Cortrium Apex 1.17

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1. Intended use and warnings

Intended use

Cortrium Apex is a software application used to prepare the Cortrium C3+ Holter monitor prior to use for a new patient, manage patient data, order, and view ECG Holter reports, download the recording in .EDF format, and to view the entire ECG recording. In addition, recording data can be downloaded and imported into third-party software for analysis. The software is compatible with both Microsoft Windows and MacOS (see section 12 for minimum requirements).

Intended users

The software is intended to be used by healthcare professionals in private practice, clinics and hospitals as well as remotely.

Warnings

- This product may only be used in accordance with its intended use as mentioned in these instructions
- Users of this product are unique, and should never share passwords
- Screenshots of the software may contain sensitive information and should be avoided
- Data shared outside of the system are at the user's own risk

2. Installation

a. You have been invited to Cortrium Apex by email. Open the invitation email on a computer where you want to install Cortrium Apex
b. Click on the link in the invitation email to set a password
c. Confirm your password
d. Select "Go to next step" to proceed to the download
e. Download the installation file for Windows or MacOS
f. When the download is complete, run the installation file
g. Once the installation is complete, Cortrium Apex will open automatically
h. You can now log in using your email address and the respective password and start using Cortrium Apex

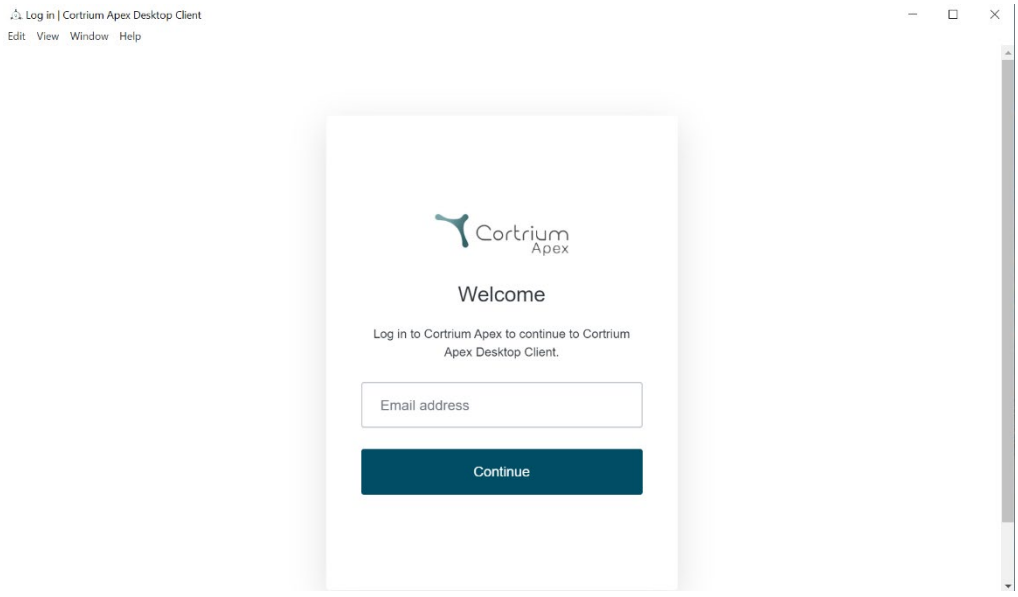
Please note that Cortrium Apex requires an internet connection. You will not be able to log in or use Cortrium Apex without an internet connection

3. Log in to Cortrium Apex

To use Cortrium Apex, you must first have a user login. If you are the administrator of the facility, this has been set up for you by Cortrium. If you are not the administrator and do not yet have a user login, this can be set up by the administrator of your facility.

Once you have installed Cortrium Apex and received your login, you can proceed with the following steps:

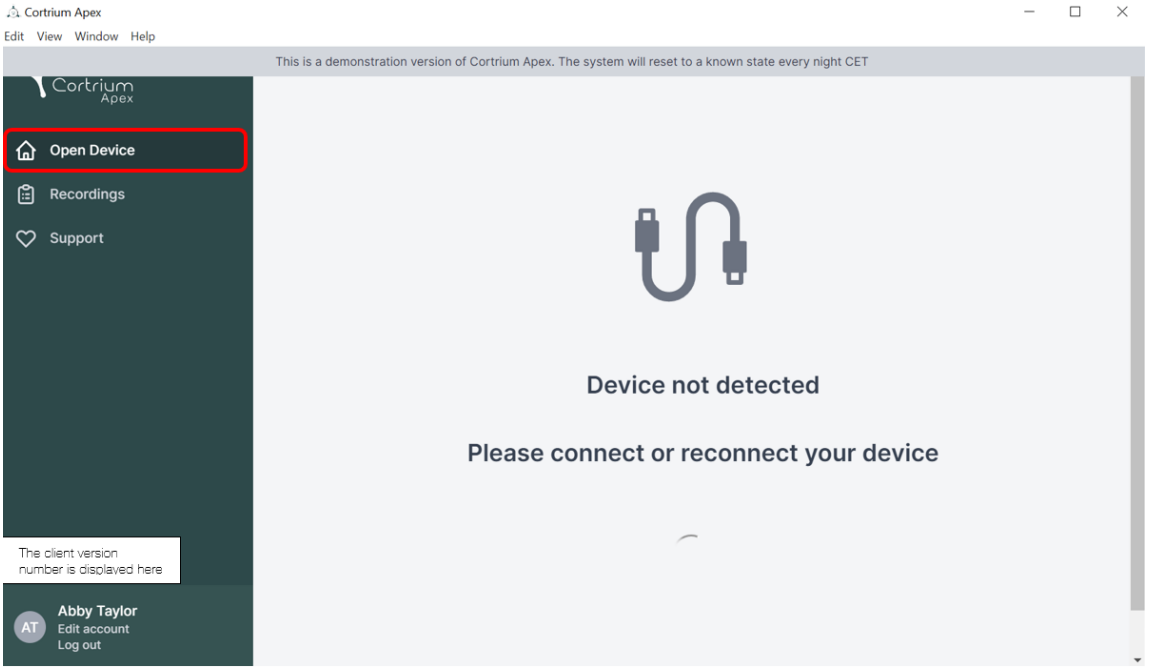
- Open Cortrium Apex on your computer by double-clicking on the Cortrium Apex icon.
- Click on "Sign in" (If you have forgotten your password, click on "Forgot your password")
- Enter your user information and press “Continue”.



4. Prepare the C3+ for a new patient

If the C3+ has already been used to record a long-term ECG, please read the section "Order a Holter report" before following the steps in this section.

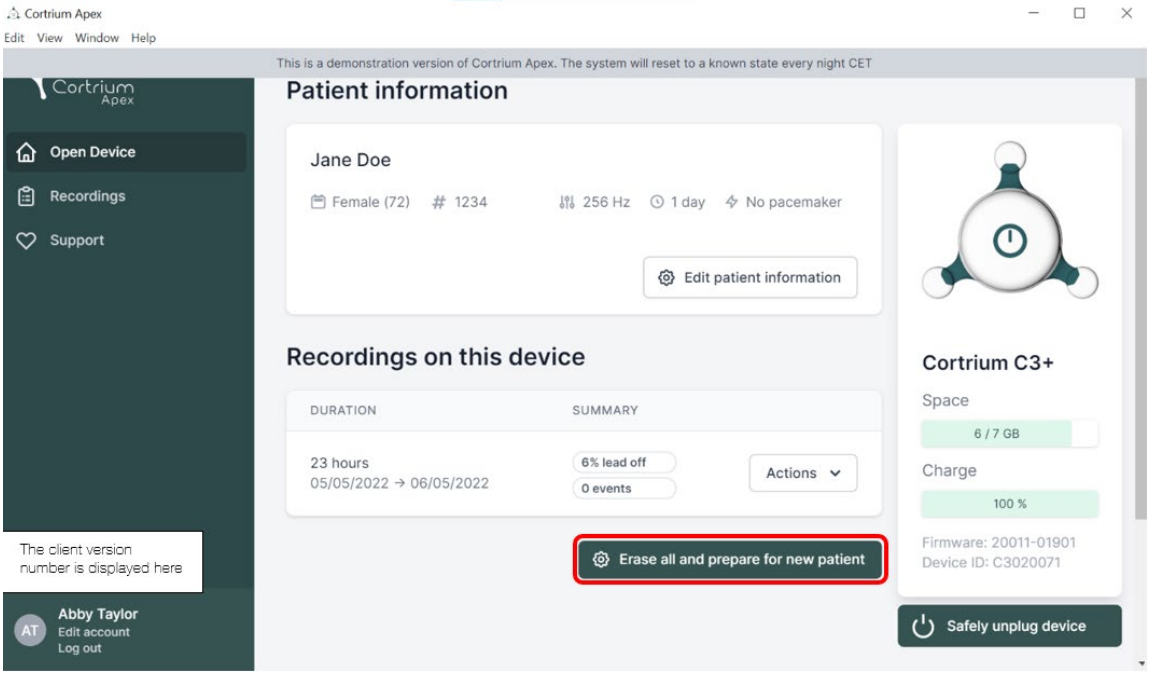
- Select the "Open Device" button.



