

Cortrium Apex 1.20

Instructions for Use

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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

Additional information

Please note that software versioning displayed in the screenshots in this manual may refer to previous versions of the software.

Eg. If no changes have been made to the user interface the version shown in the screenshots can be older than the current version of the software, however the functionality is identical.

For users who have enabled integrations, screenshots and usage may differ. For instructions on using these integrations, please refer to Appendix I at the end of this document.

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

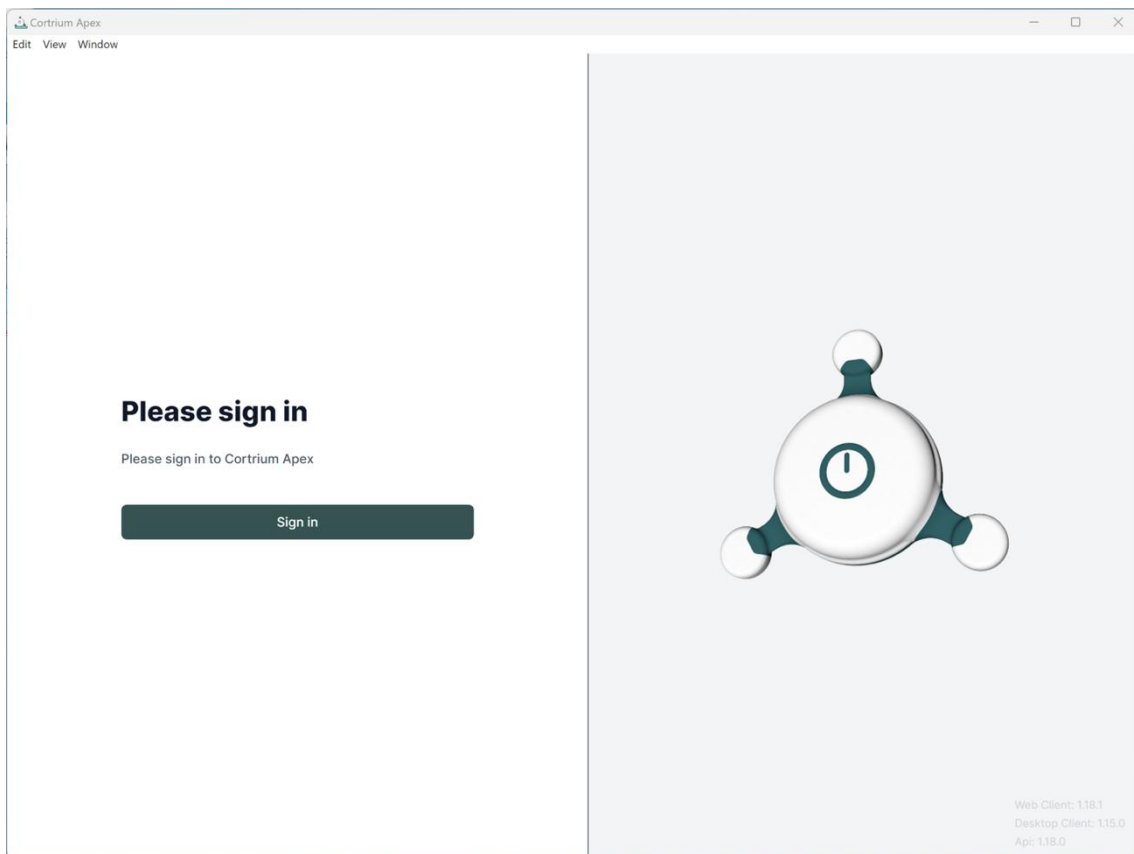
Please note that Cortrium Apex requires an internet connection. You will not be able to log in or use Cortrium Apex without an internet connection

3. Log in to Cortrium Apex

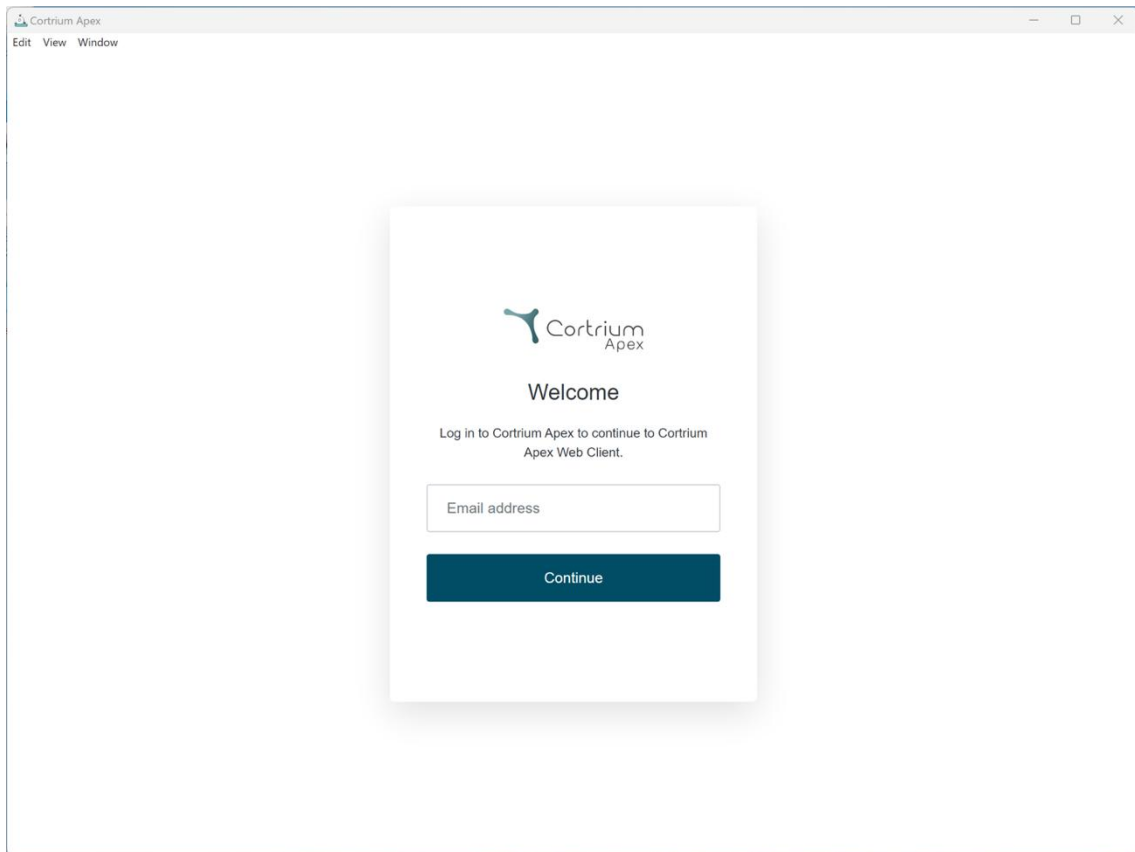
To use Cortrium Apex, you must first have a user login. If you are the administrator of the facility, this has been set up for you by Cortrium. If you are not the administrator and do not yet have a user login, this can be set up by the administrator of your facility.

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")



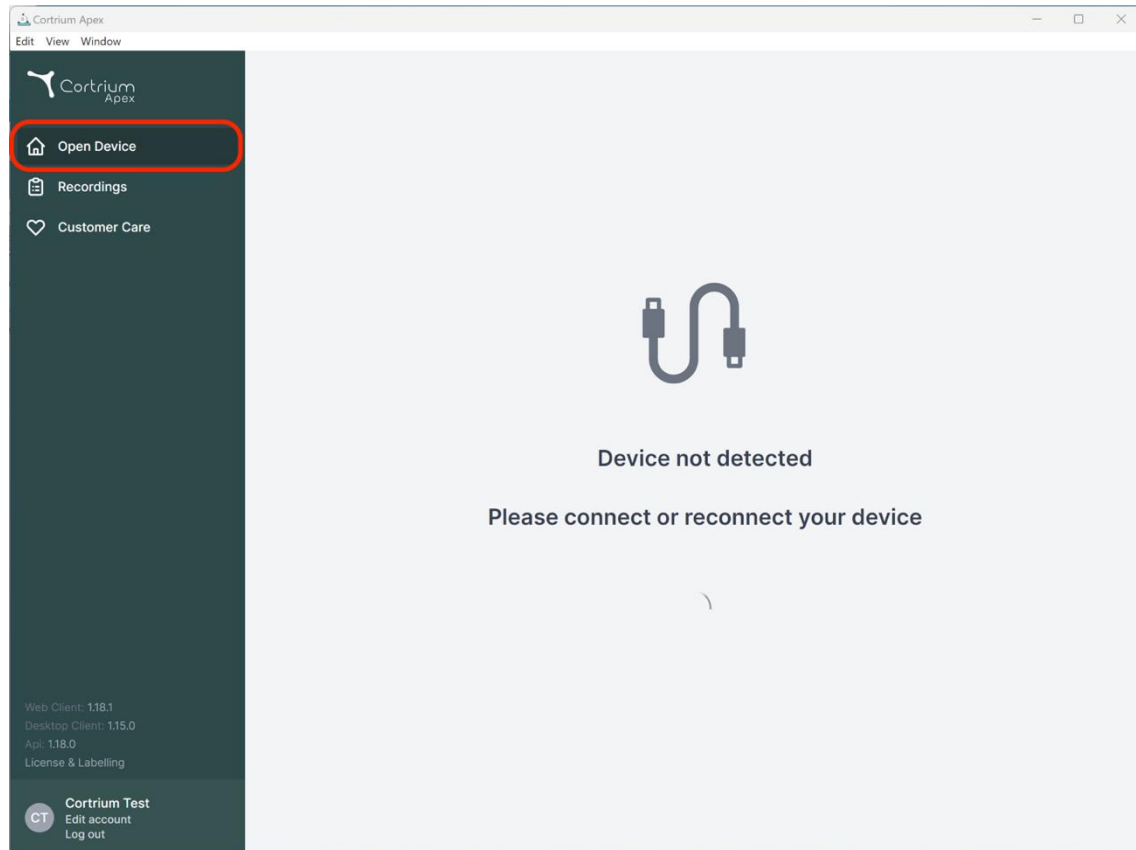
- Enter your user information and press "Continue".



