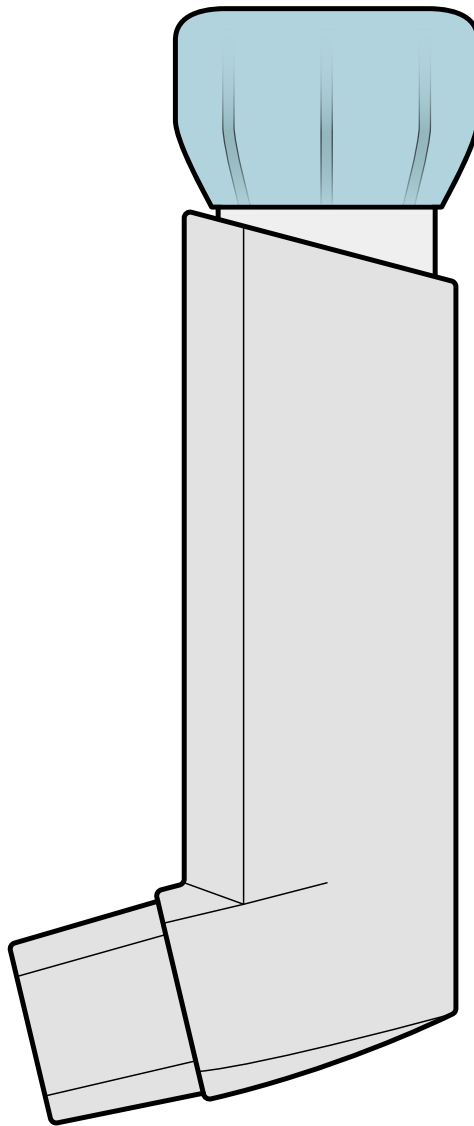


Ochsner COPD Inhaler Usage Tracker

Product Design Specification



 Designed by **innovationOchsner**

1. EXECUTIVE SUMMARY

The Ochsner Inhaler Usage Tracker (hereafter, “Product”) is a device that attaches to the top of the medicine tank of several common COPD rescue inhalers. Product provides clinicians with usage information for the inhaler. Once installed, data that includes the time of each actuation of the rescue inhaler is held in device memory until it can be sent via Bluetooth to a companion application on user’s mobile device. Clinicians will remotely monitor usage patterns and message users if certain usage criteria are met.

1.1 SUPPORTED INHALERS

ProAir

NDC Code: 59310-579-22

Teva (ProAir Generic)