- Connect the C3+ to the computer using the USB cable provided.

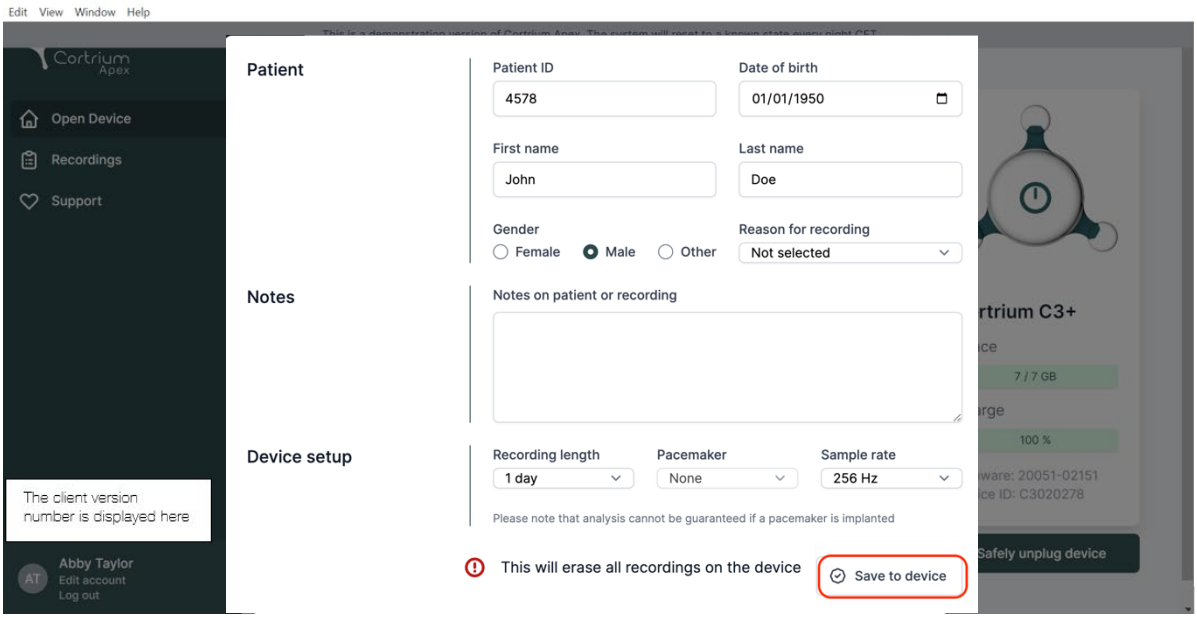
  (If you are using an Apple product, you may need a USB converter)

- Cortrium Apex displays information about the connected device and any data stored on it.



- Select "Erase all and prepare device for new patient".
- Fill in the relevant patient and recording information:

- Now click on "Save to Device". This deletes all patient data or recordings stored on the device and saves the new patient information in the system.

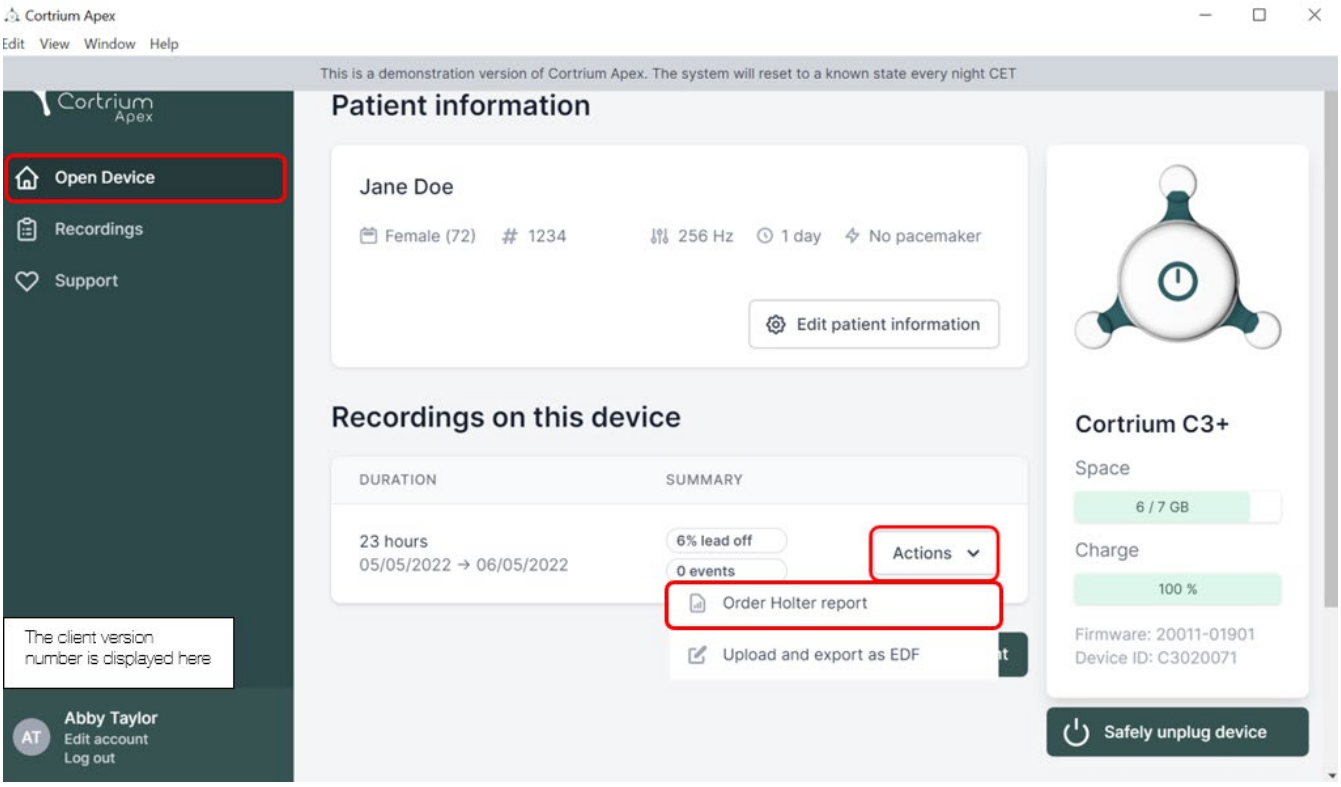


- You can now eject your device via the "Safely unplug device" button on the right-hand side.
- The C3+ is now ready for a recording on a new patient.
- In case you typed in wrong patient information, the information can be edited by clicking on “Edit patient information”.

