Clinician Frequently Asked Questions

Below are Frequently Asked Questions that may result during use of the FDA cleared Alio® Remote Patient Monitoring Platform. This information serves as an adjunct to the provided Instructions for Use and Quickstart Guide.

Alio SmartPatch™ Related Questions

- **Can I move the SmartPatch if I need to cannulate where it is currently placed?**
  Yes, the SmartPatch is intended to be used during dialysis but can be removed if it interferes with cannulation. If it must be removed, please ask the patient to replace it with a new SmartPatch over their AV access (leaving room for cannulation sites). Ideal use is replacement every 7 days.

- **Can I use tape to help secure the SmartPatch during normal wear?**
  Yes. If the SmartPatch begins to lift at the ends apply a tape (i.e., Tegaderm).

- **Can the SmartPatch be used with commonly used adhesives during dialysis (i.e., tapes such as Paper, Silk or Micropore or Coban)?**
  Yes, adhesives may be used and are acceptable to be placed over the SmartPatch during dialysis. The SmartPatch has been fully tested to meet biocompatibility standards.

- **Is the adhesive used in the SmartPatch known to cause skin irritation?**
  The nature of hydrocolloid adhesives may cause adverse skin reactions (i.e., skin irritation). The SmartPatch has been fully tested to meet biocompatibility standards and has FDA clearance. Histories of skin irritations should be considered before placing the SmartPatch on a patient. If skin irritation does occur, remove the SmartPatch until irritation subsides and then place a new SmartPatch under clinical discretion.

- **What happens if liquid/ fluid gets on the SmartPatch during dialysis?**
  The SmartPatch can get wet and can be cleaned, however, do not fully submerge the SmartPatch in water.

- **How do I order more SmartPatches?**
  Please contact your Alio representative or Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.

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- **What do I do with the patient's used SmartPatches?**
  If the SmartPatch was part of a clinical trial, it will be returned to Alio (preferably in the original packaging). Please contact your Alio representative or Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600 to return the product. If the SmartPatch was not part of a clinical trial and simply at the end of its wear time. Please discard the SmartPatch according to local laws.

- **Is the patient data secure?**
  Yes, the patient data is encrypted.

- **How will I know if a SmartPatch is working?**
  The Alio Portal will show a message in the Notifications column if there has been no data for an extended period of time.

- **Can the SmartPatch be placed over a tattoo?**
  The Alio SmartPatch should not be worn over tattoos, birthmarks, or scar tissue.

- **Can patients wear the SmartPatch in other locations?**
  No. The SmartPatch is only intended to be worn over the patient's arteriovenous (AV) access.

- **Can the SmartPatch be worn over bandages, gauze, or clothing?**
  No.

- **Can the patient shower with their SmartPatch on?**
  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.

- **How often does the SmartPatch take a reading?**
  Every three hours.

- **Is there a way to get the SmartPatch to take a reading at a specific time if we wanted to?**
  No. The SmartPatch will take readings every three hours once it is activated.

- **Can the patient take the SmartPatch off themselves and put it back on if they wanted to take a bath, for example?**
  No. The SmartPatch is Single-Use Only. Do not reapply the device once it is removed. It must be replaced with a new SmartPatch.

- **Is the SmartPatch affected by the TSA x-ray security system at the airport?**
  No.

- **How many reads will the SmartPatch store if it is not near their hub?**
  The SmartPatch can store enough data for the duration of wear, however it should be uploaded as often as possible to get the maximum benefit.

- **What is the minimum time required to be within close proximity of the hub for readings?**
  The SmartPatch uploads the data in a matter of seconds. And should the upload be interrupted; it will continue once it is back within range of the hub.

Alio Hub Related Questions

- **How is the hub set-up?**
  The hub is easy to use; all that is needed is to plug the hub into a standard wall outlet using the provided power cord. Place the hub in a convenient spot in the home where the patient frequents - near a window will provide good connectivity.

- **How do I know if the hub is working?**
  Press the button on the top of the hub and confirm that the indicator light turns green.

- **What do I do if a patient says their hub is blinking yellow or the green light does not turn on?**
  Please contact Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.

- **Can a non-functional hub be replaced with one from the clinic?**
  No. If the hub is not working, please contact Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.

- **Can the hub interfere with a patient's home monitor for their…. pacemaker, ICD, neurostimulator, glucose monitor, etc.?**
  No, the hub does not interfere with other patient home monitors. Do not stack or place the hub adjacent to other medical equipment.

- **Does the patient need to keep the hub plugged in all the time?**
  Yes

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- **Do they need to keep the hub plugged in near them throughout the day (if they move to their living room from the bedroom, for example)?**
  No, the SmartPatch stores data so continual connection with the hub is not required. The stored data will be transmitted when the SmartPatch is near the hub.

