

- b. *Target Product Cost*: Prototype can cost a fair amount of money if the ability exists to lower cost by mass production in the long run.

3. Miscellaneous

- a. *Standards and Specifications*: FDA approval may be required to make sure that device does not alter the correct amount of medication deployed by inhaler.
- b. *Customer*: Since some customers may be children, issues such as portability and discreetness must be high priorities.
- c. *Patient-related concerns*: Confidentiality should be considered, although memory will not likely hold personal information (just general usage data).
- d. *Competition*: There are some devices that can record the time and date, but not location, of inhaler usage. Current products cannot transmit wirelessly or within a reasonable time span of when the device was actually used.

- c. *Accuracy and Reliability*: Must be repeatable until study is over or until inhaler is no longer needed. GPS location and time/date should be as accurate as possible without compromising safety, but up to 200 ft of error is acceptable as long as recording is successful when symptoms occur.
- d. *Life in Service*: Should be usable across the entire globe, with GPS communicated via satellite, and should last at least as long as the inhaler. Depending on the final cost of the device, it may be necessary to use it on several different types of inhalers if it is not easily replaceable.
- e. *Shelf Life*: Will need some sort of power supply that can be either replaced or recharged. Shelf life of device will be entirely dependent on battery life.
- f. *Operating Environment*: Should be usable at temperatures conducive to inhaler use (generally 0-100 degrees Fahrenheit) and at all locations and elevations. Must be able to withstand normal wear and tear such as being dropped, stored in pockets, and (ideally) exposed to small amounts of water as well.
- g. *Ergonomics*: Must not carry enough electricity to cause damage in the event of malfunction. Wireless usage is ideal.
- h. *Size*: Must be portable and have a replaceable or rechargeable power supply within the unit. Smaller is better.
- i. *Weight*: Should be easily portable and not weigh more than 3 lbs (must not make use of inhaler difficult for children).
- j. *Materials*: Nothing should be used that could trigger allergies in users (plastic or metal that can be easily cleaned is ideal).
- k. *Aesthetics, Appearance, and Finish*: Preferably should not look bulky or out of place when attached to inhaler.

2. Production Characteristics

- a. *Quantity*: Eventually enough for thorough testing in up to 10,000 trial patients. Licensing may be considered if product is successful (mass production will make device more cost effective).

Team Members:

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Function

The aim of our team over the next two semesters is to create a prototype of an asthma inhaler (or a device attachable to an asthma inhaler) capable of communicating the time, date, and location where the inhaler was used, as well as to design the software to accompany the data. This project is important in the tracking of allergy and asthma symptoms, outbreak control, and general health observations with respect to populations in certain areas of the United States and, ultimately, the entire globe.

Client Requirements

- ◆ **Stage 1:** The creation of a prototype of an inhaler or an add-on device for existing inhalers that records the time and location when the inhaler is used.
- ◆ **Stage 2:** The physical sending of data (as often as possible) to a remote collection location.
- ◆ **Stage 3:** The mapping of use based on location so that instances can be tracked and associations made with symptoms and therefore inhaler usage. Outbreaks can be tracked to their sources based on this technology.

Design Requirements

1. Physical and Operational Characteristics

- a. *Performance requirements:* Must be able to attach to a common inhaler to minimize the extra hassle of carrying something else along with it. It must function as many times daily as the inhaler is used, which can vary from never to several dozen times depending on symptoms.
- b. *Safety:* Cannot compromise the deployment of medication (i.e. can't change pressure, loading capability, or otherwise interfere).