Bittium

Bittium Device Manager

Instructions for Use for a Professional User

Read these instructions for use before using the Bittium Device Manager and refer to the Faros Pro Instructions for use (D0000036441) when necessary. The English version is the master version of these instructions for use. If clarification is needed regarding the content, refer to the English version.

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

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GENERAL INFORMATION

Bittium Device Manager is software used to configure and manage compatible Bittium ECG devices, such as the Faros Pro. The software provides tools for configuring device settings, managing recorded data, and maintaining the device software. When a device is connected to the Windows computer, the software enables access to its configuration parameters, recording data, and status information. The user can adjust recording settings, synchronize the device time, transfer data, and update firmware.

Intended purpose

Bittium Device Manager (BDM) is software intended to be used as an accessory with Bittium cardiac devices. Bittium Device Manager (BDM) is used to select the prespecified features of Bittium cardiac devices, transfer recording data, delete recording data and update device firmware software. The prespecified features impact on the collected data and the length of recordings.

Bittium Device Manager (BDM) is suitable for use in healthcare environment. Intended users are healthcare professionals.

Indications

More information about the Faros Pro ECG recorder indications can be found from **Faros Pro Instructions for Use – Professional User.**

Contraindications

No contraindications are identified.

More information about the Faros Pro ECG recorder contraindications can be found from **Faros Pro Instructions for Use – Professional User.**

Clinical benefit

The device provides indirect clinical benefit by enabling the correct configuration, management, and controlled use of compatible medical measuring devices and by supporting the reliable handling, availability, and transfer of measurement data generated by those devices. The benefit is indirect in the sense that the software does not itself diagnose or treat, but it is clinically relevant because failure to perform as intended may lead to incomplete, delayed, or misassigned measurement data and thereby compromise the intended recording process. The clinical benefit is therefore defined as facilitation of safe and reliable completion of the ECG recording workflow and availability of measurement data for professional interpretation. Through these functions, the device contributes to the overall clinical process without independently generating clinical outcomes.

Compatible devices

This software is intended for use only with:

- Faros Pro, Prod. No. S0000035721, Bittium Biosignals Oy



Figure 1 Faros Pro device

For information regarding the setup, operation, maintenance, contraindications, warnings, and technical specifications of the compatible device, refer to the following manufacturer documentation:

- Faros Pro Instructions for Use - Professional User, D0000036441
- Faros Pro Instructions for use – Lay User, D0000036442

Users shall consult the documentation applicable to their intended user role before operating the Faros Pro device in conjunction with this software.

WARNINGS AND PRECAUTIONS

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

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

WARNING: To avoid unsupported configuration leading to data loss, check for the latest software versions as up-to-date version of the software shall always be used.

WARNING: Pacemaker event recording shall only be enabled if the patient has a pacemaker. Incorrect use may affect data interpretation.

WARNING: To avoid data loss, ensure that you have saved all necessary recording files before deleting files from the device.

WARNING: When configuring device password, store the new password securely to avoid losing access to device and data loss.

WARNING: To avoid data loss due to lack of available device storage always delete all existing recordings after saving.

WARNING: Do not modify or attempt to bypass the device security. Unauthorized modifications may lead to device failure.

CAUTION: To avoid data loss, always save configuration after making changes.

SYSTEM REQUIREMENTS

Bittium Device Manager is intended for use on a computer running Microsoft Windows 11 or a later compatible version. The computer must include a keyboard, mouse, and at least one USB port for connecting the device. For proper display of the user interface, a minimum screen resolution of 1280 × 720 pixels is required, while a resolution of 1920 × 1080 pixels is recommended. The application is designed for use in landscape orientation. An internet connection is required for certain functions, such as firmware updates and access to online documentation.

Cybersecurity

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

User responsibilities

The user must:

- Ensure that the device is used in accordance with the manufacturer's instructions.
- Follow secure password management practices.
- Install manufacturer-provided updates and security patches as instructed.
- Ensure that personnel are trained to use the device securely.
- Notify the manufacturer without delay if a cybersecurity incident or suspected security issue involving the device is identified

IT operating environment

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

These controls include:

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

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

INSTALLATION AND SETUP

The software is provided as a Windows installation package and is intended to be installed only by qualified IT personnel or other authorized persons within the user's organizational domain. Proper installation is required to ensure safe and intended operation of the software.

The installation package is made available through a manufacturer-controlled secure distribution channel. Access to the installation package is provided only to authorized customer representatives. The latest validated version of the software shall always be used. The installer guides the user through the installation process. Once started, the installation process shall not be interrupted, as this may lead to incomplete installation or software malfunction.

To install the software, perform the following steps:

1. Obtain the installation package access information from the manufacturer or authorized representative.
2. Download the installation package to the target computer
3. Locate the downloaded installation file.
4. Start the installation by double-clicking the file.
5. If prompted by the operating system, confirm that the installer is allowed to run.
6. Follow the on-screen instructions provided by the installation wizard.
7. Review and confirm any installation settings as applicable.
8. Start the installation process and wait until completion.
9. When the installation is finished, exit the installer.

After installation, the software creates a Windows desktop shortcut automatically.

Installation verification

Successful installation can be verified as follows:

- The installation process completes without error messages.
- The software application can be launched successfully from the desktop shortcut or Start menu.
- The software version displayed in the application corresponds to the intended released version.
- All required software components and services are operational.
- After installation, verify functionality before clinical use.

If issues occur during download, installation, or setup:

- Verify that the installation package was obtained through the official manufacturer-provided distribution channel.
- Verify that the installation package is complete and has not been corrupted.
- Ensure that the user has sufficient administrator rights to install software on the device.
- Ensure that the target environment meets the specified system requirements.

If the issue persists or cannot be resolved, contact Bittium Medical Device Support at medical.support@bittium.com.

OPERATING INSTRUCTIONS

This section describes how to operate the software for configuration and management of the Bittium ECG devices. The software provides tools for device setup, configuration of recording parameters, management of recording data, and access to software information and support.

Software user interface overview

The software user interface is divided into main views that provide access to device configuration and management functions. Use the navigation menu at the top of the window to switch between views. The availability of certain views depends on the ECG device's connection status. The Tools view is available only when a supported device is connected. The About view can be accessed when device search is not ongoing.

The primary views are:

- **Home view** – Configure device settings and monitor device status
- **Tools view** – Manage recording data and device security settings
- **About view** – Access software information, language options, instructions for use, and support

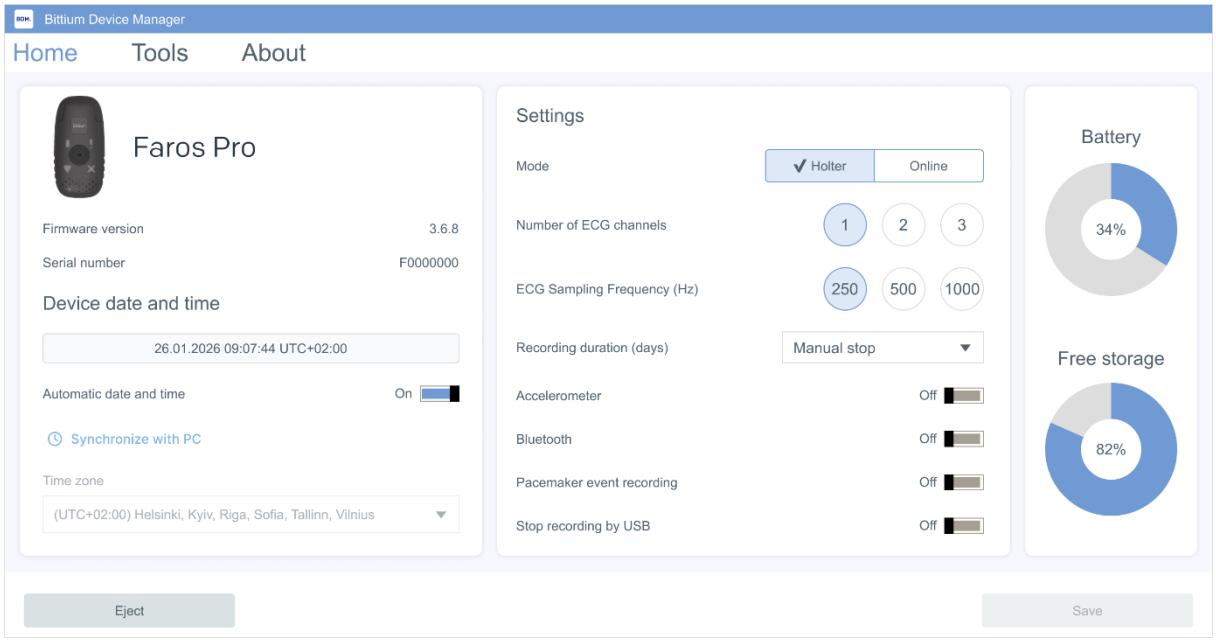


Figure 2 Home view

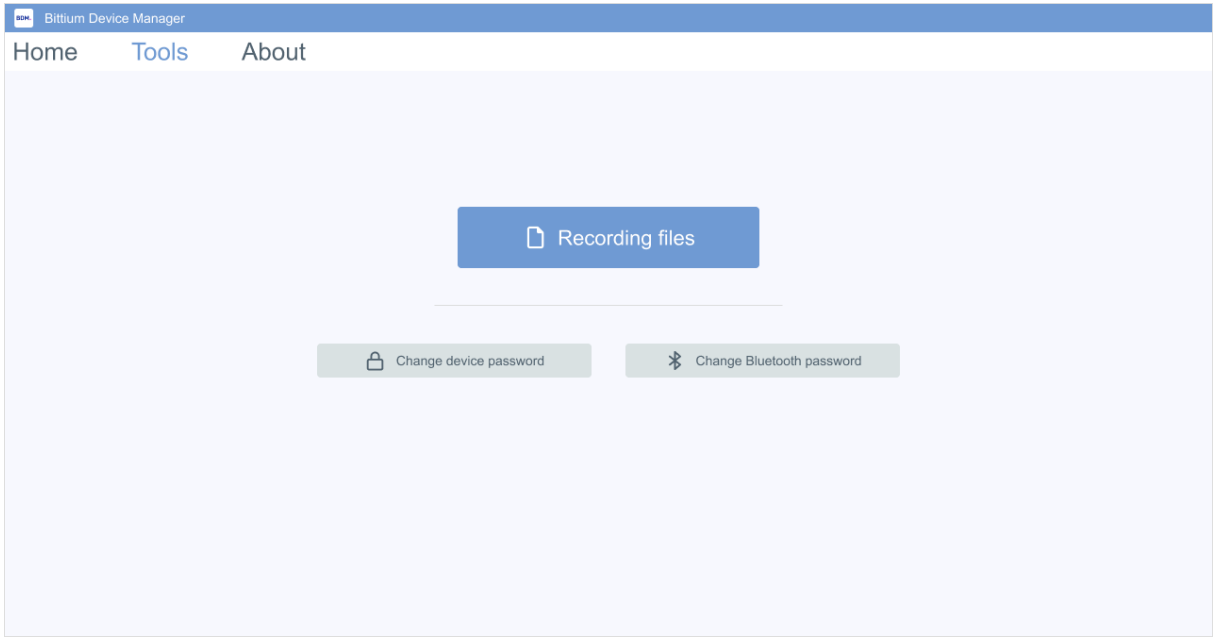


Figure 3 Tools view

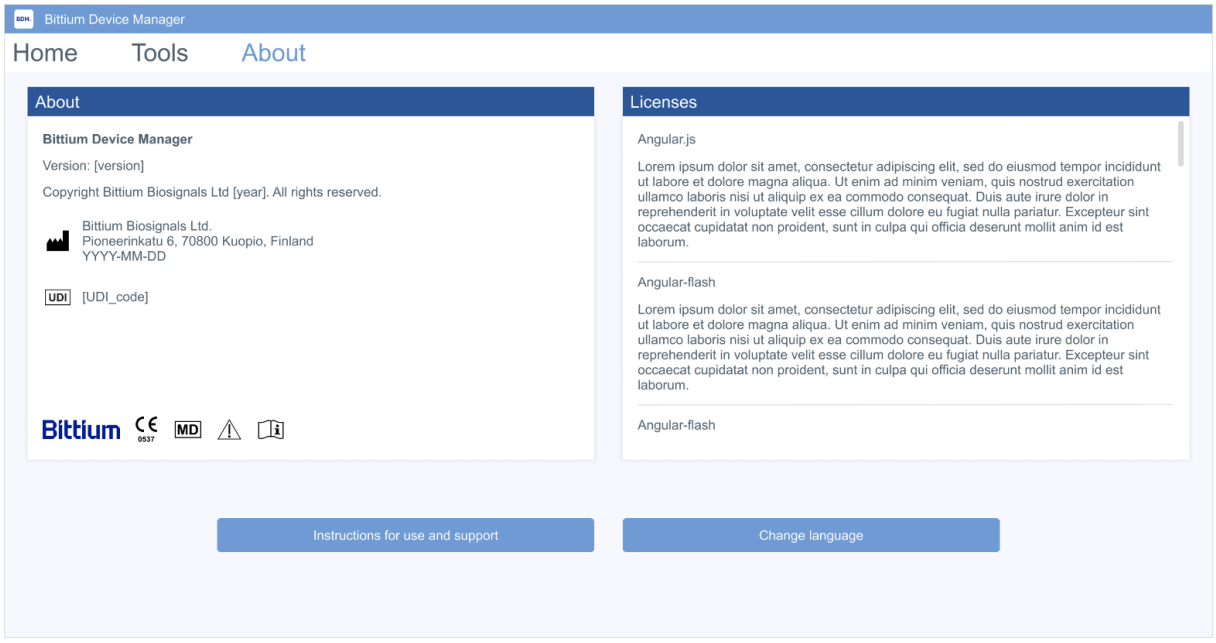


Figure 4 About view

Starting the Bittium Device Manager

The Bittium Device Manager can be started from the Windows desktop or Start menu. To start the software, double-click the desktop shortcut. Alternatively, open the Windows Start menu, locate the software, and select it. After launch, the software will open and proceed with its normal startup sequence

Connecting Bittium ECG device

To enable configuration and data management, connect the ECG device to the computer running the software. When the device is successfully connected, its information and configurable settings become available within the user interface.

