

Cortrium Apex 1.22

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).



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".



🛓 Cortrium Apex		-	×
Git View Window			
	Welcome Log in to Cortrium Apex to continue to Cortrium Apex Web Client.		
	Email address		
	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 Edit View Window		- D X
Cortrium	Patient information	
G Open Device 프 Recordings	Warning There does not appear to be any patient data associated with the recordi our software. Please setup a patient.	ngs or the device was setup from an earlier version of
🛇 Customer Care		Add patient information
	Recordings on this device	
	DURATION SUMMARY	
	No recordings found on device	
	Erase all and prepare for new patient	
		Cortrium C3+
		Space
		4 / 5 GB
		100 %
Web Client: 1.18.1 Desktop Client: 1.15.0 Api: 1.18.0 License & Labelling		Firmware: 20011-01665 Device ID: C3010072
CT Cortrium Test Edit account Log out		U Safely unplug device

- 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				- 0 X
Cortrium Apex	Patient information	on		
Open Device	Warning There does not appear	to be any patient data associated with	the recordings or the device w	as setup from an earlier version of
 Recordings Customer Care 	Patient	Patient ID 28081960	Date of birth 08/28/1960	Add patient information
		First name Cortrium	Last name Test	
		Gender Female Male Other	Reason for recording Other	
	Notes	Notes on patient or recording		ortrium C3+
	Device setup	Recording length Pacemake 1 day None Please note that analysis cannot be guarant	r Sample rate 256 Hz nteed if a pacemaker is implanted	→ ace 4/s gB
Web Client: 1.18.1 Desktop Client: 1.15.0 Api: 1.18.0 License & Labelling	 This will eras 	e all recordings on the device	Cancel 💽 Save to dev	100 % Imware: 20011-01665 Ivice ID: C3010072
				U 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

🛆 Cortrium Apex			- 🗆 X
Edit View Window			
Cortrium	Patient information		
Open Device	Cortrium Test		Edit patient information
Recordings		r 🕅 256 Hz 🕔 1 day 🍫 No pacemaker	
🛇 Customer Care			
	Recordings on this device		
	DURATION	SUMMARY	
	1 day 2023-03-13 → 2023-03-14 ③ Erase all and prepare for new patient	0% lead off 11 events Order Holter report C Upload and export as EDF	
			Cortrium C3+
			Space
			4 / 5 GB
			Charge
			100 %
Web Client: 1.18.1 Desktop Client: 1.15.0 Apl: 1.18.0			Firmware: 20011-01665 Device ID: C3010072
License & Labelling			U Safely unplug device
Cortrium Test Edit account Log out			

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.



🛓 Cortrium Apex		- 0	×
Edit View Window			
Cortrium	Patient information		
Open Device	Cortrium Test		
E Recordings	😁 Male (63) # 28081960 Q Other 🗱 256 Hz 📀 1 day 💠 No pacemaker		
🗘 Customer Care	Recordings on this device		
	DURA 1 day 2023 Please select and confirm your ordering details Image: Please select and confirm your order will include HRV assessment Image: Please select and confirm your order your recording will undergo AV-block assessment and grading Image: Please select and please se	Cortrium C3+ Space 4/5 GB Charge 100 % Firmware: 20011-01665 Device (D: C3010072)	,
Web Client: 1.19.0 Desktop Client: 1.15.0 Api: 1.19.0 License & Labelling		じ Safely unplug device	
CT Cortrium Test Edit account Log out			

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".



Cortrium Apex Edit View Window		>
Cortrium	Patient information	
Open Device	Cortrium Test	Edit patient information
Recordings	● Male (63) # 28081960 Q. Other 約 256 Hz ③ 1 day 今 No pacemaker	
🗢 Customer Care		
	DURATIO URATIO 1 day 2023-02 Order details: Order details: Image: All block (extra charges will be applied) Fast Track (extra charges will be applied) Cancel Confirm	Cortrium C3+ Space 4/5 68 Charge 100 % Firmware: 20011-01665
		Device ID: C3010072

The recording is now uploading.



