Design and Validation of Innovative Prototypes for Effective Sealing of PP Sterilization Wraps

Naveen

TU Delft

Design and Validation of Innovative Prototypes for Effective Sealing of PP Sterilization Wraps

by

Naveen

to obtain the degree of Master of Science
at the Delft University of Technology
to be defended publicly on Friday September 22, 2023 at 12:15 PM

Student number:	5459907	
Project duration:	March 1, 2023 - September 22, 2023	
Thesis committee:	Dr. ir. T. Horeman	TU Delft, Chair
	Dr. B. van Straten	TU Delft, Daily Supervisor
	Prof.dr. J. Dankelman	TU Delft
Faculty:	Faculty of Biomedical Engineering, Delft	

TU Delft

PREFACE

This project has provided me with an opportunity to contribute to the broader goal of making healthcare more sustainable and to immerse myself in the realm of new product development,. It was motivating to discover that there were currently no commercially available sealers designed specifically for this purpose. Overcoming the challenges associated with this project became even more meaningful as I realized the potential impact it could have. Throughout this journey, I have gained valuable insights into sustainability in healthcare and the practical aspects of medical instrument development and regulations. I am proud of the knowledge and experience I have acquired during this process.

I would like to express my sincere gratitude to my supervisors, Tim Horeman and Bart van Straten, for the guidance they provided. Their enthusiasm and support at every stage of the project were instrumental in motivating me to strive for excellence. I am also immensely grateful to the employees of Maastad CSA, particularly Carol, Andrea, and Corinne, for generously sharing their time and offering suggestions for improvement. I would also like to thank Patrick van Holst for his assistance with the tests.

Finally, I want to extend my deepest gratitude to my parents and sister, who have been unwavering pillars of support throughout the roller-coaster journey of my master's degree. Their constant encouragement and steadfast support have consistently enriched my life, making each moment more beautiful and meaningful.

Naveen
Delft, September 2023

CONTENTS

List of Figures

List of Tables

Design and Validation of Innovative Prototypes for Effective Sealing of PP Sterilization Wraps

Naveen
Biomedical Engineering
3ME, TU Delft, The Netherlands
Nnaveen@tudelft.nl
5459907

***Abstract*—The sterile packaging of instrument trays containing medical devices is a critical step in the sterilization process for various medical and industrial applications. This process involves wrapping instrument trays with nonwoven polypropylene sterilization wrap, which plays a crucial role during and after sterilization. Traditionally, the loose ends of the wrap are secured using autoclave tape. However, the presence of this tape poses a risk of recycling contamination when the wraps are disposed of for recycling. Additionally, in some cases, the autoclave tape has been found burnt at the end of sterilization due to excessive use during the packaging process. This study aims at designing and developing a prototype sealing device that eliminates the need for autoclave tapes while maintaining the integrity of the sterile barrier system. During the study, two prototypes of sealing devices were developed: one utilizing ultrasonic sealing technology and the other using impulse sealing technology. The ultrasonic sealer is sourced from a cold-fusion sealer, while the impulse sealer is obtained from a plastic packaging device. Both devices are upgraded and repurposed as per the drawn-up requirement specifications and development criteria. To validate the prototypes, a product characterization test is conducted optimizing the seal time settings based on seal strength tests following ASTM F88/F88M-21. The optimum seal strength, measured using the T-peel test, is determined to be 1.21±0.05 N/mm for the impulse sealer and 0.93±0.08 N/mm for the ultrasonic sealer at the optimized seal time for a test sample width of 30 mm. This is succeeded by, a demonstration of the prototypes at Maastad CSA in Rotterdam, assessing the usability and functionality of these devices. During demonstration sealed sterile packages were made following a standard envelope wrapping approach. Replacing autoclave tapes with the seals at the critical points to secure the wrap. Feedback is collected from employees regarding the new method of packaging. Two sealed sterilization packages produced following the use of both prototypes are subjected to a trial run in an autoclave for sterilization testing. The seals proved to be effective in withstanding the sterilization process without compromising the package integrity. The results of this study contribute to sustainability efforts in the healthcare sector by offering a more efficient and environmentally friendly approach to maintaining the sterility of reusable medical devices.**

***Index Terms*—Sterile barrier system, nonwoven polypropylene sterilization wraps, ultrasonic sealers, impulse sealers.**

I. Introduction

The sterilization protocols implemented in the healthcare sector play a pivotal role in ensuring a safe and effective utilization of reusable medical devices (RMDs) during surgical procedures. A standardized operating procedure (SOP) is followed based on standards ISO 11607:2019 [1] & EN 556-1:2001 [2] to achieve sterilization, encompassing multiple essential steps including cleaning, disinfection, and sterilization of RMDs. Currently, after undergoing the disinfection process, the RMDs are meticulously wrapped in polypropylene (PP) sterilization wraps before proceeding to autoclaves for sterilization. This crucial utilization of wrapped PP sterilization nonwovens acts as an indispensable sterile barrier system (SBS) throughout the entire sterilization process, as well as during transportation, storage, and the aseptic presentation of RMDs at the point of use [3].

Fig. 1: Visual representation of the envelope wrapping method forming a sterile barrier system using bonded double PP sterilization wrap.

Generally, parallel and envelope methods are employed to wrap the instrument tray using PP sterilization fabric. Autoclave tape is then utilized to secure the loose ends of the wrap to complete the formation of the SBS. The temperature-indicating autoclave tapes are replaced with paper tape as this feature was added to the instrument tray identification stickers. Nevertheless, the utilization of paper tape to secure the wraps presents notable drawbacks. Firstly, a few instances were reported at Maastad CSA, where the use of extensive length of paper tape often ends up burnt after undergoing sterilization in autoclaves. Secondly, after use, when the PP sterilization wraps are disposed of, any accidental remains of the autoclave tape pose a significant risk of recycling contamination. These drawbacks associated with the use of tape in sterile packaging can indeed be described as ”one bad apple spoils the whole barrel” with the potential to undermine the overall effectiveness of the recycling process.

