

Product Design Specifications
Aerosol Drug Delivery by CPAP
Updated: 02/10/2010

Function

To automatically deliver aerosolized drugs during use of CPAP device without compromising the function of the CPAP. This added function will improve the CPAP's effectiveness in alleviating the symptoms of sleep apnea.

Client Requirements

- Automatic
- Must not interfere with function of CPAP
- Compatible with albuterol
- Must incorporate humidifier
- Adjustable amount of drug delivery
- User interface to adjust the start time and duration of administration of up to three doses of albuterol during the patient's sleep cycle

Design Requirements

- Must be able to be used nightly for eight hours
- Must incorporate nebulizer to aerosolize drug
- Delivery must be efficient
- Must have computer interface
- Must have dosage control
- Must be sterilizable
- Easy to set up
- Must not disrupt sleep

1. Physical and Operational Characteristics

a. Performance Requirements: The drug delivery system must be capable of running efficiently every day for approximately 8 continuous hours. During this time, the drug must be delivered in accurate doses at times specified by the user. It also must be compatible with a CPAP device and not compromise the positive pressure in the patient's airway.

b. Safety: The drug delivery system must not disrupt CPAP operation. It must also not allow the possibility of a drug overdose.

c. Accuracy and Reliability: The drug delivery system must be at least as efficient as existing nebulizers at delivering aerosolized albuterol. The user must be able to have precise control over the dose of drug delivered, with control to .1 mg drug.

d. Life in Service: Parts should be made replaceable, increasing the service life indefinitely. The CPAP tubing must be replaced periodically, however the use of standardized parts should minimize this cost.

e. Shelf Life: The drug delivery system should last in storage as long as the shelf life of the commercially available parts used (the CPAP, piezo buzzer, etc.). A ten-year life span is desirable.

f. Operating Environment: The drug delivery system will be used for sleep studies conducted in a controlled environment. It must not interfere with the sleep of the individual using it, not can it interfere with any other instruments used in the study

g. Ergonomics: The computer interface should be easily navigated with minimal training. Any mask or additive to the drug compound that will contact the patient must not be irritating and be compatible with 8 h of continuous use

h. Size: The drug delivery system must be able to contain at least two doses of drug (6 mL fluid)

i. Weight: The drug delivery system must be easily moved by a single person. A weight less than 5 kg is desired.

j. Materials: Materials used must be FDA approved for use in drug delivery systems, must not alter the properties of the drug, must not promote drug adhesion, and must not be an irritant to the patient.

k. Aesthetics, Appearance, and Finish: The drug delivery system should be designed with functionality in mind, and aesthetics are of secondary concern.

2. Product Characteristics

a. Quantity: One unit will be needed.

b. Production Cost:
Estimated budget: \$250.00 - \$400.00