🕹 Cortrium Apex Edit View Window			- 0 X
Cortrium	Patient information		
Gen Device	Cortrium Test	↓18 256 Hz 💿 1 day 💠 No pacemaker	Edit patient information
	Recordings on this device		
	DURATION	SUMMARY	
	1 day 2023-03-13 → 2023-03-14	0% lead off Actions V	
	Erase all and prepare for new patient		
			Cortrium C3+
			Space 4/5GB
			Charge
			100 %
Web Client: 1.18.1 Desktop Client: 1.15.0			Firmware: 20011-01665 Device ID: C3010072
Api: 1.18.0 License & Labelling	P Uploading recording to Cortrium Apex for proc	cessing - please do not unplug your device	
Cortrium Test Edit account Log out	Copying recording to local folder 100%		

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.

à Casteium Annu									
Edit View Window									
Cortrium	Recordin	gs							
G Open Device	Search record	dings	Search C	lear	From	mm/dd/yyyy	To m	m/dd/yyyy	
Recordings	USER≡↓	PATIENT		≡↓	RECORDING	DATE	≡↓	REPORT	
Customer Care	СТ	Cortrium Test Male 2808196	(63) 60		1 day 2023-03-13			Analyse	ed
	GT	Cortrium Test Male 2808196	: (63) 60		1 day 2023-03-13			Analyse	ed
Web Client: 1181 Desktop Client: 1150 Johi 1180							Pre	vious N	ext
Api: 1.18.0 License & Labelling									
CT Cortrium Test Edit account Log out									



A Cortrium Apex Edit View Window				- 0 X
Y Cortrium	€ Recording details	S		n Delete recording
Copen Device Recordings Customer Care	Cortrium Test	3) # 28081960 Q Oth	er	/ Edit
	Uploaded By & Cortrium Test Cortri Recording Summa	um Internal > Cortrium 🗎 24	024-01-30 12:31	
	⊙ 1 day Ё 2023-03-13 11:54	 	✤ No pacemaker⊕ C3100175	O.0% lead off
	View recording			View >
	Download recording in .EDF fo	rmat		Download
Web Cleart 1191	Holter Reports			
Desktop Client: 115.0 Api: 118.0 License & Labelling	Order Holter report Ordered: 2024-02-16 07:36 Delivered: 2024-02-16 13:00			✓ Edit report PDF
CT Cortrium Test Edit account Log out	Features ordered:	Track		



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.

Cortrium Apex				- 0 ×		
Cortrium Apex						
Open Device Recordings	Cortrium Test	(cs) # 20001060 (cs)		/ Edit		
Customer Care	 D24-01-30 12:31					
	Recording Summ	ary				
	 ⊙ 1 day ⊟ 2023-03-13 11:54 	↓ 11 events↓ 256 Hz	 	⑦ 0.0% lead off		
	View recording			View >		
	Download recording in .EDF fe	ormat		Download		
	Holter Reports					
Web Client: 1.18.1 Desktop Client: 1.15.0 Api: 1.18.0 License & Labelling	Order Holter report Ordered: 2024-02-16 07:36 Delivered: 2024-02-16 13:00			Edit report ● PDF		
CT Cortrium Test Edit account Log out	Features ordered:	t Track				

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

🛓 Cortrium Apex					-	
Cortrium Apex	Recordings					
G Open Device	Search recordings	s Search <u>Clear</u>		From mm/dd/yyyy	o mm/dd/yyyy	
Recordings	USER≡↓ F	PATIENT	≡j R	ECORDING DATE	=↓ REPO	RT
♡ Customer Care	СТ	Cortrium Test (63) Male 28081960	1 2	day 023-03-13	Analy	sed
	CT C	Cortrium Test (63) Male 28081960	1 2'	day 023-03-13	Analy	sed
					Previous	Next

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

Cortrium Apex Edit View Window				- 🗆 X
Cortrium		5		Delete recording
Open Device Recordings Customer Care	Cortrium Test	3) # 28081960 Q Oth	er	/ Edit
	Uploaded By & Cortrium Test 🗈 Cortri	um Internal > Cortrium 📋 2	024-01-30 12:31	
	© 1 day	Ary ↓ 11 events	4 No pacemaker	⑦ 0.0% lead off
	2023-03-13 11:54	4% 256 Hz	@ C3100175	
	View recording			View >
	Download recording in .EDF fo	rmat		Download
	Holter Reports			
Web Client: 1.18.1 Desktop Client: 1.15.0 Apl: 1.18.0 License & Labelling	Order Holter report Ordered: 2024-02-16 07:36			/ Edit report
CT Cortrium Test Edit account Log out	Features ordered:	Track		

