

Final Report: Medication Dosing
Client: Lurie Children's Hospital

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March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Executive Summary

Upon discharge from Lurie Children's Hospital, caregivers of medically complex pediatric patients are faced with the difficult task of administering up to 25 different medications per day, many in liquid form. Along with organizational and measurement comprehension challenges, the syringes caregivers are sent home with (ENFit syringes) lack durability—their markings wash off after as few as five uses, rendering the syringes useless. Caregivers are then forced to either discard the used syringes or attempt to use the worn syringes, risking imprecision, inaccuracy, and most importantly, their child's safety. The ENdose (*Figure 1*) aims to address these challenges by preventing liquid medicine misadministration events by using a physical stop to limit the height to which a syringe plunger is raised, improving dose precision and extending the lifespan of worn syringes.

ENDose Design Overview

The ENdose physically limits the syringe plunger to be drawn back to the same height and dose each use. It integrates with caregivers' existing equipment by screwing directly onto liquid medicine bottles using a child-safe push and twist cap. The cap also serves as an adapter that allows the user to secure an ENFit syringe directly to the bottle through the cap, minimizing liquid medicine waste.

The cap of the ENdose is fixed via a hinge to the neck region, allowing the use of various syringe sizes without sacrificing portability and storage space. Along the neck slides the limiter itself, which can be adjusted using a quick release lever arm to calibrate the device to a child's current dose for the bottle the device is attached to, enabling the device to adapt to the child's ever-changing dosing regimen.

Next Steps

While the device is novel enough to be commercially viable, additional precision testing and long-term user testing should be performed before widespread distribution due to the high-risk patients and processes the ENdose is interacting with. This testing will validate the device's performance under realistic conditions, and help clarify common forms of caregiver misuse and how it fits into existing dosing routines.



Figure 1: ENdose render

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Table of Contents

Introduction	5
Project Aim	5
Role of the Solution: The ENDose	5
Background Research	7
Sources of Medication Dosing & Administration Error	7
Literature Descriptions of Dosing Inaccuracy	8
Design Requirements	9
Designing the ENDose for Safety and Usability	10
How to Use the ENDose	11
Design Features	22
ENDose Prototype Overview and Limitations	31
Cost Analysis	32
Fabrication Costs for 3D Printing	32
Manufacturing Using Low-Volume Injection Molding	33
Caregiver Financial Impact	34
Intellectual Property	36
Next Steps: Bringing the ENDose to More Caregivers	37
Right Away: Expanding Validation of the Current Prototype	37
Medium Term: Safety Validation and Extended User Testing	38
Long Term: Intellectual Property Considerations	39
References	40
Appendices	42
Appendix A: Caregiver Feedback Interviews	42
Appendix B: Specs Chart	45
Appendix C: Failure Mode and Effects Analysis (FMEA)	51
Appendix D: Cap & Bottle Finishes Research	55
Appendix E: Testing Summaries	58
Appendix F: Standards and Regulations	62
Appendix G: Finite Element Analysis for Cantilever Latch Mechanism Validation	64
Appendix H: Expert Interview Summaries	66
Appendix I: Tolerance Analysis	77
Appendix J: Color Coding Instructions for Use	81
Appendix K: Review of Relevant Intellectual Property	87

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Figures

Figure 1: ENdose render	1
Figure 2: The ENdose	9
Figure 3: Low level medication bottle	11
Figure 4: Comparison between two syringes with markings present vs faded	13
Figure 5: ENdose detached from medicine bottle	14
Figure 6: Screwing ENdose onto bottle	14
Figure 7: Setting safety syringe	15
Figure 8: The plugged ENdose	16
Figure 9: Remove plug from ENdose ENFit port	16
Figure 10: Safety syringe pushed into ENdose	16
Figure 11: Placing ENdose neck in usage position	17
Figure 12: Pressing button to adjust limiter	17
Figure 13: Releasing button to adjust limiter	18
Figure 14: Pressing latch to store ENdose	18
Figure 15: Remove safety syringe after folding ENdose into storage position	19
Figure 16: Reinserting ENFit plug	19
Figure 17: Pushing dosing syringe onto ENdose	20
Figure 18: Removing plug from ENdose for use	21
Figure 19: Dosing syringe pushed into ENdose	21
Figure 20: Inverting the medicine bottle	21
Figure 21: Lowering ENdose neck	22
Figure 22: Pulling syringe plunger	22
Figure 23: Removing air bubbles	23
Figure 24: Returning bottle upright	23
Figure 25: Folding ENdose after use	24
Figure 26: Removing syringe from the ENdose	24
Figure 27: Reinserting ENFit plug	25
Figure 28: Bottle cap attachability with the threads on the cap	26
Figure 29: ENdose push and twist cap	27
Figure 30: ENFit connection port	27
Figure 31: Arrow on ENFit connection port on ENdose	28
Figure 32: Cantilever snap joint on ENdose	28
Figure 33: ENdose in locked hinge position	29
Figure 34: ENdose neck in unlocked, hinged-down position	30
Figure 35: Limiter attached to push-button mechanism	31

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Figure 36: Limiter teeth	31
Figure 37: Neck teeth	32
Figure 38: Push button cross-section	32
Figure 39: Push button cross-section when button pressed	33
Figure 40: Push button cross-section when button unpressed	33

Tables

Table 1: Per-product expenses	35
Table 2: Data on an average household	37
Table 3: Data on monthly syringe usage	37
Table 4: Data on ENDose product	38

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Introduction

Each year, Lurie Children's Hospital treats over 266,000 children each year across a wide variety of medical needs, including chronically ill children with complex at-home care regimens [1]. Upon being discharged from the hospital, the role of administering medications shifts from highly experienced healthcare professionals to the patients' parents or other guardians, who are far less likely to have experience organizing and dosing medications. This process is especially challenging for the caregivers of patients with nasogastric or gastric tubes, which require more complicated medicine administration processes that involve a feeding tube. Moreover, managing their children's complex medication regimens at home represents a major shift in the caretaker's journey, as Lurie nursing staff have to give in-depth and customized instruction to parents, educating them about medication storage, organization, measurement, and administration. Even so, many parents early-on in their caregiving journey struggle immensely with the medication dosing process. Not only time intensive, medication management is highly complex and detail-oriented, leading to medication errors that can worsen symptoms and compromise the health of children.

Project Aim

The goal of this project was to design a product concept that could help caregivers better manage the challenging process of organizing, dosing, and administering liquid medications by decreasing the overall workload and frequency of misadministration events. The solution delivered is the ENdose, a syringe-limiter that attaches to medication bottles, allowing precise and direct measurement of liquid medications. This product can be further developed into a commercializable at-home dosing solution for Lurie Children's Hospital patients.

Role of the Solution: The ENdose

The ENdose, (*Figure 2*), reduces the frequency of misadministration events by physically limiting the syringe plunger to draw the correct volume, allowing for accurate measurement directly from the bottle regardless of the syringe's visual condition. This device primarily targets the pain point of markings rubbing off the syringes after as few as 10 washes, which usually forces caregivers to purchase more syringes without financial support or estimate medication doses without the volume markings.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers



Figure 2: The ENDose

Currently usable for syringe sizes between 3 mL and 10 mL, the anticipated benefit of adopting the ENDose into the caregiver workflow is the support of safer, more consistent medication administration, increasing user confidence, lowering the risk of misadministration by reducing caregiver reliance on syringe markings, and allowing for repeatability of dosages across caregivers.

This report presents the features and potential benefits of the ENDose in detail, including user research analysis, functionality decisions, validation testing results, and the final manufacturing specifications for the device.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Background Research

Sources of Medication Dosing & Administration Error

Medication management is a cognitively demanding and error-prone process, where both accuracy and precision are required to avoid dangerous medication errors for young patients. Even with training from hospital nurses, many caregivers return home overwhelmed and unconfident in their ability to safely manage dosing for over ten different daily medications (*Appendix A: Caregiver Feedback Interviews*). In addition, insurance limitations often restrict the supply of medication and ENFit syringes used to dose medications for patients with the aforementioned feeding tubes. This scarcity forces families to reuse devices far past their intended lifespan, introducing risk into their daily routine (*Appendix A: Caregiver Feedback Interviews*).

The tools involved in medication dosing increase the burden on caregivers. First, interpreting syringe volume measurements properly can be challenging for caregivers with low healthcare literacy, given the variety in syringe sizes and brands, which both have different volume labelling systems [2]. Critically, within as few as ten washes, these printed measurements can fade, forcing caregivers to estimate volumes or improvise ways to protect the volume measurements from washing away, such as covering a region of the outside of the syringe with clear tape. Additionally, after the medication level drops low enough in standard liquid oval medication bottles (*Figure 3*), caregivers do not have an easy method to draw liquid directly into an ENFit syringe. Although medication bottle-to-ENFit syringe adapters exist, some caregivers still pour medication into a secondary cup before drawing it up, adding unnecessary steps to the workflow and wasting valuable medication.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers



Figure 3: Low level medication bottle

To deal with these inefficiencies, caregivers often develop workarounds and habits that deviate from best medical practices. While healthcare professionals advise against pre-filling syringes due to medication stability concerns, many caregivers pre-dose medication weeks or a month in advance to avoid the daily burden of measuring (*Appendix A: Caregiver Feedback Interviews*). This behavior signals the need for a solution that enables rapid, every-day dosing that is as convenient as pre-filling but maintains medication safety standards.

Literature Descriptions of Dosing Inaccuracy

Existing research in medication dosing has demonstrated that syringes are the most effective tool for measurement accuracy [3]. Specifically, 5-mL oral syringes and 5-mL dosing spoons are the most accurate instruments; when measuring a 2.5-mL dose, these tools resulted in severe errors only 4% and 4.5% of the time, respectively [3]. It has also been widely reported that lower healthcare literacy and English as a second language status also increase the frequency of dosing errors [4].

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Design Requirements

The interviews conducted throughout the quarter highlighted the key challenges caregivers face, including the need for accurate dosing, compatibility with syringes and medication bottles they receive during hospital discharge, and safety in home environments. The following requirements guided the design by translating caregiver needs into the ENdose, as detailed in *Appendix B: Specs Chart*.

- 1) Precision of down to 0.05 mL
Pediatric medications require high precision, especially for small volumes. A precision of 0.05 mL was chosen because it is half the spacing between standard syringe volume increments, matching the precision of conventional syringes. It also allows caregivers to administer accurate amounts while minimizing medication loss and reducing the concern of misadministration.
- 2) Safety and security in the presence of young children
The ENdose must have safety features that reduce the risk of decalibration and prevent unintended access to medication in home environments where children are present, without sacrificing caregiver usability. Ideal child safety requires the device to allow no more than 15% of children to decalibrate or remove the ENdose from the bottles.
- 3) Adjustability in under 5 seconds
The ENdose must allow caregivers to adjust dosages quickly and easily. An adjustable mechanism improves convenience during medication preparation and supports easy calibration when different doses are required.
- 4) Compatibility with caregivers' existing medication bottles and syringes
The ENdose is compatible with the syringes 3 - 20 mL, and medication bottles caregivers receive during hospital discharge of neck size 18 - 38 mm. This ensures the device integrates into caregivers' existing workflows without requiring additional equipment, reducing cost and making it more accessible for families.
- 5) Ease of Adoption
Caregivers must be able to learn how to use the ENdose in under 5 minutes. client and caregiver interviews showed that caregivers have varying levels of health literacy, which can make medical instructions difficult to interpret. The device uses a simple, intuitive design that fits easily into daily routines and allows caregivers to understand and use it without extensive training.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Designing the ENdose for Safety and Usability

The ENdose connects to liquid medicine bottles and ENFit syringes, physically sets a maximum distance to which a syringe plunger can be drawn, and can be adjusted to allow a single device to accommodate a range of doses. By having a physical limiter for the plunger, the device allows caregivers to measure doses safely and consistently without relying on printed syringe markings, increasing dosing precision and extending the lifespan of the syringes used by caregivers (*Figure 4*).



Figure 4: Comparison between two syringes with markings present vs faded

The ENdose has an adjustable mechanical limiter that can be set to the desired medication dose, allowing caregivers to measure medication accurately even when syringe markings have faded, and screws directly onto the medication bottle for easy integration into existing caregiver medication bottles. Once the limiter is set for a specific medication, the ENdose allows caregivers to quickly and repeatedly draw a consistent volume of medication, improving dosing reliability during usage. The ENdose also adds minimal cost, as shown in the cost analysis section (*Page 24*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

How to Use the ENdose

Part 1: Setup and Calibration

1. Remove the cap from the desired medicine bottle (*Figure 5*).



Figure 5: ENdose detached from medicine bottle

2. Screw the ENdose onto the bottle until it feels tight and secure (*Figure 6*).



Figure 6: Screwing ENdose onto bottle

March 16, 2026

Medication Dosing

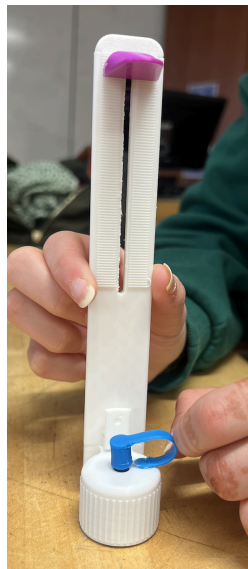
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3. Use a safety syringe with clear markings and pull the plunger of an empty syringe to the marking corresponding to the prescribed dose, without drawing medication from the bottle (*Figure 7*).



Figure 7: Setting safety syringe

4. Remove the plug from the ENDose to access the ENFit port (*Figure 8 and 9*).



March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Figure 8: The plugged ENDose

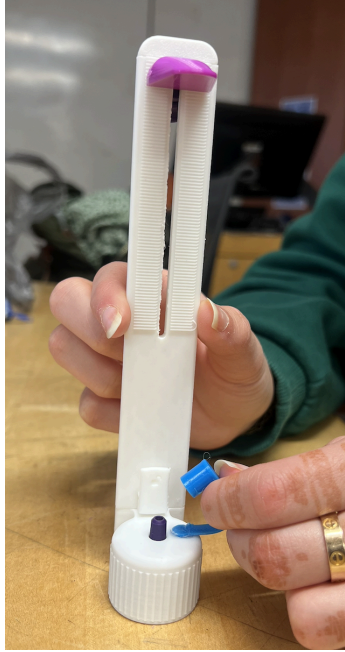


Figure 9: Remove plug from ENDose ENFit port

5. Push the safety syringe onto the ENDose ENFit port until the tip touches the flat top of the cap and the ENFit port color is no longer visible (*Figure 10*).



Figure 10: Safety syringe pushed into ENDose

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

6. Lift the neck of the ENDose onto the upright position (*Figure 11*).



Figure 11: Placing ENDose neck in usage position

7. Press the button on the pushbutton mechanism and slide the limiter down until it gently rests on the end of the syringe plunger (*Figure 12*).



Figure 12: Pressing button to adjust limiter

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

8. Release the pushbutton so the limiter locks in place and keep the correct dose setting (*Figure 13*).



Figure 13: Releasing button to adjust limiter

9. To remove the safety syringe, press the small lock button on the ENDose's neck and fold the neck out of the way (*Figure 14*).



Figure 14: Pressing latch to store ENDose

10. Remove the safety syringe from the ENDose port (*Figure 15*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers



Figure 15: Remove safety syringe after folding ENdose into storage position

11. Reinsert the plug onto the ENdose ENFit port to close the ENdose (*Figure 16*).

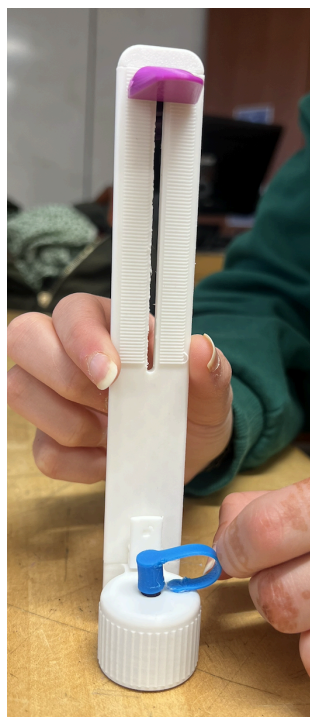


Figure 16: Reinserting ENFit plug

Part 2: Daily Use

March 16, 2026

Medication Dosing

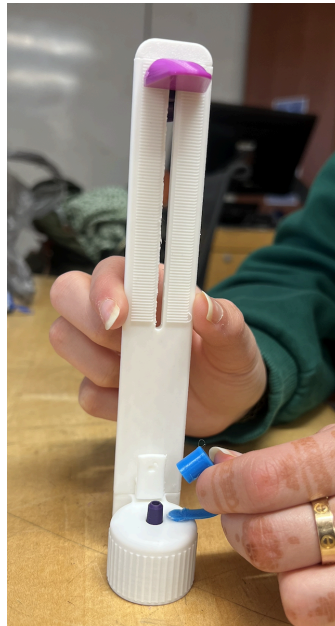
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1. Begin with the ENDose already attached to the medication bottle, calibrated to the correct dose, and stored with the neck folded down (*Figure 17*).



Figure 17: Pushing dosing syringe onto ENDose

2. Remove the plug from the ENDose to access the ENFit port (*Figure 18*).



March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Figure 18: Removing plug from ENdose for use

3. Push the dosing syringe onto the ENdose ENFit port until the tip touches the flat top of the cap and the ENFit port is no longer visible (*Figure 19*).