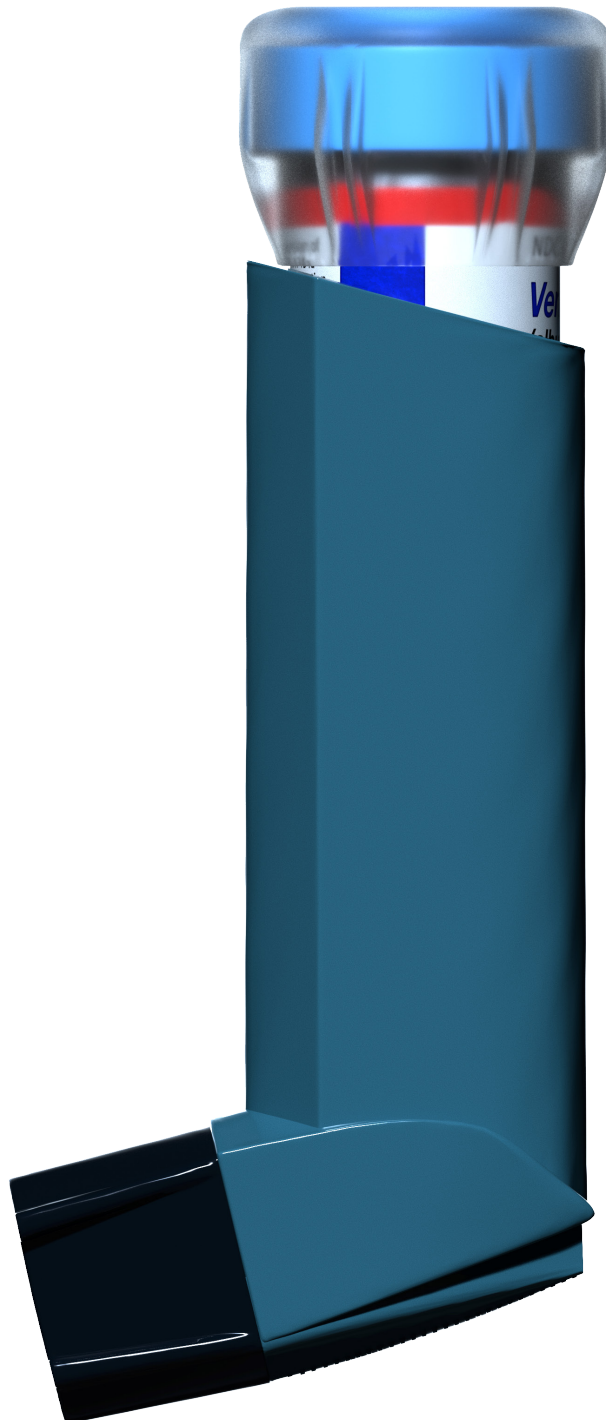
NDC Code: 0093-3174-31

Ventolin

NDC Code: 0173-0682-20

Prasco (Ventolin Generic)

NDC Code: 66993-019-68



2. INDUSTRIAL DESIGN

Product is comprised of a rigid inner Tech Stack sheathed with a pliable outer sheath. Inner Tech Stack is contained by a hard plastic enclosure.

- **TECH STACK ENCLOSURE**



Ochsner Light Blue

2925 C | 85, 24, 0, 0 | 0, 156, 214 | #0096d6

ON-DEVICE PRINTING

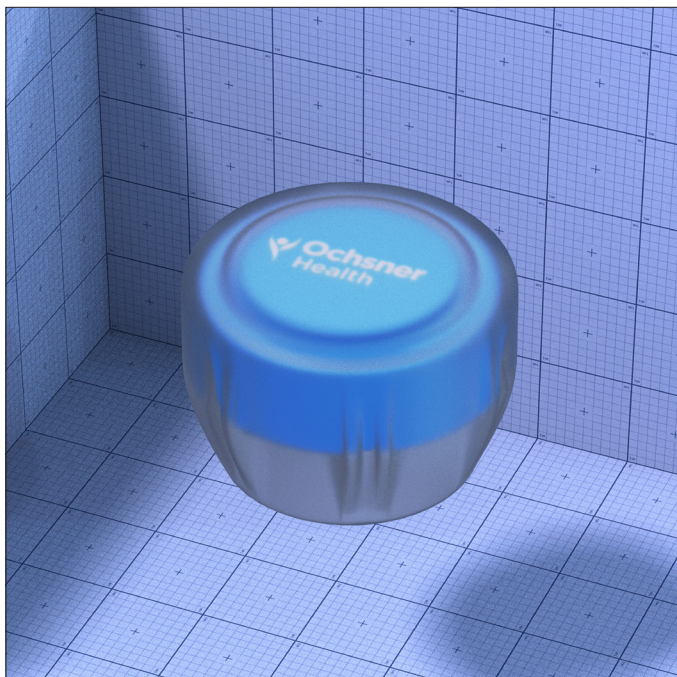
Tech Stack will have branding printed in white onto the elastomeric button, and unit-specific identification and sync information printed on the bottom.

