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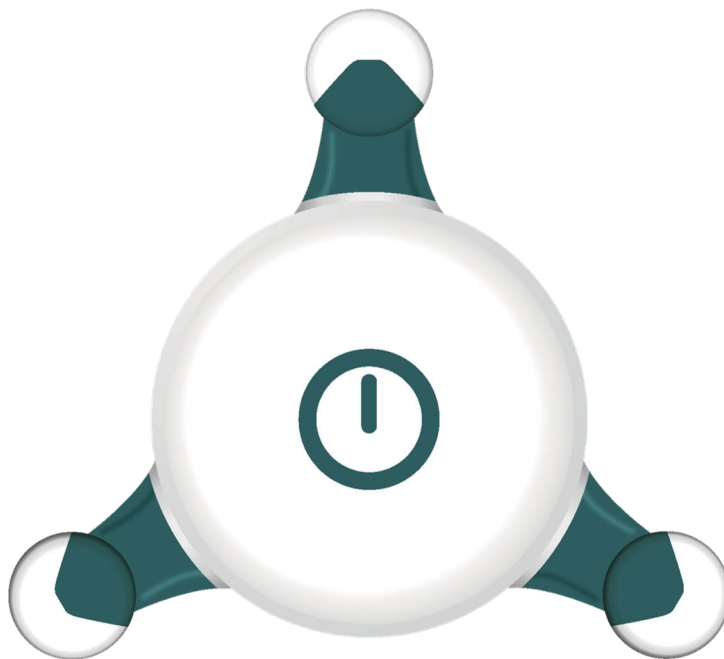
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Poulsen; Louise Flintegaard Ehlert

**Reviewer:** Andreas Stochholm

# C3w | Holter Monitor



## Instructions for Use

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## 1. Introduction

This is the manual for the C3w Holter Monitor (referred to as the “C3w” from here on). The C3w is an ambulatory ECG recorder, which can record three channels of ECG for up to 14 days continuously. The C3w is attached directly to a patient’s chest using third-party ECG electrodes. This manual contains all the information required to safely use the C3w.

### 1.1 Intended use

The C3w is an ambulatory ECG recorder, intended for recording three-channel ECG for up to 14 days. The C3w is intended for use in both healthcare and home environments. During use, the C3w continuously records and stores ECG signals and motion data directly in the internal memory. Additionally, the C3w is able to stream data wirelessly to a mobile app in order for the healthcare personnel to visually verify signal quality of the ECG (Manual for Mobile app can be found on [www.cortrium.com](http://www.cortrium.com)).

Data recorded by the device can be analysed by processing software to provide reports. This software can be either third-party or designed, maintained and/or owned by Cortrium. The C3w hardware has no capacity for automatic ECG analysis and consequently no capacity for automatically generating alerts to potentially critical cardiac conditions.

### 1.2 Patient target group

Cortrium C3w is intended for adult and paediatric patients (above 10kg) who require ECG monitoring. The C3w can be used on patients wearing an implanted pacemaker, but the C3w does not detect pacemaker pulses (see Warnings section).

Final interpretation and diagnosis are the responsibility of a trained physician.

### 1.3 Intended users

The C3w is not a consumer product. It is intended solely to be used by qualified healthcare personnel and thoroughly instructed patients.

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## 1.4 Additional software

The C3w is intended to be used with Cortrium Apex (found at [www.cortrium.com](http://www.cortrium.com))

This software is required to prepare the C3w for use on patients and for transferring recordings after use, as well as for ordering analysis of the recordings. Instructions for the software can also be found at [www.cortrium.com](http://www.cortrium.com)

Further, the C3w is compatible with other approved CE marked third-party software. And it is possible to export data as EDF using Cortriums' software for export to third-party software.

## 1.5 Additional hardware

The C3w is intended to be used with the adapter and USB cable provided in the packaging, as well as third-party electrodes. The electrodes must be CE marked ECG electrodes with a 4 mm snap connector, adhering to IEC 60601-1 and ISO 10993.

