


Figure 23 Create recording drop-down menu

2 Enter information to all the required fields (*) on the **Patient details** tab (Figure 24). If desired, other fields can be left unfilled.

NOTE Patient ID is for identifying the patient. If this field is left blank, the system will generate it. 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 Center.

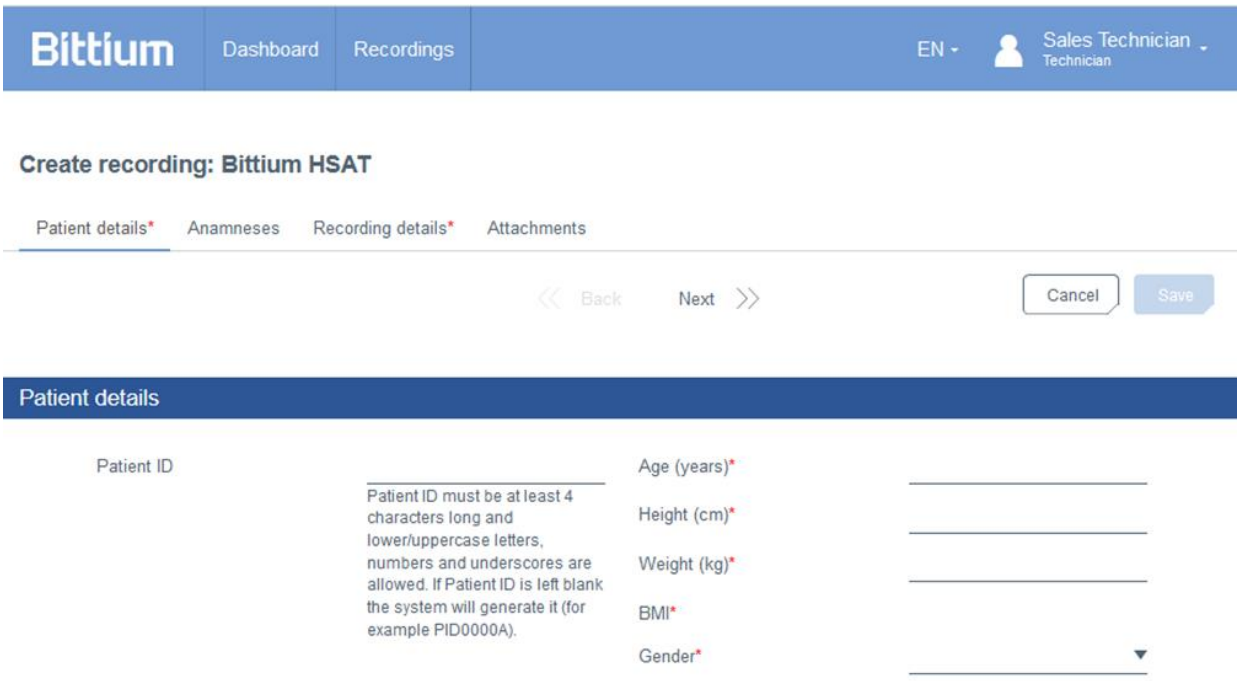


Figure 24 Create recording – Patient details tab

3 Click **Next** and enter patient anamnesis information on the **Anamneses** tab, if necessary (Figure 25 and Figure 26, optional step).

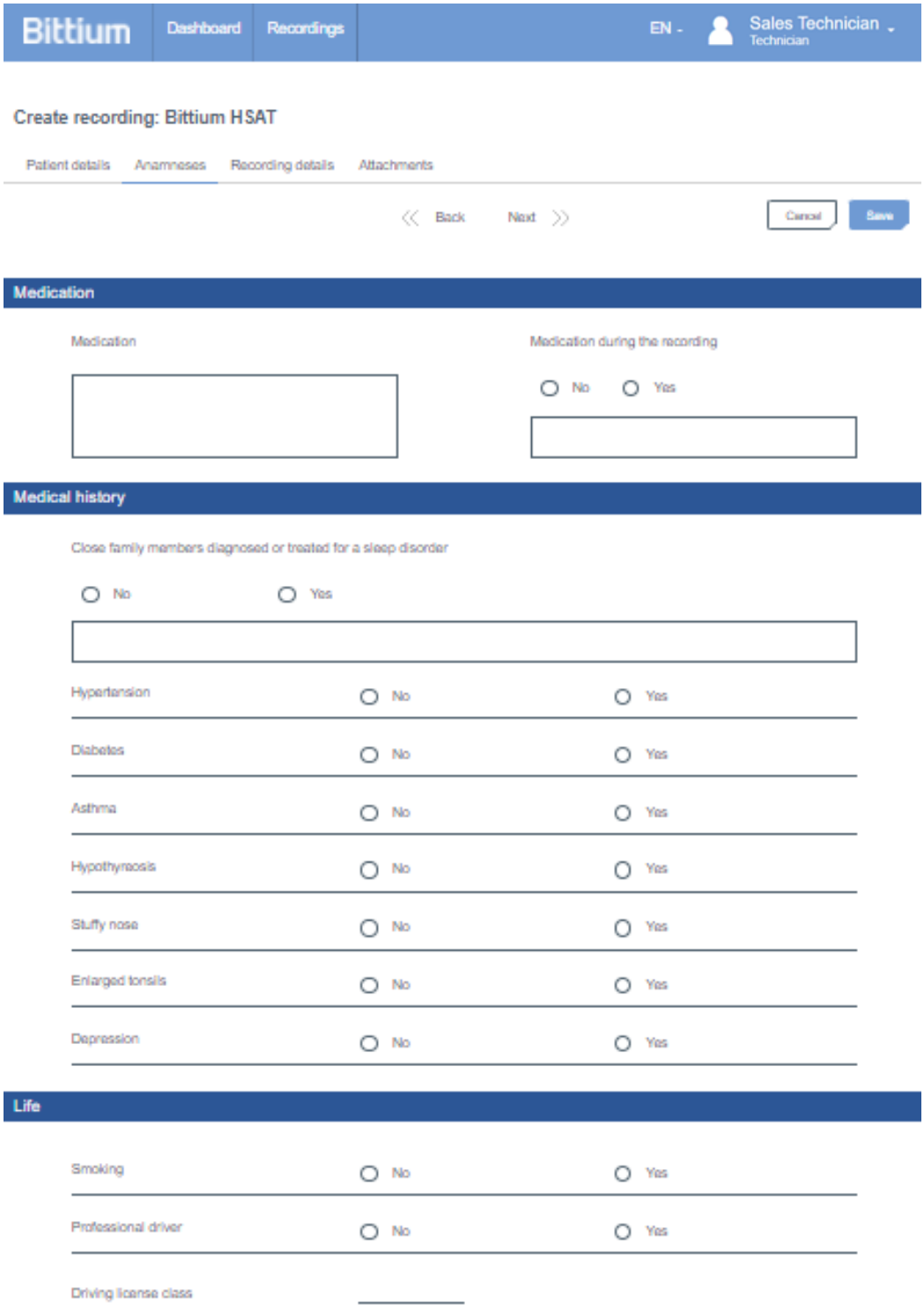


Figure 25 Create recording – Anamnesis tab (1/2)

Chance of dozing off or falling asleep in the following situations

Sitting and reading	○ Never	○ Slight	○ Moderate	○ High
Watching TV	○ Never	○ Slight	○ Moderate	○ High
Sitting, inactive in a public place (e.g. a theatre or a meeting)	○ Never	○ Slight	○ Moderate	○ High
As a passenger in a car for an hour without a break	○ Never	○ Slight	○ Moderate	○ High
Lying down to rest in the afternoon when circumstances permit	○ Never	○ Slight	○ Moderate	○ High
Sitting and talking to someone	○ Never	○ Slight	○ Moderate	○ High
Sitting quietly after a lunch without alcohol	○ Never	○ Slight	○ Moderate	○ High
In a car, while stopped for a few minutes in the traffic	○ Never	○ Slight	○ Moderate	○ High

Sleep history

Morning headache	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Dry mouth in the morning	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Daytime fatigue or snoozing	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Daytime napping	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Heartburn	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Loss of concentration	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Memory loss	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Cramping at night	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Difficulties falling asleep	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Breathing breaks while sleeping	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Pain during night	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Snoring or snorting during sleep	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Waking up during the night or restless sleep	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
A strong urge to move your feet or an uncomfortable sensation in your feet related to this urge during sleep	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
Urinary urgency during sleep	○ Never	○ Rarely	○ Sometimes	○ Often	○ Almost always
If yes, how many times per night?	○ Once	○ Twice	○ More often		
Average amount of sleep	_____ Hours				

Figure 26 Create recording - Anamnesis tab (2/2)

Click **Next** and enter recording details and device information on the **Recording details** tab (Figure 27). The required information includes:

a Organization that arranges the recording
b Requested report language (English)
c Reason for recording (optional)
d Recorder serial number (S/N), e.g., 0000528, can be found from the side of the recorder.

NOTE	Recorder serial number (S/N) is entered for device management purposes and to ensure the recording data is uploaded for the correct patient.

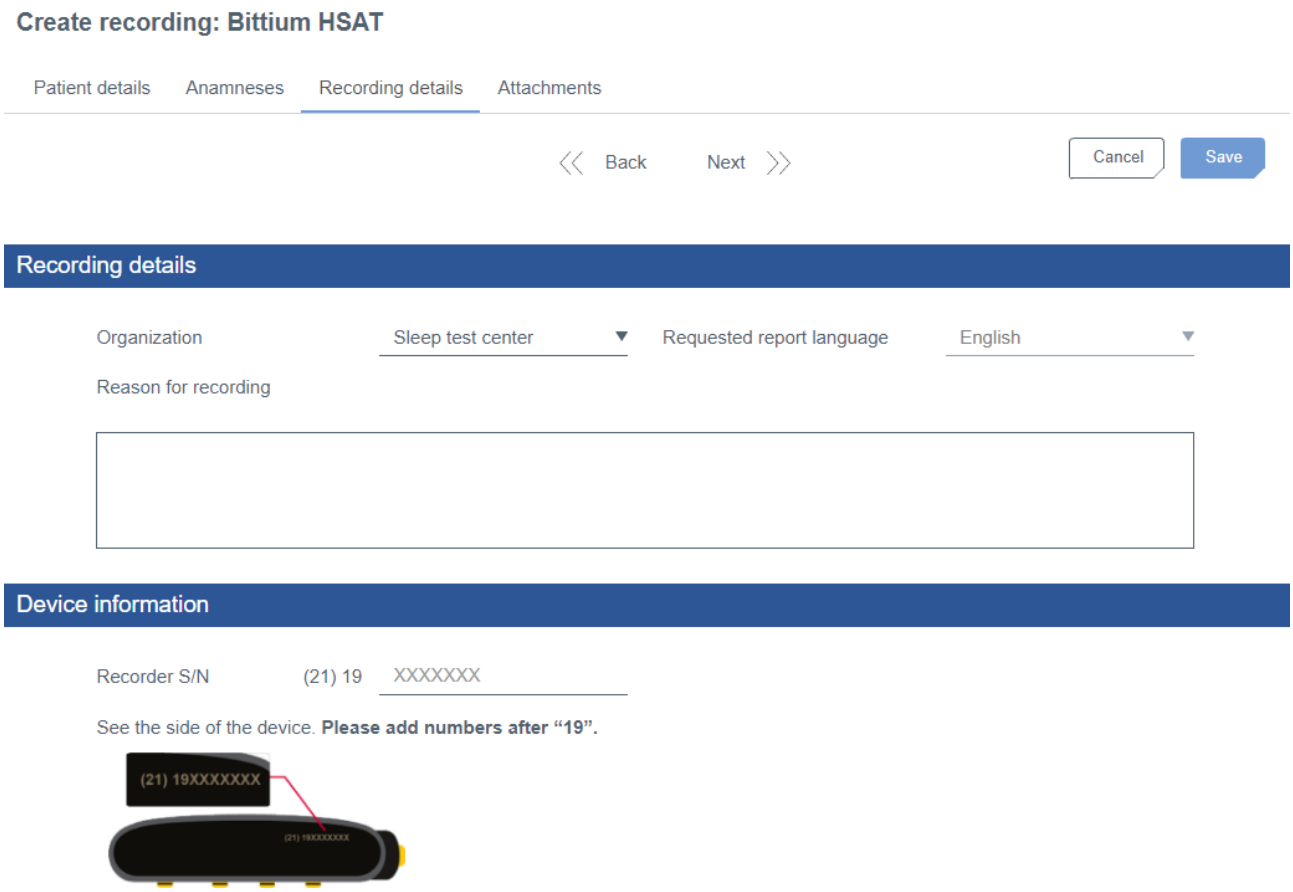


Figure 27 Create recording – Recording details tab

4 Click **Next** and attach the **recording data file** (if already available) and **other documents** (if necessary) on the **Attachments** tab (Figure 28, optional step).

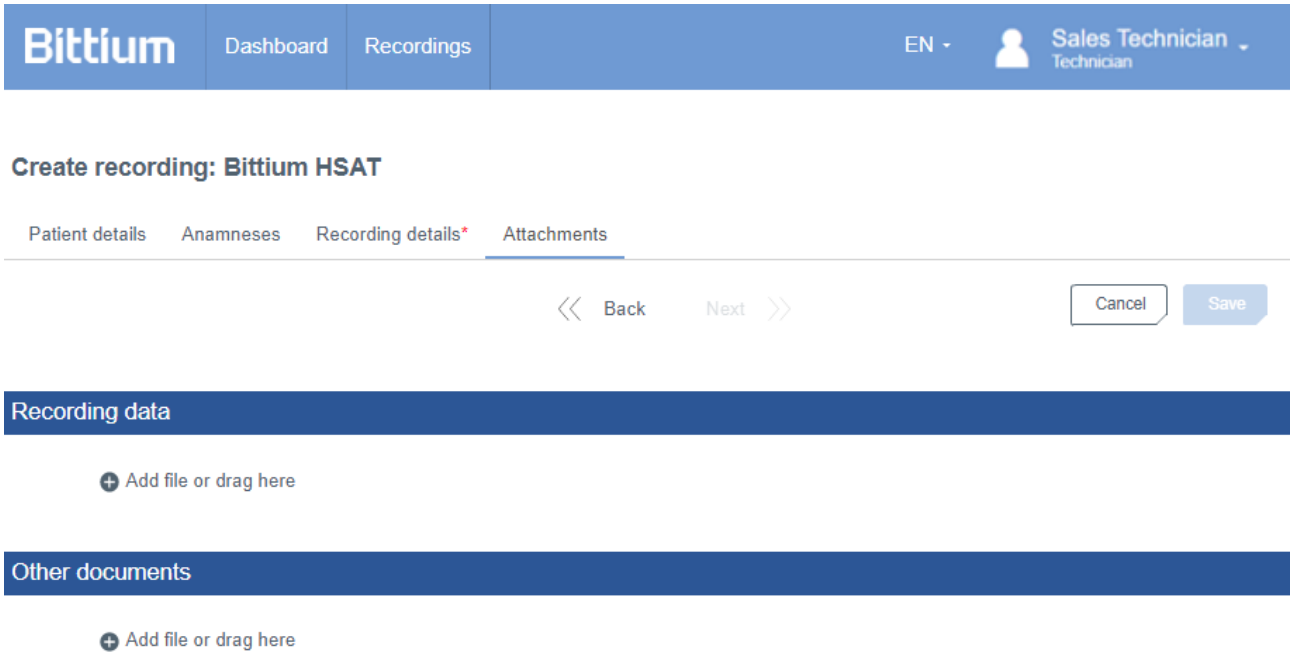


Figure 28 Create recording – Attachments tab

5 Click **Save** and a confirmation notification will open (Figure 29). Click **Create** to confirm the creation of a new recording.

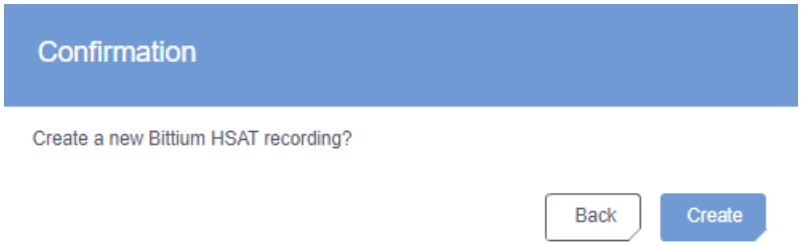


Figure 29 Create recording – Confirmation notification

NOTE If recording data file was not attached to the created Bittium HSAT recording at step 5, the recording status will be Active, and the recording will appear in the Active recordings card in Bittium MedicalSuite Center Dashboard view. This indicates that recording data can still be uploaded.

3.2.3 Setting up Respiro with Bittium Respiro Device Manager software

After creating HSAT recording on Bittium MedicalSuite Center, desired Respiro recorder settings need to be set up using Bittium Respiro Device Manager software (see also chapter 2.2).

To configure Respiro settings, follow the steps below:

1 Connect the Respiro's charging dock to a computer with the USB cable.
2 Set Respiro in the charging dock.
3 Start Respiro Device Manager (see details from chapter 2.2.2)

NOTE

If Bittium Respiro Device Manager folder is not placed on the computer, you can find the software files from Respiro recorder disk drive. Respiro will appear as a disk drive in Windows File Explorer when it is connected to a computer. The file to run the software is in RESPIRO/Respiro Device Manager folder. See details from chapter 2.2.2.

4 Wait for Respiro Device Manager to detect Respiro.
5 **Respiro Device Manager main view** opens with detected **Respiro name** and **serial number**. Configure the desired Respiro settings for the recording in Respiro Device Manager software main view (Figure 30):

   a **Change language** if needed by first selecting **About** in the main view and then Language. Available languages are Finnish and English.
   b Synchronize Respiro time with the computer time by setting **Synchronize device time** with PC time **ON**.
   c Select the desired **set up option** (configuration) you want to use for the HSAT recording.
   d Add the **pulse oximeter serial number** in **Bluetooth settings**
   a Verify that the pulse oximeter serial number corresponds to the oximeter used. Device serial number can be found from the back label of the device.
   e Set **Scheduled time** either **ON** or **OFF** depending on whether the recording is performed as scheduled or with manual start and stop. If scheduled time is set **ON**, select starting and ending times for the recording from the related drop-down lists.

