2025 Device Innovation Challenge

SanoFit

Re-Imagining Comfortable Drug Delivery

An Innovation Call from Sanofi

August 2025

1 Introduction

1.1 Background

In the scope of the Device Innovation Challenge published by Sanofi, several of us have joined forces to re-think, newly design, and critically evaluate a novel large-volume drug delivery device. Coming from diverse academic backgrounds, we combined insights from literature review, research, and our own creativity to develop and shape a unique device concept.

1.2 Significance of a novel OBDS design

State of the art Recent advances in healthcare technology and public awareness have driven significant progress in self-administered drug delivery devices. [1] On-body delivery systems (OBDS) inject a defined volume of a drug substance autonomously through the subcutaneous (SC) route, without the need of healthcare personnel or hospital facilities which reduces healthcare costs significantly. [2] Most on-body delivery systems (OBDS) are designed to administer relatively small drug volumes; however, the effective treatment of certain diseases **necessitates delivery of larger doses**. [3] Furthermore, drug formulations are being developed to achieve **lower dosing frequencies**, which in return often increases the required dosage. [4] Large-volume OBDS are relatively **new on the market**, with commonly available devices reaching 10 mL capacity (2022, SmartDose) and 20 mL (2023, enFuse). [5] In the case of Sarclisa (20 mg/mL), a drug against multiple myeloma, a dose of 10 mg per kg body weight is recommended. [6] Taking into account body weights from low end to high end, this corresponds to 20 – 75 mL, which is a considerable amount that is yet **unmet by current state-of-the-art OBDS devices**.

What current solutions are missing Current large-volume drug-delivery devices fall short in several key areas. Patients often experience **discomfort and injection pain**, which limits the SC injection volumes to 3 mL. The local injection site pain and irritation following SC injections can arise from multiple factors, including needle insertion mechanics, composition of the formulation, injection volume, and the location of administration. Reducing this burden is critical to enhance medication adherence and improving the patient experience. [7] Existing devices feature complex interfaces and lack the intuitive, user-friendly controls and built-in safety mechanisms needed to prevent errors such as accidental needle sticks or misactivation. [8] Additionally, the industry faces **sustainability** challenges, as most devices are single-use, generating substantial electronic and plastic waste. [9]

Market Landscape and Unmet Needs Market research shows that the large-volume drug delivery market is growing rapidly, with a projected compound annual growth rate (CAGR) of 9.6 - 14.9% between 2023 and 2030. At this pace, the market is expected to reach an estimated size of **USD 12–15 billion by 2029–2035**. [10] [11] [12] Market growth is primarily driven by the transition from IV to SC administration and the shift toward home-based care. This innovation enhances patient convenience and comfort with economic benefits by reducing the need for infusion infrastructure, specialized equipment, and clinical staff. [3] In addition, demand for high-volume therapies such as monoclonal antibodies (mAbs) and GLP-1 receptor agonists is rapidly increasing. Their high-viscosity formulations and long-acting profiles make them particularly well suited for large-volume delivery. This trend is further accelerating the adoption of advanced delivery systems. [13]

Next-Generation Device Design Current large-volume drug delivery devices often fall short in addressing patient comfort, safety, and sustainability, creating a clear opportunity for a next-generation solution. Our device is designed to transform the patient experience: The use of an **indwelling needle** minimizes pain and repeated punctures, while a **no-slip band** decreases the adhesive patch area, lowering the risk of skin irritation and making removal less painful. In addition, the armband helps to distribute the device's weight more evenly, reducing localized pressure and enhancing overall comfort. For patients experiencing pain during administration, our intelligent system can **adjust the flow rate**, ensuring a gentler, more tolerable delivery without compromising therapeutic effectiveness. To enhance patient comfort and minimize pain, a **vibration motor** is integrated to activate prior to needle insertion. Integrated **smart sensors** verify correct adhesion before and during delivery, significantly reducing user error and improving safety confidence for both patients and healthcare providers. **Sustainability** is built into the product, manufactured with recyclable materials and a modular architecture that allows the electronic core to be reused. After the final dose, patients simply return the reusable module to Sanofi for sterilization and refurbishment, dramatically reducing waste and total cost of ownership. This combination of comfort, safety, and environmental responsibility positions our solution as the gold standard in large-volume drug delivery for the future.

1.3 Patient experience

To better understand patient perspectives, we **reached out to over 100 individuals** who had experience using on-body delivery devices for treatment.[1] For that, we searched for Reddit threads related to on-body delivery devices, mainly through the subreddit r/cancer. Furthermore, we found patients through device and/or medication-specific subreddits, for example r/skyrizi.

We noticed that larger, more complex devices performed worse. The Neulasta Onpro, a single-use injector in the body, has been particularly well regarded. The Neulasta Onpro is a modified version of the Omnipod insulin pump. Over one million patients have used the Onpro to deliver the drug Neulasta. [14]

> You heard it buzz and click the next day so you know when it injects and u just wait a bit then pull it off and throw it away. SO nice compared to having to return to the hospital the next day to get a manual injection!
> - *Patient using Neulasta On-Body Injector Onpro*

Reliability issues are a major source of frustration. Patients using larger and more complex devices such as the Skyrizi on-body injector reported frequent malfunctions. In contrast to Neulasta Onpro, the Skyrizi body injector requires **manual placement** of the drug cartridge. [15]

> I do not like the on-body delivery device. It is prone to error. It fails for me 1 of 6 times. When it fails, there is no recourse. The entire device, including the undelivered medicine, must be returned. - *Patient using Skyrizi On-body Injector*

[1] To protect patients' identities, we reference messages only with each patient's consent and in appropriate contexts.