## 2. Safety information

The following is important information on how to use the C3w properly and safely. Carefully read this section before operating the C3w.

### 2.1 Notes on proper C3w use

- The C3w has no capacity for analysing the ECG recordings or providing diagnoses.
- The C3w 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 C3w is built to be operable by a healthcare professional. The patient should always be thoroughly instructed before using the device.
- The data recorded by the C3w 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).

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## 2.2 Warnings

- Do not use C3w before reading this manual and manual for ECG electrodes.
- Do not use C3w without cleaning it according to instructions between patient uses.
- Do not use C3w without preparing device as described in this document between patient uses.
- Do not allow patients to interact with the C3w, unless directly instructed by a healthcare professional.
- Do not touch patient and C3w simultaneously while C3w is charging.
- Do not use the C3w during MRI scans.
- Do not use the C3w with a defibrillator.
- The C3w cannot detect pacemaker pulses.
- Do not expose the device to strong sources of static electricity or electromagnetic fields.
- Do not leave C3w on top of or next to other electrical equipment.
- Do not use C3w with cables different than the one provided by Cortrium.
- Do not submerge the C3w in liquid.
- Do not clean the C3w with agents other than those listed in the cleaning instructions in this manual.
- Do not damage the C3w through drops, violent shaking or crushing.
- Do not use the C3w on patients with highly sensitive skin or known skin-related allergies.
- Do not use the C3w on breached skin.
- Do not use the C3w on patients below 10 kilos of body weight.
- The C3w is not a toy. Usage on children should be under strict supervision of adults.
- Use of accessories and cables other than the ones provided with the product may result in improper operation.
- Keep portable RF equipment at least 30cm away from the C3w to avoid degradation of the product.
- Do not put C3w into mouth under any circumstances.
- Do not alter the C3w. Any modification of the C3w is strictly prohibited.
- Only use a certified charger complying with IEC 60601-1 with a DC supply voltage of 4.75V - 5.5V.

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### 2.3 Contra indications and undesirable side effects

- The C3w device should not be used for patients that have, life-threatening conditions that could result in immediate danger.
- The C3w should not be used on breached skin.
- ECG electrodes may cause a patient's skin to react with irritation or reddening. Consult information provided with the electrodes for more information.
- As an end user, in case of side effects please consult your physician.

## 3. Device description

The following section describes the features of the C3w, accessories and accompanying information.

### 3.1 Included components

The C3w comes with the following included in the packaging:

- The Cortrium C3w Holter Monitor (medical product)
- An adapter for charging and data transfer (accessory)
- A USB-C cable – for connecting the adapter to a PC (accessory)
- Short manual with reference to Instruction for Use and Technical Documentation (this manual) also found on [www.cortrium.com/manuals/](http://www.cortrium.com/manuals/)

### 3.2 Accessories

The C3w requires these additional accessories to function as intended:

- third-party ECG electrodes per patient use (not supplied with device)
- The Cortrium Apex software found at [www.cortrium.com](http://www.cortrium.com)

### 3.3 Device layout and light

The C3w has three connectors for ECG electrodes, a single button at the centre as well as an LED indicator. Charging pads can be found on the back of the device.

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### C3w

- A) The button is used to start recordings and to log patient events in the C3w's internal memory as well as for establishing wireless connection and turning the device off
- B) The LED indicates the state of the C3w
- C) The Electrode connectors are used for attaching the third-party electrodes
- D) The charging pads are used for charging and transferring data via the adapter and USB cable

### Adapter and USB

- E) Charging pins
- F) USB-C port
- G) USB-C
- H) USB-C to A converter

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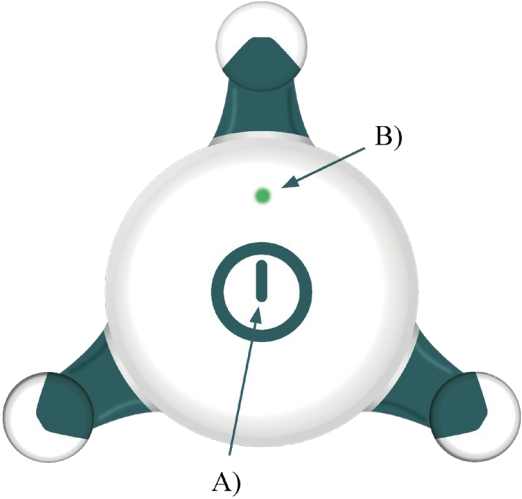

