

Health Technology Review		
Technology Ref.:	HTA23056	
Technology Name:	EO Patch Wearable Insulin Pump	
Approvals by International Bodies:	CE mark, KMFDS Certificate and MoHaP	
Company name:	Gulf Drug LLC	
Agent in UAE:	Ibrahim Choucair	
Email:	Ibrahim Choucair@gulfdrug.com	

	EO Patch is an external insulin injection device that automatically injects insulin from the outside of the body to control blood glucose levels for the treatment of diabetes.
Short Description of the Technology:	Patch can provide sustained infusion of insulin throughout the day (basal) and/or infuse additional amount of insulin over a short period of time (bolus).
	This patch is connected with EO FLOW ADM (Advanced Diabetes Manager) (Accessory for EO Patch Wearable insulin Pump) which is a remote controller that controls and manages insulin delivery from the EO Patch

Health Technology Assessment Team Recommendation:	Approve
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Summary of Review:

Wearable insulin pumps, often referred to as "patch pumps," are devices that provide continuous insulin delivery without the need for long tubing, as they attach directly to the body. They are typically controlled by a wireless remote or, in some modern cases, a smartphone app.

Advantages	Disadvantages
Approvals by International Bodies: CE mark, KMFDS Certificate and MoHaP.	The EO patch relies on the ADM for programming and controlling insulin delivery. If the PDM is lost, damaged, or out of battery, it may temporarily disrupt insulin management until a replacement is obtained.
Considered as safe and efficient system for the patients. As it's Adhere to regulations with applicable regulatory standards and requirements to ensure its safety and effectiveness	
Can provide a more stable and predictable insulin delivery, potentially leading to better blood sugar control	



User-friendly, with a simple and intuitive interface on the ADM

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

- 1. The technology may only be used after being prescribed by a healthcare professional.
- 2. Using the technology may only be started after completion of the required training from a qualified instructor.
- 3. Follow the instructions provided by the manufacturer for the users.
- 4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
- 5. Provision of regular updates and reports outcome about the product to DOH upon request.

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.



Population, setting and intended user for Technology "EO Patch Wearable Insulin Pump"

- Population/Intended User;
 - Type 1 Diabetes Mellitus
- To be performed by:
 - Healthcare professionals
 - Trained individual with diabetes
 - Trained parents whose children have diabetes
- Clinical Setting:
 - Hospitals
 - Clean environment
- Condition of use:
 - The system is intended to be used by insulin-dependent persons with diabetes mellitus, aged ≥
 6 years old
- Exclusion criteria:



- People who regularly require less than 0.1 U/h of basal insulin
- People who are not able to be in regular contact with their healthcare professional.
- People who do not understand what is required for insulin pump therapy or who are not able to follow the instructions for use of the system.
- People with skin that does not tolerate adhesive pads.
- People who are not able to notice alarms because of physical limitations.