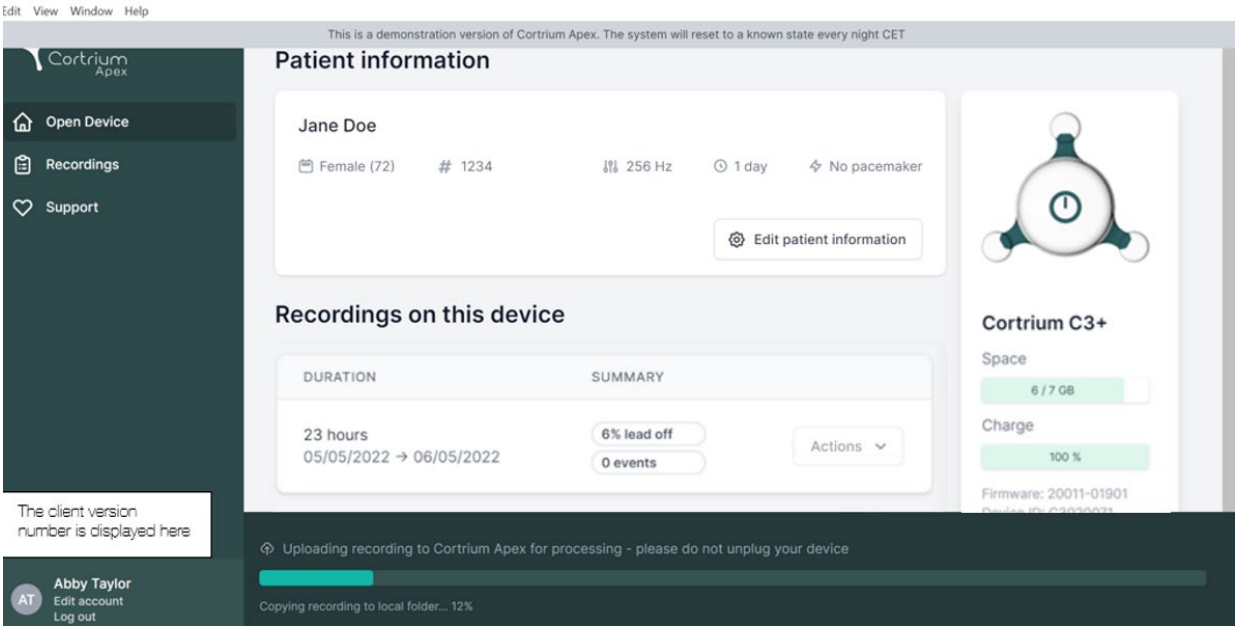
5. Order a Holter report

Cortrium Apex allows you to send recordings for analysis and download the Holter report as soon as it is available. When a device is returned with a recording, click on the Open device button and now you can select your next steps using the "Actions" button. By default, you have the following two options:

- Order Holter report
- Upload and export as EDF



To order the Holter report, click on the "Actions" button and then on Order Holter report. The recording is now uploading.



After uploading the recording, the Holter report will be made available when analysed. The device can already be prepared for a new patient as soon as the recording has been uploaded.

Depending on your account settings you will be informed via email when the Holter report is ready to view. Apex also presents newly completed reports with a red dot for easy identification.

The next section explains how to view the Holter report as soon it is analysed and how to view the entire recording right after upload.

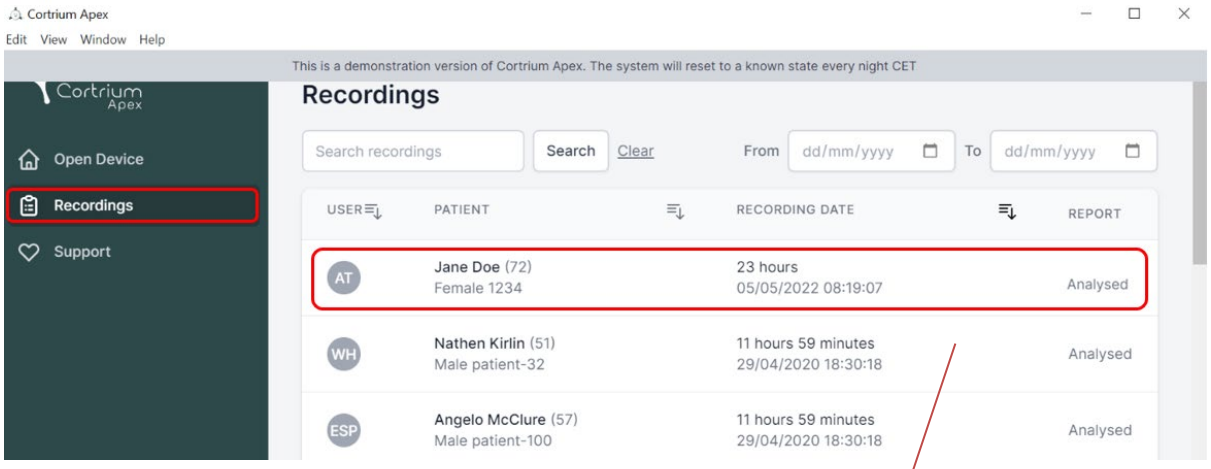
6. View Holter reports and the entire recording

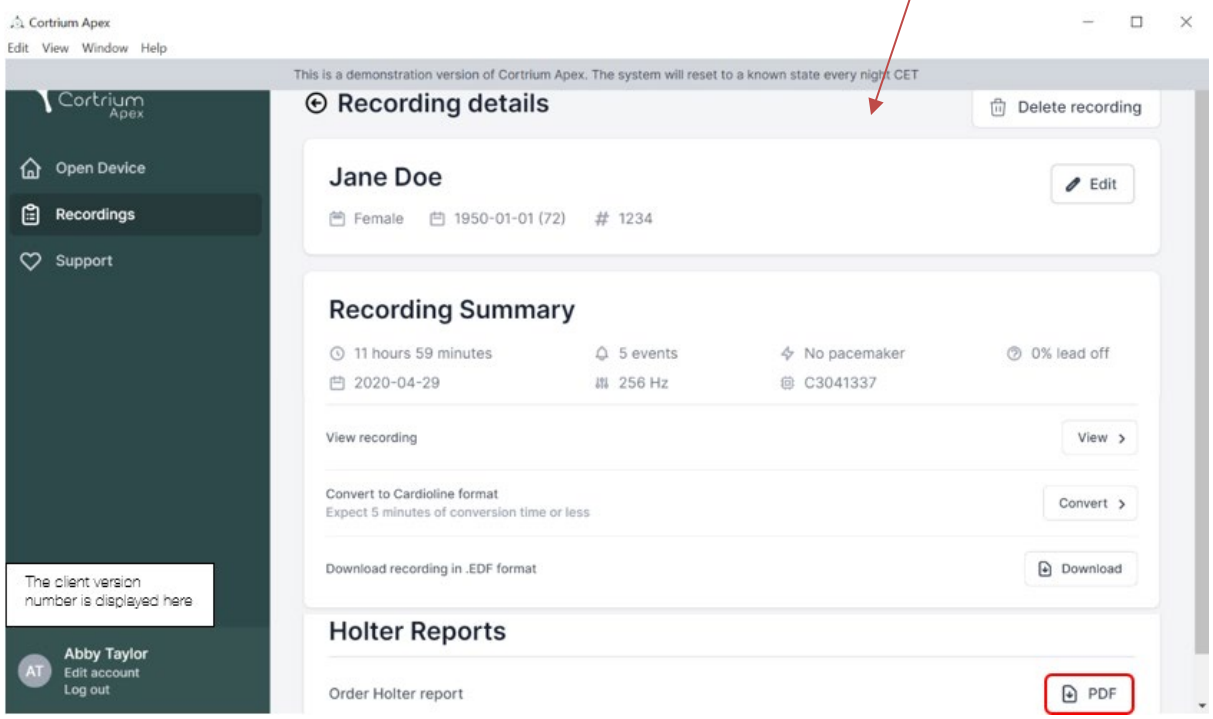
In Cortrium Apex you can view the Holter reports as PDF and you can view the entire recording right after uploading it for analysis. How to view the Holter reports is described below and how to use the ”Recording viewer” is explained in section 6.2.

6.1 View Holter reports

Once a recording has been analysed, you can view the Holter report as a PDF.

