Cortrium

C3 | Holter Monitor

Instructions for Use

and Technical Documentation

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1. Introduction

This is the manual for the C3 Holter Monitor (referred to as the "C3" from here on). The C3 is an ambulatory ECG recorder. The C3 can record ECG on three channels for up to 48 hours and data can be exported to a PC. The C3 is attached directly to a patient's torso using three third-party ECG electrodes. This manual contains all information required to safely use the C3.

1.1 Intended use

The C3 is intended for recording three-channel ECG for periods up to 48 hours, in order to record evidence of ECG abnormalities. The C3 is intended for use both in hospital general wards, ambulatory clinics, and in the home environment. During use, the C3 continuously records and stores a patient's ECG signal for later analysis by a qualified healthcare professional, after transfer to a PC through a USB cable. The C3 Holter Monitor hardware has no capacity for automatic ECG analysis and consequently no capacity for automatically generating alerts to potentially critical cardiac conditions.

1.2 Intended Users

The C3 is only intended to be operated by Healthcare Professionals. Patients are regarded as wearers, not users or operators. Therefore all information in this manual is intended for the operator (the Healthcare professional). Any instructions given to patients should comply with this manual.

1.3 Clinical Indications

The C3 is indicated for diagnostic evaluation of patients who are either asymptomatic or experience transient symptoms, including palpitations, syncope (fainting), chest pain, fatigue, shortness of breath, or dizziness.

1.4 Contraindications

The C3 device should not be used for patients that have been diagnosed with, or are suspected to have, life-threatening conditions that could result in immediate danger. The C3 should not be used on breached skin.

The C3 should not be used by patients that use a pacemaker.

1.5 Additional Software

The C3 is intended to be used with the Data Transfer Tool software tool found at
https://cortrium.com/apps/dtt/cortrium_data_transfer_tool-latest.zip

Data Transfer Tool is required to prepare the C3 for use on patients and for extracting recordings after use. Instructions for Data Transfer Tool can be found in Appendix A.

Further, the C3 is compatible with the CE marked 3rd party software CUBE by Cardioline, and CE marked software Cardiomatics.

2. Safety information

The following is important information for how to use the C3 properly and safely. Carefully read this section before operating the C3.

2.1 Notes on proper C3 use

- The C3 and the Data Transfer Tool software contain no capacity for analysing the contents of ECG recordings or providing diagnoses.
- The C3 light patterns only reflect battery status and operation mode. The lights do not reflect cardiac health in any way and should never be interpreted as an indication of patient health.
- The C3 is built to be operable by a healthcare professional. The patient should always be walked through all required instructions before wearing the device.
- The C3 is only intended to be worn but not operated by the patient.
- The data recorded by the C3 can only be used to diagnose heart-related diseases such as Atrial Fibrillation and arrhythmias when reviewed by a properly trained healthcare professional (e.g. a cardiologist).
- ECG electrodes (not supplied by Cortrium) may cause a patient's skin to react with irritation or reddening. Consult information provided with electrodes for more information.

2.2 Warnings

- Do not use C3 before reading this manual and manual for ECG electrodes.
- Do not use C3 on a patient without first cleaning it according to instructions.
- Do not use C3 without setting device up as described in this document between patient uses.
- Do not allow patients to interact with the C3, unless when directly instructed by a healthcare professional.
- Do not charge the C3 in a location where patients have access.
- Do not touch the electrodes connections while the USB plug is removed.
- Do not give the C3 to a user or patient, without the USB plug being properly closed.
- Do not touch patient and C3 simultaneously while C3 is charging.
- Do not use the C3 during MRI scans.
- Do not use the C3 with a defibrillator.
- Do not use the C3 with a pacemaker.

- Do not expose the device to strong sources of static electricity.
- Do not expose the C3 to strong electromagnetic fields.
- Do not leave C3 on top of or next to other electrical equipment.
- Do not use C3 with cables different than the one provided by Cortrium.
- Do not submerge the C3 in liquid.
- Do not clean the C3 with agents other than those listed in the cleaning instructions in this manual
- Do not damage the C3 through drops, violent shaking or crushing.
- Do not allow the C3 to come into contact with conductive materials, except when following instructions on how to charge.
- Do not use the C3 on patients with highly sensitive skin or known skin-related allergies
- Do not use the C3 on patients below 10 kilos of body weight
- The C3 is not a toy. Usage on children should be under strict supervision of adults.
- Do not use the C3 on breached skin.
- Do not put C3 into mouth under any circumstances.
- Do not alter the C3. Any modification of the C3 is strictly prohibited.

3. Device description

The following section describes the features of the C3, accessories and accompanying information.

3.1 Included components

The C3 comes with the following included in the package:
- The Cortrium C3 Holter Monitor
- A micro-USB cable for charging and data extraction
- Instructions for Use and Technical Documentation (this document)

3.2 Accessories

The C3 requires the following to function as intended:
- Three third-party ECG electrodes per patient use (not supplied with device)
- The Data Transfer Tool software
  (found on https://cortrium.com/apps/dtt/cortrium_data_transfer_tool-latest.zip)

3.3 Device layout and light

The C3 is a single-unit device with three mount-points for ECG electrodes, meant to be attached directly to a patient's torso to perform recordings for up to 48 hours. The C3 has a single button as well as an LED indicator at the center. The button is used to start recordings

and to log patient events in the C3's internal memory. The button is shown below. LED is marked as a green circle.
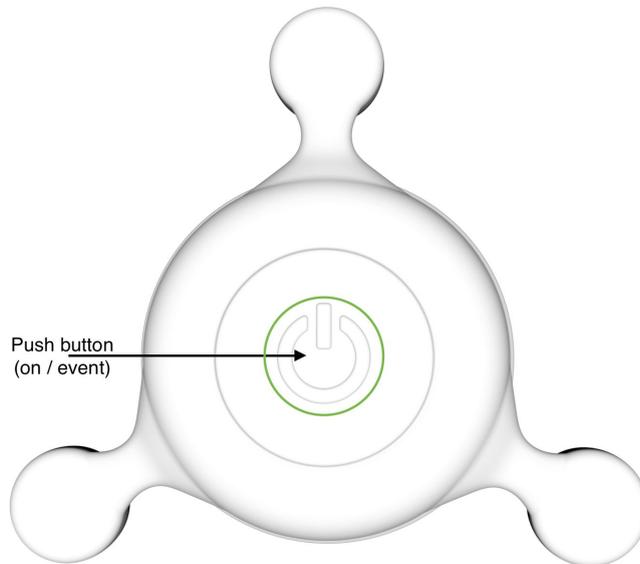
The C3 Holter Monitor: Button and light location shown