It's simple to set up and use, but when it fails it sucks. It has failed for me two ways 1) the needle did not penetrate my skin 2) it clogged 1/4 of the way into a dose. - *Patient using Skyrizi On-body Injector*

Patients also emphasized the challenges of device adhesion. **Removing adhesive patches** can be painful and devices can sometimes get caught on clothing or furniture, leading to **accidental detachment**. Older patients expressed a preference for **simpler, more reliable systems** rather than complex features.

2 Our Solution

2.1 Proposed Design

Figure 2.1 presents a rendering of our proposed design, created using Autodesk Fusion and Blender. The left panel shows a top view of the device, while the right panel illustrates its integration into an armband. The following sections detail the cartridge components and outline how this design advances beyond existing alternatives. **Technical drawings** of our prototype can be found in the appendix (section 5.1).

Figure 2.1: Mockup of the proposed design, displayed as a standalone cartridge (left) and integrated into the armband (right)

Meeting Device specification Table 2.1 provides an overview of key device specifications and outlines how our design fulfills each requirement. This summary highlights the alignment of the proposed solution with technical, safety, and usability standards, demonstrating both its manufacturability and its suitability for patient use.

Table 2.1: How our design meets Sanofi challenge device specifications

Functionality	• Safe and reliable subcutaneous delivery up to 25 mL, enabled by a precision micro-motor mechanism
Usability	• Compact design for ease of handling and portability • Companion app provides guided instructions, help access and optional reminder notifications • Integrated sensors ensure proper use
Needle	• Micro-motor enables automatic needle insertion • Spring mechanism ensures automatic needle retraction
Drug Loading	• OBDS available pre-filled for immediate use • Patients can replace the drug reservoir via a simple click-in mechanism with a pre-filled tank
Sustainability	• Armband and electronic unit are reusable
User Feedback	• LED signals needle insertion and completed delivery • Drug reservoir status displayed with a bar indicator
Form Factor	• Small trough 90° shifted needle insertion mechanism • No-slip band and adhesive patch keeps device in place, ensuring safety and comfort for at least 5 h • All sides kept under 85 mm for one-handed handling
IP Avoidance	• Thorough IP search was conducted to ensure that this device is novel
Dosage Accuracy	• Short fluidic path, precise micro-motor, and end of dose sensing
Other functions	• Sensors that ensure proper adhesion on the body • Indwelling needle and vibratory stimulation to reduce injection pain • No-slip band, to reduce area of adhesive patch, better weight distribution around arm
Manufacturing	• Manufacturing feasibility was assessed for each element

2.1.1 Device life cycle

Our proposed OBDS follows a closed life-cycle designed with **sustainability** considerations and **patient convenience** in mind. The SanoFit device life-cycle begins with the **delivery** from the manufacturing site to the patient's home (see Figure 2.2).

The patient receives handling instructions, tutorials, and optional live online support for proper **device use**. When finished, the cartridge can be easily removed from the no-slip band and returned as a complete unit to Sanofi, by this prioritizing user-friendliness and comfort through minimizing handling requirements for the patient.

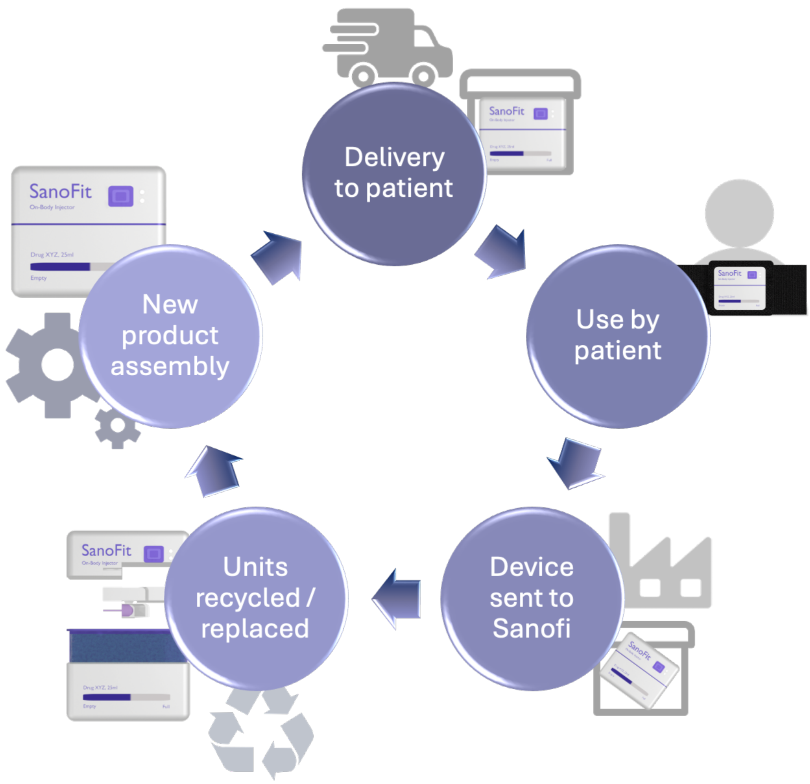

Figure 2.2: We propose the above life-cycle to maximize sustainability and patient convenience.

The device is **sent to Sanofi's** manufacturing site for disassembly, where reusable components are recovered and **recycled**, while single-use parts are **replaced**. The device is specifically designed for simple disassembly, reducing both patient effort during at-home maintenance and Sanofi's workload during processing. After **reassembly**, the device prepared for shipment, completing the cycle and creating a **closed-loop of the SanoFit system**.