1. Connect the device to the computer using the provided USB cable.
2. Start the Bittium Device Manager software.
3. The software automatically starts searching for the device.

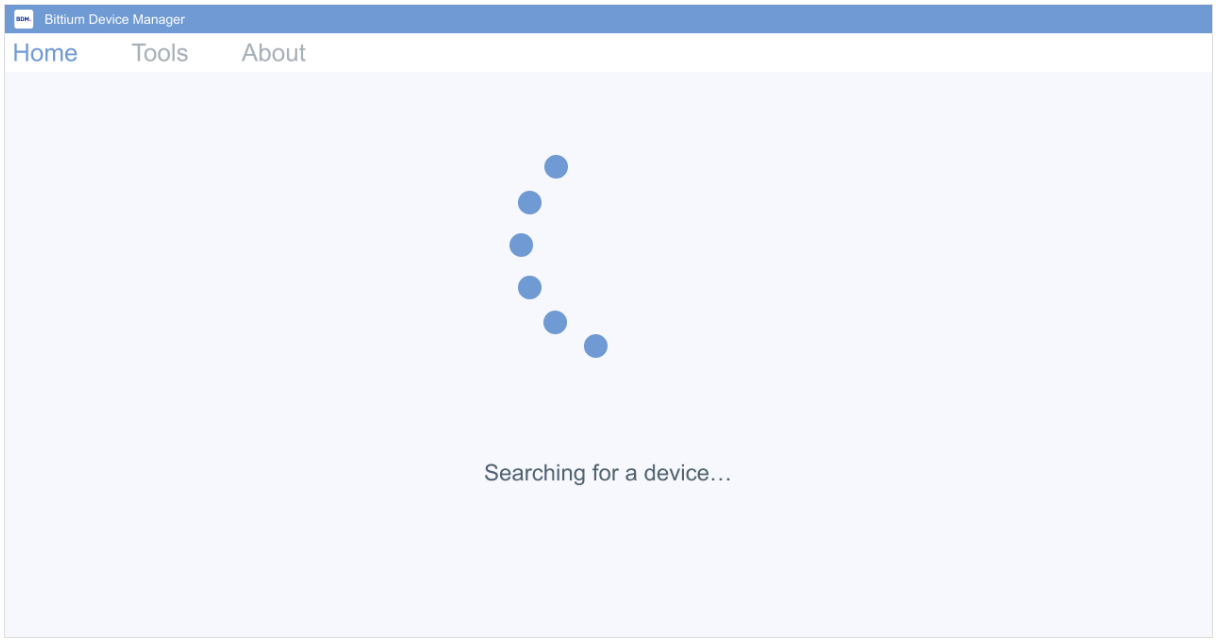


Figure 5 Connecting device to Bittium Device Manager

If issues occur during connection of the device to the software, refer to the Troubleshooting section of this document.

4. Enter the device password if prompted.

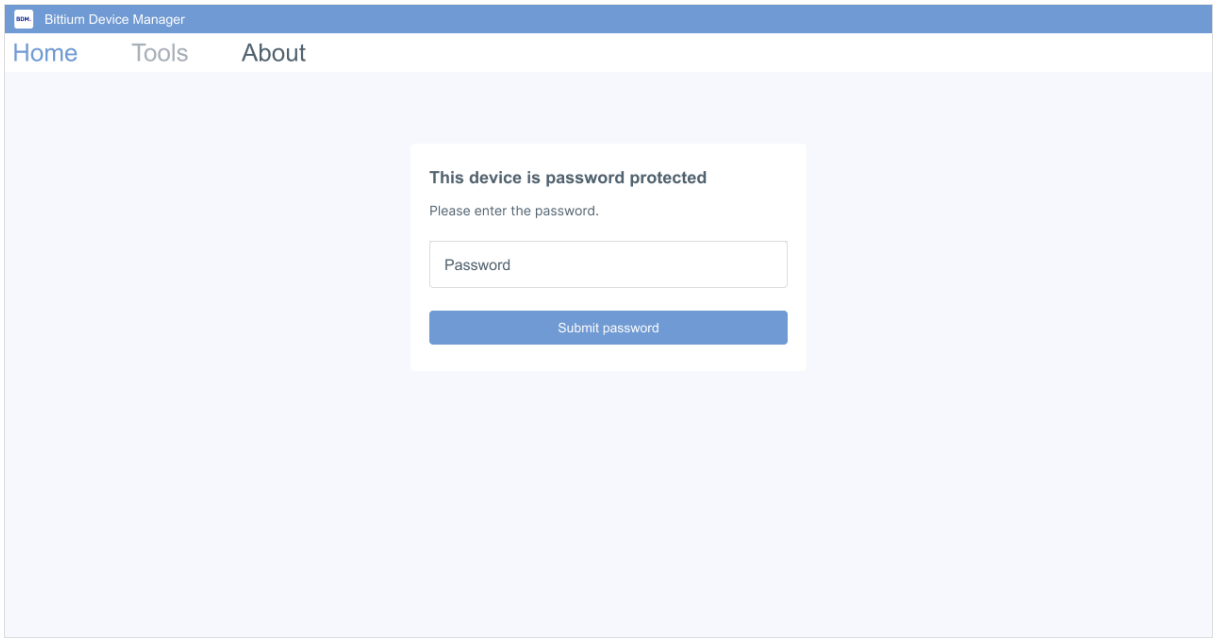


Figure 6 Enter device password

When the connection is established, the Home view displays the device information and available configuration settings.

Home view – Device configuration

The software allows the user to configure the operational parameters of the Bittium ECG device. These settings affect how data is recorded, stored, and managed. Before starting a recording with the Bittium ECG device, the user shall ensure that the required configurations described below have been appropriately selected.

The Home view displays:

- Device serial number
- Firmware version
- Battery level
- Available storage capacity

Date and time configuration

The software allows configuration of the date, time, and time zone of the connected device. Accurate settings are essential to ensure correct timestamping of recorded physiological data and alignment with clinical workflows. The device date and time are displayed in the Home view.

The device clock can be configured using one of the following methods:

- Automatic synchronization with the PC clock
- Manual synchronization with the PC clock
- Manual time zone selection

Automatic synchronization

When **Automatic date and time** is enabled, the device date and time are synchronized with the computer system time when the Home view is loaded. Automatic date and time synchronization is enabled by default.

To enable automatic synchronization:

1. Locate the **Automatic date and time** switch.
2. Set the switch to **On**.

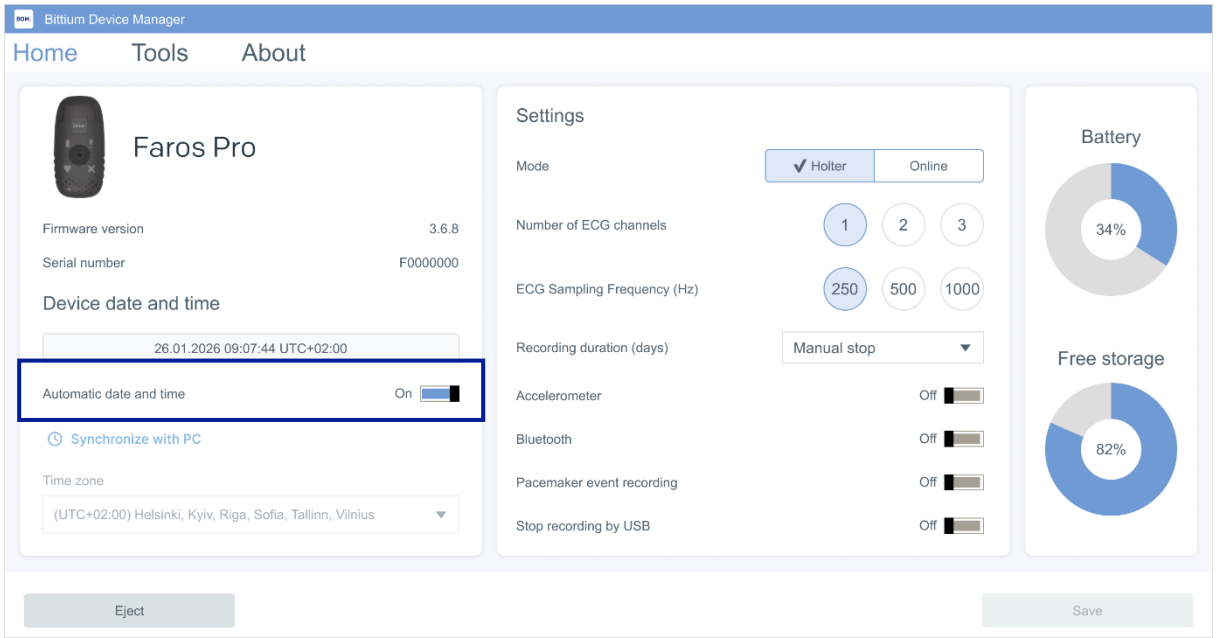


Figure 7 Automatic date and time synchronization enabled

Manual time synchronization and zone selection

When Automatic date and time is disabled, the user can either manually synchronize the device time or configure the time zone for the device. If the time zone is configured manually, the device date and time correspond to the selected time zone. This option is intended for situations where the device is configured in one geographic location and used in another with a different time zone.

To manually synchronize device time:

1. Locate the **Automatic date and time** switch.
2. Set the switch to **Off**.

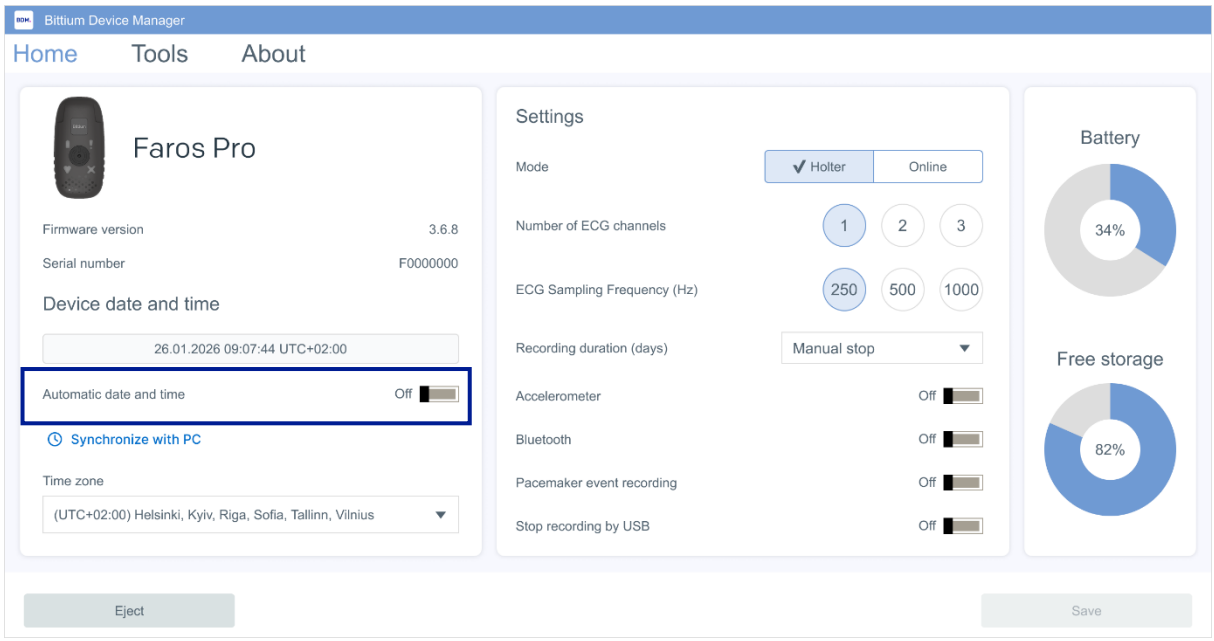


Figure 8 Automatic date and time synchronization disabled

3. Locate the **Synchronize with PC** button and click the text

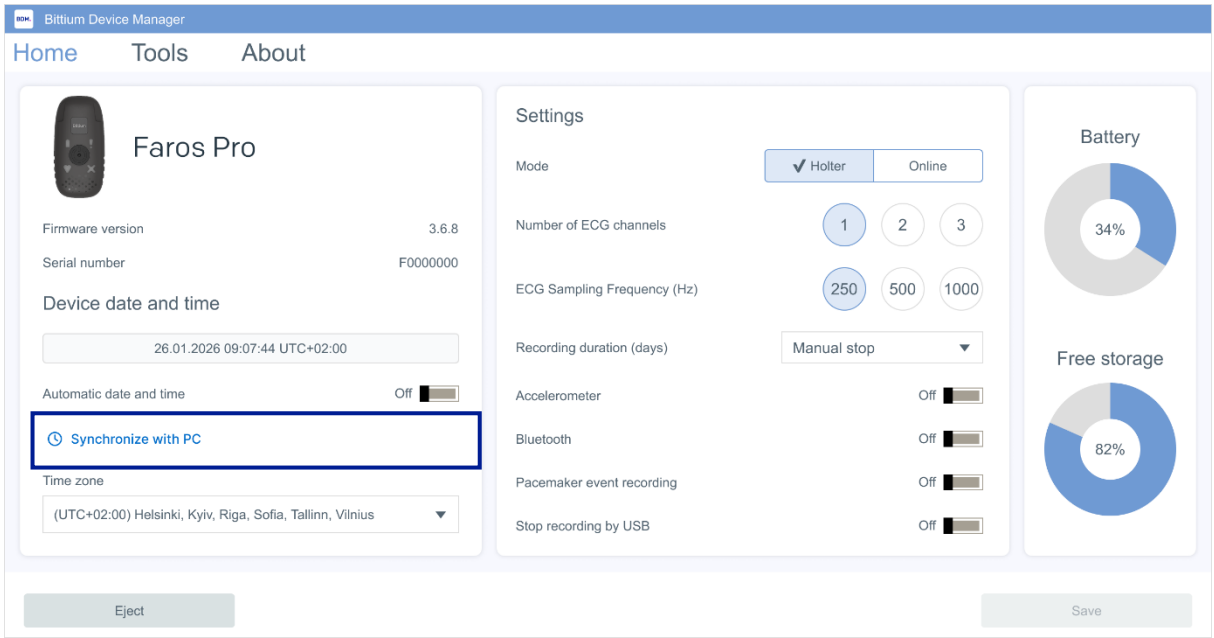


Figure 9 Synchronize with PC button

4. The device time is synchronized with the PC.

To configure the time zone manually:

1. Locate the **Automatic date and time** switch.
2. Set the switch to **Off**.
3. Open the **Time zone** drop-down list.
4. Select the desired time zone.

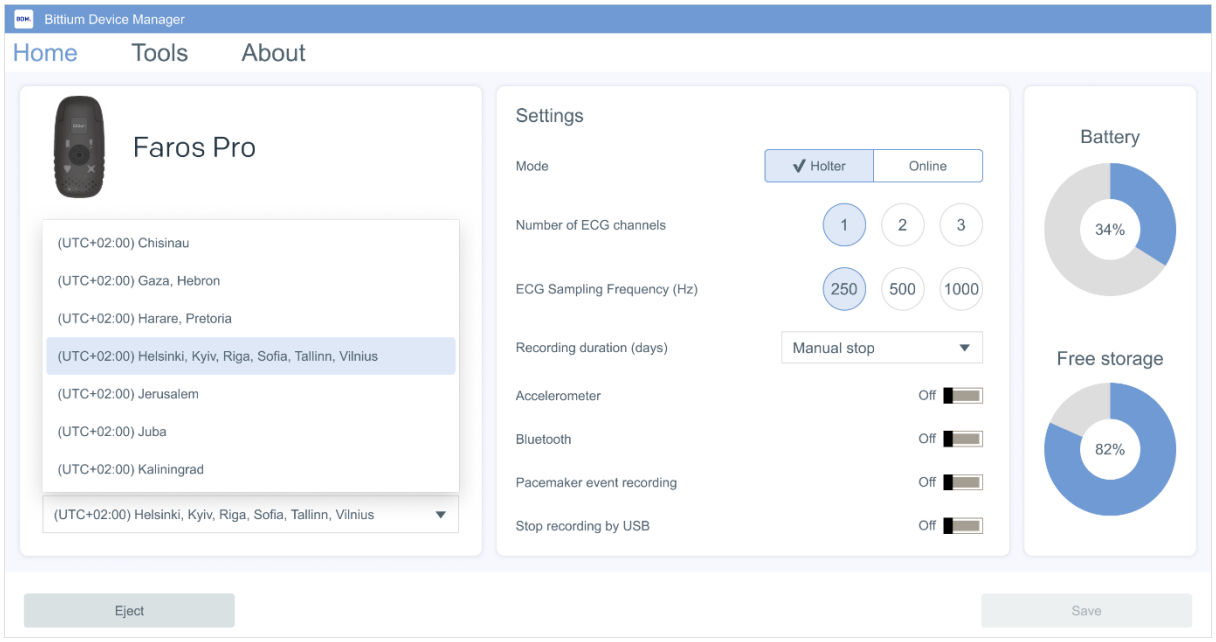


Figure 10 Drop-down list for time zones

Device configuration for recording

The software allows the user to configure recording settings that define how the device operates during recording. These settings affect data acquisition, storage, and device behavior. Before starting a recording, the user shall ensure that the required settings are correctly configured.

Changes to settings are not applied automatically. After modifying one or more settings, the user must save the changes using the **Save** function. The software indicates if there are unsaved changes.

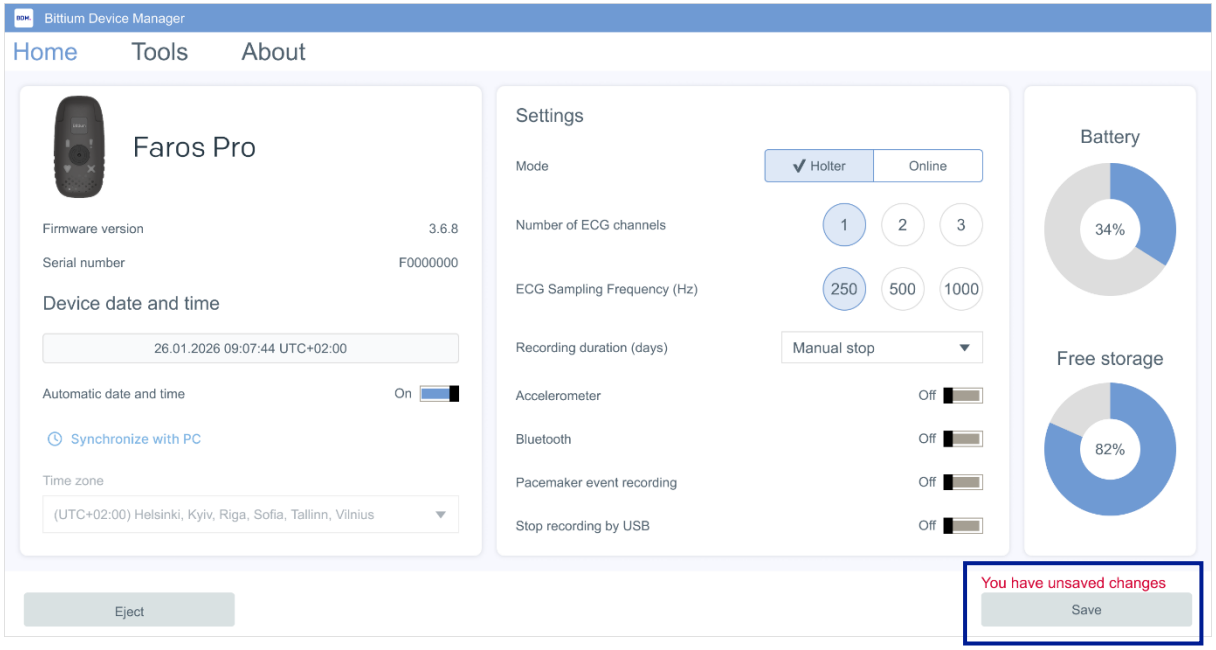


Figure 11 Unsaved changes

Operating mode

The operating mode determines how the device is used.

- **Holter mode** The device is operated manually using the power button.

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

To select operating mode:

1. Locate the **Mode** setting.
2. Select either **Holter** or **Online**.

NOTE:	When Online mode is selected, Bluetooth is automatically enabled and cannot be turned off.

NOTE:	When Online Mode is selected, the recording duration is managed externally and cannot be modified with the software.

Number of ECG channels

The number of ECG channels determines how many simultaneous ECG signals are recorded. Increasing the number of channels allows more comprehensive monitoring but increases data storage requirements.

NOTE:	For information on selecting the number of ECG recording channels and the corresponding channel configurations, refer to the Faros Pro Instructions for Use – Professional User.

To select the number of ECG channels:

1. Locate **Number of ECG channels**.
2. Select the desired number (e.g., 1, 2, or 3).

ECG sampling frequency

The sampling frequency determines how frequently ECG signals are recorded. Higher sampling frequencies provide more detailed signal resolution but increase memory consumption and may reduce maximum recording duration.

To select sampling frequency:

1. Locate **ECG Sampling Frequency (Hz)**.
2. Select the desired value (e.g., 250 Hz, 500 Hz, or 1000 Hz).

Recording duration

The recording duration defines how long the device records physiological data. The recording duration is selected from a drop-down list in the software user interface.

- **Manual stop** allows recording until it is manually stopped.
- **Fixed duration** stops recording automatically after a predefined period. (1-21 days)

To configure recording duration:

1. Locate **Recording duration**.
2. Open the drop-down list.
3. Select either Manual stop or the desired predefined duration.

NOTE:	When Online Mode is selected, the recording duration is managed externally and cannot be modified with the software.

Additional recording settings

The following device features can be enabled or disabled as required:

- Accelerometer
- Bluetooth
- Pacemaker event recording
- Stop recording by USB

To configure these settings:

- Locate the relevant setting.
- Set the switch to **On** or **Off**.

WARNING:	Pacemaker event recording shall only be enabled if the patient has a pacemaker. Incorrect use may affect data interpretation.

NOTE:	Bluetooth discovery for pairing is possible for 5 minutes after pressing the ECG device's button.

NOTE:	When Online mode is selected, Bluetooth is automatically enabled and cannot be turned off.

Remove the device from the computer

After data transfer is complete, use the **Eject** function before disconnecting the device.

To remove the device from computer:

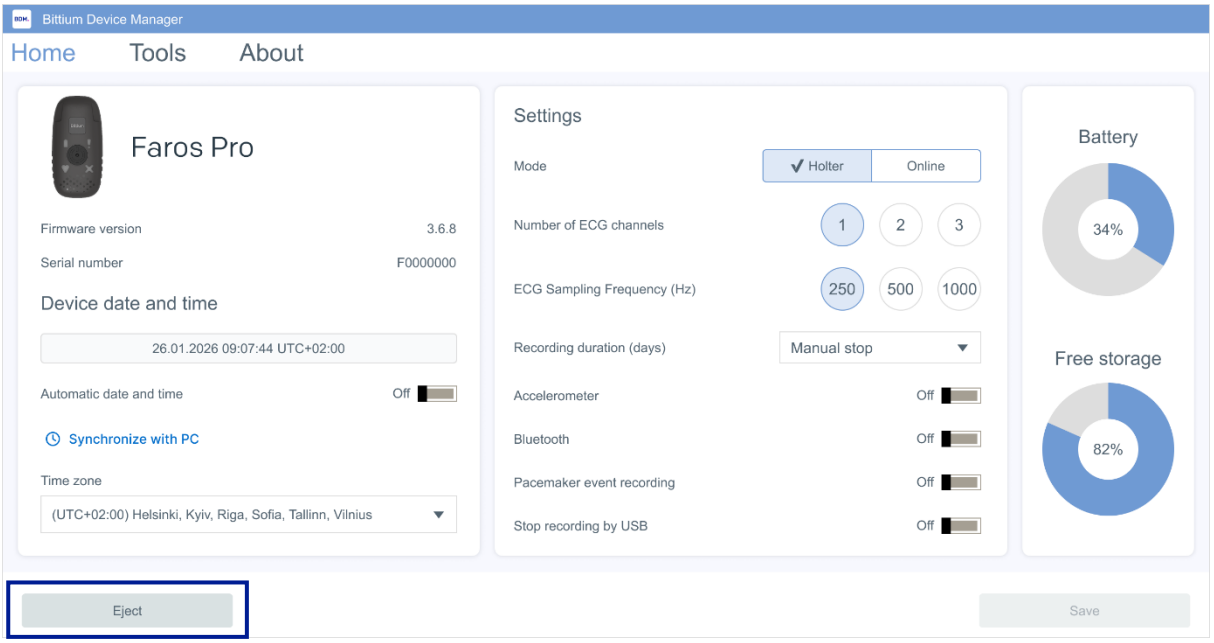


Figure 12 Eject button

1. Click the **Eject** button in the software.
2. Wait until the software indicates that the device can be safely removed.
3. Disconnect the USB cable from the device.