- **EXTERNAL ENCLOSURE**

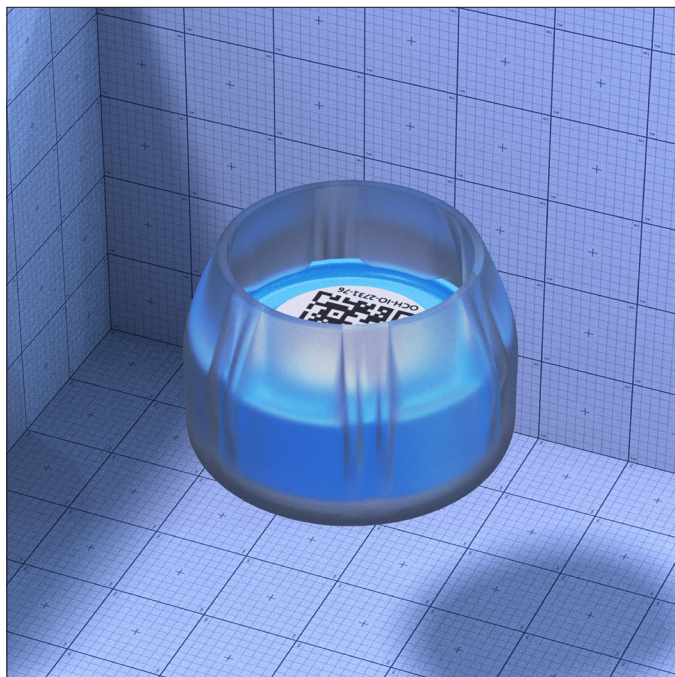
- COLOR: Translucent to allow for clear reading of branding printed on Tech Stack button
- FINISH: Frosted (if frosted is not an easy option, smooth is acceptable.)