C3 Recordings are stored in internal memory. Recordings can be transferred and removed from the device via the device's micro-USB port, when interfaced with the Cortrium Data Transfer Tool software. The C3 contains a non-replaceable, rechargeable Lithium battery.

The C3 is recharged via the device's micro-USB-port. The device will automatically enter a standby-mode when it either has had no conductive contact (e.g. skin contact) continuously for more than 1 hour, or when the battery's energy level is too low to continue recording.

3.4 Interfaces

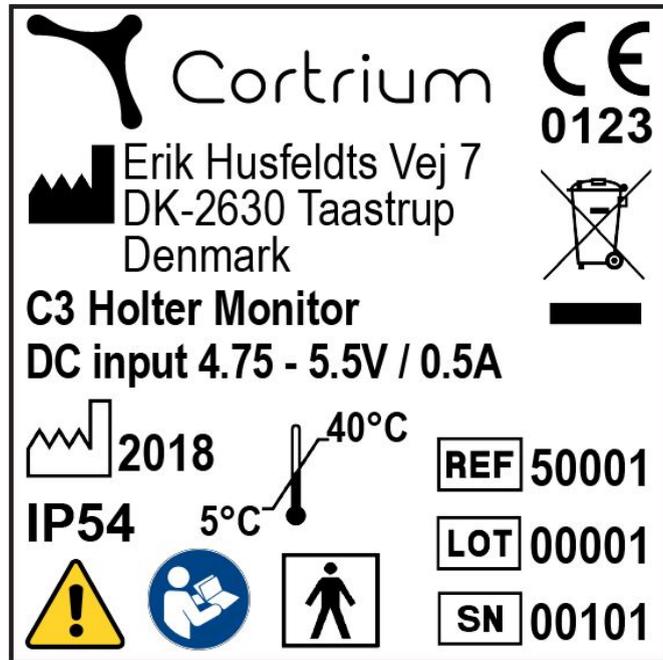The C3 is intended to interface with a PC using the accompanying USB-cable.

3.4 LED light Notifications

While not charging	
Light	**Meaning**
Green, fast flashes	On / event button pressed
Green, slow flashes	C3 is recording - normal function
Blue, fast flashes	C3 does not have proper contact to the body
Yellow, slow flashes	Low Battery

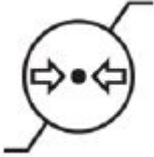| Yellow, fast flashes	Non-critical device error. Consult manual.
White	Critical device error. Stop use and consult Cortrium.

3.5 Package and device symbols

The following symbols are found on the C3 package and device body.

Device label example

Symbol	Description
	Manufacturer
	Year of manufacture
LOT	LOT / Batch code

	Temperature Limitation / Temperature Range 5 - 40 degrees Celsius (while operating) -25 - 70 degrees Celsius (while stored)
	Pressure limitation 700 - 1060 mBar
	Humidity limitation 10% - 95%
SN	Serial number (Device ID)
REF	Reference number
	Refer to instruction manual/booklet
	General warning sign. Refer to warning section
IP54	Protected against solid foreign objects (degree 5-dust protected). Protected against ingress of water. (degree 4-protected against splashing water from any direction).
	Type BF applied part

	Recycle: Electronic Equipment
C€ 0123	CE mark with notified body identification number
Cortrium	Company logo with name

4. Use Information for Healthcare Professionals

The C3 is intended to be operated by healthcare professionals, and worn by patients. The following section describes how to properly prepare and use the C3.

4.1 Installation of C3 Data Transfer Tool

Before using the C3, download and install the Cortrium Data Transfer Tool from https://cortrium.com/apps/dtt/cortrium_data_transfer_tool-latest.zip and run "setup.exe". When the C3 is connected to a PC, the device will appear as a Mass Storage Device (similar to a USB memory stick) that can be opened by Data Transfer Tool.

See Appendix A for how to install Data Transfer Tool.

4.2 Using the Cortrium C3 Holter Monitor

First-use preparation:
The C3 Holter Monitor is shipped with a clear internal storage. The C3 needs to be charged and cleaned according to instructions before first use. The user should carefully read all instructions before using the C3.

Before patient use:
To perform a recording with the C3, perform the following:
1. Clean the C3 according to instructions (see separate description in this manual)
2. Open the USB-port cover found on the bottom of the device, then connect the USB cable to this the port found below the cover. Connect the other end of the USB cable to a PC.
3. Use Cortrium Data Transfer Tool to prepare C3 for new patient (by transferring all files and clearing memory, see separate description in this manual).
4. If C3 is not fully charged, maintain connection to the computer for at least one hour.
5. Disconnect the C3, unplug the USB cable from the C3 device and close USB-port cover.
6. Prepare and instruct the patient (see separate description in this manual)
7. Snap three new ECG electrodes (not provided by Cortrium) onto the C3, keeping their protective layers around the electrode gel in place for now.
8. Press the button on the C3 device to activate the device. The C3 notification light will flash fast green flashes for approximately 10 seconds to indicate the C3 device has been turned on. After the green flashes, the C3 notification light will flash fast blue, to indicate lead-off, meaning no contact to the body.
9. Peel off the protective layer which covers the electrodes adhesive.
10. Place the C3 device with electrodes on the patient's chest and press the electrode surface firmly against the skin to ensure proper adhesion.
11. Make sure that the C3 device's notification light flashes green slowly, which indicates proper contact to the patient's body and that recording has started.

