Inova

Update on Remote Monitoring of Vascular Graft Function and Other Parameters: *where is it and where is it going?*

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VEITH SYMPOSIUM

Faculty Disclosures

Scientific Advisory Board - Alio

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Current dialysis access surveillance methods are failing patients, providers, and payors

Despite a monthly blood-draw, ESKD patients are hospitalized **~2x per year**

~80% of those admissions are driven by:

- 39% chance of **Fluid Overload** causing Heart Failure
- 33% chance of **AV Access Failure** such as stenosis and infections
- 33% chance of **Dyskalemia**, causing arrhythmias and sudden cardiac death

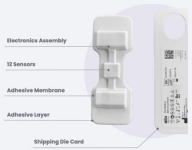
=

$ 45,000 / year per patient spent on preventable hospitalizations

Update: wearable Smart Patch system for Data Collection of AV Access

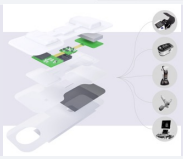
The Alio SmartPatch

- ✓Worn over dialysis access
- ✓Takes a reading every 3 hours
- ✓Wearable for up to 7 days

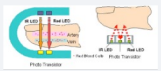


ONE wireless patch gathers multiple metrics:

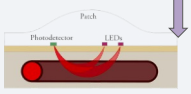
- **Hemoglobin, Hematocrit**
- **Potassium Indicator**
- **Skin Temperature**
- **Auscultation, Heart Rate**



Smart Patch: Technology Fundamentals



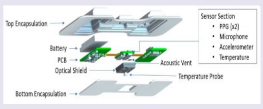
Traditional Digital Approach
(Avoid Large Vessels)



Smart Patch
(Targets Large Vessels)

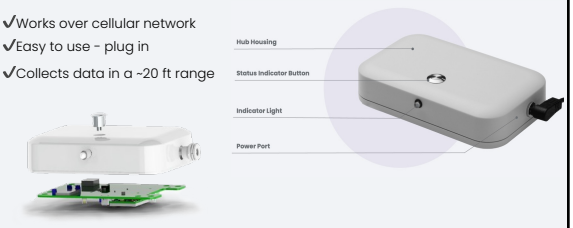
12+ sensors in ONE wireless patch gather multiple metrics

- ✓ Zero calibration
- ✓ Autocorrects for skin color
- ✓ Data from the vessel, not the skin
- ✓ Showerproof



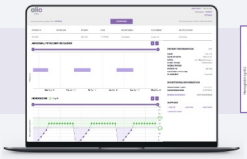
The Hub

✓Works over cellular network
✓Easy to use - plug in
✓Collects data in a ~20 ft range



Clinician Portal

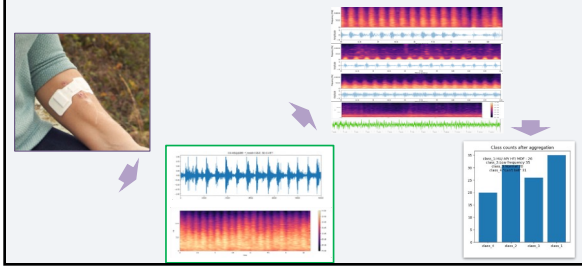
Data reception: The Clinician Portal consolidates and delivers the hemodynamic and blood parameters derived from the patch to a user workstation for comprehensive viewing at the patient-specific level



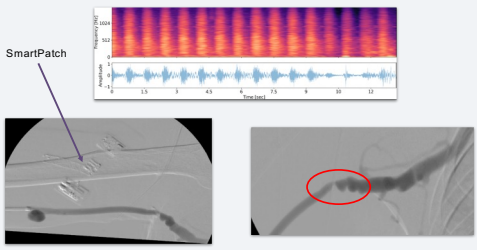
Presents trendlines, notifications & delivers potentially actionable clinical insights

Data delivery: Development of Machine Learning Models

Auscultation Data and Spectrographic Classification



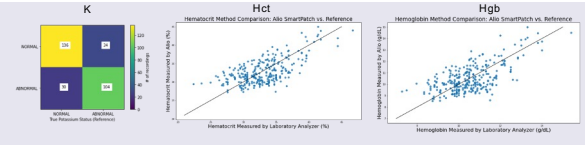
"Harsh Upstroke with Minimal Diastolic Flow" Classification



Potassium, Hemoglobin and Hematocrit Validation

Validation Study: 298 blood labs were compared to device data for FDA submission

- **Abnormal K+**: sensitivity = 81%, specificity = 82%
- **Hct**: 95% confidence interval (CI) limits of agreement (LoA) = -5.8 to 5.4 % Hct
- **Hgb**: 95% confidence interval (CI) limits of agreement (LoA) = -1.99 to 1.91 g/dL



SmartPatch Physiologic Metrics

FDA Cleared, non-invasive, clinical grade reporting

FDA Cleared and Available

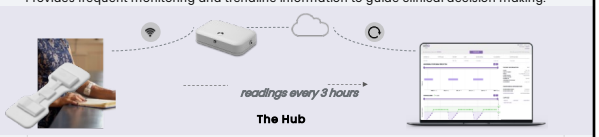
- Heart Rate (BPM)
- Skin Temperature (°C/°F)
- Auscultation
- Hemoglobin (g/dl)
- Hematocrit (%)
- Potassium Indicator

Measurement	Performance metrics	Regulatory Status
Clinical Portal	Hub-and-Spoke based centralized monitoring	Cleared
Heart Rate	3.85 RMSE +/- 4.3 BPM	Cleared
Temperature	15 C - 50 C	Cleared
Auscultation	20 - 2000 Hz	Cleared
Hemoglobin	7.3 - 15.4 g/dL range 95% CI LOA -1.99 to 1.91 g/dL	Cleared
Hematocrit	22.4 - 46.7% range 95% CI LOA -5.82 to 5.54 %	Cleared
Abnormal K+	2.2 - 7.8 mEq/L range "Abnormal": <3.5 or >5.2 mEq/L detected 81% Sens and 82 % Spec	Cleared
Absence of Periodic Signal	Email Notification if > 12 hours passes without periodic acoustic signal identified	Available

The wearable device and hub

Form a HIPAA compliant remote network

The platform can deliver vital signs, hemodynamic, and blood parameters
Provides frequent monitoring and trendline information to guide clinical decision making.



The wearable SmartPatch

Non-invasively captures key metrics to aid in care management

The Portal

Shows clinicians data, trendlines, and notifications

Additional Features in Advanced R&D

FDA Cleared*

FDA Cleared	Heart Rate (BPM) & Skin Temp (°C/°F)
	Auscultation
	Hemoglobin (g/dl)
	Hematocrit (%)
	Potassium Indicator
2H 2023	Access monitoring — Now available
	Fluid Status
R&D 2024	Blood Pressure
	Volumetric Blood Flow
	Additional locations
2025	Sodium, Urea, Creatinine

Summary

Device has demonstrated clinical success of a wearable, remote system approved to monitor vascular procedures and patient parameters

- ✓ Heart rate
- ✓ Skin temperature
- ✓ Abnormal levels of potassium (K+) (hyper or hypokalemia)
- ✓ Measured hemoglobin (Hgb) & hematocrit (Hct)
- ✓ Auscultation sound data