2.1.2 Prototyping

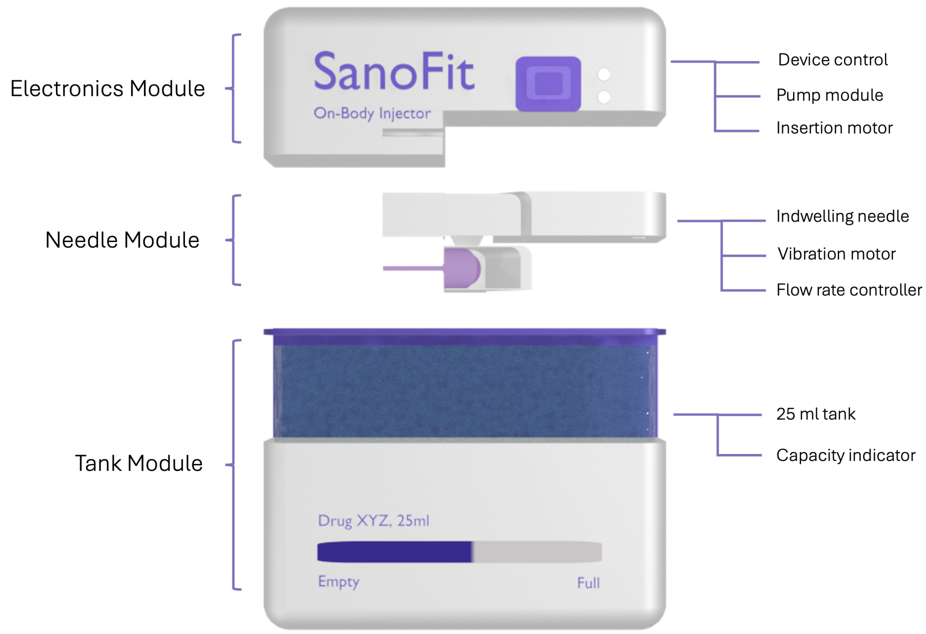

Figure 2.3: Exploded view of device cartridge, featuring the inner tank, indwelling needle, and vibration motor, added for patient comfort

Device Attachment The SanoFit device is secured to the body using a medical-grade **adhesive patch** in combination with an adjustable **no-slip band**, ensuring a stable yet comfortable fit. The adhesive patch is located around the needle insertion site and is designed to be as small as possible, while still maintaining a reliable, slip-resistant fixation. Minimizing the adhesive surface area improves user comfort, particularly by reducing discomfort during patch removal.

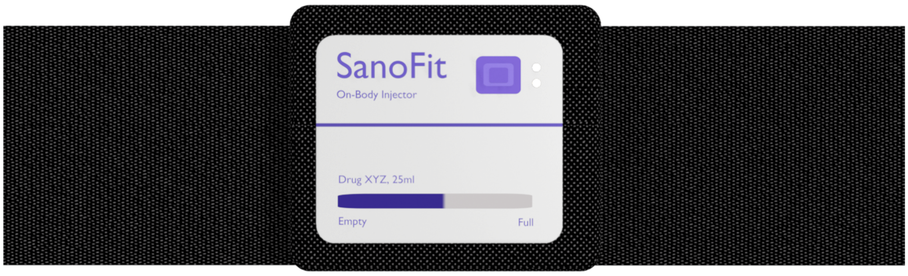

Figure 2.4: Device cartridge insertion into armband

To further enhance device stability, an adjustable no-slip band supplements the adhesive fixation. The band functions similarly to an armband used for carrying mobile devices and incorporates a **hook-and-loop fastener system**, which facilitates convenient application and removal by the patient. The adjustability of the hook-and-loop design also allows the band to accommodate a **wide range of body sizes**. The device can be worn on the upper arm, abdominal area, or upper thigh, with **interchangeable bands** available to support placement based on user preference or clinical requirements.

Cartridge Integration The device cartridge is housed within a stretchable textile **pouch** that is integrated into the band. The pouch firmly holds the cartridge in place while leaving the upper side of the cartridge exposed for visibility. On the skin-facing side, the cartridge features a recessed rim along its edge, corresponding to the thickness of the band, in order to ensure a smooth, flat interface with the skin surface.

Materials and Sustainability The no-slip band is manufactured from a hybrid textile blend of Lyocell and organic cotton. This **sustainable material composition** offers both performance and comfort benefits:

- Lyocell provides a soft, skin-friendly touch and high breathability, ensuring comfort during extended wear. Its production process operates in a closed-loop system, significantly reducing chemical waste, and the fiber itself is biodegradable.
- Organic cotton complements the blend by reducing material costs while contributing additional softness, comfort, and sustainability.

The inclusion of Lyocell also imparts the necessary elasticity for the band, ensuring both **adaptability and secure fixation** during use.

