Health Technology Review	
Technology Ref.:	HTA23012
Technology Name:	Alio System version 1.2
Approvals by International Bodies:	FDA
Company name:	Alio Inc.
Agent in UAE:	David J Kuraguntla
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Short Description of the Technology:	The Alio System is a wireless remote monitoring system consisting of the Alio SmartPatch, Alio Hub, and Alio Portal. The Alio System utilizes a wearable device (SmartPatch) on the skin to gather physiological data and then transmits it to a plug-in tabletop device (Alio Hub) located in the clinic and/or subject's home. The data is then transmitted by the Alio Hub to the Alio Cloud where it is analyzed and made available to members of the healthcare team via the Alio Portal. All data sent via the SmartPatch and Alio Hub is encrypted. The Alio SmartPatch™ is a non-implantable, flexible, silicone-encased patch which can be worn in between the cannulation sites of the arteriovenous (AV) fistula or graft, for up to seven days. It houses numerous sensor technologies, which include a microphone, accelerometer, thermistor(s), and multiple LEDs and photodetectors across several spectral bands. The sensors derive physiological data including hemoglobin, hematocrit, potassium, skin temperature, auscultation sound data, and heart rate. The Alio System is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	

The current standard medical practice for caring for dialysis patients with an arm based access or fistula is intermittent, invasive, and relies on blood draw sample collection and run times. Alio 2.1 allowed remotely monitoring function for kidney patients without the need to attend clinics for tests when they are otherwise well and do not need to see a healthcare professional.

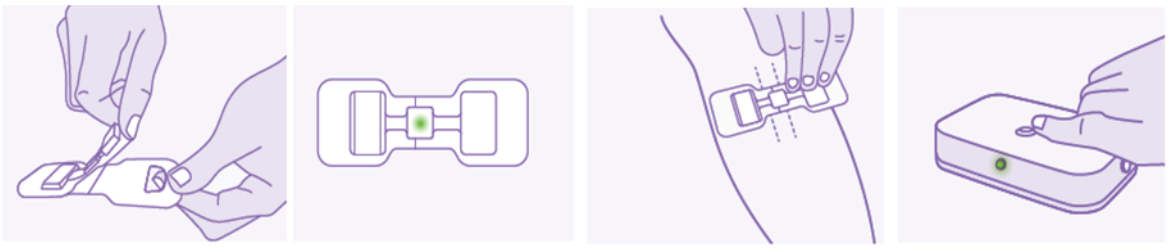
Advantages	Disadvantages
FDA approval to monitor temperature, oxygen saturation and blood pressure	Not fully approved by FDA for continuous non-invasive Potassium, Haematocrit and Haemoglobin monitoring
Alio's SmartPatches can be used remotely by patients receiving haemodialysis treatment	The device is not intended as a stand-alone diagnostic monitor
No risk to healthcare professional & patients	The device is not intended to be used during physical activity
Actionable predictive analytics & notifications available to the clinician to monitor patient trends and vascular sounds	Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact real-time monitoring
Real time data transfer when all components are within service range	
Non-invasive	
Alio System will give clinicians an early warning on the health status of patients with ESKD which could allow necessary interventions in a timely manner	
▪ Alio can assess hemoglobin concentration with 95% confidence interval limits of agreement of -1.99 to 1.91 g/dL in the range of 7-15 g/dL. ▪ Alio can identify subjects with normal or abnormal (hyper or hypokalemic) levels of serum potassium with 81% sensitivity and 82% specificity, with hypokalemia defined as serum potassium concentration <3.5 mEq/L and hyperkalemia defined as serum potassium concentration > 5.2 mEq/L	
Alio detected hyperkalaemia or hypokalaemia with 87% sensitivity and 89% specificity	

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

1. Approval on Alio System version 1.2
2. Performed by Healthcare Professionals
3. Maintain all infrastructure and data within UAE at all times
4. Continued compliance with applicable Laws, Regulations & Circulars
5. Right to audit by regulatory body (DOH)
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.

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 "Alio System version 1.2"

- Population/ Intended User;
  - Patients with Chronic Kidney Disease (CKD)
- To be performed by:
  - By Healthcare Professionals
- Clinical Setting:
  - Clinical setup process
- Condition of use:
  - As per the manufacturer instruction
- Inclusion criteria:
  - This product applies patients who are 18 years of age or older with End Stage Kidney Disease (ESKD) who are undergoing dialysis via an arm-based fistula or graft
- Exclusion criteria:
  - Skin surface issues located at the Alio placement site(s) (AVG/ AVF) that have the potential to cause subject discomfort or interfere with data collection