

Phillips Medisize

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UNIQUE MINITABLET DISPENSER MEETS FLEXIBLE ORAL DOSING NEED

Bjørn Knud Andersen, Director, Front-End Innovation & Head of Technology Accelerators and IPR at Phillips-Medisize, discusses how an innovative minitab dispenser that mounts on a standard medication container simply and effectively meets the growing needs of patients in paediatrics, geriatrics, oncology and other areas who require reliable customised oral dosing.

Meeting the varied and customised oral dosing needs of patients in areas such as paediatrics, geriatrics and oncology can be challenging. First, patients often require highly flexible oral dosing based on their age, weight, body surface area or other variables – but relatively small patient populations can make the cost prohibitive when it comes to offering multiple, finely adjusted, fixed oral doses. Second, patients may find it difficult or impossible to swallow normal-sized tablets and/or capsules.

Whilst liquid dosing may present an alternative to tablets, it comes with its own drawbacks – including poor taste (often a deterrent for young patients); the need to refrigerate reconstituted suspensions to ensure their stability over the course of treatment; potential to spill and overall annoyance of accurately dispensing a liquid formulation; and the possibility of microbial contamination.

For these and other reasons, minitab dispenser may offer a more viable option to syrups for these patient populations as they can be flexibly combined to create the proper incremental dose and the tiny pellets can be easily swallowed. However, the need to depend on the patient or caregiver's ability to accurately handle and count the minitab dispenser for the correct dose presents its own set of challenges.

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The systems currently available predominantly rely on volumetric measuring principles. For example, if it is determined that a patient-required dose of 10 minitab dispenser would occupy approximately one-tenth of a millilitre, the patient sets a syringe plunger to that amount and then fills the cavity with minitab dispenser. But with this imprecise approach, it's unclear exactly how many minitab dispenser are included in each dose and the number is also likely to vary.

BUILT-IN FLEXIBILITY, RELIABILITY AND ACCURACY

Phillips-Medisize has developed an innovative, easy-to-use minitab dispenser (Figure 1) which removes this guesswork from the equation, enabling patients and caregivers to accurately and reliably dispense the exact number of minitab dispenser needed per dose. The patented, low-cost dispenser mounts directly on a standard Ø38 mm tablet bottle neck and can be used with minitab dispenser ranging from ~2.0–2.5 mm diameter (i.e. the initial



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Figure 1: The dispenser enables patients and caregivers to dispense the exact number of minitabts needed per dose, accurately and reliably.

“With the novel integrated minitab dispenser, tablets are protected until the time they are dispensed.”

generic variant). It can be co-packaged with the medication bottle or supplied separately.

With the dispenser permanently positioned directly on the bottle (Figure 2), only counted and dispensed minitabts come into contact with the outside environment. This helps to avoid currently existing situations where the use of a dosing spoon is required to reach into the primary container or the need to pour a large amount of minitabts out of the bottle for counting and then return excess tablets afterwards. With the novel integrated minitab dispenser, tablets are protected until the

time they are dispensed. Here’s how the dispensing solution works:

- The user adjusts the dispenser to the desired minitab count between one and 20. The “set and forget” approach requires the user to pre-set the dispenser dosing disc only once. However, the setting can easily be changed if the medication dosage needs to be adjusted at any point during treatment.
- Next, the user unscrews the child-resistant bottle cap, mounts the dispenser onto the bottle and repositions the cap.



Figure 2: The user adjusts the dispenser to the desired minitab count between one and 20.

- When it’s time to dispense medication, the user unscrews the cap and inverts the bottle to shake the minitabts into the dispenser metering chamber, which has a transparent lid. Then the user turns the bottle back upright and shakes it gently. The correct number of minitabts will automatically fall into the indentations on the dosage disc (one per indentation) and the rest will shake off and fall back into the bottle.
- After visually confirming that there’s a minitab in each hole and therefore the count is correct, the user rotates the transparent metering chamber lid and pours the minitabts onto a spoon, food or other option. The device has been optimised to carefully avoid damaging or crushing the minitabts during dispensing. In addition, it prevents any potential contamination that could occur if patients poured out minitabts into their hand, counted out the ones needed, and poured the rest back into the bottle.
- If more than 20 minitabts are required per dose, the sequence can be repeated as necessary (e.g. reaching doses up to 60 minitabts).
- Once the minitabts have been dispensed, the user closes the transparent lid and puts the bottle cap back on.