2.1 PRODUCT RENDERS

TOP



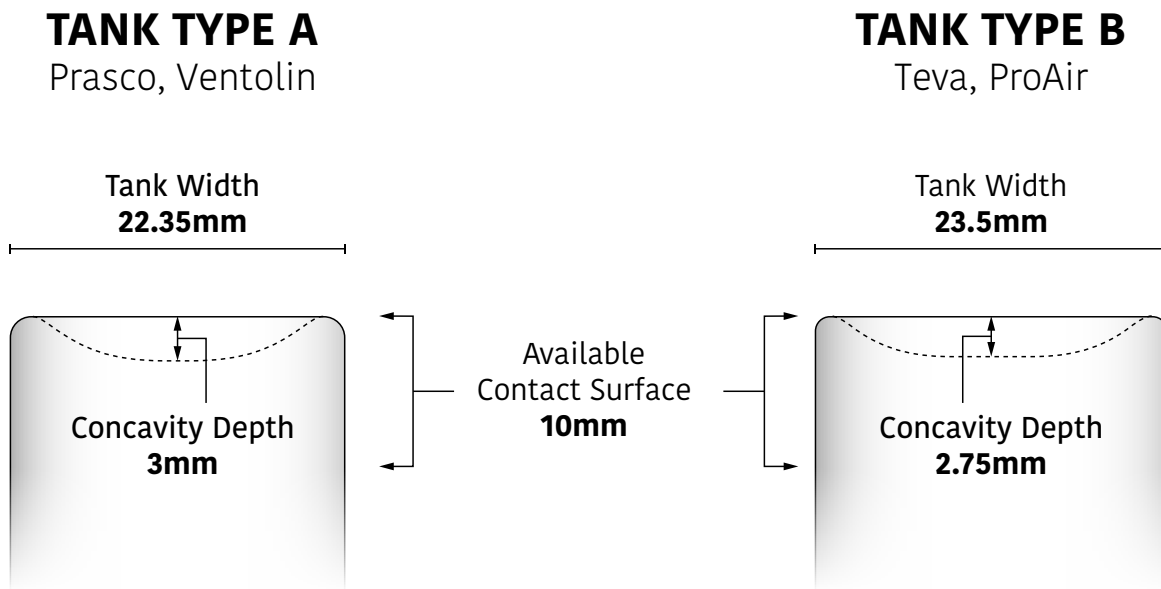
UNDERSIDE



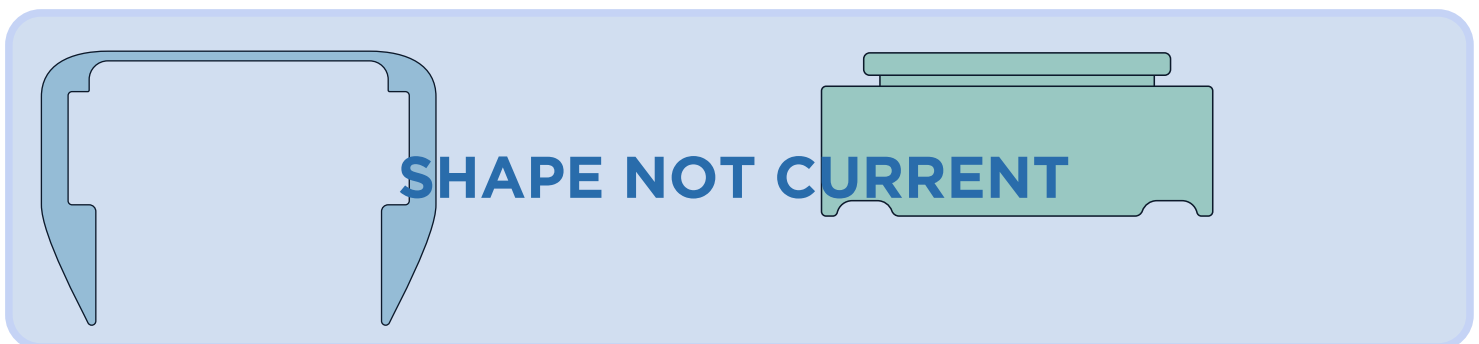
3. MECHANICAL DESIGN

3.1 INHALER TANK TYPES

The supported inhalers fall into two types that must be accommodated by a single Product design. The amount of vertical tank area that can be accessed for securing Product to inhaler is the same for all. However, the two types differ in the diameter of the tank and the depth/contour of the concavity at the top of tank.



3.2 PRIMARY COMPONENTS



EXTERNAL ENCLOSURE

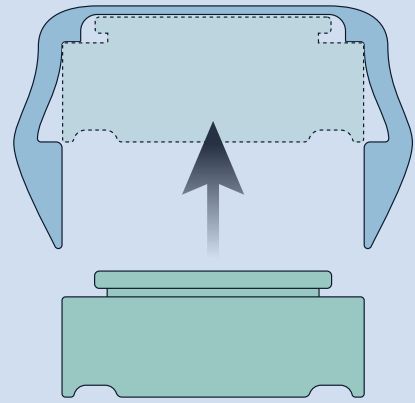
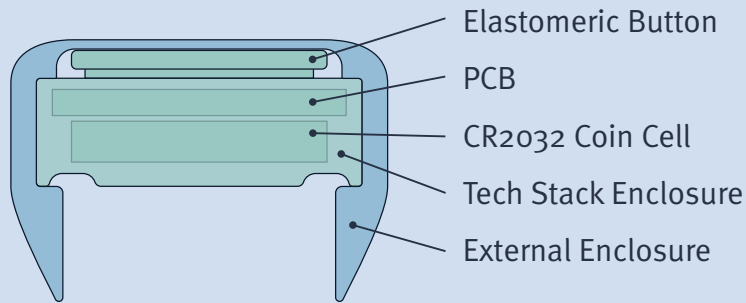
The External Enclosure is comprised of a single piece of pliable elastic material such as TPU. External Enclosure encapsulates the unified Tech Stack and provides for attachment to inhaler tank. External enclosure should be cast with a clear material to provide better visibility of the enclosed Tech Stack.

TECH STACK

The Tech Stack contains all electronics, comms, and power for Product, is contained within a rigid plastic housing, and features a top-mounted actuation button. Assembly of Product will require manually inserting the Tech Stack into the External Enclosure until it snaps into place.