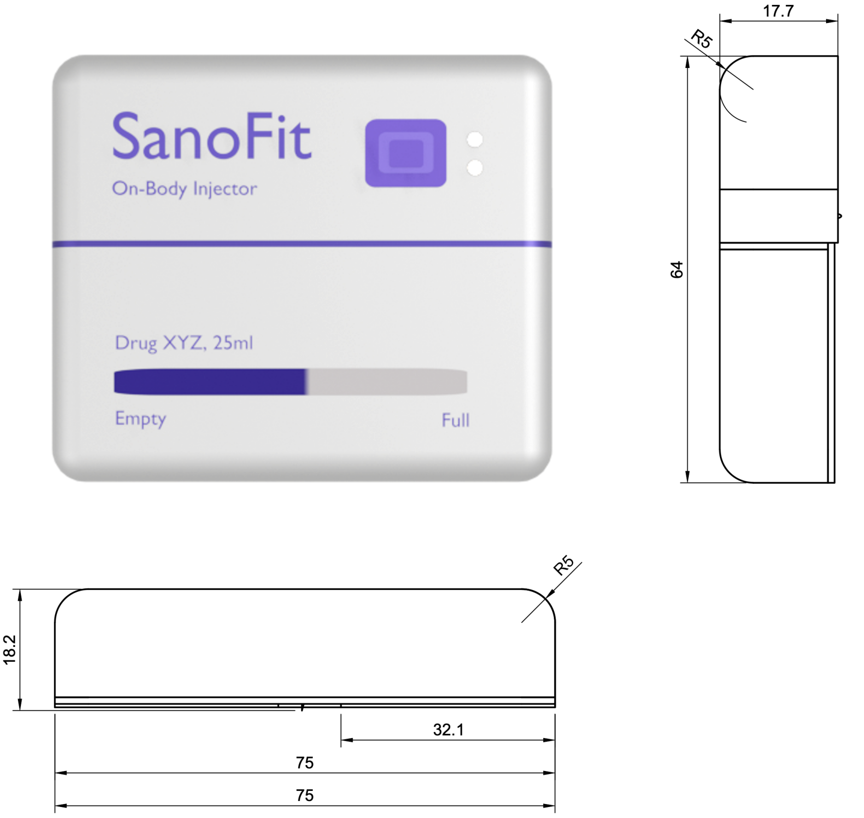

Figure 2.5: Device cartridge with dimensions. The device cartridge, with dimensions of 75mm x 64mm x 18.2mm, is designed for easy, single-handed use, with all side lengths measuring less than 85 mm to ensure one-handed handling accessibility [16].

Injection module For the injection module, we propose the use of an **indwelling needle** with a soft, flexible cannula. Compared to rigid metal needles, flexible cannula offer several advantages: They **reduce injection-site complications**, provide more **stable infusions**, and do not increase the risk of occlusion. In addition, they **enhance patient comfort** by minimizing pain during infusion and ensuring **more secure placement**. For patients requiring repeated administrations, the **needle can remain in place** between sessions, minimizing physical and psychological stress associated with frequent needle insertions. [17] [18] We propose manufacturing the indwelling needle from medical-grade **polyurethane**, selected for its biocompatibility and thermosensitive mechanical properties. Specifically, the material will be formulated to be rigid at room temperature to facilitate accurate insertion, and to soften at body temperature to **reduce vascular irritation**. Insertion will be performed using a hard metal introducer needle surrounded by the indwelling needle, after which only the softened cannula remains the skin (Figure 2.6).

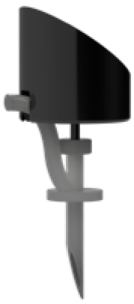

Figure 2.6: Needle assembly, consisting of the hard metal introducer needle surrounded by the flexible indwelling cannula. The metalic needle goes through a rubber stopper. A tube is connecting the indwelling cannula and the tank to enable drug flow.

Vibratory stimulation Needle insertion, and the pain that accompanies it, was one of the most frequent sources of discomfort in our research on patients' experiences. To address this, we explored a non-pharmacological solution to reduce insertion pain. We propose a simple, drug-free method that applies **vibratory stimulation** at the insertion site to reduce perceived pain. We couldn't find any other device or patent that uses this mechanism for on-body drug delivery. In a recent single-blind, randomised controlled trial, this approach produced a **threefold reduction in reported pain** and a **twofold increase in patient comfort** ratings [19]. The technique has also been popularised by clinicians on social media as a patient-comfort "lifehack," including by dentists [20].

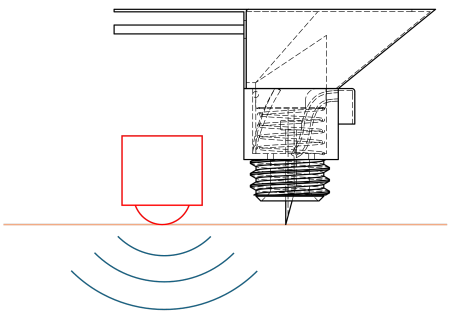

Figure 2.7: Illustration of the injection mechanism and the vibratory stimulation system shown at the interface with the skin. The vibratory stimulation will function to the skin area close to the needle.

Injection mechanism For the injection mechanism of the indwelling needle, we propose a **90° insertion** angle with a penetration depth of 4-5 mm [21]. To minimize overall device thickness while maintaining a vertical insertion path, the mechanism is designed with two main components, a pushing element and a needle element, see Figure 2.8. For improved safety during manufacturing, these components feature **non-uniform geometries** that help prevent misalignment or assembly errors. The needle element is equipped with a **protective cap** (illustrated in red) with Luer lock fitting. When a new injection is needed and a new needle is obtained within a sterile packaging, the user have to unscrew the protective cap and snap it onto the band. This ensures safety in factory production as well as preventing needlestick injury for patients and care-takers.