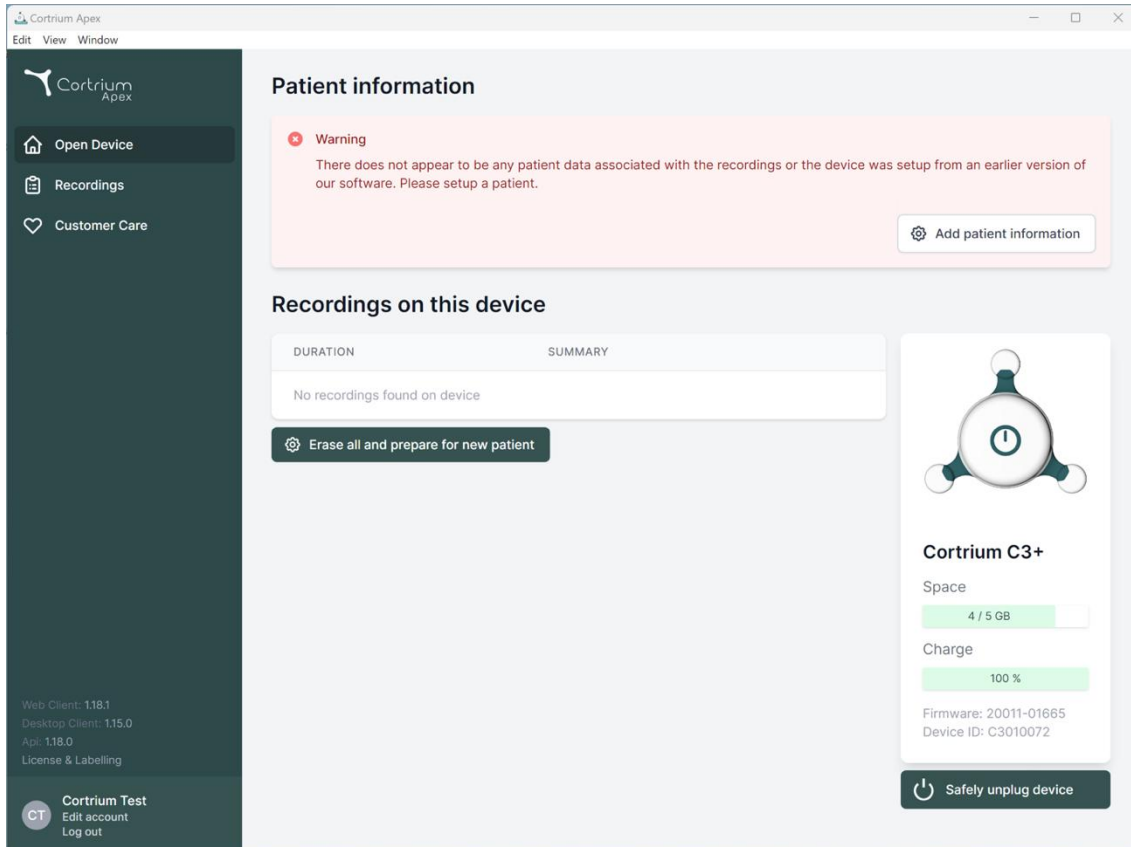
4. Prepare the C3⁺ for a new patient

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)



The screenshot shows the Cortrium Apex web interface. On the left is a dark sidebar with navigation options: 'Open Device', 'Recordings', and 'Customer Care'. At the bottom of the sidebar, it lists version information: 'Web Client: 1.18.1', 'Desktop Client: 1.15.0', 'App: 1.18.0', and 'License & Labelling'. Below this is a 'Cortrium Test' section with 'Edit account' and 'Log out' links.

The main content area is titled 'Patient information' and features a warning message: 'Warning: There does not appear to be any patient data associated with the recordings or the device was setup from an earlier version of our software. Please setup a patient.' An 'Add patient information' button is located to the right of the warning.

Below the warning is a section titled 'Recordings on this device' with a table header containing 'DURATION' and 'SUMMARY'. The table body contains the text 'No recordings found on device'. A button labeled 'Erase all and prepare for new patient' is positioned below the table.

On the right side of the main area, there is a device status card for 'Cortrium C3+'. It includes a circular icon with a clock, a progress bar for 'Space' (4 / 5 GB), a progress bar for 'Charge' (100%), and technical details: 'Firmware: 20011-01665' and 'Device ID: C3010072'. A 'Safely unplug device' button is at the bottom of the card.

- 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:

Cortrium Apex
Edit View Window

Patient information

Warning
There does not appear to be any patient data associated with the recordings or the device was setup from an earlier version of

Patient

Patient ID: 28081960
Date of birth: 08/28/1960

First name: Cortrium
Last name: Test

Gender: Female Male Other
Reason for recording: Other

Notes

Notes on patient or recording

Device setup

Recording length: 1 day
Pacemaker: None
Sample rate: 256 Hz

Please note that analysis cannot be guaranteed if a pacemaker is implanted

⚠ This will erase all recordings on the device Cancel **Save to device**

Web Client: 118.1
Desktop Client: 115.0
App: 118.0
License & Labeling

Cortrium Test
Edit account
Log out

Cortrium C3+
Space: 4 / 5 GB
Charge: 100 %
Firmware: 20011-01665
Device ID: C3010072

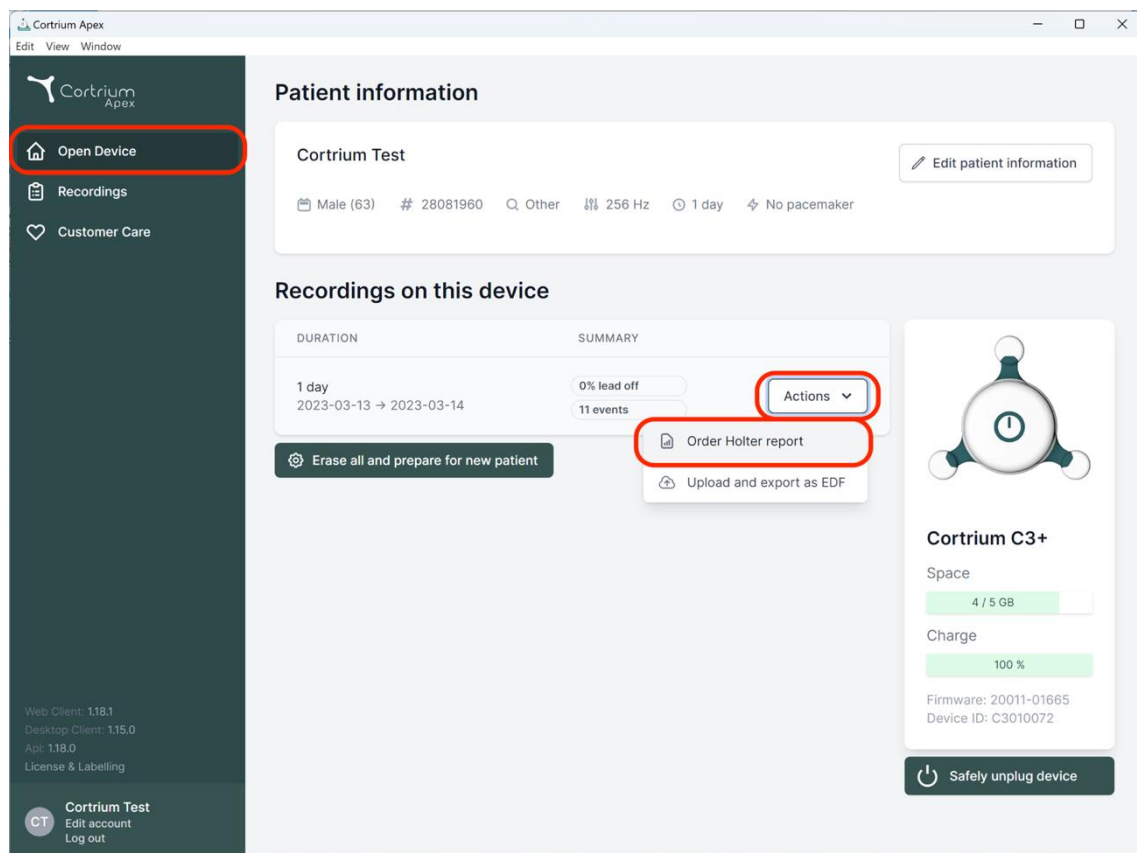
Safely unplug device

- 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

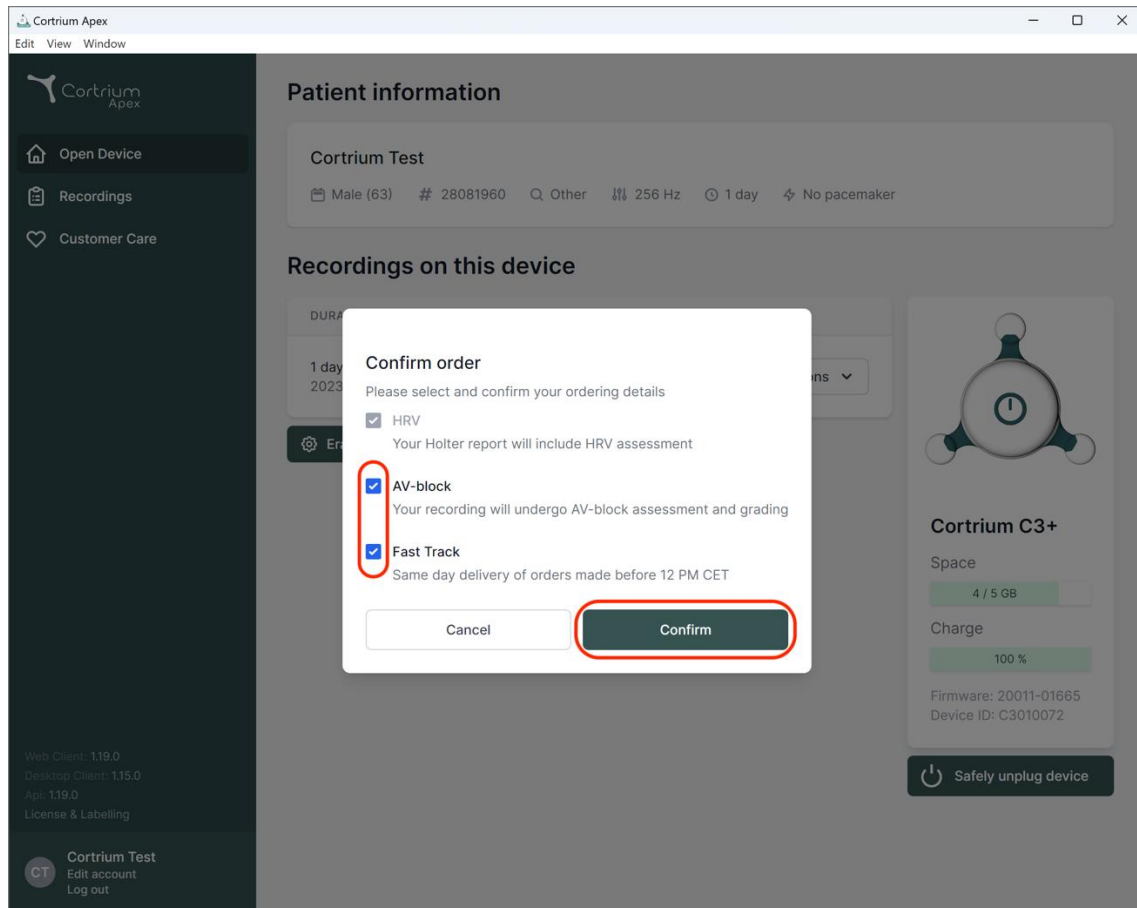
Cortrium Apex allows you to send recordings for analysis and download the Holter report as soon as it is available. When a device is returned with a recording, click on the “Open device” button and select your next steps using the "Actions" button. By default, you have the following two options:

- Order Holter report
- Upload and export as EDF



To order the Holter report, click on the "Actions" button and then on “Order Holter report”.

You will be met by a form allowing you to confirm your order or choose additional options for your analysis.