This study aims to address both of these drawbacks effectively in collaboration with Maastad CSA in Rotterdam. The proposed solution involves eliminating tapes by introducing an alternative sealing device to secure the loose ends of the PP sterilization wrap. As per the preliminary literature study, it is found that the wrapping of the nonwoven PP sterilization fabric follows a concept of 'tortuous path' for SBS, preventing any event-related compromises in the integrity of the SBS [4]. Hence, the sealing devices are required to seal the loose ends externally, without majorly altering the wrapping methods. To ensure that the validation methods accurately reflect the real-case scenarios, the test samples are made using the Halyard H400 wraps with two sheets of 62.7 g/m^2 (total gsm being 125.4 g/m^2) [5], identical to the wraps employed by Maastad CSA in Rotterdam. The melting point of all the fabric grades (H100 - H600) is found to be the same, reaching 150°C [5]. Inferring that regardless of the specific grade of fabric, they will all undergo melting at this temperature.

Following the changes needed in the sterile packaging to incorporate the proposed solution, the standard ISO 11607-1:2019 makes it mandatory to conduct the tests on package integrity (seal strength) [1]. The stability (shelf-life) tests become optional as altering the material composition and improving wrapping methods of already established protocols are not in the scope of this study [1]. In line with the proposed solution, the goal of this research is to design, develop, and validate a handheld sealer device for polypropylene blue wraps that can be used in any sterilization department.

The upcoming section (Section II) includes the requirements and criteria guiding the development of the prototype sealing devices and validation. Section III provides an overview of chosen commercially available sealing devices followed by a concise depiction of the iterative design concepts for a handheld component intended for the impulse sealer. This is followed by a concept assessment and ends with a detailed description of the final prototypes of both impulse and ultrasonic sealers. The subsequent sections of the 'Validation method' encompass the protocol for the product characterization and the method of usability and functionality demonstration as part of the validation. The outcomes derived from these procedures are showcased in Section V. The next Section VI delves into the discussion of the results, with a primary focus on outlining the requisite future steps for the effective implementation of the sealing devices. An overall conclusion is drawn in Section VII. Relevant appendices on design improvement for manufacturing, statistical analysis, and wrapping methods can be found at the end of this study.

II. Requirements and Criteria

Preliminary discussions with CSA employees resulted in noting portability as the key requirement for the usability of the sealing device. This is considering the wide range in size of the instrument trays used, and the use of prototype devices will be compared with autoclave tapes which are handy. Furthermore, no regulations are published specifically to the design of tools used in sterilization departments, while the regulation ISO/TS 22421:2021, the "common requirements for sterilizers for terminal sterilization of medical devices in health care facilities", is found to be specific to the design of sterilizer units [6].

A. Requirement specification

The key requirements for the design of the sealer devices have been divided into three categories; (a) functional requirements, (b) performance requirements, and (c) safety requirements.

1) Functional requirements: The functional requirements include the following in relation to the effective functionality of the device;

- Must be able to reach a temperature higher than the melting point of PP sterilization wraps 150°C [5].
- The sealing must not cause adverse effects such as burning of the sterilization wrap leading to compromise in the integrity of the sterile barrier.
- The device needs to be consistent in producing quality seals with good seal strength validated through tensile testing.
- The device needs to be handheld and intuitive to use.

2) Performance requirements: Based on the need for an effective sterile barrier, the following performance requirements have been listed;

- The device must be compatible with producing seals for PP sterilization wraps of fabric grade up to H400 (125.4 gsm).
- The device should not compromise the sterile barrier visually or physically.
- The seals produced by the device must be able to sustain the steam sterilization process through an autoclave (121°C for 15 minutes or 134°C for 4 minutes).
- Easy tear-off seals, providing access to the medical instruments at the point of use.

3) Safety requirements: Referring to the standards of EU-MDR 2017/745 [7] following safety and labeling requirements are listed;

- The design must not incorporate any sharp edges that can cause injuries.
- All the electric shock hazard needs to be eliminated by having no accessible live parts.
- Device needs to incorporate visual and/or acoustic alarms to alert the user to a hazardous situation (especially during sealing).
- Availability of enough space for a label on the device (Annex VI -Part C).

B. Development criteria

In addition to these requirements, the sealer device is preferred to meet the following criteria.

- Preferred to be compatible with the current wrapping methods (envelope or parallel method) of the PP blue wrap making a sterile barrier.

- Ease of use, requiring sealing to be achieved with hand-applied pressure and needing only straightforward instructions for use.
- The prototypes are reliable and provide up to fifty consistent seals.
- Components that require frequent replacements are designed to be easily replaceable for user convenience.
- Preference is fabricating plastic components using recycled Polypropylene (rPP) material, contributing to sustainability.
- Final product to be manufactured using injection molding.
- Cost of the device is comparable with the spending on autoclave tapes, monthly expenditure on the autoclave tapes are estimated at 280 €(144 rolls at 1.95 €per roll).
- The prototypes can be developed into a final product featuring various variants for use with different sizes of instrument trays.

III. Prototype Design

This section provides comprehensive information on the advancements made with the prototype development in the project. Initially, the current sealing equipment that are employed industrially, either in the production of the nonwoven fabrics or surgical masks are considered to identify the availability of feasible commercial sealers. Manufacturing of the PP sterilization wraps involve sealing of the microfibres by employing the thermal calendar rolling (heat sealer), these are specially dedicated to industrial applications and continuous production lines. Considering the fabrication of surgical masks and PPE kits made of nonwoven fabrics, generally, the industrial ultrasonic sealers with pneumatic actuators are employed to seal the layers of the fabric achieving the required pressure of 0.14-0.69 MPa [8]. Due to their bulkiness and limited portability, the existing equipment was deemed impractical for sealing sterile packages. Consequently, commercially available impulse and ultrasonic sealers were opted, as they presented viable alternatives that employed similar sealing technology. The following subsection of "apparatus" describes the specifications and working principle of the opted commercial devices along with the need for re-purposing and upgrading the sealing devices, followed by with the design concepts for the prototypes.