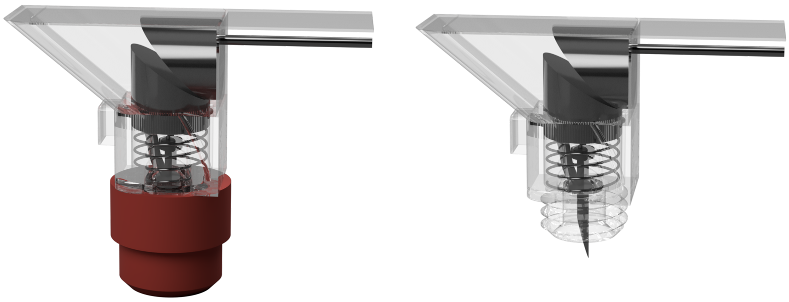

Figure 2.8: The two-component setup ensures a vertical insertion path, with the pushing element shown at the top of the needle element. On the left, the needle element is depicted with its red protective cap, which must be unscrewed before use. The right image shows the needle element without the safety cap.

During operation, the pushing element, positioned at the top is driven forward by a **micro-motor**. As it advances, the pushing element drives the needle element downward, **compressing a spring** until the needle is fully inserted and the **indwelling patch adheres securely to the skin**. Once the sensor confirms proper adhesion, the pushing element continues forward, sliding past the needle element. The compressed spring pushes the needle element upward. Guided by a groove in its design, the needle element rotates 90° as it rises, **locking into a fully upward position** and ensuring safe storage of the needle. The indwelling flexible cannula remains in the skin, connected to the drug reservoir. The section where the hard needle was housed is sealed by a rubber closure, preventing external contamination.

Adhesion to the body To ensure secure adhesion, we propose the integration of a biocompatible adhesive patch which **anchors the indwelling needle to the skin**. The patch will combine flexibility, strong adhesion under movement, and resistance to moisture, using materials **inspired by natural attachment systems** such as octopus suckers[22].

Sustainability considerations To ensure sustainability, the **micro-motor is designed to be reusable**, while the needle actuation requires replacement after each use to maintain patient safety and prevent infections. In the prototyping stage, each component will be evaluated for the feasibility of using **recycled materials, and bio-based polymers**.

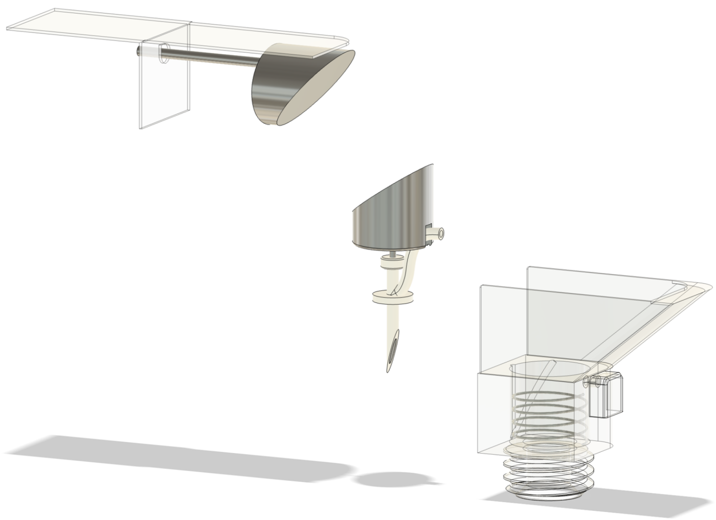

Figure 2.9: Exploded view of the needle assembly: On the top left is the horizontal pushing modules, with asymmetric holes in the cap to ensure proper assembly. In the middle is the needle part with the metal needle surrounded by the indwelling cannula and adhesive patch, with the top metal stub converting the horizontal force to vertical displacement. The tube is connected to the tank. At the bottom right is the spring with the needle module case, which enables automatic metal needle retraction.

User safety sensors To enhance patient safety and minimize device malfunction, we propose integrating a **temperature interlock** into the on-body delivery system. This feature would utilize a sensor within the adhesive patch to verify that the sensor is in place prior to needle deployment. Injection would only be permitted once the measured temperature is within the range of human body temperatures, thereby **reducing the risk of off-body or suboptimal delivery**. For sensing, we recommend an NTC thermistor encapsulated in medical-grade polyurethane as this material is biocompatible and durable. The thermistor would be integrated into the adhesive layer to monitor skin contact temperature. A microcontroller would process the sensor signal and enable motor activation only when the predefined temperature threshold is met.

Additionally, a **mechanical contact sensor** will be incorporated as a redundant safety feature. The sensor is a simple spring-loaded button, which is actuated when pressed firmly against skin, and mechanically enables the needle actuator to be activated. This sensor is an additional safeguard against off-body activation.

Sustainability considerations The proposed safety sensors are intended to be reusable across multiple applications. The NTC thermistor offers long-term durability and stability under repeated use without loss of performance. Similarly, the mechanical contact sensor is designed for reliable actuation over extended lifetimes. By enabling reuse of these components, only the disposable adhesive patch and needle element would require replacement for each application.

2.2 Cost evaluation

To approximate the budget needed for constructing a functional prototype, the expected costs of the major components were estimated. These are summarized in Table 2.2, which provides an overview of the anticipated expenditures for each element of the device.

Table 2.2: Estimated cost for the main elements for prototyping.