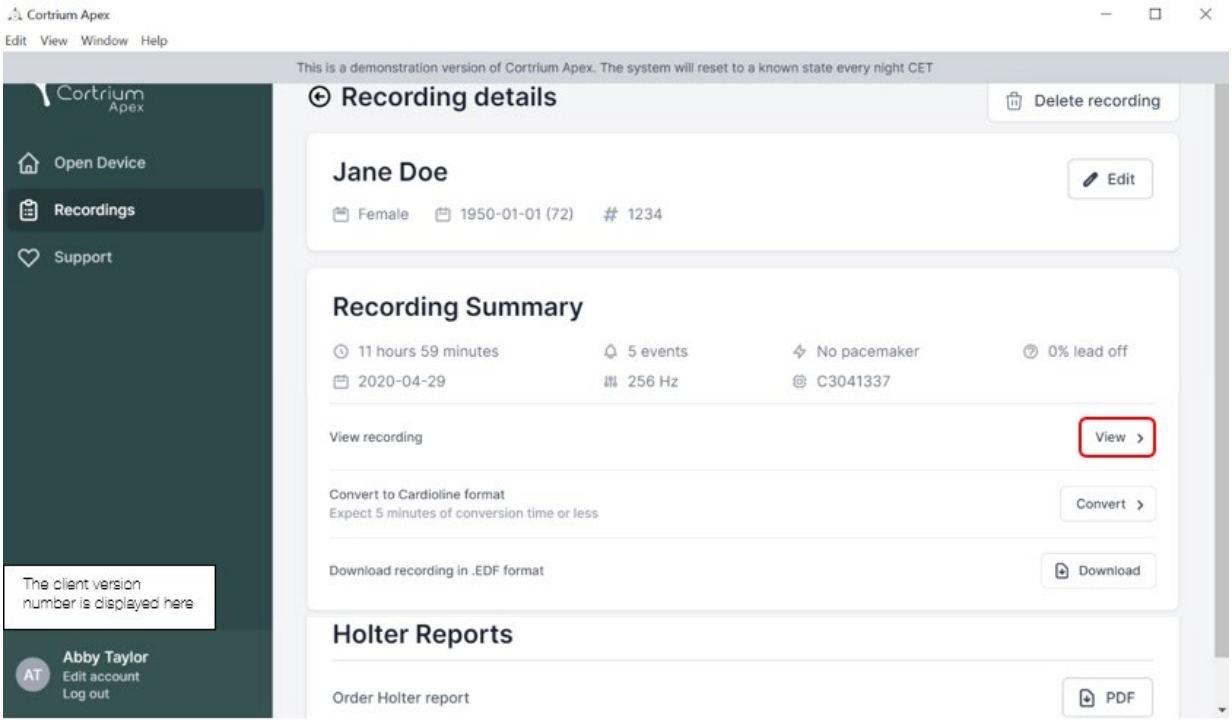
To do this, go to the menu item "Recordings" and click on the respective patient. You can then view the PDF report in the last line under Holter report. The Holter report will open in your web browser.





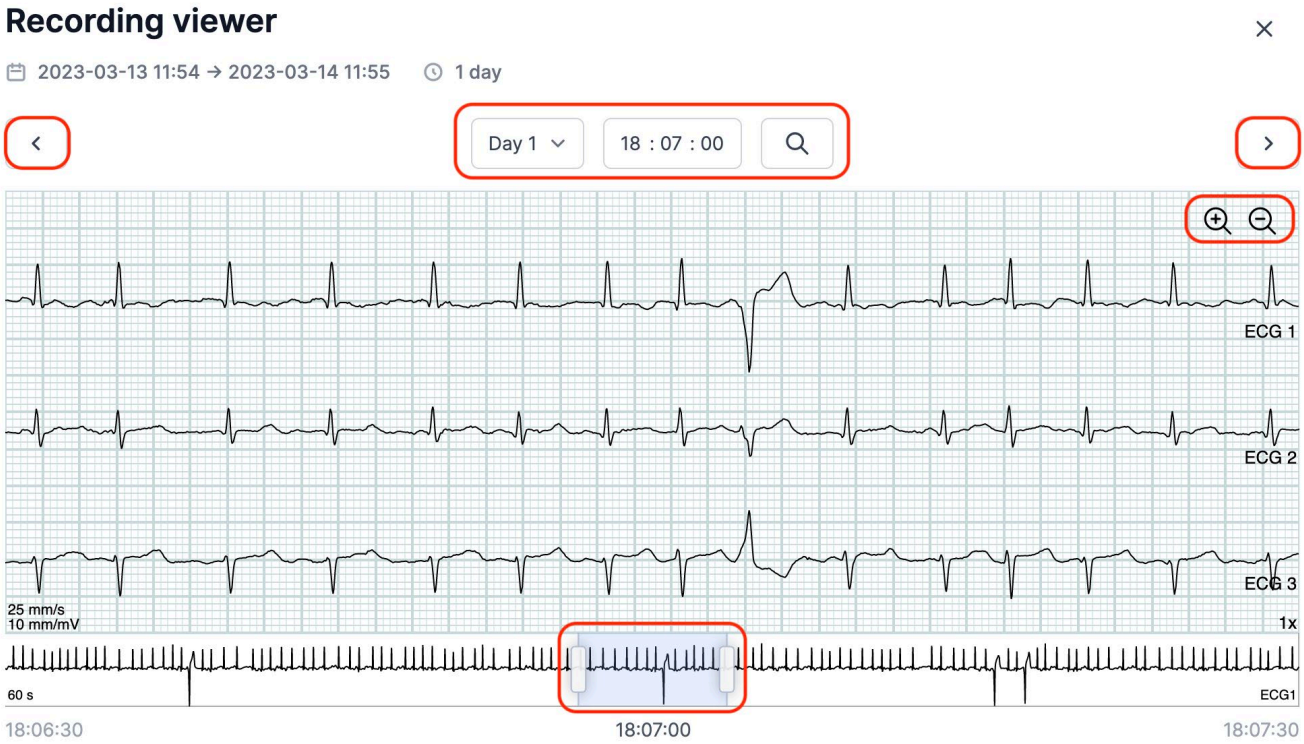
6.2 Recording viewer

To view the entire recording after upload, click on recordings and select the patient whose recording you want to view (see first screenshot in section 6.1). Now you can use the Recording viewer by pressing the ”View” button.



The recording viewer opens.

- The viewer loads 1 minute of data, and shows 7 seconds of ECG at a time.
- With the highlighted interactive features, you can choose the day, hour, minute, and second you would like to view in the recording. Select the time and click on the search icon to confirm the setting.
- By holding and dragging the light blue bar on the bottom of the viewer you can view the 60 seconds surrounding the chosen timepoint.
- By clicking on the navigation arrows or dragging the view to the edge, you can move forwards and backwards in the recording.
- Additionally, if the signal amplitude is low, you can increase it by using the zoom functionality.



To close the Recording viewer, click on the ”x” in the top right corner.

6.3 Summary editor

After receiving your report, you have the option for editing the summary if you have specific wording or information you would like to include.

To do this, click on recordings and select the patient whose report summary you would like to edit.

Now you can use the Summary editor by pressing the ”Edit report” button in the last line under Holter report.

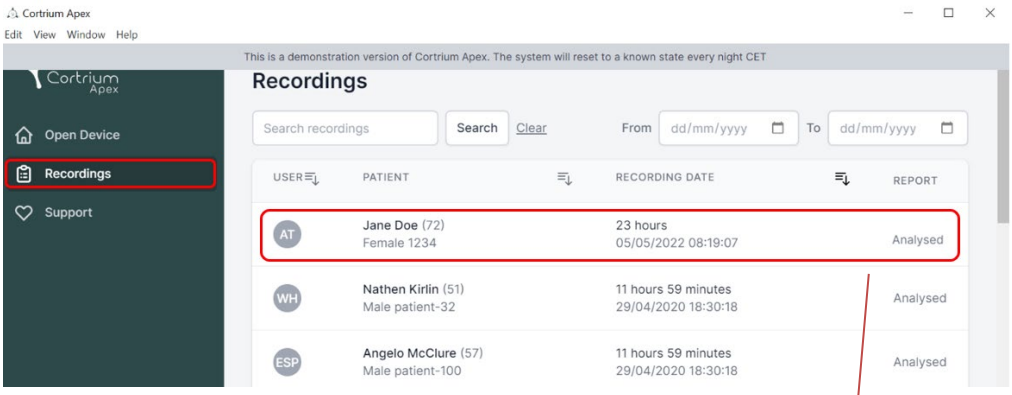
7. Edit patient details and view details of recordings

After selecting the menu item "Recordings", you can click on a recording to open a summary with the related details.