A. Apparatus

The development of the prototypes involved the utilization of commercially available sealers as the initial sealing devices. Subsequently, upgrades were made to these sealers in order to align them with the specified functional, performance, and safety requirements.

1) Impulse sealer: A 250 W heavy-duty impulse sealer (Fig 2) typically used for plastic packaging is chosen to be modified and re-purposed as per the requirements. Traditional impulse sealers tend to be bulky primarily due to the copper transformers responsible for generating high-current impulses. These impulses are then conducted through a high-resistance nichrome heating element, resulting in the generation of heat in turn facilitating the fusion of individual layers. However, these impulse sealers are designed as tabletop devices, where the material to be sealed is placed on the housing and pressed by operating the lever on top. This existing tabletop design is deemed inefficient per the requirements of this study in terms of functionality, which is one of the primary requirements.

Fig. 2: Heavy-duty impulse sealer commonly used in plastic packaging.

TABLE I: Product specification of heavy-duty impulse sealer

Specifications	
Source	220-240 VAC, 50-60 Hz
Rated power	250 W
Seal width	1.6 mm
Seal length	200 mm
Seal time	Up to 3 seconds

To overcome this limitation, a handheld piece is designed & developed as a prototype. In order to achieve a lighter and more compact design of a handheld piece, the components had to be reorganized with only the essential lighter components such as the limit switch and the sub-assembly of the heating element, relocated to the handheld piece. By optimizing the placement of components and separating them between the generator unit and the handheld piece, the prototype aims to strike a balance between functionality, serviceability, and ergonomic usability.

2) Ultrasonic sealer: A 30 W ultrasonic cold-fusion hair extension device is considered to be upgraded to seal the PP sterilization wrap. This device is tuned to reach a temperature of 120 °C to seamlessly fuse the hair extensions to the keratin. An ultrasonic sealing device utilizes an oscillator unit to convert the main supply of 220-240 VAC into high-frequency ultrasonic vibrations ranging from 55 to 60 kHz using a piezoelectric transducer coupled to a booster. The booster is then connected to a welding tool known as a sonotrode, which transfers the mechanical vibrations to the sealing area. The fusion occurs as a result of the generated heat during the process depending on the seal time.

One of the advantages of ultrasonic sealers is their low energy consumption, which results in minimal heating of the

sonotrode. As a result, the sealed material can be processed immediately. The specification of the considered device is provided below in table II.

Fig. 3: Ultrasonic cold-fusion hair extension device considered to be modified as per the requirements of sealing PP sterilization wrap.

TABLE II: Product specification of ultrasonic cold-fusion hair extension device.

Specifications	
Source	220-240 VAC, 50-60 Hz
Rated power	30 W
Weight	Handheld piece - 115 g
	Oscillator - 650 g
Frequency	55-60 kHz
Seal time	Up to 5 seconds

As for the handheld piece of the ultrasonic sealer (Figure 4), it is deemed feasible, eliminating the need for any further design concepts related to the prototype.

Fig. 4: Handheld piece of the ultrasonic cold-fusion sealer.

Conventionally, pneumatic plungers are used to apply the necessary pressure while sealing surgical masks. However, in the case of this device, which incorporates a handheld piece for sealing, the amount of pressure that can be exerted by hand is limited. Therefore, when compared to ultrasonic sealers that utilize pneumatic plungers, this device requires a longer duration to reach the required temperature for effective sealing of PP sterilization wrap.

B. Design concepts

The main focus of the concept development process was to design a handheld piece for the impulse sealers, aligning with the requirements listed in Section II. The design concepts were created using SolidWorks software.

1) Concept 1.0: In the initial concept 1.0, the design of the handheld piece resembles a conventional stapler or a hair straightener, depicted in Figure 5. A significant enhancement in this concept is the inclusion of a compliant hinge, which reduces the number of parts compared to a typical spring-reinforced hinge with a center pin. These prototypes were developed as proof-of-concept models, and as such, the auto-switching feature with the limit switch is not incorporated into the handheld piece.

Fig. 5: Design of Concept 1.0 for a handheld piece unit with an impulse sealer developed using SolidWorks.

The design philosophy of the prototype offered several advantages, including portability, intuitive and easy-to-use features, and cost-effectiveness. The overall size of the prototype measured 200 x 85 x 25 mm. The internal assembly of the prototype includes the main heating element, which is an 80 mm long nichrome strip with a width of 1.6 mm, as depicted in Figure 6.

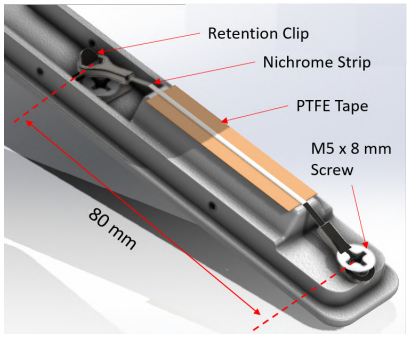


Fig. 6: Assembly of the nichrome strip (80 mm) along with the retention clip, PTFE tape, and fasteners.

To maintain portability and ergonomic usability, the length of the nichrome strip was reduced to 80 mm. However, for the prototype to meet the necessary resistance rating for a 250 W heavy-duty impulse sealer, it required a 200 mm long nichrome strip with a width of 1.6 mm. The change resulted in

a significantly lower resistance, causing the heating element to burn out after some use, rendering it unreliable. This limitation had to be addressed to achieve a more robust and functional design. Increasing the length of the heating element to 200 mm is not considered to be a feasible option as the overall size of the design would result in hindered handling and usability.

2) Concept 2.0: Acknowledging the limitations of the previous concept, a new direction on design philosophy is chosen leading to the development of Concept 2.0. This adopted the form of an ultrasonic probe as shown in Figure 7. The activation of the sealing process is made as simple as pressing the device against the intended sealing area. The support on the posterior side of the wrap is planned to be provided by the instrument tray.

Fig. 7: Design of Concept 2.0 for a handheld piece unit with an impulse sealer developed using SolidWorks.