12. If the C3 device's notification light flashes fast blue, it means that one or more electrodes do not have proper contact with the patient's body (and/or the C3 device). Remove the electrodes from the patient and the C3 device and apply new electrodes.
13. Note the time and date of when the recording was started, in the C3 logbook available on cortrium.com, then give the log to the patient and ask the patient to wear the device for a predetermined length of time (up to 48 hours) while taking precautions as instructed.

After patient use:
1. When patient recording has ended, remove the device from the patient torso (patient may have done this already)
2. Detach ECG electrodes, and dispose of them.
3. Open the USB-port cover found on the back of the device, then connect the USB cable to this the port found below the cover.
4. Connect the other end of the USB cable to a PC to open Data Transfer Tool.
5. Extract recordings using Cortrium Data Transfer Tool.
   NB!: Cortrium Data Transfer Tool will automatically discard the first 60 seconds of each recording when exporting to analysis software.

4.3 Preparing and instructing the patient

Preparing the patient's torso:
To prepare a patient, the responsible healthcare professional should:

1. If patient has significant chest hair on center torso, shave an area approximately the size of the C3 with electrodes mounted.
2. Clean the skin in the area where the C3 is to be placed with an alcohol wipe.
3. Abrade the cleaned skin with a cotton swab.

Instructing the patient:
The responsible healthcare professional should gauge the extent to which a patient is able to properly interact with the C3 as described below. For some patients, such as young patients or patients with severe disabilities, all interaction with the C3 may need to be handled by the healthcare professional during use. A normal adult layperson user, should be instructed to:

● Press the C3 button when experiencing any relevant symptoms as described by healthcare professionals - typically palpitations, syncope (fainting), chest pain, fatigue, shortness of breath or dizziness.
● If a logbook is provided by the physician (usually a paper form), note date, time and description of symptoms.
● Stop activity and remain inactive for a few minutes, if symptoms are experienced while being physically active (e.g. walking or running). This will improve the quality of the ECG recording and facilitate analysis.
● Not wear the C3 while showering or bathing, unless C3 is carefully shielded from water.
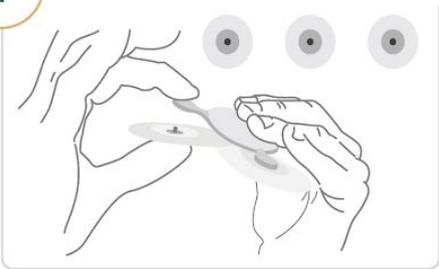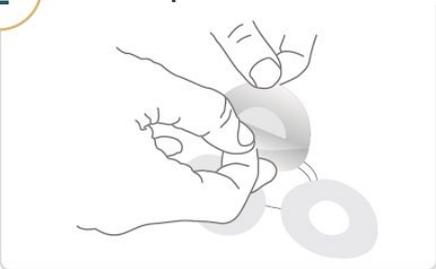
- Not to wear clothes made of materials generating large amounts of static electricity (such as pure polyester clothing).
- To react to indication of electrode detachment (lead off), first try to reconnect device to torso, then replace ECG electrodes and re-attach device to torso.
- To remove the C3 device from the torso after a set duration as determined by the responsible healthcare professional, after which the C3 will continue to show lights for 1 hour, then stop flashing and go into standby mode (no lights).
- To reactivate the device not showing lights before end of set recording duration, press the button (to wake device from standby mode).
- Do not remove the USB plug.
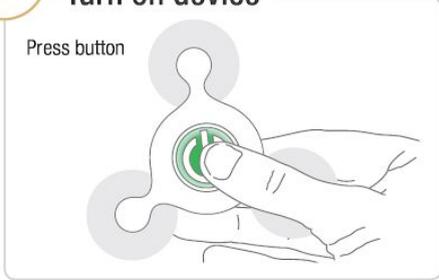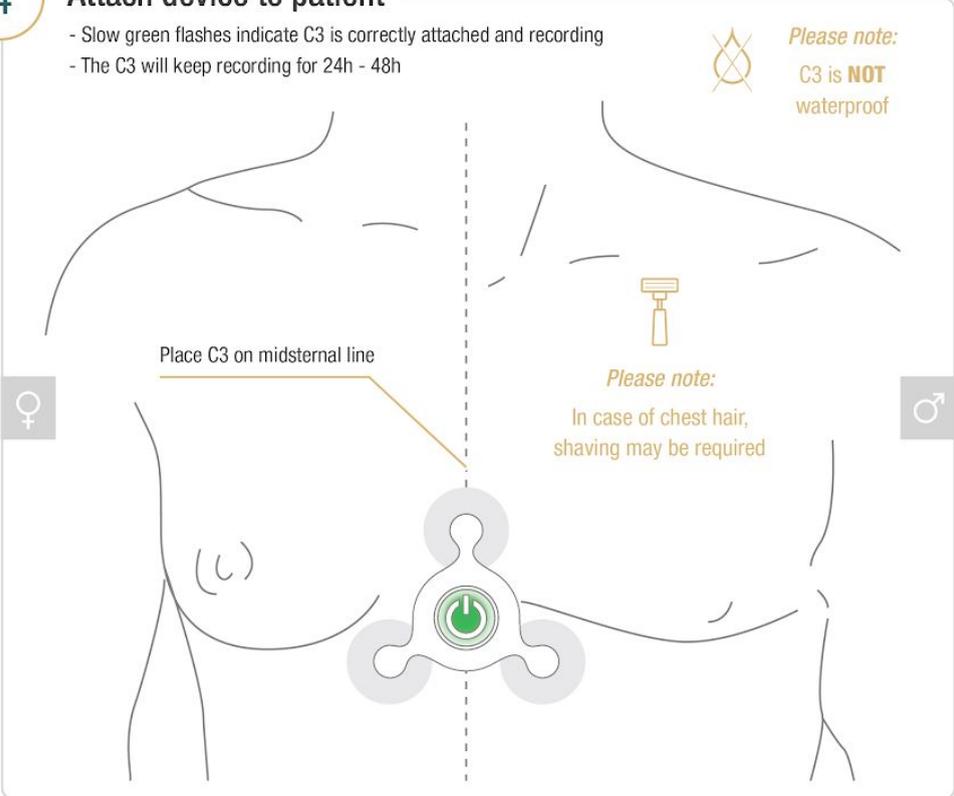- Do not try to connect a USB cable to the C3.