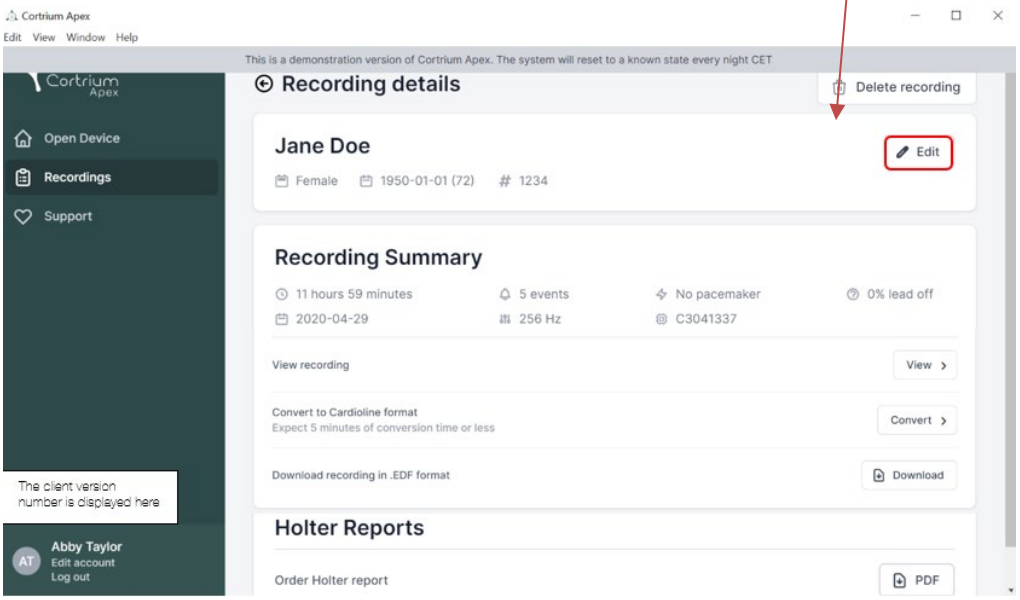
The summary of the recordings contains details such as:

- Duration of the recording
- Start date and time
- Lead off, i.e., periods when the electrodes were not in contact with the body

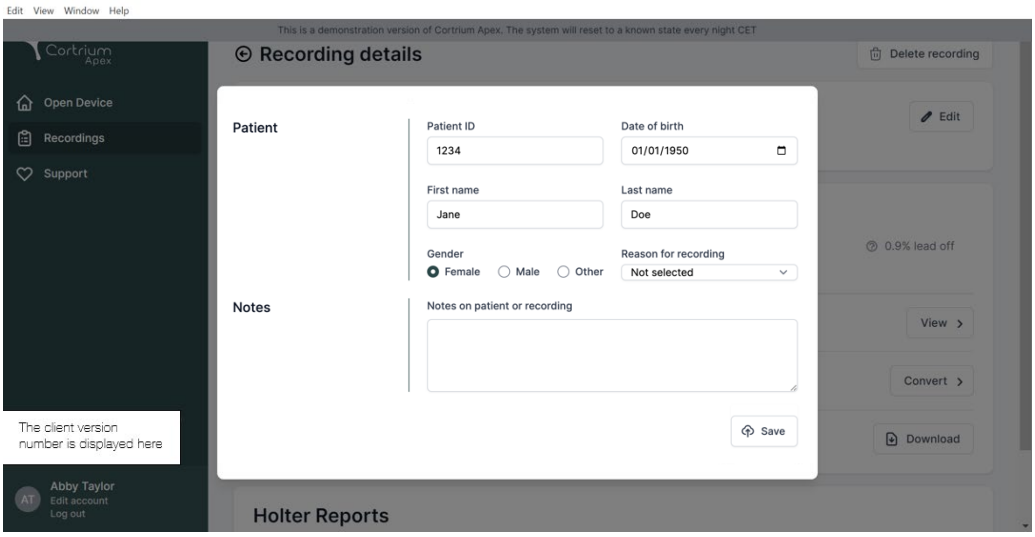
- Events, when the patient pressed the button to indicate symptoms or an event
- Sampling frequency of the ECG signal
- Information about pacemaker if noted when the device was prepared for a new patient



The patient information can be edited by clicking on the "Edit" button.