This design incorporated a heating element (nichrome strip) of the full required length (200 mm), thus the limitation of reliability and functionality were resolved. However, there are some limitations that were discovered later. As there were no features to hold the PTFE mesh in place over the heating element. Furthermore, the design did not incorporate a heat shield to protect the 3D-printed parts from melting. Based on the overall size of the design it was not ergonomic for use.

3) Concept 2.1: This incremental design change from Concept 2.0 was aimed at resolving the limitations that were discovered. The design for Concept 2.1 (Figure 8) featured a sheet metal heat shield to protect the 3D-printed parts from melting. With respect to the provision for holding a PTFE mesh over the heating element, the needed holding parts were included in the design with serviceability in focus. As this is the part that would need the most frequent replacements. Overall, the design for the enclosures was improved, the thickness of the device is reduced by 10 mm, and the width of the enclosure is decreased by 40 mm, with a reduction of around 30% in volume. Thus, this concept was finalized for the fabrication of the final prototype of the handheld piece on impulse sealer.

Fig. 8: Design of concept 2.1 for a handheld piece unit with an impulse sealer developed using SolidWorks.

C. Concept evaluation based on development criteria

An iterative process is followed to continuously improve the design of the concepts for the handheld piece of the impulse sealer. Prototypes were created on the basis of proof-of-concept prototypes and were examined. In order to ensure the best concept of the design is chosen, a Harris profile is drawn up with respect to the development criteria, as shown in Table III.

It is to be noted that from Concept 1.0 to Concept 2.1, the reliability and consistency in producing visually acceptable seals with no visible physical damages have increased from around 2 seals to more than 50 seals, without replacing any component of the device. With respect to serviceability, additional features were incorporated to facilitate the replacement of the PTFE mesh, whenever needed. As a result of these continuous improvements in performance, the manufacturability and cost have increased due to the increase in the custom-made parts from 3 to 6 in concept 1.0 to 2.1 respectively. The same can be depicted in the Harris profile that with the improvements made based on reliability, consistency, and serviceability, the factors of manufacturability and cost have taken a hit.

TABLE III: Evaluation of the concepts using the Harris profile on the basis of listed development criteria.

Development criteria	**Concept 1.0**	**Concept 2.0**	**Concept 2.1**
Compatibility			
Ease of use			
Reliability			
Consistency			
Manufacturability			
Serviceability			
Cost			

D. Final prototypes

The final prototype developed for the handheld piece of the impulse sealer and the electronic upgrades employed to

make the considered commercial sealers have been described in detail in the following subsections. These are the prototypes used to produce the seals following the protocols for validation tests.

1) Impulse sealer: The final prototype of the impulse sealer consisted of two main sub-assemblies: the generator unit and the handheld piece (Figure 9). The existing housing of the tabletop impulse sealer was found to be robust and well-built, hence this was utilized as the housing for the generator unit by removing the redundant parts. The generator unit is comprised of the bulkier components including the copper transformer, control relay, control PCB, and buzzer.

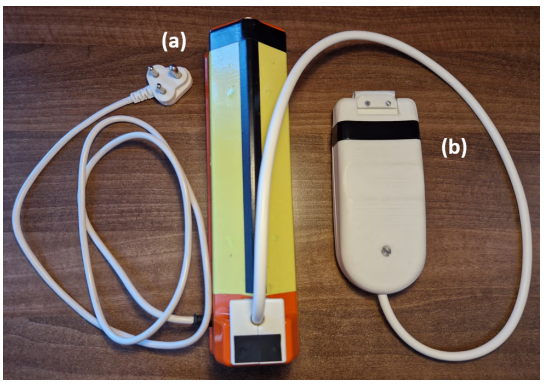


Fig. 9: Prototype of the Impulse sealer; (a) the generator unit, and (b) the handheld piece of impulse sealer.

On the other hand, the handheld piece is designed to house the essential parts required for functionality. These include a limit switch, slider, retention clip, PTFE tapes, and a heating element (Nichrome strip). The enclosures of the handheld piece are designed in the form of a probe, comprising an upper and lower enclosure. A seam seal with a length of 25 mm and width of 1.6 mm is derived from this design of the handheld piece. The functionality of the prototype is designed to be intuitive, as the tip of the handheld piece just needs to be pressed against the area to be sealed and a beep from the buzzer along with a LED indicates the seal time. However, it is advised to hold the probe steady for two more seconds after the beep to provide better seal strength. The primary instructions on safety and use are provided on the housing of the generator unit.

The prototype of the handheld piece consists of the following components (Figure 10);

(a) Upper enclosure: The enclosure's inner surface has two reinforcing ribs that guide the slider unit. The outer surface is ergonomically designed for thumb placement. To ensure a high-quality finish during 3D printing, the part maintains a thickness of 3 mm. It is assembled to the lower enclosure by aligning the lip around the edge and securing it with a flat head M5 x 30 mm screw.

(b) Lower enclosure: The lower enclosure serves as the main assembly module, housing both the limit switch and the slider unit. Like the upper enclosure, it features identical ribs on the inner surface for reinforcement and guide the slider unit. The limit switch is attached using two pan head M3 x 15 mm fasteners.

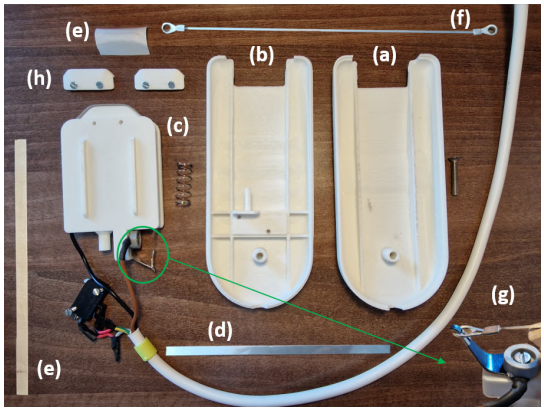


Fig. 10: The components of the handheld piece; (a) Upper enclosure, (b) Lower enclosure, (c) Slider, (d) Heat shield, (e) PTFE tape, (f) Heating element, (g) Retention clip, and (h) PTFE hold.