4.4 Short Version Manual

Cortrium C3 Holter Monitor - Instruction for Use
Cortrium C3 Holter Monitor Instruction for Use and technical documentation
Ver.: 1.0 Rev.: 06 EN, Issue date: 2019-01-10

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Additional instructions

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A — Device notification lights
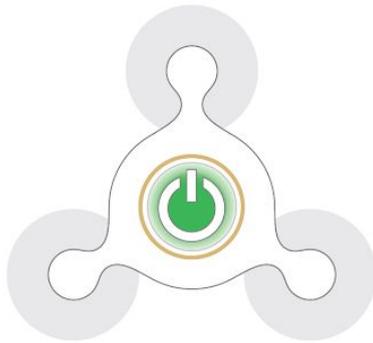
Green flashes
- Fast: ON / Event button pressed
- Slow: C3 is recording

Blue flashes
- C3 does not have proper contact to the body

Yellow flashes
- Slow: Low battery
- Fast: Non-critical Error (Consult Manual)

White flashes
- Critical Error (Contact Supplier)

B — Contents of package

Cortrium C3 unit

USB-cable

Instructions for Use
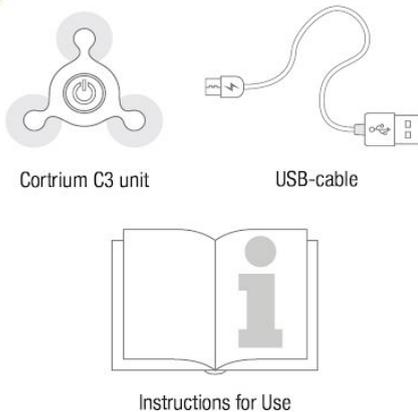
NB — Discomfort!

If sensing symptoms or discomfort, press button
- Button will flash green quickly for 10 seconds.

C — Charging the C3

Please note:
Charge for at least one hour

Micro USB socket

USB Plug

USB Cable

The back of the C3

Main power outlet

4.5 Charging

The C3 automatically charges when connected to standard USB charger or a PC via the USB cable. **NB DC supply voltage 4.75V - 5.5V**
(The C3 may charge slower when connected to a PC)

To charge, perform the following actions (potentially concurrent with data extraction using Data Transfer Tool):
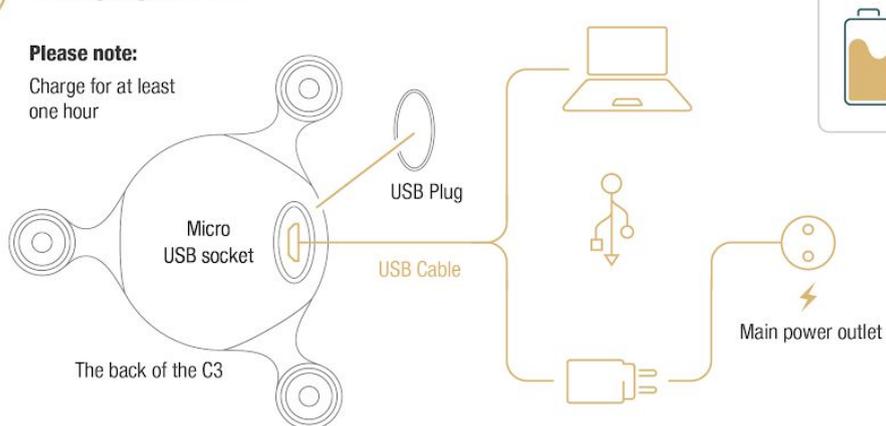1. Remove any ECG electrodes attached to the C3.
2. Connect the C3 to a charger or PC with the USB cable. Never connect the USB like this while user or patient is in contact with the electrode mount-points.
3. Maintain USB connection to the charger or PC for at least one hour.
4. Remove C3 from USB connection when an hour has passed.

4.6 Cleaning

In order to protect patients against risk of cross-contamination, the C3 should be cleaned and disinfected in preparation for a new patient (Sterilisation is not required).

To Clean
1. Apply a non abrasive liquid soap to a clean soft cloth.
2. Wipe the C3 device thoroughly.

To Disinfect
3. Apply 70 % isopropyl alcohol to a clean soft cloth.
4. Wipe the C3 device thoroughly.

DO NOT use abrasive cleaners such as acetone.

4.7 Troubleshooting

● If experiencing a non-critical error (LED is flashing fast yellow), attach device to PC with Data Transfer Tool software to reset device by preparing a "new patient". All recordings will be lost during this process.

● If experiencing a critical error (LED is white), discontinue use and contact Cortrium.

● If operator or patient experience any adverse events while using the C3, discontinue use of device and contact Cortrium immediately.

● If the C3 contains a recording that is shorter than expected (24+ hours), or no recording, or excessive noise is seen in the recording.
  ○ The patient may have detached the C3 from his/her chest for more than 1 hour.

- ○ The C3 may not have proper contact to the body. Start a new recording with the C3 properly attached to the chest with adhesive electrodes. Observe the C3 LED light notifications and refer to the section of this manual describing the LED light notifications. If the C3 does not obtain proper contact to the body within the first 3 minutes, the C3 will stop and delete the recording.

