# New Ophthalmic Drug Delivery Technologies

## - Meeting patients' needs -

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More than 285 million people worldwide suffer from visual impairment and the number of diseased patients is expected to soar in the future due to an increase in air pollution. However, about 80% of all visual impairment can be prevented or cured when considering a medicinal treatment, such as preventative eye drops.

Nowadays people with ophthalmic diseases can choose between plenty of different eye dropper devices on the market. The diversity of those ophthalmic devices include a wide range of Unit-dose vials and Multidose containers. Referring to the microbiological safety of ophthalmic preparations, the European Pharmacopoeia sets high quality standards: preparations applied to the eye have to be sterile (Ph. Eur. 5.1.4).

Unit-dose vials are often produced in the Blow-Fill-Seal (BFS) technology. This concept allows the complete manufacturing process (blowing, filling and sealing) in one step under aseptic conditions. There is no need to add a preserving agent in the formulation since the vials are microbiological sealed. The filling volume of those unit-dose vials is limited to one daily dose only and once they are opened the vials are not protected from microbiological contamination, thus can't be used anymore. This leads to a significant waste of product and packaging material.

Conventional Multidose systems are the so called "Three-Piece-Droppers", where preservatives are added to the dosing systems to reduce microbial contamination and growth in the product during use and storage. Preservatives though are best avoided since they can damage the ocular surface when used on a frequent basis, hence a device without the need of a preserving agent is highly recommended. But combining a preservative-free product with a Multidose device challenged the industry until the early 90s when Ursapharm's exclusive COMOD®-system, the first preservative-free Multidose eye dropper system, was developed.

The COMOD® is an airless dosage system combining a patented airless pump and a container with a flexible inner bag. When the system is activated the negative pressure is compensated by collapsing of the inner bag.

Following the success of this device, Aero Pump GmbH developed together with its partner URSATEC Verpackung GmbH another preservative-free Multidose System in the so called 3K®-technology, where specialist germ-reducing components inside the 3K®-system ensure the microbiological safety of the device. This pump system is available for use with plastic or

glass containers and in terms of reducing container interaction with the product, glass containers are highly recommended - especially for drug products (e.g. Prostaglandines for Glaucoma treatment).

The 3K®-system delivers an accurate dose over the whole life cycle of the product, with one measured drop per actuation. Conventional squeeze devices on the other hand are known to have an imprecise dose accuracy; some can even create an extremely uncomfortable jet when squeezed. Another disadvantage is that patients need to consider a cumulative actuation force when the liquid inside the container is reduced. This is especially noticeable for older people where it can be very difficult to eject the last few drops of the liquid, which can often lead to an increased residual volume.

Alongside the development of the Ophthalmic Multidose Devices, Aero Pump has developed various customer-friendly actuation aids which enable a convenient application of the drop into the eye for the patient. All of which can be assembled in a non-sterile environment.



*Standard Finger sleeve*



*ComfortGrip Finger sleeve*



*SideActuationDevice*

The Standard finger sleeve has a cylindrical design with expanded surface area for the finger grips, ensuring a more convenient application for the patient.

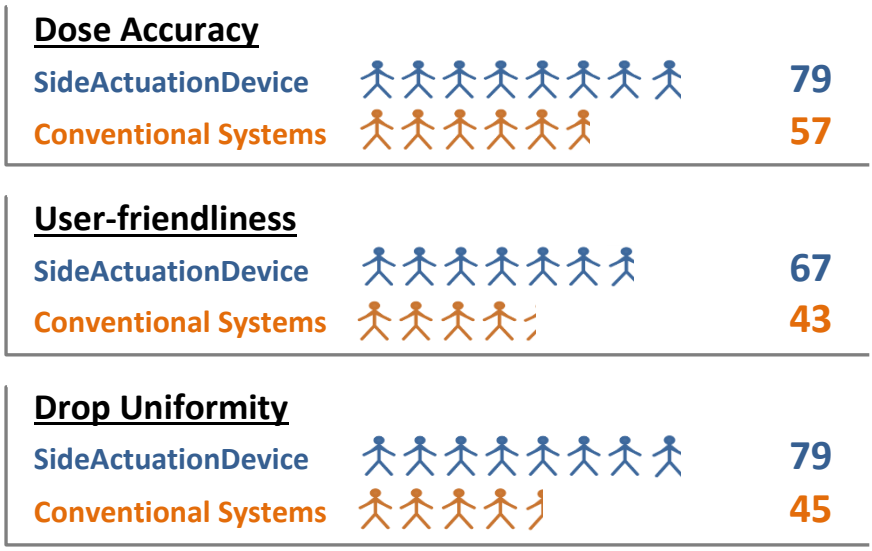
The ComfortGrip finger sleeve has an additional surface for the thumb, enabling even easier handling.

Aero Pump's latest innovation is the so called SideActuationDevice. This system combines an ergonomically designed squeeze mechanism with a metered pump technology, therefore less strength is required to actuate the pump and it fits nicely in your hand.

Aero Pump carried out a usability study together with an independent market research institution comparing their SideActuationDevice with conventional Multidose Systems in relation to patient usability.
It turns out that the most important features for an end user, when buying an eye dropper product, is a convenient packaging design and an accurate dose.

The study took into consideration a user group of 100 patients and from the group 58 participants graded the motion to activate the SideActuationDevice with a 1 (very good) or 2 (good), whereas for the conventional eye droppers only 35 people graded the device with a 1 (very good) or 2 (good).

Furthermore, the most important features for the patients were observed as follows:




*Base 100 each; information in % and T2B, 6-point scale*

**Conclusion:** Aero Pump's SideActuationDevice was preferred by the patients for the application of their eye drops. It meets the patient's needs in regards of a convenient eye dropper device and the 3K®-System is ideal for multiuse eye drops as it maintains product sterility without the need for preservatives.

**Contact**
More information about the system can be requested directly from Aero Pump GmbH via email (sales@aeropump.de)