NOTE: Do not disconnect the device from the computer's USB port until the software indicates that the monitor has been disconnected.

Tools view – Data management and device security

The Tools view provides access to three main functions via the buttons displayed:

1. **Recording Files** – Save or delete recording files stored on the device.
2. **Change Device Password** – Configure the device password.
3. **Change Bluetooth Password** – Configure the Bluetooth password.

Use the buttons to perform the corresponding tasks; instructions for each function are provided in the following sections.

Loading recording files

To load recordings from the connected device, select the **Recording Files**.

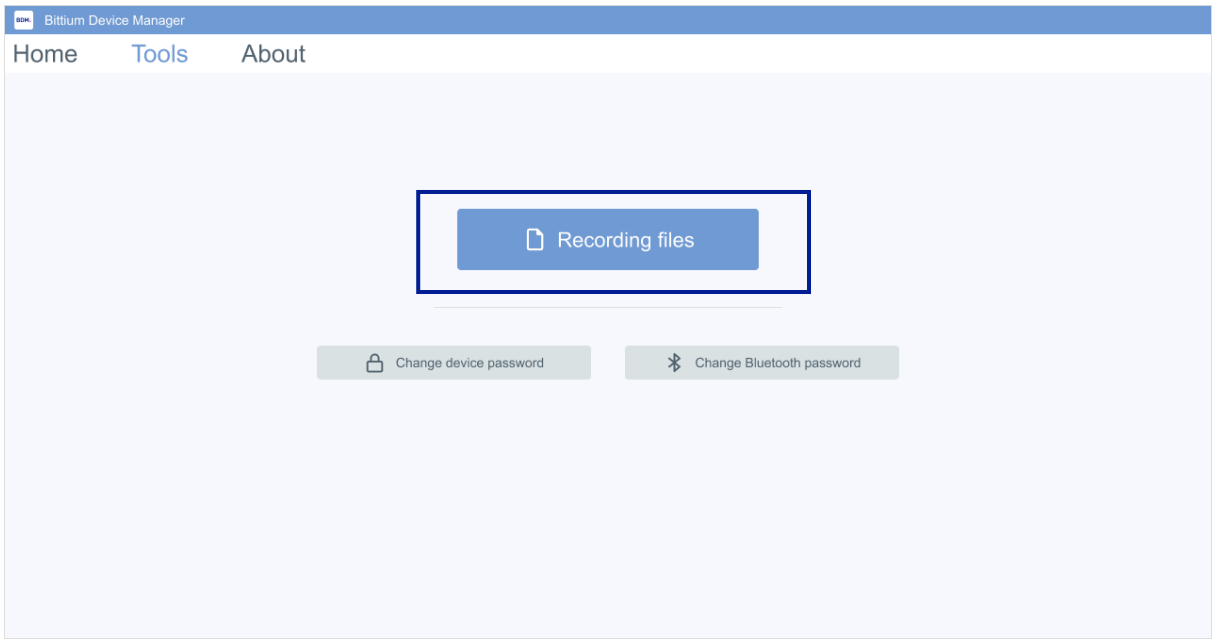


Figure 13 Tools view - loading files

Upon selecting the button, the software begins loading the recording files stored on the ECG device. An information window is displayed showing the progress of the file loading operation.

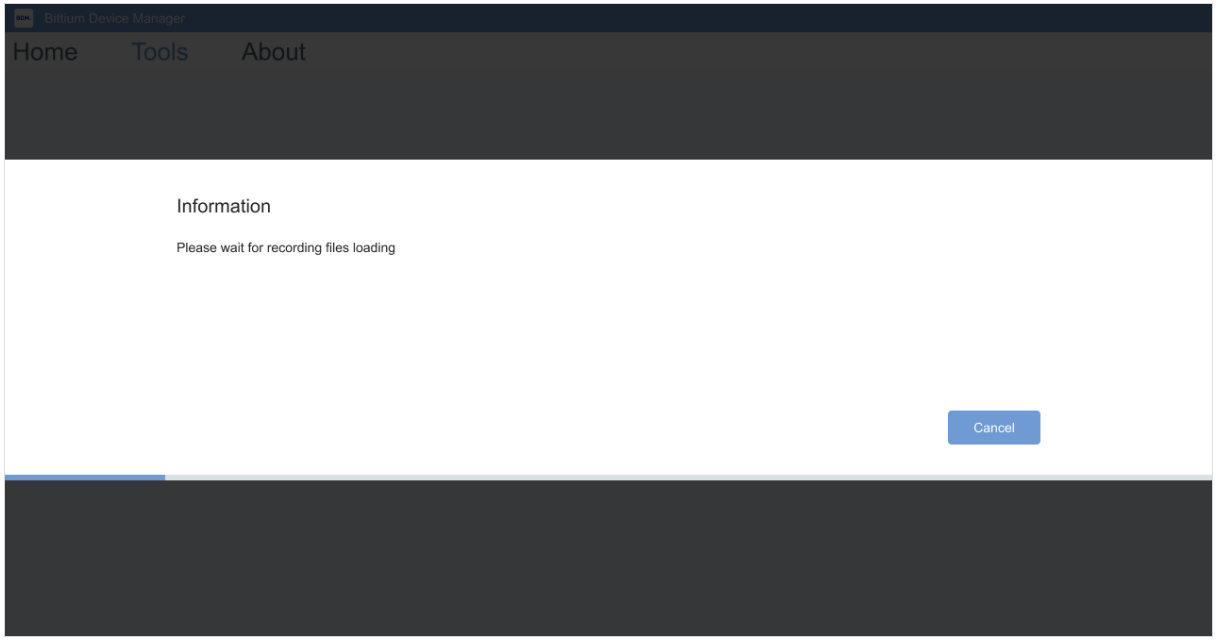


Figure 14 File loading ongoing

The progress window provides status information while files are being retrieved from the device. To stop the operation before completion, select **Cancel**. The loading process is then aborted.

Once the loading process has been completed successfully, the recordings available on the device are displayed in the recordings table.

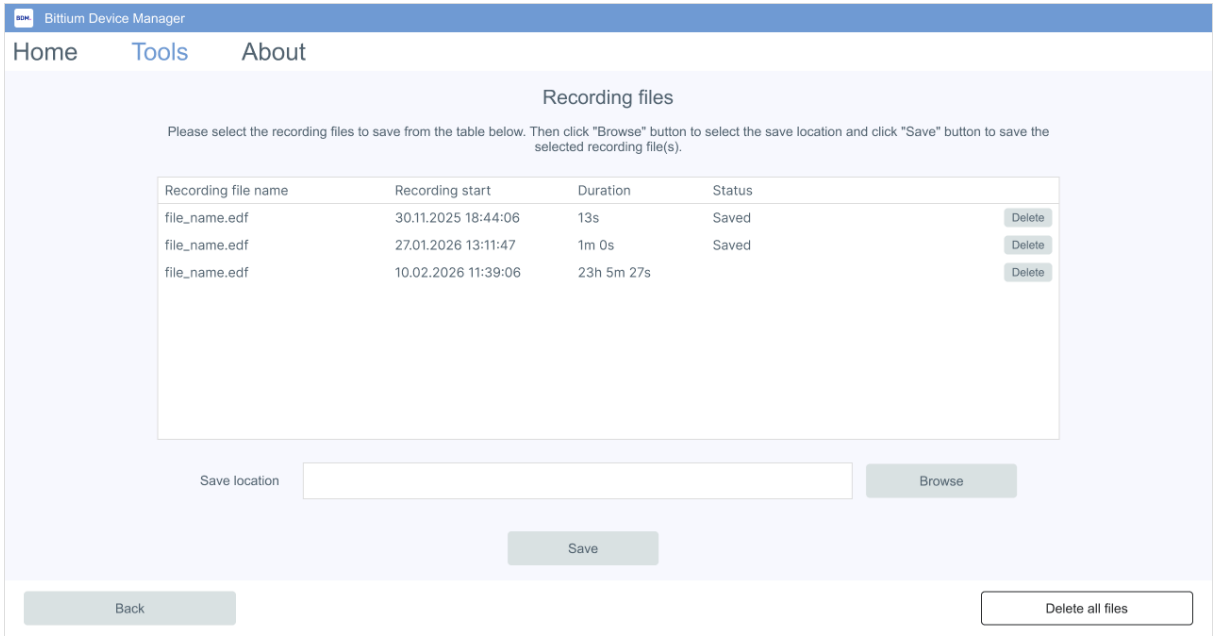


Figure 15 Recordings table

If the software detects a corrupted file during loading, the file is displayed in the recordings table with a **Corrupted File** label and a yellow warning icon. For information on corrupted files and recommended corrective actions, see section: Troubleshooting.

Saving recording files

Recording files displayed in the recordings table can be saved from the device to a computer for further analysis.

The recordings table displays the following information for each recording:

- Recording File name
- Recording start
- Duration
- Status

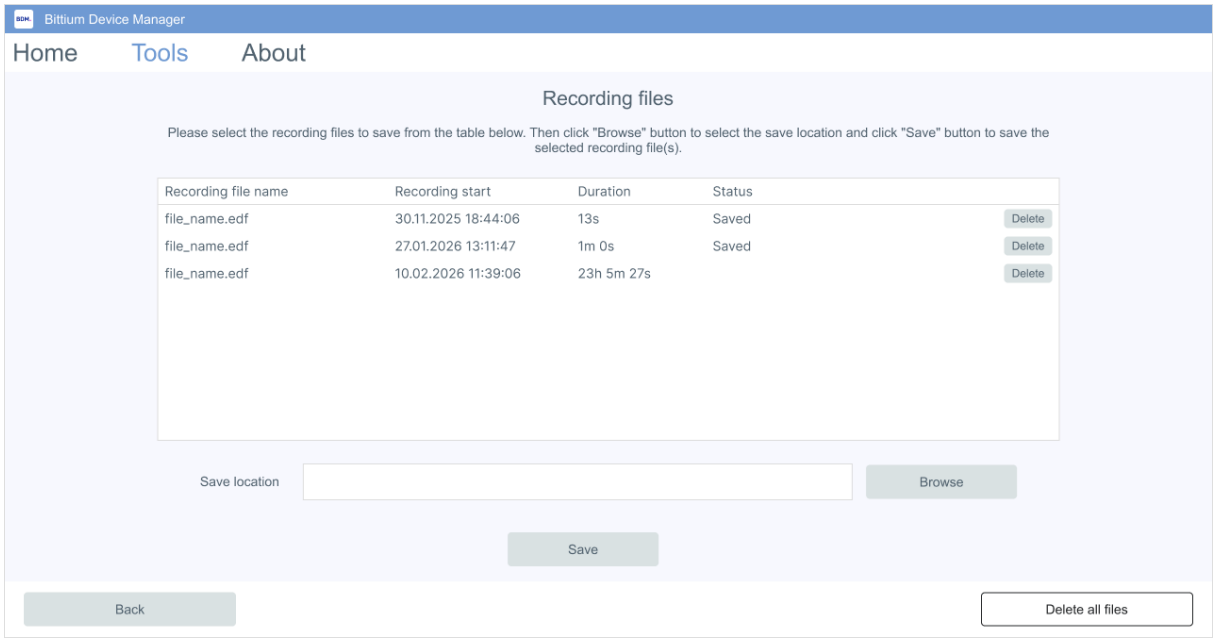


Figure 16 Recordings table

This information supports identification of the correct recordings by verifying date and duration.

NOTE Do not disconnect the device or otherwise interrupt the saving process while recording data is being saved to the computer. This may result in incomplete or corrupted data.

To save recording files:

1. In the table, select the desired recording file(s).
2. Click the **Browse** button and select the desired save location on the computer.
3. Click the **Save** button to initiate saving.

While saving a recording file, a progress window displays the progress of the operation as a progress bar and completion percentage.