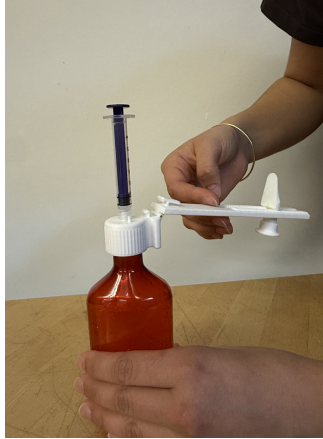


Figure 19: Dosing syringe pushed into ENdose

4. Turn the bottle upside down (*Figure 20*).



Figure 20: Inverting the medicine bottle

5. Lower the ENdose's neck until it clicks into the locked upright position (*Figure 21*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers



Figure 21: Lowering ENDose neck

6. Pull back the syringe plunger until it stops against the calibrated limiter, which prevents drawing more than the correct dose (*Figure 22*).



Figure 22: Pulling syringe plunger

7. Push the syringe plunger up and back down, until it hits the limiter again to remove any air bubbles from the dosing syringe (*Figure 23*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers



Figure 23: Removing air bubbles

8. Turn the bottle upright once the syringe has been filled to the correct amount (*Figure 24*).

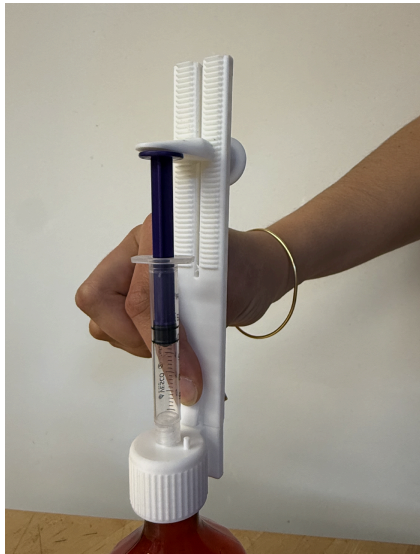


Figure 24: Returning bottle upright

9. Press the neck lock button and fold the syringe neck back down so the device returns to its storage position (*Figure 25*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers



Figure 25: Folding ENDose after use

10. Remove the syringe from the ENDose port (*Figure 26*).

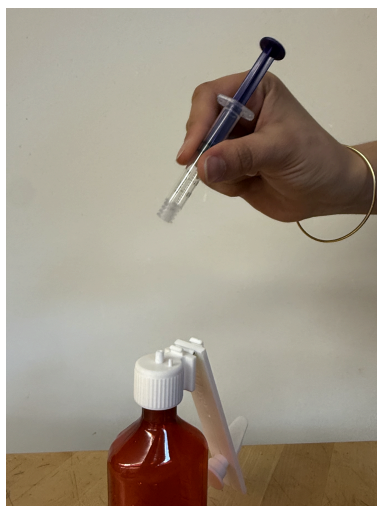


Figure 26: Removing syringe from the ENDose

11. Reinsert the plug onto the ENDose ENFit port to close the ENDose (*Figure 27*).

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

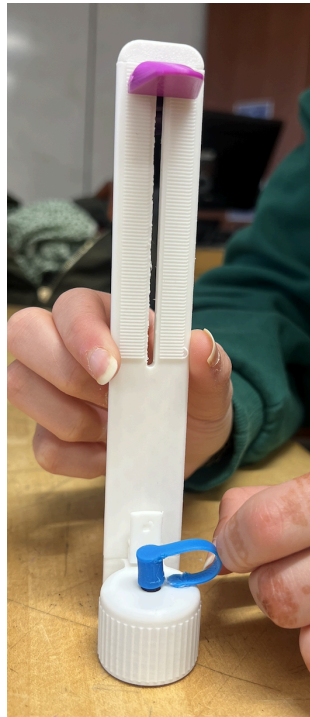


Figure 27: Reinserting ENFit plug

12. Administer the medication.

Design Features

Bottle-Compatible Threading

The ENdose secures to the medication bottle by screwing directly onto the existing threads on the medication bottle (*Figure 28*). This creates a secure connection, minimizing the risk of medication loss during the administration process. This feature is important as caregivers are often prescribed the minimum quantity of medication each month, making any loss of medication potentially harmful to the child's health. The effect of a potential failure of the ENdose to properly seal the medication bottle to which it is attached, along with several other possible failures of the ENdose, are described and explored in detail in *Appendix C: Failure Mode and Effects Analysis*.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

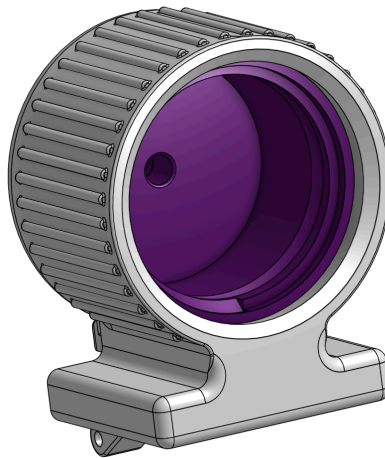


Figure 28: Bottle cap attachability with the threads on the cap

Conversations with the Walgreens pharmacists at Lurie Children's Hospital revealed that they prescribe more than three different medication bottle sizes to caregivers. Liquid medication bottles follow industry standards (GPI/SPI) define bottle finishes by outer diameter and thread pattern, with common liquid medicine sizes including 20 mm and 38 mm diameters. Additional diameters (e.g., 18 mm and 28 mm) and non-standard finishes also exist (see *Appendix D: Cap & Bottle Research Report*). The bottles obtained from the Walgreens at Lurie Children's Hospital primarily ranged between 20–24 mm in diameter. As a result, multiple ENdose thread sizes would need to be manufactured to match the range of bottle finishes.

The ENdose has a push and turn mechanism in the cap to make it child resistant (*Figure 29*). Opening the cap requires a simultaneous downward force and counterclockwise rotation, a motion difficult for young children to do. This feature helps prevent any accidental access or ingestion of medication by children in home environments. A procedure for evaluating the liquid-tight seal of the cap can be found in *Appendix E: Testing Summaries*.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

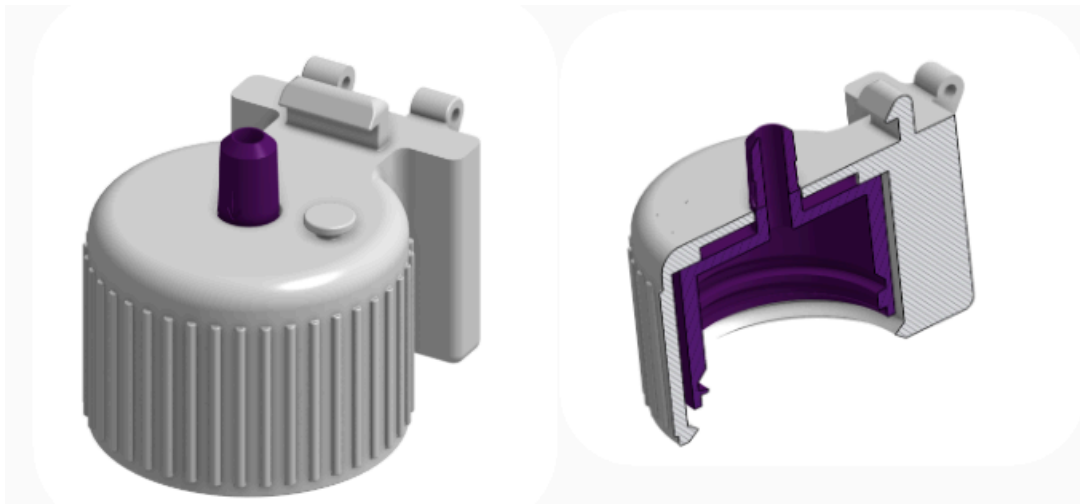


Figure 29: ENdose push and twist cap

ENFit Connection Port

The ENdose has an ENFit-compatible connection port to ensure safe and standardized attachment between the device and any ENFit syringes used (*Figure 30*), as all ENFit syringes have the same tip size. This ensures the ENdose is compatible with the enteral nutrition syringes caregivers use to administer medication at home.

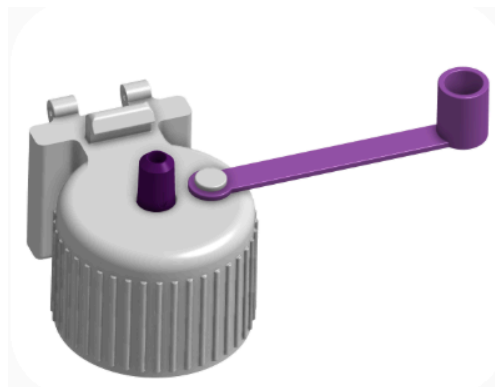


Figure 30: ENFit connection port

The ENdose ENFit connection port geometry creates a friction fit with the ENFit syringe tip. The port dimensions align with the ISO 80369-3:2016 standard ensuring compatibility with enteral syringes and prevent wrong-route connections (*Appendix F: Applicable Standards and Regulations*). The ENdose compliance with this standard reduces the risk of any misconnection with the device by limiting usage to ENFit syringes specifically.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

The ENFit connection port is a different colour from the cap as seen in *Figure 30* , providing a visual cue for caregivers when attaching a syringe to the ENdose. When the purple port is no longer visible, the syringe is fully attached to the ENdose. The port also has an arrow to be a visual indicator (*Figure 31*) that shows caregivers the correct direction for inserting the syringe.

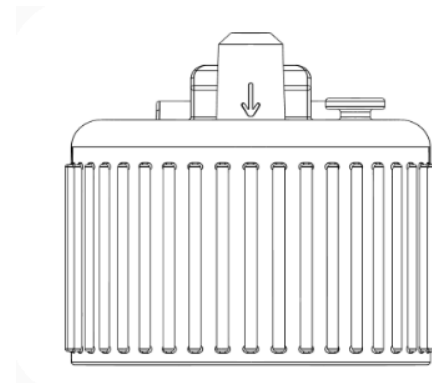


Figure 31: Arrow on ENFit connection port on ENdose

ENdose Neck

The ENdose neck has a locking hinge mechanism using a cantilever snap joint that allows the neck to pivot backwards or forward, depending on its use (*Figure 32*).

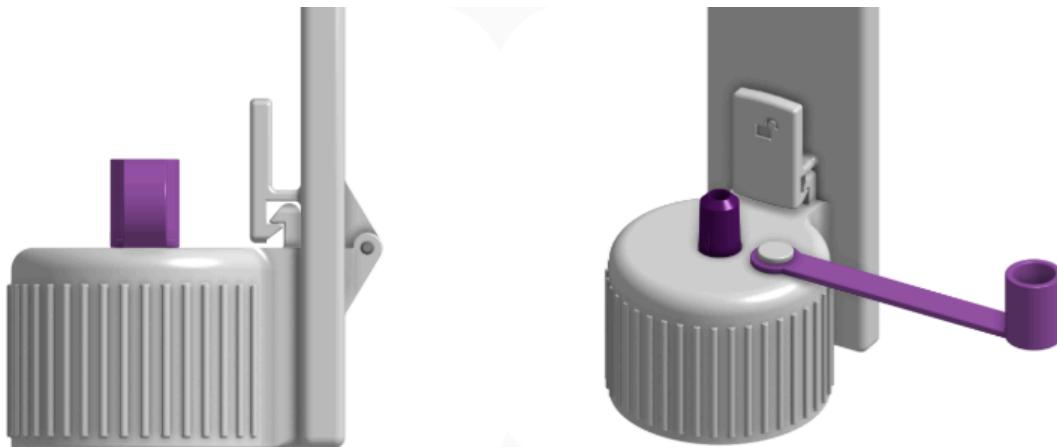


Figure 32: Cantilever snap joint on ENdose

When the ENdose is in its upright position, the hinge is locked (*Figure 33*) . The neck and cap are pressed together using a cantilever snap joint, which prevents the movement of the hinge, allowing caregivers to administer medication.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

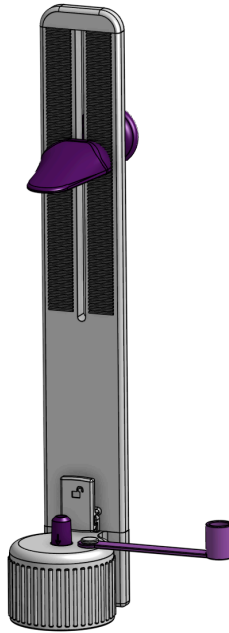


Figure 33: ENdose in locked hinge position

Pressing the tab at the base of the neck causes the snap joint to bend, releasing the snap fit and unlocking the hinge, allowing the neck to pivot backwards (*Figure 34*) for easier storage, attachment and removal of syringes. Finite element analysis was conducted to validate that the latch could bend and function as intended (see *Appendix G: Finite Element Analysis for Cantilever Latch Mechanism Validation*).



March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Figure 34: ENdose neck in unlocked, hinged-down position

Adjustability Mechanism

The ENdose has an adjustable limiter mechanism that sets the maximum distance a syringe plunger can be drawn, allowing a single device to accommodate a range of doses. This is especially useful as prescription dosages often change over time due to the patients weight, growth or response to prescribed medication (*Appendix H: Expert Interview Summaries*).

1 mL syringe Technical Challenge

Clinical stakeholders highlighted that the 1 mL syringe is most critical for the smallest pediatric patients because many prescriptions at this scale require very tight dosing control. While the 1 mL syringe is physically compatible with the ENdose port, low-volume dosing (0.1–1.0 mL) is currently considered outside the validated operating range of the ENdose (*Appendix E: Testing Summaries*), making the device compatible with 3 ml to 10 ml syringes.

Controlled testing demonstrated variability on the order of ± 0.05 mL for the ENdose and ± 0.003 mL. This deviation is acceptable at higher volumes (e.g., 2.6 mL), but at sub-milliliter doses the same absolute deviation translates into a large percentage error making tight dosing control challenging for 1 ml syringes.

Need for Adjustable and Secure Dosing

The ENdose is designed to be used in home environments, where the device could be within reach of young children. Caregiver interviews indicated that the adjustable limiter is susceptible to unintended child interaction, which could lead to decalibration of the ENdose. Preventing accidental or unauthorized adjustment of the device is essential to ensure safe and repeatable dosing. The ENdose's pushbutton mechanism simplifies adjustability for caregivers, keeping it intuitive for caregivers with different healthcare literacy levels.

How it Works

The limiter is connected to and controlled by a push-button mechanism (*Figure 35*). The limiter has teeth on its back surface (*Figure 36*), that match the teeth on the front surface of the neck (*Figure 37*). The teeth are spaced 0.041-inch apart, which corresponds to the spacing between 0.2 mL markings on a 10 mL syringe. For comparison, the spacing between 0.1 mL markings on a 3 mL syringe and 0.2 mL markings on a 5 mL syringe is approximately 0.0625 inches. The smaller spacing was selected so the device can accommodate syringes with finer measurement

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

increments, enabling precise and flexible dosing adjustments of the device across numerous syringe sizes. The geometry of the teeth, in addition to the tolerances allowed by injection molding techniques, define the precision of the ENdose. A complete tolerance stack-up analysis can be found in *Appendix I: Tolerance Analysis*.

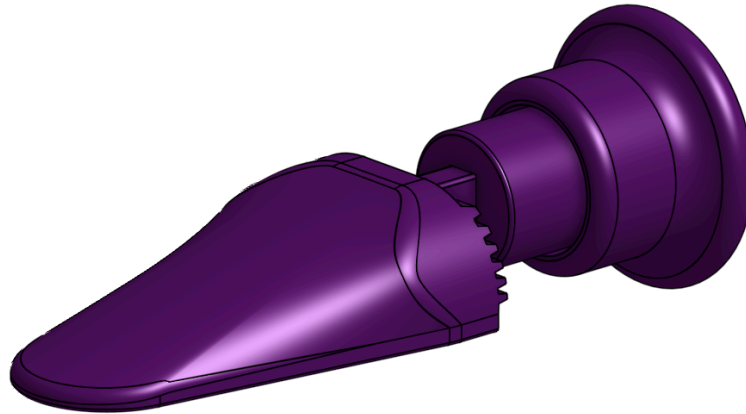


Figure 35: Limiter attached to push-button mechanism

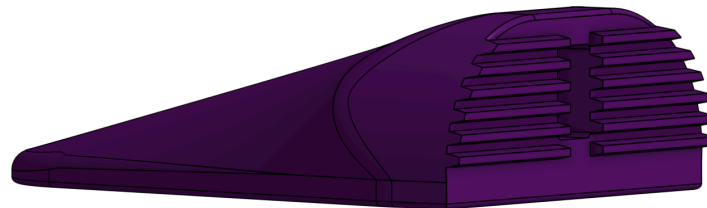
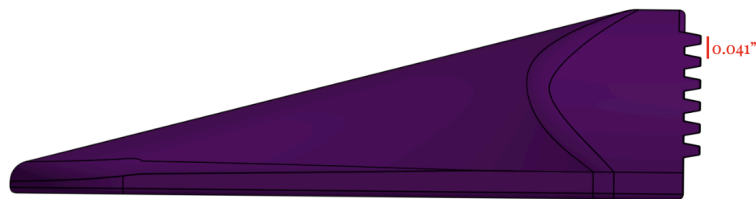


Figure 36: Limiter teeth

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

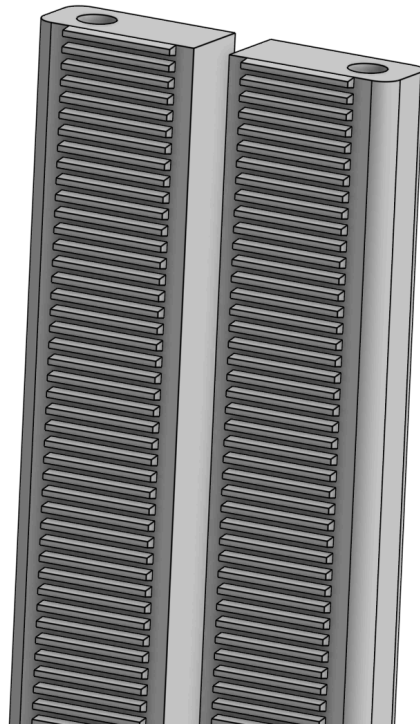


Figure 37: Neck teeth

The push-button mechanism makes use of an enclosed spring (*Figure 38*). When this button is pressed, it compresses the enclosed spring, disengaging the limiter teeth from the neck teeth (*Figure 39*). This frees the limiter to slide vertically along the neck, allowing the caregiver to set the desired dosage.

