Principles of pMDI and the ALIENhaler design

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Abstract

Inhalers are a fundamental treatment for patients with asthma or COPD, (chronic obstructive pulmonary disease) in the past inhalers were cumbersome and inconvenient until the invention of the pMDI or pressurised metered-dose inhaler. This device provides a convenient, easily transportable, and durable treatment for patients which administers a metered, controlled volume of vital drug. Many forms of pMDIs have been designed and manufactured, such as the Spacehaler™ and the K-Haler and many more variants. The design created in the project was aimed at a young age group and was named the ALIENhaler.

Introduction

pMDIs are the most popular current treatment for patients with asthma or COPD. The pMDI was developed by Riker Laboratories in 1950 to replace the inhalers at the time which were unreliable as dosage was dependent on hand pressure administered to the device [1]and, being out of glass, were fragile and inconvenient.
Different inhalers have been made since the 1700's such as the Mudge inhaler on the left, and an 1889 style inhaler [2] is on the right in figure 1.

Figure 1 – vintage inhalers [2]

Working Principles

The pMDI has many working parts to it which are all essential to its function, these parts include the container, the propellant, the drug formulation, the metering valve and the actuator [1], these can be seen in figure 2. The design may vary between inhaler models, but the basic parts remain the same.

Container

The container must be an inert, durable material which can withstand the pressure within. Early models used glass bottles which were replaced with stainless steel as they were too fragile. The current canister material used is aluminium which can withstand the internal pressure, is durable, not opaque, light and less prone to shattering. Coatings are often applied to the inside to prevent adhesion of the drug particles and degradation due to interactions with the container material [1].

Propellant

Propellants are liquified compressed gases that are in a gaseous phase at atmospheric pressure however, when compressed, form liquids. For use in a pMDI they must also be non-toxic, non-flammable and compatible with the drug formulation. Appropriate boiling points and densities are also required so vapour pressure remains constant throughout the product's lifetime [1].
CFC's (Chlorofluorocarbons) were initially used as they had perfect properties for a propellant as they form a 2-phase dynamic equilibrium, allowing vapour pressure to remain constant without regard to how full the canister is [1]. However, the use of CFC's was found to damage the stratosphere,

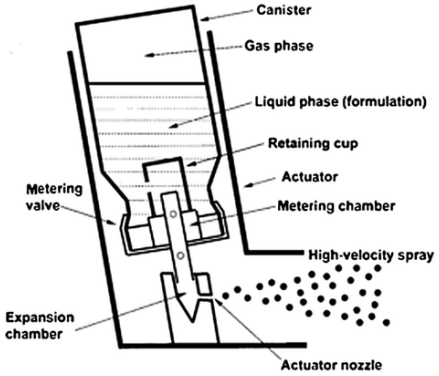

Figure 2 – functional description of pMDI [3]

leading to their phasing out [4]. Currently HCF-134a and HCF-22a (Hydrochlorofluorocarbon) and HFA (Hydrofluoroalkane) are being used as propellants as they do not catalyse ozone destruction but unfortunately, they are greenhouse gases which contribute to climate change [5].

Drug Formulation

Drugs in pMDIs are either particulate suspensions or solutions. In CFC inhalers a stable suspension is achieved as CFC's are non-polar liquids in which many of the drugs have low solubility.
Most pMDIs deliver 100-200µg of drug per dose [1].

Metering Valve

The metering valve is the most important part of the pMDI and has a volume ranging from 25µL-100µL. All metering valves work roughly the same way in which a channel is open between the container and the metering valve, however, as the inhaler is fired this channel closes and a different channel between the metering valve and the atmosphere opens. The pressurised drug formulation is pushed into the expansion chamber in which the propellant begins to boil [1].