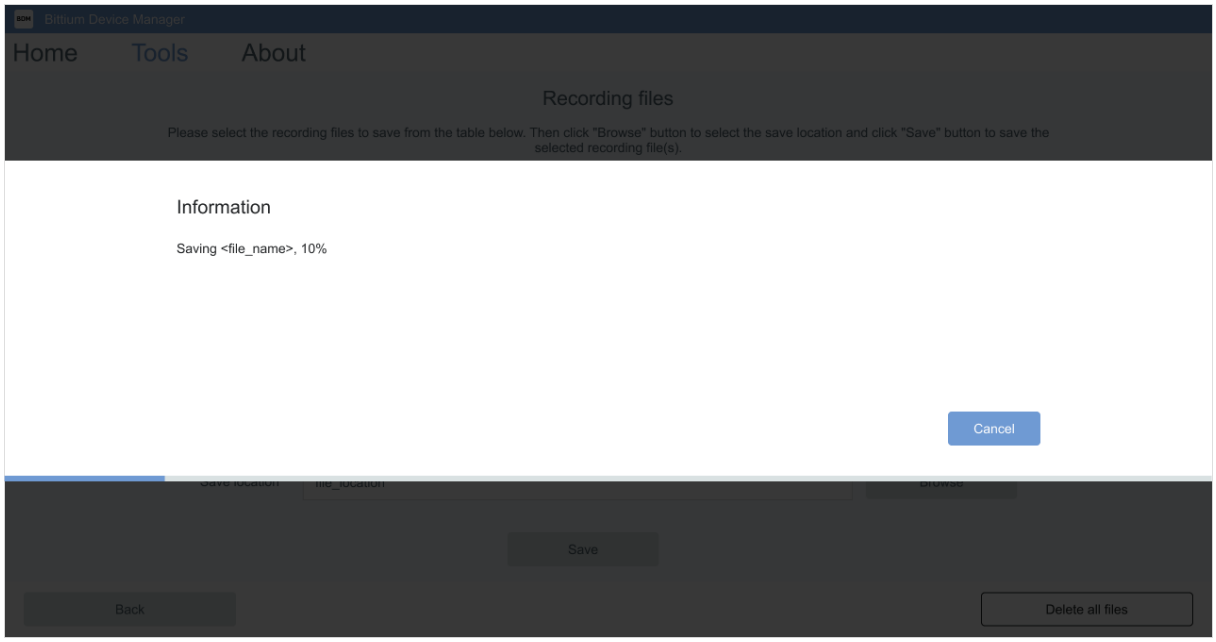


Figure 17 Saving recording file

The saving process can be cancelled at any time. If the operation is cancelled before completion, the affected files are assigned the status **Cancelled**. Files that are saved successfully are assigned the status **Saved**, which is displayed in the recordings table.

4. Select **Delete** to remove the files from the device memory immediately after saving or select **Not now** to keep the files on the device. A confirmation message is displayed after successful deletion.
5. Files can also be deleted later. For detailed instructions, see Section: Deleting recording files.

File status after saving:

- Saved – File saved successfully
- Cancelled – Saving was cancelled

Deleting recording files

The software provides three alternative methods for deleting recordings from the device. Users may select the method that best suits their workflow and operational needs. Deleting files from the device memory permanently removes all patient-related data stored on the device. Verify saved files before deleting from device.

1. Delete immediately after saving

After the files have been successfully saved, the software prompts you to confirm whether you want to delete them.

- **Delete** – Removes the files immediately from the device
- **Not now** – Keeps the files for later deletion

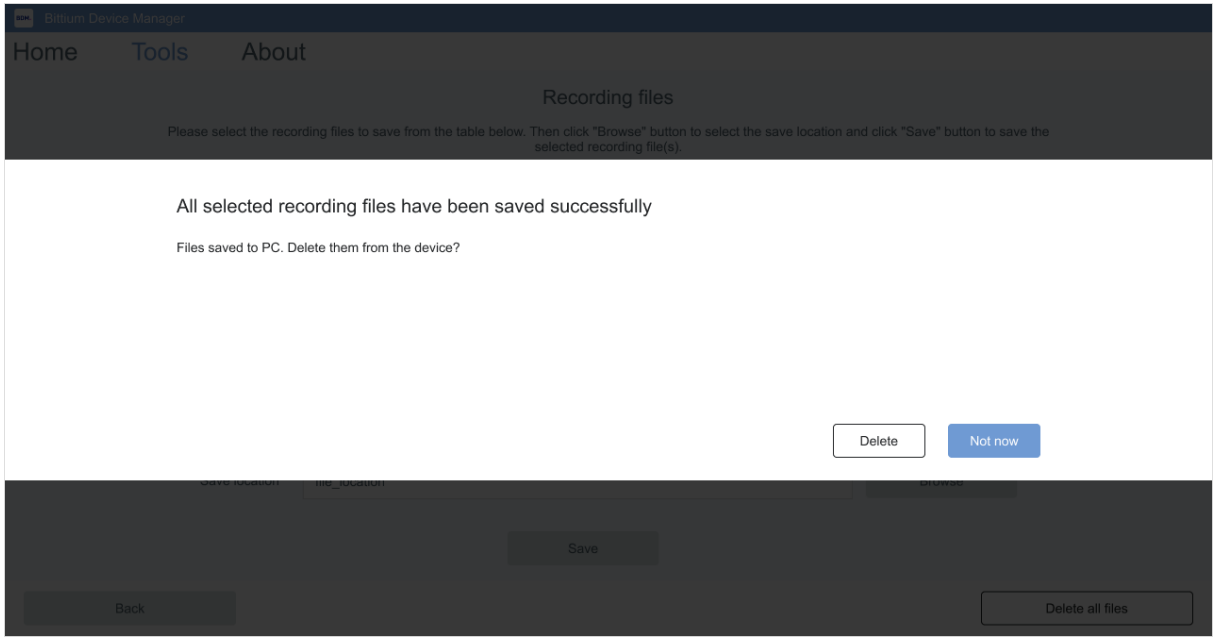


Figure 18 Delete immediately after saving

2. Delete selected files later

Recording files can be deleted individually after saving:

1. Locate the recording file to be deleted in the recordings table.
2. Click **Delete** button at the end of the applicable recording row.
3. Click the **Delete** in the confirmation window.

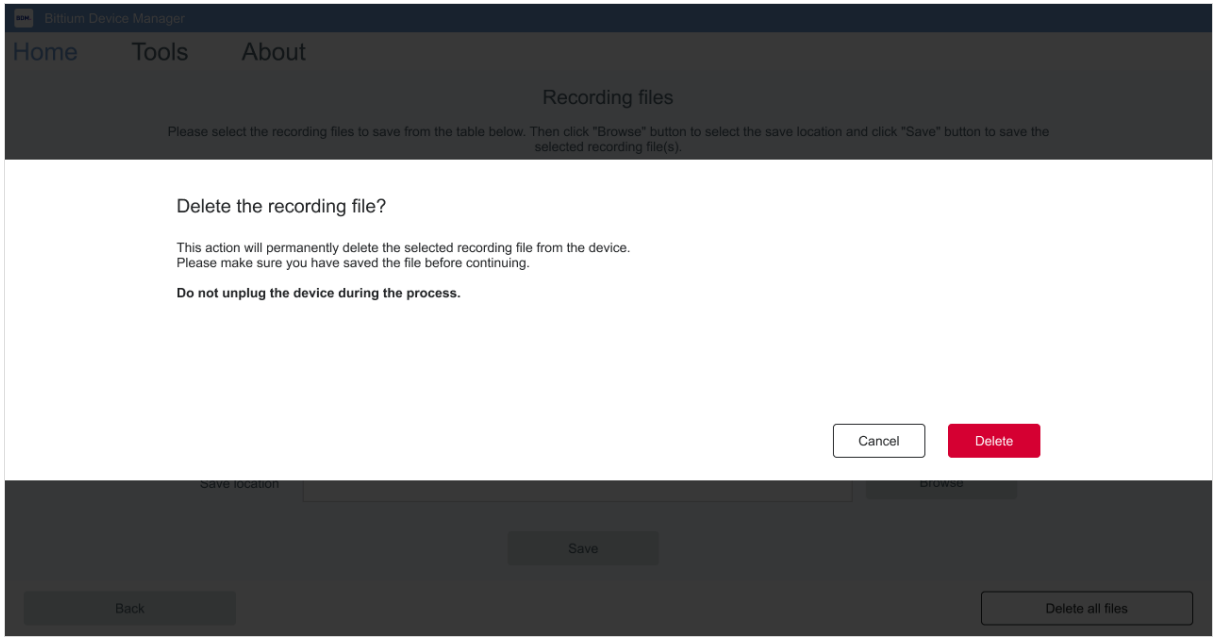


Figure 19 Delete selected files

3. Delete all files at once

Files can be deleted all at once after saving.

1. Click the **Delete all files** button.

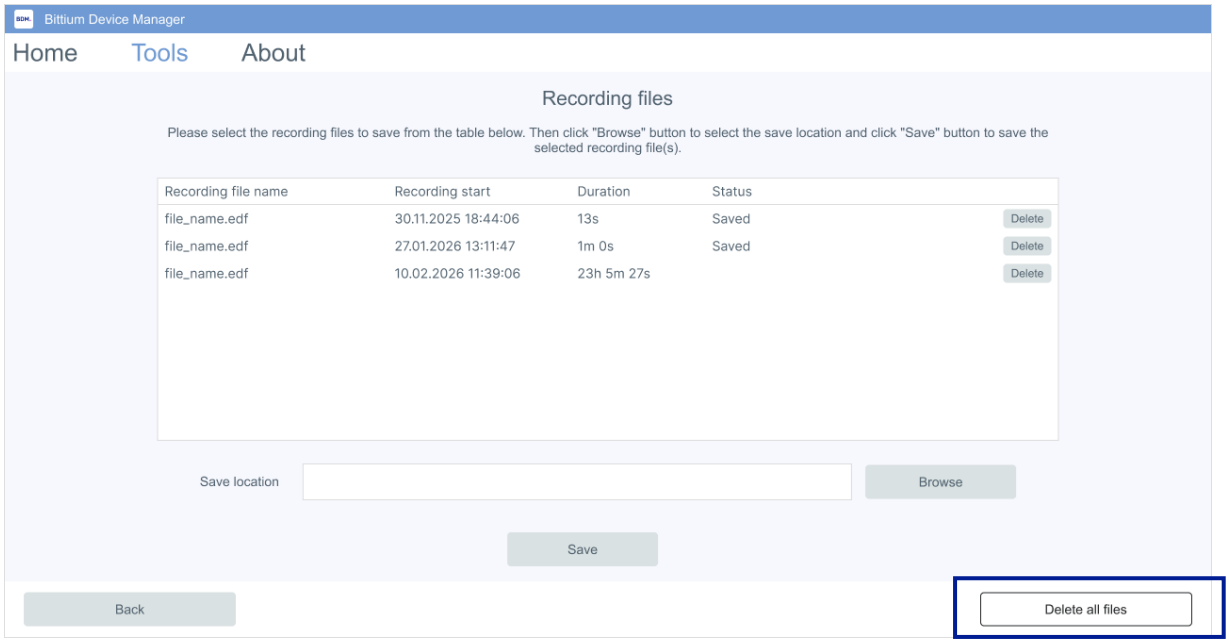


Figure 20 Delete all files button

2. Click **Delete** from the confirmation window.

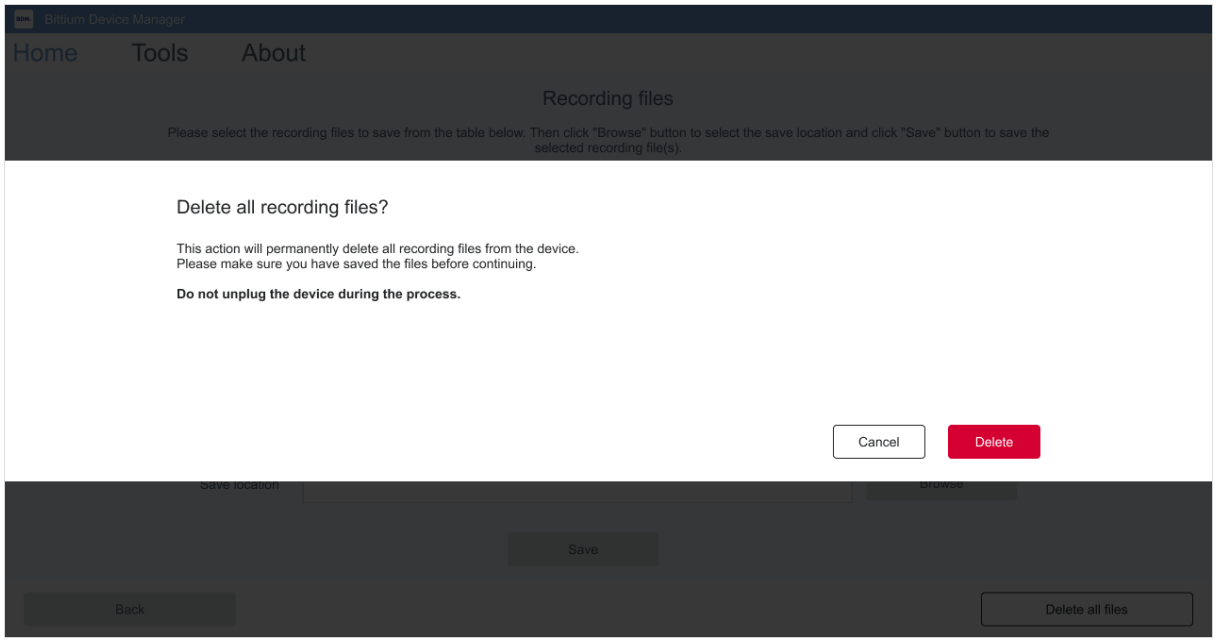


Figure 21 Delete all files at once

All files stored on the device memory are permanently deleted. The software indicates when there are no files in the device memory.