- If the C3 contains two or more recordings, the patient may have detached the C3 from his/her chest for more than 1 hour (e.g. due to taking a shower), and turned on the C3 after attaching the device again to his/her chest.

- To see the length and number recordings on the C3, connect the C3 via USB to a PC with the Data Transfer Tool installed.

5. Use information for Patient

The following information is intended for the patient wearing the device.

- Record your activity and symptoms in the provided logbook.
- Carry out your daily routines as usual.
- Do not shower or bathe while wearing the C3.
- Avoid use of electronic blankets.
- Avoid strong electromagnetic fields and use of industrial machinery.

6. Maintenance, Storage and Disposal

6.1 Maintenance

The C3 device contains no user serviceable parts, cannot be opened, and does not require routine maintenance. If a problem with the C3 is experienced, contact Cortrium.

Cortrium service contact:
Cortrium ApS - Erik Husfeldts Vej 7 - DK-2630 Taastrup - Denmark
email: support@cortrium.com - Website: www.cortrium.com

6.2 Storage

Do not store the C3 in locations in which the device would be exposed to
- Temperatures lower than -25 or greater than 70 ° Celsius
- Air humidity outside 10 - 95 %
- Heavy contamination from dirt or other foreign agents
- Running water
- Strong electromagnetic forces

6.3 Warranty

The C3 has a warranty of 2 years from the date of purchase.

6.4 Disposal

The C3 should be decommissioned when it reaches the end of its service life. The C3 should be disposed of in accordance with the EU WEEE directive for electronic waste.[1]

7. Technical and Regulatory information

7.1 Technical specification

Technical	
Type of ECG Recorder	Holter, ambulatory ECG
No. of Channels	3
Wear Time	48 hours
Recording Format	Continuous
Power Requirement	Lithium Polymer, 3.7V, 520 mAh
Dimensions	88 x 80 x 17 mm
Weight	30 grams
Sampling rate	250 Hz
Input Impedance	10 Mohm
Resolution	24 bit
Performance Standard	Design verification IEC 60601-2-47
Safety	
Safety Standard	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47
Biological	
Medicinal Substances	N/A
Tissue	N/A
Body Fluids Contacted by Device	N/A
Type of Contact to Intact Skin	Non-invasive
Duration of Skin Contact	Up to 48 hours
Mucosal Membrane Contact	N/A
Sterile or Non-sterile	Non-sterile
Biological Compatibility	ISO 10993-5 ISO 10993-10
Clinical	
Medical purpose	Ambulatory ECG
Single use / Reusable	Reusable/Rechargeable Monitor

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[1] DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE).

Recording standard	Holter
Recording Format	Continuous
Placement	Sternum and costae
Recording period	48 hours on a single charge

7.2 Regulatory information

The C3 is a class IIa medical device according to 93/42/EEC. The C3 complies with the following product standards:

DS/EN 60601-1-1	Safety Requirements for Medical Electrical Systems
DS/EN 60601-1-2	Electromagnetic Disturbances
DS/EN 60601-1-6	Medical Electrical Usability
DS/EN 60601-1-11	Home Healthcare Environment
DS/EN 60601-2-47	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
DS/EN 62366-1	Application of usability engineering to medical devices
DS/EN ISO 10993-1	Biological evaluation of medical devices
DS/EN ISO 15223-1	Symbols to be used with medical devices labels, labeling and information supplied
DS/EN 1041	Information supplied by the manufacturer of medical devices
DS/EN 62304	medical device software – software life cycle processes
DS/EN ISO 14971	Application of risk management to medical devices

7.3 Declaration of conformity

The C3 device is in conformity with the essential requirements and provisions of the EU Medical Device Directive (MDD).[2]

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[2] COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

Appendix A Data Transfer Tool - Instructions for Use

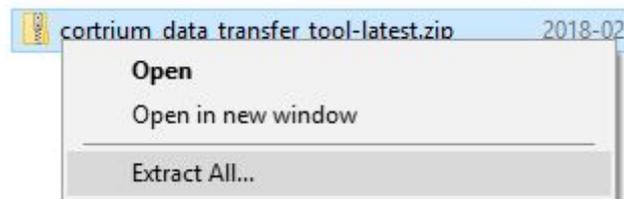# Cortrium Data Transfer Tool Instructions for Use

1. Cortrium Data Transfer Tool

The Cortrium Data Transfer Tool is a software application that is used for preparing the Cortrium C3 Holter Monitor before use with a new patient. The software is also used to extract recordings from the C3, and convert the recordings to a format that can be imported by third party software for analysis. The software is compatible with Microsoft Windows 7 and 10.
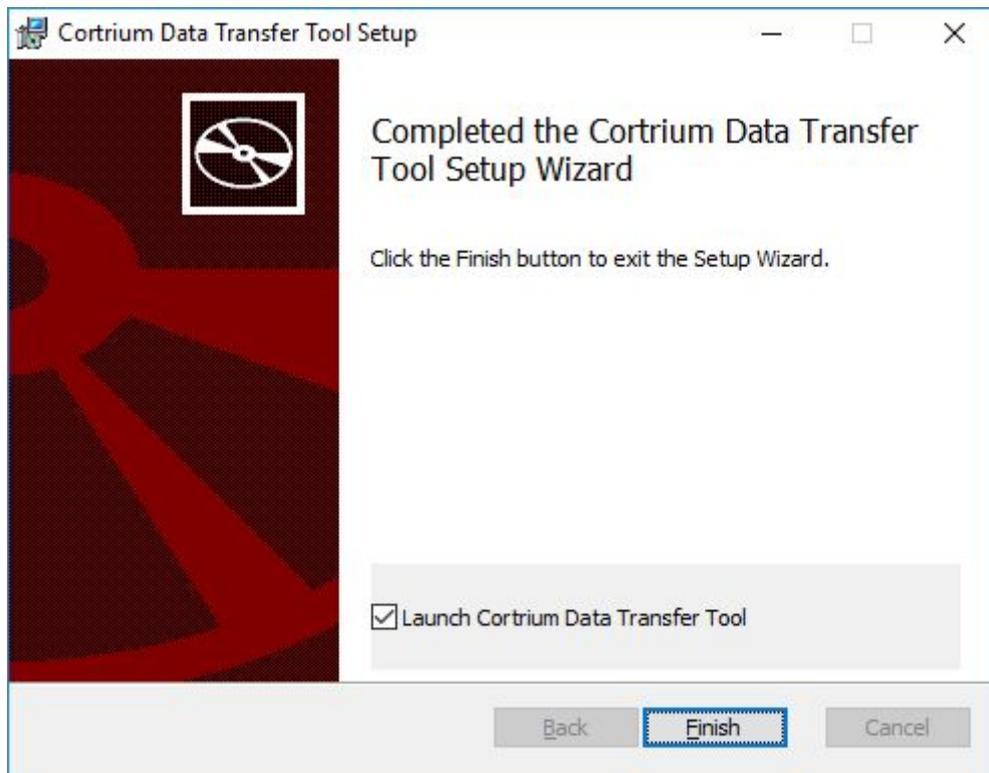
1.1 Installation

