alio

Instructions for Use

Device Description

The Alio SmartPatch is a flexible, silicone-encased patch which can be worn 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, temperature sensors, 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 data is transmitted by the Alio Hub, a plug-in tabletop device, to the Alio Cloud where it is analyzed and made available to a Healthcare Provider (HCP) via the Alio Portal.

Indications for Use

Alio is a wireless remote monitoring system intended for use by healthcare providers (HCP) to collect physiological data in clinical and non-clinical settings. The data includes measured hemoglobin (Hgb) and hematocrit (Hct), skin temperature, auscultation sound data, and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the HCP's review.

The data also include a qualitative indicator of abnormal levels of potassium derived from relative variability of photoplethysmography waveforms and medically accepted threshold values.

Alio is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to provide measurement of heart rate, skin temperature, Hgb, Hct and a qualitative risk assessment of the patient having an abnormal potassium level. The SmartPatch sensor is indicated to record and transmit auscultation sound data. For qualitative assessment of abnormal potassium levels, and quantitative measurement of heart rate, skin temperature, Hgb and Hct, the SmartPatch should be placed on an arm based arteriovenous access on patients with end stage kidney disease (ESKD).

Alio is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices. Therapeutic management decisions, including management of dyskalemia, should be made based on a complete assessment of the patient's condition and should not be based solely on Alio.

Contraindications

- The device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.
- The device is not intended to be used during physical activity.

⚠ WARNING

For Dialysis Patients – DO NOT place your patch over your needling sites as this may cause an adverse skin reaction.

- The nature of hydrocolloid adhesives may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:
  - A severe adverse event
  - An allergic reaction persisting beyond 2-3 days
- Histories of skin irritations should be considered before placing the SmartPatch on a patient.
- Do not use the SmartPatch during an MRI scan or in a location with strong electromagnetic forces.
- Only place the SmartPatch on intact skin.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.
- The subject device can only be used with a functioning arteriovenous fistula (AVF)/arteriovenous graft (AVG). A functioning AVF/AVG is defined by having sufficient flow (i.e., perfusion) which will allow the dialysis access to be exclusively used for hemodialysis (i.e., threshold greater than or equal to what is needed for the purposes of the Alio SmartPatch to function). Therefore, the device should not be used in patients without a functioning AVF/AVG (e.g., patients with a central venous catheter (CVC) still in use for hemodialysis or patients receiving peritoneal dialysis (PD)).
- Do not stack the Alio Hub or position adjacent to other medical equipment.
- Only use specified and/or provided cables and accessories.
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- Only use specified and/or provided cables and accessories.

⚠ Precautions

For data to be sent to a healthcare professional for review:

- Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact real-time monitoring. Data will be stored on the device for transfer once connectivity is re-established.
- The SmartPatch is Single Use Only. Do not reapply the device once it is removed.
- Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.
- Do not use the SmartPatch if the package has been opened, or appears used, damaged, or expired.
- The SmartPatch may be used while showering. Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry the device after showering. Do not submerge the SmartPatch or use in a sauna.
- If discomfort or irritation occurs, the SmartPatch should be removed. If mild soreness or redness is experienced after removing the device, do not apply a new SmartPatch in the same location. Choose another recommended location.
- Incorrect handling, excessive force, or dropping the SmartPatch may cause malfunction or permanent damage.
- Keep the SmartPatch away from children and pets. The SmartPatch may be a choking hazard and may be harmful if swallowed.
- Keep the Hub away from any liquids which could accidentally spill.
- If any component of Alio fails to operate, contact Alio immediately.
- Dispose of the SmartPatch per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste.

Temperature Reference Site

The SmartPatch measures skin temperature via direct mode at the point of SmartPatch placement. The SmartPatch records skin temperature to an accuracy of +/- 0.3 C within the range of 27 C to 43 C.

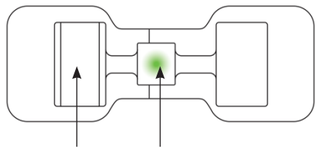
SmartPatch Operating Instructions

Note: It is recommended that healthcare providers advise users to replace the SmartPatch either when the SmartPatch falls off or after 7 days of use. To preserve data, the SmartPatch must be connected to the Hub prior to the end of battery life (up to 7 days).