(c) Slider: The slider unit is designed with functionality as the primary focus. It consists of multiple components such as the retention clip, heat shield, PTFE tape, PTFE hold, and heating element. Two guiding ribs on each side facilitate smooth movement of the slider unit within the enclosure. Additionally, the slider unit acts as an insulator, effectively separating the live and ground connections of the heating element. This insulation ensures the device operates safely, preventing any undesired electrical contact or short circuits.

(d) Heat shield: To safeguard the 3D printed PLA slider from melting, a heat shield is employed. This shield comprises a 0.5 mm thick, 8 x 200 mm stainless steel sheet that is bent and positioned over the slider.

(e) PTFE tape: To prevent unwanted electrical contact with the heat shield, and ensure a heat-resistant non-sticky surface an adhesive PTFE tape is applied between the heat shield and the heating element. Furthermore, a non-adhesive layer of PTFE is placed over the heating element to prevent the PP sterilization wrap from sticking to the handheld piece.

(f) Heating element: A 1.6 x 250 mm Nichrome strip with a thickness of 0.1 mm and lugs crimped at the ends is used as the heating element. Assembled over the adhesive PTFE tape, with one end connecting to the retention clip (live) and the other end secured with a pan head M4 x 10 mm screw (ground).

(g) Retention clip: The retention clip is assembled to the slider unit with a pan head M4 x 10 mm screw, along with a live connection. This places the heating element under constant tension, preventing it from burning itself due to thermal expansion.

(h) PTFE hold: Assembled on either side of the slider unit using two flat head M3 x 8 mm screws, this helps in securing the non-adhesive layer of PTFE over the heating

element. This allows for easy replacement of the PTFE layer when necessary, enhancing serviceability.

2) Ultrasonic sealer: The considered ultrasonic cold-fusion device was found to be tuned to reach a temperature of 120 °C. The sonotrode, booster, and piezoelectric transducer (PZT) are the mechanical components that could be changed to improve the sealing, however, these components were already tuned to reach a maximum temperature of up to 200 °C. As the ultrasonic sealer utilizes mechanical vibrations and pressure to produce frictional heat, the duration or seal time plays a crucial role. The longer the power supply produces mechanical vibration and the longer the pressure is held, the higher temperature is reached. Hence the necessity was to increase this duration or the seal time. The seal time in the PCB of the oscillator unit is found to be utilizing an adjustable timer using 555 & trimmer potentiometer as shown in Figure 11.

A 10k ohm potentiometer was being used to tune the seal time from 0 to 5 seconds, which would only reach a temperature of 120 °C. However, a temperature of 150 °C or higher is needed to achieve an efficient seal on the PP sterilization wrap. Hence, this potentiometer is upgraded from 10k ohm (BOURNS 3362P-1-103LF) to 100k ohm (BOURNS 3362P-1-104), upgrading the seal time from a maximum of 5 seconds to 8 seconds. This fulfilled the requirement to produce an effective seal on the PP sterilization wrap based on preliminary seals produced by the upgraded sealer.

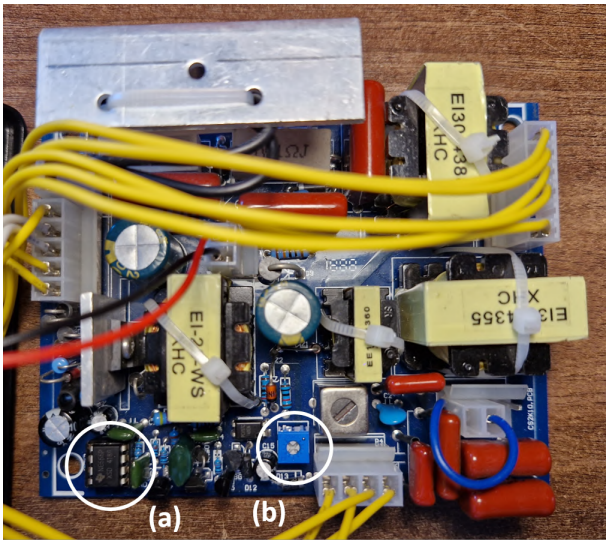


Fig. 11: The components of an adjustable timer using 555 & potentiometer found on PCB of oscillator unit of ultrasonic sealer; (a) 555 timer, and (b) 10k ohm trimmer potentiometer.

IV. Validation Method

In accordance with the requirements outlined in Section II, the final prototypes of both the impulse and ultrasonic sealers underwent validation. The functional and performance requirements are validated through the product characterization test and the usability & functionality tests. Apart from validating the prototypes, the results of the seal strength from the product characterization tests are utilized to find an optimum seal time for sealing. Additionally, since the instrument trays need to be unwrapped at the point of use, the maximum force encountered during the tensile test provides an indication of the maximum effort required to tear off the seals at the point of use. Safety considerations were integrated into the design and fabrication from the initial stages. To ensure this the final prototypes were evaluated by a safety expert from Van Straten Medical, and upon receiving approval, further tests were planned to assess functionality and performance requirements. Table IV, represents the validation techniques employed within this study in relation to the requirements.

TABLE IV: Summary of requirement validation techniques employed within this study.

Tests	Requirements
Product characterization test 1. Seal strength test 2. Seal time optimization	Functional 1. Ability to seal PP sterilization wraps. 2. Seal strength ranges from 1 to 1.5N/mm. Performance 1. Sealing upto H400 grade of blue wraps.
Usability and functionality 1. Wrapping method 2. Prototypes	Functional 1. Ability to seal PP sterilization wraps. 2. Handheld device. Performance 1. Integrity of sterile barrier. 2. Sustain the steam sterilization through autoclave. 3. Easy tear-off of the seals.
Design phase & Visual examination	Safety 1. No sharp edges. 2. No electrical hazards. 3. Visual and/or acoustic alarm. 4. Labeling space.

A. Product characterization test

The specimens to produce the test samples are strips of H400 Halyard "Quick Check" sterilization wraps with the dimensions of 30 x 100 mm as depicted in Figure 12.