NOTE

If Scheduled time is set ON, the recording starts and stops automatically at the predefined time. Otherwise, the patient starts and stops the recording manually by pressing Respiro recorder button.

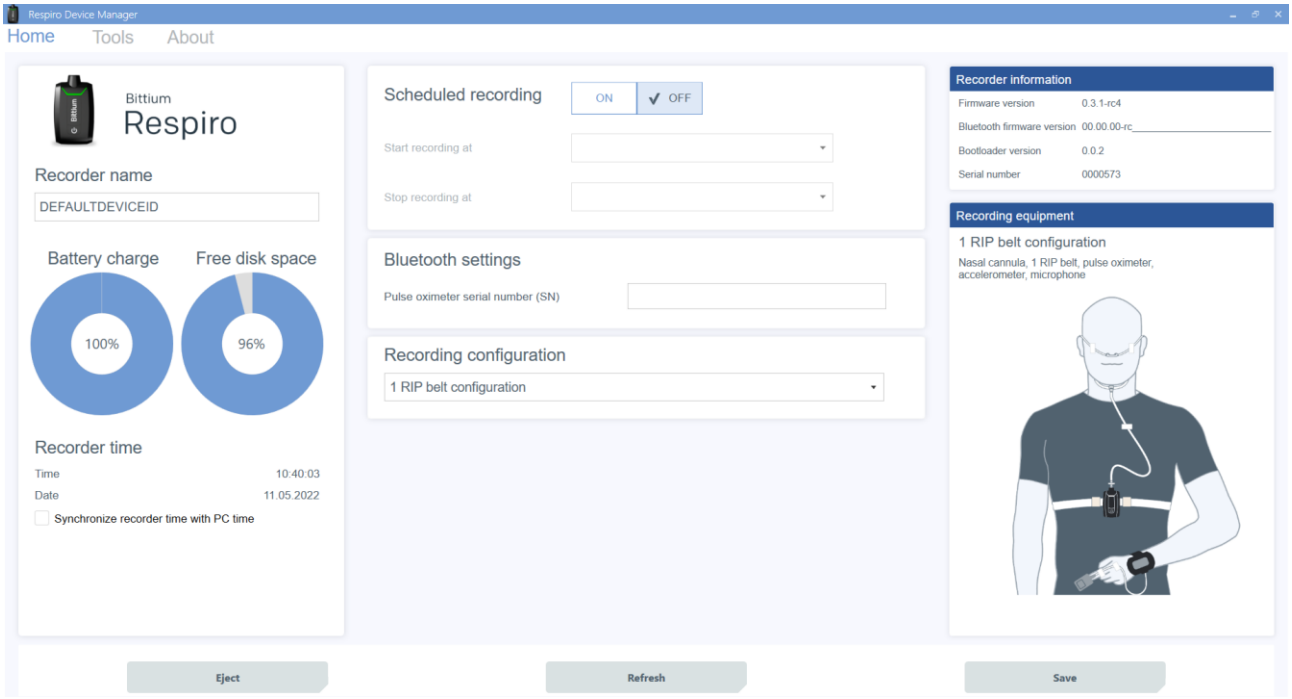


Figure 30 Bittium Respiro Device Manager - Main view

7 Click **Save** settings to set the selected settings to Respiro.
8 Click **Eject** to safely remove Respiro from the computer.

3.3 Performing Bittium HSAT recording

After preparing the recording, a Bittium HSAT recording is performed at patient's home, and finalized at a clinic. This stage consists of several separate phases such as attaching the recording equipment, starting a recording, running a recording, stopping a recording, completing a recording, uploading and validating the recording data, setting recording ready for analysis, and assigning a recording to a specific diagnostic user or diagnostic group. Detailed instructions for performing Bittium HSAT recording are described in the following chapters.

3.3.1 Attaching recording equipment

Before starting a recording, Respiro, pulse oximeter and sensors are attached onto a patient according to the instructions related to the recording configuration used. The recording equipment can be attached either already at the clinic or by the patient at home. When all sensors are attached, the devices are switched on and the device connectivity and sensor functionality is checked using Respiro LED indicators. See the recording configuration specific **Quick Guide** and **Respiro Operating Instructions** for more detailed information on attaching recording equipment, recording configurations and Respiro LED indicators.

3.3.2 Starting recording

Bittium HSAT recording can be performed as scheduled or with manual start and stop. The used operating mode is selected using **Bittium Respiro Device Manager** (see chapter 3.2.3 for more details).

3.3.2.1 Scheduled recording start

In HSAT service it is possible to set Respiro recorder to start and stop the recording at a predefined time in cases where the patient may not be able to start it. The function is activated in the main view of Bittium Respiro Device Manager. Respiro turns automatically on at the selected starting time and starts to record data from the sensors. Starting the recording is indicated by a short vibration in Respiro.

It is not needed to schedule the pulse oximeter since it turns on and starts the recording automatically after putting the finger into the sensor. Alternatively, the pulse oximeter can be turned on by pressing its power button with a fingernail. Also note, that a pulse oximeter turns off automatically after removing the finger from the sensor.

After the recording has started, the patient can check the device connectivity and sensor functionality using Respiro recorder LED indicators. The correct operation of a pulse oximeter can be verified from the pulse oximeter display. See **Respiro Operating Instructions** for more details.

3.3.2.2 Manual recording start

When Bittium HSAT recording is performed with manual start and stop, the patient starts a recording manually by pressing the Respiro button (Figure 31) first shortly, **less than 3 seconds**, to wake up the device and then about **8 seconds** press to start a recording. Starting a recording is indicated by a short vibration. A pulse oximeter starts automatically when a finger is set into the sensor. Also note, that a pulse oximeter turns off automatically after removing the finger from the sensor. The correct operation of a pulse oximeter is checked from the pulse oximeter display.

Figure 31 Respiro recorder button

After the recording has started, a patient (or nurse) checks the device connectivity and sensor functionality using Respiro LED indicators. The correct operation of a pulse oximeter is checked from the pulse oximeter display. See **Respiro Operating Instructions** for more details.

After the start of a recording, it is also recommended that a patient writes down bedtime according to the given instructions.

3.3.3 Running recording

When Bittium HSAT recording is ongoing, the recording data is automatically stored on Respiro. While awake during a recording, the patient may make patient event markings on the recorded data by pressing the Respiro button shortly (less than 3 seconds) to indicate going to bathroom, drinking or eating, lying on bed, reading a book or other reason. This is indicated by blinking blue LED.

3.3.4 Stopping recording

Bittium HSAT recording can be set to stop automatically with scheduling time or with manual stop. The used operating mode is selected using **Bittium Respiro Device Manager** when setting up Respiro for a recording (see chapter 3.2.3 for more details).

3.3.4.1 Scheduled recording stop

A scheduled recording stops automatically at the predefined time. Respiro stops recording and turns off automatically at the scheduled ending time, whereas a pulse oximeter stops recording and turns off automatically when the finger is removed from the sensor. Stopping of Bittium Respiro recording is indicated by vibration of three times and with blue LED lights (lit in blue one by one from left to right). Note that the blue (and stabile) Respiro LEDs are lit for 5 minutes after stopping (Figure 32), but the recorder can be detached from the body and packed to the carry case.

3.3.4.2 Manual recording stop

When Bittium HSAT recording is performed with manual start and stop, the patient stops the recording manually by pressing the Respiro button continuously about **3 seconds** when waking up. Stopping the recording is indicated by vibration of three times and with blue LED lights (lit in blue one by one from left to right. (Figure 32). Note that the blue LEDs of Respiro are lit continuously for 5 minutes after stopping, but the device can be detached from the body and packed to the carry case. A pulse oximeter turns off automatically when the finger is removed from the sensor.

Figure 32 Respiro recorder button

3.3.5 Completing recording

Just after waking up in the morning and stopping the HSAT recording, it is recommended that a patient writes down the sleep details (see below) about according to the given instructions.

For proper HSAT data analysis, answering to the following **relevant questions** available for a recording in MedicalSuite Center is needed:

1. In your estimation, when did you fall asleep?
2. What time did you wake up in the morning?

Additional questions available for a recording in MedicalSuite Center include:

3. When did you go to bed?
4. In your estimation, how many hours did you sleep?
5. How did you sleep (bad, ok, good)?
6. Did you get out of the bed during the recording (yes, no)?
7. How did you sleep compared to usual (worse, normal, better)?

In addition, patient can also write down the **details of events** (time, duration, and reason for awakenings) occurred during the recording period. These patient-marked events can later be added to the recording data in MedicalSuite Center (Figure 33).

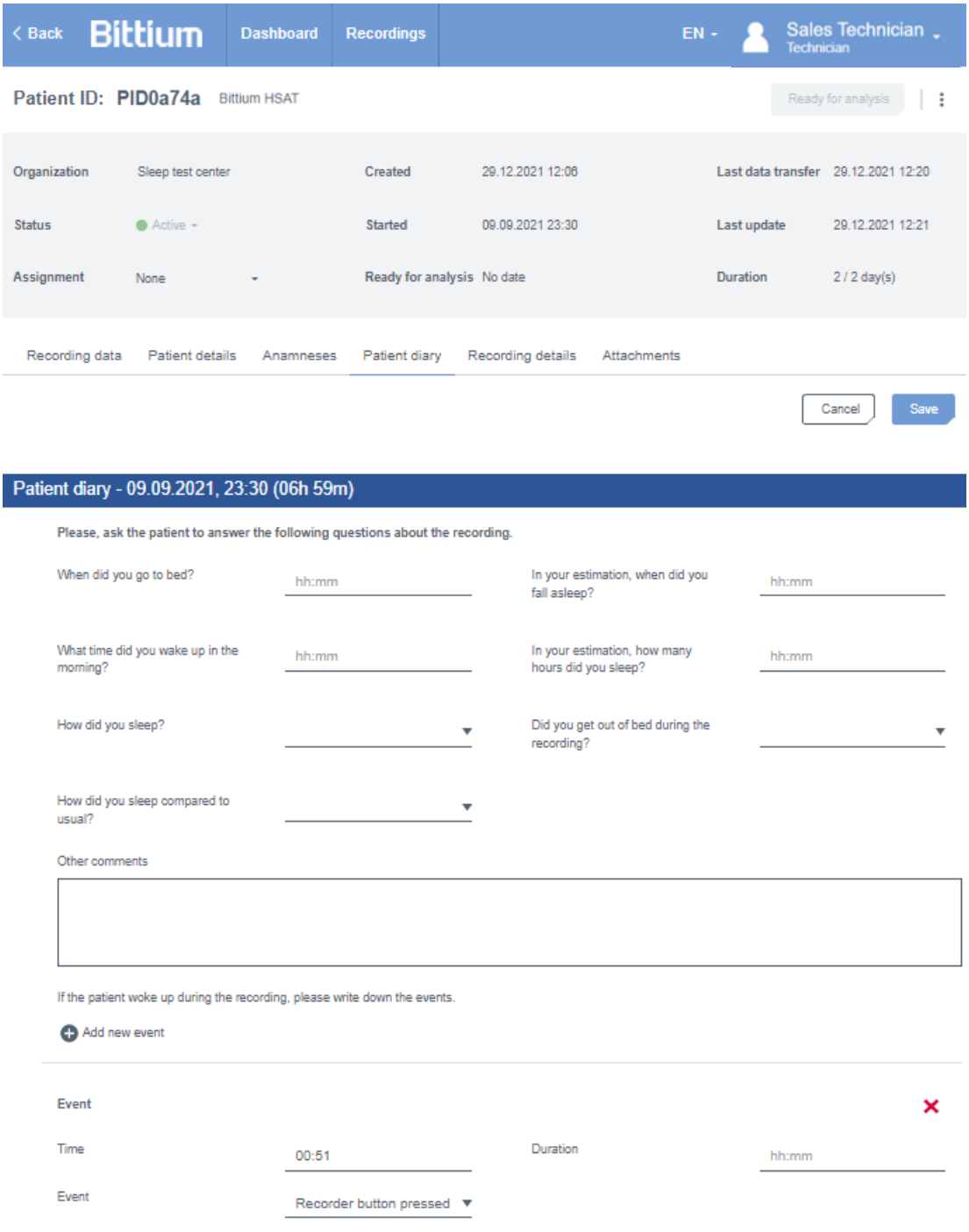


Figure 33 Adding patient marked events in MedicalSuite Center

When a recording has been stopped, a patient may detach the devices and sensors from the body. Finally, the patient returns the recording equipment and possible diary markings as instructed.

3.3.6 Uploading and validating recording data

When the recording equipment and other documents are returned to a clinic, the recording data needs to be uploaded and validated on Bittium MedicalSuite service platform (MedicalSuite Center and Respiro Analyst). This helps a clinic to evaluate whether data can be used for further analysis, or if a new recording is needed. After validation also other documents such as a scanned patient diary can be uploaded to a recording to help in analysis.

3.3.6.1 Uploading and validating recording data file in Bittium MedicalSuite Center

After the recording equipment is returned to a clinic, the recording data file(s) is manually uploaded from Respiro to the **Active** recording and automatically validated in **Bittium MedicalSuite Center**. Respiro is put in the charging dock that is connected to a computer, and the upload process is carried out in Bittium MedicalSuite Center.

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 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 34). After adding files, they start to be uploaded (Figure 35).

Figure 34 Add file icon on "Recording data" tab

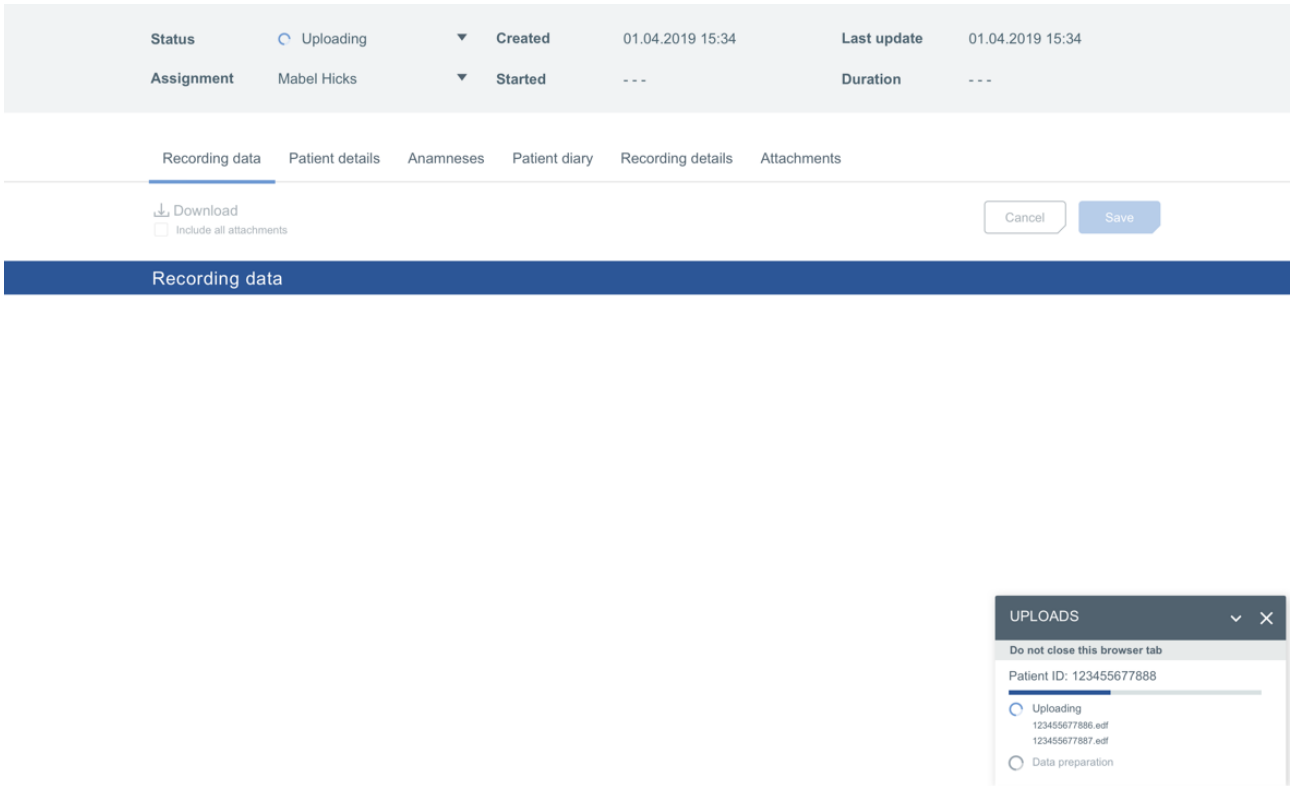


Figure 35 File upload ongoing in Bittium HSAT recording

After the recording data has been uploaded to MedicalSuite Center, the data file(s) are automatically validated on MedicalSuite **Center**. When the file(s) is validated, the validation spinner change to **remove icons**. If the file(s) is found not to be valid, an error text shows which files are not valid and for what reason (see below) will be displayed. You can remove the file(s) which is not valid. You can also add more files to be uploaded if needed. This will start a re-validation of the given files. Selected file(s) are saved to MedicalSuite Center when you click **Save**. (Figure 36)

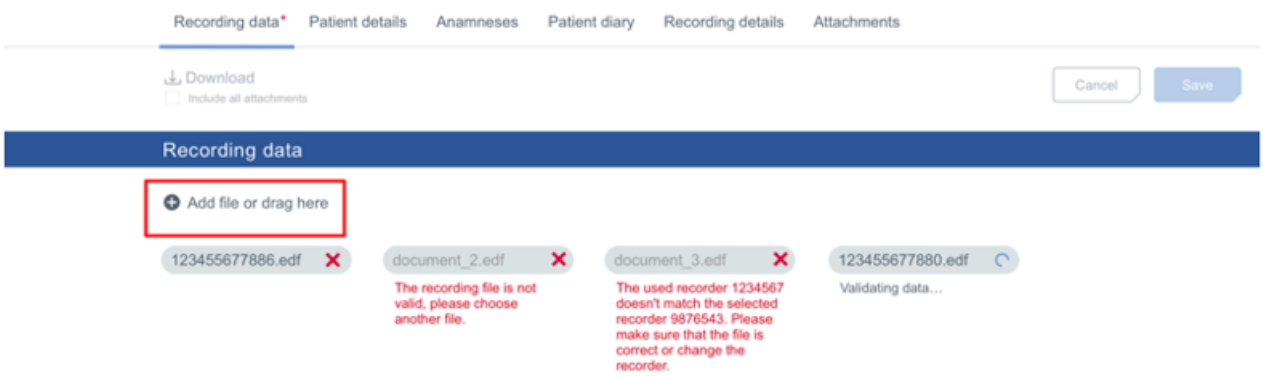


Figure 36 Data file validation in Bittium HSAT recording

NOTE	One EDF-file means one night. Usually there is only one EDF-file in one recording.