Releasing the push-button allows the spring to extend, pushing the limiter teeth back into the neck teeth (*Figure 40*). The depth and position of the teeth on both the back limiter and the front of the neck allows the two to interlock when the push button is not pushed, mechanically locking the limiter in place, preventing decalibration.

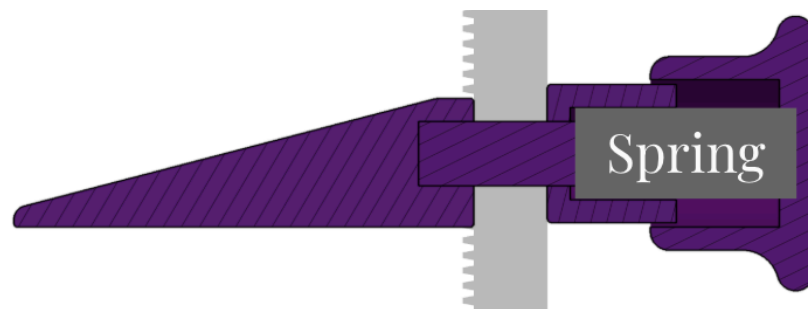


Figure 38: Push button cross-section

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

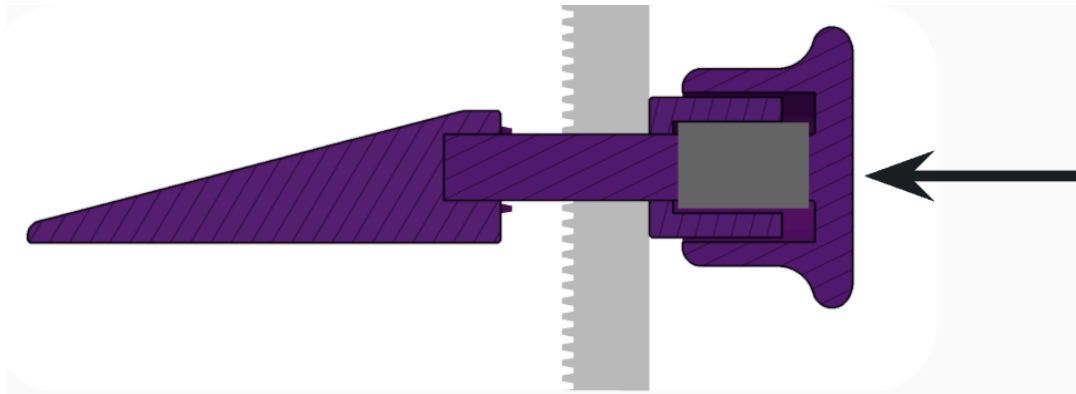


Figure 39: Push button cross-section when button pressed

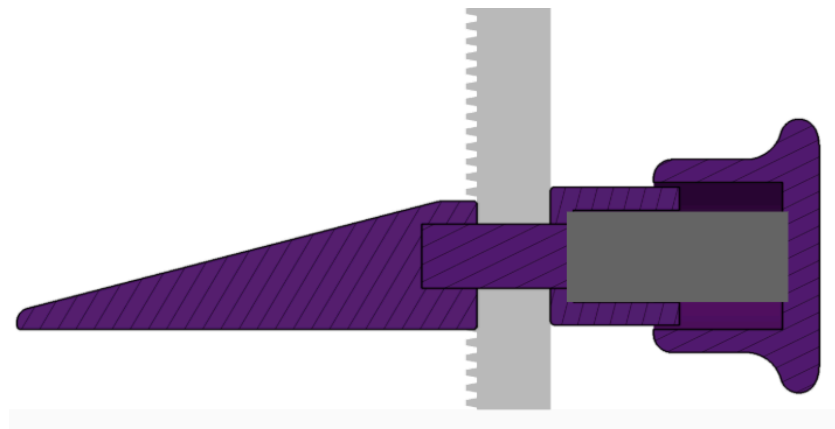


Figure 40: Push button cross-section when button unpressed

Precision Testing

The team evaluated dosing precision, a fundamental design goal of the ENDose, through precision testing following design of experiments (DoE) principles. This testing measured how precisely and accurately the device draws up medication through repeated trials, knowing that both are paramount to the safety of the child receiving a dose. To complete the test, the team followed the procedure in *Appendix E: Testing Summaries*, measuring various volumes of water in an unaccompanied syringe and an ENDose paired with a syringe over a series of 18 trials to assess the presence of precision errors for the ENDose and how its precision compares to a fresh syringe.

The testing demonstrated that the ENDose can be precise up to 0.05mL, as long as the design can be fixed to no longer pull bubbles into the syringe with the liquid. Data collected indicate that the ENDose caused significant precision errors (mean 0.11mL), with a critical misdosing of over 10% on four out of the nine measurement trials due to air bubbles that were pulled into the

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

syringe. These bubbles seemed to arise because the 3D-printed cap does not create an airtight seal with the liquid. Analyzing the precision without air bubbles to examine the performance of the adjustability mechanism alone provides an average dosing error of 0.05mL for the ENdose. This indicates that the device would be precise up to 0.05mL when the issue with the bubbles is resolved. Using a slightly different procedure that did not include pulling the liquid up through the cap of the ENdose, and hence not controlling for the inclusion of air bubbles, the syringe caused an average dosing error of 0.003mL. Both devices yielded only underdosing errors.

ENDose Prototype Overview and Limitations

Current prototypes of the ENdose are printed using a Bambu Lab X1 Carbon FDM printer (X1C), using both polyethylene terephthalate glycol (PTG) for the limiter and neck, and polylactic acid (PLA) for the other plastic components. While these prototypes are printed using 0.08 mm layer heights, the minimum possible on the X1C, teeth of the appropriate dimensions (.041" pitch x .03" tall) are distorted by the printer, leaving them dysfunctional. Thus, several prototypes have been produced using teeth double the size of those recommended, which are functional when printed using the X1C. This challenge would be eliminated by manufacturing the ENdose using custom injection molded parts, an option that will be discussed later in this report.

The cap of these prototypes is made purely of PLA, which is not ideal and has led to issues with minor leaking while in use. While this issue may be resolved with changing the material for the body of the ENdose to injection-molded high-density polyethylene (HDPE), future designs should also include a narrow rubber or foam gasket on the upper interior surface of the inner cap. This would improve the liquid-tight seal of the cap against the medication bottle to which it is attached by enabling the elastic deformation of the gasket to seal any leak points.

The plug for the ENFit port, currently made of thermoplastic polyurethane (TPU), would also benefit from a material change; a final design should include a more flexible and easily manufacturable silicone plug, which could be cast easily without significant to the plug's current geometry.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Cost Analysis

This section details two different future stages of prototype production: cost of small-scale fabrication by fused deposition modeling (FDM) 3D printing, and cost of larger-scale production via injection molding manufacturing. 3D printing is ideal for refining and testing the design of the product, whereas injection molding manufacturing is ideal for high-quality, consistent, and cost effective production at scale.

Fabrication Costs for 3D Printing

Fabricating the ENDose requires filament for 3D printing, mechanical hardware stickers for the organization system, and an accompanying instruction sheet. The cost of a 3D printer and pliers are not factored into this analysis, as Lurie already has 3D printers onsite. Fabrication costs were estimated by using product listings on Amazon and their prices as of February 17, 2026. The amount of each product needed was quantified by examining the current V1 ENDose prototype. The retail price was divided by the quantity that could be made with one purchase of the given item to calculate the unit cost. The unit costs were added together for the final fabrication cost of one ENDose.

Table 1: Per-product expenses

Item	Quantity	Retail price	Quantity that could be made with one purchase of the item	Unit cost
White Polyethylene Terephthalate Glycol 3D-printer Filament	24.2 g	\$16.99 /1 kg spool	41	\$0.41
Purple Polyethylene Terephthalate Glycol 3D-printer Filament	4 g	\$17.99/ 1kg spool	250	\$0.08
Purple	3 g	\$26 for one	413	\$0.06

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Thermoplastic Polyurethane 3D-printer Filament		1.24Kg spool		
1.5 x 16 mm Stainless Steel Rods	2	\$4.79 for 30 rods	15	\$0.32
Multicolor Color Coding Stickers	3	\$6 for 480	160	\$0.04
Animal Stickers	2	\$8.99 for 500	250	\$0.04
0.625" Long, 0.360" OD, 0.302" Compression Spring	1	\$13.16 for 12	12	\$1.10
Printed usage instruction sheet	1 (per pack)	\$0.10	N/A	\$0.10
Total (per ENdose)				\$1.99

The unit cost for one ENdose is about two dollars. Savings could be made by purchasing materials in bulk from a supplier, or by transitioning to injection molding to mass manufacture the final product. These materials also include the required stickers for a sticker-based organization, a method used by many parents of Lurie Children's Hospital patients. An example of how the ENdose can interact with these systems can be found in *Appendix J: Color Coding Instructions for Use*.

Manufacturing Using Low-Volume Injection Molding

A low-volume injection molding manufacturer like Protolabs, Xometry, or Fictiv could be used for initial injection molding, as these companies manufacture relatively small amounts of the product on demand. An online quote for the cost of producing 250 ENdose units with Protolabs, using aluminum molds, yielded a total per-unit cost of \$8.08 and a total mold cost of \$36,675 [11]. These costs correlate to the plastic body of the piece which do not include packaging, assembly, shipping, and other associated costs.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Protolabs also offers higher volume production that uses multiple-cavity molds, allowing for a lower cost for the production of each unit, but a higher investment cost for each mold. This could be used for larger-scale production of the ENDose, but other options such as overseas production should be considered as well.

Total per-unit cost: \$3.37

Total mold cost: \$156,245

Caregiver Financial Impact

To justify adoption, the price of a ENDose must be lower than what caregivers currently spend on standard syringes. Caregivers indicate that they use 90 syringes per month, given that they dose, on average, ten medications, three times per day, 30 days per month, under the constraint that one syringe lasts for ten uses before the markings fade (*Appendix A: Caregiver Feedback Interviews*) (*Table 2*). Knowing that insurance companies in Illinois provide 30 syringes per month under Local Coverage Determination for Enteral Nutrition (L38955), leaving caregivers with a shortage of 60 syringes per month that they need to purchase or attain via other means [12]. Using a cost of \$0.33 per syringe when purchased in a pack of 100 syringes [on Amazon](#), caregivers spend an extra \$19.80 per month on new syringes (*Table 3*). Scaling this up to the 24 month lifespan of a single ENDose, one household would spend \$475.20 on extra syringes (*Table 4*). Without having to purchase extra syringes beyond the 30 given per month by insurance, each household would save \$47.52 per ENDose. This projects a maximum willingness to pay of \$47.52 per ENDose which should be attainable given the fabrication costs explained above.

Table 2: Data on an average household

Medications dosed on a daily basis	10
Dosages per day	3
Medication doses given per day	30
Medication doses given per month	900

Table 3: Data on monthly syringe usage

Syringes supplied per month by insurance	30
Uses per syringe	10
Insurance-supplied doses	300

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Syringes purchased per month out-of-pocket	60
Cost per syringe	\$0.33
Out of pocket spendings per month on syringes	\$19.80

Table 4: Data on ENdose product

Units purchased per household	10
Lifespan of one product (doses)	2160
Lifespan of one product (months)	24
Savings per month by using one ENdose	\$19.80
Savings per 24 months by using one ENdose	\$475.20
Projected maximum willingness to pay for one ENdose	\$47.50

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Intellectual Property

For the ENDose to be distributed to a larger population of the client's patients' families and caregivers, whether through commercialization, open-sourcing, or another avenue, the product must comply with domestic regulations and standards and be free from intellectual property (IP) infringement. Because the ENDose requires usage with third-party products, specifically ENFit syringes, this review evaluates whether patents or standards restrict implementation of the proposed design. A detailed description of the current IP landscape and how the ENDose fits into it can be found in *Appendix K: Review of Relevant Intellectual Property*. This section summarizes a preliminary patent landscape review and identifies areas of distinction between existing IP and the ENDose concept.

While various aspects of the design of the ENDose, including the ENFit port, the quick release clamp, and the push-and-turn childproof cap, borrow inspiration from existing products and technologies, the manner in which these components are brought together is nonobvious and unique to the ENDose. For example, although both plunger fixation and ENFit bottle adapters are included in existing IP literature (US10265477B2 and US20230211140A1, respectively), no examples were found of the unity of the two ideas. Thus, the novelty of the product and its method of use suggest it is patentable and licensable for manufacturing and distribution at a commercial scale.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Next Steps: Bringing the ENDose to More Caregivers

Through this project, the ENDose concept was developed and iteratively refined through prototyping, interviews, and early testing. The current prototype demonstrates the feasibility of a bottle-mounted mechanism that physically limits the height (and corresponding dosage) to which a syringe plunger is raised.

At this stage, the project has reached a point where several pathways are available for further development. If continued work on the ENDose is pursued, the following steps outline opportunities for expanding validation, evaluating safety features, and preparing the device for broader deployment.

Right Away: Expanding Validation of the Current Prototype

The most immediate opportunity is to expand validation of the design with a broader caregiver population.

Expanded Caregiver Testing and Prototype Fabrication

Additional copies of the ENDose could be fabricated to support expanded caregiver testing. Producing approximately 20-30 ENDose units would allow the device to be evaluated by a larger group of caregivers or nurses in inpatient settings while remaining feasible through in-house 3D printing or similar rapid prototyping methods.

Testing could include caregivers across a range of use contexts that may influence dosing accuracy, including differences in medication regimen complexity, caregiver experience level, primary language, and hand strength or fine motor control. This testing would help evaluate:

- Intuitiveness of the device when first encountered
- Ease of securing the bottle and syringe
- Caregiver confidence when setting and drawing doses
- Integration into existing medication preparation workflows

Observations from this stage may also generate ideas for further design refinement and help distinguish mechanical error from user-driven variability.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Medium Term: Safety Validation and Extended User Testing

Once the design has been further validated through expanded caregiver testing, additional evaluation could focus on safety features and longer-term real-world use.

Child Tamper Resistance

The current prototype includes an adjustable sliding limiter. To check that the limiter doesn't have unintended up or down movement once the dose is set, formal child-resistance testing should be conducted in alignment with performance criteria outlined in 16 CFR §1700.20, which defines standardized procedures for evaluating child access to regulated consumer packaging.

Performance validation should measure child unlock success rate, targeting <20% unsuccessful containment (marginal) and <5% (ideal), consistent with child-resistance benchmarks established under federal regulation.

For the push-and-twist cap feature, additional testing could also evaluate adult usability to ensure that safety gains do not introduce barriers for caregivers, such as excessive force requirements, difficulty performing the push-and-turn motion, or challenges for users with limited hand strength or dexterity.

Small-Scale Manufacturing for Extended Testing

As the design becomes more defined through testing, the ENDose could be produced using small-scale manufacturing methods to create higher-fidelity prototypes. Services such as Protolabs could produce limited quantities of these devices using production-grade materials. These prototypes would be more durable than 3D-printed versions and could support extended caregiver testing.

Evaluating Reliable ENDose Performance for Low-Volume Dosing (0.1–1 mL)

1 mL syringes are typically used for medications that require high dosing precision because their smaller measurement increments allow caregivers to measure very small volumes more accurately. Using the higher-fidelity prototypes described above, testing could evaluate whether the ENDose can reliably support doses between 0.1 and 1 mL. Testing could also quantify total system error across these doses and assess repeatability under realistic use conditions. If the mechanism consistently meets tighter tolerance thresholds, future iterations of the ENDose may be validated for use with 1 mL syringes.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Longitudinal In-Home Testing

Short-term usability testing does not fully capture how the ENdose performs within the complexity of daily caregiving routines. Future work could include structured in-home longitudinal testing in which caregivers use the device within their normal medication workflows over an extended period, allowing observation of real-world behaviors such as calibration practices, cleaning methods, storage conditions, integration with existing medication organization systems, and potential workarounds or unintended use patterns.