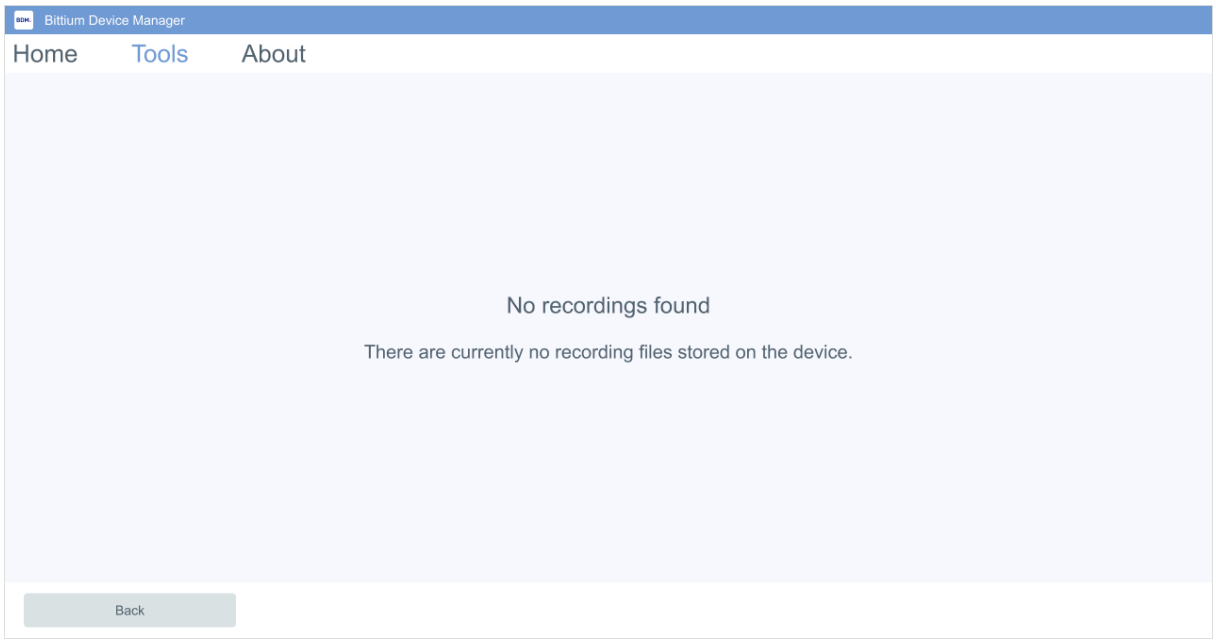


Figure 22 No recordings in device memory

Changing device password

The Bittium ECG devices use password-based security mechanisms to prevent unauthorized access to the device memory. Devices are shipped with integrated password protection. A custom password can be set using Bittium Device Manager software. Strong password policies and password security standards should be followed when managing device passwords.

NOTE: If the device password is changed, the original integrated password cannot be restored by the user. If the original integrated password needs to be restored, the device must be returned to an authorized service center for reset or recovery.

To set device password:

1. Click **Change device password**.

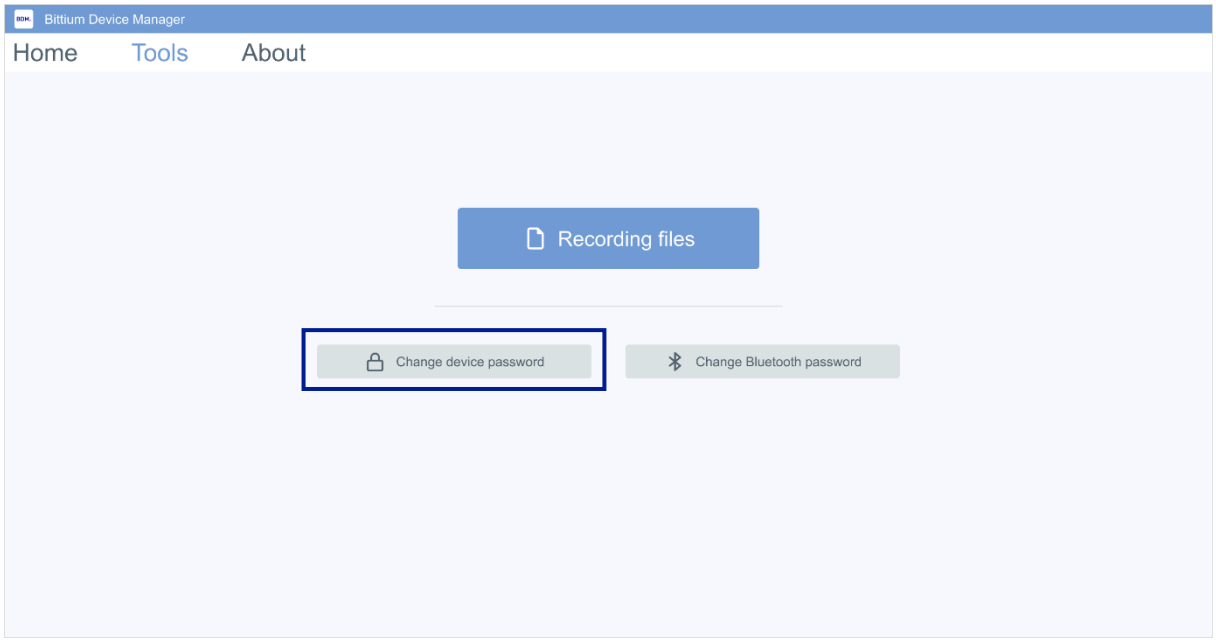


Figure 23 Change device password 1

2. The **Change password** window is displayed.

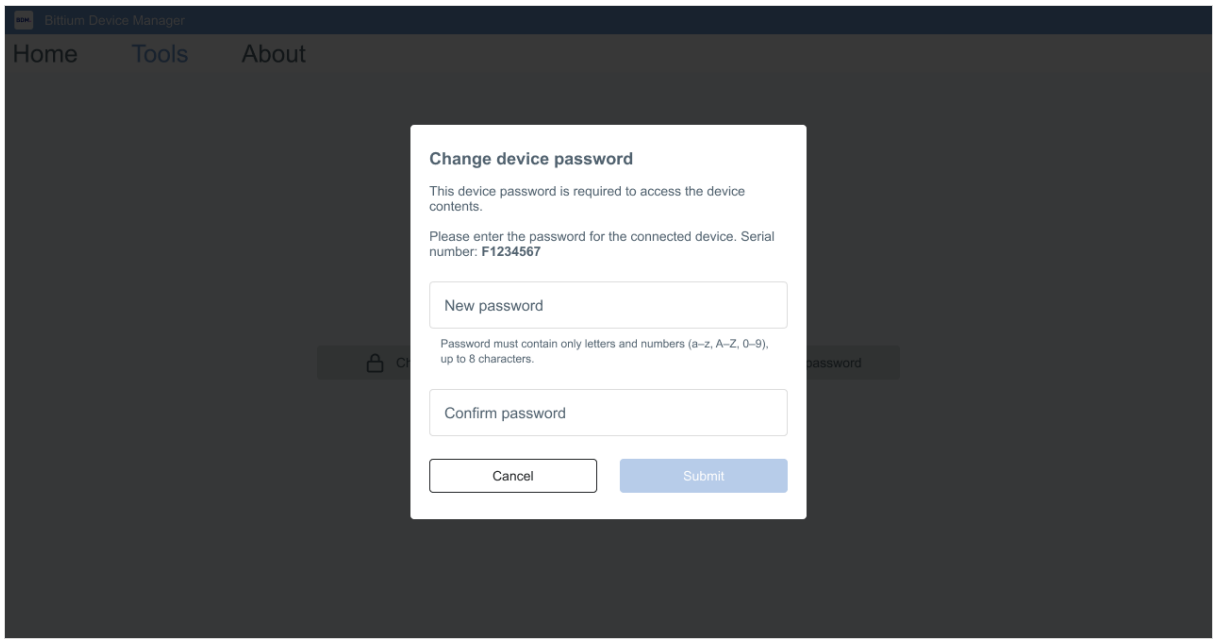


Figure 24 Change device password 2

3. Enter the new device password in the **New password** field.
4. Re-enter the password in the **Confirm password** field.

5. Click **Submit**
6. Password confirmation window is displayed.
    a) Click **Change** to confirm the password update
    b) Click **Cancel** to cancel the password change and return to the previous window

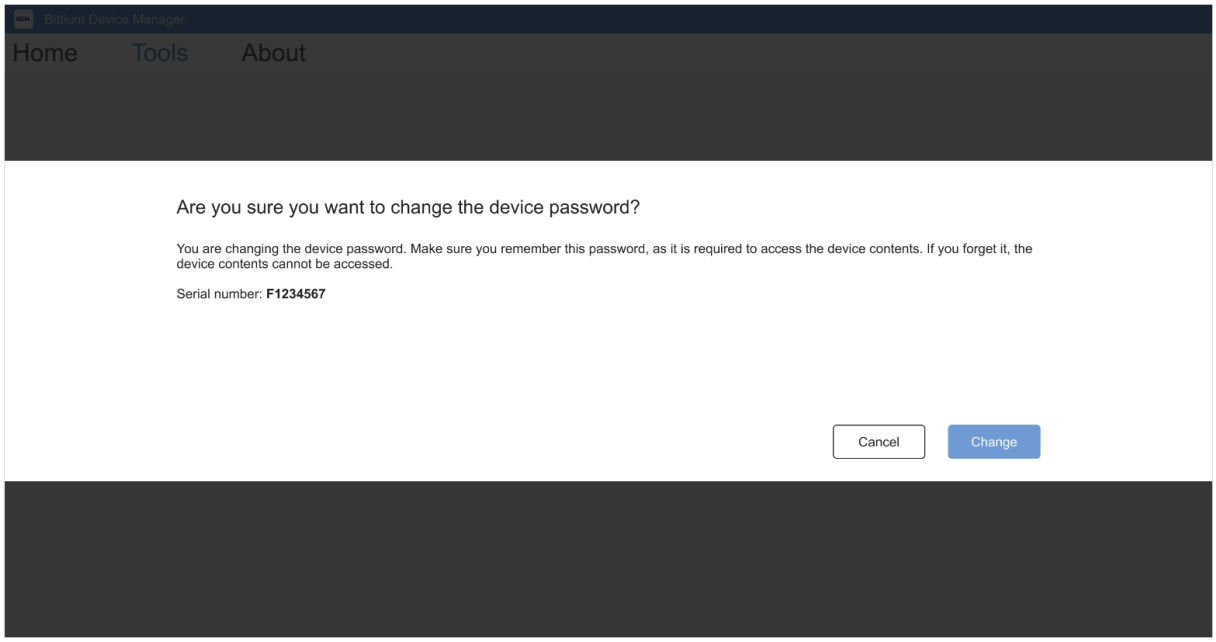


Figure 25 Device password change confirmation window

7. After successful update, a confirmation message is displayed

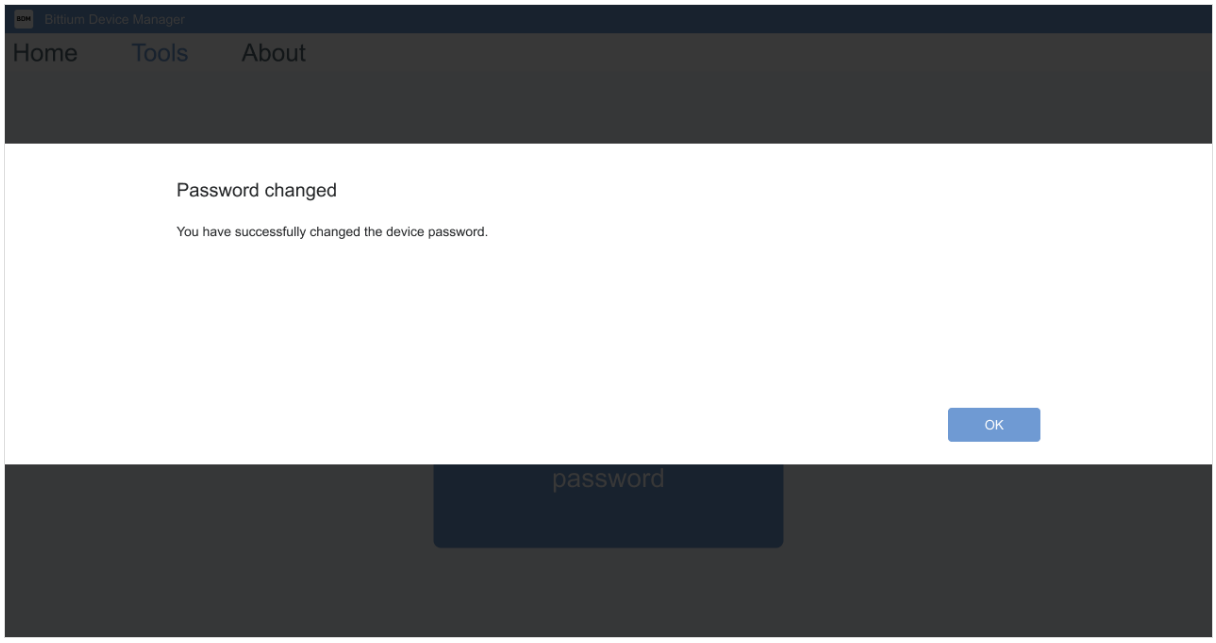


Figure 26 Device password changed successfully

8. Select **OK** to complete the process.

If issues occur during the password change process, refer to the Troubleshooting section of this document.