The recording data file can be **not valid** for following reasons:

a. The file size and duration can be insufficient.
b. The used recorder does not match with the selected recorder.
c. The file is not from Respiro recorder.

An upload widget will open to indicate the upload progress. Do not close or refresh the browser tab while the upload process is running. While the upload is running, recording status is **Active** (Figure 37*)*. Depending on the size of the uploaded recording data, the upload may take a while. Once the upload is done and the data is processed/analyzed, the recording status will change from **Active** to **Preparing**.

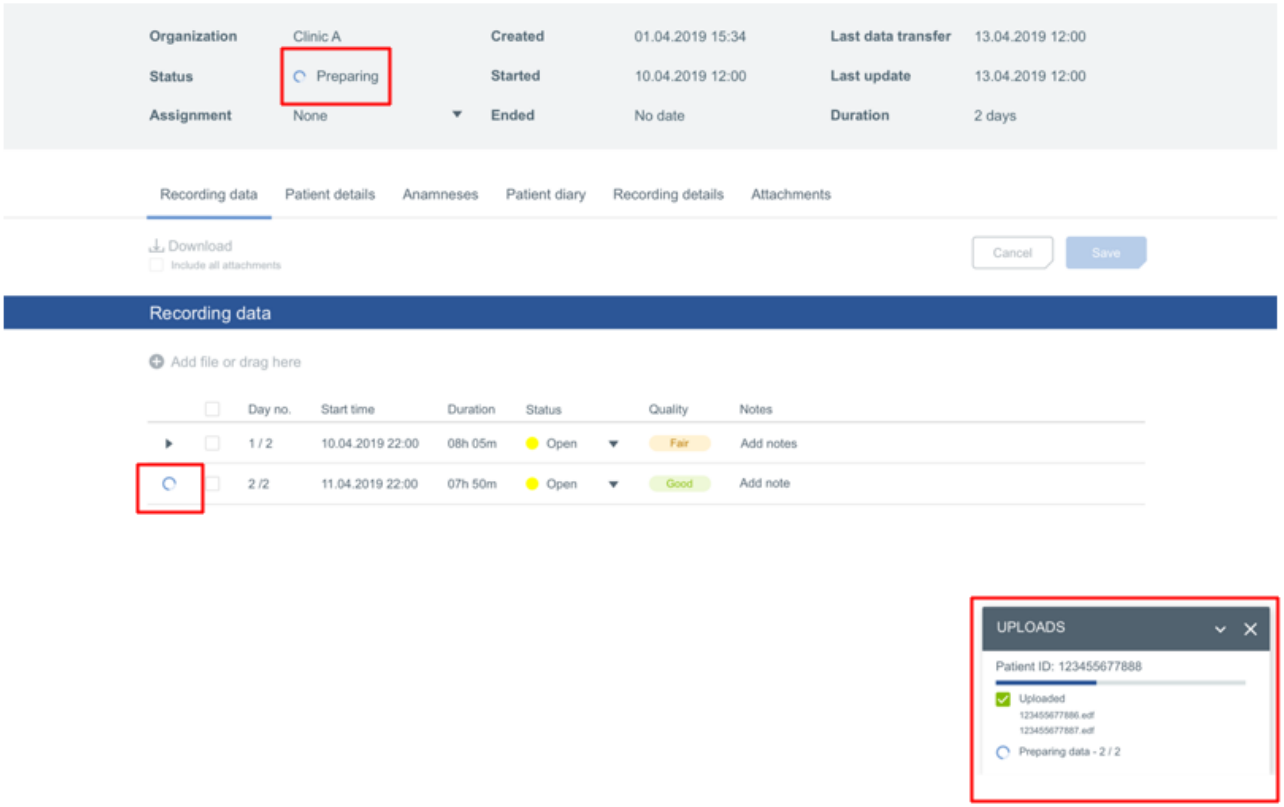


Figure 37 Recording in Preparing state during data upload in Single recording view

3.3.6.2 Validating recording data quality on Bittium MedicalSuite service platform

When the recording data file(s) is validated and saved on Bittium MedicalSuite Center, the recording data is transferred to **Bittium Respiro Analyst** for automatic data quality validation. After data quality validation the quality information is sent back to **MedicalSuite Center,** and a clinic can check from the **Single recording view** if the recording data quality is **good**, **fair**, or **poor**. This helps a clinic to evaluate whether data can be used for further analysis, or if a new recording is needed. (Figure 38)

NOTE The recording data quality is automatically validated in Respiro Analyst after data upload.

NOTE Recording data can be analysable if data quality is good or fair. A doctor makes a final decision if data can be analysed (fair data quality). If the recorded data is not valid for some reason, the recording can be repeated for example next night.

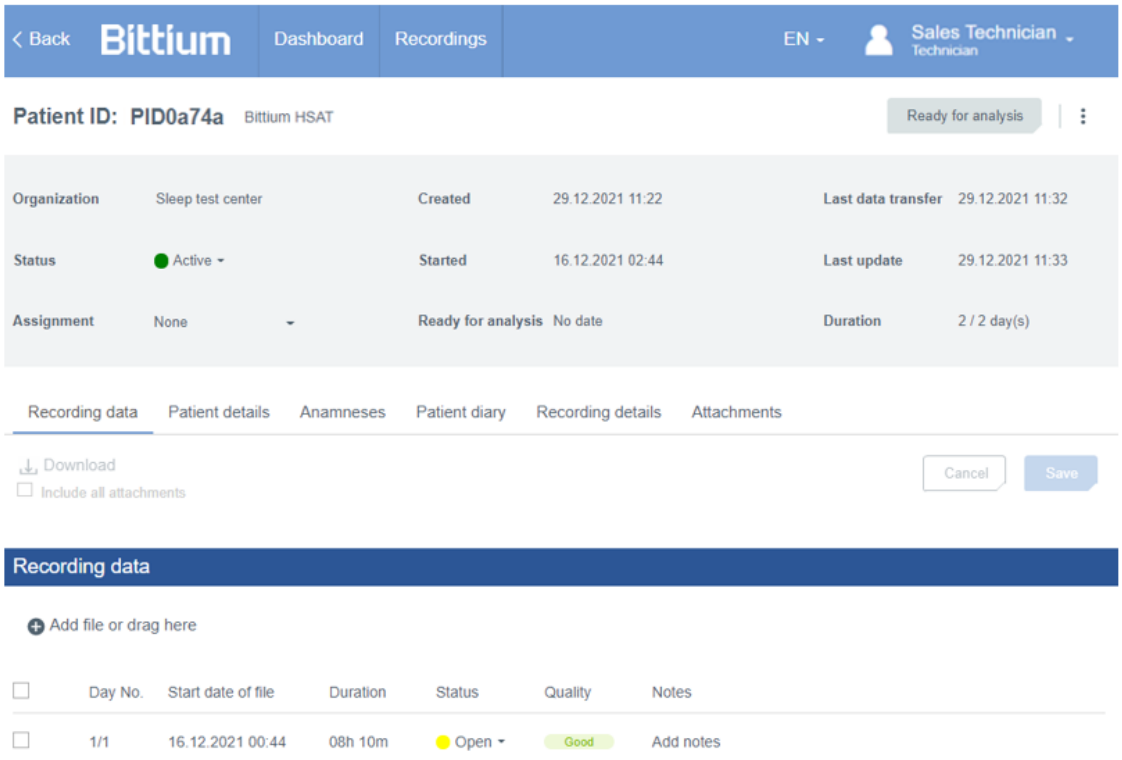


Figure 38 Recording data quality in Single recording view

Following factors result in the recording data quality to be evaluated as **good**:

- Length of the recording is **> 5 hours**
- There is **at least 4 hours** technically adequate signal in the important channels:
    - Blood oxygen saturation (SpO2) and pressure flow OR
    - Blood oxygen saturation (SpO2) and RIP thorax and RIP abdomen

Following factors result in the recording data quality to be evaluated as **fair**:

- Length of the recording is **< 5 hours**
- There is **less than 4 hours** technically adequate signal in the important channels:
    - Blood oxygen saturation (SpO2) and pressure flow OR
    - Blood oxygen saturation (SpO2) and RIP thorax and RIP abdomen

Following factors result in the recording data quality to be evaluated as **poor**:

- Length of the recording is **< 4 hours**
- There is **less than 4 hours** technically adequate signal in the important channels:
    - Blood oxygen saturation (SpO2) and pressure flow AND
    - Blood oxygen saturation (SpO2) and RIP thorax and RIP abdomen

NOTE The signal in one channel does not need to be technically adequate continuously, since the technically adequate signal can consist data of separate channels (e.g., pressure flow and RIP)

After the recording data has been validated, the **recording data status** informs whether the data can be used in further analysis. Select **Unusable** and write down a reason(s) if a recording is Unusable. If the recording data is selected as unusable, it cannot be used for final data analysis and a new recording needs to be taken. If the data usability is not clear, the data can be assigned to diagnostic user for checking and then the status changes automatically from **Open** to **Pending** except for the status has been changed to **Done** when all stages have been done. (Figure 39, Figure 40)

NOTE Unusable status can also be set automatically by the system if major error(s) occurred during data validation and in that case unusable status cannot be changed by the user.

NOTE

At the discretion of the user, recording data that has not been fully transferred and validated may be used. This allows for the analysis of records that, for some technical reason, are not complete but still contain enough information for successful analysis.

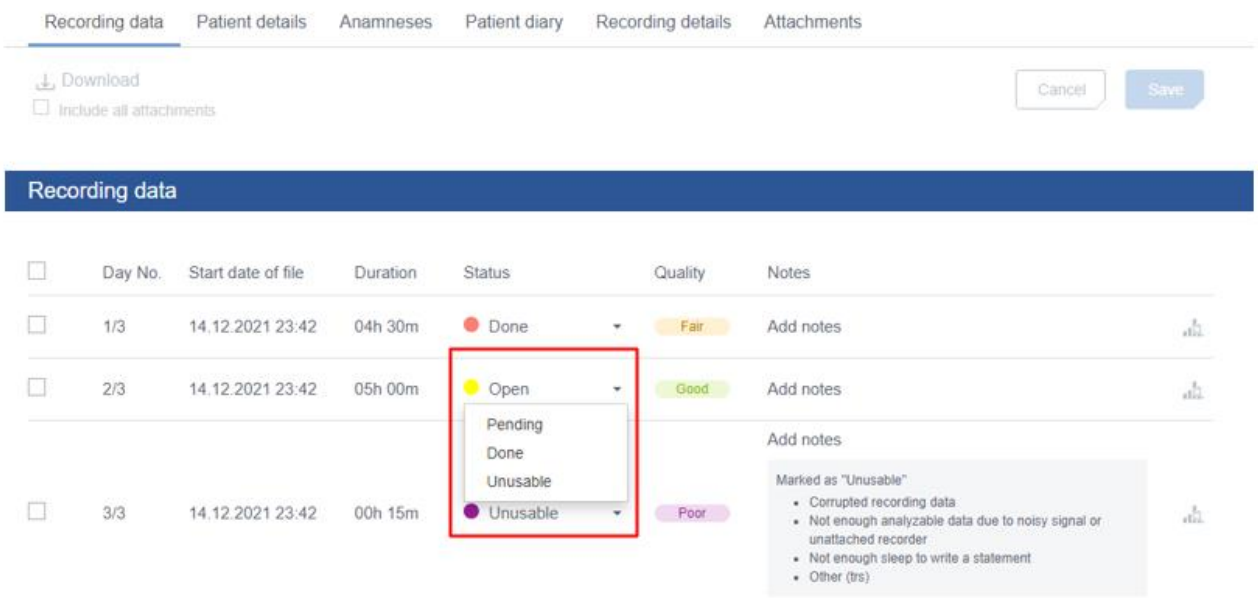


Figure 39 Selecting recording data status

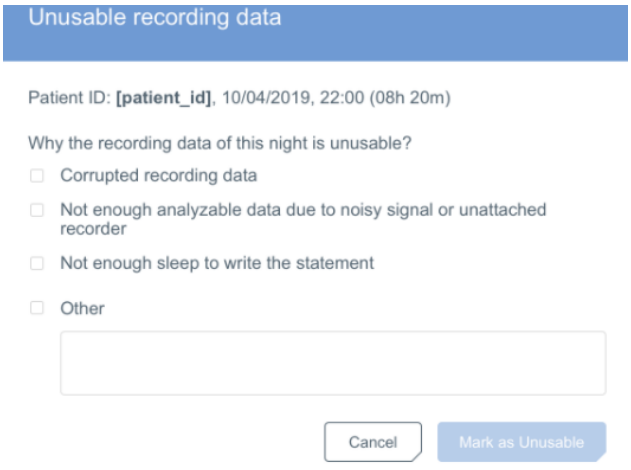


Figure 40 Selecting reason for unusable recording data

When the complete recording data has been uploaded and validated successfully, the Bittium HSAT recording is **ended** (set “Ready for analysis”) to indicate that final analysis can be performed for the recording (see chapter 3.3.7)

3.3.6.3 Uploading other documents to MedicalSuite Center

A scanned patient diary or additional patient background information can be uploaded as other documents to Bittium HSAT recording. For example, patients are commonly asked to mark down the awakenings and other events occurring during a recording which can be important for proper analysis of the recording data. Such documents can be attached to a recording on Bittium MedicalSuite Center to make them available for the diagnostic user when the recording data is analyzed.

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

1 Open the recording either from the **Active recordings** card in the Dashboard or the Recordings view in 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 41)

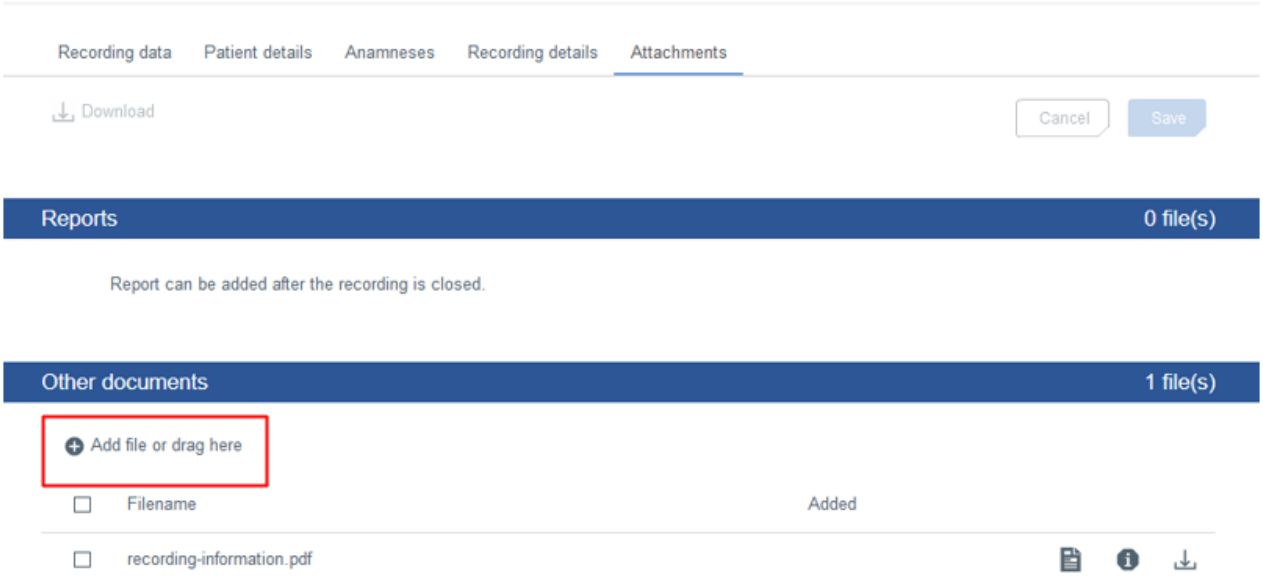


Figure 41 Add file icon on "Attachments" tab

*The uploaded document will appear in the Other documents section on the **Attachments** tab (*

Figure 42).

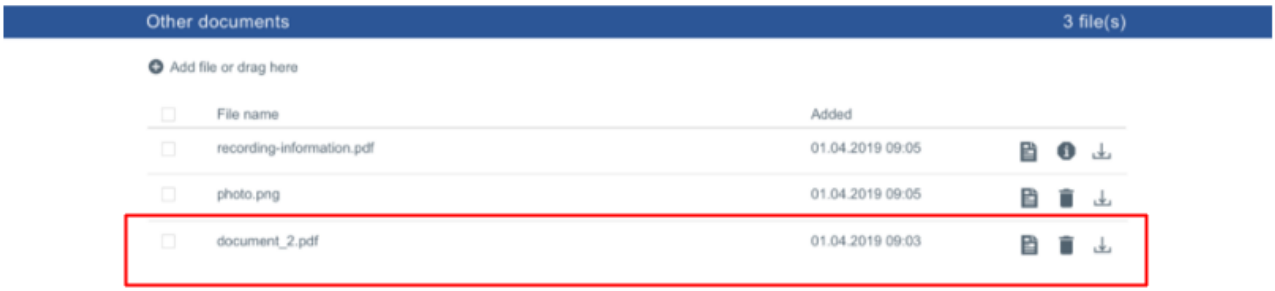


Figure 42 Uploaded document on "Attachments" tab

3.3.7 Setting recording ready for analysis (ending)

When the complete recording data has been uploaded and validated successfully, the Bittium HSAT recording is **ended** to indicate that the final analysis can be performed for the recording.

