



Health Technology Review	
Technology Ref.:	HTA22019
Technology Name:	Accu-Chek Solo Patch Pump
Approvals by International Bodies:	CE Mark
Company name:	Roche Diabetes Care GmbH
Agent in UAE:	Pharmatrade LLC.
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Short Description of the Technology:	<p>Accu-Chek Solo tubeless patch pump is a medical device intended for the subcutaneous continuous insulin delivery. The system is intended to be used by insulin-dependent persons with diabetes mellitus, aged ≥ 2 years old.</p> <p>The system consists of a tubeless insulin pump wirelessly controlled by the diabetes manager, which also has an integrated blood glucose meter and bolus calculator; both help the patients in calculating the recommended dose of insulin or carbohydrate amounts.</p> <p>A tubeless patch pump helps increase the adherence to the continuous subcutaneous infusion therapy, since it is discrete and flexible, and consequently helps patients to achieve their glycaemic targets.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>With the rapid development of technologies for type 1 diabetes, insulin pumps can help people with diabetes conveniently manage their blood sugar. The small lightweight pump is tube-free and easily placed on different infusion sites, detachable when necessary and deliver doses of insulin at specific times.</p>	
Advantages	Disadvantages
Safety is improved. Insulin Pump Therapy improves glycemic control hence resulting in better diabetes management reducing & delaying related complications and hospitalization	Risk of diabetic ketoacidosis (DKA) from pump
The technology will improve accuracy and	Risk of site malfunction due to clogging (mainly

outcomes and give the local community access to high healthcare technology	by insulin inside the tubing) and air bubbles impairing pumping.
Accu-Chek Solo requires less upfront investment from healthcare provider hence reduce wasted resources due to early pump drop that could happen for conventional Insulin Pump users	Infection at the area where the catheter goes into the skin is a common problem with insulin pumps.
Significantly positive impact in terms of patients' psychosocial outcomes: reduce burden and diabetes distress, hypoglycaemia (worry, fear, confidence).	
Improved recovery, complications and longevity	
CE Mark	
Visibility of disease stat and sleep were improved. Interference in daily life was reduced.	
Small devices deliver doses of insulin at specific times	

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

1. The technology may only be used after having been prescribed by a healthcare professional
2. Using the technology may only be started after completion of the required training from a qualified instructor
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
4. 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 “Accu-Chek Solo Patch Pump”

- **Population/ Intended User;**
 - Diabetes Mellitus, Type 1
- **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 2 years old
- **Exclusion criteria:**
 - The micropump system should not be used by children under 2 years of age
 - People who regularly require less than 0.1 U/h of basal insulin
 - People who are not able or willing to perform at least 4 blood glucose tests per day.
 - 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 micropump system.
 - People who cannot be relied upon due to drug addiction, substance abuse or mental illness.
 - People who are exposed to high ambient temperatures on a regular basis.
 - People with skin that does not tolerate adhesive pads.
 - People who often experience a cannula occlusion.
 - People who are not able to notice alarms because of physical limitations.