# DELIVERY OF INHALED DRUGS THROUGH CPAP

Product Design Specifications

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**FUNCTION:**

The purpose of this project is to create a device for in-home use to automatically provide pulsed delivery of inhaled aerosol medication, achieved by mechanical shaking and timed actuation, in line with commercial CPAP machines using the circuit (tubing) and flow generated by the CPAP.

**CLIENT REQUIREMENTS:**

- The device will be used for clinical trials to test the efficacy of the hypothesis that the delivery of long-acting asthma medication in the early morning hours will reduce the need for fast-acting inhalers during the day
- The device will only be used on adults
- Due to the possible complications of inhaling oral steroids through the nose, a full face mask will be integrated into the design to allow for oral inhalation of the medication

**DESIGN REQUIREMENTS:**

1) **Physical and Operational Characteristics**
   a) *Performance requirements*:
      - Used by one patient every night during sleep for 30 night trials
      - Each use will be administered at approximately 4 am and will deliver one pulse of the drug, unless otherwise specified by the patient's physician or otherwise needed to deliver the full dose of drug (determined by testing)
      - Delivery of medication should be coordinated with inhalation to provide maximal delivery to lungs
      - The inhaler must sit in an upright position when actuated
      - Current drugs that will be delivered are orally inhaled aerosols intended for use as long-acting asthma medications

- Device should allow for use of various aerosolized drugs and respective canisters
- Patients with limited dexterity should easily be able to disassemble any parts involved in replacement of drug canisters and be able to interact with the feedback (counting) mechanism of the device once a stand-alone unit is designed and produced

b) *Safety*:
- Must meet FDA requirements relating to drug administration, drug/material interactions, dosage accuracy, and mechanical ventilation
- Drug should be delivered through mouth to avoid damage to and discomfort in nasal mucosal membranes
- Cannot compromise enclosed nature of ventilation circuit - connections must pass pull test with protocol to be determined after further prototype development
- Controls for setting dosage and time of delivery must be programmable by physician but unalterable by patient
- Edges/corners must be rounded to prevent patient injury during movement in sleep
- Changes in dosing through integration with CPAP to be determined in order to prevent over- or under dosing of a patient
- If device is placed in close proximity to face of patient, miniaturization of product required to reduce claustrophobic sensations experienced by user

c) *Accuracy and Reliability*:
- Drug delivery must occur during inspiration only
- Deviation from set internal pressure of CPAP machine caused by activation of device cannot be greater than ±1 cm $H_20$
- Power sources used to run device must ensure proper working conditions each night
- Circuitry developed must be flexible enough to account for variations among patient expiration temperatures and thus signal amplitudes
- Actuation of drug canister must be completed by mechanism that consistently returns to proper starting position, or have ability to be reset by patient
- If device is place away from the mouth of the patient, testing should be done to quantify the amount of drug reaching the patient and the dose delivered (i.e. number of actuations) should be adjusted to provide the prescribed dose to the patient
- Medication must be agitated with an energy input equal to that of a manual shake for 5 seconds in order to achieve suspension level of mixture equal to that of what is produced by following manufacturers' instructions
- Incorporate in-line actuator to produce same results as depressing inhaler in mouthpiece device provided with the original inhaler canister

d) *Life in Service*:
- One year minimum
- Batteries must last through 30-night clinical trials

*e)* *Operating Environment*:
- Will be used in the home; not exposed to external environment
- Used by one patient for life of device

- Dosing may change during lifetime, e.g. 2 actuations vs. 1 actuation
- CPAP masks involved will allow for mouth delivery of aerosolized drug
- Sleeping environment (uncontrolled movement of patient, passive interaction of patient with integrated system while asleep)

f) *Ergonomics*:
- Drug cartridge replacement should be easily accomplished by patients with minimal hand dexterity.
- Total device should not interfere with patient's sleeping conditions and comfort should not be reduced further than what is comparable to use of CPAP

g) *Size*:
- Tubing and any connections must be compatible with patient circuit
- Portion of device that actuates drug release should add no more than 3 cm to each dimension of canister (goal of future development)
- Device will ideally be placed in area near patient's face to allow for optimal placement of drug canister; this cannot, however, interfere with patient comfort, especially in terms of sleeping and claustrophobic sensations
- If placed away from the face, should be able to fit on a bed-side table or any other existing piece of furniture
- Circuitry must be incorporated into a microprocessor and printed circuit to further reduce added dimension to current system

h) *Weight*:
- Must be lightweight to avoid deformation of original CPAP tubing leading to disruptions in ventilation
- If system is incorporated near the head region of the patient, it cannot be bulky or add excessive weight that may compromise the efficacy of CPAP or drug delivery, and also not interfere with user comfort

i) *Materials*:
- Cannot have negative interactions with drugs used, may have to be disposable or easily cleaned by individual patients, hypoallergenic

j) *Aesthetics, Appearance, and Finish*:
- Finish should be simple and mimic commercial CPAP machine
- System must be self-contained

**2) Production Characteristics**

a) *Quantity*:
- Ultimately one device per patient will be needed
- One prototype for developmental purposes; more devices may be needed if human studies are performed

b) *Target Product Cost*:

- $1000 maximum for initial prototype

**3) Miscellaneous**

a) *Standards and Specifications*:
- Bioengineering unit at University of Wisconsin must test and approve device prior to use in client's research
- Final device must meet FDA regulations for medical devices
- Any testing involving human subjects to determine proper dosing, efficacy, etc. must have protocol approved by IRB

b) *Customer*:
- Use of humidifier in ventilation circuit preferred by half of client's patients to prevent drying of mucosal membranes, although will not necessarily be taken into account during initial design of integrated device
- Full face mask must be used to ensure inhalation through the mouth
- OPAP mask could be option for this system which would also direct flow of air and drug directly to mouth

c) *Patient-related Concerns*:
- Minimal bulk near face will prevent patient claustrophobia and discomfort.
- Portion of device in line with ventilation circuit should be easily cleaned to remove drug residue.
- Size, weight, and noise of device should not disrupt patient sleep

d) *Competition*:
- Research currently performed on pediatric patients to develop similar system
- Current research regarding integration of aerosol delivery with CPAP or other ventilation systems focuses on nebulizer deliver system rather than the use of MDIs, and most studies are concerned with invasive ventilation (intubation)
- No commercial or research product has been found that is applicable for adults
- Stand-alone CPAP being researched to determine affects on sleep apnea patients with concurrent asthma, but currently no published studies found on effects of CPAP with integrated inhalers