Element	**Parts**	**[€]**
Outer part	• No-slip band / Case	8.0
Needle	• Metal needle	5.0
	• Indwelling needle	3.0
	• Adhesive patch	2.0
	• Vibration module	5.0
	• Pushing and needle part	1.0
Subtotal		16.0
Electronics	• Arduino Nano	20.0
	• Micro-motor	6.0
	• LiPo battery (300–500 mAh)	3.5
	• Charger / power-management IC	2.0
	• Regulator (LDO / DC–DC)	1.0
	• Connectors, passives, LEDs, switch	2.0
	• Buzzer / indicator	1.5
	• Potting / conformal coating	1.5
	• Mechanical contact sensor	5.0
Subtotal		42.5
Tank	• Reservoir (25 mL)	10.0
	• Elastomer plunger / diaphragm	1.0
	• Septum / port	1.0
	• One-way check valve	1.5
	• Microbore tubing	0.5
	• Cap / closure	0.5
Subtotal		14.5
TOTAL		**81**

2.3 IP Research / Novelty

A comprehensive intellectual property review was performed to assess potential overlaps with existing designs and technologies. A summary of the findings from the most relevant patents is presented in the table below. Numerous additional patents were reviewed; however, they are not included here as they were deemed irrelevant to the present design. Based on this analysis, our design and its **individual components appear to be unique and do not infringe on any active patents**. Nonetheless, to ensure complete certainty, a formal Freedom-to-Operate analysis by a qualified patent attorney is recommended to validate these conclusions.

Table 2.3: Summary of IP review for SanoFit innovations.

Innovation	Patent Number
• No-slip band	US20180117251A1
Explanation: Protects a wearable autoinjector device with a slot for attaching a band, combined with spring-driven mechanisms for needle extension and drug delivery. **IP Infringement?** Does not infringe. Our device is distinct in purpose and implementation as the device physically interlocks with the band, not just leaving a slot for an attachment point to a band. Our band also incorporates a casing that applies pressure to maintain contact with the skin. This differs from the simple slot-based band attachment disclosed in the patent.	
• Indwelling needle	US20160022902A1 (expired)
Explanation: Covered an indwelling needle design including a needle, cannula, hub, tubing connection, and a controlled mechanism for safe needle withdrawal. **IP Infringement?** Does not infringe. Patent is expired. Our design incorporates similar functionality but is free to use.	
• Indwelling needle	EP1790372B1 (expired)
Explanation: Describes an indwelling needle assembly with inner/outer needles, hubs, and tubing allowing communication between internal cavities, with parallel axis alignment. **IP Infringement?** Does not infringe. Patent is expired and therefore not a concern.	

<table>
<tr><th>Innovation</th><th>Patent Number</th></tr>
<tr><td>• On-body injector</td><td>JP3204337U (expired)</td></tr>
<tr><td colspan="2">Explanation: Protects a vial/container connected to a needleless injector, with detachable nozzle or adapter forming a pre-assembled kit.

IP Infringement? Does not infringe. Expired patent and specific to needleless injectors, which is outside the scope of our design.</td></tr>
<tr><td>• On-body injector</td><td>US11571164B2</td></tr>
<tr><td colspan="2">Explanation: Protects an integrated OBI configuration combining a sensor patch and an injectable dispenser, with physiological monitoring, data handling, and RFID tagging.

IP Infringement? Does not infringe. Our device does not use the claimed architecture or interlocking dispenser-sensor patch arrangement, and differs in system integration.</td></tr>
<tr><td>• Temperature sensor</td><td>JP7051293B2</td></tr>
<tr><td colspan="2">Explanation: Claims a controller that locks injection when the medication temperature is outside acceptable bounds, with alerts and mechanical locks.

IP Infringement? Does not infringe. Our device measures body temperature to confirm placement, not medication temperature. Mechanism and purpose differ.</td></tr>
<tr><td>• Environmental sensors</td><td>US9775957B2</td></tr>
<tr><td colspan="2">Explanation: Protects retrofitting OBIs with smart modules containing sensors, processors, indicators, and connectivity features for operational monitoring.

IP Infringement? Does not infringe. Our device is not a retrofit module, but a purpose-built system. It integrates sensors as part of its original design, avoiding overlap with the claimed scope.</td></tr>
<tr><td>• Vibration motor</td><td>–</td></tr>
<tr><td colspan="2">Explanation: The use of vibration to reduce injection pain is described in academic literature but not actively patented (to our knowledge).

IP Infringement? Does not infringe. Our design incorporates a vibration module to attenuate injection discomfort. No conflicting IP identified.</td></tr>
</table>

Innovation	Patent Number
• Design patents	US D806,234 S1; US D806,235 S1; US D878,550 S1; US D840,024 S1; US D877,893 S1; US D951,434 S1; US D1,078,037 S1; US D1,086,450 S1

Explanation: A range of design patents protecting ornamental features of wearable injectors, including shapes, surfaces, proportions, and contours.

IP Infringement? Does not infringe. SanoFit has a proprietary, custom design that does not replicate the ornamental features claimed in existing design patents.

3 Next steps

We have prepared a **month-by-month plan** for the next phase of the challenge to validate feasibility, demonstrate innovation, and gauge market impact within the available timeframe.

3.1 Testing and Validation Protocol

In this phase, we will produce a functional prototype and run a focused set of **proof-of-concept experiments** covering all critical subsystems: fluid handling, insertion mechanics, system integration, electronics and firmware, user workflow, and safety/fail-safes. The planned experiments are summarized below.