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



🛓 Cortrium Apex				- 0 X
Edit View Window				*
Cortrium	Recording det	ails		Delete recording
Open Device	Cortrium Test			/ Edit
Recordings	🖻 Male 📋 1960-08-2	28 (63) # 28081960 Q Other		
🗘 Customer Care				
	Patient	Patient ID	Date of birth	
		28081960	08/28/1960	2
		First name	Last name	
		Cortrium	Test	
		Gender	Reason for recording	@ 0.0% load off
		○ Female ● Male ○ Other	Other	
	Notes	Notes on patient or recording		
				View >
				Download
			Cancel 💮 Save	
				2
Web Client: 1.18.1 Desktop Client: 1.15.0	Order Holter report			
Apl: 118.0 License & Labelling	Ordered: 2024-02-16 07:3			
- Cortrium Test	Delivered: 2024-02-16 13 Features ordered:			Edit report
CT Edit account Log out	HRV AV-block	Fast Track		



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".

🛓 Cortrium Apex Edit View Window				- 0 ×
Cortrium	Recordings			
G Open Device	Search recordings	Search Clear	From mm/dd/yyyy	To mm/dd/yyyy
Recordings	USER = PATIENT	≡↓	RECORDING DATE	=, report
交 Customer Care	Cortrium Test (6 Male 28081960	33)	1 day 2023-03-13	Analysed
	CT Cortrium Test (6 Male 28081960	33)	1 day 2023-03-13	Analysed
				Previous Next
Cortrium Apex Edit View Window				- 0 X
Y Cortrium	€ Recording details			Delete recording
G Open Device Ê Recordings	Cortrium Test	3) # 28081960 Q Othe	ir.	C Edit
♥ Customer Care	Uploaded By & Cortrium Test 🗈 Cortriu	m Internal > Cortrium 🗎 20	124-01-30 12:31	
	Recording Summa	iry		
	⊙ 1 day Ё 2023-03-13 11:54	 ↓ 11 events ↓ 256 Hz 	No pacemaker© C3100175	⑦ 0.0% lead off
	View recording			View >
	Download recording in .EDF for	mat		Download
Web Client: 118.1 Desktop Client: 1.15.0 Api: 118.0 License & Labelling	Holter Reports	7	.oading data	
COTTIUM Test Edit account Log out				



🛓 Cortrium Apex Edit View Window		- 0 ×
Y Cortrium Apex		Delete recording
G Open Device	Cortrium Test	/ Edit
Recordings	🖱 Male 🗎 1960-08-28 (63) # 28081960 🔍 Other	
♥ Customer Care	Uploaded By & Cortrium Test: 📑 Cortrium Internal > Cortrium 🖻 2024-01-30 12:31	
	Confirm delete You are removing Cortrium Test Cortrium Test Cortrium Test Cancel	② 0.0% lead off View >
	Download recording in .EDF format	Download
Web Glient: 1.18.1 Desktop Glient: 1.15.0 Apr: 1.18.0 License & Labelling Cortrium Test Edit account	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".

🕹 Cortrium Apex			- 🗆 ×
Edit View Window	Patient information		
Open Device Recordings Customer Care	Cortrium Test	- Ĵli 256 Hz _⊙ 1 day - 4⁄2 No pacemaker	Edit patient information
	Recordings on this device		
	DURATION 1 day 2023-03-13 \rightarrow 2023-03-14 O Erase all and prepare for new patient	SUMMARY O% lead off 11 events Order Holter report C Upload and export as EDF	
			Cortrium C3+ Space
			Charge 100 %
Web Client: 118.1 Desktop Client: 115.0 Api: 118.0 License & Labelling			Device ID: C3010072
CT Cortrium Test Edit account Log out			