3.3 ASSEMBLY

SHAPE NOT CURRENT



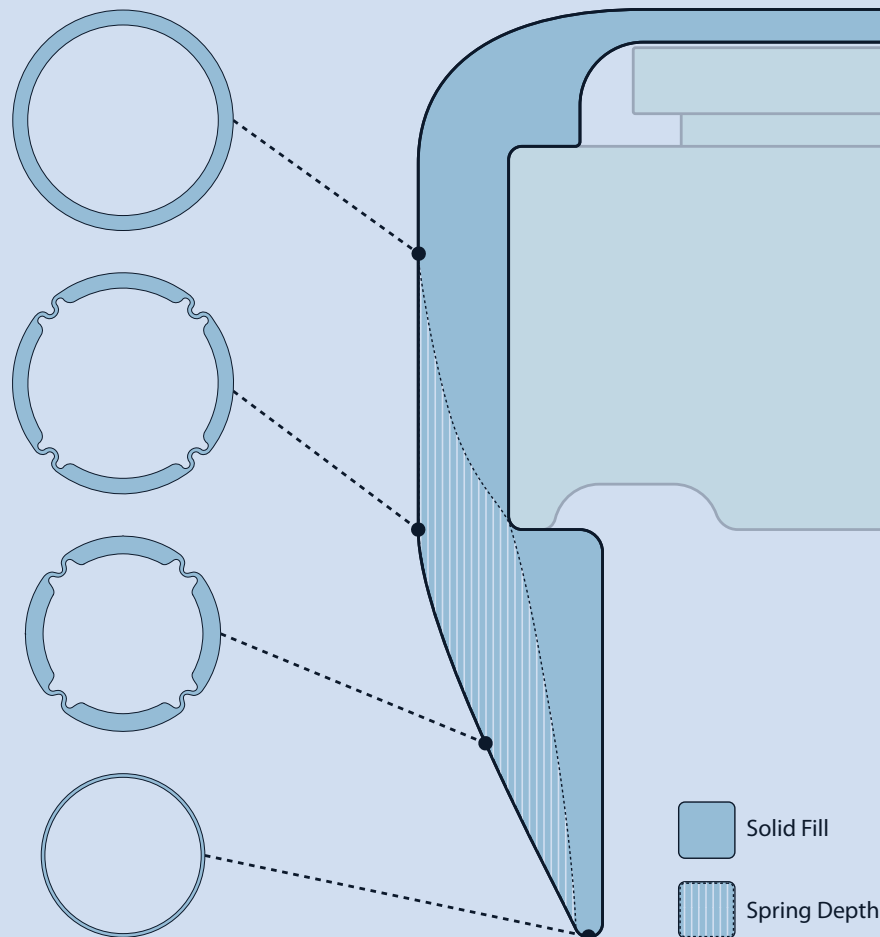
3.4 INTEGRATED SPRINGS

Current design employs a series of longitudinal integrated spring mechanisms to allow for optimal radial expandability while retaining sufficient vertical stiffness to prevent buckling of the External Enclosure when downward force is applied as user mounts Product to top of tank.

3.5 INTEGRATED SPRING EXPANDABILITY

The radial expandability of External Enclosure at any given latitude is determined by varying the amount integrated spring in relation to solid material.

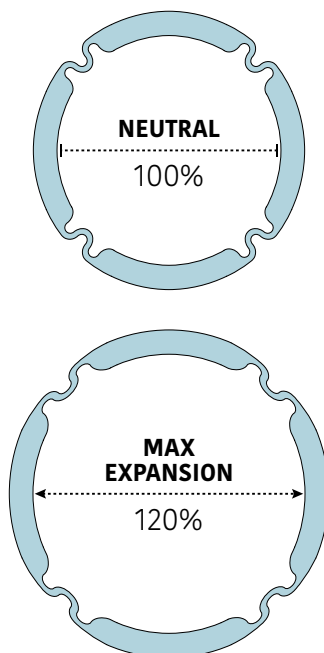
SHAPE NOT CURRENT



3.6 EXPANDABILITY VARIABLES

External Enclosure should provide a level of expandability that allows insertion of Tech Stack into External Enclosure at time of Product assembly, while ensuring enough tension for Product to remain firmly in place when attached to the smaller inhaler tank. Producer should work with manufacturer to determine the ideal

