

Curated list of relevant clinical documentation and scientific research related to Cortrium's Holter Monitor

Curated by Cortrium's Chief Scientific Officer and founder Erik S. Poulsen, MD, MSc (BME)

THE ARTICLES ARE GROUPED BY THE FOLLOWING TOPICS AND CONTENT

- Clinical validation of Cortrium's Holter monitor
- Advanced algorithms and Artificial Intelligence (AI)
- C3+ Holter Monitor supporting scientific research
- C3+ Holter Monitor in ongoing scientific studies
- Holter Monitoring compared to 'R'-tests
- About Cortrium and the C3+ Holter Monitor

CLINICAL VALIDATION OF CORTRIUM'S HOLTER MONITOR

C3+ Holter Monitor is an innovative ambulatory long term ECG recorder (Holter monitor), intended for recording a three-channel ECG and accelerometer data (movement) for up to 7 days, for use in both healthcare and home environments. The C3+ is easy to manage and minimally interfering, records continuously and stores all data directly in the internal memory. The following clinical studies validate the C3+ Holter monitor.

Clinical Data Validation of Novel Wireless Cortrium C3 Monitor for Continuous Electrocardiogram Measurements

The purpose of this study is to validate the quality of the ECG-signal acquired with the Cortrium C3 monitor. The intention is to evaluate whether the diagnosis of atrial fibrillation based on the ECG signal from the C3 monitor concurs with the current monitoring methods used in clinical practice. 158 participants were enrolled in the study.

Link: <https://clinicaltrials.gov/ct2/show/NCT02714907>

Clinical Testing of the Cortrium C3 Device

Clinical data validation of the C3 device as a Vital Sign Monitoring System for patients under cancer treatment. 21 patients were enrolled in the study.

Link: <https://clinicaltrials.gov/ct2/show/NCT03387891>

Cortrium test of Cardiomatics' accuracy in AF detection of 60 cases

The aim of the project is to test the quality of automated ECG analysis based on data obtained with the Cortrium C3 Holter monitor. The intention is to validate that the diagnosis of AF based on Cortrium's system is consistent with the current Holter service used in the clinic. 60 patients were enrolled in the study.

Link: <https://www.cortrium.com/holter-comparison>

ADVANCED ALGORITHMS AND ARTIFICIAL INTELLIGENCE (AI)

The relevance and importance of AI and machine learning in cardiology are increasing. In the following, some interesting articles are selected.

Artificial Intelligence in Cardiology: Present and Future

Artificial intelligence (AI) is a nontechnical, popular term that refers to machine learning of various types but most often to deep neural networks. Cardiology is at the forefront of AI in medicine. For this review, we searched PubMed and MEDLINE databases (..) Articles were selected for inclusion on the basis of relevance. We highlight the major achievements in recent years in nearly all areas of cardiology and underscore the mounting evidence suggesting how AI will take centre stage in the field.

Link: <https://pubmed.ncbi.nlm.nih.gov/32370835/>

A Review of Atrial Fibrillation Detection Methods as a Service

Atrial Fibrillation (AF) is a common heart arrhythmia that often goes undetected, and even if it is detected, managing the condition may be challenging. In this paper, we review how the RR interval and Electrocardiogram (ECG) signals, incorporated into a monitoring system, can be useful to track AF events(..) The main impetus behind the idea of developing a service is that a greater data volume analysed can lead to better patient outcomes.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7246533/>

C3+ HOLTER MONITOR SUPPORTING SCIENTIFIC RESEARCH

C3+ Holter Monitor is instrumental in providing data and documentation to support clinical research - covering various topics from disease management to workflow optimization.

Arrhythmias in Patients with COVID-19 (ACOVID)

The study is a prospective clinical cohort study of consecutive patients hospitalized at all hospitals of greater Copenhagen with a laboratory confirmed diagnosis of COVID-19. The investigators aim to

examine if continuous ECG monitoring can be used to understand the contribution of COVID-19 infection in the acute phase to the development of cardiac arrhythmias, especially focusing on cardiovascular outcomes. In all patients included, the investigators aim to examine if continuous ECG monitoring - alone and in combination with biomarkers - can be used to detect early signs of cardiac complications and predict long-term risk of cardiovascular morbidity and mortality following COVID-19 infection. Enrolment of 1000 patients.

Link: <https://clinicaltrials.gov/ct2/show/NCT04395664>

Use of Wearables for Early Detection of Complications After Major Acute Abdominal Surgery

The purpose of the study is to investigate whether glucose profile, sleep disturbances and heart rate variability measured with wearable devices is associated with postoperative recovery and complications within 30 days after major emergency abdominal surgery. The study is designed as an explorative, prospective cohort study. 40 patients undergoing major emergency abdominal surgery at Zealand's University Hospital Køge are included in the study, and inclusion occurs within 24 hours of end of surgery.

Link: <https://clinicaltrials.gov/ct2/show/NCT04257344>

C3+ HOLTER MONITOR IN ONGOING SCIENTIFIC STUDIES

Cortrium participates in several ongoing studies. As an example, the following has been selected. On <https://clinicaltrials.gov> most studies can be found by searching for "Cortrium" or "C3+".

Embolic Stroke of Undetermined Source, Continuous Electrocardiography and Transthoracic ECHO cardiography in Hospitalized Patients with Ischemic Stroke (ESECHO)

Brief Summary: Transthoracic echocardiography (TTE) is recommended in patients with ischemic stroke when cardiac etiology is suspected to help plan secondary stroke management. However, discrepancy for specific clinical recommendation exists between cardiologists and neurologists, and data evaluating usefulness of TTE in unselected patients with cryptogenic strokes (CS) and embolic strokes of undetermined source (ESUS) are lacking. The investigators sought to evaluate the value of routinely performed echocardiography in consecutive CS/ESUS patients. The investigators will perform TTE as recommended by guidelines including agitated saline contrast and speckle-tracking to investigate potential implications for secondary stroke management. In addition, the researchers aim to evaluate the effectiveness of long-term continuous electrocardiogram (cECG) monitoring with newer Holter monitors to detect cardiac arrhythmia in patients with CS/ESUS. 500 patients are participating.

Link: <https://clinicaltrials.gov/ct2/show/NCT04808258>

HOLTER MONITORING COMPARED TO 'R'-TESTS

Holter Monitoring is a well-established methodology to detect AF. Below is an article demonstrating the accuracy of selected Holvers.

A randomized trial evaluating the accuracy of AF detection by four external ambulatory ECG monitors compared to permanent pacemaker AF detection

Purpose: Several external cardiac monitors (ECMs) have recently been developed. These have never been compared to 'gold standard' monitoring with concurrently implanted DDDRP pacemakers. The accuracy of AF detection of Zio XT Monitor (ZM), NUUBO Vest (NV) and Carnation Ambulatory Monitor (CAM) compared with Novacor 'R' Test 4 (RT) in patients (pts) with DDDRP PPM advanced Holvers as the comparator, was evaluated. 21 patients participated.

Link: <https://pubmed.ncbi.nlm.nih.gov/30741360/>

ABOUT CORTRIUM AND THE C3⁺ HOLTER MONITOR

Cortrium ApS is a Danish medical technology company founded by, among others, Dr. Erik S. Poulsen, MD, MSc (BME) in Copenhagen in 2014. Based on his experience from the cardiology ward, the idea of making long-term ECGs easier to use appeared. As a modern all-in-one solution for long-term ambulatory ECG monitoring, Cortrium has developed the C3⁺ Holter Monitor and combined it with AI-based analysis software. All Cortrium products are designed, developed, and produced in Denmark.