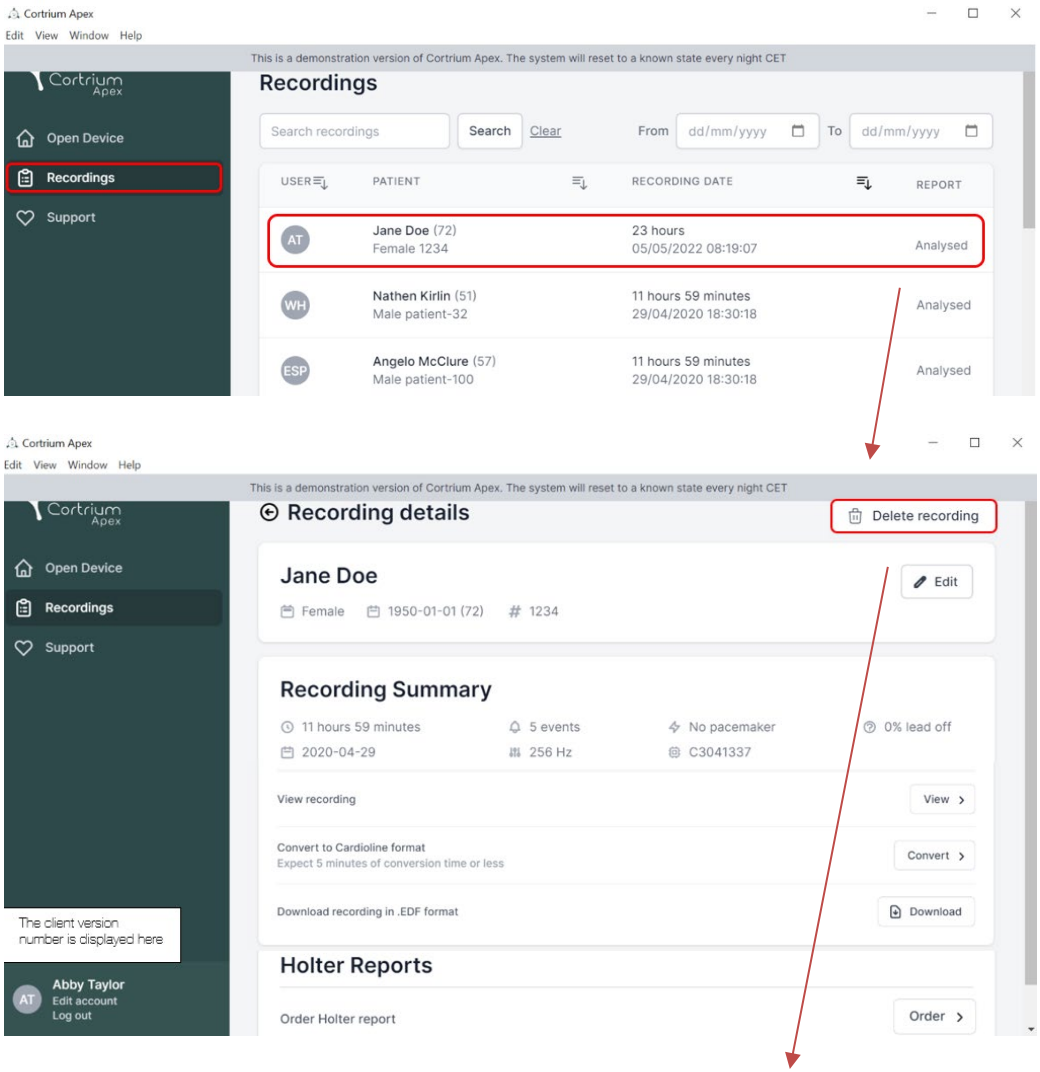


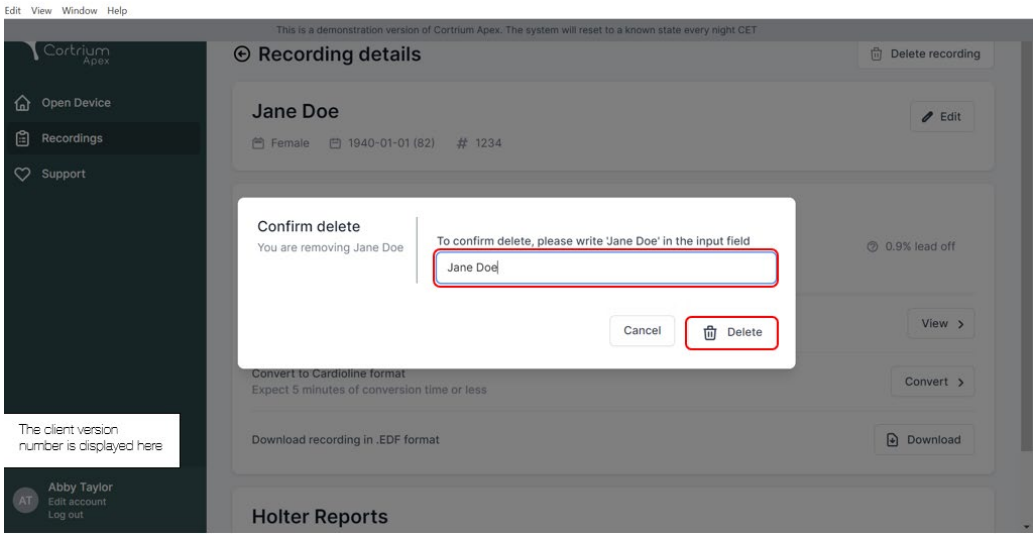
The adjustments can be saved by clicking on the “Save” button.



8. Delete a recording

To delete a recording, open the “Recordings” section and click on the recording you want to delete. Now click on “Delete recording” in the top right corner. After typing in the patient name the deletion must be confirmed by pressing “Delete”.




Edit View Window Help
This is a demonstration version of Cortrium Apex. The system will reset to a known state every night CET
Cortrium Apex
Open Device
Recordings
Support
Recording details
Delete recording
Jane Doe
Edit
Female
1940-01-01 (82)
1234
Confirm delete
You are removing Jane Doe
To confirm delete, please write 'Jane Doe' in the input field
Jane Doe
Cancel
Delete
0.9% lead off
View
Convert to Cardioline format
Expect 5 minutes of conversion time or less
Convert
Download recording in .EDF format
Download
The client version number is displayed here
Abby Taylor
Edit account
Log out
Holter Reports

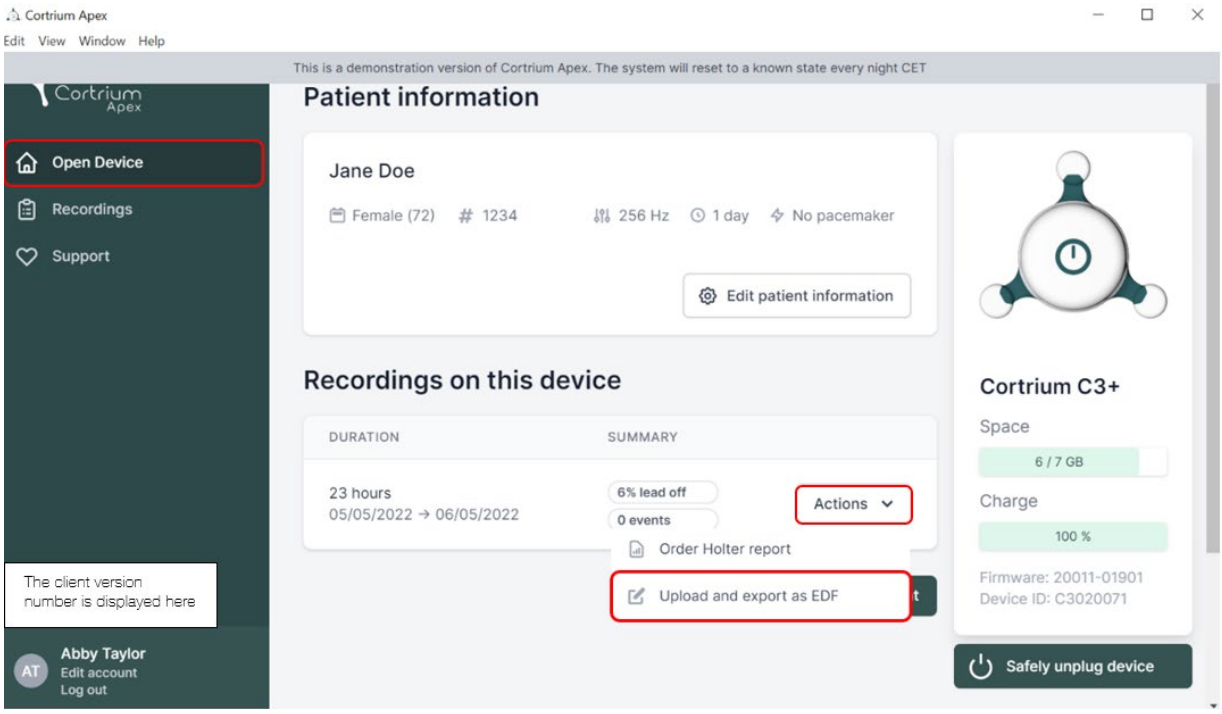
9. Download EDF file

The EDF file can be downloaded before ordering the Holter report or after. The two different cases are described in the next sections.

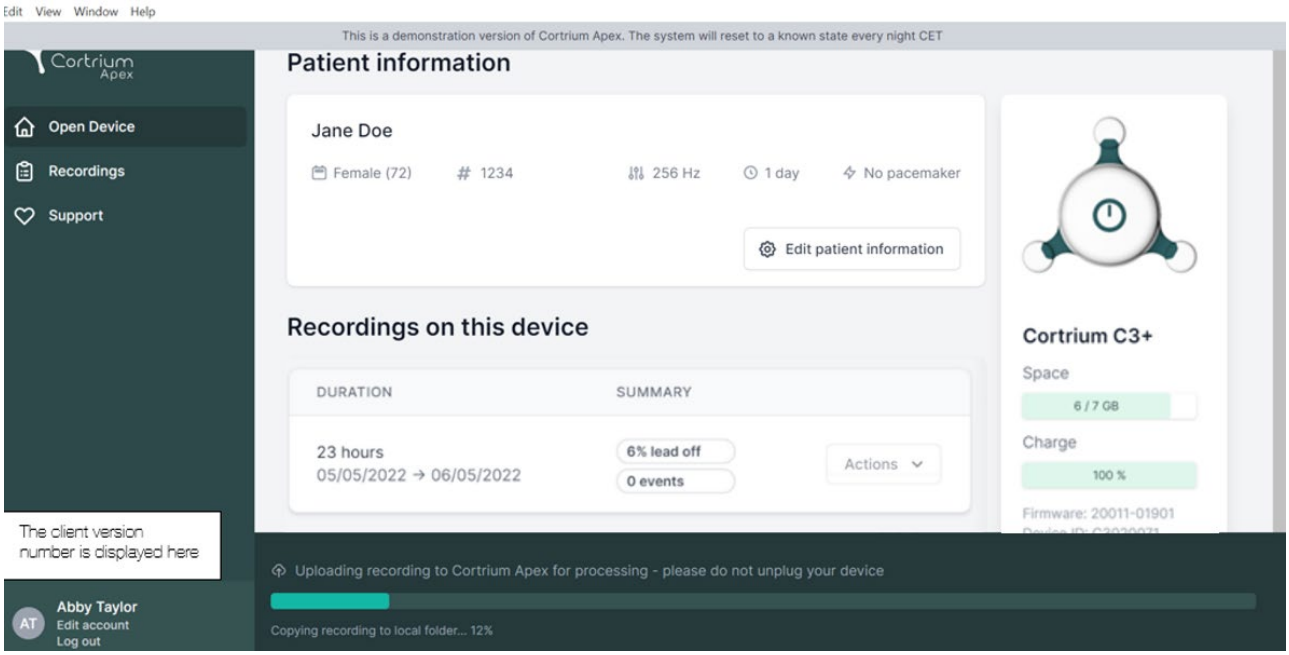
9.1 How to download EDF file before ordering the Holter report