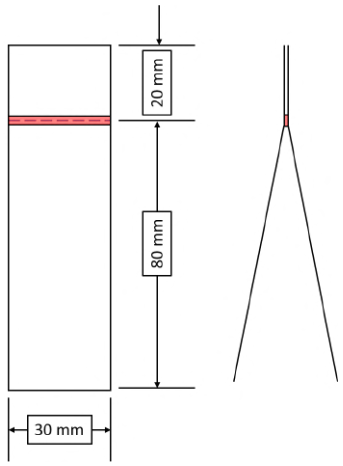


Fig. 12: Schematic representation of the dimensions of the test samples for the tensile test.

These specimens are then stacked making up to four individual layers and sealed with every available seal time setting on both prototypes. The sample size of each available seal time setting is set at four (n = 4), to study the reproducibility and reliability of the seal strength from the prototypes. To ensure a standardized tensile test obtaining reliable results on seal strength, the protocol is established based on the ASTM standard for Seal Strength of Flexible Barrier Materials, specifically ASTM F88/F88M-21 [9]. Continuing with the protocol for the test, a line is marked at 80 mm, indicating the area to be sealed.

- *Impulse sealer*: The prototype takes the form of a probe with adjustable seal time settings. For sealing, the probe tip is placed on the marked sealing area on the stacked specimen, pressed until the beep, and then held for two seconds for cooling. Since the handheld piece needs support from the posterior end, the test samples are sealed by placing them on a stainless steel sheet metal emulating the instrument tray.
- *Ultrasonic sealer*: The protocol for sealing using the ultrasonic sealer involves performing two spot seals on the marked sealing area on the stacked samples. The prototype of the ultrasonic sealer resembles a stapler, and the sample is placed between the sonotrode and the bottom rest of the handheld piece. Hand pressure is applied for the duration indicated by the LED on the oscillator unit, followed by holding for an additional two seconds for cooling.

Once the test samples are sealed, a visual examination is performed to note any physical damages such as burning of the PP sterilization wrap or failure in sealing all four individual layers of the sample. Further, the arms of the test samples are clamped to the universal tensile machine (Zwick 1446 tensile tester) and pulled apart at a rate of 300 mm/min for a displacement of 50 mm, until failure as shown in Fig 14.

Fig. 13: Zwick-Roell 1446 tensile tester apparatus used for the seal strength test setup.

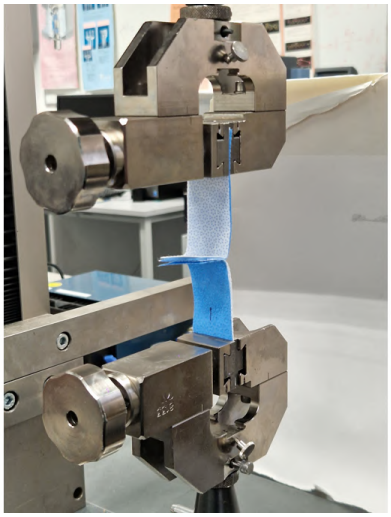


Fig. 14: Test setup for the seal strength with the sample placed between the upper and lower arm of UTM.

1) Statistics: The Statistical Package for the Social Sciences (SPSS) software (IBM, SPSS v.28.0.1.1, Armonk, NY, USA) is utilized for conducting all statistical analyses. Seal strength from each of the test samples is calculated by considering the maximum force encountered during the tensile test, divided by the width of the test sample (30 mm). Mean values and standard deviations are obtained through descriptive analysis of each case of seal time setting. This is proceeded with a Shapiro-Wilk test to examine the normal distribution of data ($p > 0.05$). Later the significance of the seal strength data with respect to the seal time is assessed using the One-way ANOVA test ($p < 0.05$). The null hypothesis stated that there is no significant difference in seal strength with respect to the seal time ($p > 0.05$). The complete data on statistical analysis can be found in Appendix D.

B. Usability and functionality test

The functionality test assesses the effectiveness of sealed sterile packages with slight modifications in employed wrapping methods. When it comes to wrapping instrument trays for sterilization, there are several methods that CSA professionals follow. Halyard as the manufacturer of sterilization wraps, provides specific guidelines on the envelope and parallel wrapping methods which are two of the most followed methods. However, it is worth noting that CSA facilities may have their own specific protocols and guidelines for wrapping the instrument trays for sterilization. At Maastad CSA, the protocol for the wrapping method predominantly follows the envelope wrapping method with some minor changes. In contrast, the usability test is focused on evaluating the ease of using the prototypes to seal the sterile packages.

To facilitate the use of the sealing devices, both the envelope wrapping method and the parallel wrapping method are compared based on the critical points to seal. Initially, it is examined that the upgraded ultrasonic sealer can seal up to a total of 8 individual layers, while the prototype of

impulse sealer can seal only up to 4 individual layers. Using the ultrasonic sealer, the envelope method needed a total of three spot seals. A total of 8 individual layers are to be sealed in each case. Using the impulse sealer, the envelope method needed a seal at the final stage at the front end, sealing a total of 4 individual layers. Whereas theoretically, the parallel wrapping method would require fewer seals, as only the right and left flaps are to be joined, securing the sterile package. However, practically the parallel method would require the sealers to seal up to 16 individual layers. This is not a feasible scenario with handheld devices as sealing beyond 8 layers requires higher compression pressure to ensure that the layers are tightly held together without any air gaps between them.

(a) Parallel wrapping method.

(b) Envelope wrapping method.

Fig. 15: Photographs of commonly employed sterilization wrapping methods.

Moreover, while considering an identical instrument tray with dimensions of 480 x 250 x 60 mm, the envelope method required a PP sterilization wrap of size 1140 x 1140 mm, whereas the parallel method requires larger wrap measuring 1370 x 1370 mm. Hence, the parallel method is not recognized as a viable option, and the envelope method is modified to achieve a reduced number of layers at the sealing point for effective results ensuring that the integrity of SBS is maintained. Two wrapping methods with minor changes were planned to achieve a sterile barrier: the ultrasonic sealer and the impulse sealer. The detailed pictorial representation of these wrapping methods and sealing are presented in Appendix E. With the final method of wrapping based on the suggestions from employees of Maastad CSA, a trial run is conducted by introducing two sealed packages into the autoclave for sterilization. The reliability of the seals is tested both visually and by deliberately tearing the sterile barrier to access the instruments after sterilization.