NOTE Bittium HSAT recording must have a recording data uploaded as described in chapter 3.3.63.4.1 before it can be ended.

NOTE In Bittium HSAT recording Respiro recorder is released automatically after setting a recording "Ready for analysis" so that the recorder can be used in other recordings.

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

1 Open the recording e.g., from the **Active recordings** card in the Dashboard or the Recordings view in the Bittium MedicalSuite Center by clicking on the recording.
2 Click **Ready for analysis** button on the single recording top bar (Figure 43). The same action can also be made by changing the recording status from **Active** to **Ended** either on the single recording top bar (Figure 43), or directly on the Recordings view (Figure 44).

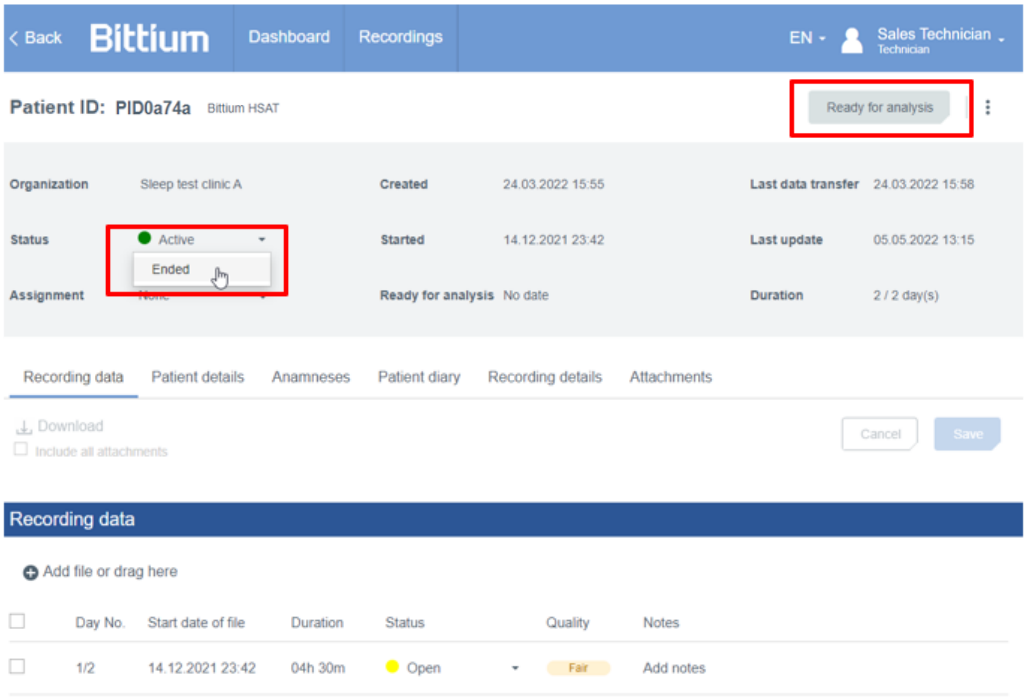


Figure 43 Setting recording "Ready for analysis" on the single recording top bar

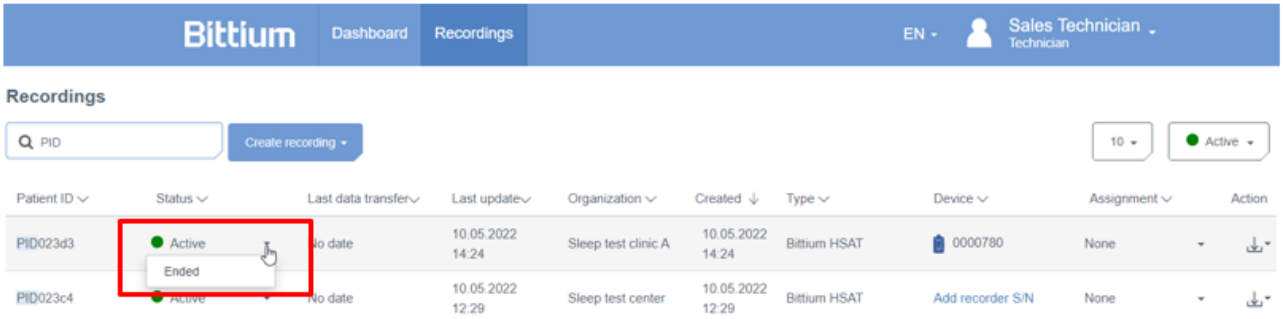


Figure 44 Changing recording status to "Ended" in Recordings view

3 Confirm the ending by clicking **Ready for analysis** (Figure 45).

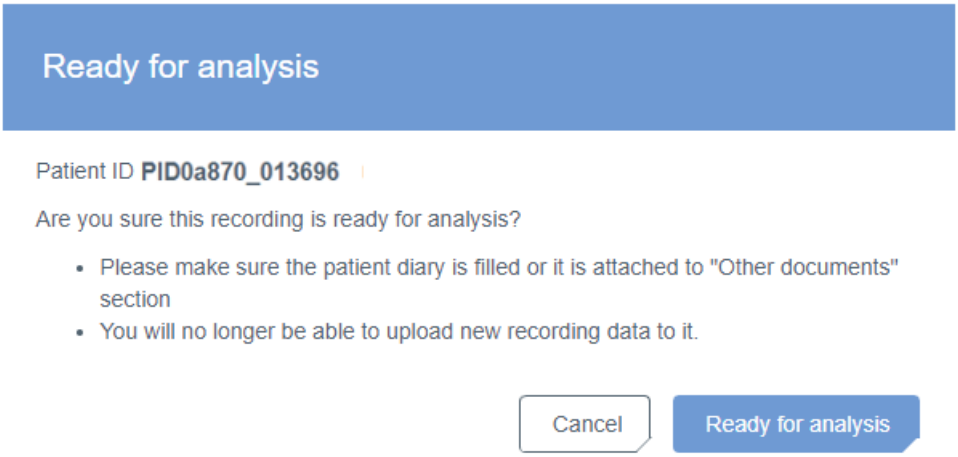


Figure 45 Confirming ending of a recording

The complete recording data is now available on Bittium MedicalSuite service platform for detailed analysis, and the recording appears in **Diagnostic report needed** dashboard card (Figure 46). Once the recording is assigned to a diagnostic user or diagnostic group (see chapter 3.3.8), the associated user(s) can analyze the recording in **Bittium Respiro Analyst**. The complete recording data gets automatically transferred to the related Bittium Respiro Analyst for further analysis. The complete data can also be manually downloaded from Bittium MedicalSuite service platform in EDF+ format (see chapter 4.2.1).

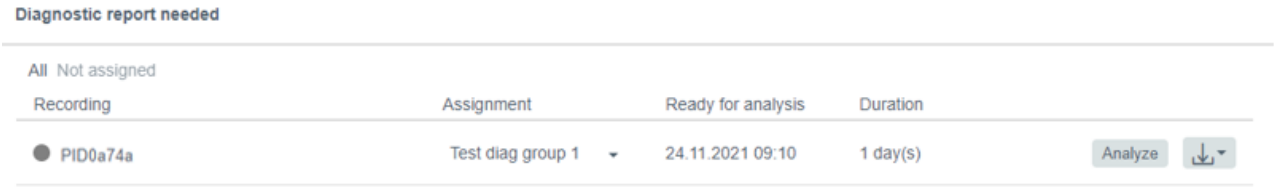


Figure 46 "Diagnostic report needed" dashboard card

3.3.8 Assigning recording to diagnostic user or diagnostic group

For final analysis purposes a recording is assigned either to a specific diagnostic user or diagnostic group responsible for the analysis of the patient recording. An assignment can be made before, during or after a recording period.

When a recording is assigned, the associated diagnostic user or members of the diagnostic group can analyze the recording in Bittium Respiro Analyst analysis software. Primarily, 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 47).

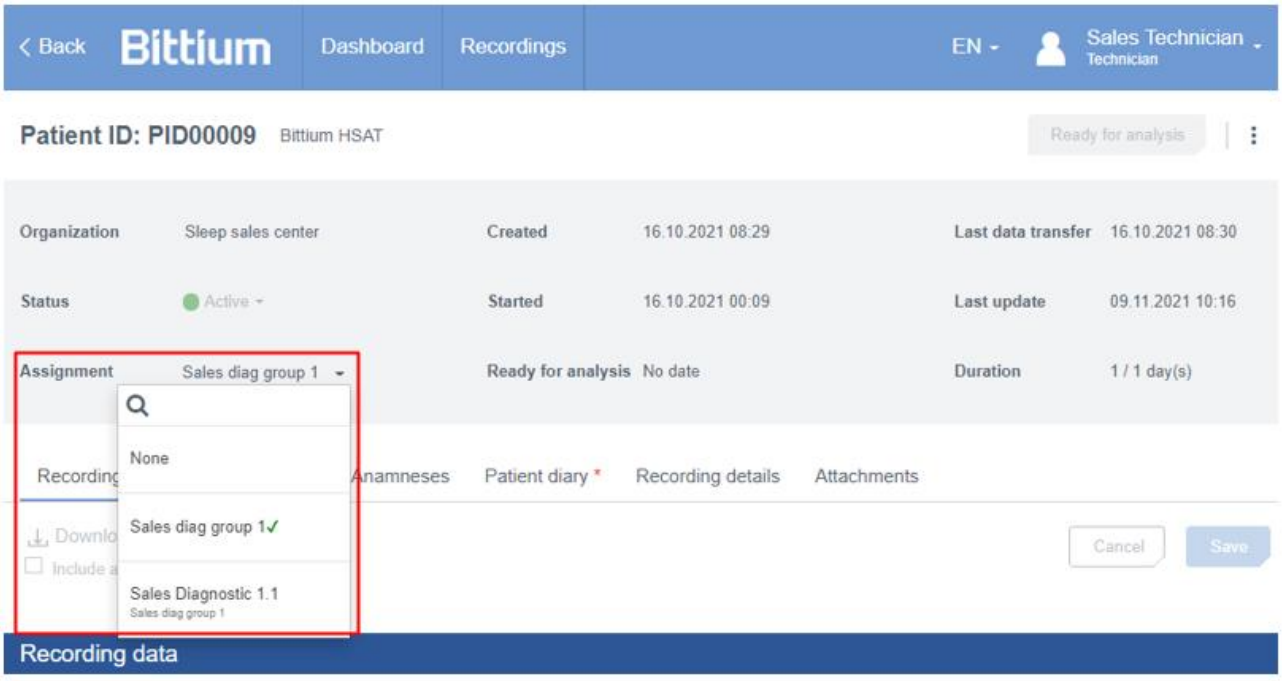


Figure 47 Assigning the recording

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 the 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 in such a way that a diagnostic user can only change the assignment inside the diagnostic group or, alternatively, remove the whole assignment from the recording.

3.4 Processing Bittium HSAT recording

After stopping the recording and returning the recording equipment and a possible diary to a clinic or hospital the HSAT recording data needs processing. This stage consists of several separate phases such as analysing the recording data, closing and approving the recording, and rejecting and/or deleting the recording data. Detailed instructions for performing these phases are described in the following chapters.

3.4.1 Analyzing recording data in Bittium Respiro Analyst and creating a diagnostic report

Final analysis of the acquired HSAT data is performed by a specific diagnostic user or a member of the diagnostic group to whom the recording is assigned. Analysis of HSAT events is performed using **Bittium Respiro Analyst**. When a recording is set **Ready for analysis**, the recording data is in Bittium Respiro Analyst analysis software for the associated diagnostic user or members of the diagnostic group.

After the recording data is analyzed, a diagnostic report including the statement notes is created and finally accepted in Bittium Respiro Analyst analysis software to be attached to the recording on Bittium MedicalSuite Center.

NOTE This feature is available only for technician and diagnostic users who have access to Bittium Respiro Analyst.

To perform final analysis of a recording and to create a diagnostic report in Bittium Respiro Analyst, follow the steps below:

1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard

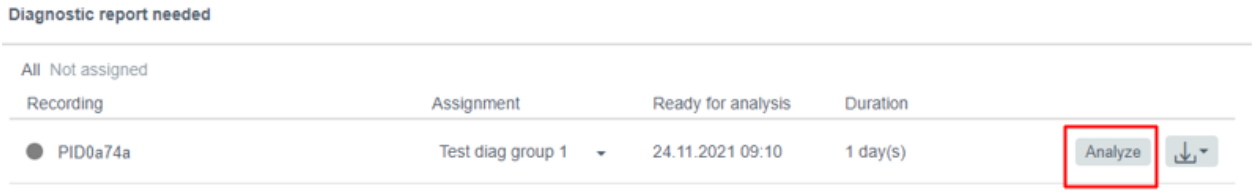


Figure 48 Analyze button on "Diagnostic report needed" dashboard card

2 Open a recording in Bittium Respiro Analyst by clicking **Analyze** (Figure 48). If you need to go back to MedicalSuite Center, use **Back** button in Bittium Respiro Analyst (Figure 49).

NOTE If automatic analysis shows that recording data cannot be analyzed due to e.g., errors, the analysis results are not shown to the user.

3 Review the recording summary (patient, summary, respiratory events, SpO2, snoring, position, cardiac events and pulse, patient diary, anamnesis and recording details) (Figure 49).

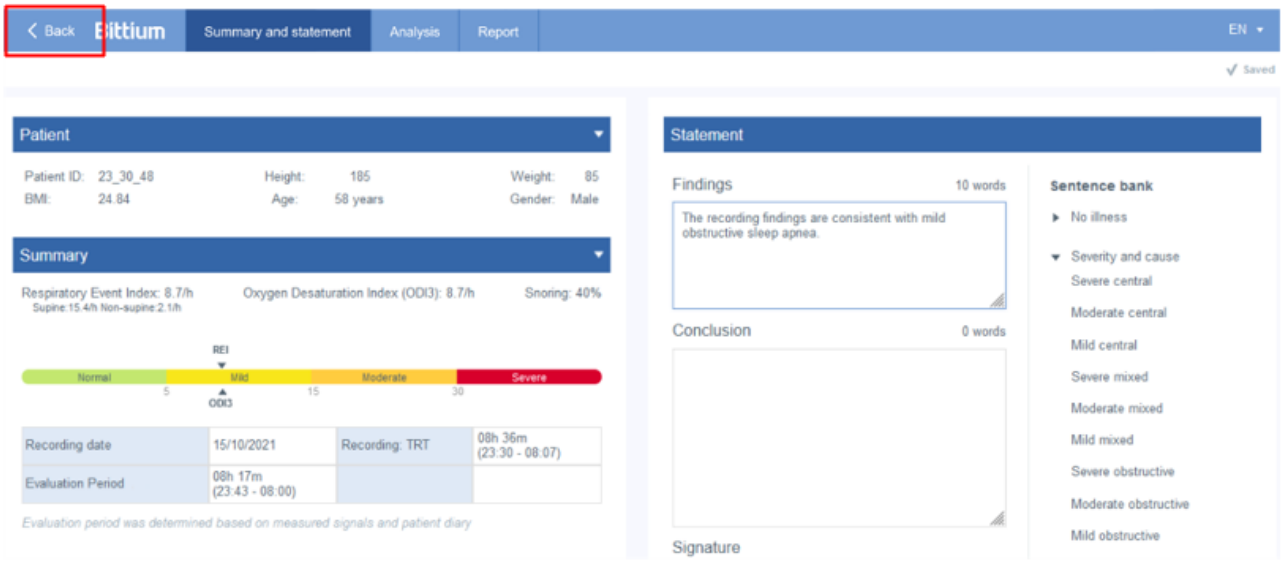


Figure 49 Reviewing summary and writing statement in Bittium Respiro Analyst

4 Analyze the recording data for HSAT events on the Analysis tab in Bittium Respiro Analyst (Figure 50).

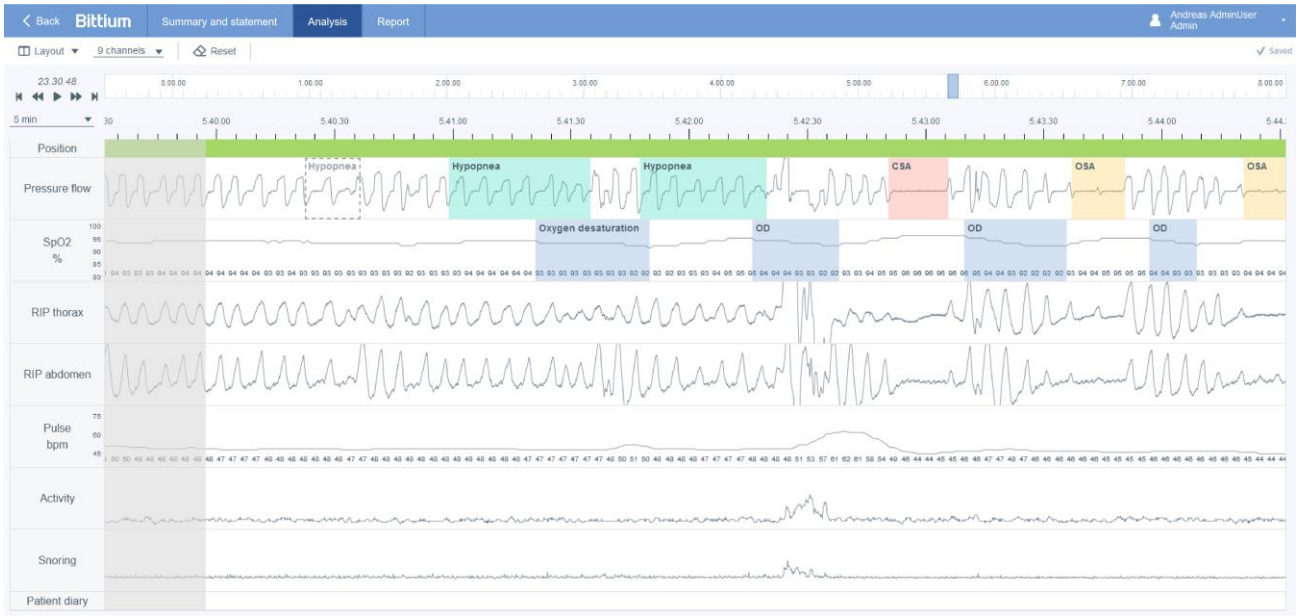


Figure 50 Analyzing HSAT recording on the Analysis tab in Bittium Respiro Analyst

5 Write a statement including findings, conclusions and signature on the Summary and statement tab (Figure 49).

More detailed instructions for the use of Bittium Respiro Analyst can be found on a separate Bittium Respiro Analyst User Guide.