Actuator

For use by patients, the inhaler canister is fitted into a plastic actuator. The plastic actuator determines the size of the particles through the nozzle diameter which ranges from 0.14mm to 0.6mm. The size of the particles affects how well the drug is deposited in the lungs.
When the drug leaves the nozzle, the liquid ligaments are pulled apart by aerodynamic forces which form smaller droplets of the drug which forms the dispersed vapour.
Smaller nozzle diameters result in higher average lung deposition. However, the smaller nozzle diameter results have a wider spray cone.
Actuators have a short mouthpiece of roughly 3cm allowing for convenient storage and portability. Since there is no way to know how empty or full

the canister is, a dose counter is normally included with actuator [1].

Advantages and Limitations

pMDIs are great because they are small, portable, convenient, and inexpensive. The dose can be administered very quickly and easily compared to other treatments and the contents of the canister are protected from outside contaminants and pathogens.

However, misuse of the pMDI by patients through mistimed or improper inhalation of a dose can lead to the inhaler being ineffective [1]. This can be through the cold-Freon effect which causes patients to stop inhaling when the cold feeling reaches the throat, leading to improper dosage and too low a deposition in the lungs [6].

Spacers and Spacehaler™

Spacers are large volume attachments for pMDIs which reduce oropharyngeal deposition and prevents the cold-Freon effect by slowing flow rate and reducing the turbulence. These devices can be more favourable for patients who use high-dose corticosteroids or who are prone to develop candidiasis with inhaler steroids. Many spacers are attachments on to the actuator of a standard pMDI however, these devices are cumbersome and inconveniently sized.

The Spacehaler™ however has been developed as a smaller version of this which is more convenient and portable [6]. These can be seen in figure 3.

Breath Actuated pMDIs

Breath actuated inhalers have been developed for patients who have poor or inefficient inhaler technique and poor coordination. It is a standard pMDI with springs attached to the top of the canister which are stretched when a low inhalation flow rate is present. This allows proper dosage to be administered without reliance on the patient's technique or coordination [8].

examples of breath actuated pMDIs includes the K-Haler in which the dose is contained in a kinked tube which is straightened by a breath operated lever, releasing the dose. Another is the Smartmist which is a microprocessor-controlled pMDI actuator device which delivers dose when a threshold combination of flow rate and volume is achieved. A basic breath actuated design can be seen in figure 3.

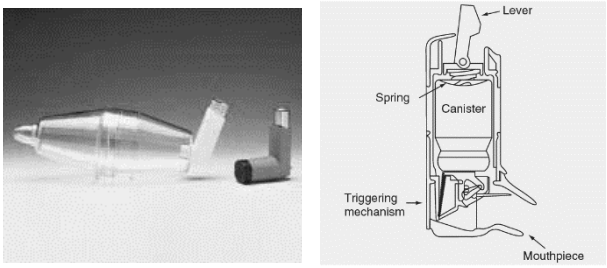

Figure 3 – Spacer on the left, SpaceHaler™ then breath actuated inhaler on right [7][9]

Our Design – ALIENhaler

Specification

The inhaler our group designed is specified for children aged 3+, it is also a smart inhaler with a locator app which causes the inhaler to emit a noise allowing it to be found when missing. This will involve a radio receiver implant in the inhaler. Since the inhaler will be used for small hands, the antenna have been designed to act as handles where they can be held in the palms and the canister can be pushed down with the thumbs to administer dosage, textured blue handgrips are also at the sides to accommodate slightly larger hands in aiding two-handed dose administration.

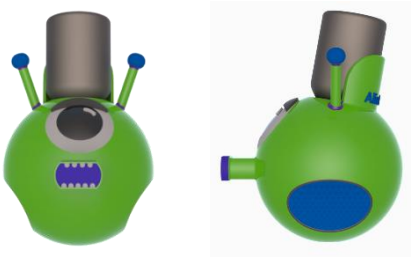

Figure 4 – The ALIENhaler front and side profiles

Design

As seen in figure 4, the actuator was a fun alien design. The inhaler can be charged using a USB-A port in the bottom which can be connected to the male counterpart which is located on the base, the base design was based on a UFO to stick with the alien theme. The inhaler also comes with a cap which covers the mouthpiece to keep debris getting in the actuator. Figure 5 in the appendix shows how the Inhaler comes apart and how the actuator attaches to the charging base. The app will allow the doses to be counted and monitored and will be able to send notifications when the canister needs changed.

