



Health Technology Review	
Technology Ref.:	HTA23038
Technology Name:	Omnipod DASH® Insulin Management System
Approvals by International Bodies:	FDA, CE mark, SFDA and MoHaP
Company name:	Insulet Middle East & Developing Markets as a branch office of Insulet Netherlands B.V.
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Short Description of the Technology:	<p>Omnipod DASH® Insulin Management System is an insulin pump that is used by individuals with diabetes to manage their blood glucose levels. The Omnipod system consists of two components: The Pod and the Personal Diabetes Manager (PDM).</p> <ol style="list-style-type: none"> 1. Pod: The Pod is a small, lightweight device that is worn directly on the body. It is a patch-like device that contains an insulin reservoir, a cannula for delivering insulin into the body, and a built-in adhesive to keep it securely in place. The Pod is waterproof and can be worn while showering, swimming, or participating in various physical activities. 2. Personal Diabetes Manager (PDM): The PDM is a handheld device that wirelessly communicates with the Pod to control insulin delivery. It functions as a remote control and also provides information about insulin delivery, blood glucose readings, and other important data. The PDM has a built-in blood glucose meter for convenient blood sugar monitoring.
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>Omnipod consist of tubeless insulin pump used for the management of diabetes. It is an insulin delivery system that provides continuous subcutaneous insulin infusion (CSII) therapy. Unlike traditional insulin pumps that are connected to the body via a tube, the Omnipod system consists of two components: a tubeless, waterproof pod that holds and delivers insulin, and a wireless personal diabetes manager (PDM) that controls the pod. Before using the Omnipod system it's essential to consult with a healthcare professional who specializes in diabetes management. They can evaluate patients' specific needs, lifestyle, and medical</p>	



history to determine if an insulin pump is suitable for the patient.

On 24th of November, 2022 Circular No.(2022/259) was issued from the Department of Health alerting all Healthcare Facilities, all Healthcare Professionals and the public about the safety alert issued by the Ministry of Health and Prevention (MOHAP) on medical device Omnipod DASH® Insulin Management System manufactured by Insulet. The above alert is due to the fact that manufacturer received reports from some Omnipod DASH users regarding PDM battery issues, including battery swelling, fluid leaking from the battery and in rare cases extreme overheating which may pose a fire hazard. The manufacturer “insulet” investigation has determined that the Omnipod DASH PDM is at increased risk if charged to full capacity, particularly, if left to charge for extended periods of time (e.g. overnight). Omnipod DASH PDMs in use more than 18 months may have an increased likelihood of this issue occurring.

Advantages	Disadvantages
Approvals by International Bodies: FDA, CE mark, SFDA and MoHaP	The Pod has a limited insulin reservoir capacity compared to some traditional insulin pumps. This means that users may need to change the Pod more frequently, typically every 2-3 days.
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	The Omnipod system relies on the PDM 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.
Tubeless design provides greater freedom of movement and reduces the risk of entanglement or dislodging.	The Omnipod system may have associated costs, including the initial purchase of the PDM and ongoing expenses for Pods, which need to be replaced regularly.
User-friendly, with a simple and intuitive interface on the PDM	It does not offer automation of Insulin delivery which is becoming the standard in Insulin pump therapy
Customizable basal rates which allow users to program and adjust their basal rates according to their individual needs throughout the day, providing flexibility in insulin delivery	
The integrated bolus calculator helps users calculate and deliver accurate insulin doses based on their current blood glucose levels, carbohydrate intake, and insulin sensitivity.	
The Pod is designed to be waterproof, allowing users to wear it while participating	

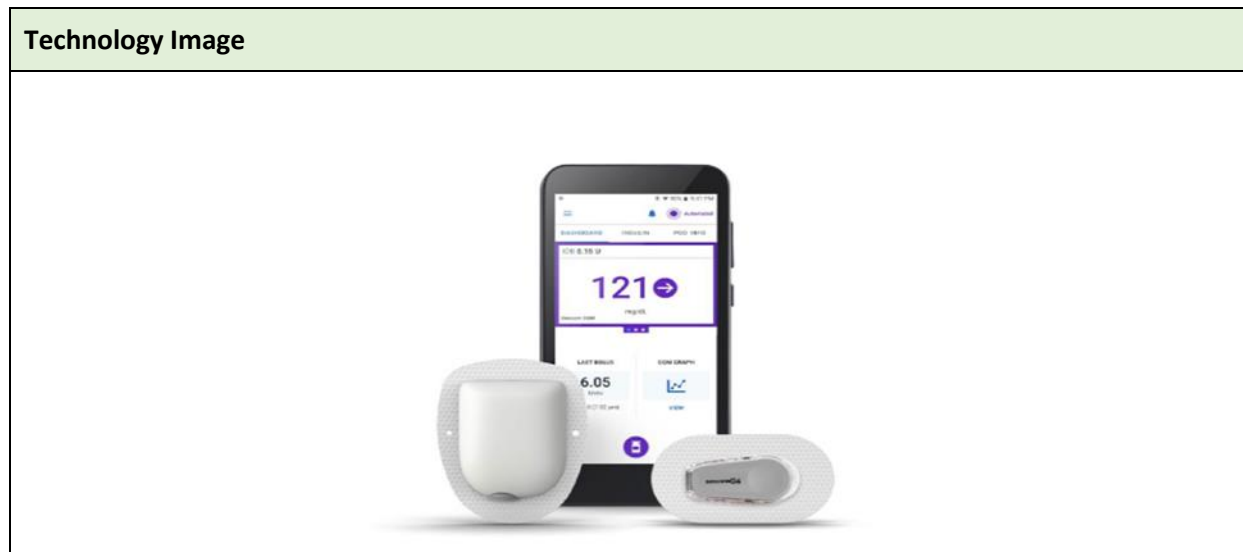
in water-related activities.	
The Omnipod system incorporates various alerts and alarms to help users manage their insulin delivery and monitor their blood glucose levels effectively	

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.

Technology Image



Population, setting and intended user for Technology “Omnipod DASH® Insulin Management System”

- **Population/ Intended User;**
 - 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 \geq 6 years old
- **Exclusion criteria:**
 - The micropump system should not be used by children under 6 years of age
 - 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.