To get and install the Cortrium Data Transfer Tool, please follow the instructions below.

1. On a computer running Windows 7 or 10, use an internet browser to visit the Cortrium website (www.cortrium.com), and download the Data Transfer Tool.
    Alternatively, download the Data Transfer Tool directly from:
    https://cortrium.com/apps/dtt/cortrium_data_transfer_tool-latest.zip
2. When the download is complete, locate the downloaded file on the computer. It will be a zipped (compressed) folder. Unzip (uncompress) the folder by right-clicking the folder and selecting "Extract all…"

3. In the unzipped folder, double-click the setup file to start the Data Transfer Tool Setup Wizard. In the last step of the Setup Wizard, make sure the option "Launch Cortrium Data Transfer Tool" is selected, and then click "Finish".

4. When installation has finished, Data Transfer Tool will be started. It will automatically start when you start Windows.
    a. If a C3 is not connected via USB to the computer, Data Transfer Tool will be minimized to the Windows System Tray (also called Notification Area).
    b. If a C3 is connected via USB to the computer, Data Transfer Tool will open a window listing connected C3 devices.
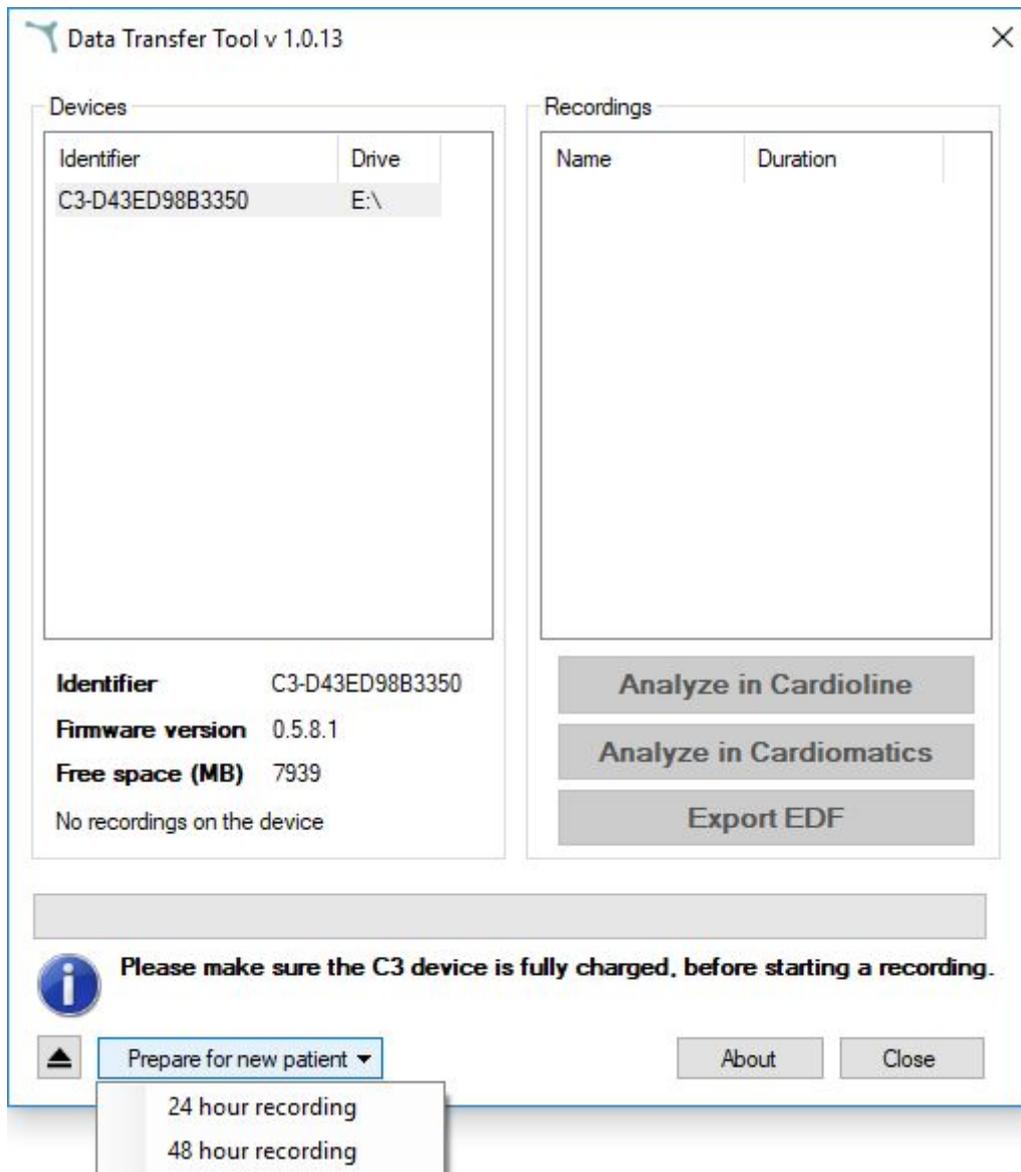
1.2 Prepare C3 for a new patient

If the C3 has been used to make recordings from a patient, please refer to the section titled "Transfer recordings from C3", before following the steps in this section.