Long Term: Intellectual Property Considerations

If continued testing demonstrates consistent safety, usability, and dosing accuracy, the ENdose could be further developed for larger-scale production and distribution. Preliminary patent research did not identify direct infringement concerns related to the ENdose design (see *Appendix K: Review of Relevant Intellectual Property*). However, prior to broader distribution or commercialization, a more formal intellectual property review is advisable. This would help clarify ownership considerations and support responsible advancement of the device.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

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March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

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March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Appendices

Appendix A: Caregiver Feedback Interviews

Jessica Etheridge Interview Report

Summary

Andre Pang and Nathaniel Rogers met with Jessica Etheridge over Zoom on October 9th to learn more about Jessica's experience as a caretaker for Avonlea, her daughter with cardiofaciocutaneous syndrome. Jessica is the primary caretaker for her five-year-old daughter, Avonlea, who is non-mobile, non-speaking, and tube-fed via a G-tube due to her genetic condition.

Avonlea takes 15 different medications with frequently changing dosages and timing, creating a constant challenge for coordination among the six total caretakers (including a nurse, husband, and school staff). To manage this complexity, Jessica's nurse pre-fills 4-5 days of medication—a one-hour process done with tupperware containers and color-coded tape. She faces logistical pain points, including medication loss from spills or stomach pressure shooting medicine out of the G-tube; difficulty with dissolving pills; and the need for specialized bottle caps to easily fill syringes. Insurance typically only covers an insufficient four syringes per month. Thus, syringe durability is also a major issue: the numbers quickly rub off and they become sticky, necessitating time-consuming "life hacks" to elongate their lifespan like using clear fingernail polish as a protectant and olive oil as a lubricant. Jessica emphasizes the need for user-centered, pediatric, and non-medical-feeling products, such as a longer-lasting syringe and more accessible filling tools, while encouraging new parents to seek out community and embrace trial and error.

Tyler Robinson Interview Report

Summary

Aranza, Suraya, and Amantle met with caregiver Tyler Robinson on January 8th over Zoom to get feedback from her regarding the critical function mockups. Tyler shared that Autumn's medication schedule and dosing process have remained largely unchanged since the previous interview, though they have recently discovered she has a form of kidney disease that may slightly change her usual medications. She evaluated three critical function mockup concepts: the colour coding, the syringe clips, and the syringe sliding adjustability mockups.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

While colour coding was nice visually and would help with organisation, she cared more about how our solution feels in her hand during medicine administration, the size of the solution, and how easily the product fits different syringes. Tyler also felt that the sliding adjustability mockup was more complicated than helpful, saying that it made it harder to use, as the syringes already had markings.

Overall, she preferred solutions that were universal, comfortable to use, and didn't add extra parts or steps to her already rigorous routine, which helped clarify key design considerations for creating a more universal, intuitive, and caregiver-friendly dosing solution.

Brianna Dascher Interview Report

Summary

Andre, Amantle, and Nathan met with Kim Tyk and Brianna Dascher over Zoom on the evening of October 2nd to understand the caretaker's perspective on the problem and learn about her experience taking care of Vivian, her daughter. Brianna Dascher is the primary caretaker for her seven-year-old daughter, Vivian, who uses a wheelchair, has limited communication, and relies on a surgically-placed G-tube for all feeding and medication. Vivian received the gastric tube due to dysphasia developed after uncontrolled epilepsy. Vivian's medication regimen is well-controlled and administered multiple times daily via the G-tube. Brianna had to learn crucial preparation techniques, like the "pull-back syringe method" for crushing tablets. She learned this information primarily from other parents in online support groups rather than from nurses or hospital staff, indicating a gap in formal caregiver training. Brianna is highly organized and has memorized the routine, though she has occasionally caught herself drawing up the wrong amount before administration. She receives 50 syringes monthly, which is ample, but notes that they quickly become sticky or have their measurement numbers wear off after only a few days of twice-daily use. This short lifespan forces her to discard them and highlights a product durability issue, though Brianna consciously avoids soaking her syringes to prevent marking loss.

Reem Osman Interview Report

Summary

Aranza and Suraya met with Reem over Zoom to learn how she organizes, prepares, and administers daily medications for her daughter, who has epilepsy (G-tube). The conversation covered physical setup, dosing workflow, connectors and syringes, error-proofing,

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

pharmacy/insurance logistics, training/learnability, automation attitudes, and route/formulation constraints.

Reem has developed a tightly streamlined, low-error system built around prepping each morning for that day only, strong spatial separation of a.m./p.m. doses, color and size coding of syringes per medication, and bottle adapters to prevent spills and speed drawing. She dislikes screw-type connectors (ENFit/Luer-lock) because the extra seconds to screw/unscrew add up across high-frequency use; she prefers a quick push-fit extension. Logistics are optimized through mail-order specialty pharmacies, 90-day prescriptions, and active management of dual insurance billing. Error prevention relies on syringe-count cues (3 syringes for a.m. dose, and 4 syringes for p.m. dose), labeling when handing off, and a stable division of roles with her spouse.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Appendix B: Specs Chart

Introduction

This specs chart has been continuously updated throughout the duration of the project, with each entry informed by user conversations, secondary research, or general brainstorming of ideal product attributes. All specs are compared against a standard single-use ENFit syringe, since it is the primary piece of equipment used for liquid medicine administration by our target users.

Need	Metric	Units	Marginal value	Ideal value	How we know	Single-Use ENFit Syringe
Precision	Limit of precision of desired dose	mL	< the distance between the smallest markings on a syringe	< ½ the distance between the smallest markings on a syringe	The marginal value is the full distance between minor markings on the syringe, and the ideal value is half the distance between the smallest increments on the syringe.	½ the distance between the smallest markings on a syringe
Compatibility	Compatible bottle neck widths range	mm	20-28	18-38	1/31 - Bottle & Cap Finishes Research Notes	
	Compatible bottle thread finish types	GPI/SPI Neck Finish Designation	20-400, 24-400	20-400, 24-400, 28-400, 20-415, 24-415, 28-415	1/31 - Bottle & Cap Finishes Research Notes	
	Compatible syringe volumes	mL	3, 5, 6, 10, 12	1, 3, 5, 6, 10, 12, 20	Supplier catalogs and owned syringes	1, 3, 5, 6, 10, 12, 20
	Range of adjustability	% of total syringe volume	20-100	0-100	standard doses in a 1mL syringe range from 0.2-1mL. In rare cases, some patients use overly-sized syringes to measure small amounts of liquid new: Nurses at Luries explained that medication doses change frequently, often every four weeks as infants grow. Fixed-dose components are not viable.	0-100
	Maximum volume of medication bottle	mL	88.7	59.1	Centor, a major manufacturer of bottles lists the available sizes of liquid ovals (medication bottles) on their website. 88.7mL correlates to their 3oz size, while 59.1mL correlates to their smallest 2oz size. https://www.centorrx.com/product-solutions/liquid-oval/plastic-liquid-oval	
	Minimum volume of medication bottle	mL	354.9	473.2	Centor, a major manufacturer of bottles lists the available sizes of liquid ovals (medication bottles) on their website. 354.9mL correlates to their 12oz size, while 473.2mL correlates to their largest 16oz size. https://www.centorrx.com/product-solutions/liquid-oval/plastic-liquid-oval	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

	Maximum medication bottle height (bottom to top of neck)	cm	16.51	17.1	The height of the 12oz liquid ovals synthesized by USP is shown to be 6 1/2 inches. https://www.usplastic.com/catalog/item.aspx?itemid=127920&catid=1352 While the height of their 3oz bottle is shown to be 6 3/4 inches which correlates to 17.1cm. https://www.usplastic.com/catalog/item.aspx?itemid=153316&catid=1352	
	Minimum medication bottle height (bottom to top of neck)	cm	11.1	9.8	The height of the 2oz liquid ovals synthesized by USP is shown to be 3 inches and 7/8 of an inch. https://www.usplastic.com/catalog/item.aspx?itemid=101427&catid=1352 While the height of their 3oz bottle is shown to be 4 3/8 inches which correlates to 11.1cm. https://www.usplastic.com/catalog/item.aspx?itemid=131784&catid=1352	
Ease of Implementation	Time for healthcare professionals to teach users how to use	Minutes	10	5	Conversation with client (SRALab nurses).	60+
	Time for users to complete any necessary preparation before medicine administration process.	Minutes	15	5	Discussion with caregiver in which she recounted the complete process of medicine planning and administration.	0
	Time for users to complete medicine administration process.	Minutes	10	5	Discussion with caregiver in which she recounted the complete process of medicine planning and administration.	10
Dimensions	Height when not in use	inches	4	2.5	Medicine bottles are approximately 6 inches tall, and the smallest of vertical cubboards tend to be 10 inches tall	3.1
	Area added to bottle footprint	in ²	2	0	User interview.	0
Attachability	Force required to detach device	Newtons (N)	25-15	8-12	source claims that maximum pinch strength of elderly people is 40-60N. Looking for approximately 1/3 of peak pinching strength to ensure security and usability	
	Feedback Mechanism. Presence of clear confirmation that target dose has been reached.	Visual, Tactile, Auditory	Visual	Visual, Tactile, Auditory	Review of product pages and past hands-on experience with syringe and dosing cup. Nurses at Luries rejected hard stop mechanisms because they prevent users from pushing the plunger back to remove air bubbles, they preferred visual confirmation w control.	Visual
Ease of Use	Force required to unlock	Newtons (N)	15-5	<5	https://journal.gerontechnology.org/archives/341-343-1-PB.pdf The pinch strength of elderly females (often the weakest user group) can drop below 20. Extrapolating this to be one fourth of their maximum strength, yields an ideal unlocking force of 5N.	
	Force required to move while locked	Newtons (N)	>60	>110	source claims that the average maximum pinch strength of people is 60N. Pinching is the motion used when pulling up the syringe with the limiter in place.	
	Force required to move while unlocked	Newtons (N)	3-5N or 7-9N	5-7N	A resistance of 5-7N prevents the slider from "flopping" or slipping freely (drift) but is smooth	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

	Time required to adjust from minimum to maximum dosage	Seconds	<5	<3	enough to adjust precisely. Discussion with caregiver in which she recounted the complete process of medicine planning and administration.	0.5
	Caregiver confidence after first use	Likert scale (1–5)	≥3	≥4	Standard usability testing practice for home medical devices.	
Label integration	Available flat surface area for labeling	cm ²	≥ 1	≥ 3	Most caregiver interviews, and all client meetings, revealed frequent use of stickers and handwritten labeling systems to track medication type and dosage, especially for multi-medication regimens (15+ medications). Stickers are currently applied directly to syringes and often interfere with dose markings. Providing ≥1–3 cm ² of flat, non-curved surface area enables safe visual labeling without obscuring calibration or mechanical function.	
Accessibility	Percentage of caregivers who correctly dose and administer the target volume on the first attempt without written English instructions	Percent of users (%)	80	95%	Conversation with client about demographics they serve (SRALab nurses).	
	Colorblind friendliness	Groups who can interpret and use the limiter	red-green color blind	Red-green, and blue-yellow color blindness	Approximately 8% of males and 0.5% of females (4.5 average) worldwide are estimated to have some form of red-green color blindness, and approximately 1% of people have blue-yellow color blindness. https://www.mdpi.com/2227-9032/13/16/2031	Red-green, and blue-yellow color blindness
Safety and child safety	Smallest detachable component size	mm	≥32 mm	≥40 mm	Based on the Small Parts Test Cylinder defined in 16 CFR §1501.4 by the U.S. Consumer Product Safety Commission . Any component or fragment that fits entirely within the cylinder presents a choking hazard for children under 3. This standard is used as a conservative safety reference for home-use products in environments where children may be present. Values above 32 mm ensure components cannot enter the cylinder even after foreseeable detachment or breakage.	
	Number of simultaneous dissimilar actions required to adjust the limiter	quantity of steps	1	2	Source states that children under the age of 5 developmentally struggle to coordinate two different directional forces at the same time (cognitive barrier) and often lack the hand span/strength to execute them (physical barrier).	
	Minimum edge radius on all exposed and detachable edges	mm	≥0.5	≥1.0	16 CFR §1500.49 – Technical requirements for determining a sharp metal or glass edge in products intended for children, defining when an edge is hazardous by cutting tape under controlled force. https://www.ecfr.gov/current/title-16/chapter-II/subchapter-C/part-1500/section-1500.49 Product will be used in home pediatric environments with frequent child contact. Interview with caregiver raised concerns with product being safe for child to interact with: https://docs.google.com/document/d/1wysqQciV62S3V_uTeqiatcTMOjulP3mijfKJnglOGLw/edit?tab=t	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

					0	
Child tamper resistance	Percentage of children under 52 months of age who can remove the device within five minutes without assistance	%	<20	<15	The device will be used in home pediatric environments with frequent child interaction and the risk of exposure to potent pharmaceutical chemicals. ISO 8317 Child-resistant packaging demonstrates that packaging is to be regarded as child resistant if no more than 15 per cent of the children can open the package within the first five minutes. Over the whole testing period of ten minutes, no more than 20 per cent of the children should be able to open the packaging.	
	Percentage of children under 52 months of age who can remove the decalibrate the device within five minutes without assistance	%	<20	<15	The device will be used in home environments with other children present, where decalibration could cause measurement errors on the device. Seeing as this is less directly harmful, the intervals are 2x the standards set by ISO 8317 Child-resistant packaging . Hence ideal child safety would be if no more than 30% per cent of the children can open the package within the first five minutes. Marginal child safety would be that no more than 40 per cent of the children should be able to open the packaging within 5 minutes.	
Durability	Number of washing cycles undergone before impacts to usability	Repetitions of cycles	15	INF	Conversation with caregiver, manufacturer-suggest cleaning procedure (for syringe, also applied to dosing cup due to similar marking manufacturing process).	5
	Number of administration uses undergone before mechanical failure	Repetitions of uses	125	1460	Conversation with caregiver, manufacturer-suggest cleaning procedure (for syringe, also applied to dosing cup due to similar marking manufacturing process). $\sim 4 \text{ doses/day} * 31 \text{ days} + 1 \text{ (cushion)} = 125$; $\sim 4 \text{ doses/day} * 365 \text{ days} = 1460$	5
	Drop height with function retained	Feet	4	10	Validated with nurse-provided syringes.	
	Maximum of operational temperature range	°C	35	70	Review of ISO 80369-3 Standard. Source states that dishwasher maximum temperature sanitize cycles are approximately 70 degrees.	60
	Minimum of operational temperature range	°C	10	-40	Review of ISO 80369-3 Standard.	-40
	Percent change in mass when immersed 95% isopropyl alcohol (rubbing alcohol) for 48 hours	Percent of total mass	1%	<0.5%	Review of ASTM D543 Resistance of plastics to chemical agents. Source .	
	Percent change in mass when immersed in 0.6% NaClO (Bleach) for 48 hours	Percent of total mass	1%	>0.5%	Review of ASTM D543 Resistance of plastics to chemical agents. Source .	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Cleanability and Hygiene	Presence of enclosed crevices or internal features that trap liquid medication	Yes / No, verified by inspection	No enclosed crevices <2 mm deep or <2 mm wide	No enclosed crevices or blind features. All surfaces are fully accessible to soap and water cleaning	Fixed caregiver cleaning behavior assumption. Validity by most of the caregivers we've talked to and also initial client meeting notes on how caregivers are recommended to clean syringes when dispatched from hospital. "3A Standards require that surfaces in direct contact with products are smooth and devoid of pits and crevices to prevent microbial harborage and ensure easy cleaning." - https://www.betterengineering.com/blog/the-role-of-3a-sanitary-standards-for-industrial-cleaning-systems/?srsltid=AfmBOoqKFmMstL3Orzd_b2Klz1EuRd8bkWVurkp1caTvYadcWXsaa55&utm_source=fda-reusable-medical-device-design-guidance-emphasizes-smooth-debris-free-geometry-conducive-to-effective-cleaning " FDA reusable medical device design guidance emphasizes smooth, debris-free geometry conducive to effective cleaning." - https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/working-together-improve-reusable-medical-device-reprocessing	
	Ability to be cleaned in dishwasher without damage	Yes / No, verified by inspection	No	Yes		No
Cost	Cost per dose administered	USD (cents)	0.02	0.01	Review of product pages for unit price / # of possible administration instances before discarding.	0.036
	Cost per month	USD(\$)	10.8	1	Reviewed product pricing for bulk syringes, and dosing cups in the current market	10.8
Waste & Sustainability	Volume of medicine wasted per use.	mL	≤0.01	0	Source. Luries visit 1/20. experience with syringes	0-0.005
Biocompatibility	percent concentration of plastic additives di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP)	% concentration	0.1	0.05	Source indicates that the regulatory limit of these three compounds is 0.1% in children's toys	
	Pass ISO 10993 cytotoxicity screening	Pass/Fail	Pass	Pass	The ENdose most likely falls under Class I for medical devices (low risk), which means that it must be biocompatible if patient-contacting: 1. https://qservegroup.com/stay-ahead-with-iso-10993-12025-the-new-standard-for-biological-evaluation?utm_term=biocompatibility%20testing%20iso%2010993&utm_campaign=(Z)++ISO+10993++CRO&utm_source=adwords&utm_medium=ppc&hsa_acc=6359874837&hsa_cam=23275854186&hsa_grp=188399034666&hsa_ad=784765103194&hsa_src=g&hsa_tgt=kwd-454574604950&hsa_kw=biocompatibility%20testing%20iso%2010993&hsa_mt=e&hsa_net=adwords&hsa_ver=3&gad_source=1&gad_campaignid=23275854186&gbraid=0AAAAAD8xOmSgj4-TNu3ARH7lzxZsx2aj&gclid=CjwKCAjAkbbMBhB2EjwANbxtbVBNPVwL9uvo248CDtI_g7tbPEFKIWOcMhXzfH_tDm78cEJil_gsnrCRoCwc4QAvD_BwE 2. ISO 10993-1:2025 - Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

					management process	
Slider resistance consistency over wash cycles	% change in adjustment force after 20 wash cycles	%	≤ 20	≤ 10	Caregiver interviews report syringe sticking and friction changes over repeated washing, resulting in sudden medication release or dosing errors. Since slider resistance directly governs dose-setting precision, drift in adjustment force over time may lead to unintentional movement or calibration shift. Limiting force change to $\leq 20\%$ after 20 wash cycles (marginal) and $\leq 10\%$ (ideal) aligns with mechanical stability expectations for reusable medical components and supports consistent user-controlled adjustment. https://docs.google.com/document/d/1mJLCZ8Ru1SYhjLCLdK2WY7P2CsTfwgrcS4iKPtpIT28/edit?tab=t.0	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Appendix C: Failure Mode and Effects Analysis (FMEA)