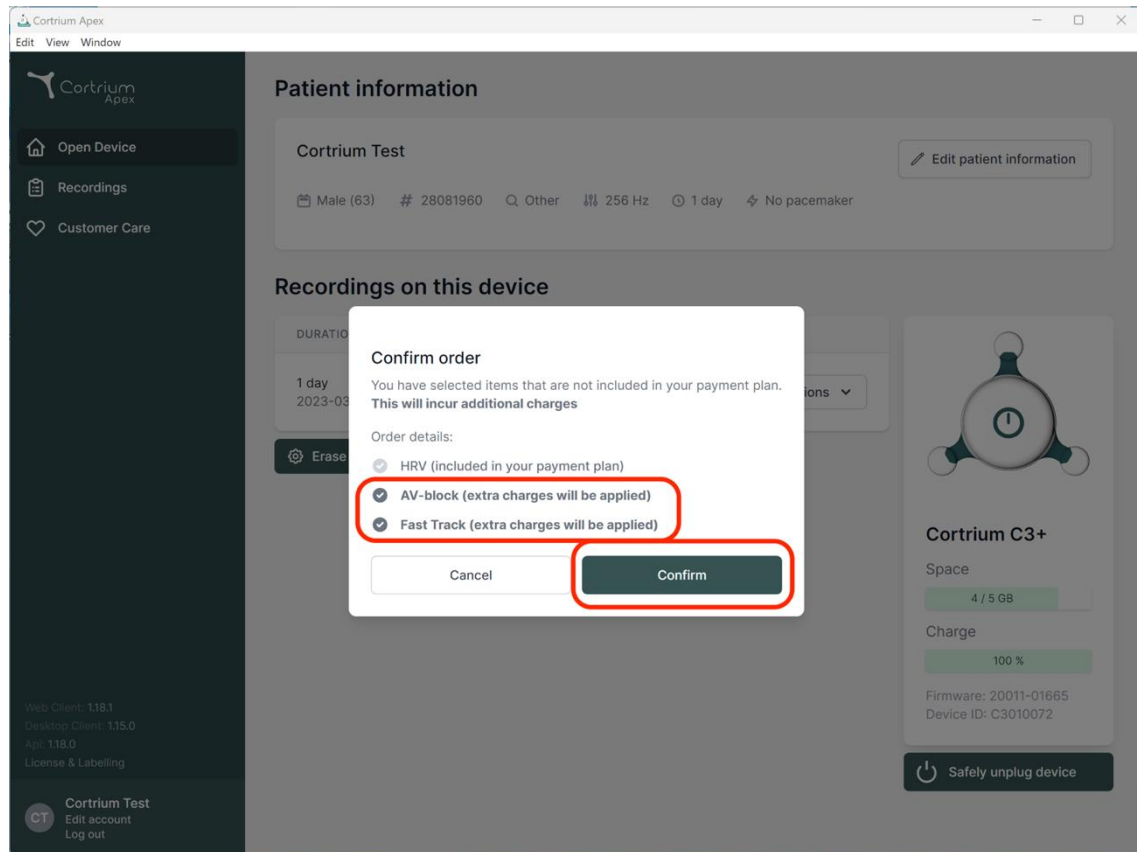
Your add-on options are:

- **HRV:** Your Holter report will include heart rate variability(HRV) assessment
- **AV-Block:** Assessment and grading of AV-Block by a senior specialist
- **Fast Track:** Same day delivery of orders made before 12pm CET

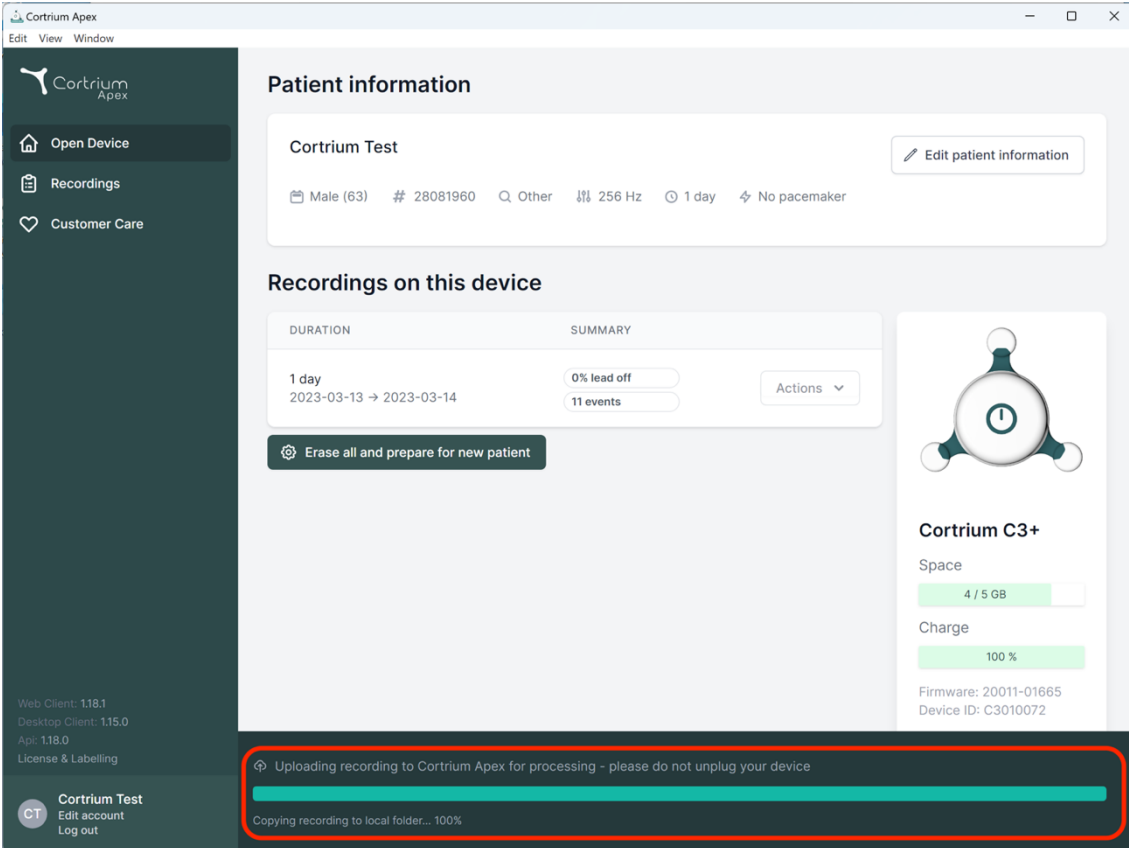
When you are satisfied with your choice of analysis options you can click “Confirm” to continue.

In case you have chosen add-ons to your analysis you will be prompted with a message informing if your selections will incur additional charges.

To continue click on “Confirm”.



The recording is now uploading.



The screenshot displays the Cortrium Apex web application interface. On the left is a dark sidebar with navigation options: Open Device, Recordings, and Customer Care. The main content area is titled 'Patient information' and shows details for 'Cortrium Test', including gender (Male, 63), ID (28081960), and recording duration (1 day, 2023-03-13 to 2023-03-14). Below this, the 'Recordings on this device' section shows a recording with 0% lead off and 11 events. A 'Cortrium C3+' device status card on the right indicates 4/5 GB space and 100% charge. At the bottom, a red-bordered box highlights a progress bar for 'Uploading recording to Cortrium Apex for processing - please do not unplug your device' and 'Copying recording to local folder... 100%'. The sidebar also lists version information and user options like 'Edit account' and 'Log out'.

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.

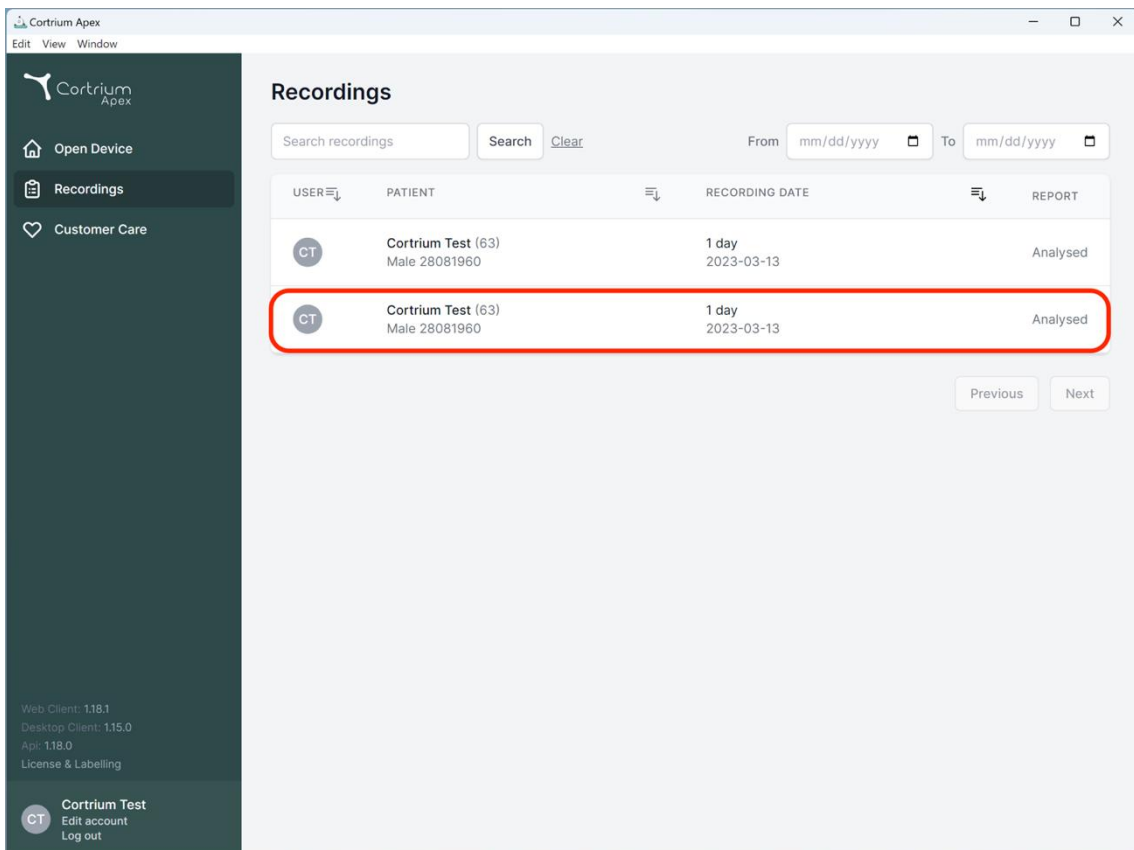
6. View Holter reports and the entire recording

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.



The screenshot displays the 'Recordings' section of the Cortrium Apex web application. The interface includes a dark sidebar on the left with navigation options: 'Open Device', 'Recordings' (selected), and 'Customer Care'. The main content area features a search bar, date filters, and a table of recordings. The table has columns for 'USER', 'PATIENT', 'RECORDING DATE', and 'REPORT'. Two entries are listed, both for 'Cortrium Test (63)' with patient ID 'Male 28081960', recording date '2023-03-13', and duration '1 day'. The report status is 'Analysed'. The second entry is highlighted with a red box. Below the table are 'Previous' and 'Next' navigation buttons. The footer of the sidebar shows version information and user options for 'Cortrium Test'.