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Front of C3w	Back of C3w
<p><i>Push button and light location shown.</i></p>	<p><i>Charging pads and electrode connector location shown.</i></p>
	

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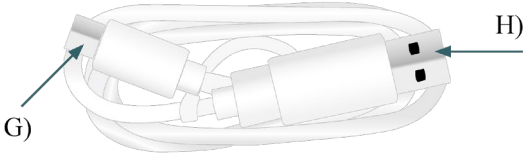
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Adapter	USB cable
<i>Charging pins and USB port shown</i>	<i>USB cable with C-A connector</i>
	

### 3.4 Interfaces

The C3w is intended to interface with a PC using the included adapter and USB-cable, as well as wirelessly to mobile devices.

### 3.5 Button presses

	Press pattern	Meaning
●	Single press	Turn on / Mark event
● ●	Double press	Activate Bluetooth
—	Long press (3 seconds)	Turn off (Note: Device must not have connection to body)

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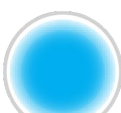


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### 3.6 LED light notifications

Color	Light pattern	Meaning
 Green	Slow: Fast: Constant:	Recording in progress Turning ON / Event button pressed Fully charged
 Blue	Slow: Fast:	Streaming Bluetooth Pairing with Bluetooth
 Yellow	Slow: Fast: Constant:	Memory full Low battery / Turning off Charging
 White	Fast:  Constant:	Lead OFF detected, C3w does not have proper contact to body. Error. Contact Cortrium or supplier

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### 3.7 Package and device symbols

The following symbols are found on the C3w device, adapter and packaging.



*Device label example*



*Adapter label example*

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Symbol	Description
	Manufacturer and year of production
	Temperature limitation and range 5° - 40° degrees Celsius (while operating) -20° - 60° degrees Celsius (while stored)
	Pressure limitation 700 - 1060 hPa
	Humidity limitation 10% - 95%
	Serial number (Device ID)
	Refer to instructions for use
	General warning sign Refer to warning section
<b>IP67</b>	Protected against solid foreign objects (degree 6-dust protected) Protected against ingress of water (degree 7- Protection against immersion in water)

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<p style="text-align: center;"><b>IP21</b></p>	<p>Protection against solid objects &gt; 12.5 mm (degree 2-dust protected) Protection against vertically falling water drops (degree 1-protected against splashing water from any direction)</p>
	<p>Type BF applied part</p>
	<p>Medical Device</p>
	<p>Recycle: Electronic equipment</p>
	<p>CE mark with notified body identification number</p>
	<p>Company logo with name</p>

## 4. User instructions

The following section describes how to properly prepare and use the C3w.

### 4.1 Installation of Cortrium software

Before using the C3w, download and install Cortrium Apex from [www.cortrium.com](http://www.cortrium.com). When the C3w is connected to a PC and the software is opened, the C3w will appear in the software.