Changing the Bluetooth password

The Bluetooth password is used for Bluetooth pairing and connection authorization. Setting or changing the password does not establish a Bluetooth connection by itself. The Bluetooth password must be managed according to customer's organizational security policies.

NOTE:	Bluetooth password is used to generate separate Bluetooth PIN-code which needs to be used when pairing devices to Faros Pro using Bluetooth.

To set the Bluetooth password:

1. Click **Change Bluetooth password.**

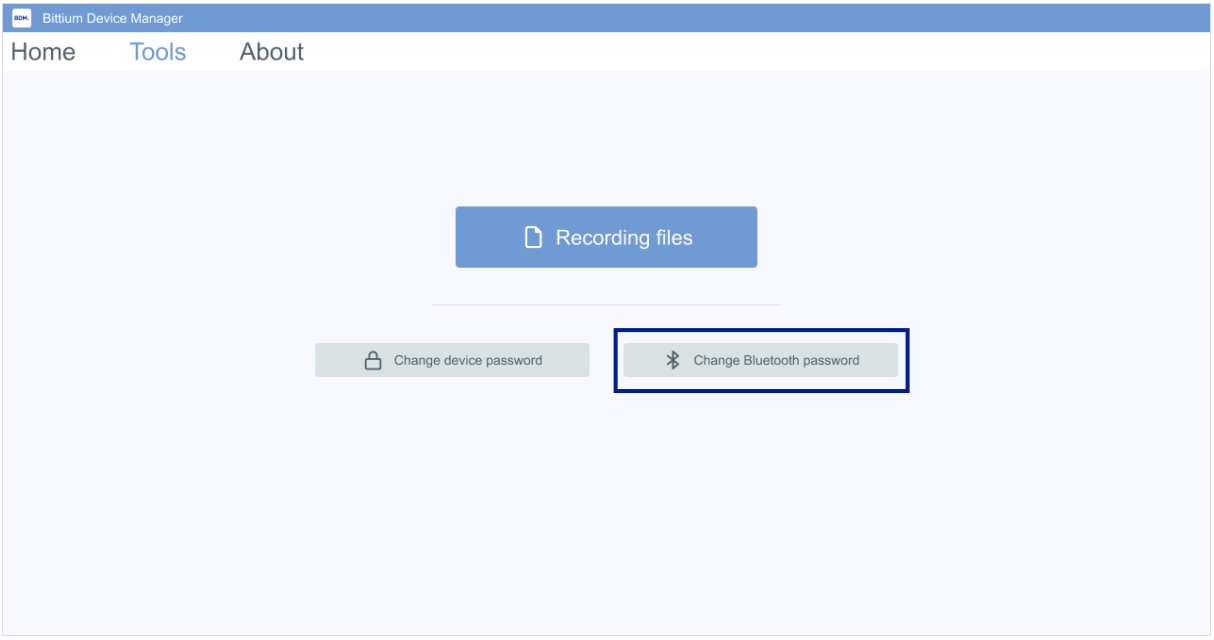


Figure 27 Change Bluetooth password 1

2. The **Change Bluetooth password** window is displayed**.**

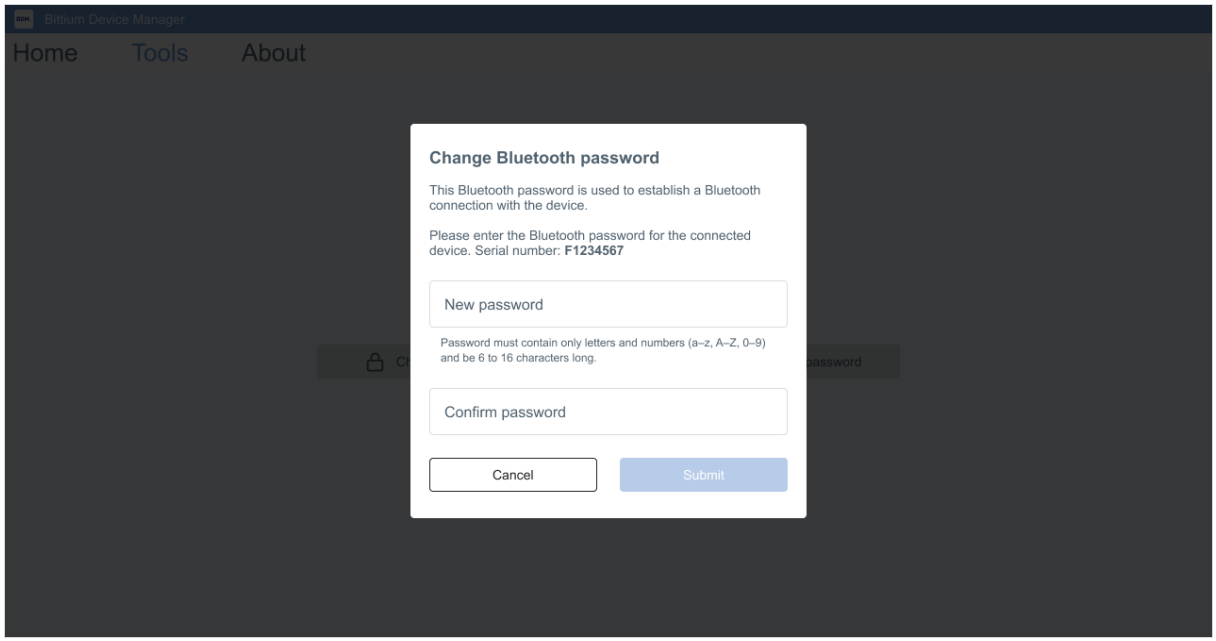


Figure 28 Change Bluetooth password 2

3. Enter the new Bluetooth password in the **New password** field.
4. Re-enter the password in the **Confirm password** field.
5. Click **Submit**
6. Password confirmation window is displayed.
    a) Click **Change** to confirm the password update
    b) Click **Cancel** to cancel the password change and return to the previous window

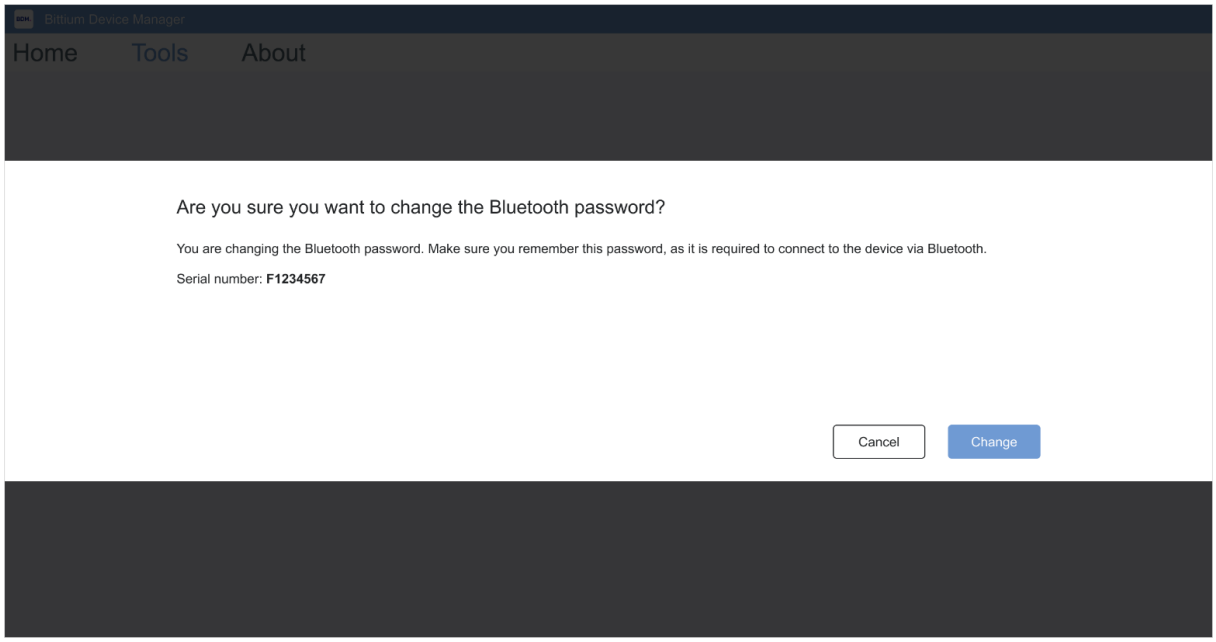


Figure 29 Bluetooth password change confirmation window

7. After successful update, a confirmation message is displayed

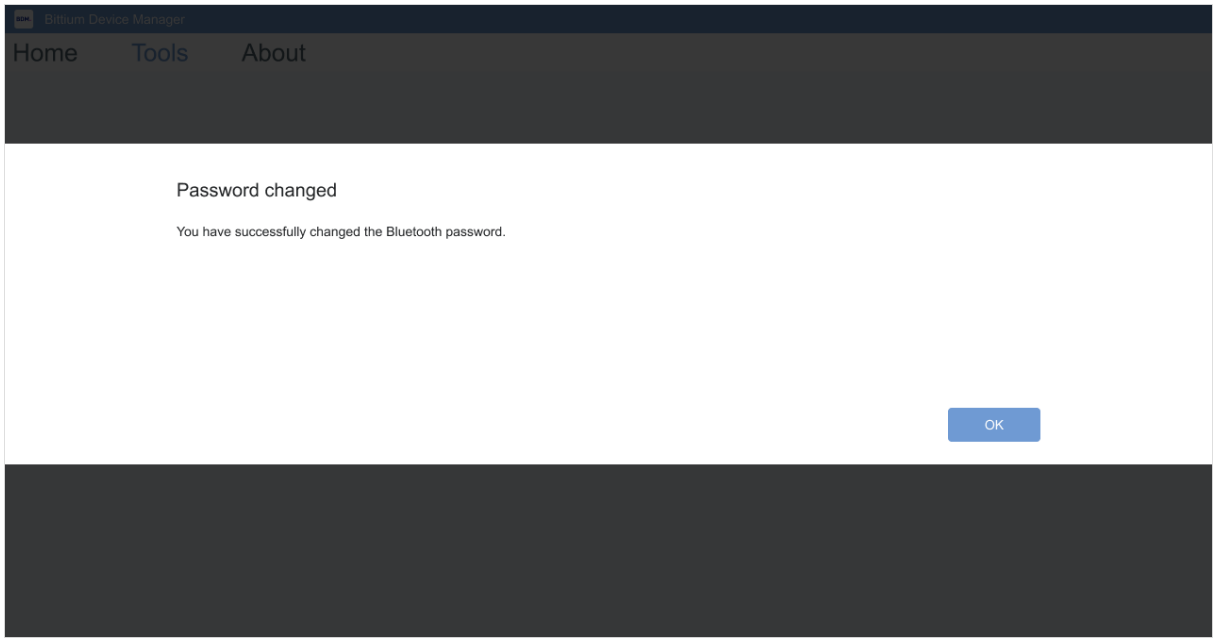


Figure 30 Bluetooth password changed successfully

8. Select **OK** to complete the process.

If issues occur during password change, refer to the Troubleshooting section of this document.

About view – Software and support information

The software provides access to regulatory, identification, and legal information in the About view, including software version details, manufacturer information, regulatory markings, and third-party software license information.