1. Make sure the C3 is fully charged.
2. Turn on the computer that the Data Transfer Tool was installed on.
3. Connect the C3 to the computer via the included USB-cable.
4. Data Transfer Tool will open and show a list of connected C3 devices.
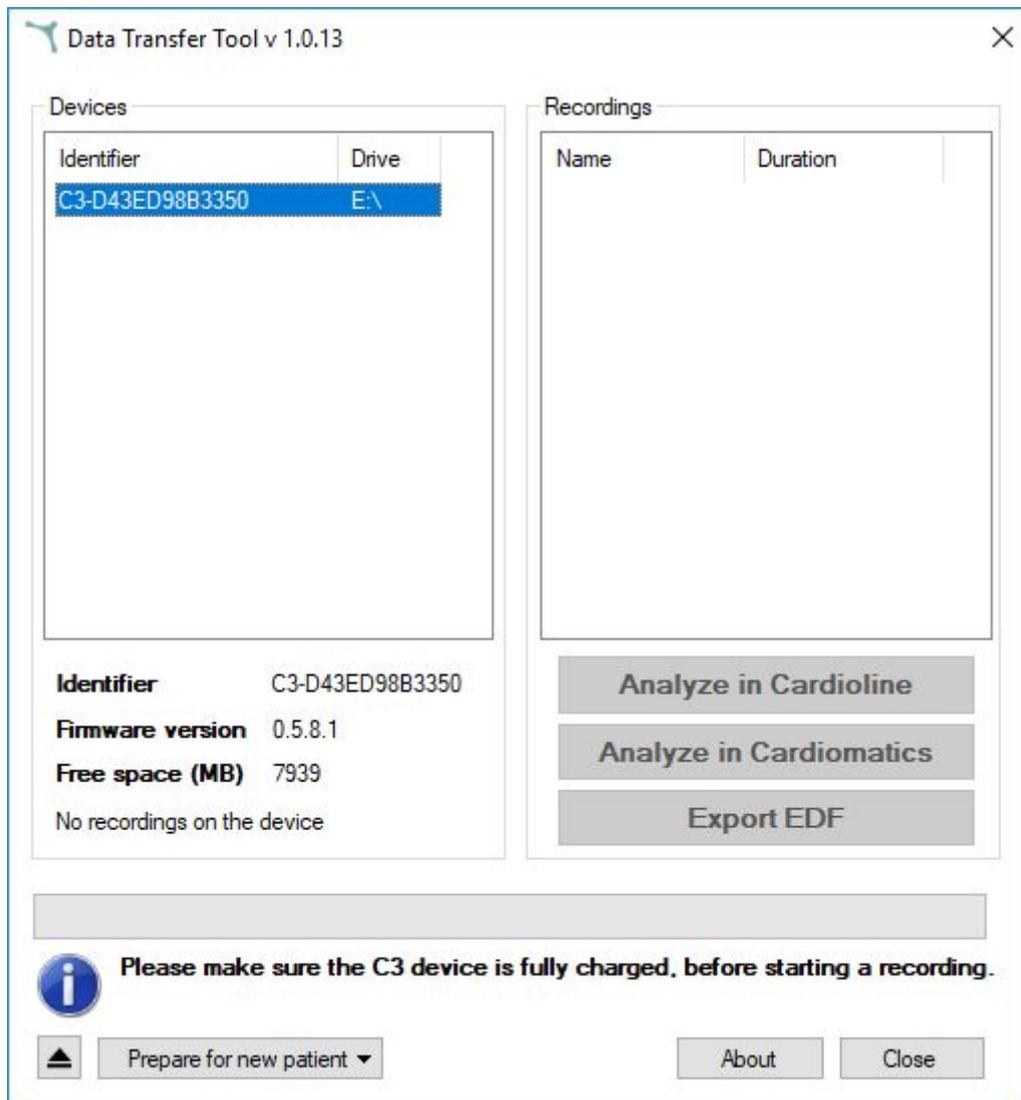
Example of how the Data Transfer Tool will appear when a C3 is connected via USB.

5. Click on the C3 identifier in the list of devices, to select the C3.
6. Click on the pop-up menu called "Prepare for new patient", and choose the desired recording length, "24 hour recording" or "48 hour recording".

7. Data Transfer Tool will display a message informing you that all recordings on the C3 will be deleted, and ask if you want to proceed.