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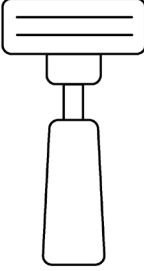
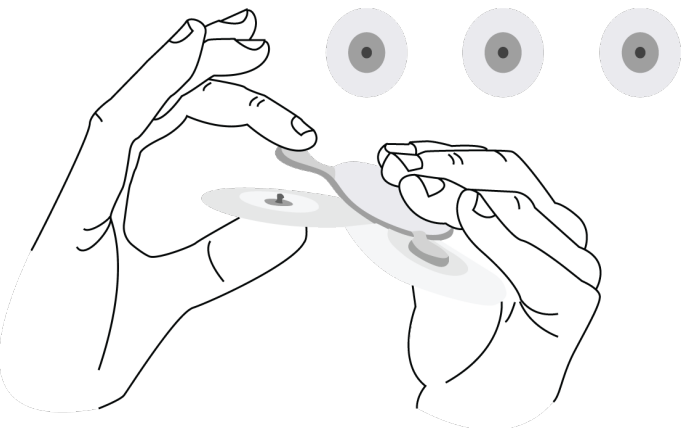
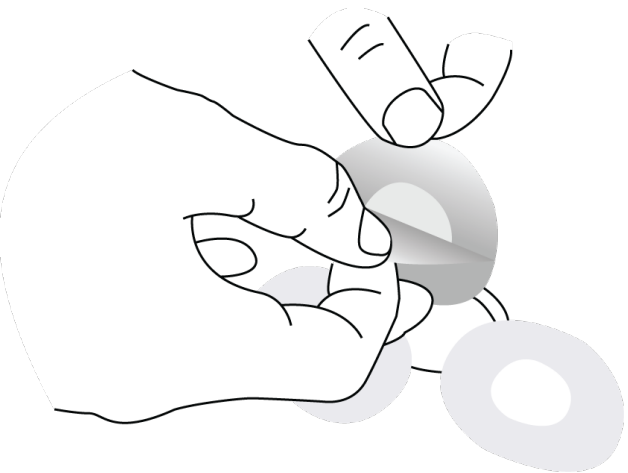
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## 4.2 How to start a recording

Before starting a new recording, ensure that the C3w is sufficiently charged as described in section 4.4, and has been setup for the intended recording duration.

<p><b>1. Prepare Skin</b></p>	
<ul style="list-style-type: none"> <li>- Start by shaving all hair in the area where the electrodes will be placed</li> <li>- Clean and abrade the skin with a cotton swap and appropriate alcohol (denat. 80%)</li> </ul>	
<p><b>2. Attach electrodes to each electrode connector</b></p> 	<p><b>3. Remove plastic from electrodes</b></p> 