Table 3.1: Testing and Validation Protocol for SanoFit

Needle Insertion Mechanism • Insertion depth precision: 4 - 5 mm target • Penetration force profiling across synthetic skin • Retraction mechanism reliability • Thermoplastic polyurethane surface friction • Disinfection method check (UV irradiation, Ethylene Oxide, Autoclave) • Vibration motor integration: frequency range, timing, insertion interference

Drug Delivery Performance

- Fluid flow modelling via COMSOL
- Viscosity range testing: 1–50 cP using glycerol-water solutions
- Flow rate stability: 0.5–5.0 mL/min with $<10\%$ variation over 5-hour delivery
- Dosage accuracy: across full volume range (5 -25 mL)
- Dead volume quantification: total system <0.5 mL target

Adhesion System Performance

- Adhesive patch bond strength: minimum 2 N/cm^2 over 5-hour period
- Patch area minimization while maintaining secure attachment
- No-slip band tension force: optimal pressure distribution measurement
- Moisture resistance: adhesion under perspiration simulation
- Weight distribution analysis: device stability under movement simulation

System Integration & Safety

- Complete injection cycle validation for 25 mL
- Contact and temperature sensor reliability
- End-of-dose sensing accuracy and priming volume optimization
- Off-body activation prevention: 100% detection success rate required
- Micro-motor precision: speed accuracy for consistent drug delivery
- Electronic component integration: Arduino functionality, battery management, LED indicators
- User workflow simulation: setup, activation, monitoring, completion, removal
- Safety interlock testing: improper adhesion detection, over-pressure protection
- Fail-safe mechanism validation: emergency stop response <1 second

We are confident that, upon entering the next phase of the challenge, these experiments will allow us to refine and optimize the design while clearly demonstrating the merit and value of our design concept.

3.2 Timeline

Table 3.2: Timeline for SanoFit project.

Tasks	Experiments
October: Low-fidelity prototype	
• Source prototyping materials for low-fidelity prototype • Build first low-fidelity prototype • Sanofi x IDEO coaching hours: get feedback on first prototype	• Fluid flow rate testing (varied rheologies, viscosities) • Needle insertion experiments (depth tests) • Fluidic modeling using COMSOL software
November: Refined prototype	
• Source final prototype material samples (needle, insertion mechanism, tank, pump, patch, band, sensor, etc.) • Build refined prototype • Troubleshoot mechanical integration and assembly • Sanofi x IDEO coaching hours: feedback on refined prototype	• Dead volume experiments and optimization • Cannula performance + insertion tests (skin/tissue-mimicking materials)
December: Finalized design	
• Prototype iteration and refinement to final prototype • Final CAD designs • Sanofi x IDEO final coaching hours	• Electronic component integration + functional testing • User interface and workflow simulation • Safety and fail-safe validation
January: Pitch	
• Prepare pitch	• Full-system mechanical testing (validate integrated operation)

4 References

[1] R. Dorati, D. Cosco, L. Battaglia, M. Cirri, B. Conti, T. Borghi, M. Gabriele, G. M. Bruno, P. Rocco, F. Selmin, F. Maestrelli, *Drug Discovery Today* **2025**, *30*, 104441.

[2] C. Gross, *ONdrugDelivery* **2022**, Expert View article in “Wearable Injectors” issue, 6–9.

[3] P. Green, A. Schneider, J. Lange, *mAbs* **2024**, *16*, 2402713.

[4] S. Ren, *Journal of Pharmaceutical Sciences* **2025**, *114*, 103877.

[5] M. Parker, K. Chellappan, D. Cottenden, *ONdrugDelivery* **2023**, Expert View article in “Wearable Injectors” issue, 12–15.

[6] Sanofi, SARCLISA 20 mg/mL concentrate for solution for infusion – Patient Information Leaflet, electronic Medicines Compendium (eMC), Last updated on eMC: March 21, 2025, **2025**.

[7] A. V. Badkar, R. B. Gandhi, S. P. Davis, M. J. LaBarre, *Drug Des Devel Ther* **2021**, *15*, 159–170.

[8] ten23 health, Addressing the Challenges of Developing Large Volume Drug/Device Combination Products for Parenteral SC Delivery, Contract Pharma, **2022**, `www.contractpharma.com/library/challenges-of-developing-large-volume-drugdevice-combination-products-for-parenteral-sc-delivery`.

[9] S. Duband, *ONdrugDelivery* **2021**, 36–40.

[10] Grand View Research, *Grand View Research* **2024**, Global on-body injectors market estimated at USD 5.5 billion in 2024, projected to reach USD 12.7 billion by 2030 (CAGR 14.9 %).

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5 Appendix

5.1 Computer-aided Design and Drafting of SanoFit

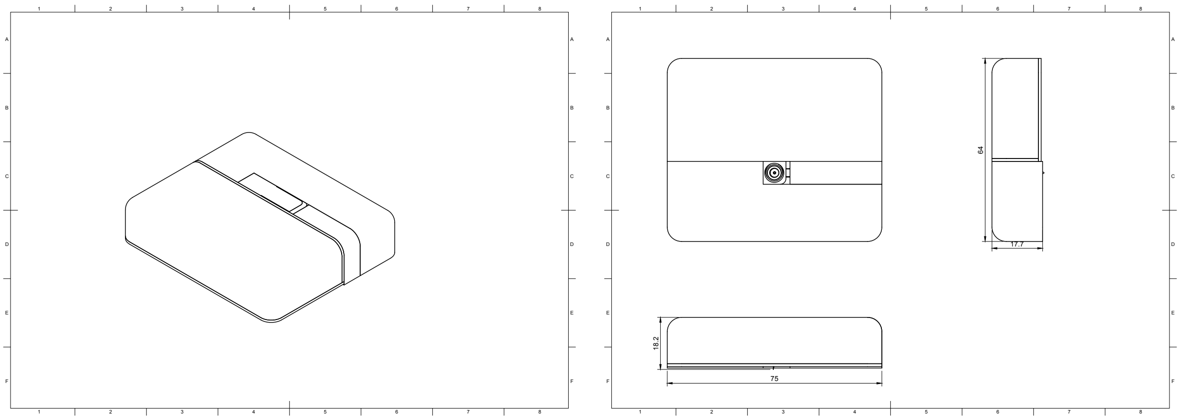

Figure 5.1: Geometries and dimensions of the device.