- **Material thickness**
- **Spring Depth**
- **Number of longitudinal springs**



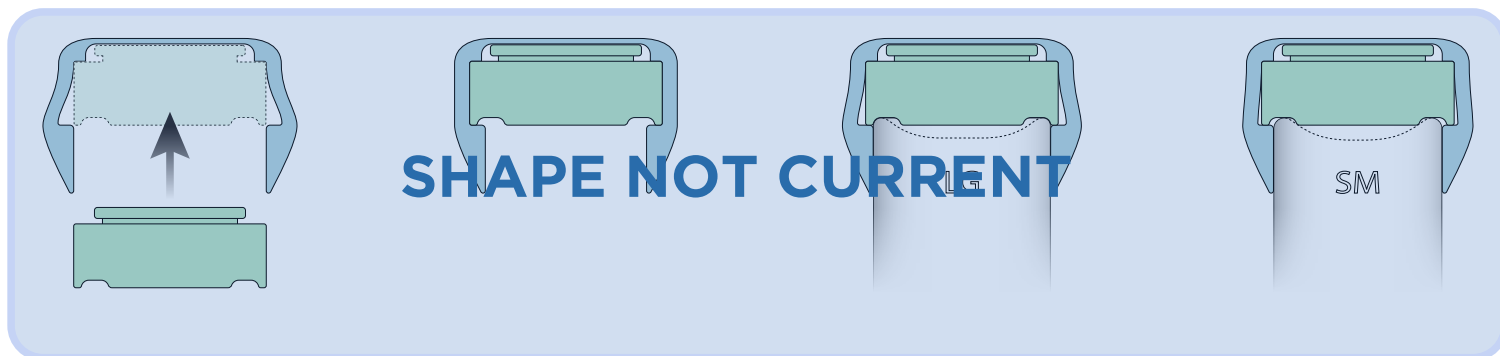
SLEEVE EXPANSION STATES

ASSEMBLY
Max. Expansion

UNMOUNTED
Min./Neutral

MOUNTED
Large Tank

MOUNTED
Small Tank



3.7 FORCE TRANSMISSION

Product transmits the downward force required to release medication from inhaler. Primary actuation point is the wide button mounted to the top of the Tech Stack. Forces are then transmitted through the rigid Tech Stack enclosure to hard contact points at the rim of tank.

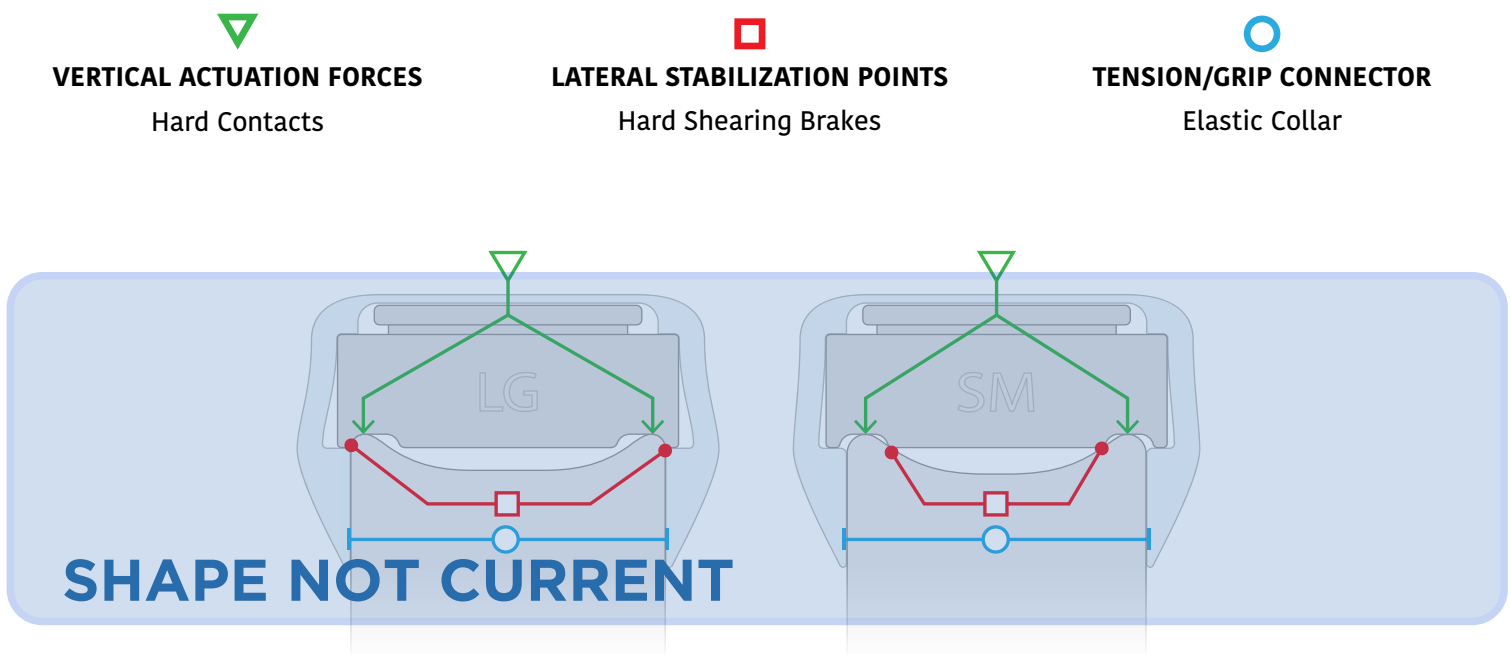
Because the Tech Stack is secured to inhaler tank with a firm - but elastic - material, Product is designed to mitigate the effects of shearing forces that can occur when inhaler is actuated. Current design includes a circular groove at the base of the Tech Stack enclosure that limits horizontal travel of both the small and large tanks.