8. If you choose to proceed to prepare for a new patient, Data Transfer Tool will open a dialog box where you can specify patient information. Please fill in any applicable information and proceed by clicking "OK".
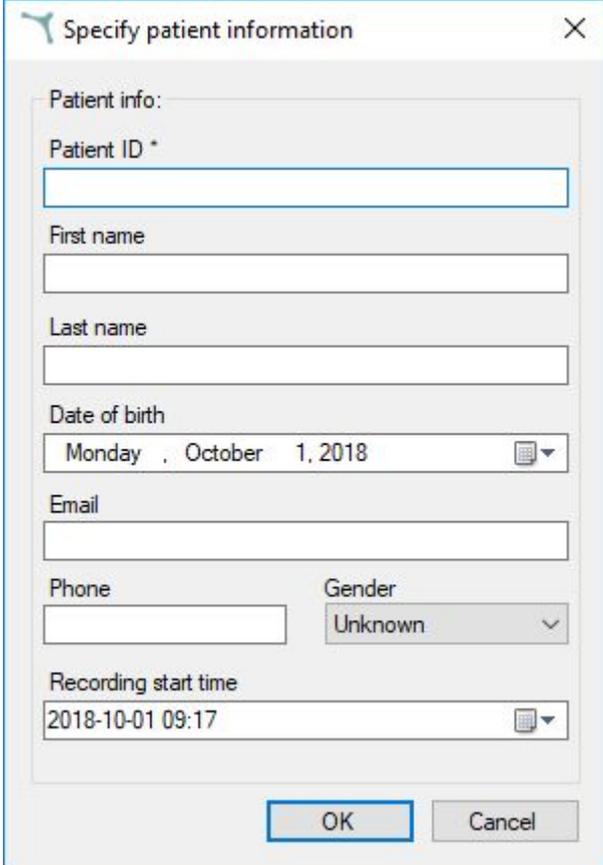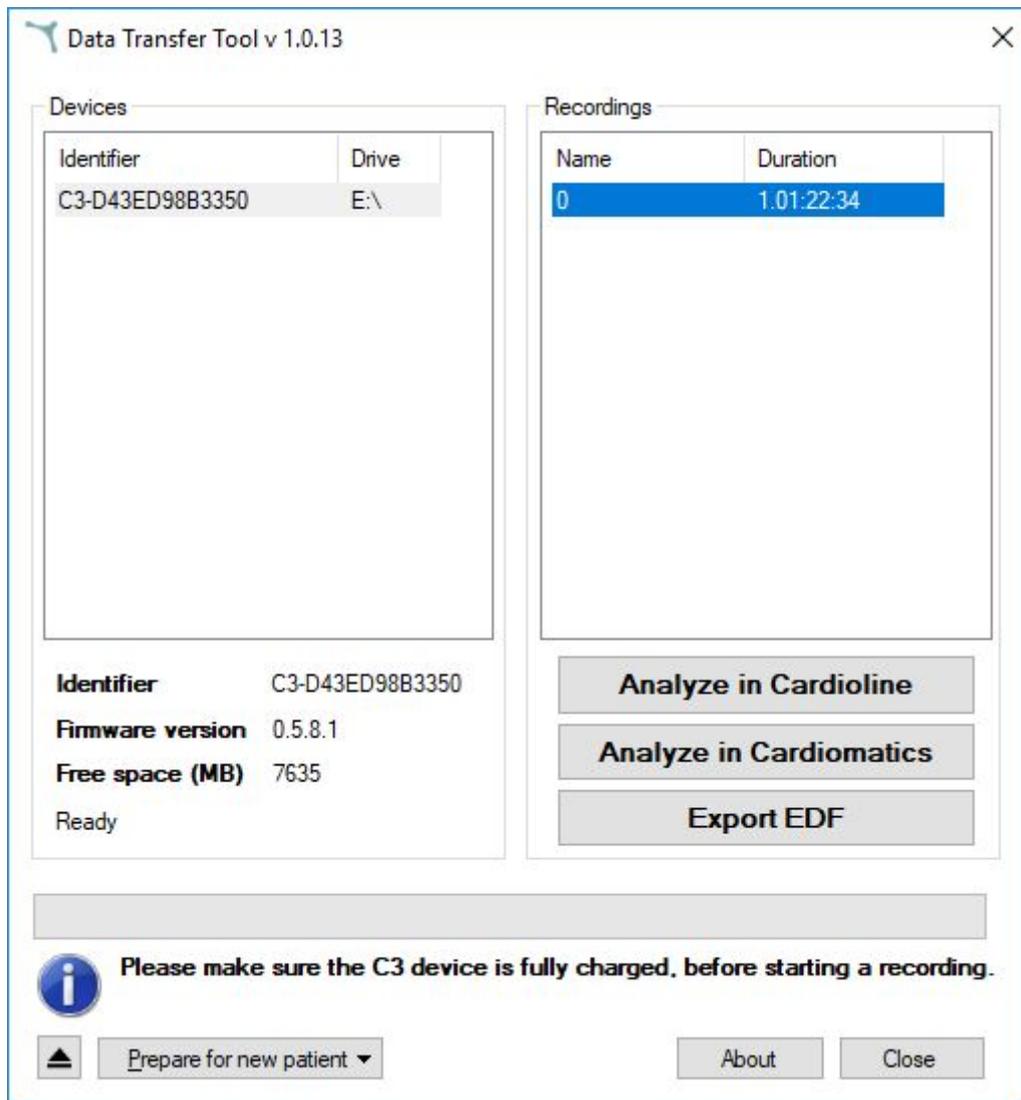
The "Specify patient information" dialog box.

9. Data Transfer Tool will now inform you that it is safe to unplug the Cortrium C3 device.
10. The C3 is now ready for making a recording on a new patient.

1.3 Transfer recordings from C3

To transfer and convert recordings from the C3, to a format that can be imported by third party software, please follow the steps in this section. **Important:** this procedure can only be completed if the third party software is already installed, or you have an online account for the chosen software.

1. Make sure the C3 is fully charged.
2. Turn on the computer that the Data Transfer Tool was installed on.
3. Connect the C3 to the computer via the included USB-cable.
4. Data Transfer Tool will open and show a list of connected C3 devices.
5. Click on the C3 identifier in the list of devices, to select the C3.
6. Click on a recording in the list of recordings, to select it for transfer and conversion.

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7. Click the button "Analyse in Cardioline" or "Analyze in Cardiomatics" to start the transfer and conversion. Or click "Export EDF" to convert the recording to an EDF file.
8. Data Transfer Tool will ask you to verify or specify information about the recording.
9. The recording will either be transferred over the internet for analysis, or stored locally, depending on your choice in step 7.
10. To transfer and convert additional recordings, please repeat steps 6 - 9.
11. When you have completed transfer and conversion of recordings, proceed to prepare the C3 for a new patient (please see the section titled "Prepare C3 for a new patient"). Alternatively, safely eject the C3 by clicking the Eject-button in the Data Transfer Tool, if you wish to complete preparations at a different time.