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



Cortrium Apex			- 0 X
Cortrium	Patient information		
Copen Device Recordings Customer Care	Cortrium Test ── Male (63) # 28081960 Q Ott	her 🐰 256 Hz _⊙ 1 day 💠 No pacemaker	Edit patient information
	Recordings on this device	e	
	DURATION 1 day 2023-03-13 → 2023-03-14 ③ Erase all and prepare for new patient	SUMMARY 0% lead off Actions ~ 11 events Actions ~	
			Cortrium C3+ Space 4 / 5 GB Charge
	Uploading recording to Cortrium Apex for p	orocessing - please do not unplug your device	Firmware: 20011-01665 Device ID: C3010072
Cortrium Test Edit account Log out	Copying recording to local folder 100%		
Cortrium Apex			- o x
Cortrium	Patient information		
Open Device E Recordings V Customer Care	Cortrium Test ← Male (63) # 28081960 Q Ot	her 🏼 월 256 Hz 💿 1 day 🛷 No pacemaker	Edit patient information
	Recordings on this device	e	
	DURATION 1 day 2023-03-13 → 2023-03-14	SUMMARY 0% lead off 11 events	
	Erase all and prepare for new patient		
			Cortrium C3+



• 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

A Cortrium Apex				- 0 X
≺ Cortrium Apex	Recording details	Delete recording		
Open Device Recordings Customer Care	Cortrium Test	3) # 28081960 Q Oth	er	🖉 Edit
	Uploaded By			O.0% lead off
	View recording Download recording in .EDF fo	rmat		View >
Web Client: 118.1 Desktop Client: 115.0 Api: 118.0 License & Labelling Contrium Test Edit account Log out	Holter Reports Order Holter report Ordered: 2024-02-16 07:36 Delivered: 2024-02-16 13:00 Features ordered: HRV AV-block Fast	Track		PDF

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



🛓 Cortrium Apex Edit View Window				- 0 ×
Y Cortrium Apex	Recording detail	Delete recording		
G Open Device G Recordings	Cortrium Test			/ Edit
Customer Care	🗎 Male 🗎 1960-08-28 (6	3) # 28081960 Q Othe	er	
	Uploaded By & Cortrium Test 🛛 🗈 Cortri	ium Internal > Cortrium 🗎 2(024-01-30 12:31	
	Recording Summ	ary		
	③ 1 day 曲 2023-03-13 11:54	↓ 11 events↓ 256 Hz	 ✤ No pacemaker ⊕ C3100175 	Ø 0.0% lead off
	View recording			View >
	Download recording in .EDF fo	ormat		Download
	Holter Reports			
Web Client: 1.18.1 Desktop Client: 1.15.0 Api: 1.18.0 License & Labelling	Order Holter report Ordered: 2024-02-16 07:36 Delivered: 2024-02-16 13:00			Credit report
CT Cortrium Test Edit account Log out	Features ordered:	Track		

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 11 Big Sur (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 <u>https://apex.cortrium.com</u> 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
i	Refer to instruction manual/booklet	ISO 7000 - 1641
	Caution sign	ISO 7000 - 0434A
<b>CE</b> 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	Used by Microsoft Azure Application
dc.services.visualstudio.com	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.

#### • Patient Referral

The Patient Referral process allows healthcare professionals to attach and manage referral documents when ordering a recording. This ensures that relevant patient information is available for review or billing purposes during the analysis and reporting process.

#### • Report Approval Flow

The Report Approval Flow ensures that reports undergo a structured review by a third-party approver within the process before being delivered to the requester.



#### 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.

🛓 Cortrium Apex			– 🗆 X
Edit View Window	<b>T</b>		
Cortrium	Patient	GDT patient file	
Open Device			
Recordings		Patient ID Date of birth	2
💙 Customer Care		mm/dd/yyyy	
		First name Last name	
		Gender Reason for recording	
		○ Female ○ Male ○ Other Not selected ∨	U)
	Notes	Notes on patient or recording	
Web Client: <b>1.20.1</b>			um C3+
Desktop Client: <b>1.15.0</b> Api: <b>1.20.0</b>			6 GB
License & Labelling	Device setup	Recording length         Pacemaker         Sample rate           1 day         V         None         V         256 Hz         V	
CT Cortrium Test Edit account Log out		Please note that analysis cannot be guaranteed if a pacemaker is implanted	100 % 1: 20011-