Table 1: Rating Criteria

Rating	S	O	D
1	No effect User: No discomfort Device: Device has no damage	Rare (≤ 1 in 1000 doses)	Almost certain detection Detected during setup before dosing
2	Minor temporary discomfort User: Small spill Device: Minor cleaning	Infrequent (1 in 200 doses)	
3	Treatment disruption User: Small administration error Device: Small dosing error ($\leq 10\%$)	Occasional (1 in 50 doses)	Moderate detection (small leak) Detected during use
4	Significant harm possible User: Missed dose (ER visit likely) Device: Major malfunction (large dosing error, $>10\%$)	Frequent (1 in 10 doses)	
5	Severe harm possible User: High-risk overdose Device: Major failure with undetectable dosing error	Very Frequent (≥ 1 in 10 doses)	Undetectable until harm occurs (Silent overdose or underdose) Not detected until harm

Table 2: FMEA Table

Function	Failure Mode	Effect(s) of Failure	Cause(s) / Mechanism(s) of Failure	Current Controls	Original				Recommended Action(s)	Updated				Next Step(s)
					S	O	D	(RPN = $S \times O \times D$)		S	O	D	(RPN = $S \times O \times D$)	
Attaching ENDose to medication bottle	Cap of ENDose isn't fully screwed onto medication bottle	ENDose falls off, medicine spills upon bottle inversion	User doesn't have detexterity/strength to tighten cap all the way	Geometry provides tangible but overcomeable resistance when screwing ENDose onto bottle	3	2	3	18	Improve geometry for comfortable resistance, include clear instructions for securing ENDose to medicine bottle	3	2	3	18	Add a rubber gasket to inner surface of the cap, and validate and optimize instructions for use (Appendix: Instructions for Use)
		ENDose isn't seated properly, medicine leaks out upon bottle inversion			2	2	3	12		2	2	3	12	
		ENDose falls off, medicine spills upon bottle inversion	User doesn't have any indication of when the ENDose is properly seated on medicine bottle		3	1	3	9		3	1	3	9	
		ENDose isn't seated properly, medicine leaks out upon bottle inversion			2	1	3	6		2	1	3	6	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

	Neck snaps off of cap	ENDose is left unusable	User holds the device by distal end of neck to screw the cap onto the bottle and applies excessive force when tightening, leading to a strain higher than failure strain of cap/neck material.	Ridges on cap to facilitate proper screwing	4	1	1	4		4	1	1	4	
	Cap of ENDose is chipped/broken/warped	ENDose falls off, medicine spills upon bottle inversion	Deviation from standard bottle cap finish	Standard bottle threading	4	1	3	12		4	1	3	12	
		ENDose isn't sealed properly, medicine leaks out upon bottle inversion			4	1	5	20		4	1	5	20	
		ENDose falls off, medicine spills upon bottle inversion	Damage to the bottle (e.g., after dropping)	Material selection to avoid deformation	4	1	1	4		4	1	1	4	
		ENDose isn't sealed properly, medicine leaks out upon bottle inversion			4	1	1	4		4	1	1	4	
	Inserting syringe Into ENDose	Syringe isn't fully inserted into cap of ENDose	Medication loss	Geometry provides leakless seal with standard ENFit syringe tip, while allowing some give to overcome blockages	2	3	3	18	Make region on top of ENDose cap an obviously different color than the tip of common ENFit syringes to make space from incomplete insertion visible	2	2	3	12	Validate current and future colorways to ensure users know when syringe is fully inserted
			Increase in baseline plunger height		4	3	5	60		4	2	5	40	
			Buildup of material between male syringe tip and female port, resulting in increase in baseline plunger height		4	2	3	24		4	2	3	24	
		Incorrect syringe is selected for usage with ENDose for a given dose	Incorrect Dose	Universal syringe compatibility leads to incorrect syringe size used	5	2	5	50		5	1	1	5	Reduce number of necessary types of stickers down to one
	Syringe fully inserted but not fully sealed in ENDose	Medication loss	Damage or poor quality control leads to improper fitment of male syringe tip into female port, leading	Tolerance stackup analysis, manufacturing recommendations in final	4	1	3	12		4	1	3	12	

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

			to leak	report										
Matching correct ENdose to medication bottle	A given ENdose is compatible with and applied to a liquid medicine bottle its calibration is not meant for (for example, after washing and reattaching)	Incorrect dose	Misunderstanding of color coding or other organizational system	Caregiver training before discharge from hospital, obvious compatibility with only a single bottle finish	5	1	5	25	Have a clear labeling system, colour coding, and a matching label chart. Also potentially have the hospital standardise where exactly stickers/colour coding will be placed	5	1	3	15	Validate and optimize color coding instructions for use (Appendix: Color Coding Instructions for Use)
		Medication loss	Leaky seal between ENdose and bottle	Single-bottle compatibility, strong plastic to prevent force-induced deformation	2	1	3	6		2	1	3	6	Injection molding for more precise geometry
Verifying ENdose calibration	Decalibrated ENdose goes unchecked (user is overreliant)	Incorrect dose	Unaddressed calibration due to mechanical disturbance (dropping, falling, child interference, etc.)	Teeth and spring mechanism to only allow movement along neck if lever arm is lifted away	5	1	1	5	Direct user to recalibrate ENdose after each mechanical disruption (including wash or drop)	5	1	1	5	Direct user to recalibrate ENdose after each mechanical disruption (including wash or drop)
Production	Miscalibration	Incorrect dose	Device not manufactured to recommended tolerances	Tolerance stackup analysis and instructions for manufacturing provided in final report	4	1	4	16		4	1	5	20	Injection molding for more precise geometry
Maintaining calibration	The adjustability mechanism shifts after the ENdose is dropped, knocked over, or cleaned	Decalibration	Stopper and neck teeth lose contact, allowing limiter to move along neck	The teeth on the limiter and neck prevent accidental shifting through usage of device	4	3	1	12	Increase spring constant to increase resting normal force between limiter and neck	2	3	1	6	
	Child alters the position of the limiter relative to the neck	Decalibration	The child lock is inadequately challenging for children to manipulate adjustment mechanism	Two step mechanism for height adjustment	4	1	1	4	Refine and verify child lock mechanism	4	1	1	4	Design additional child locking mechanism for adjustability system

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

	Stopper shifts as user is removing calibrating or non-calibrating syringe	Decalibration	Extended plunger applies vertical force on limiter that isn't seated properly, adjusting its height.	Caregiver training before discharge from hospital, locking lever arm	4	3	5	60	Design limiter to stay in place relative to neck even when quick release clamp arm is lifted	4	3	5	60	Geometry optimization so teeth slide into locked position whenever button isn't pressed
	General wear leading to loosening of plastic component fitment relative to each other	Decalibration	Wear		4	1	5	20	Expiration date/recommended duration of usage included in instructions for use or other product documentation	4	1	5	20	Expiration date/recommended duration of usage included in instructions for use or other product documentation
		Eased decalibration	Spring constant is decreased over time		3	1	3	9	Select springs rated for repeated compression cycles	3	1	3	9	Test wear of adjustability system over many uses
Adjusting Calibration	Stopper height can no longer be adjusted	Device failure	Residue buildup in teeth	Smooth plastic to facilitate cleaning	3	1	1	3		3	1	1	3	

Appendix D: Cap & Bottle Finishes Research

Introduction

Designing a device capable of forming an airtight seal between itself and a full bottle of liquid medicine requires precise physical compatibility between the two objects. While a screw-on cap is an established method of sealing liquid medicine bottles, these bottles come in numerous different sizes and thread finishes, meaning a cap or other device that fits onto one medicine bottle will not always be compatible with others. This research was conducted to establish the standards and conventions of liquid medicine bottles and cap finishes, and to inform design decisions regarding the compatibility of our device with commonly used liquid medicine bottles.

Results

Five specific measurements define any bottle finish: outer diameter including the thread (“T”), outer diameter without the thread (“E”), inner diameter (“I”), distance from the top of the neck to the top of the uppermost thread (“S”), and neck height (“H”) [1]. Pictured in *Figure 1*, these dimensions allow a bottle finish to be empirically determined with calipers or a similar measuring device. Notably missing are the pitch (the vertical displacement of a thread after one full loop around a neck or cap) and specific geometry of the threads. These values are difficult to access, and are likely only visible through paid standards like ASTM D2911/D2911M-16 [2].

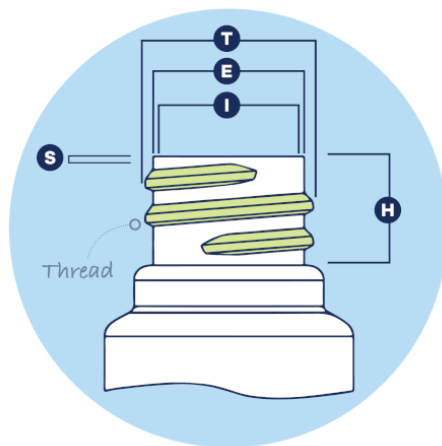


Figure 1: Key Finish Dimensions [1]

However, extrapolated from the “E” measurement and by counting the number of times the thread wraps around the neck of a bottle (or cap), the Glass Packaging Institute (GPI) and the

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Society of Plastics Industry (SPI) established a convention for referring to common finishes using a two digit number followed by a three digit number, in the format XX-YYY, where XX is “E” measured in millimeters, and YYY is a three digit code beginning with four, which refers to the number of times the thread loops around the bottle neck (400 is one full loop, 410 is one and a half, 415 is two full loops) [3].

Liquid medicine bottles, particularly those we have physically interacted with, appear to most frequently have 20 mm or 24 mm outer diameters (“E” values, *Figure 1*), with either one or one and a half loops of threading, suggesting 20-400, 20-410, 24-400, and 24-410 should be targets for our design [3, 4, 5]. One source included the pitch values for GPI/SPI standard dimensions ending in -400, which varies depending on the outer diameter of the finish [6]. Despite these common values, however, some specific medicine bottles may adopt other dimensions, like the 21 mm outer diameter bottle purchased from Amazon and used for research and prototyping purposes earlier in this project.

Conclusion

For this project, this research suggests pursuing compatibility with bottles with external diameters (“E”, *Figure 1*) of 18, 20, 24, and 28 mm, where 20 and 24 mm versions are more important to produce than 18 and 28 mm versions, and one to two thread loops (one marginal; one, one and a half, and two ideal). In other words, up to twelve possible versions of the final prototype should be produced (four diameters times three thread lengths). Dimensions for thread geometry and pitch should be gathered empirically.

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March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

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[6] “Neck Finishes – Multi Design Packaging inc.” Accessed: Jan. 31, 2026. [Online]. Available: <https://multidesign.ca/en/glossaire/neck-finishes/>

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Appendix E: Testing Summaries

Precision Test Summary

Data collected indicate that the ENdose caused significant precision errors (mean 0.11mL), with a critical misdosing of over 10% on four out of the nine measurement trials. This imprecision was caused predominantly by air bubbles that were pulled into the syringe on five out of the nine trials. These bubbles seemed to arise because the 3D-printed cap does not create an airtight seal with the liquid, allowing air bubbles to be pulled in at the same time as the liquid. Analyzing the precision without air bubbles to examine the performance of the adjustability mechanism alone provides an average dosing error of 0.05mL for the ENdose. This indicates that the device would be precise up to 0.05mL when the issue with the bubbles is resolved. Using a slightly different procedure that did not include pulling the liquid up through the cap of the ENdose, and hence not controlling for the inclusion of air bubbles, the syringe caused an average dosing error of 0.003mL. Both devices yielded only underdosing errors.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Bottle Compatibility Test Procedure

Purpose

This procedure verifies that the ENdose functions correctly with the standard amber oval medication bottle finish it is designed for. The test evaluates whether the device screws properly onto the bottle threads, maintains a leak-tight seal, and remains securely screwed on during basic handling. This procedure can also be used in future development to evaluate ENdose iterations designed for other medication bottle finishes.

Materials

- 1 ENdose prototype
- 1 standard amber oval medication bottles
- Water
- Paper towels
- Timer or stopwatch

Measurements Recorded

Metric	Description
Screw success	ENdose screws fully onto the bottle threads
Time to screw	Time required to fully screw the device onto the bottle: from first contact with bottle threads until the device is fully screwed down
Leak score	Severity of leakage during testing
Retention	Device remains securely screwed on during handling

Leak Severity Scale

Score	Description
0	No leakage observed
1	Moisture or dampness
2	Visible drops

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

3	Continuous stream
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Controls

- Fluid type: water
- Fill volume: x mL
- Dryness of the equipment
- Static inversion time: 180 s (or until failure, whichever is first)
- Environment: room temp
- Same tester

Design

The test consists of 5-10 repeated trials of the same procedure using the same ENDose prototype and bottle finish.

Test Procedure

Preparation

1. Ensure the bottle neck and ENDose threads are clean and dry.
2. Fill the bottle with water to approximately 75% capacity.
3. Wipe the outside of the bottle dry.

Screw Test

1. Start the timer when the ENDose first contacts the bottle threads.
2. Push down and screw the ENDose onto the bottle.
3. Continue screwing until the ENDose seats against the bottle lip and cannot be tightened further by hand.
4. Stop the timer.
5. Record:
 - a. Screw success (Yes / No)
 - b. Time to screw
 - c. Observations (cross-threading, resistance, visible gaps)

Static Leak Test

1. Place a clean paper towel on the work surface.
2. Invert the bottle over the paper towel.
3. Hold the bottle inverted for 180 seconds without movement.
4. Observe the connection between the bottle and ENDose.
5. Record:

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

- a. leak severity score.

