



Health Technology Review	
Technology Ref.:	HTA22040
Technology Name:	LifeSignals ECG Remote Monitoring Platform
Approvals by International Bodies:	FDA, TGA, CE
Company name:	Tausch Medical Supplies Trading LLC
Agent in UAE:	Dr Afaf Ashoor
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Short Description of the Technology:	<p>LifeSignals ECG Remote Monitoring Platform (with Holter Business logic integration, also called as Holter Connect Platform) is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of electrocardiography (ECG) and heart rate (optional) data in home and healthcare settings. Patient physiological data is transmitted wirelessly from the LifeSignals wearable Biosensor to a remote Holter Connect secure server for storage and analysis. The LifeSignals Holter Connect Platform is intended for non-critical, adult population, who are 18 years of age or older.</p> <p>LifeSignals ECG Remote Monitoring Platform (with Holter Business logic integration, also called as Holter Connect Platform) LX1251E containing:</p> <ol style="list-style-type: none"> 1- LifeSignals wearable Biosensor – LP1251E 2- Holter Connect Relay Application – LA1252-R 3- Holter Connect Secure Server Application – LA 1252-S 4- Holter Connect Business Logic – LA12525-C
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The ECG Remote Monitoring Patch Platform is a wireless remote monitoring system & Portable electrocardiogram (ECG) intended for use by healthcare professionals for continuous collection of Electrocardiography (ECG) & Heart Rate monitoring at home and healthcare settings. It records the electrical activity of the heart continuously over 24 hours or longer. Patient physiological data is transmitted wirelessly from the LifeSignals wearable Biosensor to a remote Holter Connect secure server for storage and analysis.</p>	
Advantages	Disadvantages
Improves the quality of life for cardiac patients; Wearable patch, comfortable & easy to use with no wires.	Appropriate training with clear instruction for use to ensure the accurate ECG readings and right position
Useful diagnostic tool, it allows to record the ECG for the patient and helpful in early detection & management of cardiac conditions.	Disposal patches may affect negatively on the environment

Healthcare Professional could have access to patient's data any time (Access interactive reports within 36 hours, and full-disclosure ECG waveforms)	Some people have minor discomfort or skin irritation where the sensors were placed
FDA, TGA and CE marked device	No local cost effectiveness studies provided

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

1. Ensuring the dataset residency and access are compliant to the applicable Laws & Regulations.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patient
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 “Holter Connect”

- **Population/ Intended User;**
 - Non-critical, adult population, who are 18 years of age or older
- **To be performed by:**
 - By healthcare professionals
- **Clinical Setting:**
 - Home and Clinical Facilities
- **Condition of use:**
 - As per the manufacturer instructions
- **Exclusion criteria:**
 - The Biosensor is not intended for use on critical care patients.
 - The Biosensor is not intended for use on patients with any active implantable devices, such as defibrillators or pacemakers
 - In case the patient has skin condition or allergic to adhesives or electrode hydrogels.