3.4.2 Closing recording and attaching diagnostic report

Closing HSAT recording means that a diagnostic report is shown on the diagnostic user's Dashboard if it has been attached to a recording. A recording can be closed **automatically** or **manually** as well as attaching a diagnostic report.

3.4.2.1 Automatic closing and attaching diagnostic report

Bittium HSAT recording is closed automatically when final analysis of a recording is performed, and a diagnostic report accepted. If a recording is assigned to a diagnostic user or diagnostic group, the recording appears on the diagnostic user's Dashboard. Accepting a diagnostic report in **Bittium Respiro Analyst** attaches the report to the recording and closes it.

NOTE	This feature is available only for technician and diagnostic users who have access to Bittium Respiro Analyst.

To close a recording automatically by accepting a diagnostic report, follow the steps below:

1 Find the recording from Bittium MedicalSuite Center e.g., from the **Diagnostic report needed** card on the Dashboard

2 Open a recording in Bittium Respiro Analyst by clicking **Analyze** (Figure 51). If you need to go back to MedicalSuite Center, use **Back** button in Bittium Respiro Analyst (Figure 49)

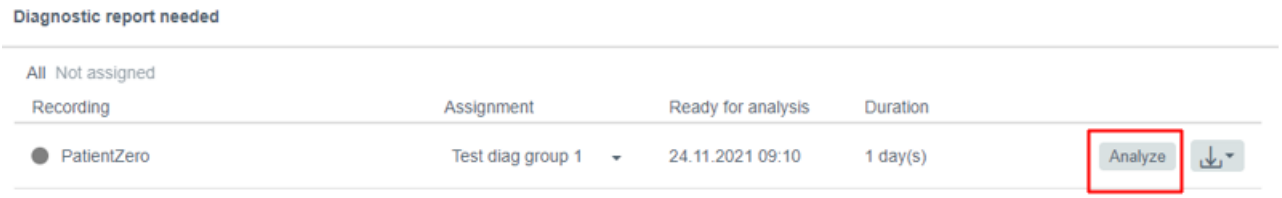


Figure 51 Analyze button on "Diagnostic report needed" dashboard card

3 Click **Accept** report in Bittium Respiro Analyst to attach the already created diagnostic report to the recording on MedicalSuite Center (Figure 52).

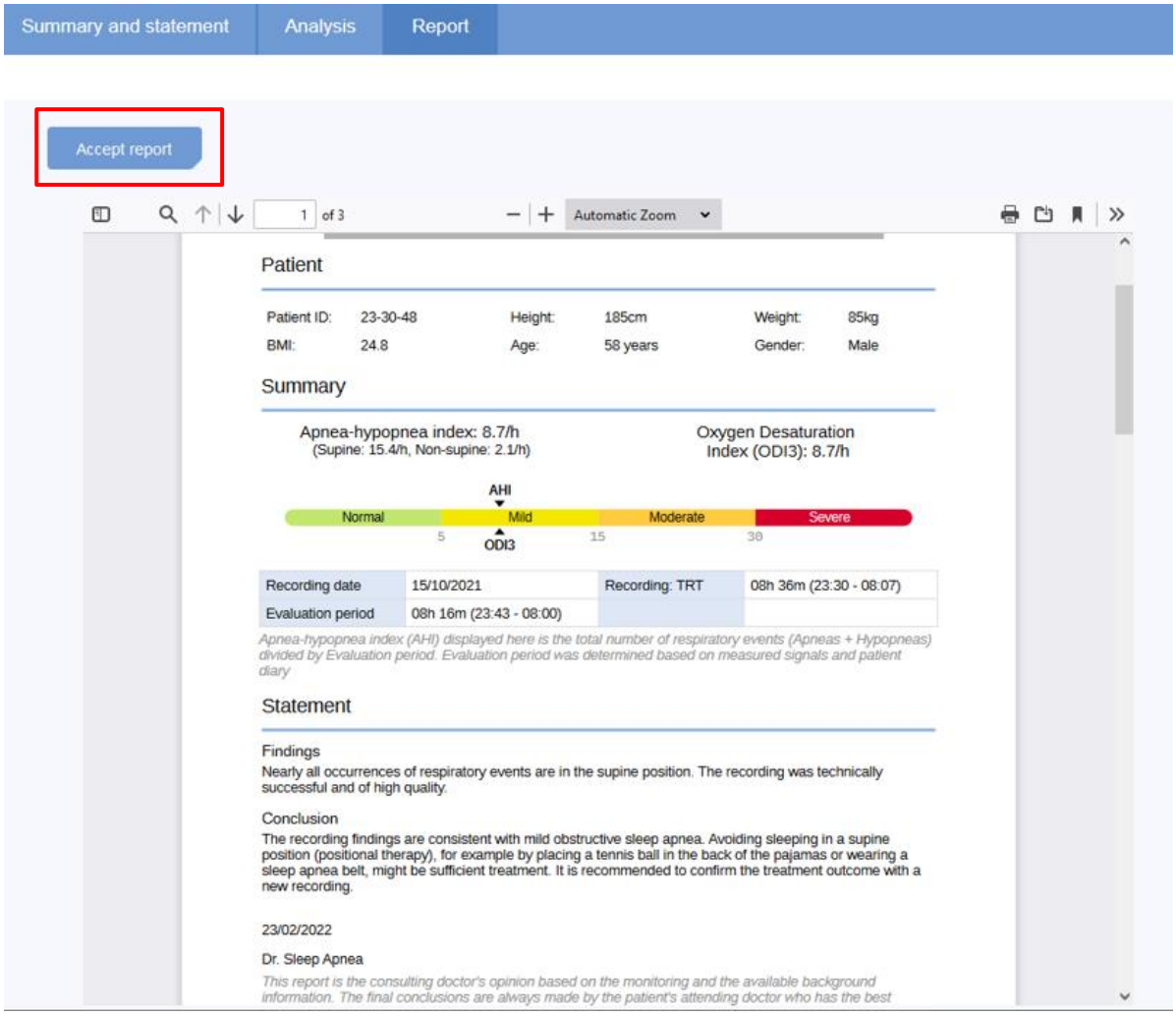


Figure 52 Report view in Respiro Analyst

4 Confirm the accepting by clicking **Accept** (Figure 53).

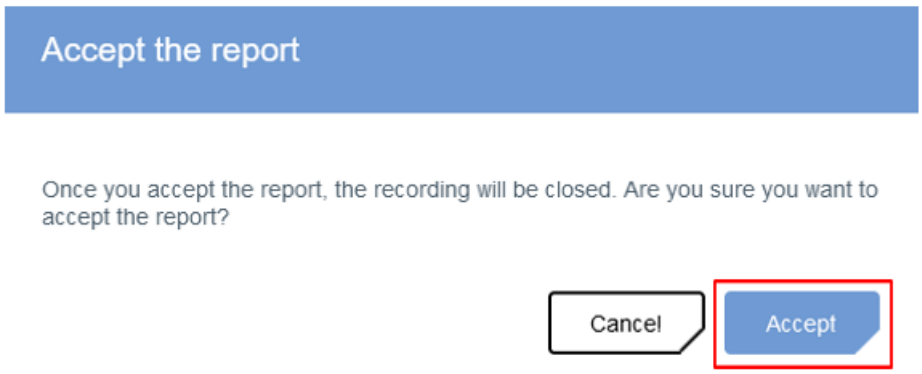


Figure 53 Confirming accepting of a diagnostic report

After accepting a report, a recording is automatically closed, and a diagnostic report created to the recording in Bittium Respiro Analyst are available in Bittium MedicalSuite Center.

Attaching a diagnostic report to a recording removes the recording from the **Diagnostic report needed** dashboard card. After a diagnostic report is attached to the recording on Bittium MedicalSuite service platform, the recording will appear on the **Latest reports** dashboard card.

3.4.2.2 Manual closing and attaching diagnostic report

Bittium HSAT recording can also be closed, and diagnostic report attach to it **manually**, if the closing is not done automatically. Manual closing can be performed without analyzing the recording or attaching a report to it. If a recording is assigned to a diagnostic user or diagnostic group, the recording appears on the diagnostic user's dashboard.

To close a recording manually, follow the steps below:

1 Find a recording from Bittium MedicalSuite Center e.g., by searching it by the patient ID or the recorder S/N in the **Recordings view**.
2 Click **Close** button related to the recording that you want to close directly from the single recording top bar (Figure 54), 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 54), or directly in the Recordings view (Figure 55).

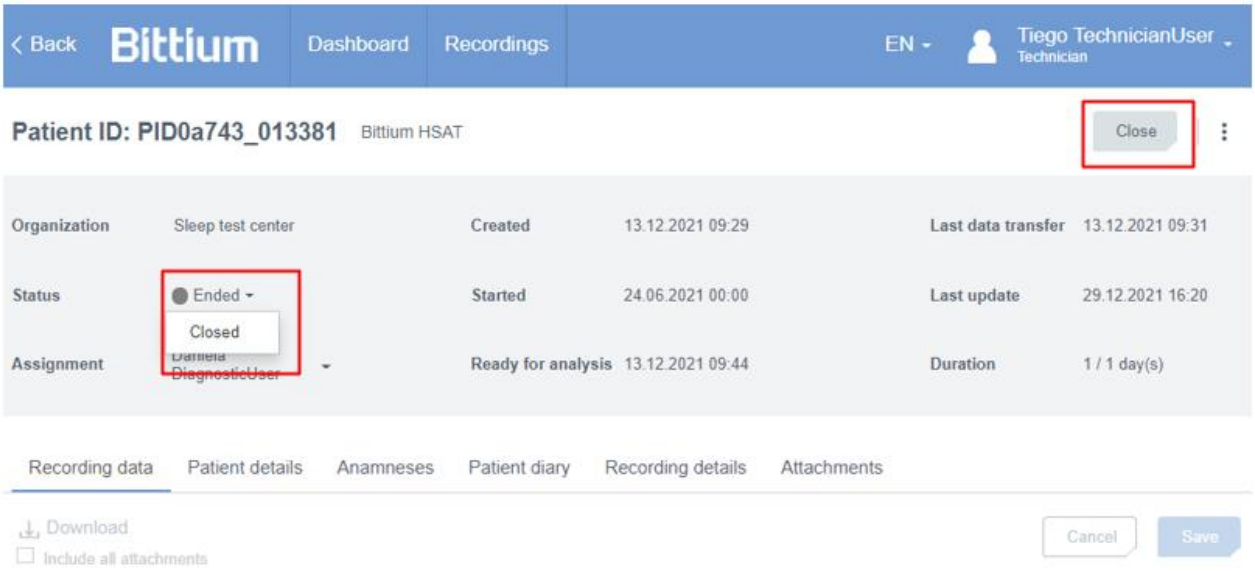


Figure 54 Closing recording in Single recording view

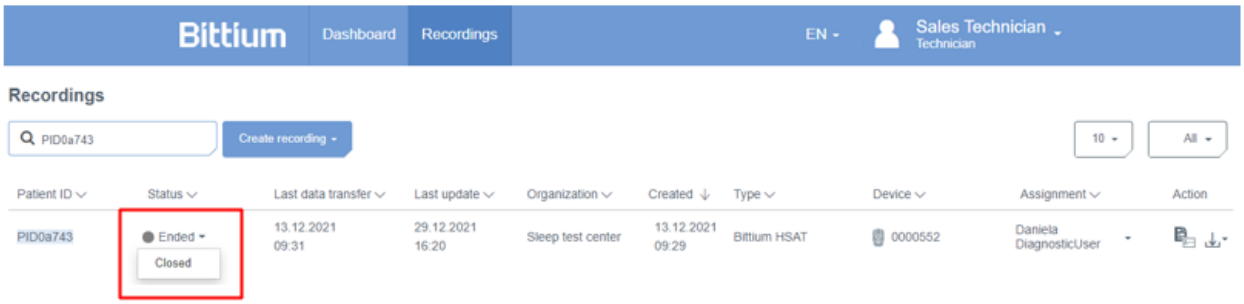


Figure 55 Changing recording status to "Closed" in Recordings view

3 **Add file** to select a report or **drag-and-drop a file** from your computer in Single recording view if needed (Figure 56)

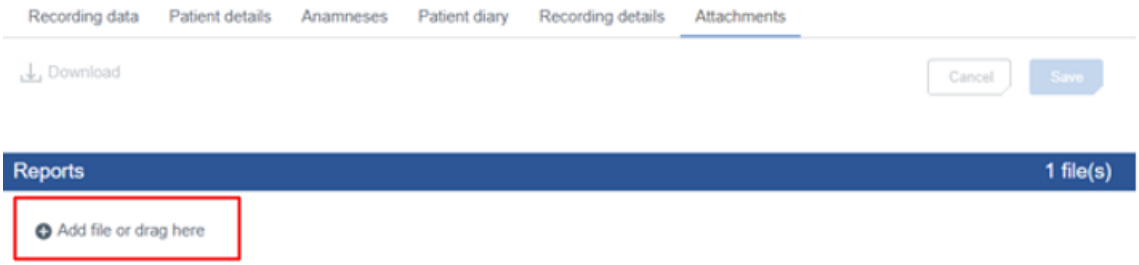


Figure 56 Add file icon on Attachments tab

4 Confirm closing by clicking **Close** (Figure 57).

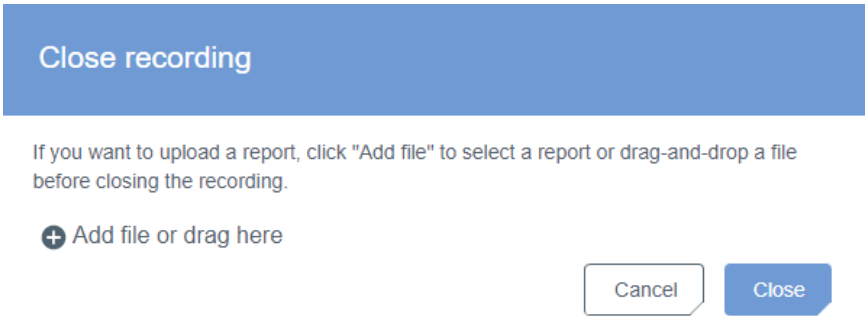


Figure 57 Confirming closing of a recording

If a diagnostic report is created to the recording in Bittium Respiro Analyst, it will be available in Bittium MedicalSuite Center when the recording is closed. After a diagnostic report is attached to the recording on Bittium MedicalSuite service platform, the recording will appear on the **Latest reports** dashboard card.

3.4.3 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 Center, 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 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 58) or on the Recordings view (Figure 59).

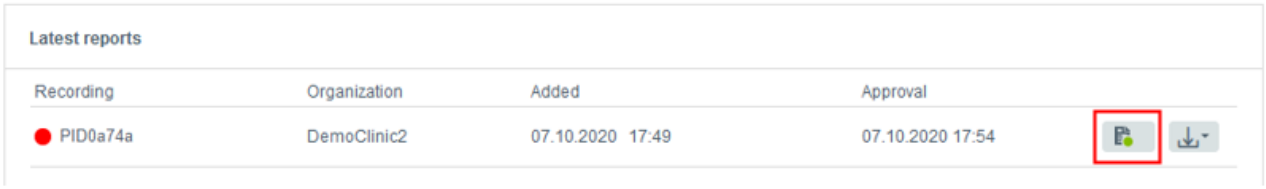


Figure 58 Preview icon on Latest reports dashboard card

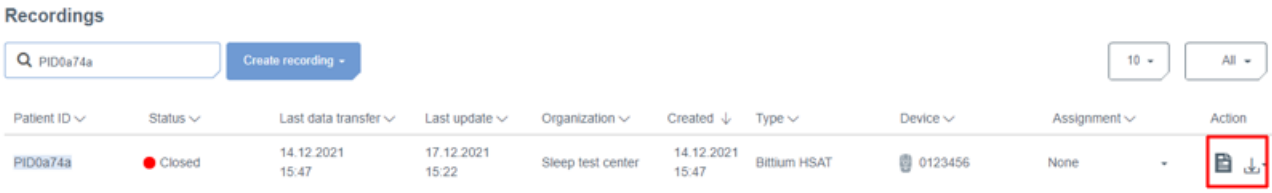


Figure 59 Preview icon in Recordings view

If you clicked the preview icon in the Recordings view (Figure 59), 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 below:

3 Click **Approve** button related to the recording whose report(s) you want to deliver to the associated lower-level organization directly from the **Latest reports** card on the Dashboard (Figure 60) or on the single recording top bar (Figure 61, open first the recording by clicking it).