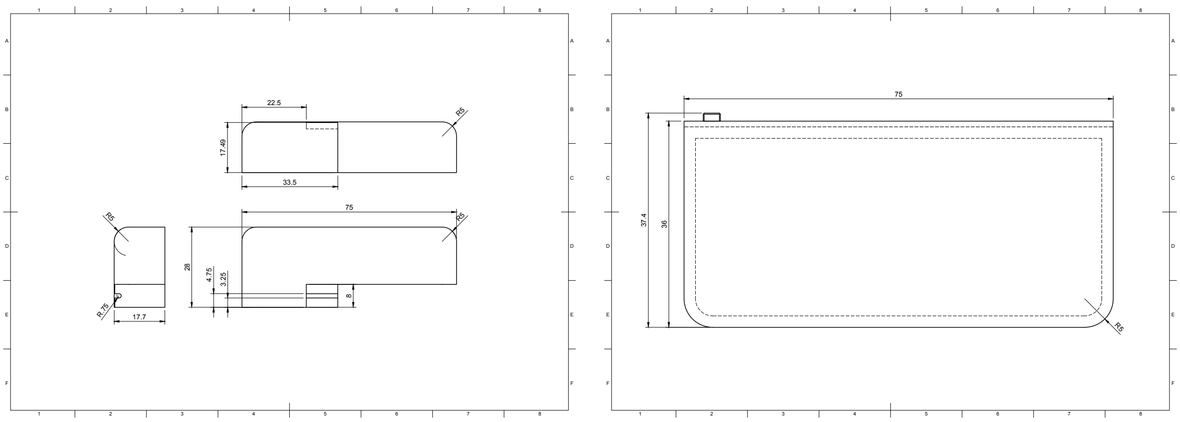

Figure 5.2: Geometries and dimensions of the electronic modules (left) and the drug tank (right).

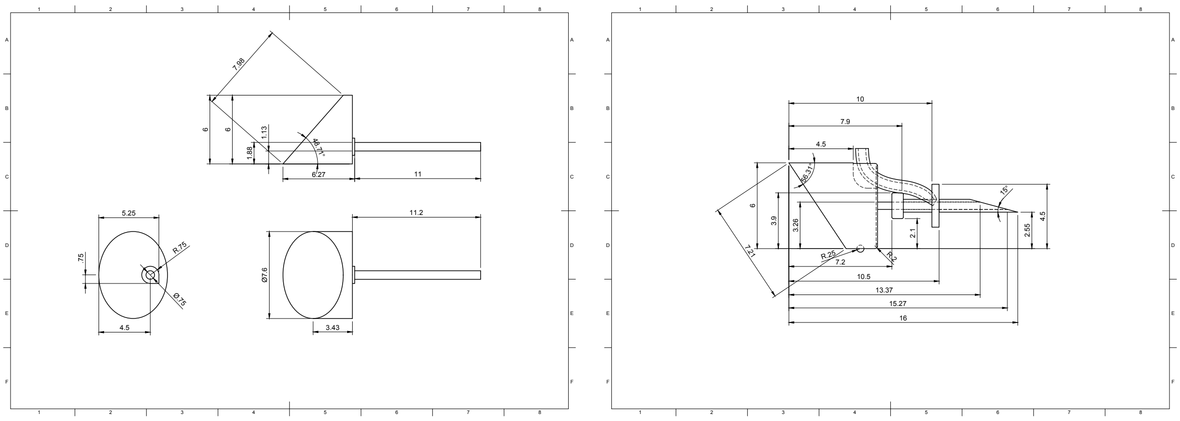

Figure 5.3: Geometries and dimensions of the needle part inside needle modules.

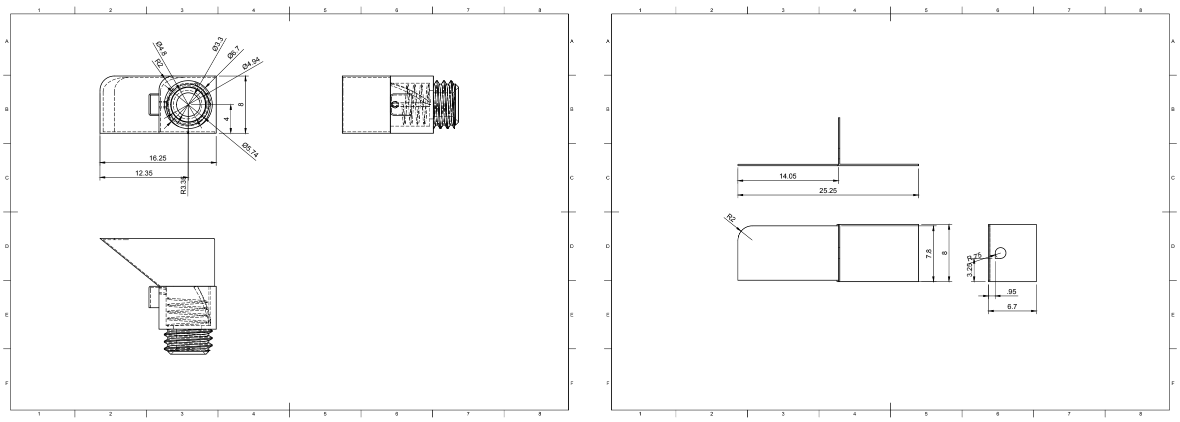

Figure 5.4: Geometries and dimensions of the needle modules with the main part (left) and the cap (right).