#### 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

🛓 Cortrium Apex				-	×
Edit View Window					
Cortrium	Uploaded By				•
Open Device	🖧 Cortrium Test 🛛 📠 Cort	rium Internal > Cortrium	2024-07-10 09:03		
Recordings					
🛇 Customer Care	Recording Summ	nary			
	① 1 day	1 events	🍫 No pacemaker	⑦ 0.1% lead off	
	2024-07-03 11:45	∛∜ 256 Hz	@ C3040293		
	View recording			View >	
	Download recording in .EDF	format		Download	
	Holter Reports				
Web Client: 1.20.1	Order Holter report				
Api: <b>1.20.0</b>	Ordered: 2024-07-10 09:03				
License & Labelling	Delivered: 2024-07-10 12:08		/ Edit report	DICOM DICOM	
CT Cortrium Test Edit account Log out	Features ordered:	st Track			•



#### 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.

🛓 Cortrium Apex	-	o x
Edit View Window		
Cortrium Apex Patient	CPR number Date of birth	
G Open Device	Search mm/dd/yyyy	
🛱 Recordings	First name Last name	
🛇 Customer Care		
	Gender     Reason for recording       Female     Male     Other       Not selected     V	
Notes	Notes on patient or recording	
		)
Device setup	Recording length Pacemaker Sample rate Im C3+	
Web Client: <b>1.20.1</b> Desktop Client: <b>1.15.0</b> Api: <b>1.20.0</b>	Please note that analysis cannot be guaranteed if a pacemaker is implanted GB	
License & Labelling	will erase all recordings on the device Cancel 3 Save to device	
CT Contrium Test Edit account Log out	00 % Firmware: 20011-	



#### v. Uploader Only Role

• Once enabled for a user, the user can only upload and order reports without seeing patient information or reports.

🔔 Cortrium Apex			- 🗆 X
Edit View Window			
<b>Y</b> Cortrium Apex	Patient information		
G Open Device	XXXXXXXX XXXX		
🛇 Customer Care		ther 🕴 256 Hz 🕔 1 day 🍫 No pacemaker	
	Recordings on this devic	e	
	DURATION	SUMMARY	
	1 day 2023-03-13 → 2023-03-14	0% lead off 11 events a) Order Holter report	
			Cortrium C3+
			Space
			4 / 5 GB
			Charge
Web Client: 1.21.0			100 %
Desktop Client: <b>1.21.0</b> Api: <b>1.21.0</b> License & Labelling			Firmware: 20011-01665 Device ID: C3010072
CT Cortrium Test Edit account Log out			( ¹ ) Safely unplug device



#### vi. Active Directory Integration

• Once enabled for an organization, the login screen will display a custom single sign-on login screen for that organization. Below is Cortrium's login screen; the actual login prompt may appear different.

	Cortrium
Cortrium testreports@cortrium.com Enter password Password Sign in with another account	



#### vii. Patient Referral

- If Referral Integration is active, the option to upload a Referral PDF File will appear.
- Click Select File and choose the appropriate patient Referral PDF from your computer.
- The Referral PDF is automatically attached to the Patient Recording upon upload.

🛓 Cortrium Apex	_	
Edit View Window		
Cortrium	Patient information	
Open Device	Cortrium Test	
E Recordings	🗎 Male (64) 🛛 # 28081960 🔍 Other 🖓 256 Hz 💿 1 day 🛷 No pacemaker	
Customer Care	Rec   Confirm order   Please select and confirm your ordering details   HRV   Your Holter report will include HRV assessment   Your recording will undergo AV-block assessment and grading   Fast Track   Same day delivery of orders made before 12 PM CET   Referral   Your referral file will be attached to the recording   Your referral file will be attached to the recording   Choose File No file chosen	
	Cancel Confirm 0 % Firmware: Device ID: C3100175	
Web Client: 1.22.0 Desktop Client: 1.21.0 Api: 1.22.0 License & Labelling	し Safely unplue device	
CT Cortrium Test Edit account Log out		

• If Referral Integration is active and a recording has been ordered, the referral can be accessed under recording details.



