



Health Technology Review	
Technology Ref.:	HTA22059
Technology Name:	Tablo Hemodialysis System
Approvals by International Bodies:	FDA approved
Company name:	Global Medical Supply Chain
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Short Description of the Technology:	<p>The Tablo® Haemodialysis System is a self-contained Haemodialysis system intended for acute and chronic dialysis therapy, with or without ultrafiltration, in an acute or chronic care facility or in the home. The device includes the Tablo Console, a single module consisting of multiple fluidic systems that perform the activities of a water purification system (WPS) and a conventional dialysis delivery system (DDS), and a Tablo Cartridge.</p> <p>Indication: The Tablo® Haemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Haemodialysis System is also indicated for use in the home.</p>
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Health Technology Assessment Team Recommendation:	Approved
Summary of Review:	
<p>Tablo mobile Haemodialysis system delivers standard Haemodialysis treatments for patients with acute and/or chronic renal failure. The Tablo Haemodialysis system features expanded wireless data transmission capabilities, with two-way cloud communication. This allows users to access treatment data anywhere. Tablo received approval from the FDA in April 2020 for use in patients in their homes. Due to its size it could be used at the ICUs in hospitals and homes.</p>	
Advantages	Disadvantages
Device is FDA approved and CE marked	Required special training specially if it's meant for home Haemodialysis.
Portable device and easy to operate, it could be used in ICUs and homes and it connect easily to hospital network.	The Blood Flow Rate is Up to 400 mL/min, this means that dialysis times to achieve a given 'dose' of dialysis are required to be longer in comparison with conventional dialysis machines.
Enhance the patient quality of life, the patient could have the Haemodialysis procedure from	Feed water temperature must be 5-32, and since it will be applied in UAE, thus it requires a



the comfort of their houses and it is Ideal for overnight Haemodialysis .	specific attention or warning in this regard that the feed water shall be from the chiller not tab water.
The machine delivers multiple treatment modalities and have several features such as automated self-cleaning, treatment duration flexibility ranging.	Consumables cost as cartridges are high thus it recommended the localization of cartridge production which eliminates the costs associated with air freight delivery of the cartridges, streamlining distribution and logistics.
The Tablo cartridge does not require manual set-up, thus reducing the setting and take-down time. The dialysate on-demand allows water to be purified and dialysates to be produced in real time	The same known side effect of Haemodialysis applied

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

1. Approval on the device version Tablo Hemodialysis System PN-1006001 and Tablo Treatment Cartridge PN-0005451.
2. Conditional information security approval until 24/01/2024.
3. The enforcement of anonymization is requestor's responsibility.
4. Ensure data residency and confidentiality as per Department of Health regulation.
5. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device.
6. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
7. Provision of regular updates and reports about the product to DOH upon request.
8. 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 “Tablo Hemodialysis System”

- **Population/ Intended User;**
 - Patients with acute and/or chronic renal failure.
- **To be performed by:**
 - By trained healthcare professionals.
- **Clinical Setting:**
 - Acute or chronic care facility.
 - The Tablo Hemodialysis System is also indicated for use in the home.
- **Condition of use:**
 - Treatments must be administered under physician’s prescription and observed by a trained individual who is considered competent in the use of the device.
- **Exclusion criteria:**
 - If the patient has condition that prevent him/her from conducting dialysis.