USER	PATIENT	RECORDING DATE	REPORT
CT	Cortrium Test (63) Male 28081960	1 day 2023-03-13	Analysed
CT	Cortrium Test (63) Male 28081960	1 day 2023-03-13	Analysed

Cortrium Apex
Edit View Window

Cortrium Apex

- Open Device
- Recordings**
- Customer Care

Web Client: 1.18.1
Desktop Client: 1.15.0
App: 1.18.0
License & Labelling

CT Cortrium Test
Edit account
Log out

Recording details

Cortrium Test Edit

Male 1960-08-28 (63) # 28081960 Other

Uploaded By

Cortrium Test Cortrium Internal > Cortrium 2024-01-30 12:31

Recording Summary

1 day 11 events No pacemaker 0.0% lead off
2023-03-13 11:54 256 Hz C3100175

View recording View >

Download recording in .EDF format Download

Holter Reports

Order Holter report

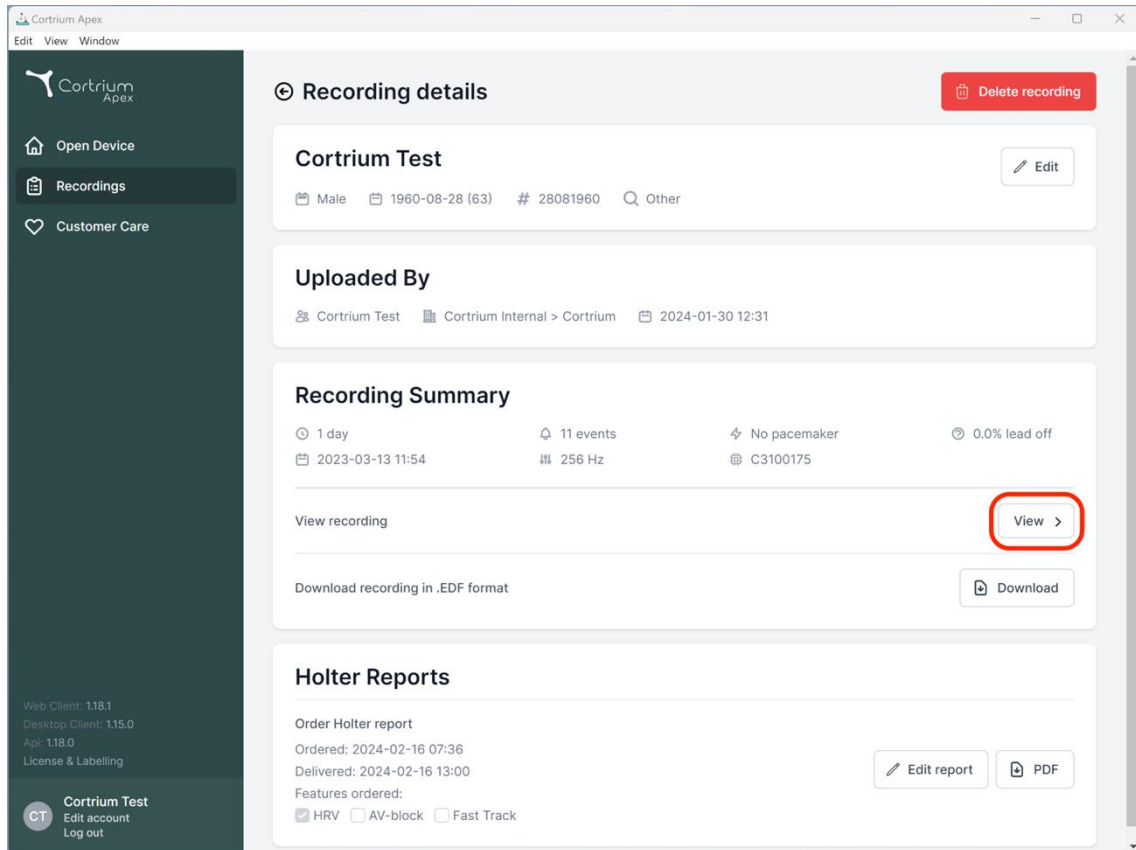
Ordered: 2024-02-16 07:36
Delivered: 2024-02-16 13:00

Features ordered:
 HRV AV-block Fast Track

Edit report PDF

6.2 Recording viewer

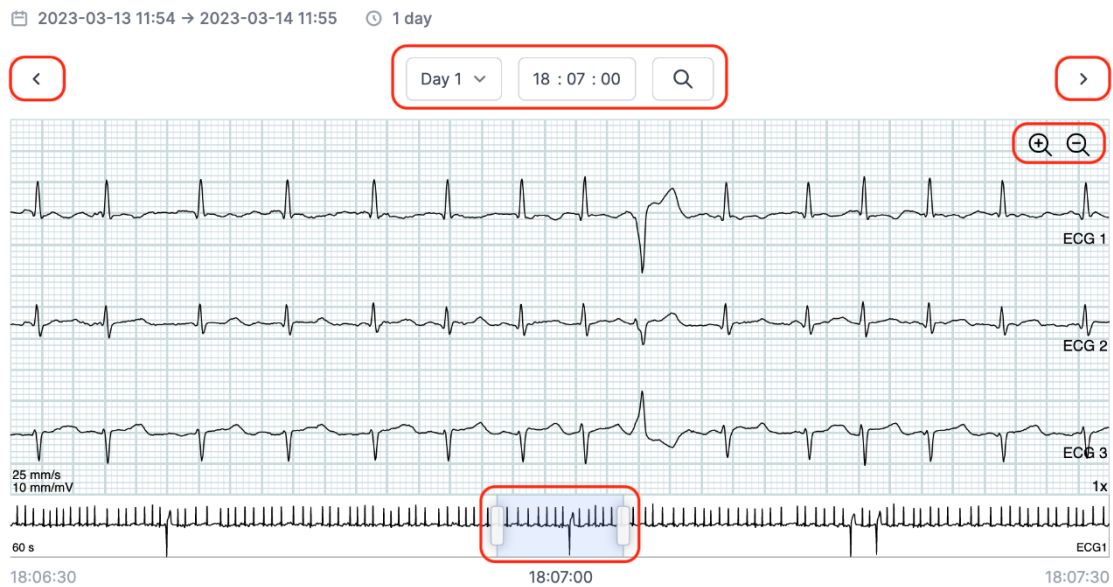
To view the entire recording after upload, click on recordings and select the patient whose recording you want to view (see first screenshot in section 6.1). Now you can use the Recording viewer by pressing the "View" button.



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.

Recording viewer



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.

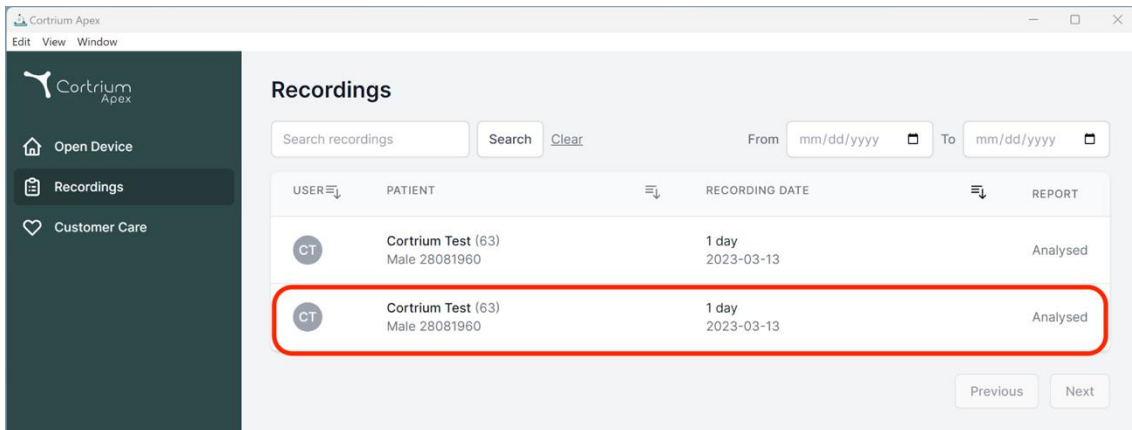
7. Edit patient details and view details of recordings

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

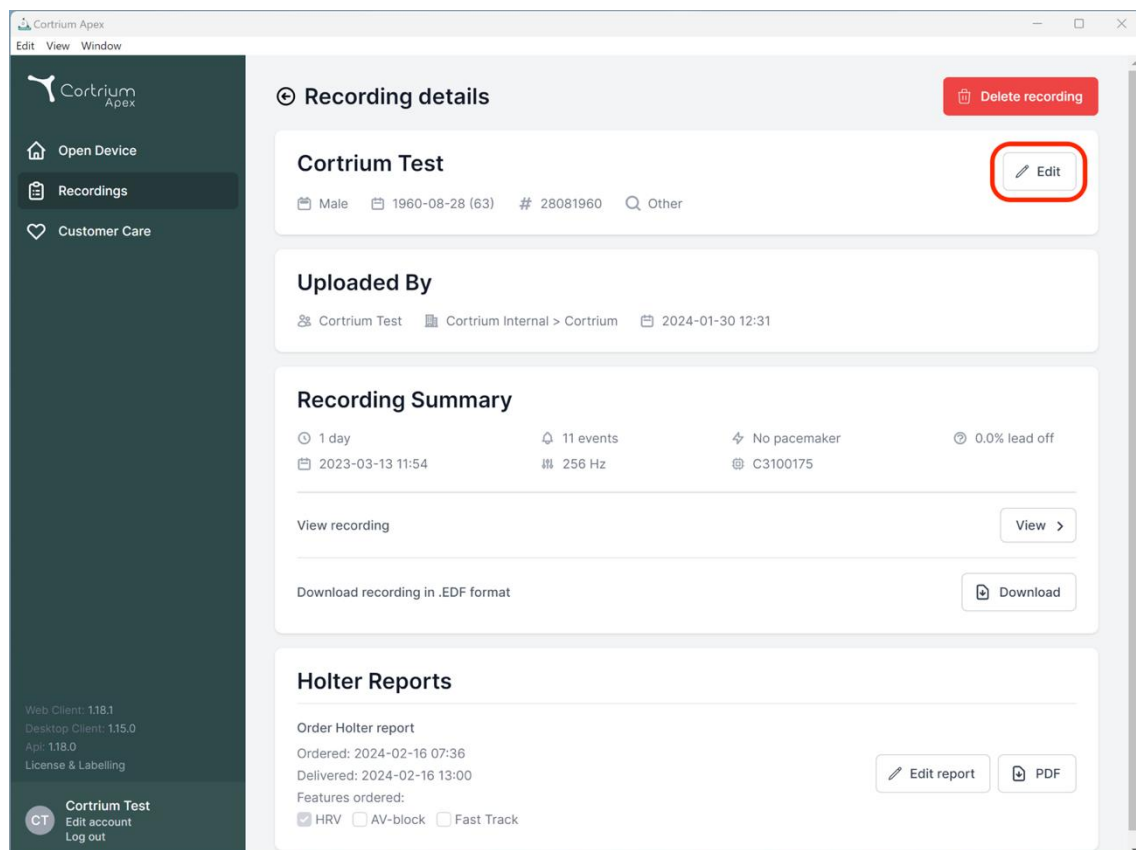
The summary of the recordings contains details such as:

- 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

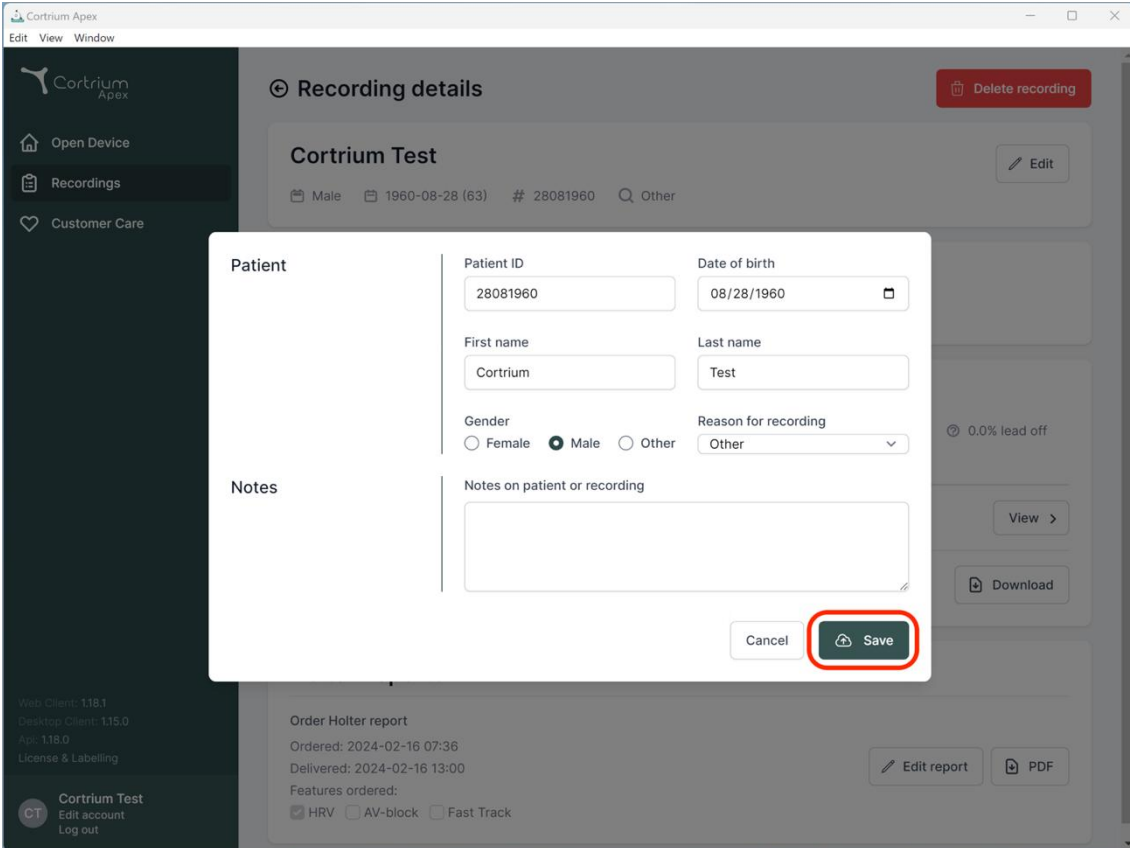
- Information about pacemaker if noted when the device was prepared for a new patient



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



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



Recording details

Cortrium Test

Male 1960-08-28 (63) # 28081960 Other

Patient

Patient ID: 28081960 Date of birth: 08/28/1960

First name: Cortrium Last name: Test

Gender: Female Male Other Reason for recording: Other

Notes

Notes on patient or recording

Cancel Save

Web Client: 118.1
Desktop Client: 115.0
App: 118.0
License & Labelling

CT Cortrium Test
Edit account
Log out

Order Holter report
Ordered: 2024-02-16 07:36
Delivered: 2024-02-16 13:00
Features ordered:
 HRV AV-block Fast Track

0.0% lead off

View >

Download

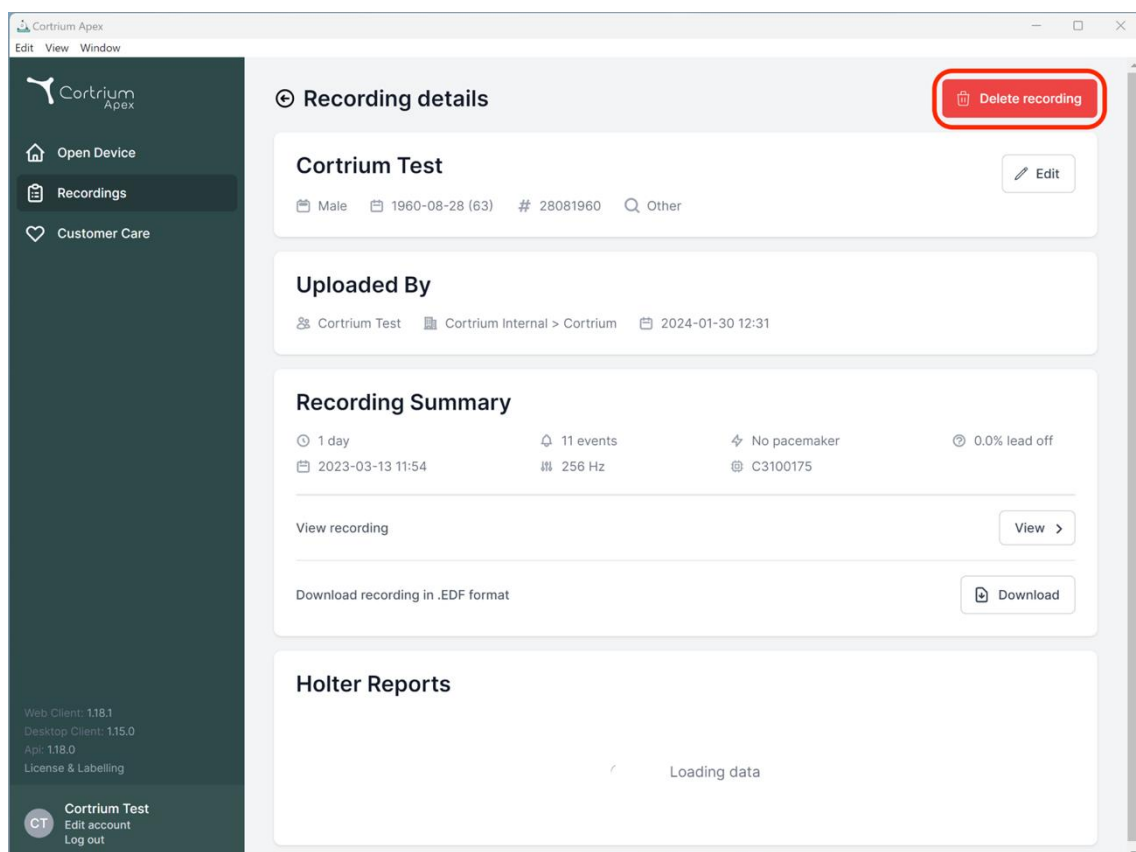
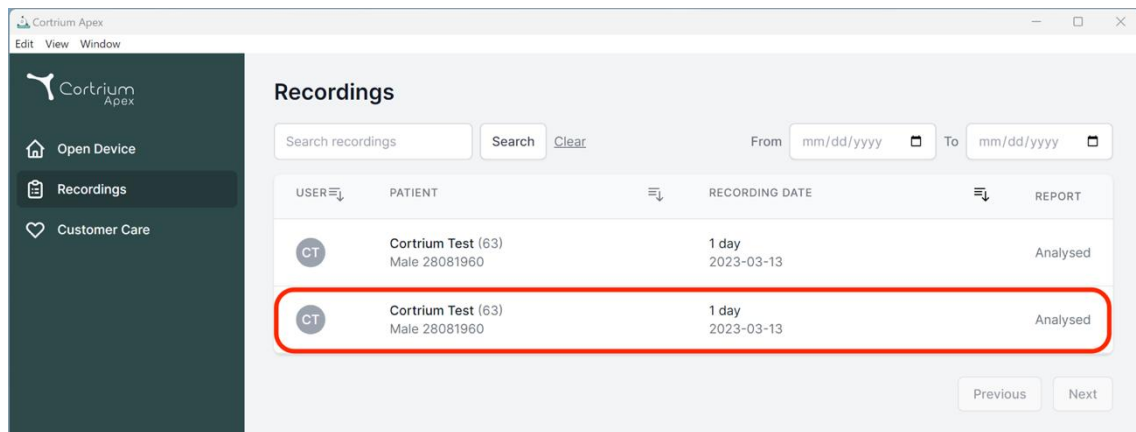
Edit report PDF

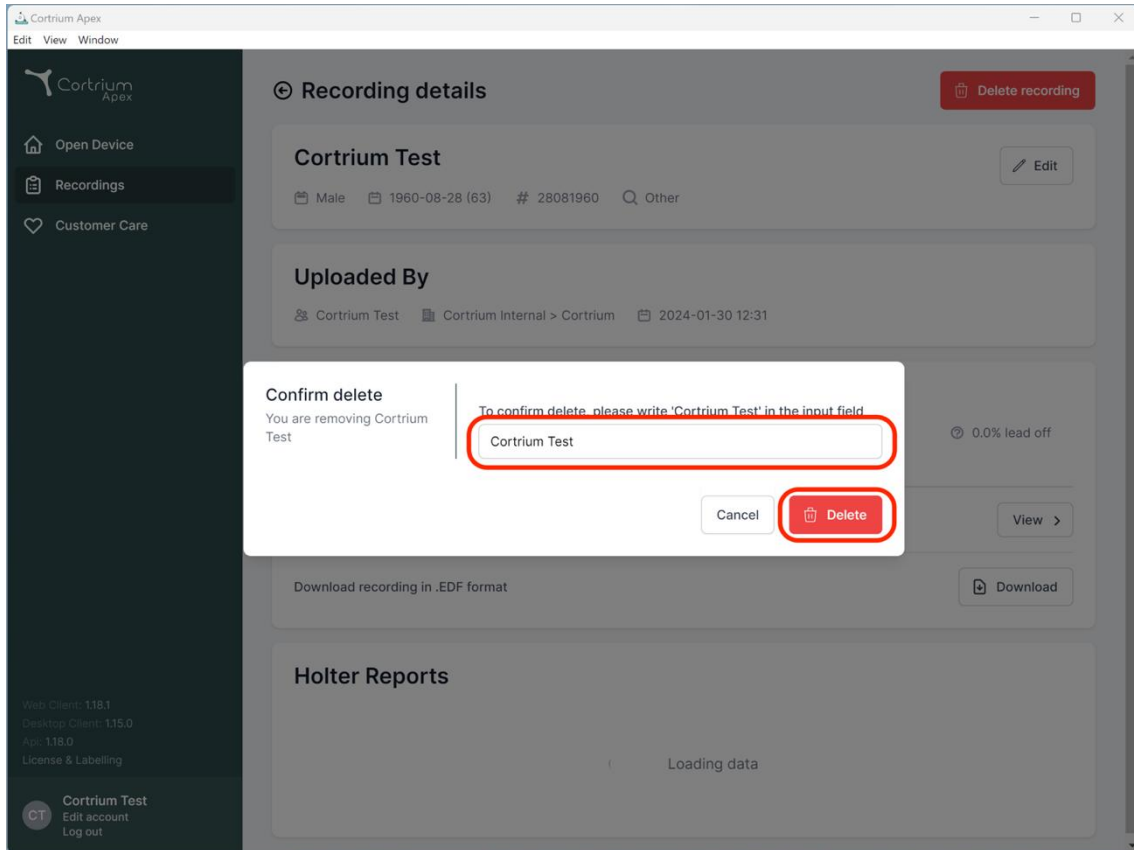
Delete recording

Edit

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”.