🔬 Cortrium Apex					-		×
Cortrium Apex	Recording details     Action      Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Action     Ac	S			Delete record	ding	•
<ul> <li>G Open Device</li> <li>In Recordings</li> <li>♥ Customer Care</li> </ul>	Test Patient	4) <i>#</i> 12345678	Q Afib screening		d Edit	:	
	Uploaded By Test User 03 Distributor Organisation	01 > Approver n > Test Clinic	²⁰²⁵⁻⁰²⁻ 12 10:41	²⁰²⁵⁻⁰²⁻ 12 10:41 ¹⁰	Referra		
	<ul> <li>⊙ 32 minutes</li> <li>⋣ 2020-01-16 11:31</li> </ul>	Q 0 events № 256 Hz	✤ No pacer	naker 5	⑦ 0.0% lead off		
	View recording				View	>	
Web Client: <b>1.22.0</b> Desktop Client: <b>1.21.0</b> Api: <b>1.22.0</b> License & Labelling	Convert to Cardioline format				Convert	>	
CT Cortrium Test Edit account Log out	Order Holter report						Ţ



• A blue dot on a recording in the "Recordings" view indicates that an attached referral has not yet been downloaded or viewed for the specific report.

🔔 Cortrium Apex				– 🗆 ×
Edit View Window				
Cortrium	Recordings			
Open Device	Search recordings	Search <u>Clear</u>	From dd/mm/yyyy	To dd/mm/yyyy
Recordings				
💭 Customer Care	USER = ↑ PATIENT	=	RECORDING DATE	<b>≓↑</b> REPORT
	Test Patient Male 123456	(74) 78	<b>32</b> minutes 2020-01-16	In review
				Previous Next
Web Client: 1.22.0 Desktop Client: 1.21.0 Api: 1.22.0 License & Labelling				
CT Cortrium Test Edit account Log out				



#### viii. Report Approval Flow

- If Approval Integration is active and a recording has been ordered, the report will be available for an organization member with approval rights after analysis.
- Reports awaiting approval can be viewed by selecting "Awaiting Approval".
- If Referral Integration is active, a blue dot on a recording in the "Recordings" view indicates that an attached referral has not yet been downloaded or viewed for the specific report.

🛓 Cortrium Apex				– – ×
Edit View Window				
<b>Y</b> Cortrium Apex	Recordings			
Open Device	Search recordings	Search <u>Clear</u>	From dd/mm/yyyy	To dd/mm/yyyy
Recordings				Awaiting approval
🛇 Customer Care	USER=↑ PATIENT	=	RECORDING DATE	REPORT
	Test Patie Male 1234	nt (74) 5678	<b>32 minutes</b> 2020-01-16	In review 이
				Previous Next
Web Client: <b>1.22.0</b> Desktop Client: <b>1.21.0</b> Api: <b>1.22.0</b> License & Labelling				
CT Cortrium Test Edit account Log out				



• Reports that are awaiting review can be accessed and reviewed by an organization member with approval rights by accessing the recording details and selecting "Review report".

🔔 Cortrium Apex				– 🗆 X
Edit View Window				
Cortrium	🗎 Male 🗎 1950-10-01 (	74) # 12345678	Q Afib screening	
Open Device	Uploaded By			
Recordings	Test	01 > Approver	2025.02 2025.02	
♡ Customer Care	8 User Distributo 03 Organisati	ion > Test Clinic	E 2025-02 ⁻ E 2025-02	Referral
	Recording Summ	nary		
	③ 32 minutes	Q events	🎸 No pacemaker	⑦ 0.0% lead off
	2020-01-16 11:31	111 256 Hz	@ C3020195	
	View recording			View >
	Convert to Cardioline format	:		Convert >
	Holter Reports			
Web Client: 1.22.0	Order Holter report			
Desktop Client: 1.21.0	Ordered: 2025-02-12 10:41			
Apr: 1.22.0 License & Labelling	CAS ID: 102950			Review report
	Features ordered:			
Cortrium Test Edit account Log out	HRV AV-block Z Fa	st Track		



- The approver will have the option to review the report and findings and add to the report summary.
- When the report summary is displayed, information about the approver is added to the summary, along with the option to add supporting notes for the report.
- Once the report has been reviewed, it can be approved by clicking "Approve report".
- When the report is approved, it will be delivered to the requester.
- If a report cannot be approved, please contact Cortrium Customer Care with the CAS ID (listed under Holter report on the recording details).









02/2025

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