Points of contact for actuation forces and shearing mitigation fall in different locations for small and large tanks.

3.8 Actuation Force

The ideal actuation force falls safely below the force required to release medication from inhaler and above the force that could lead to accidental actuation of Product in the course of normal handling of Product-equipped inhaler. Accidental actuation scenarios would include inserting and removing device in/out of pockets and purses, as well as short drops.

In general, purposeful actuations are of longer duration than accidental ones. Filtering out shorter-duration button depressions may further improve ability to identify and ignore erroneous actuations. This approach would require an output signal that would allow for reading the duration of a press, providing that such an approach would not incur too high a penalty in power consumption. Ideally, press duration information would be stored in the log of actuations in Product memory where it will be part of the sync payload and filtered at the App level.



4. ELECTRONICS

4.1 PCB BOARD

4.1.1 Power

- **Battery**
 - CR2032 Coin Cell
- **Lifespan**
 - Shelf: 4 Years
 - Frequent use: 1 - 2 Years
- **Power Modes**
 - Rest Mode - periodic Bluetooth ping
 - Active Mode - Triggered by actuation

4.1.2 Connectivity

- **Bluetooth Module**
 - Advertising Rate optimized for low-power rest mode
- **Signal Payloads**
 - Pairing
 - ♦ MAC Address
 - ♦ ...others TBD
 - Sync
 - ♦ Actuation Log
 - ♦ Battery status at time of sync
 - Firmware Update
 - ♦ Updated firmware code
- **Memory**
 - Actuation Log
 - Signal Cache, per actuation
 - ♦ Time of actuation
 - ♦ Duration of actuation

4.1.3 Processing

4.1.4 Firmware

- **Firmware should support wireless updates over Bluetooth**

5. LOGIC

5.1 PAIRING

- **Actuation Button Depression 5 seconds -> Emit Bluetooth Pairing signal**
- **Receive Pairing Confirmation -> Stop Pairing Signal**

5.2 SYNC

- **Master device Bluetooth connection -> Sync**
- **Receive Sync Confirmation -> Clear Actuation Log from memory**

5.3 ACTUATION

- **Depression of Actuation Button -> Log time and duration of actuation in Actuation Log**

6. UX SCENARIOS

6.1 ACTIVATION

- Product is activated when battery isolation tab is removed.

6.2 PAIRING

Users will have two methods of pairing Product with mobile companion app. If primary method is unsuccessful user will be prompted by mobile companion app to use fall-back method.

- **QR Code Pairing [PREFERRED METHOD]**
 - User scans Product QR code, awaits pairing success message
- **Button-press Pairing [FALL-BACK METHOD]**
 - User holds actuation button down for five seconds, awaits pairing success message

6.3 MOUNTING

- After pairing, or when switching to a new inhaler, user attaches product to top of inhaler tank by firmly pressing Product into place.