The screenshot shows the Cortrium Apex web application interface. A 'Confirm delete' dialog box is open in the foreground, overlaid on the 'Recording details' page. The dialog box contains the following text and elements:

- Confirm delete**
- You are removing Cortrium Test
- To confirm delete, please write 'Cortrium Test' in the input field.
- An input field containing the text 'Cortrium Test'.
- Buttons for 'Cancel' and 'Delete'.

The background page, 'Recording details', shows the following information:

- Recording details** (with a 'Delete recording' button)
- Cortrium Test** (with an 'Edit' button)
- Male, 1960-08-28 (63), # 28081960, Other
- Uploaded By**
- Cortrium Test, Cortrium Internal > Cortrium, 2024-01-30 12:31
- 0.0% lead off
- Download recording in .EDF format (with a 'Download' button)
- Holter Reports**
- Loading data

The left sidebar contains navigation options: Open Device, Recordings, and Customer Care. At the bottom of the sidebar, there is a user profile for 'Cortrium Test' with options to 'Edit account' and 'Log out'. The top of the browser window shows 'Cortrium Apex' and standard window controls.

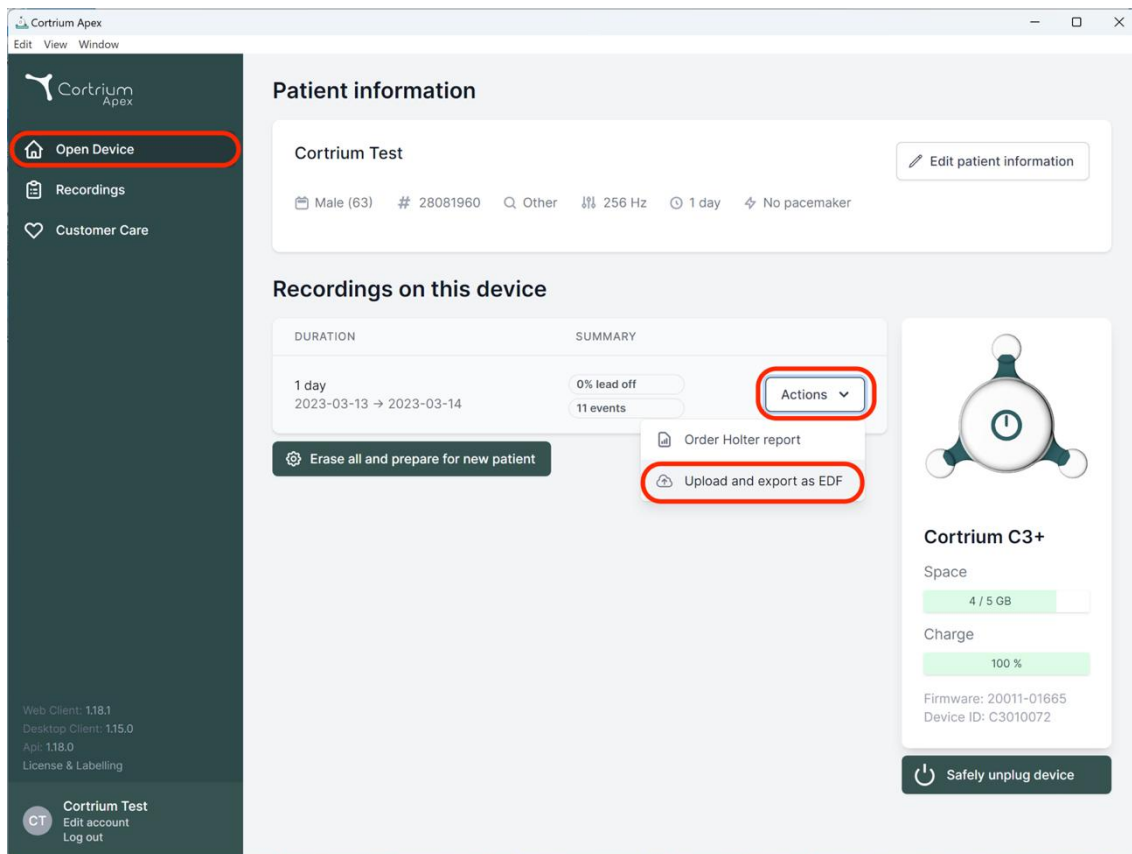
9. Download EDF file

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

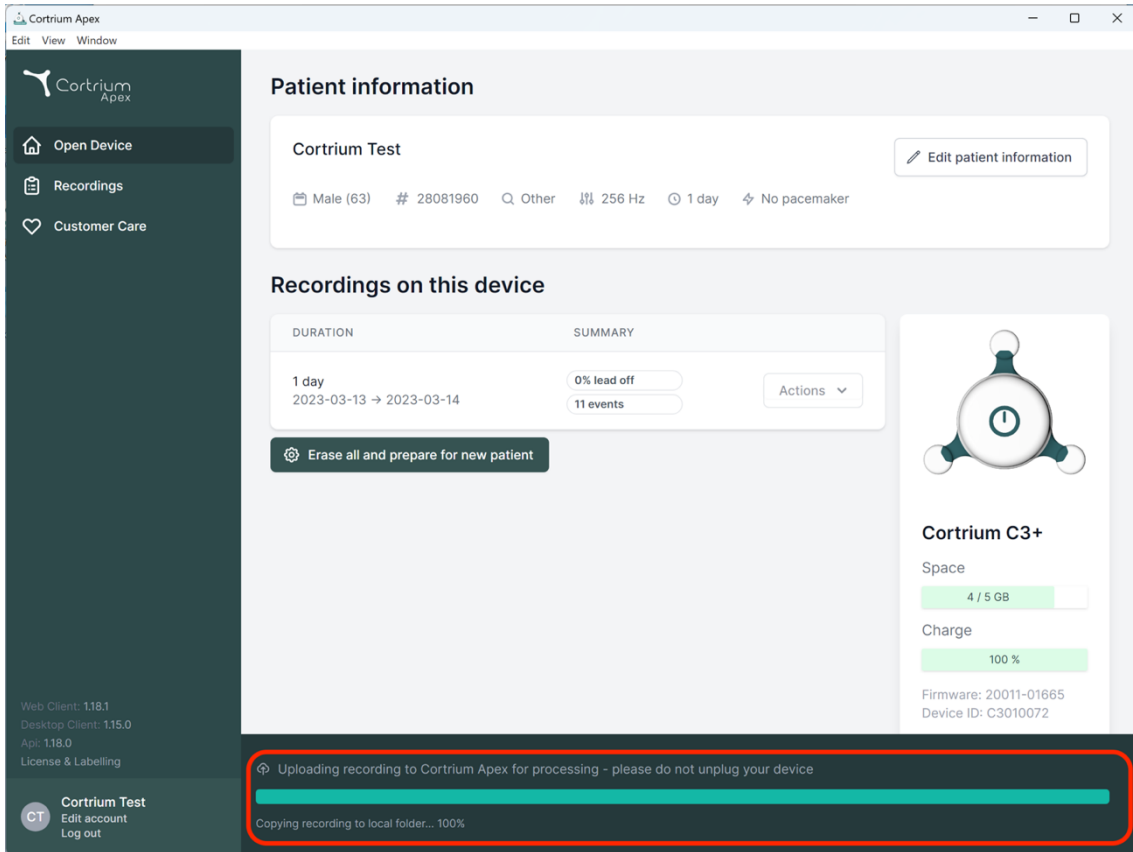
9.1 How to download EDF file before ordering the Holter report

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".



Cortrium Apex
Edit View Window

Patient information

Cortrium Test Edit patient information

Male (63) # 28081960 Q Other 256 Hz 1 day No pacemaker

Recordings on this device

DURATION	SUMMARY	Actions
1 day 2023-03-13 → 2023-03-14	0% lead off 11 events	Actions

Erase all and prepare for new patient

Cortrium C3+

Space: 4 / 5 GB

Charge: 100 %

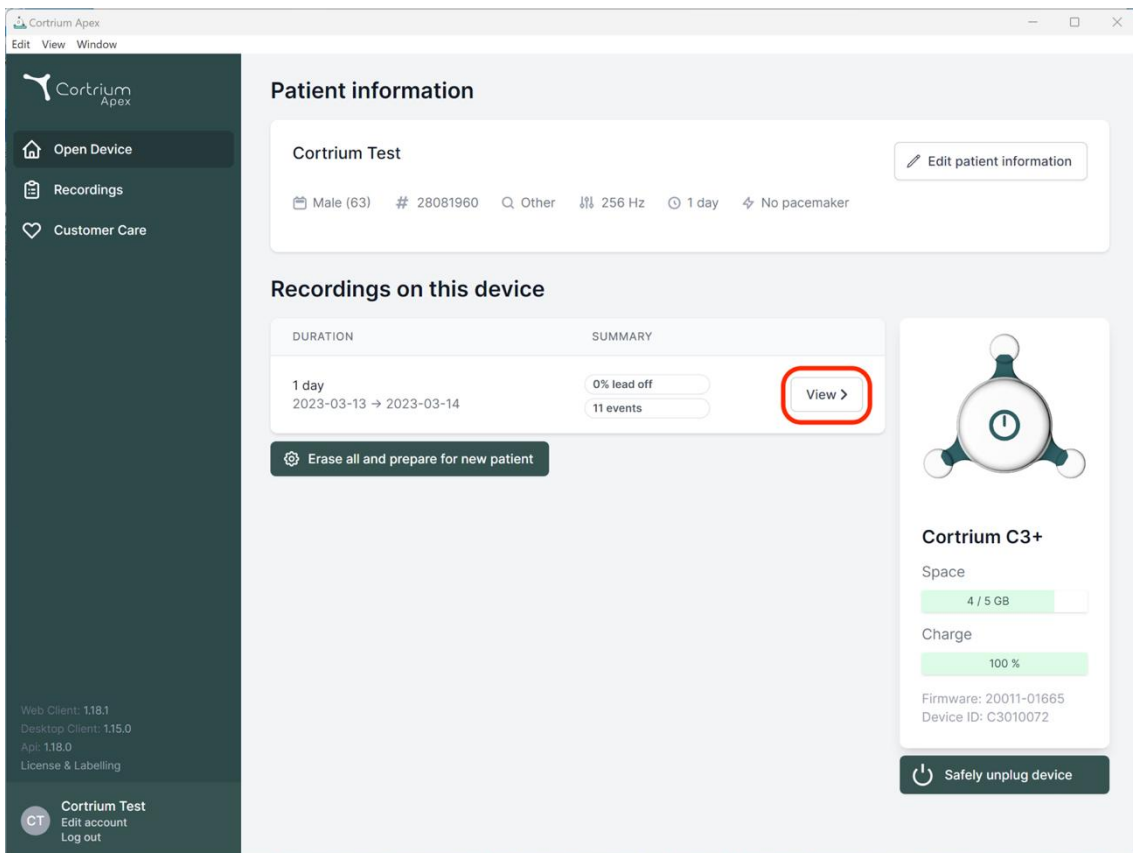
Firmware: 20011-01665
Device ID: C3010072