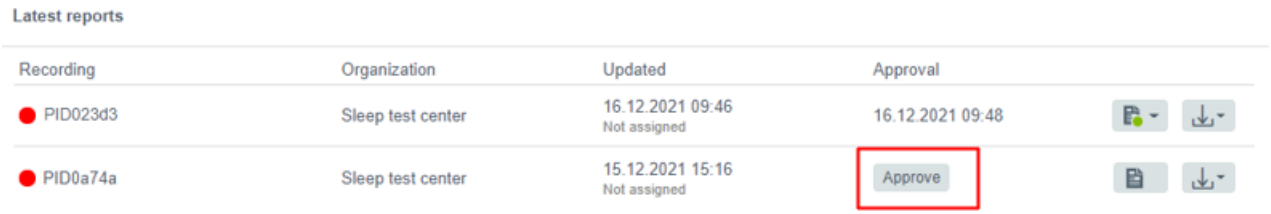


Figure 60 Approve button on "Latest reports" dashboard card

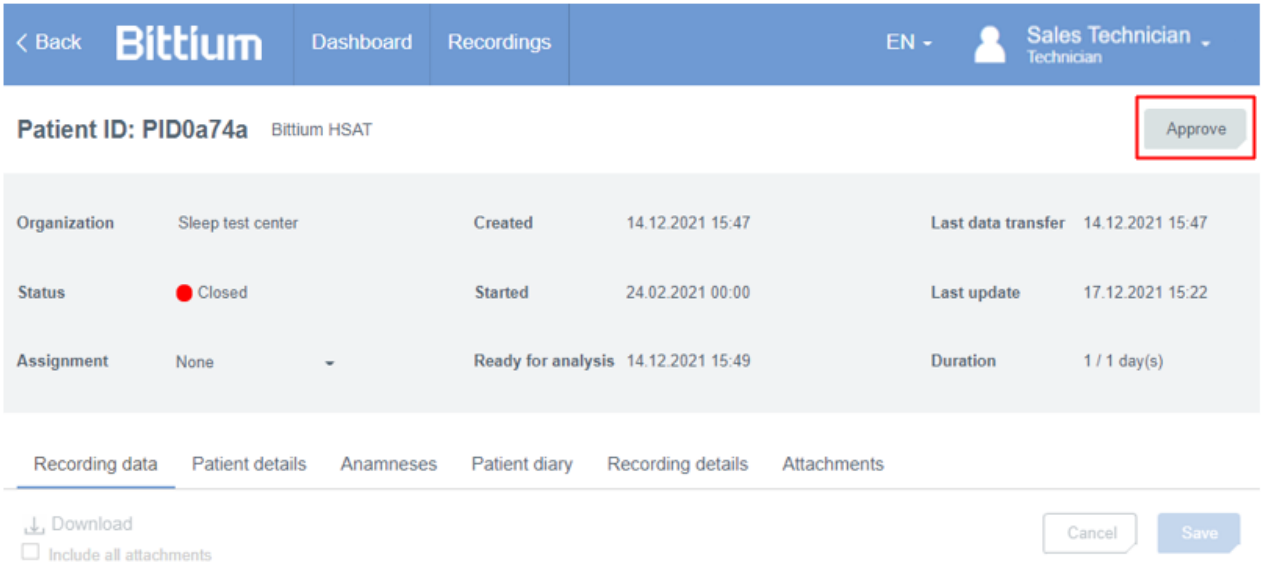


Figure 61 Approve button on single recording top bar

4 Confirm approving by clicking **Approve** (Figure 62).

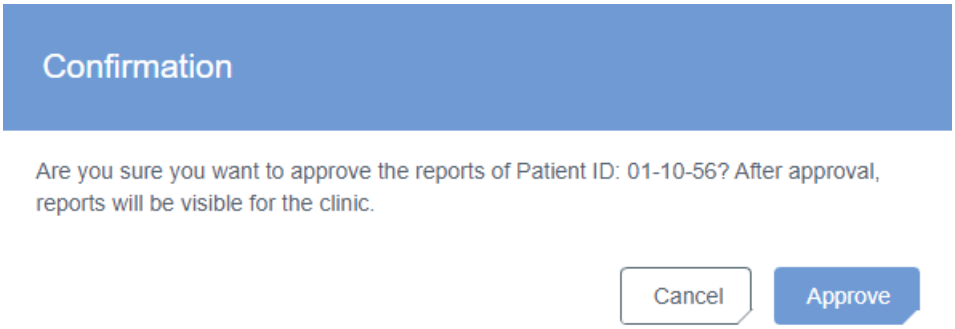


Figure 62 Confirming approving of a recording

When a recording is approved (Figure 63), the related diagnostic reports available on Bittium MedicalSuite service platform are delivered to the associated lower-level organization, and the related preview icons have a green dot indicating the report delivery (Figure 64).

Figure 63 Recording approved

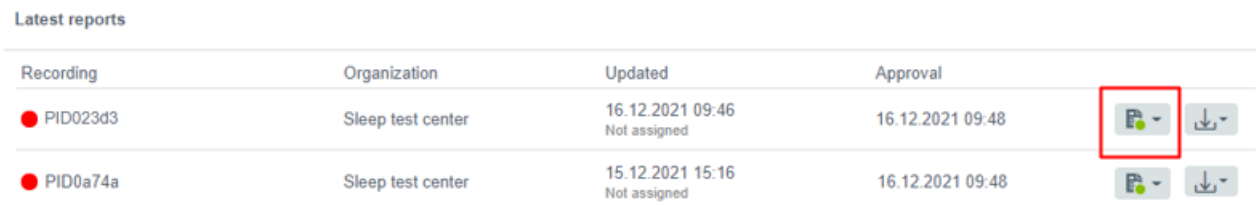


Figure 64 Preview icon with a green dot indicating report delivery

3.4.4 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 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 65) or on the Recordings view (Figure 66).

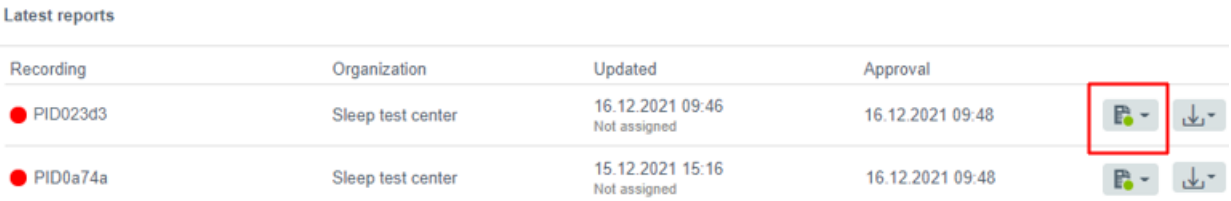


Figure 65 Preview icon on "Latest reports" dashboard card

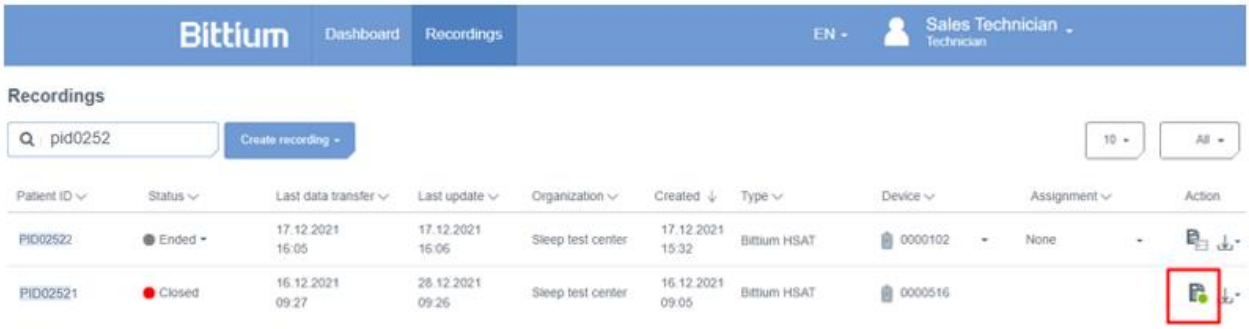


Figure 66 Preview icon in Recordings view

If you clicked the preview icon on the Recordings view (Figure 66), 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 below:

1 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 67) or on the Recordings view (Figure 68) and select the document you want to download.
2 Store the downloaded document(s) to the desired location.

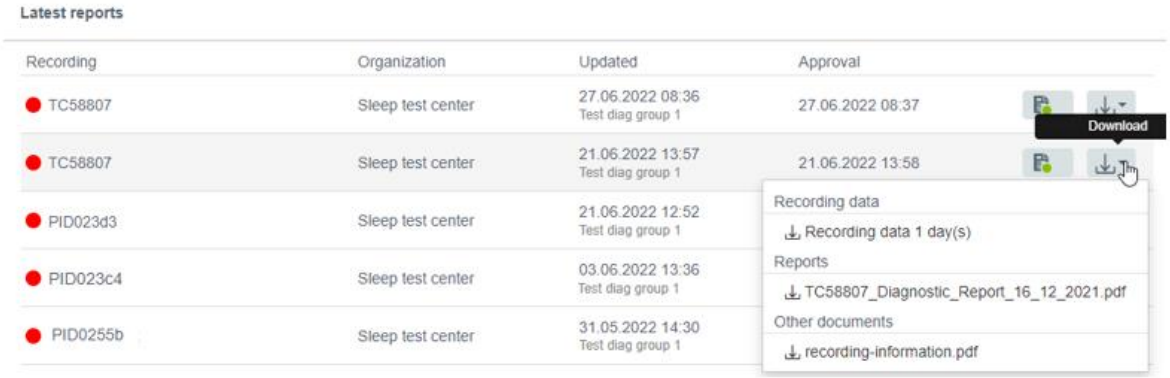


Figure 67 Download icon on Latest reports dashboard card

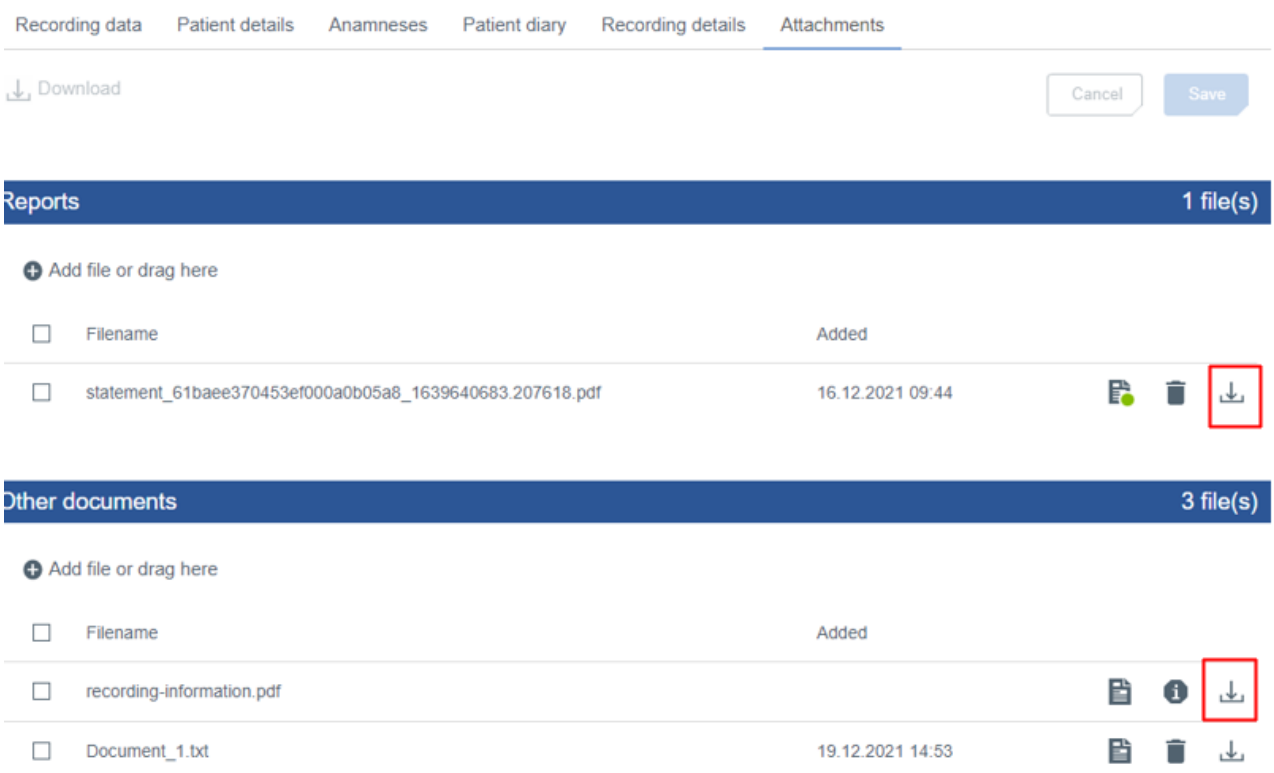


Figure 68 Download icons on "Attachments" tab of a recording

3.4.5 Rejecting and deleting recording data

3.4.5.1 Rejecting and deleting recording data in MedicalSuite Center

Recording data can be manually rejected and deleted in MedicalSuite Center if the data cannot be used for further analysis or no data have been recorded. Both rejecting and deleting actions can be performed in single recording view of MedicalSuite Center (Figure 69, *Figure 70*, *Figure 71*).

NOTE A recording that contains recording data can only be rejected. A recording without recording data or with Error status can be rejected and deleted.

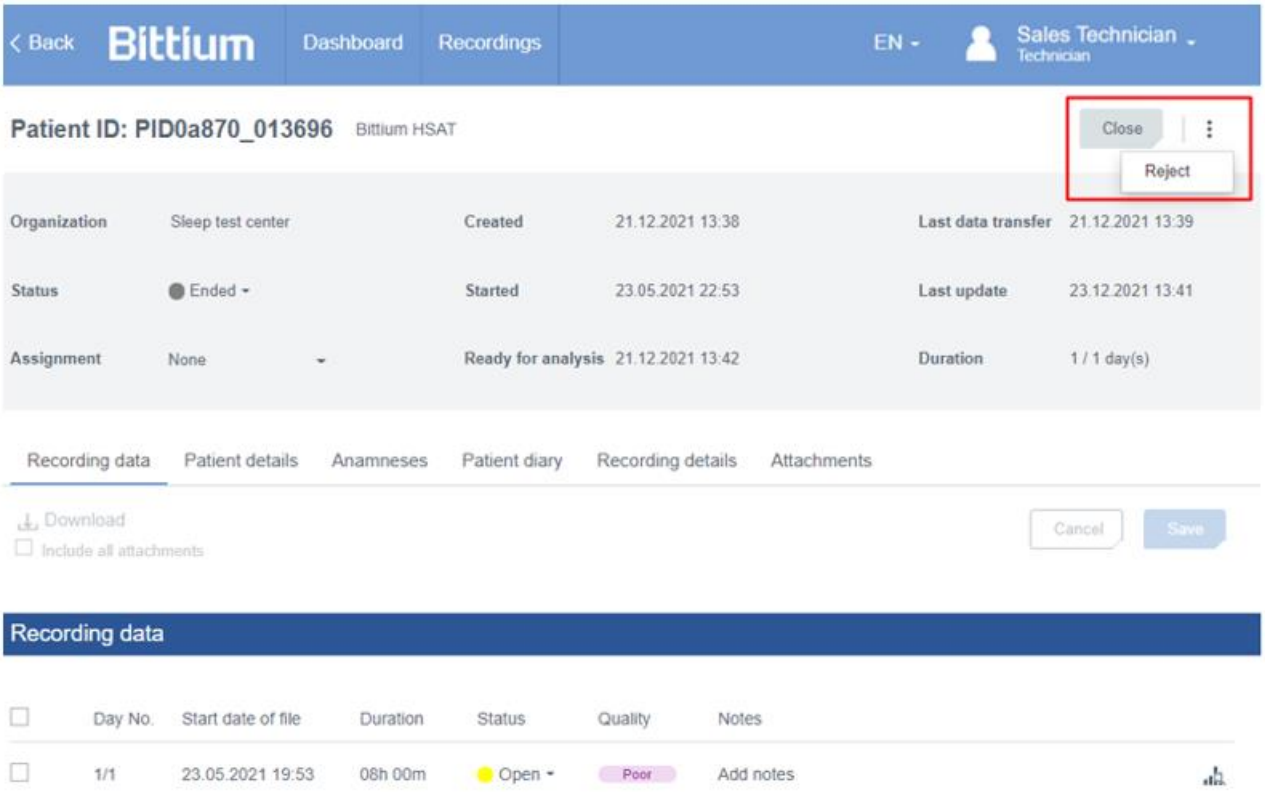


Figure 69 Rejecting recording in Single recording view

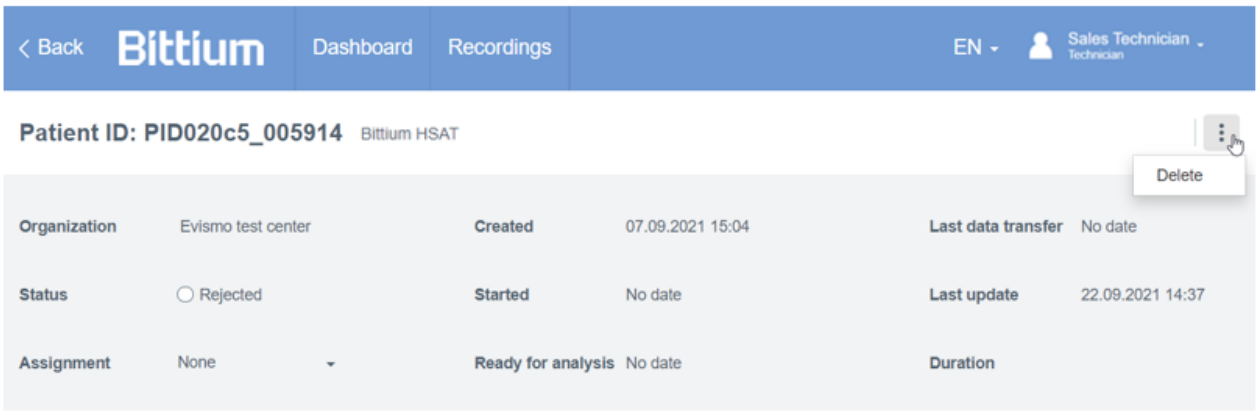


Figure 70 Deleting recording in Single recording view

When rejecting a recording, a **reason for rejection** is needed. A reason can be selected from a category, or it can be specified with free text. **After rejecting the recorder will be released, and this action cannot be cancelled** (*Figure 71*). **When deleting a recording, it is informed that the recorder will be released, and this action cannot be cancelled** (*Figure 72*).

