



Health Technology Review	
<b>Technology Ref.:</b>	HTA24021
<b>Technology Name/Version/Model:</b>	Advanced Hybrid Closed Loop MiniMed 780G Insulin Pump System Version: MiniMed 780G
<b>Approvals by International Bodies:</b>	CE mark, FDA and MoHaP
<b>Company name:</b>	MEDTRONIC – META
<b>Agent in UAE:</b>	Issam theeb
<b>Email:</b>	<a href="mailto:isaamtheeb@mpchealthcare.com">isaamtheeb@mpchealthcare.com</a>

<b>Short Description of the Technology:</b>	The MiniMed 780G system is an insulin pump designed for automatic adjustment of insulin levels to help manage Type 1 Diabetes. It features SmartGuard™ technology, remote monitoring capabilities, and connectivity for up to five caregivers to ensure comprehensive patient monitoring and safety.
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<b>Health Technology Assessment Team Recommendation:</b>	<b>Approve</b>
<b>Summary of Review:</b>	
The technology is recognized for significantly reducing severe hypoglycaemic events, decreasing insulin doses, and improving patient quality of life by enhancing blood glucose control compared to standard Multiple Daily Injections (MDI).	
<b>Advantages</b>	<b>Disadvantages</b>
Approvals by International Bodies: CE mark, FDA and MoHaP.	As with any medical device, there's a risk of malfunctions or technical issues, which can disrupt insulin delivery and necessitate swift troubleshooting or medical intervention.
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 upfront cost of the insulin pump and the ongoing expenses for supplies like sensors, transmitters, and infusion sets can be considerable.
Reduced frequency of insulin injections	Patients and caregivers need to undergo comprehensive training to operate the pump effectively.
The system continuously anticipates insulin needs, adjusting delivery autonomously, which significantly reduces the burden on the patient to manually manage their insulin levels throughout the day.	Continuous use of the infusion set can cause skin irritation or infections at the insertion site, requiring careful skin care and regular site rotation.
Automatic uploads of patient data to hospital	

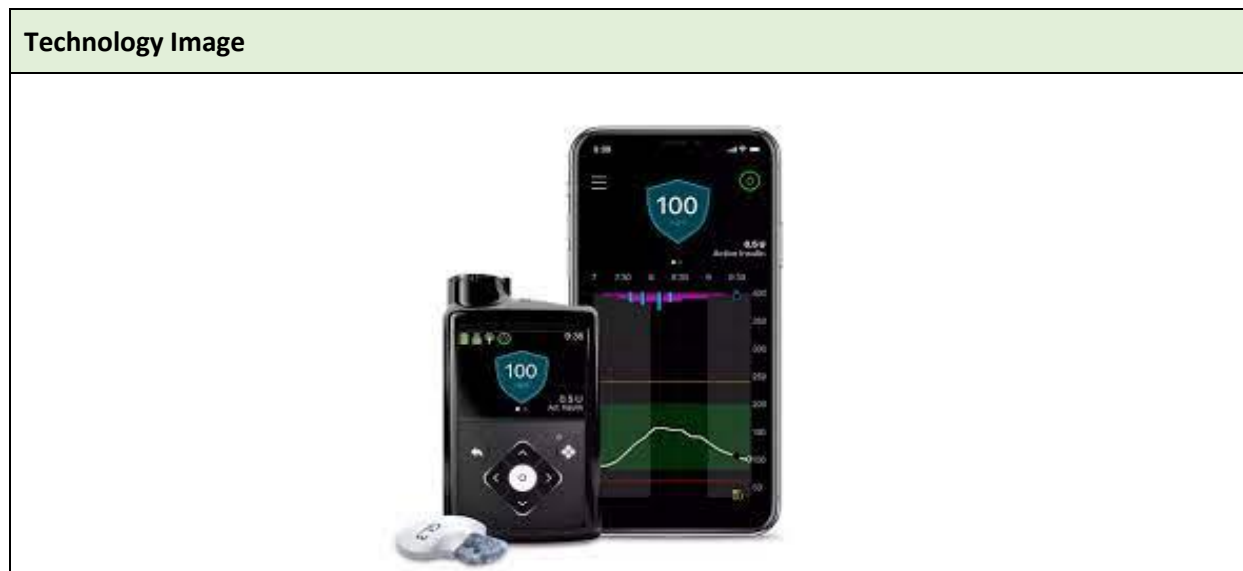
systems facilitate better tracking of patient status and outcomes, allowing healthcare providers to make informed adjustments to treatment plans.	
Decreased hospital admissions related to diabetes complications	
Up to five caregivers can monitor the patient's status remotely, enhancing safety and providing peace of mind for both patients and their families.	

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

1. Advanced Hybrid Closed Loop MiniMed 780G Insulin Pump System, Version: MiniMed 780G.
2. Recommended for patients with type 1 adults and children with poor glycemic control and unable to reach HbA1c and time in Range targeted levels.
3. Using the technology may only be started after completion of the required training from a qualified instructor.
4. Follow the instructions provided by the manufacturer for the users.
5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
6. 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 “Advanced Hybrid Closed Loop MiniMed 780G Insulin Pump System”

- **Population/ Intended User:**
  - Type 1 adults and children with poor glycaemic control and unable to reach HbA1c and Time in Range targeted levels.
  - Patients with severe glycaemic variability.
  - Patients with frequent episodes of hypoglycemia.
  - Recurrent diabetic ketoacidosis (DKA)/ recurrent hospitalizations.
  - Dawn Phenomenon
  - Gastroparesis.
  - Patient preference, meal timing flexibility and normalization of lifestyle.
  - Low insulin Requirements (not easily measured by via a syringe) Inability to self-administer insulin.
- **To be performed by:**
  - Healthcare professionals
  - Trained individual with diabetes
  - Trained parents whose children have diabetes
- **Clinical Setting:**
  - Hospitals
  - Clean environment
- **Condition of use:**
  - As per manufacturer instructions.
- **Exclusion criteria:**
  - People who are not able to be in regular contact with their healthcare professional.
  - People with skin that does not tolerate adhesive pads.
  - People who are not able to notice alarms because of physical limitations.