The SmartPatch should be placed along the course of an AVF/AVG, directly over a portion of the access that would be amenable to cannulation, but that does not interfere with active cannulation sites. The location may be varied with changes in cannulation sites.

Each box of SmartPatches is intended to support 28 days of wear. Five SmartPatches are included to ensure you can complete 4 weeks of wear.

SmartPatch Overview



Instructions

1. Plug in your Alio Hub

Place the hub in a convenient spot for you in your home where you frequent - near a window will provide good connectivity. Plug it in using the power cord.

2. Locate where your SmartPatch will go on your arm

The SmartPatch will be located between your cannulation sites on a mature vascular access. Be sure to choose a location with intact skin. The SmartPatch should not be applied to compromised skin.

3. Clean your skin over your dialysis vascular access

Next, clean the skin where you will wear the SmartPatch with an alcohol wipe and let dry for 20-30 seconds. The skin should be free of oily residues, soaps, lotions, other products, and sweat.

4. Open the plastic SmartPatch pouch

Pull apart the top and bottom layers to open.

5. Remove SmartPatch backing and look for a blinking green light

Hold the SmartPatch by the loose end and remove the hard plastic backing. A green light will blink 3 times to signal it is on. Call us for help if there is no light.

6. Place SmartPatch on skin

Holding the same loose end without exposed adhesive, place the SmartPatch on your cleaned skin. Ensure it is not placed over your needling site and/or broken skin.

7. Make sure SmartPatch is secure by firmly pressing adhesive to the skin for 30 seconds

Remove the remaining thin plastic. Secure the SmartPatch to the skin by pressing fingers along the edge of the SmartPatch and holding the whole SmartPatch down firmly for 30 seconds.

8. Check for a green light on the Alio Hub

Press the button on the top of your Alio Hub and confirm that the indicator light turns green. Call us if you see a blinking yellow light so we can help.

9. Replace your SmartPatch every 7 days or as needed

Go about all daily activities while wearing the SmartPatch. *Avoid* submerging the SmartPatch in a bathtub or swimming pool.

When disposing of your old SmartPatch, please observe local laws for disposal of battery-operated electronic products.

Note: The SmartPatch device is Single Use Only. Do not reapply the device once it is removed.

Contact Information

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SmartPatch Electromagnetic Emission Declaration

The SmartPatch is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The SmartPatch uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SmartPatch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Sensor Functionality and Essential Performance

- Hemoglobin range 7-15 g/dL with root-mean-square error (RMSE) ≤ 1.0
- Hematocrit range of 21-45% with root-mean-square error (RMSE) ≤ 3.0
- Potassium classifier: (K+ < 3.5 mEq/L or K+ > 5.2 mEq/L) w/ a sensitivity & specificity of 80%
- Temperature (2 skin-side)
  - +/- 0.3ºC 27-43ºC
  - Resolution: 0.005ºC
- Heart Rate range of 30-200 bpm with RMSD ≤ 5
- Acoustic
  - Total Harmonic Distortion: <0.25%
  - Signal-to-noise: 65 dBA
  - Frequency range: 55 Hz-2 kHz
  - Sample rate: 4 kHz
  - Resolution: 12 bit
  - Auto-gain control: 2.5-40x
- Angular Position/Vibration
  - Bandwidth: 500 Hz
  - Range +/-2g
- Optical (Photoplethysmography)
  - 12 channels
    -2xIR (940 nm)
    -2xRed (650 nm)
    -2xGreen (530 nm)
    -4 Photodiodes
  - Resolution: 22 bits
  - Auto gain adjustment
- The hub remains connected to the network when cellular service is available.

*Only a single value outside this range was included in the clinical validation study.

Data Capture

Lifetime
- Up to 7 days operational
- 6 months shelf life

Data Storage
- 7 days onboard while disconnected

Bluetooth Specification

- Protocol: BLE 4.2 compatible
- Secure many-to-many peering
- RF output power: +3 dBm
- Module Frequency: 2400-2480 MHz
- Receive Sensitivity: -87 dBm
- Range: 20-50' line of sight (off-body)
- Security: AES128 Encryption

Mechanical Properties
Dimensions:
105mm x 52mm x 7.6mm
Minimum Radius of Curvature: 25mm

Power

- 3.0v Lithium Manganese Oxide battery
- Battery Certifications:
  - UN 38.3
  - UL 1642
  - IEC 60086-4

FCC Compliance (FCC ID:SPO-VCI-VP2)

The SmartPatch and Hub comply with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation (FCC Title 47, Subpart A, Part 15.19(3)).