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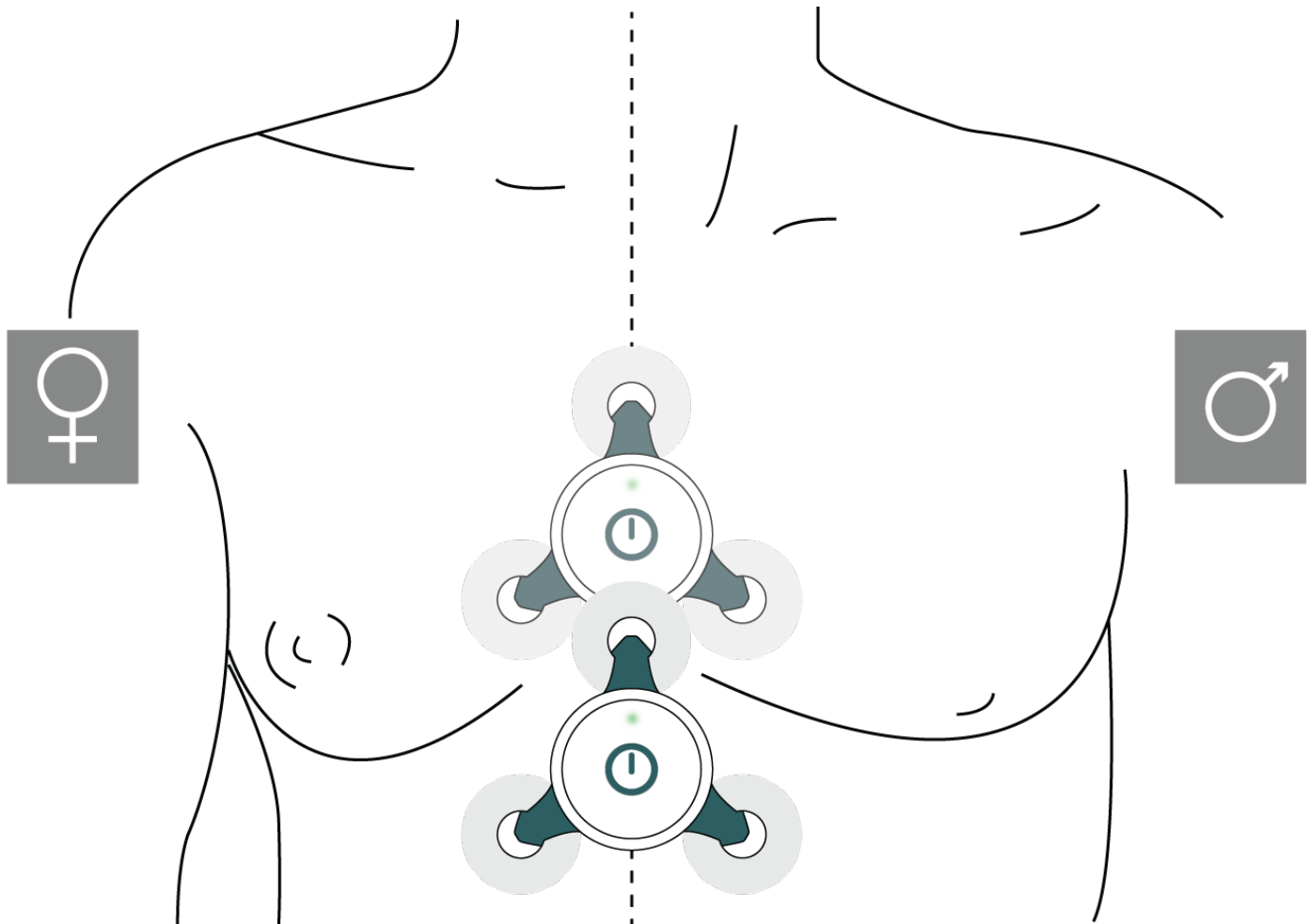
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#### 4. Attach device to patient



- Remove chest hair for proper skin contact
- Ensure the electrodes sticks properly to the skin
- Ensure there is no air between electrode and skin
- Place C3w on midsternal line
- Choose position in relation to the patients anatomy

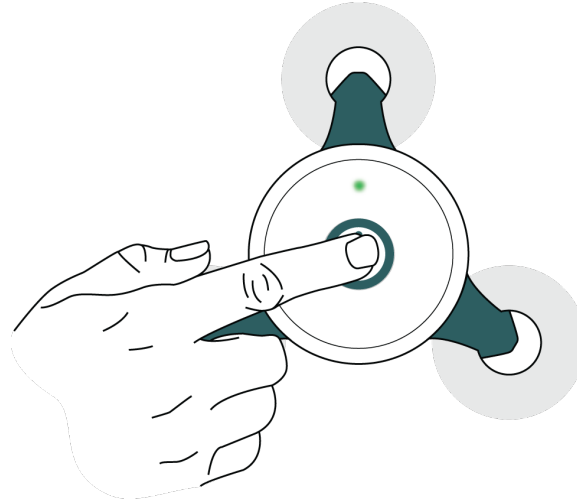
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## 5. Start Recording



- Press the button
- The green light will flash
- The C3w is now recording

### 4.3 After Use

1. Remove the device from the patient (patient may have done this already)
2. Detach ECG electrodes and dispose of them
3. Connect the C3w to a PC via the provided adapter
4. Offload recordings via Cortrium Apex
5. Clean and store the C3w according to instructions in section 4.5 and 5.2

### 4.4 Charging

The C3w automatically charges when connected to a PC or charger via the adapter

Please note: Any charger used must be a certified charger complying with IEC 60601-1 with a DC supply voltage of 4.75V - 5.5V.