V. Results

This section delves into the presentation and analysis of the results obtained from the performance assessment of the prototypes. It encompasses the outcomes of all the tests conducted, shedding light on the overall findings of the study.

A. Product characterization tests

The tuning of the seal time setting is based on the visual examination of the seals along with consistency and the maximum seal strength measured during a tensile test of the specimens. The maximum force encountered during the tensile test is noted and divided by the width of the specimen (30 mm) to arrive at the seal strength value (N/mm). While the maximum force is observed as an indicator of the effort needed to break the seals, the seal strength is used to tune the prototype sealers. Results of the tests are discussed below individually for the impulse and ultrasonic sealers.

Impulse sealer: A total of 32 samples were prepared for the tensile testing. Observations during the preparation of samples showed that the lowest seal time (I-1) effectively sealed only two individual layers of the sample. Seal time settings I-2 and I-3 were capable of sealing up to three individual layers.

TABLE V: Results of the tensile test on samples from the impulse sealer. The seal strength (mean ± SD) [N/mm] and max. force [N] from a sample size (n) on each case of seal time.

Seal time	n	Max. Force [N]	Seal strength [N/mm]
I - 1	4	17.47	0.40 ± 0.13
I - 2	4	14.46	0.34 ± 0.17
I - 3	4	32.97	0.82 ± 0.28
I - 4	4	40.15	1.05 ± 0.20
I - 5	4	38.33	1.21 ± 0.05
I - 6	4	42.91	1.19 ± 0.18
I - 7	4	48.82	1.34 ± 0.31
I - 8	4	50.29	1.43 ± 0.23

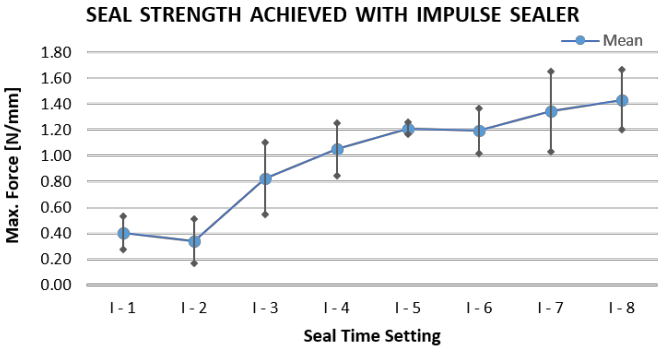


Fig. 16: Plot representing the mean seal strength along with standard deviation (SD) observed with individual seal time setting on the impulse sealer, based on the performed tensile test.

However, the highest seal time setting (I-8) resulted in burning at the corners of the seals, which is undesirable as it can compromise the sterile barrier's integrity. These observations were noted to evaluate the seal strength. Tensile tests were performed on all the 32 samples. A maximum force of 50.29 N is measured at a seal time setting of I-8, representing the effort needed to break the seals while opening the sterile barrier. Table V presents seal strength (mean ± SD) [N/mm], maximum force encountered [N], and sample size (n) as the results of the tensile test on samples with respect to each case of seal time.

Ultrasonic sealer: A total of 24 samples were introduced for the tensile tests. A maximum force of 28.02 N is noted at the highest seal time setting (U-6), representing the effort needed to break the seals while opening the sterile barrier. Table VI presents seal strength (mean ± SD) [N/mm], maximum force encountered [N], and sample size (n) as the results of the tensile test on samples with respect to each case of seal time. Due to an unforeseen crash of the software with the tensile testing apparatus, data on the fourth trial of the U-2 case was lost, hence the sample size was reduced to n = 3 for that particular case.

TABLE VI: Results of the tensile test on samples from the ultrasonic sealer. The seal strength (mean ± SD) [N/mm] and max. force [N] from a sample size (n) on each case of seal time.

Seal time	n	Max. Force [N]	Seal strength [N/mm]
U - 1	4	18.00	0.39 ± 0.25
U - 2	3	29.34	0.69 ± 0.25
U - 3	4	25.61	0.65 ± 0.17
U - 4	4	22.27	0.46 ± 0.24
U - 5	4	21.56	0.60 ± 0.08
U - 6	4	31.34	0.93 ± 0.08

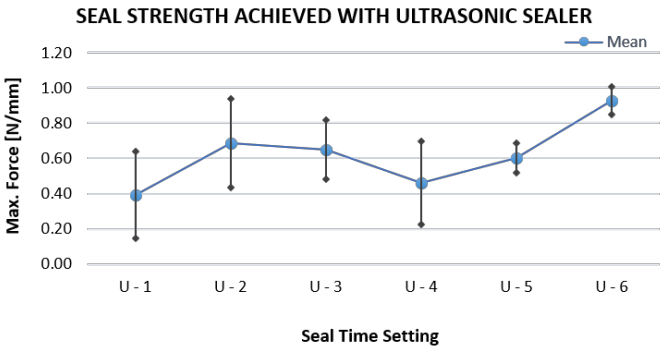


Fig. 17: Plot representing the mean seal strength along with standard deviation (SD) observed with individual seal time setting on the ultrasonic sealer, based on the performed tensile test.

Seal profile: Since all the samples were tested for failure, the progression of the failure modes is differentiated based on the seal profile and visual examination during testing. The progression of failure is classified as the initial break at the edge of the seal, delamination, and finally, tear/separation. For instance, considering one of the trials with seal time U-6, as shown in Figure 18.