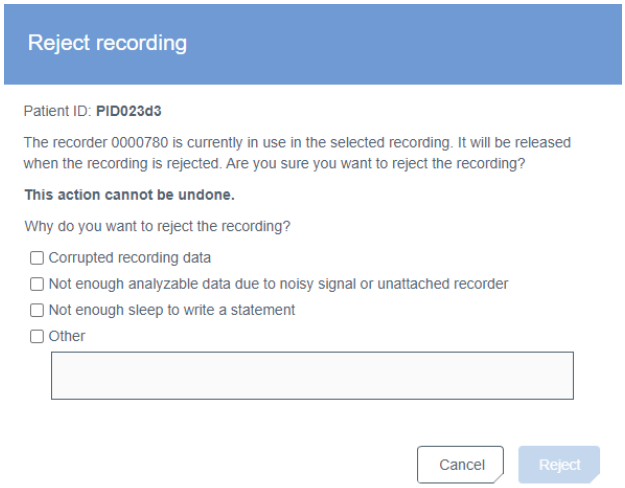


Figure 71 Note when rejecting recording

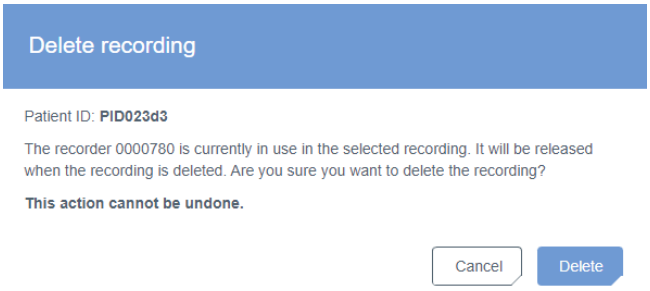


Figure 72 Note when deleting recording

You can inspect rejected recording(s) with reasons and other details from Recordings view or Single recording view on MedicalSuite Center (Figure 73, Figure 74).

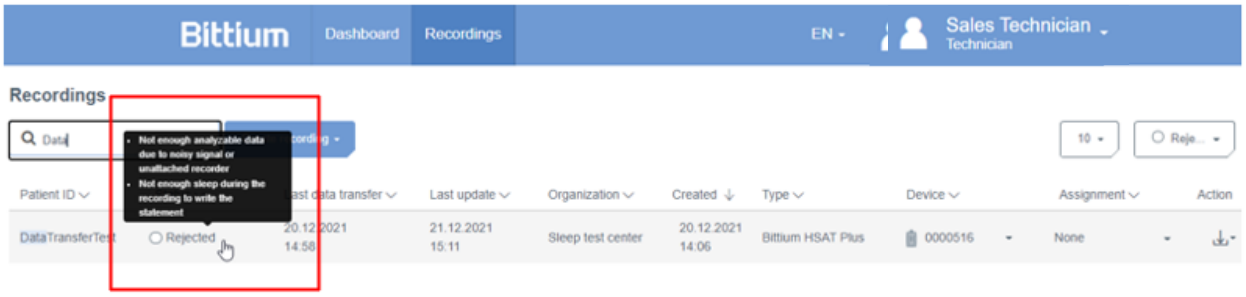


Figure 73 Inspecting rejected recordings in Recordings view

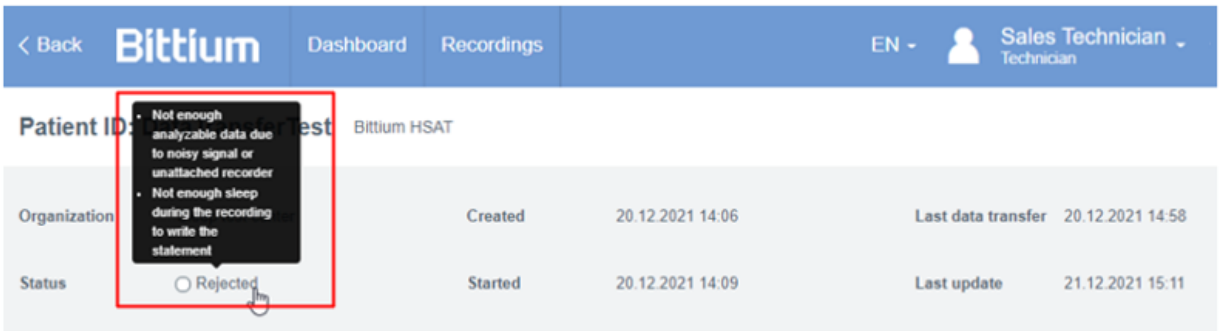


Figure 74 Inspecting rejected recording in Single recordings view

3.4.5.2 Deleting recording data from Respiro using Bittium Respiro Device Manager

In HSAT service the data of the previous recording needs to be manually deleted for privacy reasons from Respiro recorder for using Bittium Respiro Device Manager before starting a new Bittium HSAT recording for another patient. If Respiro is protected with password, the recording data needs always to be deleted using Respiro Device Manager. See details from chapter 4.2.2.

NOTE	Data of the previous recording needs to be manually deleted from Respiro before a new Bittium HSAT recording is started.

4 OTHER ACTIONS

4.1 Cleaning recording equipment

Respiro, pulse oximeter, wristband, RIP belt(s), Respiro patches, charger dock as well as the carry case, laminated Quick Guide and laminated Notes and Warnings must all be cleaned and disinfected (eg. isopropanol, except for Respiro and pulse oximeter which must be cleaned with mild detergent) before first use and after every recording. Cannulas, ECG adapter as well as ECG electrodes are disposable. RIP belts can be used more than once with same patient.

Item	Cleaning method	
	Non-fluffing cloth dampened with water and mild detergent.	**Non-fluffing cloth dampened with water and isopropanol alcohol**
Respiro	X Avoid wiping the nasal cannula interface with a too wet cloth.	
Pulse oximeter	X	
RIP belt(s)		X
Respiro patches		X Check that the patch is intact. The patch can be used in approx. 20 recordings.
Charger dock	X	
Carry case		X
Laminated quick guides and Notes and Warnings		X
The pulse oximeter's wristband is handwashed using a mild detergent in 30 °C water.		

Table 2 Cleaning recording equipment

Ensure that the devices and the wristband can dry properly after the cleaning. Use air-drying and do not tumble dry the wristband, for example. Dispose of used nasal cannulas, ECG adapters and ECG electrodes as energy waste.

4.2 Downloading and deleting recording data

4.2.1 Downloading recording data from Bittium MedicalSuite Center

For storing Bittium HSAT recording data for further analyzing with non-integrated analysis software, the data can be manually downloaded from Bittium MedicalSuite Center in EDF+ format.

To download data from Bittium MedicalSuite Center, follow the steps below:

1 **Open the recording** either from the **Dashboard** or the **Recordings view** on Bittium MedicalSuite Center by clicking on the recording.
2 **Select Recording data** tab.
3 **Select the recording nights** you want to download the data of. Every EDF-file relates to one recording night. If you wish to also download the related attachments e.g., the recording information PDF file that contains patient details, also check the box of “Include all attachments”. (Figure 75)

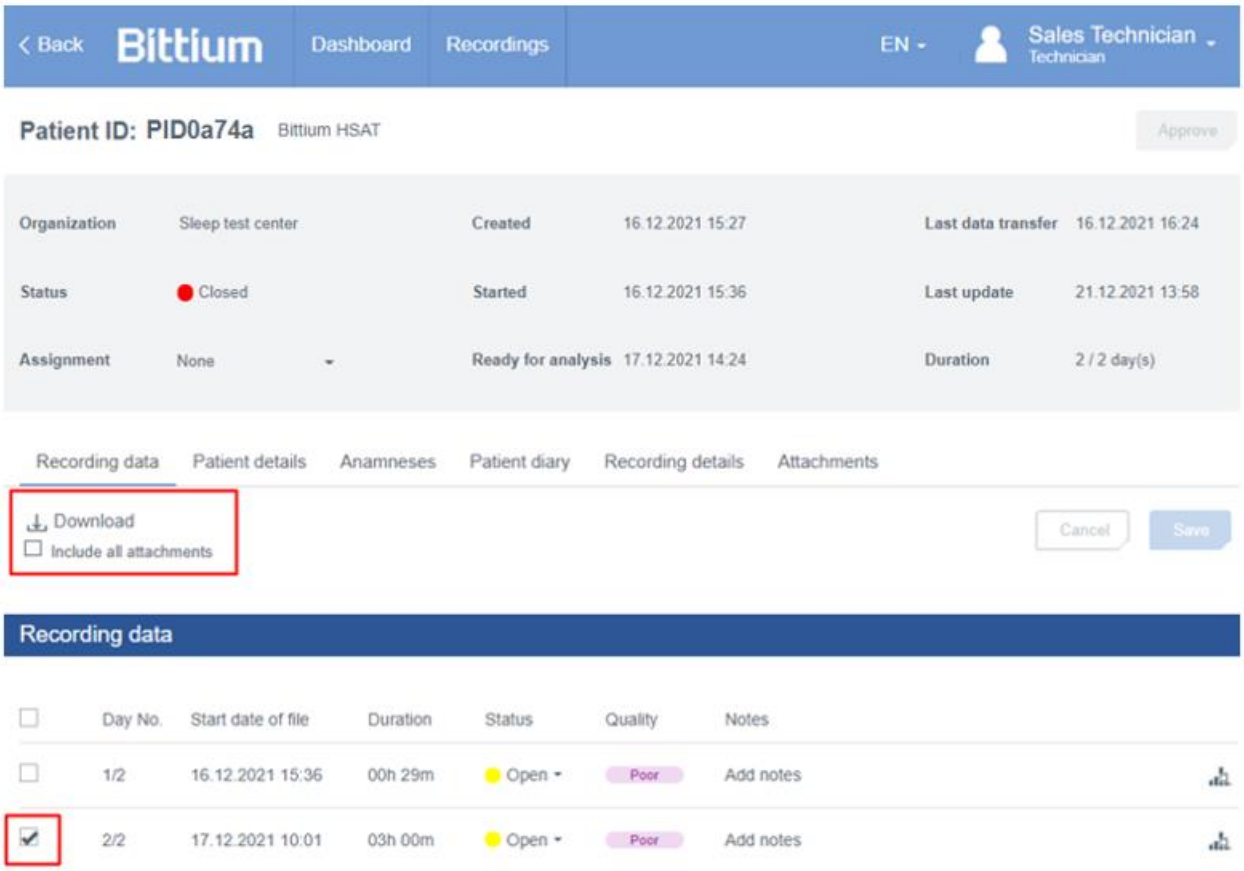


Figure 75 Selecting the day(s) for download

4 Click **Download** (Figure 75).

The recorded data of the selected nights is downloaded as a zip file that contains the recording 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 analysis software for further analysis.

4.2.2 Downloading and deleting recording data from Respiro

In Bittium HSAT service the recording data can also be downloaded and deleted straight from Respiro using Bittium Respiro Device Manager. Respiro Device Manager works in Windows 10 operating system.

Follow these instructions to download the recording data from Respiro:

1 Connect the charging dock to a computer with the USB cable.
2 Set the Respiro in the charging dock. Ensure that the device rests properly in the charging dock.

NOTE	Do not remove Respiro from the charging dock while downloading recording data. Respiro memory's read function may malfunction and cause an error state that can only be repaired in a service.

NOTE	If a recording state is accidentally on in Respiro recorder it is ended automatically when the Respiro is set in the charging dock.

3 Start Respiro Device Manager (see chapter 2.2.2). Wait for the software to detect Respiro recorder. Respiro Device Manager main view opens.
4 Select **Tools** from the top of the view.
5 Click **Save** recording files (Figure 76).

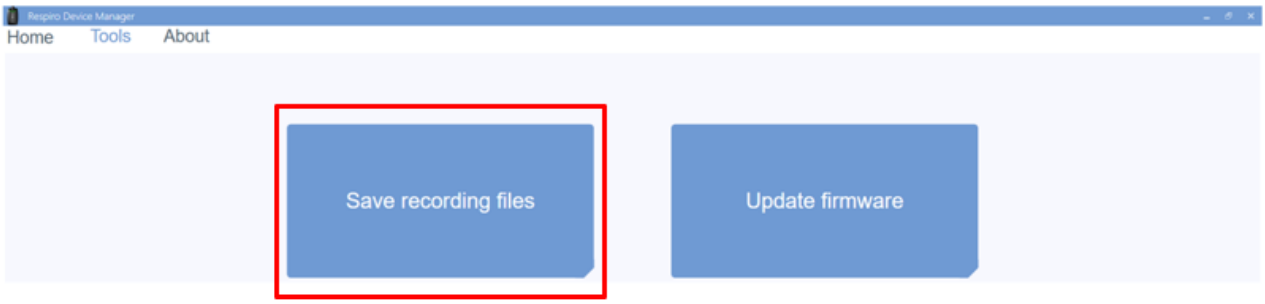


Figure 76 Downloading recording data with Respiro Device Manager

6 **Select** the downloaded **file(s)** and click **Browse.** Select saved location for the file(s) and click **Save** (Figure 77).

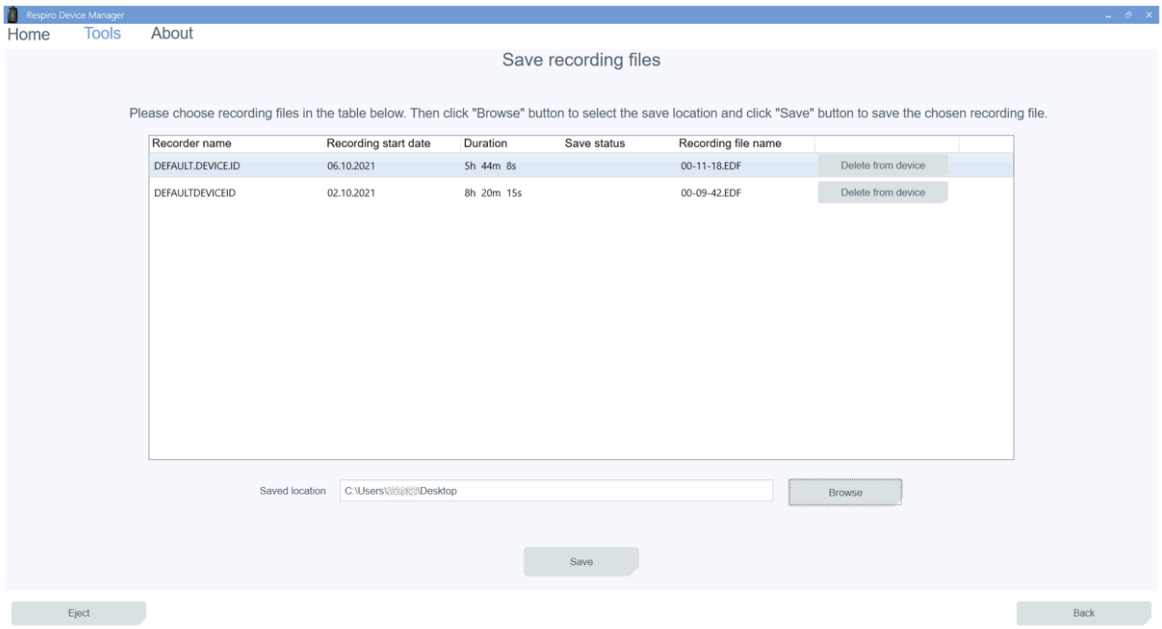


Figure 77 Selecting downloaded files in Respiro Device Manager

After the files are saved, the recording data can be **deleted** from Respiro by clicking **Yes** in the Information view (Figure 78).

NOTE If Respiro recorder is protected with password, the recording data needs always to be deleted using Respiro Device Manager.

Figure 78 Deleting files from Respiro with Respiro Device Manager

7 Click **Eject**. You can remove Respiro from the charging dock when the application instructs you to do so.

NOTE If Respiro contains corrupt files they will appear with a yellow notification triangle. These unusable files can be deleted from Respiro in the same way as other files using Respiro Device Manager.

4.3 Connecting Respiro to pulse oximeter

Respiro and the pulse oximeter in the carry case are already connected by the manufacturer. Find Bittium Respiro Device Manager software from Respiro's internal memory by following next steps if you need to connect Respiro to the pulse oximeter again due to e.g., a device failure:

NOTE If Respiro is already connected to the pulse oximeter, the previous connection needs to be removed before establishing a new one. Replace the previous device's serial number with a new device's serial number in Respiro Device Manager main view and connect the devices again.

1 Connect Respiro recorder's charging dock to a computer with the USB cable.
2 Set Respiro in the charging dock.
3 Start Respiro Device Manager (see details from chapter 2.2.2).
4 Wait for the software to detect Respiro recorder. Respiro Device Manager main view opens (Figure 79).
5 Remove the batteries for two minutes from the pulse oximeter and reinsert the batteries.
6 Enter the pulse oximeter's serial number in the pulse oximeter device name field in the Respiro Device Manager main view and click **Save**.

NOTE If you need to add a name for the Respiro recorder you can enter it in the Recorder name field. Do not use the patient's name!

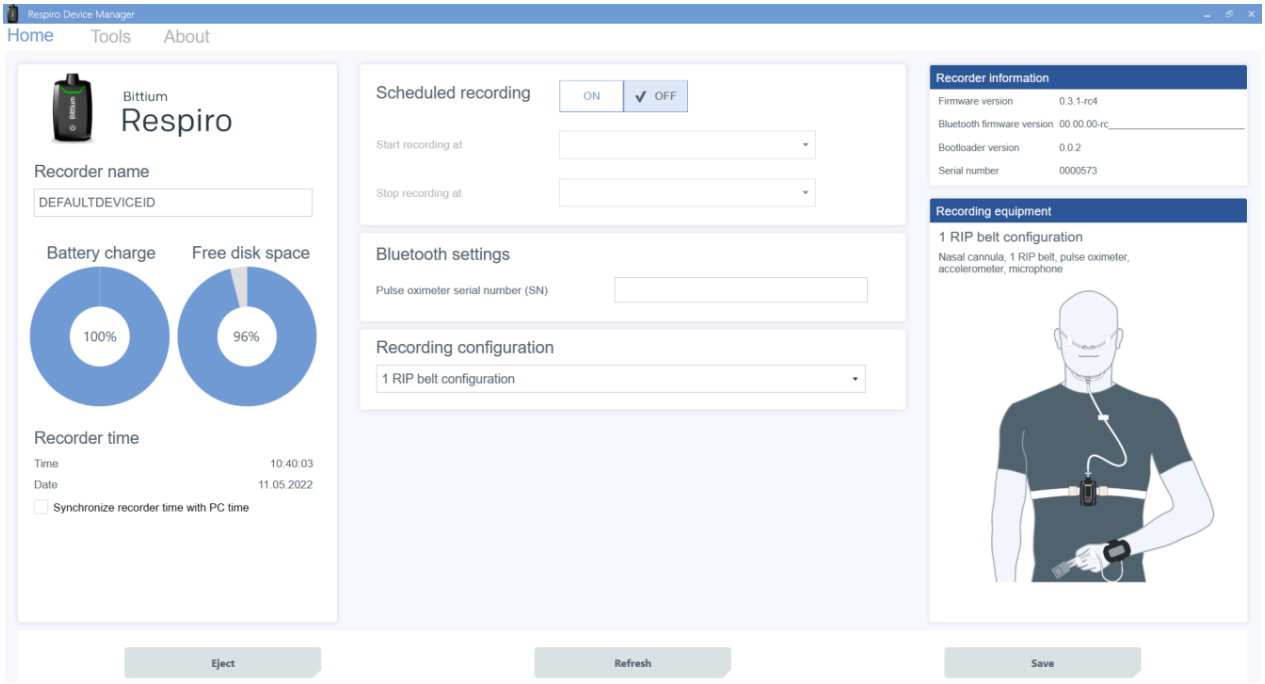


Figure 79 Bittium Respiro Device Manager - main view

6 Start the pulse oximeter by pressing its power button with e.g., your fingernail when the software requests you to do so and click **OK**. Connecting starts and completes (Figure 80).