Web Client: 1.18.1
Desktop Client: 1.15.0
App: 1.18.0
License & Labelling

Cortrium Test
CT Edit account Log out

Uploading recording to Cortrium Apex for processing - please do not unplug your device

Copying recording to local folder... 100%



Cortrium Apex
Edit View Window

Patient information

Cortrium Test Edit patient information

Male (63) # 28081960 Q Other 256 Hz 1 day No pacemaker

Recordings on this device

DURATION	SUMMARY	Actions
1 day 2023-03-13 → 2023-03-14	0% lead off 11 events	View >

Erase all and prepare for new patient

Cortrium C3+

Space: 4 / 5 GB

Charge: 100 %

Firmware: 20011-01665
Device ID: C3010072

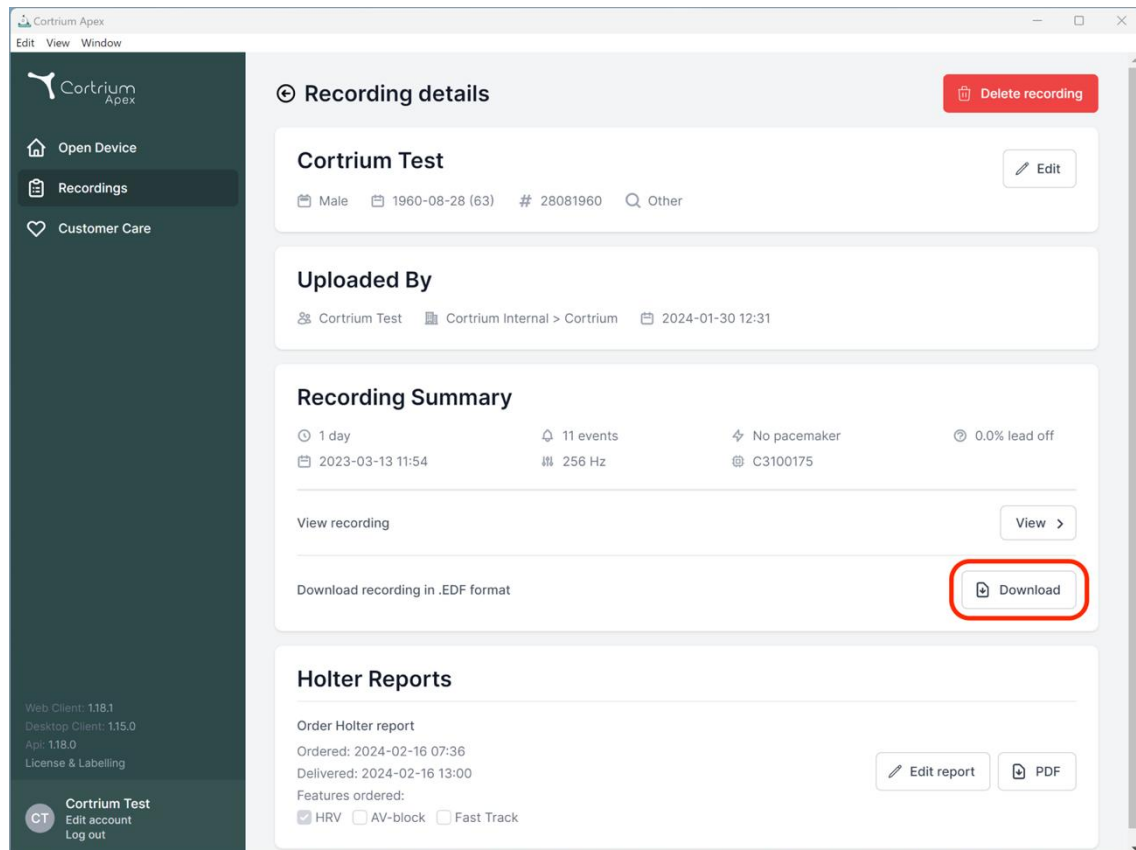
Safely unplug device

Web Client: 1.18.1
Desktop Client: 1.15.0
App: 1.18.0
License & Labelling

Cortrium Test
CT Edit account Log out

- 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



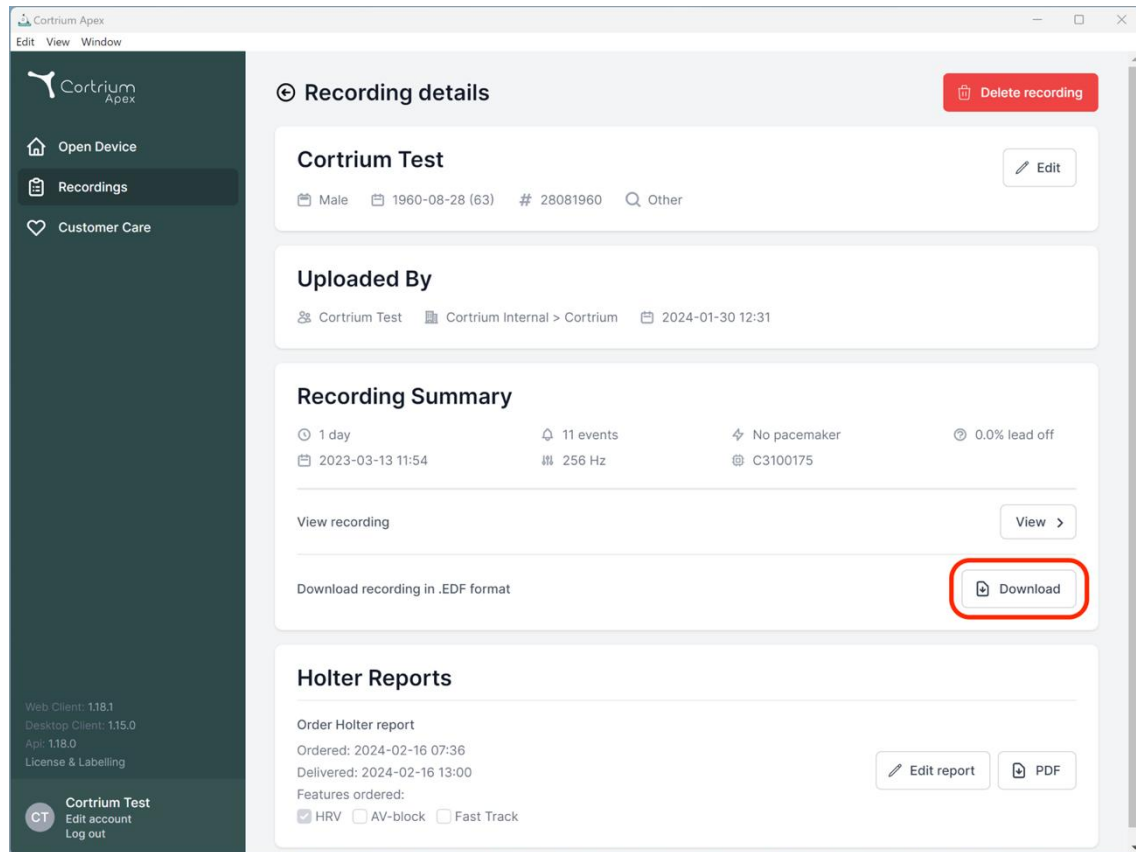
9.2 How to download EDF file after ordering a report

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
	CE approved device with notifying body identification number	MDR (EU/745/2017)
	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	Cortrium 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).
cortriemeurecordingapex.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.

Appendix I

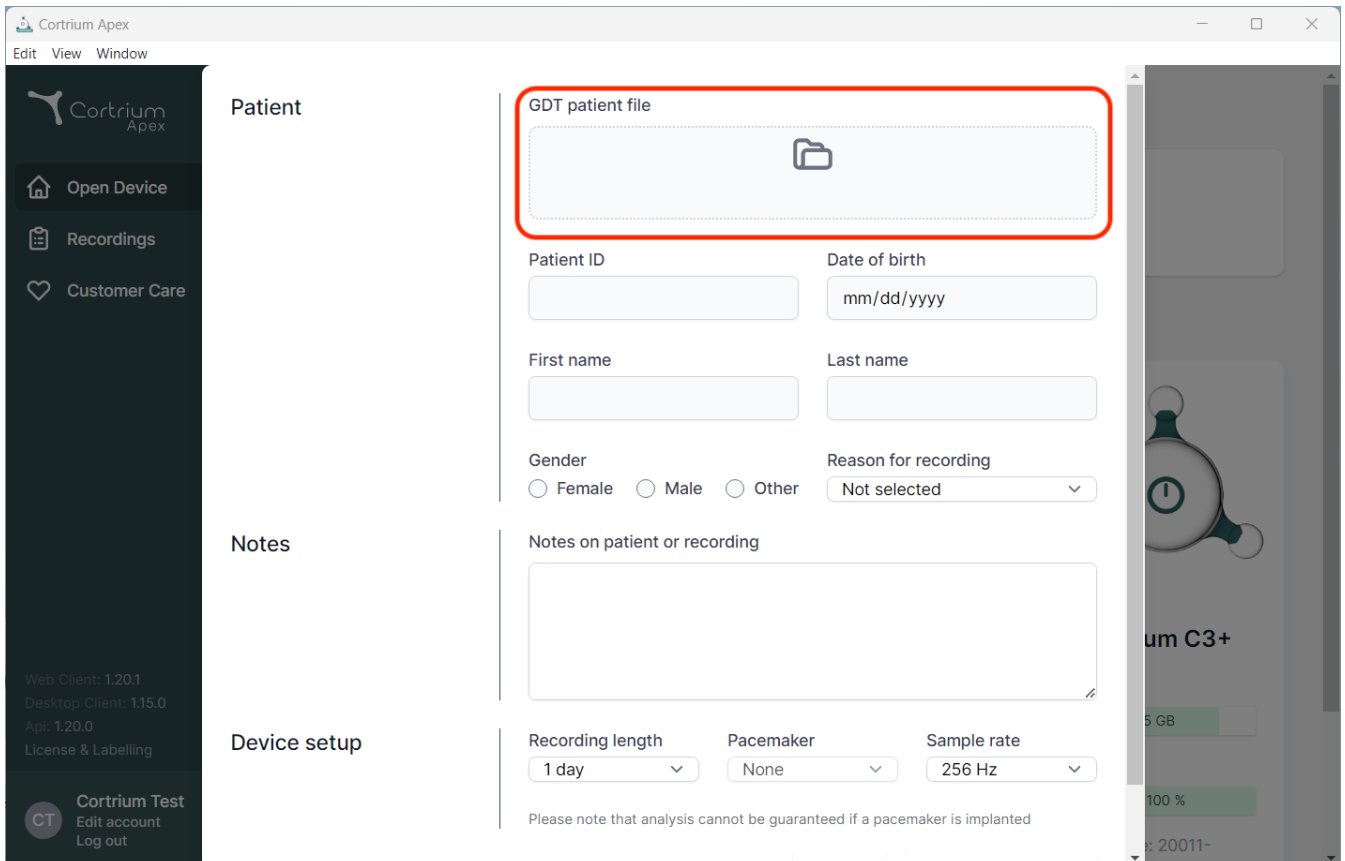
i. Available Integrations

The following integrations are country-specific and therefore not enabled for all customers:

- **GDT Patient File**
Enables Apex to set up a patient using a GDT patient file.
- **DICOM Encapsulated Report**
Enables Apex to download a report encapsulated in DICOM-formatted patient information.
- **CPR Patient Lookup**
Enables Apex to set up a patient using a Danish CPR number lookup.

ii. GDT Patient File

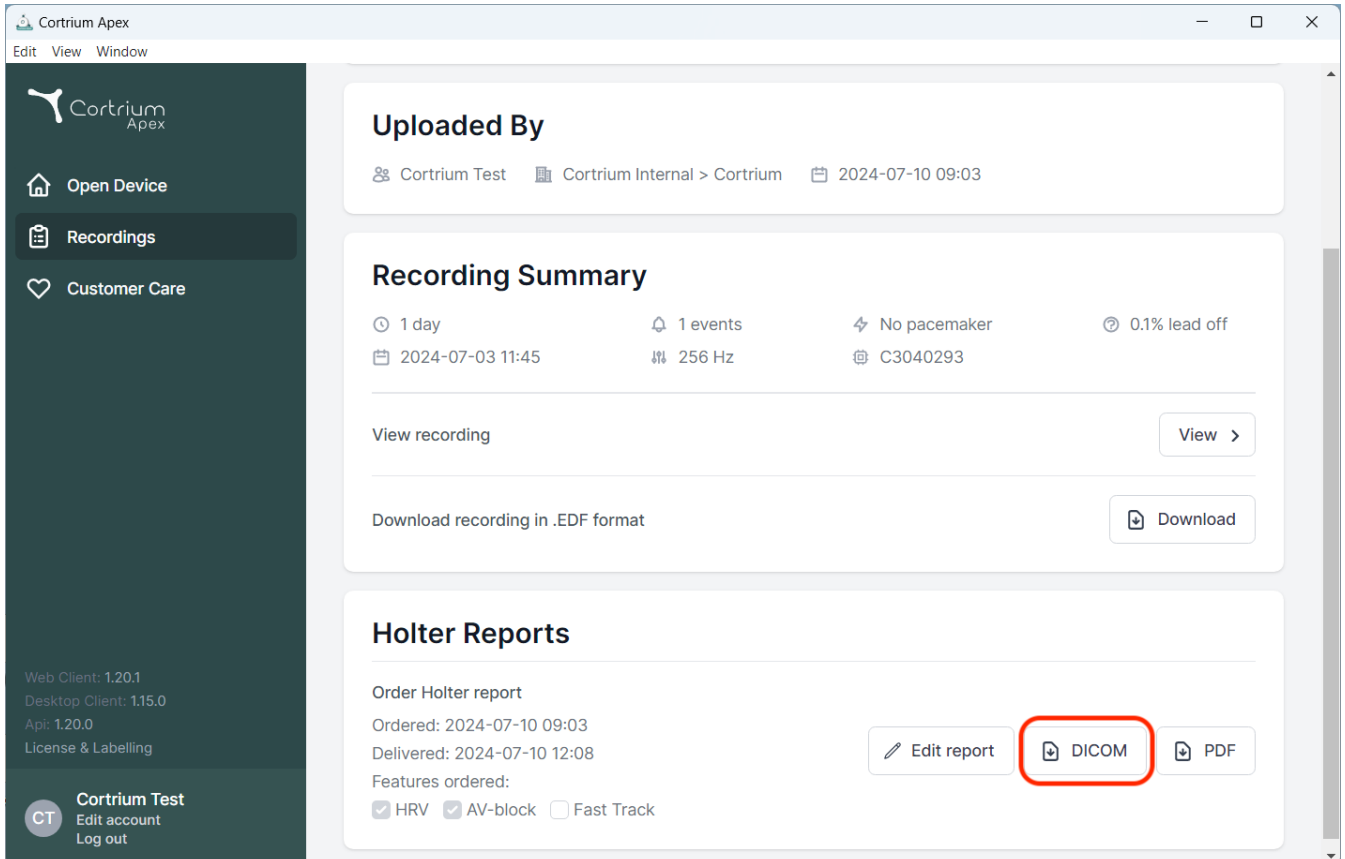
- Click to select or drag the GDT patient file onto the GDT input field in Apex.
- Once the file has been loaded the patient information is filled out.
- Loaded information cannot be edited.



The screenshot displays the Cortrium Apex web application interface. The left sidebar contains navigation options: Open Device, Recordings, and Customer Care. The main content area is divided into three sections: Patient, Notes, and Device setup. The Patient section features a 'GDT patient file' upload field, which is highlighted with a red box. Below this are input fields for Patient ID, Date of birth (mm/dd/yyyy), First name, and Last name. There are also radio buttons for Gender (Female, Male, Other) and a dropdown menu for Reason for recording (Not selected). The Notes section has a text area for 'Notes on patient or recording'. The Device setup section includes dropdown menus for Recording length (1 day), Pacemaker (None), and Sample rate (256 Hz). A disclaimer at the bottom states: 'Please note that analysis cannot be guaranteed if a pacemaker is implanted'.

iii. DICOM Encapsulated Report

- To download DICOM Encapsulated Report click the download button in the holter report section under the selected patient.
- Once the button is click the file is downloaded, the file ending is .DCM



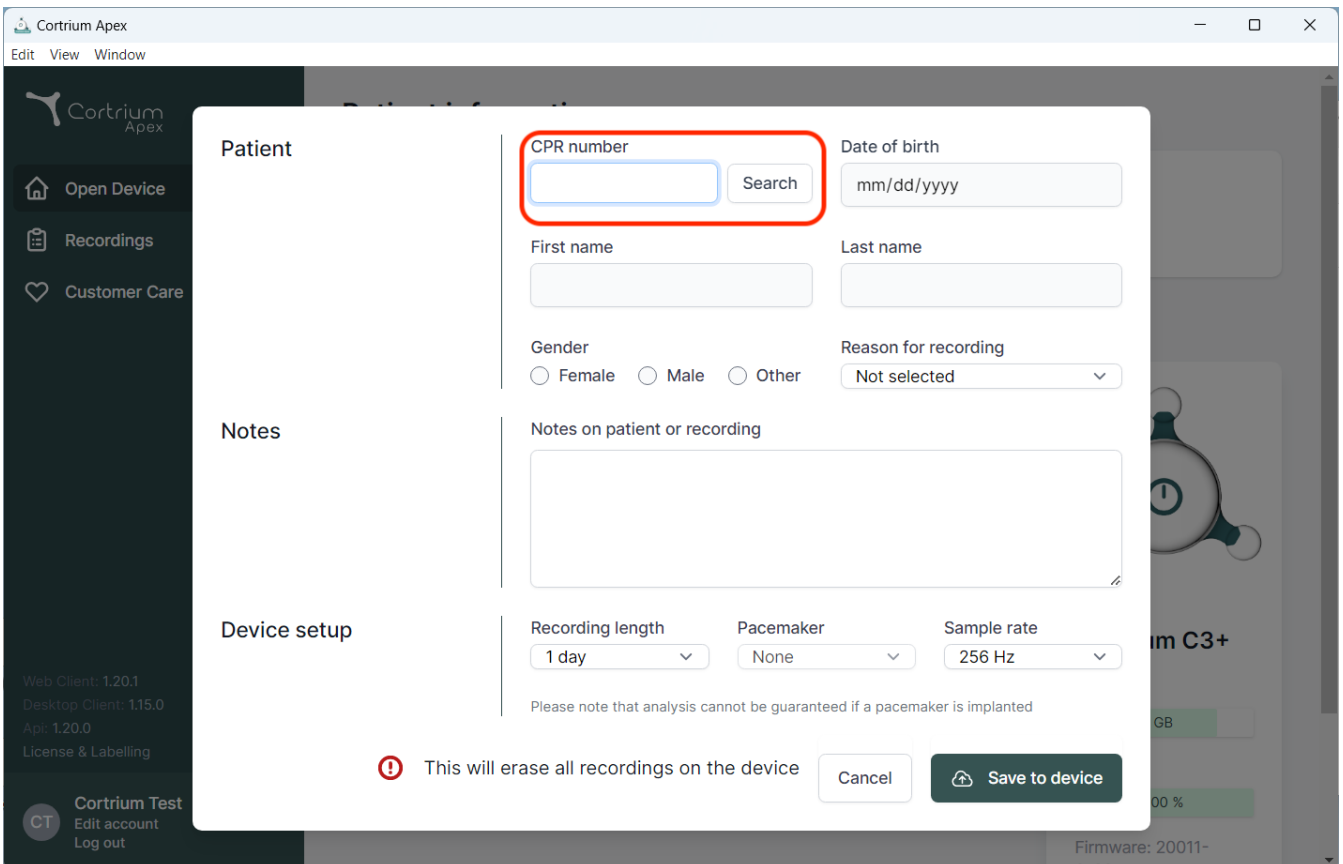
The screenshot displays the Cortrium Apex web application interface. On the left is a dark sidebar with navigation options: Open Device, Recordings, and Customer Care. The main content area is divided into three sections:

- Uploaded By:** Shows 'Cortrium Test' for 'Cortrium Internal > Cortrium' on '2024-07-10 09:03'.
- Recording Summary:** Displays recording details: 1 day duration, 1 event, No pacemaker, 0.1% lead off, and a recording date of 2024-07-03 11:45. It includes buttons for 'View recording' and 'Download recording in .EDF format'.
- Holter Reports:** Shows 'Order Holter report' with 'Ordered: 2024-07-10 09:03' and 'Delivered: 2024-07-10 12:08'. It lists ordered features: HRV (checked), AV-block (checked), and Fast Track (unchecked). Three buttons are present: 'Edit report', 'DICOM' (highlighted with a red circle), and 'PDF'.

At the bottom left of the sidebar, there is a user profile for 'Cortrium Test' with options to 'Edit account' and 'Log out'. Version information for Web Client (1.20.1), Desktop Client (1.15.0), and Api (1.20.0) is also visible.

iv. CPR Patient Lookup

- Enter the patient's Danish CPR into the field and press “Search.”
- The patient information is retrieved from the CPR register.
- The retrieved information is filled into the patient information fields.
- Loaded information cannot be edited.



The screenshot shows the Cortrium Apex web application interface. A modal window titled "Patient" is open, displaying a form for patient lookup. The form is divided into several sections:

- Patient:** Includes a "CPR number" field (highlighted with a red box) and a "Search" button. Other fields include "Date of birth" (mm/dd/yyyy), "First name", "Last name", "Gender" (Female, Male, Other), and "Reason for recording" (Not selected).
- Notes:** A text area for "Notes on patient or recording".
- Device setup:** Includes "Recording length" (1 day), "Pacemaker" (None), and "Sample rate" (256 Hz).

At the bottom of the modal, there is a warning message: "This will erase all recordings on the device" with a red exclamation mark icon. Below the warning are "Cancel" and "Save to device" buttons.



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