The actuator nozzle diameter is 0.5mm in diameter as recommended to give a good lung deposition yet a narrow spray cone. The mouthpiece sticks out of the actuator at a standard 3cm.

Personal Contribution

My personal contribution to the group involved modelling the charging base and rendering the model on Solidworks Visualise, I also created the design board which is attached in the submission. The design board was alien and space themed, appropriate to the design.

Appendix

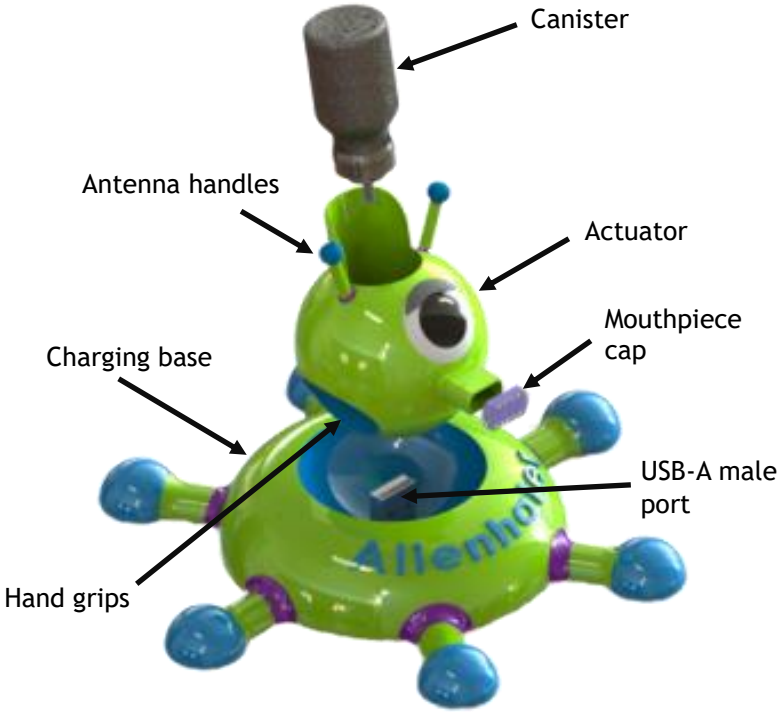

Figure 5 – Exploded view of ALIENhaler and components

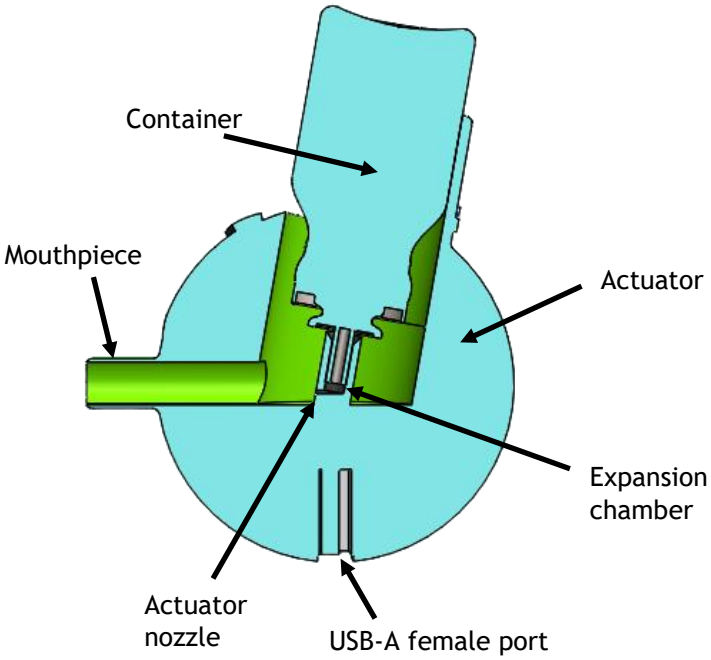

Figure 6 – Section view of ALIENhaler

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