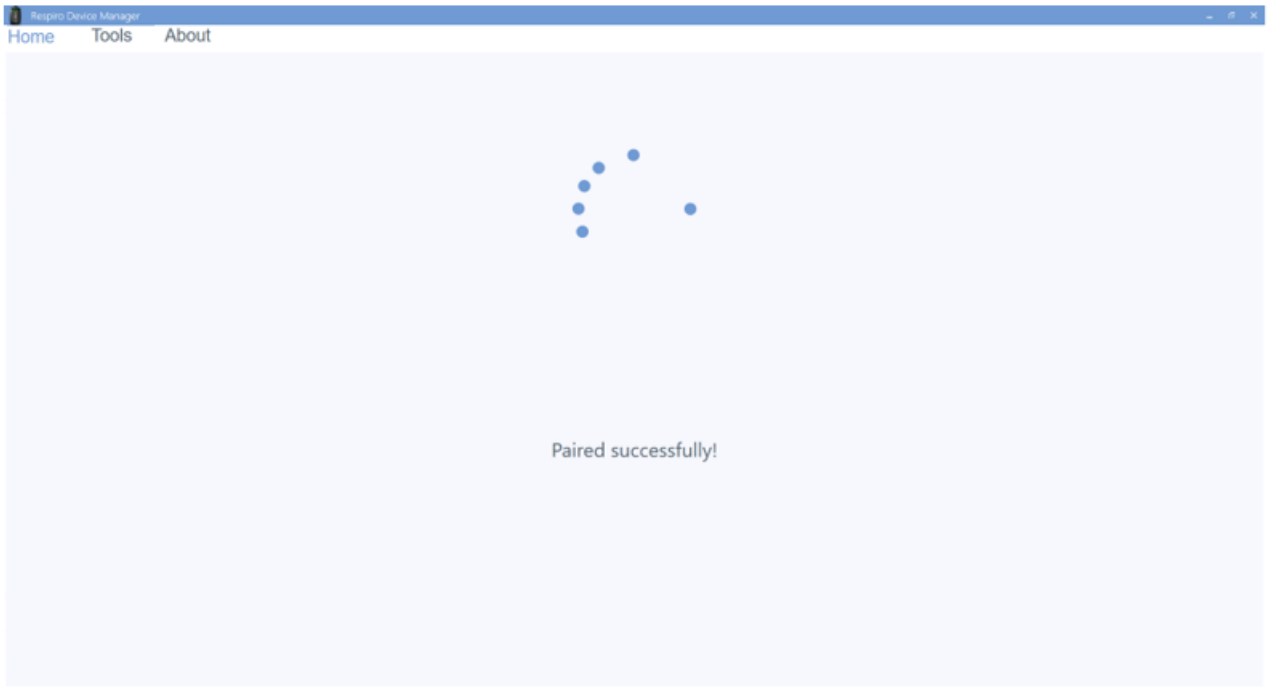


Figure 80 Device connected successfully in Respiro Device Manager

7 The Respiro Device Manager notifies you if the connection was successful. If the connection was not successful, try again (retry) and follow the on-screen instructions (Figure 81). Note that it is also possible that the pulse oximeter is already connected to another Respiro, and therefore the connecting fails. In this case enter the oximeter's serial number in the pulse oximeter device name field in the Respiro Device Manager main view and click **Save**.

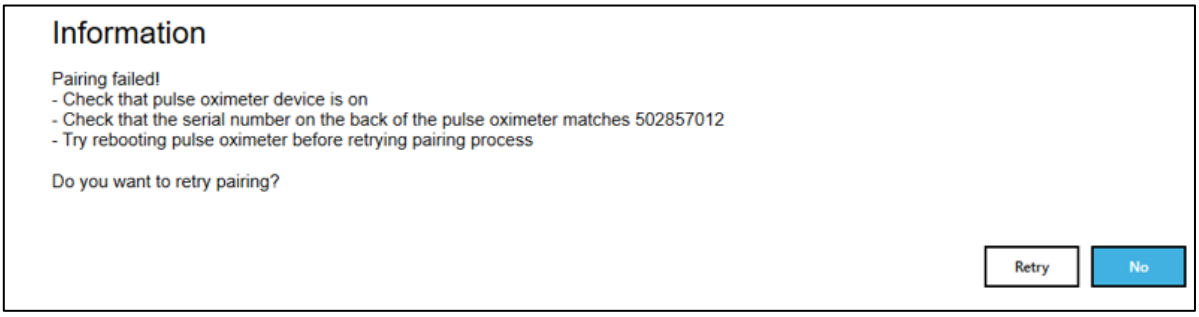


Figure 81 Connecting failed in Respiro Device Manager

4.4 Updating Respiro firmware

Before taking Respiro into use, make sure it has the latest firmware. Checking and updating Respiro firmware is performed using Bittium Respiro Device Manager that also has other functionalities (see chapter 2.2.1).

To update Respiro firmware using Bittium Respiro Device Manager, find it from Respiro's internal memory by following the steps below:

1 Connect the charging dock to a computer with the USB cable.
2 Set the Respiro recorder in the charging dock. Ensure that the device rests properly in the charging dock.
3 Start Respiro Device Manager (see Chapter 2.2.2). Wait for the software to detect Respiro recorder. Respiro Device Manager main view opens (Figure 82).

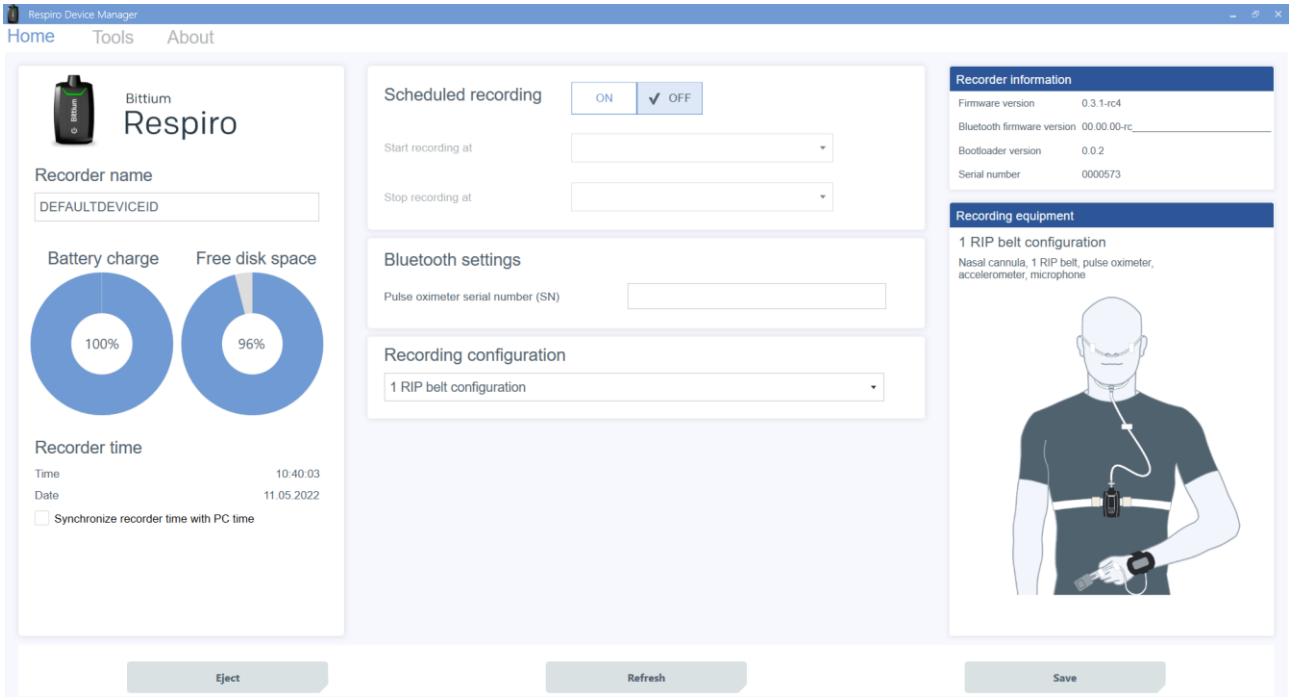


Figure 82 Bittium Respiro Device Manager - main view

NOTE

If Bittium Respiro Device Manager software folder is not placed on the computer, you can find the software files from Respiro recorder disk drive. Respiro will appear as a disk drive in Windows File Explorer when it is connected to a computer. The file to run the software is in RESPIRO/Respiro Device Manager folder.

NOTE	Bittium Respiro Device Manager folder can be saved to a computer and the software then run directly from there.

NOTE	Download the latest version of Bittium Respiro Device Manager from https://www.bittium.com/medical/support or request it from Bittium technical support (MedicalSuite.support@bittium.com).

4 Select **Tools** from the top of the view (Figure 83).
5 Select **Update firmware**.
6 Locate the update package by clicking the **Browse** button. The update package is delivered separately, and it must be available on the computer in some pre-defined location.
7 Select the file and click **Open** (Figure 83). After a while Respiro update is completed (Figure 84).

NOTE	Do not move Respiro from the charging dock while the firmware update is ongoing.

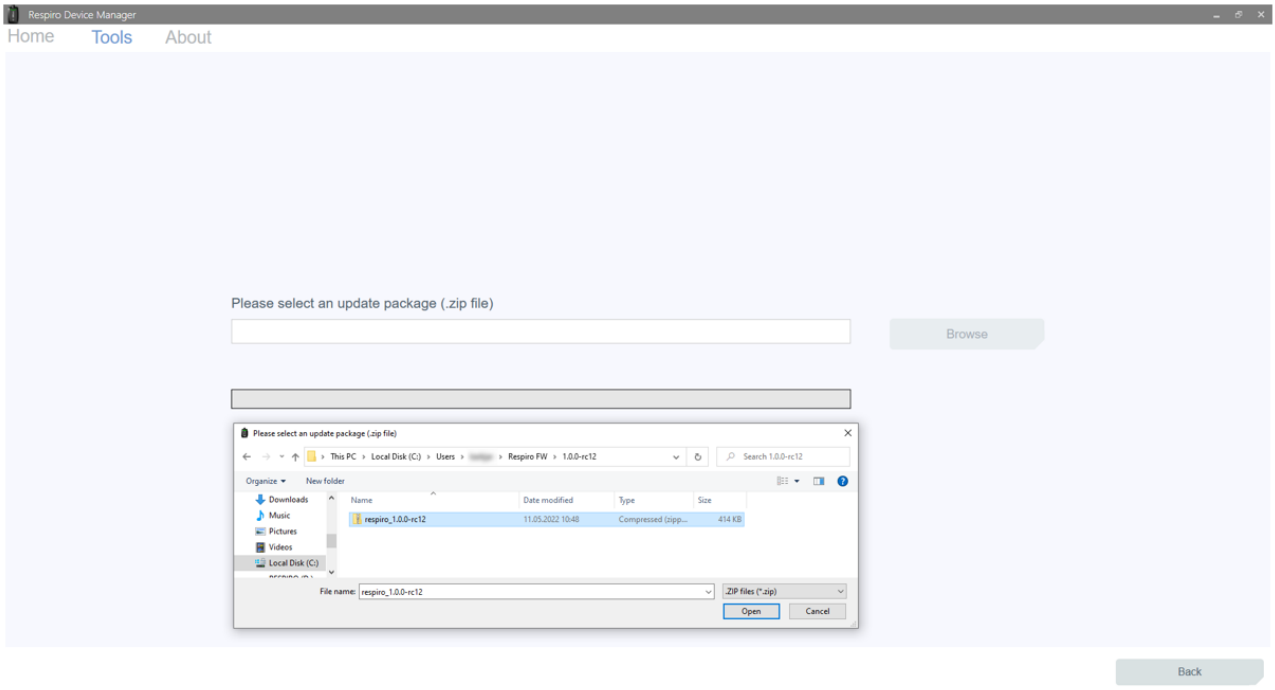


Figure 83 Selecting and opening update packet in Respiro

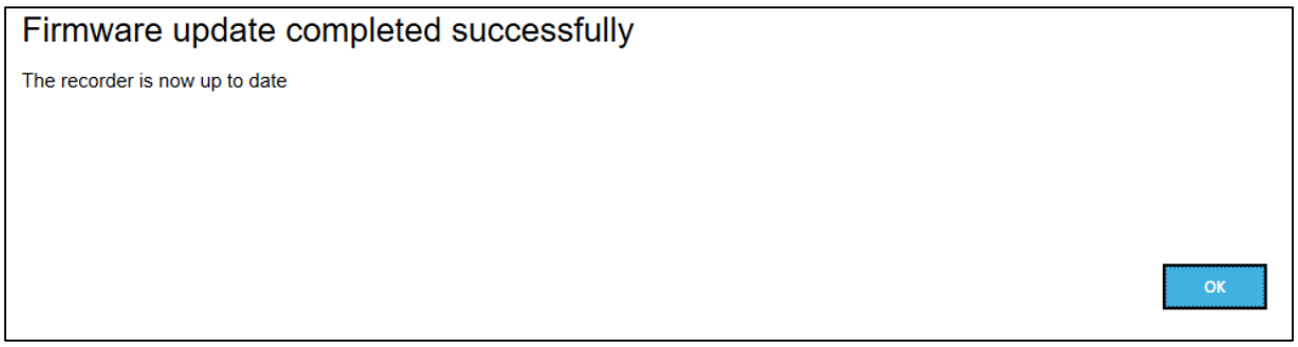


Figure 84 Firmware updated successfully

8 Firmware update starts after you have selected the update package with the Open button. Respiro Device Manager returns to main view after the update is complete (Figure 85).

9 Click **Eject** from the bottom-left corner of the Bittium Respiro Device Manager software to safely remove Respiro recorder from the computer (Figure 85).

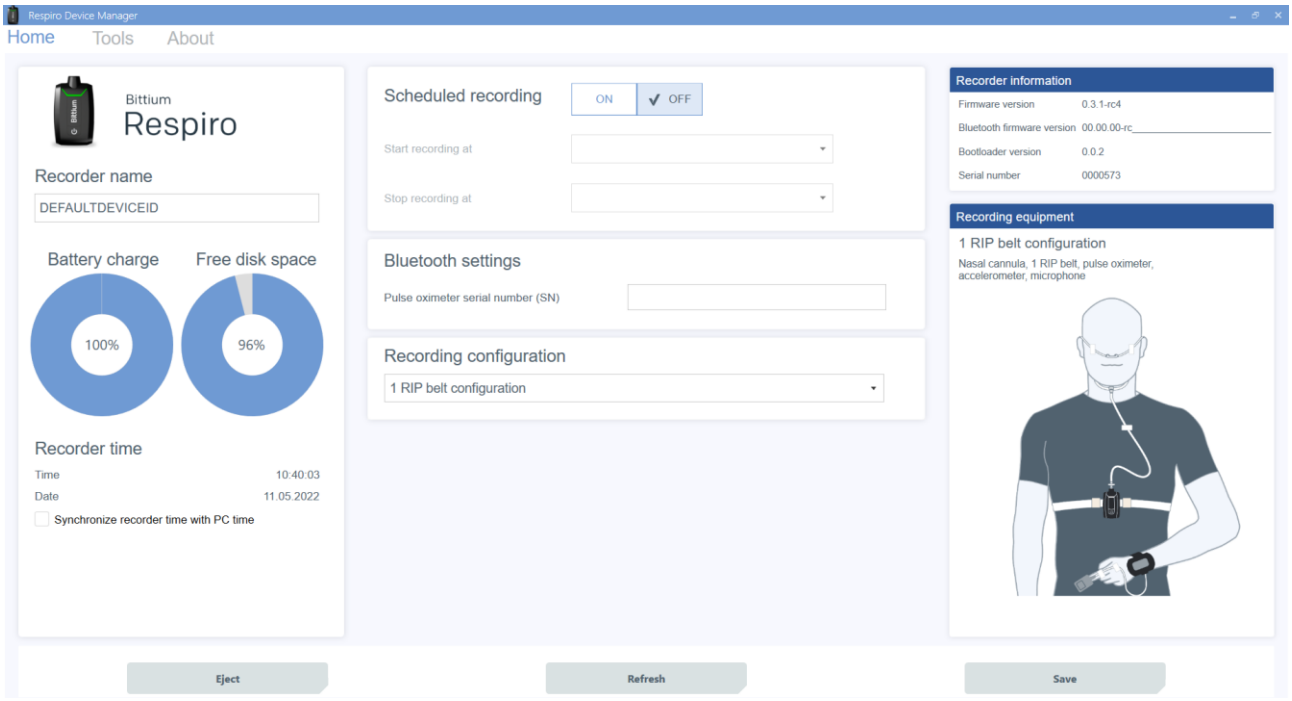


Figure 85 Bittium Respiro Device Manager - main view

4.5 Troubleshooting

If you have other troubles with the recording equipment, please see details from the **Respiro Operating Instructions**.

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