To charge, perform the following actions:

1. Remove any ECG electrodes attached to the C3w
2. Place the C3w in the adapter
3. When using the adapter, ensure:

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- a. The charging pins and charging pads are aligned
- b. The C3w is securely fastened
4. Connect the adapter to a PC or charger via the USB cable. Never do this while a user or patient is in contact with the electrode connectors
5. Keep charging until the light indicator turns continuously green

## 4.5 Cleaning

In order to protect patients against risk of cross-contamination, the C3w should be cleaned and disinfected when preparing 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 C3w thoroughly

### To Disinfect

3. Apply 70 % isopropyl alcohol to a clean soft cloth
4. Wipe the C3w thoroughly

DO NOT use abrasive cleaners or solvents such as acetone.

## 5. Maintenance, Transportation, Storage and Disposal

### 5.1 Maintenance

The C3w device contains no user serviceable parts, cannot be opened, and does not require routine maintenance. If you experience a problem with the C3w, contact Cortrium or your local supplier.

Customer Care contact:

Cortrium ApS - Erik Husfeldts Vej 7 - DK-2630 Taastrup - Denmark

e-mail: [customercare@cortrium.com](mailto:customercare@cortrium.com) - Website: [www.cortrium.com](http://www.cortrium.com)

### 5.2 Storage and transportation

Do not transport or store the C3w in ways or locations in which the device would be exposed to:

- Temperatures lower than -20° or greater than 60 ° Celsius
- Air humidity outside 10 - 95 %

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- Pressure limitation 700 - 1060 hPa
- Heavy contamination from dirt or other foreign agents
- Running water
- Strong electromagnetic forces

### 5.3 Warranty and expected lifetime

The C3w has a warranty of 2 years from the date of purchase and an expected lifetime of 5 years.

### 5.4 Disposal

The C3w should be decommissioned when it reaches the end of its service life. The C3w should be disposed of in accordance with the EU WEEE directive for electronic waste.<sup>1</sup>

## 6. Trouble shooting

Problem	Possible Cause	User Action
C3w does not turn on	Battery is depleted	Connect the C3w to the USB adapter and charge for at least 30 minutes.
C3w not indicating charging	USB adapter not connected properly or faulty	Ensure USB cable is securely connected to the adapter. Try using another USB port or adapter.
C3w disconnects from skin	Electrode application or skin preparation not done correctly	Clean the skin area and apply new electrodes following the instructions in this manual.
No data recorded	Electrodes not in proper contact with skin	Remove electrodes, clean the skin and apply new electrodes following the instructions in this manual.
ECG signal appears noisy	Poor electrode contact or excessive motion	Ensure proper electrode adhesion and minimize movement.
Wireless connection to mobile app fails	Wireless function is not enabled, or device is out	Enable wireless function or bring device closer to phone. Restart the app and retry

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

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	of range	connection.
Data upload not starting	Device is not detected by software, or the USB connection is interrupted	Ensure USB cable and adapter are intact and positioned correctly. Restart Apex.
Device gets warm during use	Normal operation or charging	Slight warming during charging is normal. Disconnect if device becomes excessively hot and contact Customer Care.
Device shows memory full	Internal storage is almost full	Upload data via USB connection before reuse. Do not continue use without clearing memory.
Device does not respond after firmware update	Update interrupted or failed	Reconnect the device to USB and retry the update. If issue persists, contact Customer Care

## 7. Technical and Regulatory information

### 7.1 Table - Technical specification

Technical	
Type of ECG Recorder	Holter, ambulatory ECG
No. of Channels	3
Wear Time	Up to 14 days
Recording Format	Continuous
Power Requirement	Lithium Polymer, 3.7V, 680 mAh
Dimensions	85 x 80 x 15 mm
Weight	36 grams
Sampling Rate	256 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

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Duration of skin contact	Up to 14 days continued contact
Mucosal membrane contact	N/A
Sterile or non-sterile	Non-sterile
Biological compatibility	ISO 10993-5 ISO 10993-10
<b>Clinical</b>	
Medical purpose	Ambulatory ECG
Single use / reusable	Reusable/Rechargeable Monitor
Recording standard	Holter
Recording format	Continuous
Intended placement	Midsternal line
Recording period	Up to 14 days on a single charge

### 7.2 Table – Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The C3w Holter Monitor uses RF energy only for internal function. Therefore, its RF emissions are very low.
RF emissions CISPR 11	Class B	The C3w Holter Monitor is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Not applicable (battery-powered)	Not applicable to battery-powered equipment.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	Not applicable to battery-powered equipment.