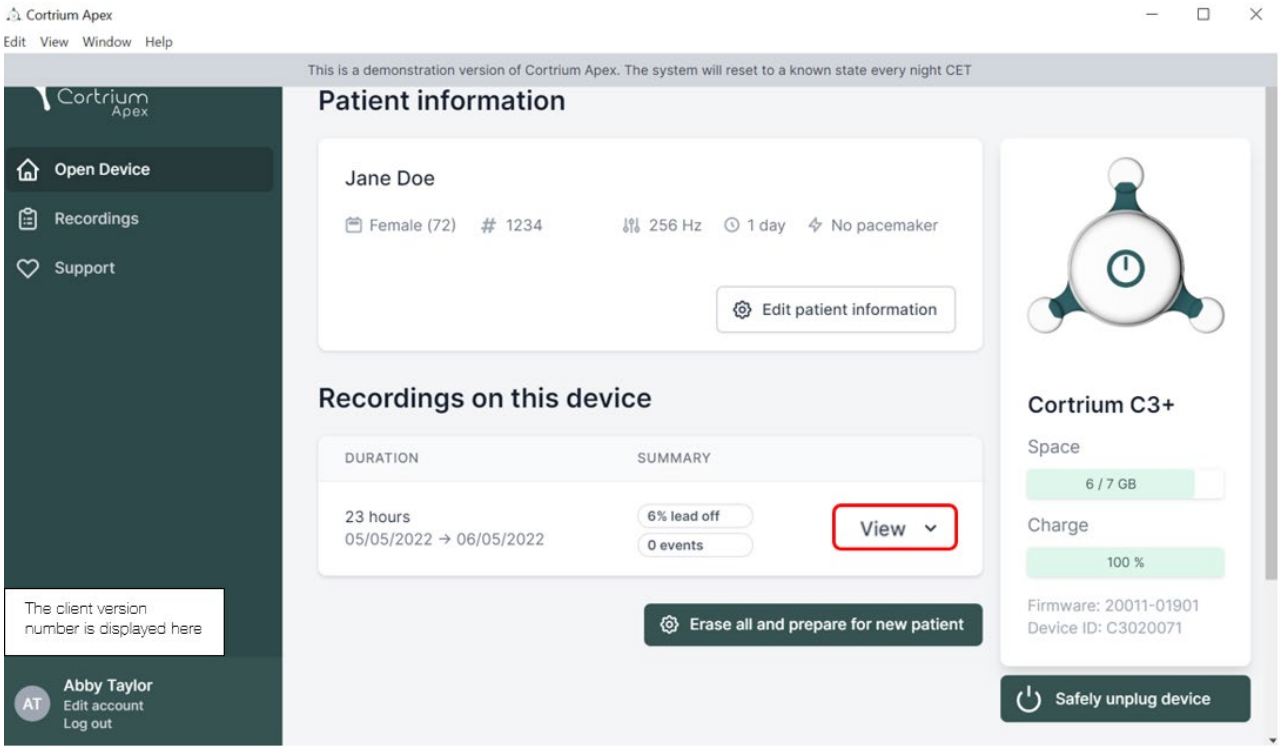
Follow these steps to convert a recording to EDF format:

- Connect the C3+ Holter monitor to the computer and press the “Open Device” button in the left menu.
- Click on the "Actions" button and select "Upload and export as EDF".



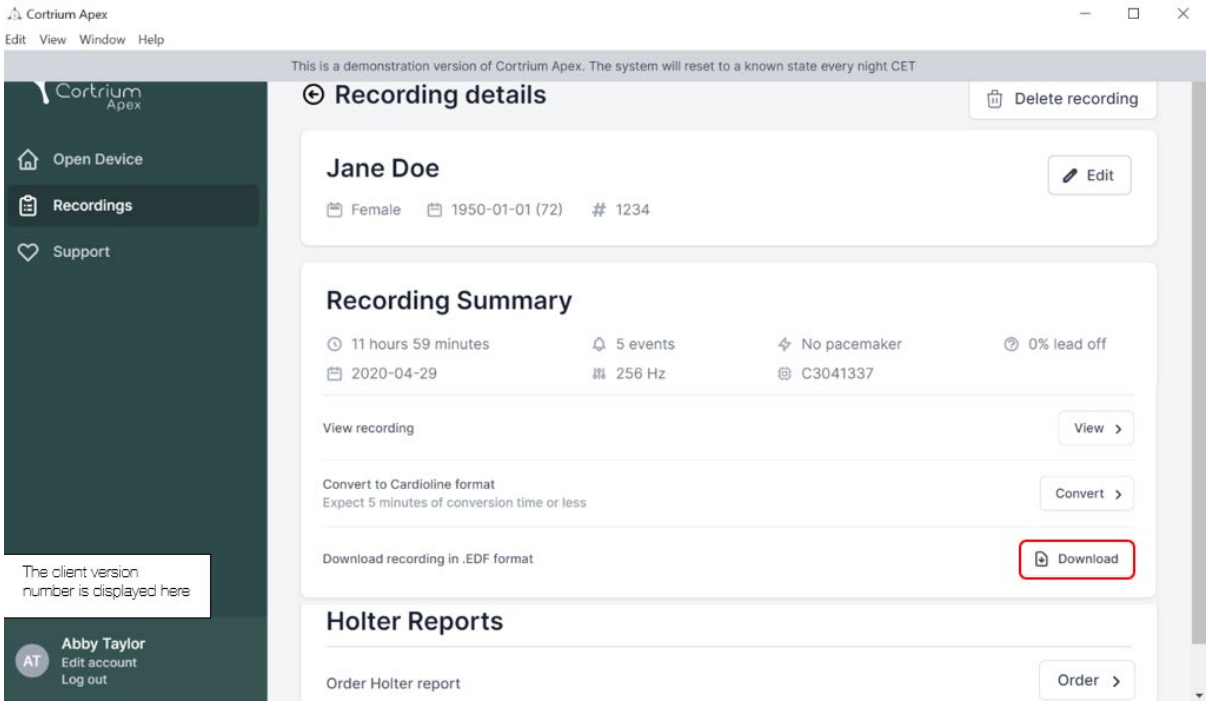
- The recording is transferred to Apex.
- When the transfer is complete, the "Actions" button changes to "View".