6.4 ACTUATION

- Actuation of Product, and the resulting log of data, should occur when user actuates inhaler as they normally would, by pressing firmly until medicine is released.

7. REGULATORY/COMPLIANCE

7.1 FCC COMPLIANCE

- **Product must comply with all FCC rules that apply to Bluetooth components used therein.**

8. PRODUCTION AND DELIVERY

8.1 ON-UNIT PRINTING

- **QR Code and Product Identification**

Each Tech Stack will have information printed on the bottom face of Product. Importantly, the Bluetooth pairing QR code and the MAC address are specific to the unique chipset of each unit. Therefore, a printing process will be required that ensures that the printed information corresponds to the individual unit on which it is printed.

- **Branding**

Current design assumes that branding graphics will be printed on the wide surface of the elastomeric button, and will be readable through the transparent elastic material of the External Enclosure. Single ink (white).

8.2 ASSEMBLY

- **Tech Stack to be fully assembled with all internal components, battery, and battery isolation tab**

8.3 Delivery

Tech Stacks and External Enclosures to be delivered separately to allow for easy removal of battery isolation tabs. Ochsner staff will insert Tech Stack into External Enclosure prior to distribution to user.

- **TECH STACKS**

- Battery installed, with battery isolation pull-tabs in place
- Individually wrapped
- Packed to protect against impact damage

- **EXTERNAL ENCLOSURES**

- Bulk packaging will be fine

9. COMPANION MOBILE APPLICATION

9.1 Concepts for initial consumer version [CV1] of app

- CV1 Device and app achieve a single function: Track time and duration of actuations of the Rescue inhaler to which Device is attached.
- Maintenance inhalers are not supported in CV1.
- Authenticate via MyChart Credentials
- Use **React Native** as much as possible
- Internal development will focus on iOS App. Ultimately Android will require support as well, but port process YTD.
- Ideally, there will be no direct user input to app after pairing.
- Display of patient information and response to questionnaires will be handled by existing apps and SMS messaging.
- For CV1, pairing and initial setup will be typically completed by O-Bar staff, but process should be intuitive enough for end-users to handle with no support beyond in-app guided pairing routine.

9.2 Functions

- **PAIRING**

Users will have two methods of pairing Product with mobile companion app. If primary method is unsuccessful user will be prompted to use fallback method.

QR Code Pairing [PREFERRED METHOD]

- User scans Product QR code, awaits pairing success message

Button-press Pairing [FALLBACK METHOD]

- User holds actuation button down for five seconds, awaits pairing success message

- **SYNC**

- Time and duration of actuation are stored in Product memory and synced with app when in Bluetooth range
- GPS position at time of sync should be associated with synced data from Product and sent along with it to Epic

- **Auto re-launch via React Native**

- **Push Notifications**

- Acknowledging successful actuation
- Upon killing of App, remind user that app must stay running in background to function

- **Proactive Refresh Token upon sync via React Native**

10. CONTACTS

Contact the people below any time. Please CC Matthew Hales in all communications relating to this project.

- **PROJECT LEAD**

Matthew Hales

matthew.hales@ochsner.org

504.228.0149

- **PROJECT ADMINISTRATION**

Kimberly Phillips

kimberly.phillips@ochsner.org

Sarah Joyce

sarah.joyce@ochsner.org

- **MECHANICAL DESIGN**

Jack McGee

john.mcgee@ochsner.org

- **INDUSTRIAL DESIGN**

McKenzie Hutchinson

mckenzie.hutchinson@ochsner.org

- **ELECTRONICS**

Thomas O'Connor

thomas.oconnor@ochsner.org

FCC Warning:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies 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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This document contains confidential and privileged information for the sole use of the intended recipient(s). Review, use, distribution or disclosure by others is strictly prohibited. If you are not the intended recipient or authorized to receive information on behalf of the recipient, please contact the sender by reply email, and delete all copies of this document.

Ochsner is a 501(c)3 not-for-profit organization, founded on providing the best patient care, research, and education.

©2020 Ochsner Health