### 7.3 Table – Electromagnetic Immunity

Phenomenon	Immunity Test	IEC 60601 Test Level	Compliance Level
<b>Electrostatic discharge</b>	IEC 61000-4-2	±8 kV contact, ±15 kV air	±8 kV contact, ±15 kV air
<b>Radiated RF</b>	IEC 61000-4-3	10 V/m, 80 MHz – 2.7 GHz	10 V/m
<b>Electrical fast transients</b>	IEC 61000-4-4	±2 kV AC power; ±1 kV signal lines	Not applicable (battery-powered)
<b>Surge</b>	IEC 61000-4-5	±1 kV differential mode; ±2 kV common mode	Not applicable (battery-powered)
<b>Conducted RF</b>	IEC 61000-4-6	3 Vrms, 150 kHz – 80 MHz	Not applicable (battery-powered)
<b>Power frequency magnetic field</b>	IEC 61000-4-8	30 A/m at 50/60 Hz	30 A/m
<b>Voltage dips / interruptions</b>	IEC 61000-4-11	0%, 40%, 70% dips; short interruptions on AC line	Not applicable (battery-powered)

### 7.4 Table – Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band / Service	Modulation	Power (W)	Distance (m)	Immunity Test Level (V/m)
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385	TETRA 400	Pulse modulation	1.8	0.3	27
450	CDMA 450 / LTE	Pulse modulation	2	0.3	28
710, 745, 780	LTE 700	Pulse modulation	0.2	0.3	9
810, 870, 930	GSM / iDEN / TETRA	Pulse modulation	2	0.3	28
1720, 1845, 1970	GSM 1800 / CDMA 1900 / DECT	Pulse modulation	2	0.3	28
2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation	2	0.3	28
5240, 5500, 5785	Wi-Fi 5 GHz	Pulse modulation	2	0.3	28

### 7.5 Table – Immunity to Proximity Magnetic Fields

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz <sup>1</sup>	Continuous Wave (CW)	8
134.2 kHz	Pulse Modulation <sup>2</sup> (2.1 kHz)	65 <sup>3</sup>
13.56 MHz	Pulse Modulation <sup>2</sup> (50 kHz)	7.5 <sup>3</sup>

### 7.6 Table – RF Wireless Communication Specifications

Parameter	Value
RF Technology	Low-power 2.4 GHz short-range wireless communication
Operating Frequency Range	2400 MHz to 2480 MHz
Modulation Scheme	Gaussian Frequency Shift Keying (GFSK)
Channel Bandwidth	2 MHz
Number of RF Channels	40 (including control and data channels)
Channel Spacing	2 MHz
Maximum Radiated Power (EIRP)	+8 dBm (programmable output power)
Antenna Type	Integrated PCB antenna (0 dBi)
Duty Cycle	Typically less than 1%
Intended Operating Range	Up to 10 meters typical (line-of-sight up to 50 meters)
Intended Environment	Home healthcare and professional medical environments

### 7.7 Regulatory information

The C3w is a class IIa medical device according to Regulation (EU) 2017/745 on medical devices (Medical Device Regulation, MDR) Annex VIII. The C3w complies with the following product standards:

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	Related 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 device labels, labelling 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
EN 301 489-17 V3.1.1	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band

## 7.8 Serious Incidents

In case of serious incidents in relation to the device, please contact your local competent authority as well as Cortrium by e-mail: [customercare@cortrium.com](mailto:customercare@cortrium.com) without undue delay.

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## 7.9 Declaration of conformity

The C3w is in conformity with the General Safety and Performance Requirements and provisions of the Regulation (EU) 2017/745 on medical devices (Medical Device Regulation, MDR).

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