- Click on the "View" button to see the recording overview.
- The sub-item "Download report in EDF format" shows the following information:
    - While the recording is being converted, the progress is displayed

- When the EDF file is ready, click the "Download" button to save the EDF file on your computer



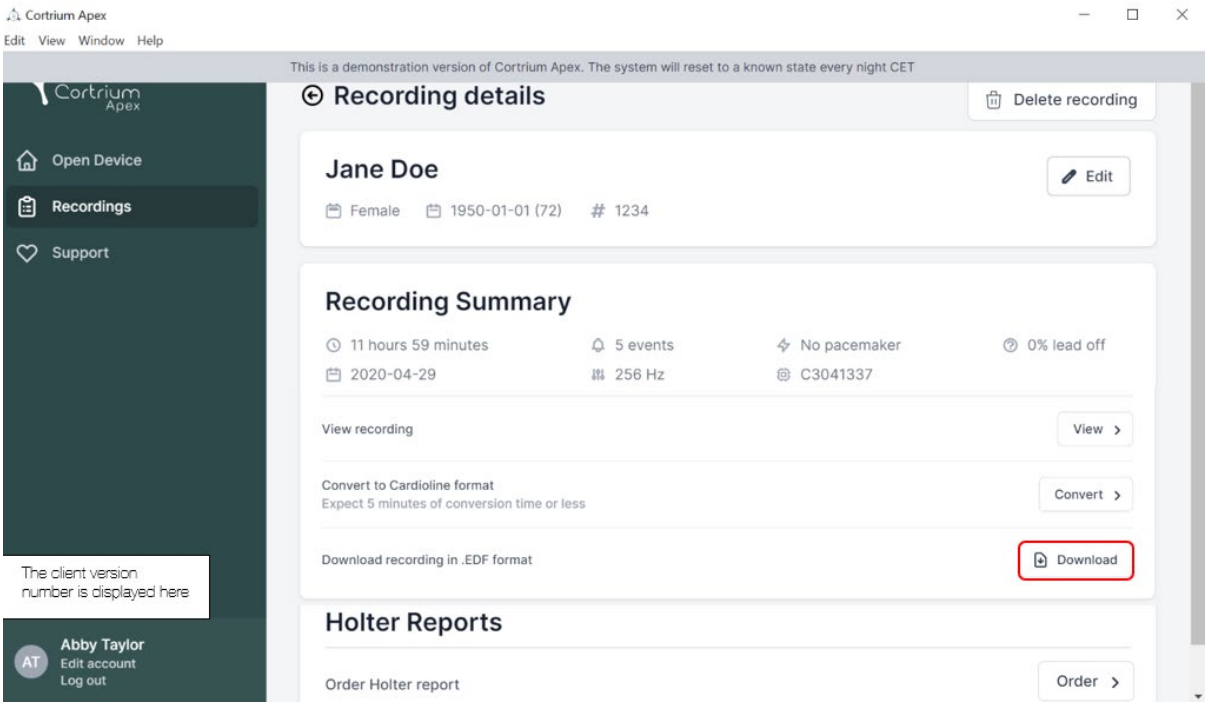
9.2 How to download EDF file after ordering a report

If you have just ordered a report of a recording and now want to download the recording in EDF format, proceed as follows:

- When the device is connected, click on the menu item "Open device", then click on the "View" button next to the recording.
- In the “Recording details” screen, click on "Download" to download the EDF file.

If you want to download a previous recording in EDF format:

- click on the menu item “Recordings”
- click on the recording you want to download in EDF format
- and then click on “Download” as illustrated below



10. Log out of Cortrium Apex

It is important to remember to log out of the application by clicking on the "Log out" button in the bottom left corner.

Cortrium Apex will automatically log out of your user account after an extended period of inactivity.

If your institution has multiple users with separate accounts for Cortrium Apex, but the users are working from the same computer, please ensure you log out of Cortrium Apex when you have finished your tasks.

11. Software-Updates

When started, the application automatically checks for available updates and installs them immediately.

12. Minimum technical requirements

The minimum requirements for the operation of Cortrium Apex are:

- Windows 10 or MacOS Catalina (Intel).
- 1280 x 960 Pixel screen resolution.
- 4 GB RAM.

- 5 GB free hard disk space.
- Internet connection.

Cortrium Apex requires an internet connection. The upload speed of the connection determines the time it takes to upload a recording when you order a report or convert the recording to another format. The download speed determines the time it takes to download a converted recording.
Downloading and viewing a report usually takes only a few seconds on a 10 Mbps internet connection.

13. Troubleshooting

13.1 “The device seems to be set up for a patient..."

If you see the warning: "*Warning. The device appears to be set up for a patient, but we cannot find the patient data in the system. Please set up a patient for the records*",
simply click the "Add Patient Information" button to set up the device for use with Cortrium Apex. This will not remove the records on the device.

13.2 Recording summary shows "n/a lead off" or "n/a events"

If the recording summary shows "n/a lead off" or "n/a events", this is because the firmware on the connected C3^{+} unit is a version that does not support immediate lead off or event summary. However, the recording is still valid.

13.3 The internet connection was interrupted.

If you see the message "Cortrium Apex is having trouble accessing the Internet", your internet connection may have been interrupted or lost. Please contact your facility's IT support or your internet service provider for assistance in restoring your internet connection.

- Cortrium Apex automatically tries to connect to the Internet again. A message indicates when the next connection attempt will be made
- If there is no internet connection when Cortrium Apex is started, a message will be displayed indicating that you appear to be offline

- If you were transferring a recording when the internet connection was lost, you may need to restart the transfer when the connection is restored

13.4 Apex is newly installed but does not open

This issue may occur due to a firewall blocking the Cortrium Apex application. In case Apex does not start due to a firewall, please ensure that the URL links in section 16 “Infrastructure statement” are unblocked or “whitelisted” in the firewall. Please contact your facility’s IT for support.

14. Security information

User management

- Every user of Cortrium Apex must use their own account.
  You can create and delete as many user accounts as you need at https://apex.cortrium.com
  It is important that you are able to determine and regulate who has access to the sensitive data of your patients.

Passwords

- Ensure that you are using a safe password
- Do not share your login and/or password with others
- Avoid using the same password for multiple accounts
  Re-using the same password could result in that an adversary may be able to gain access to all your systems and computers, if just one password is compromised.
- Remember to log out of Cortrium Apex
  If you remain logged in, other users actions in the system will appear to be yours

Encryption and additional protection

Before installing Cortrium Apex on a computer we recommend you:

- Enable disk encryption
  In case the computer is lost or stolen sensitive data on the computer will not be readable
- Enable automatic system updates
  Increases the chance that the computer stays up-to-date with security updates
- Enable built-in security software (e.g. Windows Security) if available
- Firewall, anti-malware, anti-phishing and anti-virus protection is built into Windows. We highly recommend you enable it.

15. Labelling and symbols

The following is a representation of the labelling and symbols found in Cortrium Apex:

Example of label

Symbol	Name	Requirement / note
	Date of Manufacture	ISO 15223-1
	Refer to instruction manual/booklet	ISO 7000 - 1641
	Caution sign	ISO 7000 - 0434A
0123	CE approved device with notifying body identification number	MDR (EU/745/2017)
MD	Medical Device	ISO 15223-1:2021

16. Infrastructure statement

Cortrium ApS declares that its product, Cortrium Apex is deployed in the Microsoft Azure cloud computing service. Some of the URLs are dependent on the location where the product is being used. The table below contains addresses used by the system:

URL	Description
api.apex.cortrium.com	Cortrium Apex API.

viewer.apex.cortrium.com	Cortrium Recording Viewer API.
apex.cortrium.com	Cotrium Apex administrator interface.
client.apex.cortrium.com	Cortrium Apex web client.
login.cortrium.com	Auth0 login endpoint.
assets.apex.cortrium.com	Assets downloads, such as Desktop Client.
support.cortrium.com	Support website.
cortriumukrecordingapex.blob.core.windows.net	Recordings blob storage (UK South).
cortriumfrrecordingapex.blob.core.windows.net	Recordings blob storage (France Central).
cortriumeurecordingapex.blob.core.windows.net	Recordings blob storage (Germany West Central).
cortriumaurecordingapex.blob.core.windows.net	Recordings blob storage (Australia East).
rt.services.visualstudio.com dc.services.visualstudio.com	Used by Microsoft Azure Application Insights (telemetry).

Port 443 (HTTPS) needs to be opened for all the URL's above. The first 7 rules of this list can be simplified by whitelisting the whole Cortrium domain (*.cortrium.com). This also reduces the risk of needing to make future adjustments, when this list changes.