Handling Test

1. Return the bottle to an upright position.
2. Slowly invert and return the bottle upright three times.
3. Invert the bottle one more time, so the cap of the ENdose is facing the paper towels and Shake the bottle three times.
4. Inspect whether the ENdose has unscrewed.
5. Record:
 - a. Leak score (if leakage occurs)
 - b. Retention pass (Yes / No)

Reset

1. Unscrew the ENdose from the bottle.
2. Dry the bottle and device.
3. Repeat the full test for additional trials if needed.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Appendix F: Standards and Regulations

Level	Standard/ Regulation	Source	Summary	Core Expectation	ENDose Design Impact
MUST	ISO 14971:2019 – Medical Devices Risk Management (Current Edition)	ISO 14971:2019 - Medical devices — Application of risk management to medical devices	Standard explaining how medical products must identify and reduce safety risks.	Identify hazards, evaluate risks, implement controls, document residual risk.	FMEA must demonstrate mitigation of dosing error, misuse, mechanical failure, and child safety risks.
MUST	ISO 80369-3:2016 – Enteral Connectors (Current Edition with amendments)	https://www.iso.org/standard/50731.html	Ensures enteral connectors fit correctly and prevent wrong-route connections.	Meet dimensional and functional compatibility requirements.	ENDose geometry must not interfere with ENFit systems or introduce misconnection risk.
MUST	21 CFR Part 801 – Medical Device Labeling (Living Regulation)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801	U.S. federal labeling requirements for medical devices.	Provide clear instructions, warnings, intended use, and proper identification.	Instructions must clearly communicate dose setting, compatibility, cleaning, and warnings.
MUST	21 CFR Parts 174–177 – Food Contact Materials (Living Regulation)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-174	U.S. regulatory framework for safe materials used in contact with food.	Materials must comply with indirect food additive regulations.	Provides additional chemical safety benchmarks for polymer selection.
MUST	16 CFR Part 1501 – Small Parts Regulation (Living Regulation)	https://www.ecfr.gov/current/title-16/chapter-II/subchapter-C/part-1501	Regulation prevents choking hazards from small detachable components.	Components must not fit within small parts of the test cylinder if child-accessible.	Detachable components must not create choking hazards.
MUST	16 CFR Part 1700 – Poison Prevention Packaging Act (Living Regulation)	https://www.ecfr.gov/current/title-16/chapter-II/subchapter-E/part-1700	U.S. law requires certain packaging to resist access by children.	Meet formal child-resistant performance testing requirements.	Any child-resistant mechanism must meet validated panel testing criteria.
MUST	ISO 17664-1:2021 / ISO 17664-2:2021 – Processing of Medical Devices (Current Editions)	https://www.iso.org/standard/81720.html	Standard outlining validated cleaning and maintenance instructions.	Provide validated cleaning, durability, and maintenance instructions.	Wash-cycle durability testing and cleaning instructions must be evidence-based.
SHOULD	IEC 62366-1:2015 + AMD1:2020 – Usability Engineering (Current Edition)	https://www.iso.org/standard/63179.html	Standard focused on reducing user error in medical products.	Conduct structured usability testing to reduce use-related risks.	Cold-use testing must demonstrate safe and accurate caregiver operation.
SHOULD	ISO 20417:2021 – Information Supplied by Manufacturer (Current Edition)	https://www.iso.org/standard/67943.html	Defines what safety information manufacturers must provide.	Include proper instructions, warnings, and compatibility disclosures.	Labeling and IFU must clearly define intended use and limitations.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

SHOULD	ISO 15223-1:2021 – Medical Device Symbols (Current Edition)	https://www.iso.org/standard/77326.html	Standardized symbols for medical device safety communication.	Use internationally recognized symbols where applicable.	Supports low-literacy labeling strategy.
SHOULD	ISO 7886-1:2017 – Sterile Hypodermic Syringes (Current Edition)	https://www.iso.org/standard/64790.html	Defines dimensional and performance requirements for syringes.	Establish syringe tolerances and graduation accuracy requirements.	Dose-stop mechanism must account for syringe dimensional variability.
SHOULD	FDA Guidance (2023 Update) – Reprocessing Medical Devices	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling	FDA recommendations for validating cleaning of reusable devices.	Demonstrate effective cleaning and provide validated labeling.	Cleaning durability testing must support safe reuse claims.
SHOULD	ASTM F963-23 – Standard Consumer Safety Specification for Toy Safety (Current Mandatory U.S. Version)	https://www.cpsc.gov/FAO/Toy-Safety	Safety standard addressing mechanical and physical hazards in children's products.	Evaluate sharp edges, pinch points, mechanical hazards, and breakage risks.	Provides hazard screening framework for child-accessible environments.
SHOULD	16 CFR Part 1307 – Phthalates (Living Regulation)	https://www.ecfr.gov/current/title-16/chapter-II/subchapter-B/part-1307	Restricts harmful plasticizers in children's products.	Phthalate content must not exceed regulatory limits.	Polymer material selection must avoid restricted additives.
FUTURE	21 CFR Part 820 (QMSR Final Rule 2024) – Quality Management System Regulation	https://www.federalregister.gov/documents/2024/02/02/2024-01768/medical-devices-quality-management-system-regulation-amendments	U.S. regulation aligning device QMS with ISO 13485.	Implement compliant quality systems under FDA authority.	Required for U.S. commercialization.
FUTURE	21 CFR Part 830 – Unique Device Identification (Living Regulation)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830	Regulation requiring traceable device identification.	Assign and maintain unique device identifiers.	Required if ENdose enters regulated medical device market.
FUTURE	EU Regulation (EC) No 1935/2004 – Food Contact Materials (Current)	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celext:32004R1935	EU regulation ensures materials in contact with food are safe.	Materials must not transfer harmful substances.	Relevant for international expansion.
FUTURE	EU Regulation (EU) No 10/2011 – Plastics in Food Contact (Current)	https://eur-lex.europa.eu/eli/reg/2011/10/oj/eng	EU regulation defining migration limits and authorized plastics.	Meet specific migration and substance restrictions.	Supports international material compliance strategy.

Appendix G: Finite Element Analysis for Cantilever Latch Mechanism Validation

Introduction

The cantilever snap-fit latch mechanism responsible for holding the neck of the ENdose in an upright position while the device is in use relies on the repeatable elastic deformation of the latch region of the neck shown in *Figure 1*. Ideally, the pressable region, marked with a symbol representing an open padlock, stays rigid under applied force while the thin plastic connecting this region with the body of the neck would bend to disengage the cantilever snap joint.

This deformation is a function of two design choices: geometry and material selection. However, because HDPE, the recommended material for production of the ENdose's parts at scale, is incompatible with traditional fused deposition modeling (FDM) 3D printing, this deformation had to be modeled using finite element analysis (FEA) to verify its functionality.

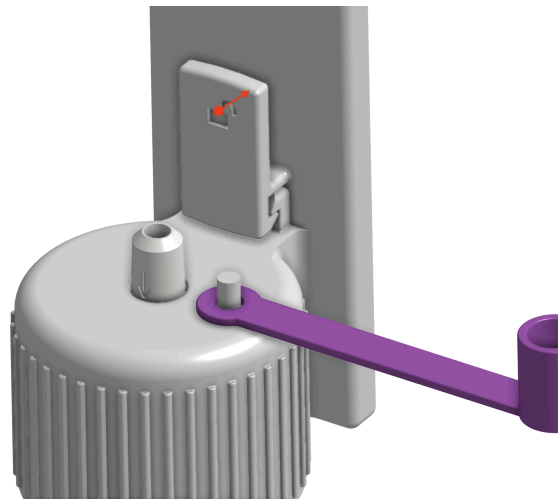


Figure 1: Closed latch mechanism with origin and direction of applied force marked with red dot and arrow, respectively

Methods

The FEA was executed using Abaqus/CAE (“Abaqus”) from Dassault Systèmes. Only the neck model was used to execute the FEA, since no other part of the ENdose assembly was expected to affect the deformation of the neck region in question. The part was assumed to be made of high density polyethylene (HDPE), and the bottom surface of the neck (relative to the orientation in *Figure 1*) was fixed to force a deformation under load. Finally, the load was applied as shown in *Figure 1*, and the results were captured using geometric depiction and a heat map of the strain, as shown in *Figure 2* to *Figure 4*.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

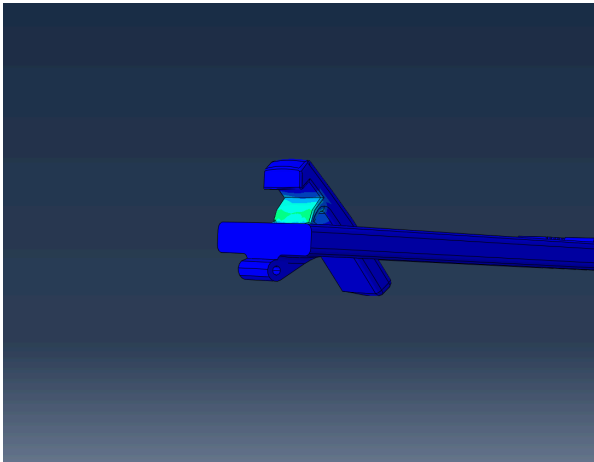


Figure 2: FEA of deformation under pressing load, viewed from bottom

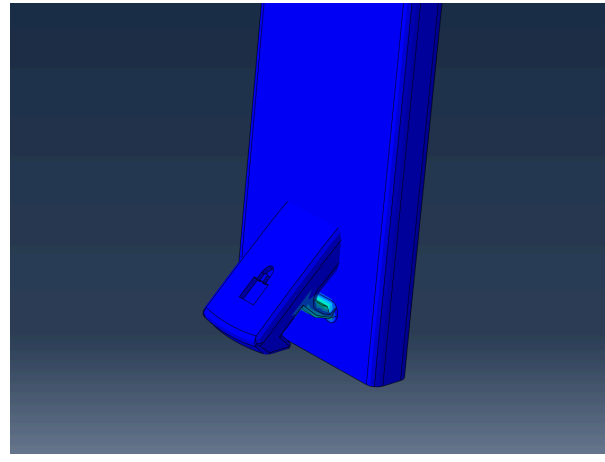


Figure 3: FEA of deformation under pressing load, viewed from back

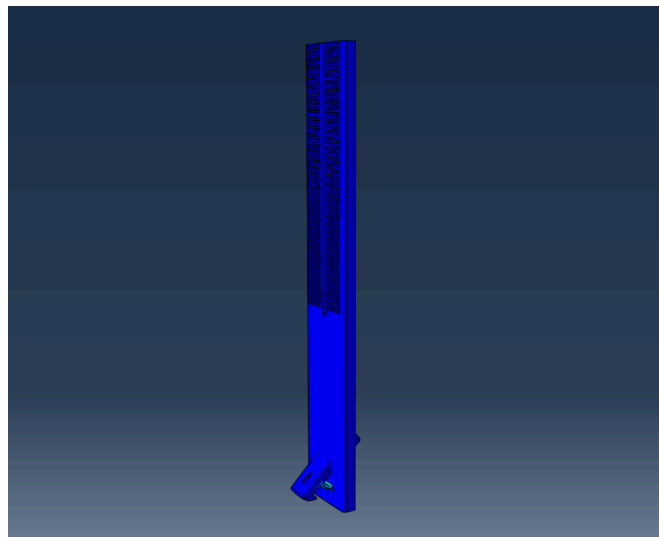


Figure 4: FEA of deformation under pressing load, zoomed-out isometric view

Results

Figures 2-4 predict that if manufactured using HDPE, the latch will deform as desired, allowing the cantilever snap joint to be repeatedly engaged and disengaged. In other words, the latch mechanism should function as expected if the part is made, in its current geometry, out of HDPE. Should the future design of the ENdose require a different latch geometry or material, this analysis should be repeated ahead of mass manufacturing to validate functionality without the risk of requiring retooling or redesigning.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Appendix H: Expert Interview Summaries

Emma Kowiak Interview Report

Introduction

This subject matter expert (SME) interview, conducted between Andre Pang and Aranza Noriega, took place via Zoom on Thursday, January 15th, 2026. Emma Kowiak is a nurse practitioner with prior experience working as a registered nurse in emergency medicine and medical-surgical care. Her clinical background includes experience administering medications through enteral feeding tubes and educating patients and caregivers on medication protocols. The goal of this interview was to gain insight into professional medication dosing workflows and patient education practices, as well as to gather expert feedback on the two current design directions, presenting the most up to date prototypes for the syringe attachment and the bottle attachment. This interview aimed to evaluate their feasibility, usability, and potential to reduce medication dosing errors for caregivers in home settings.

Summary

Emma Kowiak provided insight into professional medication dosing workflows in both hospital and home-transition contexts, emphasizing the contrast between highly structured clinical protocols and the variability caregivers face after discharge. She described hospital medication administration as guided by detailed electronic orders and nursing training, while noting that time pressure, limited resources, and patient eagerness to discharge can result in gaps in education and inconsistent practices once patients return home. A recurring concern was caregiver error stemming from low medical literacy, incomplete teach-back, and the lack of simple, repeatable tools to support accurate dosing outside the clinical setting.

When reviewing the two design directions, Emma initially gravitated toward the syringe attachment concept, as it felt more intuitive based on how it was explained and aligned closely with her experience administering medications in a hospital setting. She noted that physically limiting the plunger's movement could meaningfully reduce overdosing and eliminate reliance on faded syringe markings, making it especially valuable for clinical use and for less-experienced practitioners. This suggests that mechanical constraints may serve as a more reliable safeguard than visual cues alone, such as syringe markings, especially in situations where users may lack training, confidence, or consistency in measurement.

As the conversation progressed and the discussion shifted more explicitly toward caregiver use in home settings, Emma suggested that the bottle attachment may be better suited for at-home

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

medication administration, particularly due to its potential to reduce improvised workarounds. Across both concepts, she emphasized that successful adoption would depend on intuitive use, clear onboarding, and minimizing additional cognitive load for caregivers already under significant stress.

Conclusion

Emma highlighted compatibility as a critical constraint, noting that both wide variation in medication bottle neck sizes and differences across syringe brands could limit adoption if not addressed. She expressed a strong preference for the syringe limiter to work across multiple syringe sizes and manufacturers, rather than being locked to a single system. For the bottle cap adapter, she indicated that dishwashing rigid components would be acceptable in home settings, while disposable or replaceable tubing would better address sterility concerns. Finally, she emphasized that the underlying problem extends beyond pediatric care, suggesting strong applicability for geriatric and diabetic populations, and encouraged outreach to additional stakeholders with experience in insulin-related patient education to further validate these opportunities.

Lin Sanders Interview Report

Introduction

This subject matter expert (SME) interview, conducted between Nathaniel Rogers, Andre Pang, and Nurse Lin Sanders, took place via Zoom on Friday, January 16th, 2026, from 12:30 - 1:10 pm CST. Lin is a nurse with Stanford Health Care. She has experience working in the intensive care unit (ICU), and the Post-anesthesia care unit (PACU). The goal of the interview was to collect insight on the professional medication dosing process and seek feedback on the syringe limiter and bottle cap adapter mockups to clarify one as the prime solution. Questions were meant to leverage the interviewee's domain-specific medical knowledge.

Summary

Lin Sanders provided insight into the distinct differences between hospital protocols and home care. She noted that hospital procedures generally rely on single-use, pre-dosed medications, eliminating the wear-and-tear issues regarding syringe markings that home caregivers face. Sanders described her personal procedure for drawing medication out of a pull-tab dose, which utilizes blunt needles to access the measured dose and pull up a specific amount, then transfer that amount into an ENFit syringe secondarily. This method contrasts with pulling medication

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

via the ENFit tip directly, which can be messy. She also highlighted that some hospital systems are inconsistent in their usage of syringe types and locking mechanisms.

A significant portion of the discussion focused on the mechanics of liquid measurement and the risks associated with pre-filling syringes. Lin emphasized that drawing liquid almost always introduces air bubbles, requiring a specific technique where the nurse overdraws the medication and then pushes the plunger back to expel air and reach the target dose. Because of this complexity, she expressed concern regarding pre-filling syringes. She noted that without the rigorous labeling standards found in hospitals, pre-filled syringes could lead to medication errors. Additionally, she advised the team to conduct testing with fluids of varying viscosities, such as cough syrup, as water does not accurately reflect the behavior of many liquid medications.

Regarding the team's prototypes, Sanders raised concerns about the mechanical stability of the adjustment mechanisms, noting that loose components could lead to dosing drift. She also mentioned that a physical plunger stop might hinder the necessary "push-back" motion required to remove air bubbles, potentially making the dosing process awkward or inaccurate. She suggested that a visual indicator or a "ruler" style guide might be preferable to a hard stop to allow for this necessary movement. She reacted positively to the concept of a built-in ENFit bottle adapter. She ultimately recommended that any solution needs to be universal across different syringe sizes to be truly effective.

Dr. Joseph Avni-Singer Interview Report

Introduction

This subject matter expert (SME) interview, conducted between Nathaniel Rogers and Dr. Joseph Avni-Singer (Dr. Joe), took place via Zoom on Friday, November 14, 2025, from 1:00 - 1:30 pm CST. Dr. Joe is a pediatrician as a member of Child and Adolescent Care, which has offices in New Haven and Woodbridge, Connecticut. The goal of the interview was to collect additional insight—specifically from the perspective of a physician—on the various problems faced by caregivers of pediatric patients in charge of administering several liquid medications. Questions were meant to leverage the interviewee's domain-specific medical knowledge. The interview concluded with a review of existing solution ideas and corresponding mockups.

Summary

Conversation began with a discussion about how Dr. Joe communicates with parents. Almost all communication happens through an online portal, which allows the physician to write and reply

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

with several repeatable stock phrases. The portal has a bank of documents corresponding to various medical interventions that are sent to parents as necessary. While Dr. Joe, as a general pediatrician, doesn't have much experience with high medical necessity patients, this suggests a general lack of individualization for physician-caregiver interactions. For less tech-literate parents, Dr. Joe prints out documents, acknowledging that those documents likely get discarded soon after the appointment, anyways.

Similar to caregivers' accounts of only being prescribed exactly as much medication as is necessary for a given period of time, Dr. Joe included that he avoids anything close to over-prescription because he fears caregivers will use too much medication or use it too frequently.

In response to the existing mockups, Dr. Joe floated the idea of making a limiter adjustable, but restricting caregivers' ability to adjust it themselves, perhaps incorporating a mechanism that only healthcare professionals have a "key" to adjust. He reiterated his support for making them adjustable, however, especially as children's weights change so rapidly as newborns and toddlers, and many sensitive medications are body weight-dependent. He closed by supporting a kind of closed-loop solution, using continuous glucose monitors (CGMs) and insulin pumps as model systems. .

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Melanie Turenne Interview Report

This caregiver interview with Melanie Turenne was conducted by Nathaniel Rogers and Suraya Osman on February 12th and spanned one hour. Through our Zoom call, she showed us how advanced her at home medication management system was for her son, which took years to evolve into what it is today. He follows a very complex dosing schedule and has three nurses for additional help. As a mechanical engineer she has developed useful techniques to ease the stress of at home medication dosing.

The most important takeaways from this interview included Melanie's medication management system which showcased that medication dosing is an intricate and structured workflow that has been designed over many years. She heavily depends on visual tools to make the experience as seamless as possible. She uses color coding stickers, detailed schedules, and a log book for every medication her son gets. She strongly believes that failure is not an individual mistake but a systematic design failure. Another important insight she discussed was how critical precision is and how important it is to design with children in mind. This includes a child lock safety mechanism and parts to ensure accuracy.

