

VeriHaler



Sagentia Innovation

VeriHaler, developed by Sagentia Innovation, is a connected health system designed for monitoring adherence in asthma or COPD patients.

VeriHaler uses wireless acoustic monitoring to provide valuable feedback to the user, clinician or healthcare provider through promoting correct inhaler usage and rapidly detecting any deterioration in a patient's condition.

Expertise and domain knowledge

- Software engineers
- Mechanical engineers
- User interface design
- Data management
- Image processing
- Human Factors
- Medical adherence
- Patient needs
- Patient remote monitoring
- Medical grade software development
- Commercial insight and understanding
- Low power electronics





Our client asked:

Lack of adherence (or non-compliance) to the drug dosage regimen is a large and growing problem for the healthcare industry and is potentially life threatening. It is thought that adherence to inhaled drug therapies such as COPD and Asthma have only 40% to 60% of patients correctly adhering to the prescribed regimen and only 10% of patients performing all essential steps correctly. Sagentia Innovation's medical team wanted to design a system capable of better monitoring patient adherence to ultimately improve it.

The technology:

The core sensor technology incorporates a small, inexpensive condenser microphone attached to the device casing. It is non-invasive in the drug flow path and does not affect inhaler performance. It can be retrofitted to an existing inhaler platform and works with both metered dose (pMDI) and dry powder (DPI) inhalers.

A proprietary algorithm removes unwanted background noise from the acoustic signal and extracts key information about the use of the device. For example, inspiratory flow rate, timing of breath, and the delivery of the drug.

User feedback and remote connectivity to the carer is critical for the success of this system. An iPhone App communicates with the inhaler via a Bluetooth® Low Energy connection. The iPhone user interface has been designed to ensure that the user is presented with clear, actionable information on the level of their compliance. The App is also capable of logging peak flow data (by a Bluetooth connected digital peak flow meter or via user input). This allows the patient to spot any deterioration in their condition early on.

Finally, the logged data are then uploaded to a cloud server via a secure connection to a secure web portal, that the patient and clinician can review during a consultation.

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Results: deliverables and outcomes

We anticipate the App will be regulated as a Medical Device in accordance with the FDA's guidelines on Mobile Medical Apps. This means that the system must be carefully designed to ensure that critical data processing steps are not carried out on the smart mobile device processor, but either within the medical device or on a remote server.

Elements of the technology have been used by two pharmaceutical companies in their clinical trials (one pMDI, one DPI).

This technology is available for licensing as a rapid development platform for a range of connected health applications, both within and beyond drug delivery.

The challenges addressed in this technology development:

- Low disposable CoG Inhaler
- Adding a sensor to an existing inhaler design
- Avoiding acoustic interference
- "Basic" data processing (Embedded s/w)
- Low power electronics
- Streaming data in real time over Bluetooth LE
- Creating a medically regulated app and developing it to IEC62304
- "Dumb UI" as far as possible
- The efficient UI design ensures timely, actionable data is presented to the patient
- Server security
- "Complex" data processing
- Stakeholder specific, hierarchical UI design
- Data processing, transmission back to the App in a timely fashion