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

Mechanical Material

Type: Pt Cured Silicone
Durometer: 30A
Color: White
Texture: Smooth

Adhesive

Duration: Up to 7 Days
Thickness: ~ .2mm
Biocompatibility: ISO10993 certified

Environmental

- Waterproofing: IP63
- Operational Temp: 0 to 40 C
- Long-term Storage: 5 to 30 C
- Humidity: 20 to 90%
- Pressure: 700 hPa to 1060 hPa

PCB Trace Antenna

Item	Description
Frequency Range	2400 – 2500 MHz
Peak Gain	0.5 dBi typical
Average Gain	–0.5 dBi typical
Return Loss	10 dB minimum

Hub Bluetooth Specification

- Protocol: BLE 4.2 compatible
- Secure many-to-many peering
- RF output power: +7.5 dBm
- Module Frequency: 2400-2480 MHz
- Receive Sensitivity: -93 dBm
- Range: 20-50' line of sight (off-body)
- Security: AES128 Encryption end-to-end

Power

5v, 3A power supply

Onboard Cellular Communications

LTE Cat 4 (3G fallback)

Mechanical Properties

Dimensions: 5.9 x 3.7 x 1.4 inches

Environmental

Waterproofing: IP22
Operational Temp: 5 to 40C
Humidity: 20 to 90%
Pressure: 700 hPa to 1060 hPa

Guidance and Declaration– Electromagnetic Immunity

(For ME equipment ME system that are not life-supporting)
The SmartPatch is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Immunity Test:
Radiated RF IEC 61000-4-3

IEC 60601 test level:
10 V/m 80 MHz to 2.7 GHz

Compliance level: 10 V/m
Electromagnetic Environment – guidance: Portable and mobile RF communications equipment should be used no closer to any part of the SmartPatch than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
$d = 1.17\sqrt{d}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 800MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:

Immunity Test: Electrostatic discharge (ESD) IEC 61000-4-2
IEC 60601 test level: ± 8 kV contact ± 15 kV air
Compliance level: ± 8 kV contact ± 15 kV air
Electromagnetic Environment – guidance: Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Immunity Test: Power frequency (50/60 Hz) magnetic field IEC 61000-4-8
IEC 60601 test level: 30 A/m
Compliance level: 30 A/m
Electromagnetic Environment – guidance: Power and frequency of magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended separation distance between portable and mobile RF communications equipment and Alio

(For ME equipment ME system that are not life-supporting)

The SmartPatch is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartPatch as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.17	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. The SmartPatch complies with the applicable requirements and relevant provisions of the Radio Equipment Directive 2014/53/EU (RED).

Common EM Emitters

Specific common emitters may interfere with the function of Alio.
Users should avoid close proximity to EM emitters such as radio-frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), nearfield communications (NFC) systems, wireless power transfer and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. In the unlikely event of EMI, it is recommended that the user moveaway from EM emitter.

Quality of Service

Alio is capable of preforming a measurement without a wireless connection to the Hub. When the connection becomes available, the data is transferred without compromising the quality and accuracy of the data.

Symbol	Title
IP63	Protected from water spray less than 60 degrees from vertical.
	Refer to instruction manual
MR	MR Unsafe
	Do not use if package is damaged
	Single use only
	Type BF applied part
	Caution, consult documents
NON STERILE	Non-sterile
	Non-ionizing radiation
Rx ONLY	Prescription use only
	Crossed out wheelie bin
5° C 50° C	Temperature limits (storage)
20° C 90° C	Humidity limits (storage)
SN	Serial number
REF	Catalogue number
LOT	Batch code
	Use-by-date

To Remove a SmartPatch

1. To remove a SmartPatch, gently peel from the skin.
2. Then clean off all adhesive residue with adhesive remover or baby oil.
3. Ensure all adhesive residue is removed from skin by using an alcohol wipe prior to placing a new SmartPatch.

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