Accessing instructions for use and support

The software provides access to Instructions for Use (IFU) and support resources through the About view.

To access the Instructions for Use:

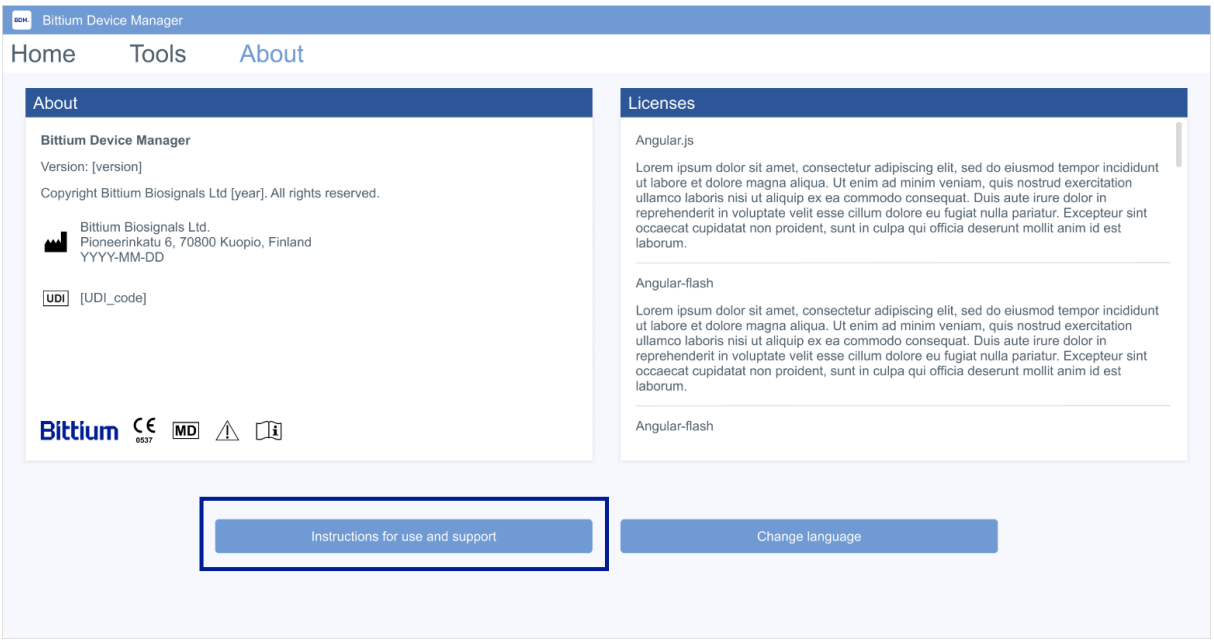


Figure 31 Instructions for use and support button

1. Click the **Instructions for use and support** button.
2. The support website opens in the default web browser of the operating system, where the user can locate the appropriate user manual and other supporting documentation.

Changing the user interface language

The software allows the user to change the language of the user interface.

Changing the language updates the displayed text in the software to the selected language.

To change the language:

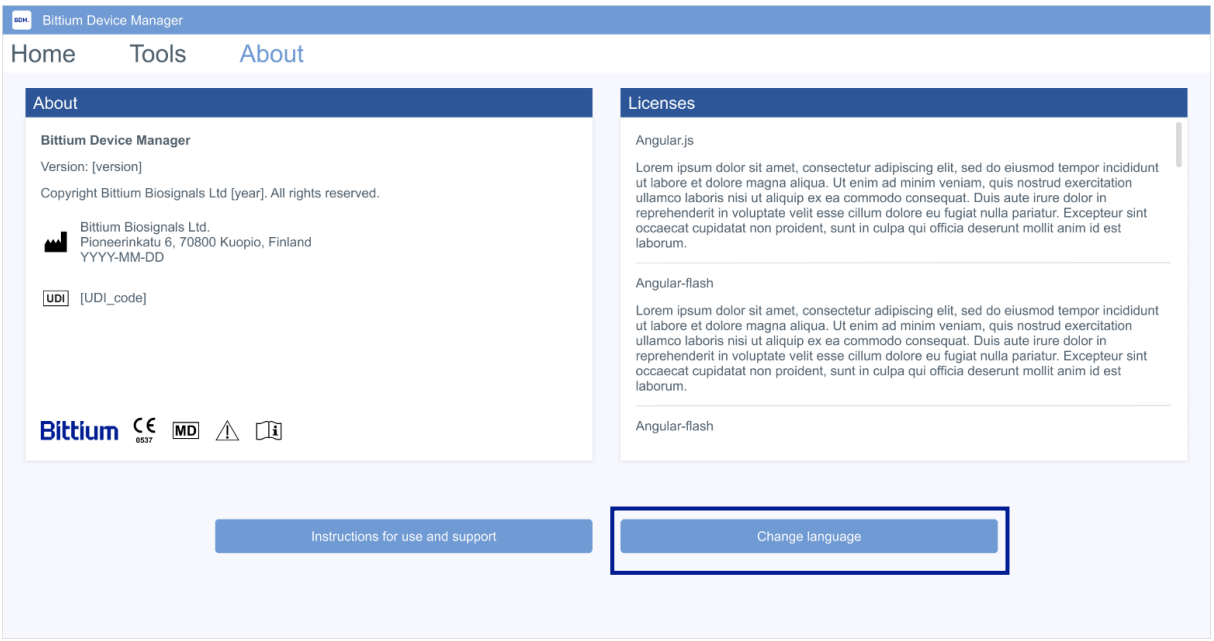


Figure 32 Change language button

1. Click the **Change language** button.
2. Select the desired language from the available options.
3. Save the selection.

The user interface will update according to the selected language.

TROUBLESHOOTING

This section lists common problems that may occur during operation of the software and device, along with possible causes and corrective actions. Identify the message displayed in the software and follow the corresponding corrective actions.

Device connection issues

This section lists issues that may occur during connection of the device to the software, along with possible causes and corrective actions.

Problem	UI message	Possible cause	Corrective action
Device not found	“No Device found. Please make sure device is connected to your PC.”	The device is not connected or not detected via USB.	Ensure the device is properly connected using the USB cable. Select “Search again”
Unsupported device detected	“Unsupported device detected. This application is compatible only with the Faros Pro. Please ensure you download the correct application. Refer to the device’s manual for the right application.”	A device not supported by the software is connected.	Ensure that the connected device is supported (Faros Pro). Verify that the correct application is installed, if using other devices.
Multiple devices detected	“Multiple devices detected. This application can be used with only one supported device at a time. Please keep only a single device connected.”	More than one device is connected simultaneously.	Disconnect additional devices. Ensure only one supported device is connected. Select “Search again”.
Error occurred while connecting the device	“An error occurred while connecting the device. Please disconnect and reconnect the device, close and open the application again.”	Temporary communication failure between the device and the software.	Disconnect and reconnect the device. Close and restart the application. Select “Search again”.
Incorrect password	“Incorrect password. Try again.”	The entered password is incorrect.	Enter the correct password. If unknown, the device must be returned to authorized service for reset or recovery.
Password not entered	“Enter password”	No password entered.	Enter the correct password.

Device system issues

This section lists issues that may occur during device configuration, along with possible causes and corrective actions.

Problem	UI message	Possible cause	Corrective action
Unexpected error	“An unexpected error occurred. Contact customer support if you need help.”	An unexpected error occurred during application operation, device communication, or system loading.	Restart the application. Disconnect and reconnect the device if applicable. If the issue persists, contact customer support.
Unsupported configuration detected	“Unsupported configurations. The connected device contains configuration values that are not supported by the application. You can continue using the application, but configuration changes are disabled. Contact customer support if you need help.”	The device contains configuration parameters not supported by the application (for example, incompatible or modified settings). Depending on the device configuration, the software displays a list of unsupported items.	Contact customer support.
Time synchronization error	“Error. Failed to load time settings from device. Please reconnect the device and try again. Contact customer support if you need help.”	Failure to load time settings due to corrupted or modified configuration file, or mismatch between device time zone and configuration file (e.g., changes made outside the application).	Reconnect the device and restart the application. Ensure device time and time zone settings are consistent. If the issue persists, contact customer support.
Save error	“Error. Failed to save the new settings to the device. Please reconnect the device and try again. Contact customer support if you need help.	The configuration file cannot be updated. The file may be reserved by something else.	Reconnect the device and restart the application. If the issue persists, contact customer support.

Recording management issues

This section lists issues that may occur when saving or deleting recordings, along with possible causes and corrective actions.

Problem	UI message	Possible cause	Corrective action
Failed to save recording(s)	“Error. Failed to save recording file(s).”	Failure during file saving (e.g., communication error, insufficient system resources, or device issue).	Attempt to save the recording again. Ensure the device remains connected during the operation. If the issue persists, restart the application and reconnect the device.
Failed to delete recording(s)	“Error. An error occurred while deleting files. Please check the files in the recording list, make sure the files are not in use and try again. Please reconnect the device, restart the application and try again. If the problem persists, please contact customer support.”	Files may be in use, locked, or a communication error occurred with the device.	Ensure the files are not in use. Reconnect the device and restart the application, then attempt deletion again. If the issue persists, contact customer support.
Corrupted recording file	Indicated by a warning symbol (yellow triangle) next to the file name.	The recording file is corrupted or incomplete.	Do not use the corrupted file. If possible, repeat the recording. If the issue occurs repeatedly, contact customer support.

Device disconnection issues

This section lists issues that may occur when the device is disconnected or removed, along with possible causes and corrective actions.

Problem	UI message	Possible cause	Corrective action
Failed to eject device safely	“Error. Failed to eject the device safely. Please close the software and other processes which use the device disk, then perform ‘Safely Remove Hardware’.”	The device is still in use by the application or another process.	Close the application and any other processes accessing the device. Perform “Safely Remove Hardware” again before disconnecting the device.

Device unplugged during operation	“Error. An error occurred because the device was unplugged.”	The device was disconnected during an active operation.	Reconnect the device and repeat the operation. Ensure the device remains connected until the operation is complete

Device or Bluetooth password issues

This section lists issues that may occur when setting or changing the device or Bluetooth password, along with possible causes and corrective actions.

Problem	UI message	Possible cause	Corrective action
Passwords do not match	“Password you entered doesn’t match the new password.”	The confirmation password does not match the entered new password.	Re-enter the password and ensure that both entries match exactly.
Invalid device password format	“Password must contain only letters and numbers (a–z, A–Z, 0–9, up to 8 characters).”	The entered password does not meet the required format or length constraints.	Enter a password that meets the specified requirements.
Invalid Bluetooth password format	“Password must contain only letters and numbers (a–z, A–Z, 0–9) and be 6 to 16 characters long.”	The entered password does not meet the required format or length constraints.	Enter a password that meets the specified requirements.
Failed to change password	“Failed to change password. Something went wrong while updating the password. Please try again later.”	Temporary failure during password update (e.g., communication or system error).	Attempt the password change again. If the issue persists, restart the application and reconnect the device. Contact customer support if the problem continues.

MAINTENANCE AND UPDATE

Bittium Device Manager software update

Software updates are mandatory to ensure safe and intended operation of the software. Updates are provided as Windows installation packages and shall be installed only by qualified IT personnel or other authorized person within the customer organization. Updates are made available through a manufacturer-controlled secure distribution channel. Before updating, verify the currently installed software version and ensure that the correct update package is used. The update process shall not be interrupted once started.

To update the software, perform the following steps:

1. Obtain access to the update package from the manufacturer or authorized representative.
2. Verify the currently installed software version.
3. Download the applicable update package to the target computer.
4. Close the software if it is running.
5. Start the installation by double-clicking the downloaded file.
6. If prompted by the operating system, allow the installer to run.
7. Follow the on-screen instructions.
8. If the installer requires removal of a previous version, uninstall the existing version using standard Windows application management tools and restart the installation.
9. Complete the installation and wait until it finishes.

Verification of successful software update and related troubleshooting activities are performed using the procedures defined in the chapter Installation verification.

Device firmware update

The software supports firmware updates for compatible ECG devices. When a supported device is connected and the Home view is loaded, the software automatically determines whether a firmware update is available for the device. If an update is available, the software notifies the user and provides instructions for performing the update.

During the firmware update process, progress information is displayed in the software. The update process must not be interrupted once started. Interrupting the update may render the device inoperable. After the firmware update is completed, the software automatically searches for the device again. During this process, the user interface returns to the device search view. If the device is protected with a device password other than the default password, the software prompts the user to enter the password again after the device is detected.

If an error occurs during the update process, the software displays an error message indicating the type of issue, such as device disconnection or a general update error.

After the update is completed, the software indicates whether the firmware update was successful.

SYMBOLS

	CE marking of conformity. May include Notified Body reference number
	Refer to instruction manual
	Manufacturer
	Unique device identifier
	Medical device
	Caution