- **If the patient travels out of town for a weekend or goes on a vacation, do they need to take their hub with them?**
  Yes, to maximize the benefits of the SmartPatch the hub should travel with them.

- **How close does the hub need to be to the patient to get readings from the SmartPatch?**
  The hub collects data from the SmartPatch when in a ~20 ft range.

- **Is there a phone interface/APP to communicate to the hub if you are a considerable distance away from the hub?**
  No.

- **Does the hub have to connect to the patient's cell phone or home internet?**
  No, once the hub is plugged in it will automatically connect to a cellular network. It connects via LTE Cat 4 (3G fallback) cellular signal and does not require the patient's cell or home internet. There is no cost to the patient or use of their data.

- **What are the power requirements for the hub?**
  5V, 3A power supply which is met using a standard wall outlet.

- **Can multiple patients use the same hub?**
  Each patient will receive their own hub. A SmartPatch can communicate with any hub, but we recommend one hub per patient.

Alio Portal Related Questions

- **Where are the instructions for use?**
  The Instructions for use can be found on the portal at the top right of the page when you click on the NEED HELP button.

- **What do I do if I forget my portal login?**
  Retrieve portal login information by contacting Alio Customer Support via email – support@alio.ai or phone (US) +1 855 979 1600.

- **What do I do if I forget my portal password?**
  Request to have your password reset on the portal login page.
- **What should be done if there is no data in the portal?**
  Contact Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.
- **What should be done for a value out of range on the portal?**
  Follow your clinic policy.
- **How many personnel at a clinic can have log-in privileges?**
  There is no limit to the number of users that can be added to the portal by an authorized administrator.
- **How can personnel access be granted to the portal?**
  The authorized administrator can add new users. This can be done in the Clinical Users tab by selecting "Add New User" and following the prompts.
- **How can personnel access be removed from the portal?**
  The authorized administrator can remove users. This can be done in the Clinical Users tab by selecting "Deactivate" and following the prompts.
- **How can a patient be added to the portal?**
  Before placing SmartPatches, a patient must be added to the portal. This can be done from the portal Dashboard by selecting "Add Patient" and following the prompts.
- **How are notifications received for out-of-range values on a patient?**
  When values are out of range for a particular metric, the Alio platform will send email notifications to the selected clinic recipient. The out-of-range values can also be seen in the portal on the dashboard or specific patient page.
- **What happens if notifications come in overnight or on a weekend?**
  Follow your clinic policy.
- **Does someone need to be "on call" for notifications?**
  Follow your clinic policy.
- **Can portal data be shared with patients?**
  Follow your clinic process.
- **Can portal data be shared via email with someone outside the clinic users?**
  No.

- **Can a clinic choose what parameters to see in the portal? Are the parameters configurable?**

  Clinic authorized administrators can set the parameters the clinic would like to receive notifications for. These parameters would be applicable to all clinic patients. For users, you would have to contact your authorized system administrator.

Alio Platform General Questions

- **What do I do if a patient says their Alio product is functioning incorrectly?**

  Refer the patient to contact Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.

- **What do I do if the patient says their SmartPatch is causing pain or discomfort?**

  Ask them to remove the SmartPatch until the pain or discomfort has resolved and consult with their clinical team. The SmartPatch can be replaced once instructed by the clinical care team.

- **What metrics does Alio platform monitor?**

  The metrics monitored by the Alio platform include measured hemoglobin (Hgb) and hematocrit (Hct), potassium (K+), skin temperature, auscultation sound data, and heart rate.

- **Does the Alio platform replace monthly blood draws?**

  The Alio platform is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care blood draws. The Alio platform takes measurements every 3 hours and provides notifications via the portal if a patient's values are out of range. Any 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 data.

- **Is there a phone number or email for patients to contact Alio if they have questions about their SmartPatch or the hub?**

  Yes. Please contact Alio Customer Support via email - support@alio.ai or phone (US) +1 855 979 1600.

- **Do the patients get billed by Alio for the SmartPatches or the hub?**
  The Alio platform is paid for either by the patient's insurance and/or by the clinical site which provided the remote patient monitoring platform. As such, only a standard co-pay may apply. For further questions, please have the patient contact their insurance or their clinical care team.

- **Does the hub or SmartPatch make any sounds?**
  No, none of the Alio platform components make sounds.

- **Does the hub or SmartPatch light up or blink throughout them wearing it?**
  The SmartPatch has a green light that will blink 3 times when the SmartPatch is first turned on. The hub has a green indicator light that will turn on when plugged in and then turn off. If there is a yellow blinking light, the patient should call the Customer Care line for troubleshooting.

- **Do I need to return SmartPatches or the hub after use?**
  The SmartPatches can be disposed of as per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste. If part of a clinical trial, please return the SmartPatches. The hubs should be returned to Alio once the patient is no longer being monitored using the Alio platform.