Care Context

- Melanie is a mechanical engineer & manages medications for her 9-year-old son with a complex dosing schedule.
- Medications are prepared in her son's bathroom.
- Separate storage:
 - Shelf-stable liquid and tablet medications in bathroom
 - Refrigerated medications stored in closet
 - Large backup supply closet for overflow inventory
- Her son receives many medications per day, administered every two hours (not including night time).
- There are three nurses assisting with his schedule.
- There is a clear schedule designed for any caregiver to follow.

Color-Coding System

- Medications and syringes are color-coded with matching labels. (Refer to images below)
- Labels are made using a Cricut.
- Sticker packs stored in the drawer and updated whenever dosage changes.
- Tape is applied over stickers to preserve markings and show exact dose.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Color meanings:

- Pink- given 24 hours/day
- White- medications in J-tube (food + some meds)
- Yellow & Purple- daytime meds
- Green- overnight meds

Logging & Documentation

- Melanie keeps an extremely detailed journal/logbook:
 - “The log book has been life-changing and saving.”
 - Records every medication, dose, and time since birth.
 - Helps detect new or unusual behavioral trends.
- Written paper schedule with initials to confirm administration.
- Posted reference sheets for:
 - Daily schedule
 - Activities
 - Special cases

Syringe Use & Accuracy

- She explained that when selecting a syringe size, the finest measurement increment should be no greater than 10% of the total dosage volume to ensure accuracy.
- Hospital-provided white syringes are preferred, leading to oversupply of regular syringes.
- Syringe lifespan varies by medication.
- O-ring syringe used with oil-like medication to clean the tube.
- When syringes fail (plunger stuck), sticker-based system helps maintain dosing.
- Child has micro-J tube:
 - If clogged then a hospital visit is required.
- She has a syringe washing set up as well.

System Evolution

- The current system developed over many years.
- The earlier medication schedule was simpler (5-6 meds vs around 20 today).
- Color-coding was introduced when her son was 4 years old.
- Melanie says:
 - Failure is a system failure, not an individual failure.
 - Every failure is an opportunity to redesign the system.
- Nurses typically learn the system within a few days.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Prototype Feedback - Bottle-Mounted Syringe Stopper (ENDose)

- She collects and regularly uses purple bottle cap adapters.
- She pours medications into new bottles to make them compatible with the cap adapters.
- She has not experienced syringes detaching from the adapters while drawing medication
- Many of the medications are viscous enough that they do not drip out when the bottle is inverted without a syringe.
- She has to haggle to obtain the preferred white syringes from the hospital.
- She does not prefill syringes in advance.

Initial Reactions

- Straightforward usability.
- Quick-release mechanism appreciated.
- Concept seen as helpful for parents sending kids to school.

Concerns & Risks

- The device may be too bulky given the number of medications.
 - Transport and storage is a problem.
- Needs secondary limiter / fail-safe:
 - If calibration shifts then dose accuracy is lost.
- Risk that caregivers become over-reliant and stop double-checking.
- Question of who calibrates and verifies accuracy.
- Concern that simplification may introduce hidden errors, overrely.

Mechanical Considerations

- Including the threaded portion of the ENFit port could increase syringe security in the device but:
 - Risk of over-tightening by nurses.
 - Over-tightening previously caused sticking issues.
- When asked about if she would ever use our product she said she likely would not switch, because her current system is highly optimized and trusted.
- Greatest use would be for:
 - New caregivers
 - Parents without established systems
 - School medication administration

(Gemini was used to clarify language and help organize notes)

Photos:

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Closet organization system, these include an oversupply of syringes she keeps receiving but does not use.



Washing station with taped syringe stickers to keep markings from fading.



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[illegible]

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Color coded stickers with specific dosing due to frequent changes.



Follow Up Melanie Turenne Interview Report

Introduction

On March 5, Aranza Noriega and Amantle Pelowetse met via Zoom with caregiver Melanie Turenne to review the latest iteration of the BMSS in Cad files. This was the second time the team met with Melanie, making this session an opportunity to revisit the design with a more developed prototype and assess how well it addresses earlier concerns.

The primary goals of this session were to evaluate how intuitive the current BMSS prototype appears when first encountered without instruction and to understand how the device might integrate into a complex caregiver medication workflow. Melanie was first asked to observe and interpret the device independently, describing what she believed each component did and how she imagined it would function. This approach allowed the team to assess whether key features—including the hinge, locking mechanism, and stopper adjustment system—communicated their purpose clearly through form and physical cues. The discussion then explored workflow integration, caregiver training needs, and broader considerations such as syringe variability across manufacturers and existing caregiver organizational systems.

Key Take Aways

Overall, this meeting provided insight into how the updated BMSS design is interpreted when first encountered without instruction. Melanie was able to correctly infer several aspects of the device's functionality simply by observing the prototype, including the hinge allowing the neck to move out of the way for syringe insertion and removal, the locking mechanism that releases the hinge, and the teeth along the neck that engage with the stopper to prevent it from freely sliding. These observations suggest that the mechanical language of the device communicates its function relatively clearly. However, it is important to note that Melanie is a mechanical engineer, so her ability to interpret the device quickly may not fully reflect how intuitive the design would be for the broader caregiver population.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

The strongest design feedback centered on the adjustability mechanism and the tradeoffs between usability, manufacturability, and safety. Melanie responded positively to the push-in mechanism because she felt it could be easier for people with limited hand movement and could support one-handed use. At the same time, she noted that having to maintain pressure while adjusting may be difficult for some users. She also pointed out that a screw mechanism may be more cost-effective to manufacture, but preferred the push mechanism because of the reduced risk of small swallowable pieces if a screw-based mechanism were to fail.

Melanie also saw value in the BMSS as a tool that could reduce the need to constantly check syringe markings while drawing medication. She noted that this could make dosing easier and could also help newer nurses who may struggle with identifying exactly where to draw up to. At the same time, she raised an important unresolved use-case: situations where the same bottle is used for two different doses at different times of day, since that would require the stopper position to change between administrations.

Finally, the discussion raised syringe variability as an important technical concern. Melanie noted that syringe gradations can differ across brands, even for syringes of the same size, and that this could create problems if the BMSS is calibrated or used around only one syringe type. She emphasized that if a calibration or safety syringe is used, it would need to match the syringe brand used for administration. More broadly, her feedback suggests that full universality may not be realistic, and that brand consistency may need to be communicated clearly if it becomes part of the system.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

Appendix I: Tolerance Analysis

Introduction

The precise volume to which a syringe is filled when using the ENdose is determined by the distance between the upper surface of the cap (onto which the syringe is pressed) and the bottom surface of the limiter. To allow perfect precision, this distance must be exactly the same across doses/uses; of course, this is unreasonable, as tolerance must be built into both the hinge mechanism to allow smooth motion, and because injection molding the plastic components of the ENdose will induce manufacturing-related variability in feature geometry.

To allow for consistent dosing within half of the smallest increment included on a new ENFit syringe, as outlined in *Appendix B: Specs Chart*, the total tolerance should be less than 0.041 inches (the distance between 0.2 mL increments on a 10 mL syringe). This tolerance analysis investigates whether this design criteria is currently met, or whether design or manufacturing changes will be necessary to meet it.

Approach

Assuming the cantilever snap joint holds the neck tightly against the cap of the assembly, the ENdose has three regions that will be the primary sources of tolerance concerns. The three regions are shown below in *Figure 1* to *Figure 3*, in which points at which nominal clearance (NC) were measured are marked in red. NC values at these points were considered alongside geometry-related tolerances standard for injection molded parts made of HDPE, as are all of the plastic components of the ENdose. These tolerance values were sourced from the most recent publication of The Society of Plastics Industry, Inc.'s *Standards and Practices of Plastics Molders: Guidelines for Molders and Their Customers* [1].

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

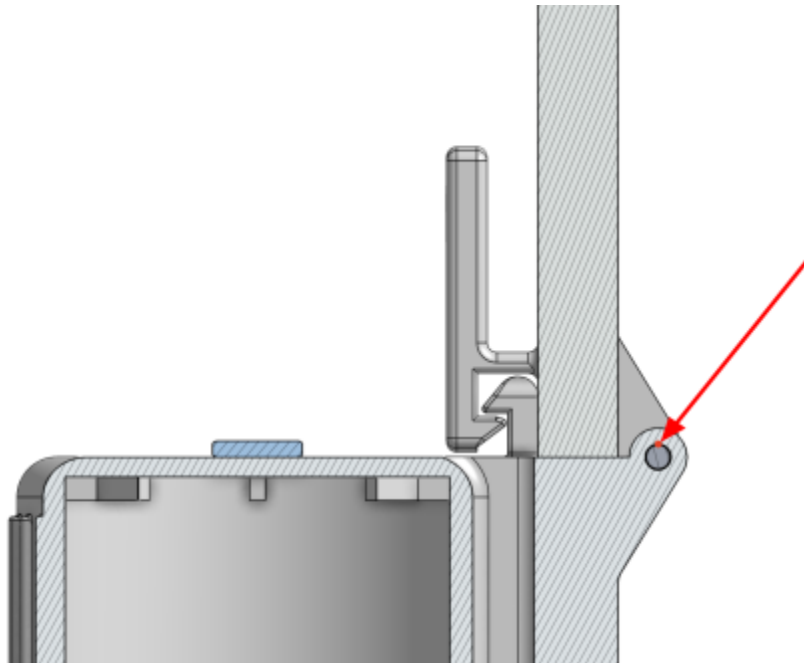


Figure 1: Location of NC measurement between cap and pin

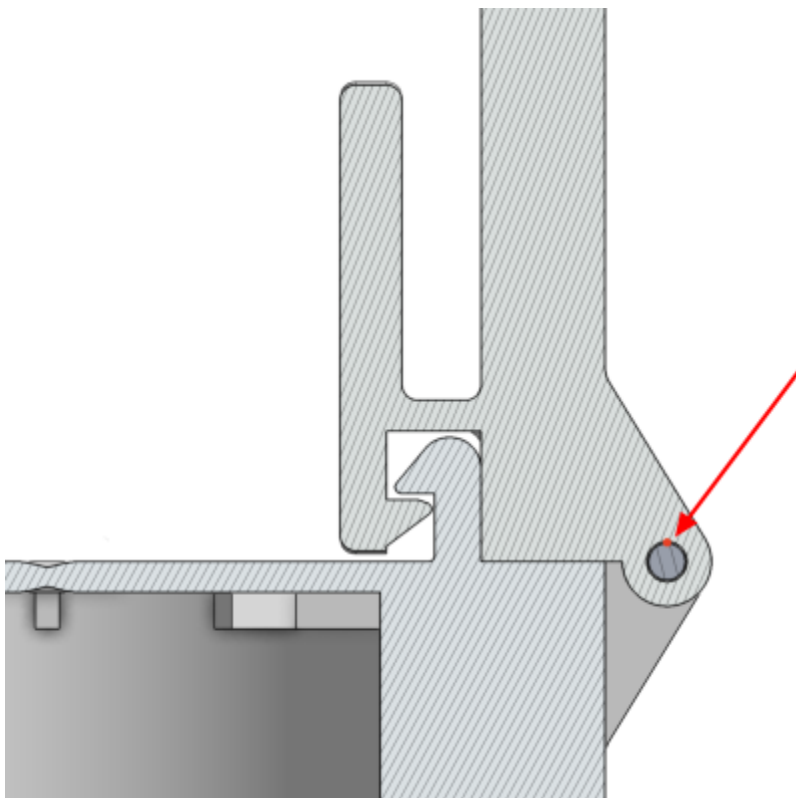


Figure 2: Location of NC measurement between pin and neck

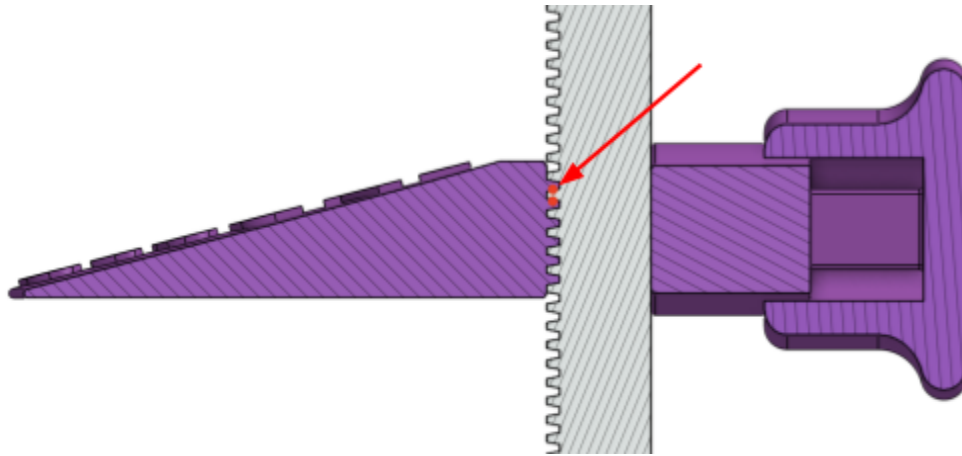


Figure 3: Location of clearance NC measurement between limiter teeth and neck teeth

The geometry-related tolerances were combined with the nominal clearances using a root-sum-square approach. This sum was then added (linearly) to the user error tolerance, which was defined as the expected maximum space between the tip of the syringe and the top surface of the cap that a user could leave upon inserting a syringe without noticing misuse¹. The result was the maximum vertical tolerance between the upper surface of the cap and bottom surface of the limiter; *Table 1* depicts the full calculation.

Feature	Figure	Tolerance Component	Material	SPI Geometry (A-H) [1]	Tolerance Value (in)
Hinge (Cap to Pin)	1	Cap Hole	HDPE	F	0.003
		Pin Diameter	Stainless Steel		0.0003
		NC			0.006
Hinge (Pin to Neck)	2	Neck Hole	HDPE	F	0.003
		Pin Diameter	Stainless Steel		0.0003
		NC			0.006
Teeth (Stopper to Neck)	3	Neck Teeth	HDPE	E	0.006
		Stopper Teeth	HDPE	E	0.006

¹ This value was roughly approximated using the subjective estimates of the designers, and should be validated and refined upon further development of the device.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

		NC			0
<i>*Expected maximum space between the tip of the syringe and the top surface of the cap that a user could leave upon inserting a syringe without noticing misuse¹.</i>				Subtotal (Molded Components)	0.0126
				User Error Tolerance*	0.025
				Total	0.0376

Conclusion

The total tolerance stack up is 0.0376 inches—smaller than the goal tolerance of 0.041 inches—meaning that the ENdose’s current geometry and suggested manufacturing methods will allow it to dose precise enough doses of liquid medication that harm to the pediatric patients will be avoided. However, two sources of error could override these findings: user misuse (see *Appendix C: FMEA*, which includes several anticipated examples of user misuse and existing controls for each) and poor quality control, further reinforcing the need for high-quality instructions for use included with the device (see *Appendix J: Color Coding System Instructions for Use*), and compliance with good manufacturing practices.

References

[1] Society of the Plastics Industry, Inc., Standards and Practices of Plastics Molders: Guidelines for Molders and Their Customers, SPI-AQ-102, 1998. [Online]. Available: https://www.controlplastics.com/technical-resources/SPI_Standards&PracticesOfPlasticsMolders.pdf

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Appendix J: Color Coding Instructions for Use

Introduction

While the BMSS enforces a relationship between type of medicine and dosage volume, it does not directly address caregivers' struggle to organize an array of liquid medications and ensure they are each administered at the correct, scheduled time each day. However, the BMSS can integrate into the kinds of organizational systems recommended and used by both medical professionals and caregivers (*Appendix A: Caregiver Feedback Interviews*). The instructions for use below use an example pediatric dosing regimen to illustrate how inexpensive, store bought stickers and a chart can be used alongside the BMSS to facilitate caregiver organization.

Table 1: Example syringe size to sticker color map

Syringe Size (mL)	Sticker Color ²
1	Red
3	Yellow
5	Green
10	Blue
12	Purple
20	Pink

Table 2: Example detailed daily dosing regimen

Drug Name	Commercial Name	Tube Used (G/J)	Dose	ENFit Syringe Size	Time(s) of Day	Stickers
Furosemide	Lasix	G-tube	3.5 mL	5 mL	8:00 AM, 8:00 PM	Green, Dog
Spironolactone	CaroSpir	G-tube	3.5 mL	5 mL	8:00 AM, 8:00 PM	Green, Cat

² Colorblind users may prefer to use letters over colors as syringe stickers.

