



Health Technology Review	
<b>Technology Ref.:</b>	HTA21060
<b>Technology Name:</b>	External ECG-Loop Recorder, CardioMem CM 100 XT
<b>Approvals by International Bodies:</b>	CE Marked - Australian register of Therapeutic goods certificate
<b>Company name:</b>	CBC Medical Store
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<b>Short Description of the Technology:</b>	External ECG-Loop Recorder incl. PhysioGate® App, CardioMem CM 100 XT is a mobile ECG loop recorder designed to acquire and record ECG stripes. Its auto-trigger (detection of tachy-cardia, bradycardia, atrial fibrillation and pauses), its intended to continuously analyse and periodically record ECG data for later evaluation by a medical professional. The device could be used in home and clinical environments in order to document arrhythmias on patients whose symptoms occur infrequently, document the impact of an initiating drug therapy for arrhythmias, document the recurrence of arrhythmias after discontinuation of a drug therapy, document the results after an ablation procedure for arrhythmias and evaluate syncope on patients whose symptoms occur infrequently.

<b>Health Technology Assessment Team Recommendation:</b>	<b>Approve</b>
<b>Summary of Review:</b>	
<p>The device is an ECG monitoring system that records cardiac activities of a subject continuously for a long time. When the heart palpitations are not the frequent and of nonspecific character, it is difficult to diagnose the disease. ELR is providing the non-invasive diagnosis by long-term monitoring of heart signal of the patient, and will assist in early detection of symptoms of abnormalities. It's been used in Saudi Arabia and registered in UAE Ministry of Health</p>	
<b>Advantages</b>	<b>Disadvantages</b>
<p><b>Increase the Quality of Life</b> for patients: Aids in performing a faster diagnosis and early initiation of treatment, which help in Decreasing heart failure hospitalizations</p>	<p><b>Required Training</b> for the patients on how to wear the device &amp; required testing before the actual application.</p>
<p><b>User Friendly:</b> wearable device with No lead wires Portable and easy to use by the patient; disposal electrode (recommend to change every 2-3 days); colourful alert system indications to notify the patients on the device status</p>	<p><b>Limitation:</b> The device provides timely detection of abnormal ECG patterns for further diagnosis by healthcare professionals however; it does not identify specific cases of cardiac disorders.</p>
<p><b>CE Marked</b> – MoHap approved</p>	<p><b>Cost:</b> Unavailability of Economic Study effectiveness</p>

<b>Efficacy:</b> Operation up to 14 days with one battery	<b>Infosec:</b> Risk of Patient Information data leak – the device includes the PhysioGate® App which records the data / transfer information to health professionals
<b>Safety:</b> No reported issues with device safety and performance	
The use of ELR avoids the surgical implantation of electrodes; Good alternative for patients with complications and high risk for infections at surgery.	

We recommend an **approval of using this technology** with the following conditions:

1. Ensuring the dataset residency and access are compliant to UAE Laws & Regulations
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

#### Technology Image





## Population, setting and intended user for Technology “CardioMem CM 100 XT”

- **Population/ Intended User;**
  - Cardiac arrhythmia patients
- **To be performed/ ordered by:**
  - By cardiologist
- **Clinical Setting:**
  - Hospitals, specialized centers
- **Condition of use:**
  - For patients who are eligible for External ECG-Loop Recorder
- **Exclusion criteria:**
  - Other conflicting medical issues