ADDING VALUE THROUGH CONNECTED HEALTH

Phillips-Medisize has the capability to design adaptations to the standard product, such as accommodating different minitab dimensions, preset count ranges and bottle interface designs. In the future, the device could potentially be part of the growing connected health ecosystem. By integrating a low-cost connectivity electronics module into the dispenser, it could be possible to detect tablet metering, dispensing activity and other patient behaviours, thereby helping to monitor, measure and support medication adherence.

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Phillips-Medisize's ability to manufacture the electronics internally makes connectivity much more affordable. As a Molex company, Phillips-Medisize can take advantage of its vast global electronics design expertise, manufacturing capability and purchasing power to minimise the cost of connectivity, as well as total manufacturing costs.

PREPARED TO SCALE UP PRODUCTION

Initially, Phillips-Medisize began developing the device with a global pharmaceutical company to deliver a medication which the customer had already formulated into minitablets. Rather than filling capsules with the minitablets, the company was looking for a way to dispense them directly to paediatric patients (Figure 3), and the flexible dispenser concept generated enthusiasm at paediatric conferences.

The customer has assigned its intellectual property rights supporting the innovative dispenser to Phillips-Medisize. In turn, Phillips-Medisize has validated the device's child resistance and senior friendliness, as well as validated its usability through five formative and one summative human factors engineering (HFE) studies. With final industrialisation complete, Phillips-Medisize now aims to make the dispenser available to an array of pharmaceutical companies globally.

The Phillips-Medisize minitabulet dispenser is a Class I medical device in the EU and Class I 510(k) exempt in the US. It carries the CE mark and is ready for clinical trials or co-packaging for commercial launch.

While the initial generic variant has been designed for use with a standard Ø38 mm tablet bottle neck and to be used with minitablets ranging from ~2.0–2.5 mm in diameter, the platform can easily be adjusted to accommodate other tablet dimensions and bottle formats. Furthermore, customisation is possible for other functional parameters, such as tablet preset range.

CONCLUSION

For special patient populations with customised oral dosing needs where minitablets are the best option, Phillips-Medisize's innovative dispenser offers a promising solution. Its patented design enables patients and caregivers alike to experience improved accuracy in counting the tiny pills without requiring a new or different



Figure 3: The innovative minitabulet dispenser meets a growing need for paediatric patients who require reliable customised oral dosing.

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bottle. At the same time, the container minimises the risk of contamination. The ability to add connectivity in the future will help encourage medication adherence.

ABOUT THE COMPANY

Phillips-Medisize, LLC, a Molex company, is an end-to-end provider of innovation, development, manufacturing and post-launch services to the pharmaceutical,

diagnostics, medical device and speciality commercial markets. Post-launch services include a connected health app and data services. Backed by the combined global resources of Molex and its parent company Koch Industries, Phillips-Medisize's core advantage is the knowledge of its employees to integrate design, moulding, electronics and automation, providing innovative high-quality manufacturing solutions.

ABOUT THE AUTHOR

Bjørn Knud Andersen has been with Phillips-Medisize since 1997 and is part of the Front-end Innovation team responsible for innovation to translate pharmaceutical drug delivery needs into competitive, patient-centric device solutions. As part of that role, he also heads activities related to developing the Phillips-Medisize Technology Accelerators. Mr Andersen is an industry expert with more than 20 years of experience within medical diagnostics, electronic drug delivery devices and connected health systems.

Leading the Way in Medical Devices and Connected Health

Phillips-Medisize, a Molex company, is committed to serving pharmaceutical, diagnostics and medical device customers by creating technology and products to improve people's lives.

We operate innovation centers in North America, Europe and Asia, and manufacturing sites at 26 locations in 10 countries.

With over 5,500 employees working in a quality-conscious culture, we take you safely and quickly through the process of bringing your medical product to market.



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