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Captopril	Capoten	G-tube	3.5 mL	5 mL	6:00 AM, 2:00 PM, 10:00 PM	Green, Rabbit
Digoxin	Lanoxin	G-tube	2.8 mL	3 mL	9:00 AM, 9:00 PM	Yellow, Hamster
Sildenafil	Revatio	G-tube	3.5 mL	5 mL	6:00 AM, 2:00 PM, 10:00 PM	Green, Panda
Enalapril	Epaned	G-tube	5 mL	10 mL	8:00 AM	Blue, Koala
Aspirin	Low-dose aspirin liquid	G-tube	4 mL	5 mL	8:00 AM	Green, Lion
Omeprazole	First-Omeprazole	G-tube (preferred)	10 mL	10 mL	7:30 AM	Blue, Tiger
Potassium Chloride	KCl oral solution	G-tube	13 mL	20 mL	12:00 PM	Pink, Elephant
Acetaminophen (PRN)	Tylenol	G-tube	16 mL	20 mL	Every 6 hrs as needed (e.g., 6 AM, 12 PM, 6 PM, 12 AM)	Pink, Giraffe

Example Animals (30): Dog, Cat, Rabbit, Hamster, Panda, Koala, Lion, Tiger, Elephant, Giraffe, Monkey, Bear, Fox, Wolf, Owl, Penguin, Flamingo, Dolphin, Shark, Octopus, Turtle, Frog, Lizard, Snake, Horse, Cow, Pig, Chicken, Butterfly, Bee

Table 3: Example simplified daily dosing regimen

Time	Medicine	BMSS/Bottle Sticker	Syringe Size/Sticker	Dose
6:00 A.M.	Capoten	Rabbit 🐰	5 mL	3.5 mL
	Revatio	Panda 🐼	5 mL	3.5 mL
	Tylenol	Giraffe 🦒	20 mL	16 mL

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

7:30 A.M.	First-Omeprazole	Tiger 🐅	10 mL	10 mL
8:00 A.M.	Lasix	Dog 🐕	5 mL	3.5 mL
	CaroSpir	Cat 🐱	5 mL	3.5 mL
	Epaned	Koala 🐨	10 mL	5 mL
	Aspirin	Lion 🦁	5 mL	4 mL
9:00 A.M.	Lanoxin	Hamster 🐹	3 mL	2.8 mL
12:00 P.M.	Potassium Chloride	Elephant 🐘	20 mL	13 mL
	Tylenol	Giraffe 🦒	20 mL	16 mL
2:00 P.M.	Capoten	Rabbit 🐰	5 mL	3.5 mL
	Revatio	Panda 🐼	5 mL	3.5 mL
6:00 P.M.	Tylenol	Giraffe 🦒	20 mL	16 mL
8:00 P.M.	Lasix	Dog 🐕	5 mL	3.5 mL
	CaroSpir	Cat 🐱	5 mL	3.5 mL
9:00 P.M.	Lanoxin	Hamster 🐹	3 mL	2.8 mL
10:00 P.M.	Capoten	Rabbit 🐰	5 mL	3.5 mL
	Revatio	Panda 🐼	5 mL	3.5 mL

Instructions for Use

1. Retrieve the following materials from nurses before discharge from Lurie Children's Hospital:
 - a. One bottle of each liquid medication
 - b. One BMSS for each bottle of liquid medication
 - c. At least one month's supply of each syringe size necessary for the patient's dosing regimen
 - d. Plastic-based sticker sheets
 - i. One or more with animal stickers (at least one animal per medication type)

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

- ii. One with small, solid-colored stickers (at least one color per syringe size)
 - e. A table mapping each syringe size to a specific color of sticker, as shown in *Table 1*
 - f. Up to seven (one per day of the week) detailed daily dosing regimens for physician reference, as shown in *Table 2*, to accommodate for irregular weekly dosing schedules
 - g. Up to seven (one per day of the week) simplified daily dosing regimens for caregiver reference, as shown in *Table 3*, to accommodate for irregular weekly dosing schedules
2. Replace each medicine bottle cap with a properly-fitting BMSS. Screwing the BMSS on should feel similar to screwing on the original bottle cap.
 3. Using the simplified daily dosing regimen(s), for each bottle + BMSS assembly, apply two matching animal stickers (“bottle sticker”, Step 1.d.i), one on the limiter of the BMSS and one to the bottle (*Figures 1 and 2*).



Figure 1: Applying bottle sticker to BMSS



Figure 2: Applying bottle sticker to medicine bottle

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

- Using the labels on the medicine bottles and the simplified daily dosing regimen(s) (Step 1.g), apply a solid colored sticker (“syringe sticker”, Step 1.d.ii) on the upper surface of the cap of the BMSS (*Figures 3 and 4*).

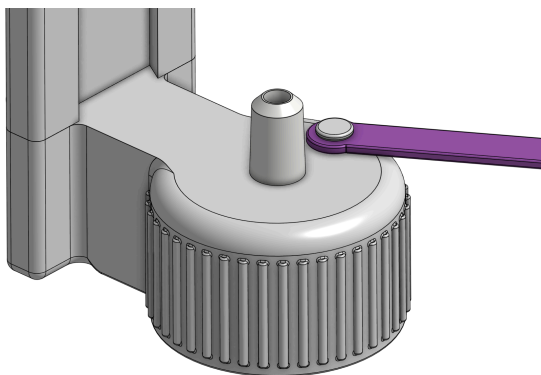


Figure 3: BMSS cap without syringe sticker

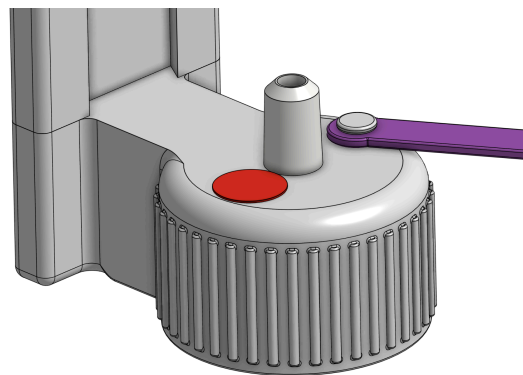


Figure 4: BMSS cap with syringe sticker

- Using the markings on the syringes and the simplified daily dosing regimen(s) (Step 1.g), apply a solid colored sticker (“syringe sticker”) onto the body of **every** syringe **such that it is not covering any of the syringe markings** (*Figures 5 and 6*).



Figure 5: Correct placement of syringe sticker on syringe



Figure 6: Incorrect placement of syringe sticker on syringe

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

6. For each daily dosing instance, consulting the simplified daily dosing regimen(s) (Step 1.g), match the sticker color of a clean syringe with the sticker color on the desired BMSS cap (*Figure 7*).
 - a. After removing a BMSS from a medicine bottle for washing, make sure the animal on its bottle sticker matches the animal on the medicine bottle it's being reattached to.



Figure 7: Matching a syringe with a BMSS

7. Use the BMSS to dose liquid medicine as described in the body of the report.

Appendix K: Review of Relevant Intellectual Property

Patents related specifically to ENFit-compatible liquid medicine bottle adapters were the first kind of interest. Fortunately, the ENFit tip and port are not and cannot be patent-protected, as they are publicly established and available in the international standard ISO 80369-3: Connectors for Enteral Applications [1]. However, several patents pertain to bottle caps and accessories that use the ENFit geometry with novel technology, like US20230211140A1 (expires in 2042), which describes two accessories: 1) a reversible insert, compatible with both ENFit and slip-tip syringes to transfer fluid directly out of the medicine bottle and into the syringe (*Figure 1*), and 2) a screw-on, childsafe cap with the same goal, but with a unique child locking mechanism (*Figure 2*) [2]. While the ENdose would benefit from a child locking cap feature, other, non-patent protected mechanisms could be used without infringement.

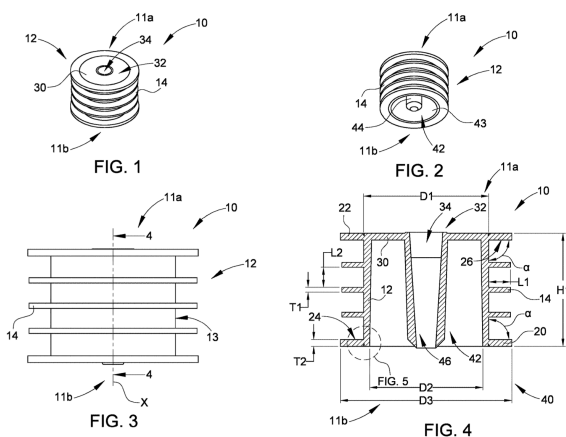


Figure 1: Reversible bottle insert

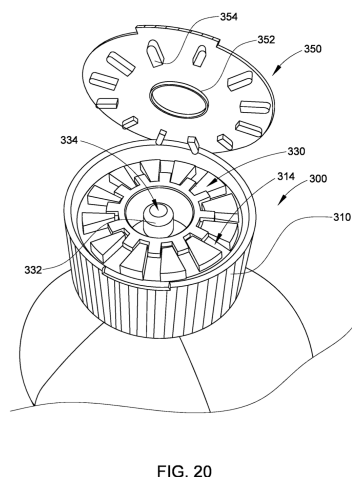


Figure 2: Childsafe fluid transfer cap

Another patent written by the same inventors describes a similar product, except instead of deriving novelty from the childproofing mechanism, it does so with a built-in plug (*Figure 3*) [3]. This patent, US12036183B2 (expires in 2038), includes the possible application of the technology in a universal adapter for bottles of different diameters, which, while useful, is unpatentable and used in other patented ENFit adapter products, such as in US20190350815A1 (expires in 2037), which was prepared by unaffiliated inventors (*Figure 4*) [3, 4].

March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

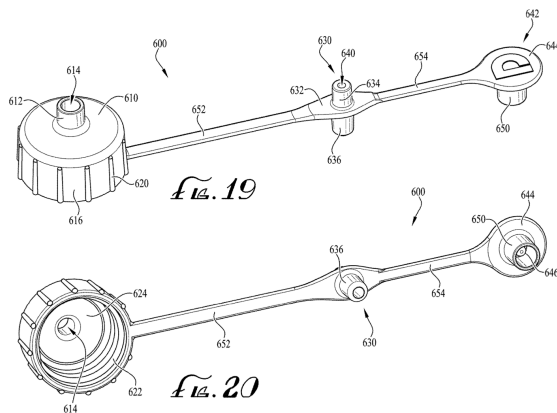


Figure 3: Fluid transfer cap with connected plug

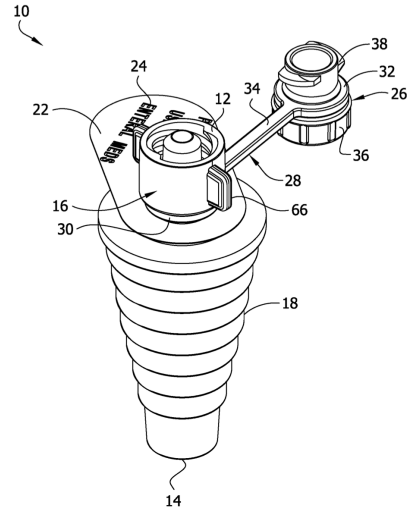
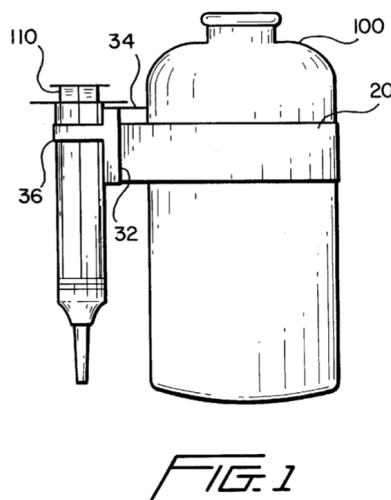


Figure 4: Universal bottle-to-ENFit adapter

Only one patent, US6565054B2 (expired), was identified which proposed a novel system for securing a syringe to a liquid medicine bottle without relying on the syringe tip [5]. Shown in *Figure 5*, this system uses an elastic band wrapped around the body of a medicine bottle and holds a bracket into which a syringe may be inserted [5]. The novel aspects of this system are dissimilar to those used to physically relate a syringe to a bottle within the ENdose, and because this patent is expired, the technology is open to public use.



a.

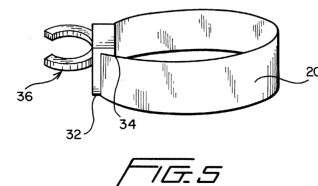


FIG. 5

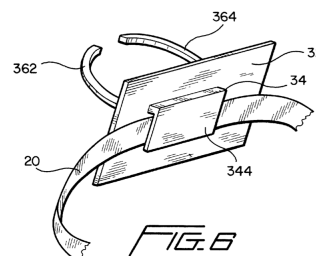


FIG. 6

b.

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

While some patents propose devices and methods for physically stopping a syringe plunger to improve dosing precision, all did so by changing the design of the syringe (e.g., US20210213208A1 [pending approval]) or attaching an accessory to the syringe itself (e.g., US10265477B2 [expires in 2035], US11771834B2 [expires 2041], and US11806513B2 [expires in 2038]) [6, 7, 8, 9]. The twisting mechanism described in US20210213208A1 used to select a dosage at which the plunger will be stopped, while again, used to achieve similar ends as the ENdose, does so via completely different means, including relying on a syringe to be filled to maximum volume and then stopped part of the way through its emptying, rather than restricting the syringe's initial filling [6].

Three patents, US10265477B2, US11771834B2, and US20210275751A1, propose systems that fasten onto the body or flanges of a syringe and restrict its filling above a specified dosage. Two are non-adjustable, differentiating them from the ENDose: US11771834B2, granted to Genentech Inc. in October of 2023, appears to be a tool for restricting plunger motion during manufacturing or industrial handling (*Figure 6*), significantly different from the use case of the ENDose [8]; US20210275751A1 resembles prototypes used earlier in this project, though with the additional ability to restrict movement of the plunger inwards towards the body of the syringe (*Figure 7*) [9].



March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Figure 6: Genentech Inc. plunger stopping system. a) Stopper assembly with limiter component disengaged. b) Stopper assembly with limiter component engaged.

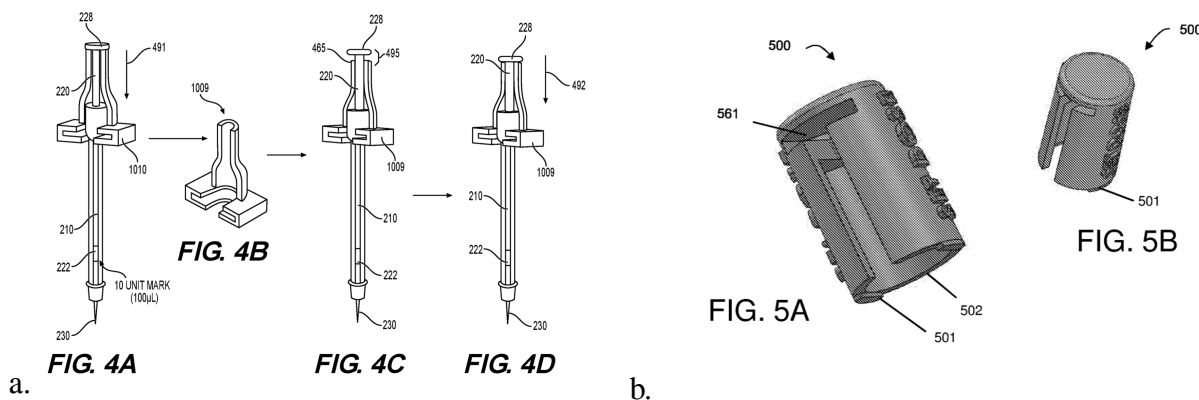
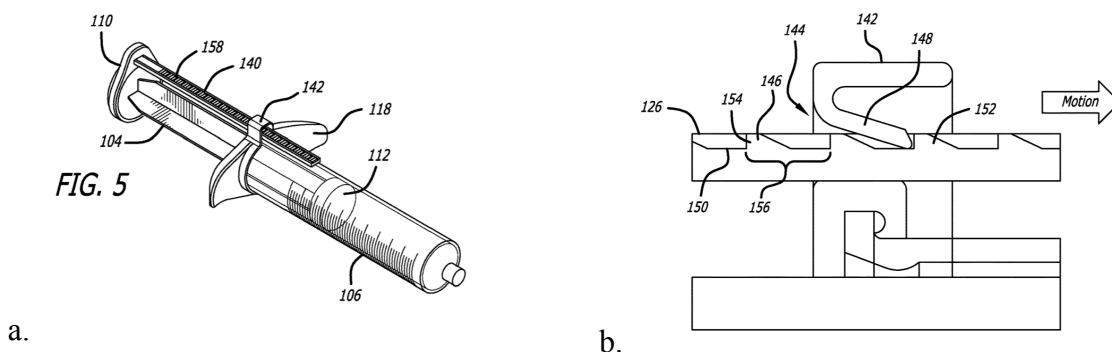


Figure 7: Flange- and plunger-attached syringe limiter accessories. a) Flange-attached accessory. b) Plunger-attached accessory.

The only adjustable syringe limiter patent found, US10265477B2, uses a ratcheting mechanism to restrain the syringe plunger at a specific, preconfigured height (*Figure 8*), a notable difference when compared to the continuous adjustment mechanism of the ENdose [7]. Again, no patents were found that implemented a syringe limiter mechanism as a medicine bottle accessory.

The ENdose does not infringe on any intellectual property found throughout the course of this patent research. While several patents describe systems for facilitating wasteless fluid transfer from liquid medicine bottles to ENFit syringes, and several others describe syringe limiter mechanisms to increase dosing accuracy and precision, none unite the two ideas. Combined with various other discrepancies between the intellectual property described in these patents and the design of the ENdose, with sufficient legal consultation, the prospect for commercializing the ENdose is promising.



March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Pelowetse, Nathaniel Rogers

Figure 8: Adjustable syringe limiter system. a) Fully assembled and mounted system. b) Ratcheting mechanism.

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March 16, 2026

Medication Dosing

Aranza Noriega, Suraya Osman, Andre Pang, Amantle Peloewetse, Nathaniel Rogers

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