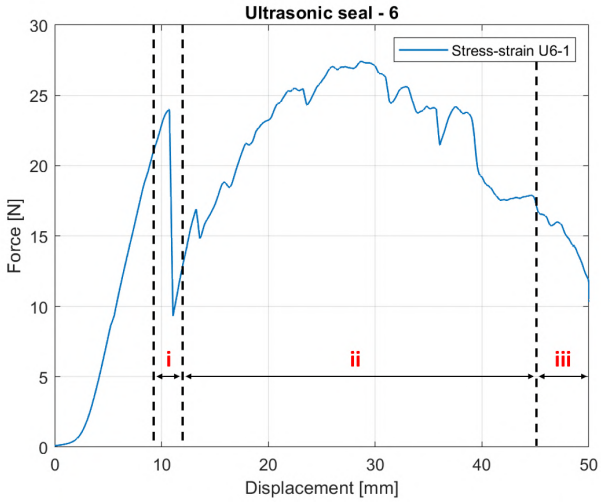


Fig. 18: Defining the progression of failure modes based on the seal profile; (i) break at the edge of the seal, (ii) delamination, and (iii) tear/separation.

The first mode of failure is the break at the edge of the seal, this is identified on the seal profile with an initial peak and then a drop of around >20% in the measured force during the tensile test. Delamination is the period observed after the initial break at the edge, here the resistance is mainly offered by the randomly oriented thermally bound fabrics of the nonwoven sterilization wrap. The final mode of failure is a full tear or the separation of the specimens. The seal profiles of individual tests have been presented in Appendix C.

B. Usability and functionality test

The prototypes of the ultrasonic and impulse sealers were demonstrated as per the methods discussed in section IV and described in Appendix E. First, sterile packages were made using the ultrasonic sealer, the resulting sterile package is shown in Figure 19.

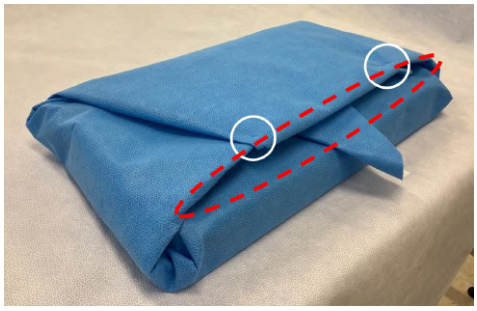


Fig. 19: Sterile package achieved using the ultrasonic sealer; white circle highlights the areas sealed using an ultrasonic sealer, and the red dashed circle highlights the resulting gap.

Based on the demonstration of using the ultrasonic sealer, suggestions were noted on the need to reduce the required hand applied pressure for the seals to be effective. Overall feedback from the employees on the seal strength and the prototype were noted to be favorable, however, the feedback on the functionality of the sterile barrier was based on the visible gap in the package (Fig 19). Though the instrument tray is physically not accessible through the sealed package, the gap on the top is thought to be detrimental to the integrity posing a risk during the sterilization in the autoclave or transportation and storage of the sterile packages.

Moving forward to the construction of sterile packages using an impulse sealer, the result is as shown in Figure 20. Based on the demonstration, the impulse sealer was considered more favorable as the packages didn't present a visible gap. The effort needed to seal the wraps using impulse sealer was seen to be more feasible when compared to the ultrasonic sealer. However, the seal joining the right & left flap of the wrap was not achievable as the impulse sealer prototype needs a solid support below the layers to be sealed. Thus, the sterile barrier was secured with a single seal in the final stage over the top cover at the front (Fig 20).

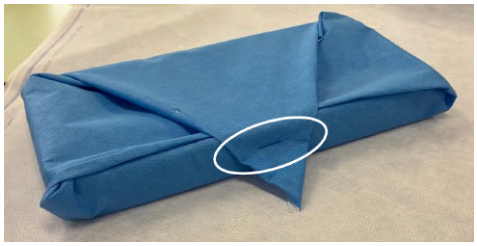


Fig. 20: Sterile package achieved using the impulse sealer; white circle highlights the area sealed using an impulse sealer.

Noting these feedback on the demonstration of the sterile packaging constructed using impulse and ultrasonic sealers separately, the protocol for wrapping method was further tweaked. The improved sterile packaging method followed the same envelope wrapping method but employed both the ultrasonic and impulse sealers to secure the wrap. The right and left flaps were sealed at the center with a spot seal using an ultrasonic sealer as shown in Figure 21.

Fig. 21: The right and left flap during the envelope wrapping method is sealed once using the ultrasonic sealer.

As a final step, the top cover is folded over and sealed at the front using the impulse sealer. The impulse sealer is used twice just to ensure better strength while introduced into the autoclave for sterilization as shown in Figure 22.

Fig. 22: The top flap is folded over and sealed twice using the impulse sealer, two similar sterile packages were introduced into the autoclave for trial runs of sterilization.

Two samples of these sealed sterile packages following the final method of using both the ultrasonic and impulse sealer were introduced to the autoclave for steam sterilization as trial runs. Both the sterile packages were enclosing identical instrument trays of dimensions 480 x 250 x 60 mm filled with a set of surgical instruments. Both the sealed sterile packages presented positive results with the seals capable of maintaining the integrity of the sterile packages during and after the sterilization process. The sterile packages were then ripped opened to check the ease of accessibility to the surgical instruments within. Ripping off the seals of sterile package resulted in damage to the sterilization wrap proving that the seals are solid. As an added benefit, this observed damage can help in detecting if the sterile packages were tampered before delivering them to the final point of use.

VI. Discussion

This work involved developing two prototypes based on re-purposing the commercially available sealers to seal the PP sterilization wraps. While all the requirements were satisfied with the tests conducted, some of the development criteria were outside the scope of this study. For instance, the manufacturability of the enclosures through injection molding using recycled polypropylene and the cost indications. Though some factors of design for assembly and serviceability were taken into consideration during design phase, since the enclosures were fabricated using 3D printers, the thickness was increased to gain better strength & an overall finish. However, the design of the enclosures can be improved for injection molding with some minor changes like featuring the drafts for the vertical faces and separating the locator feature of the spring from the lower enclosure. Additionally, the material usage and cost can be further reduced by decreasing the overall thickness of the enclosures. Furthermore, after incorporating these necessary changes the should-costing can be efficiently implemented for further ideation on cost reduction.

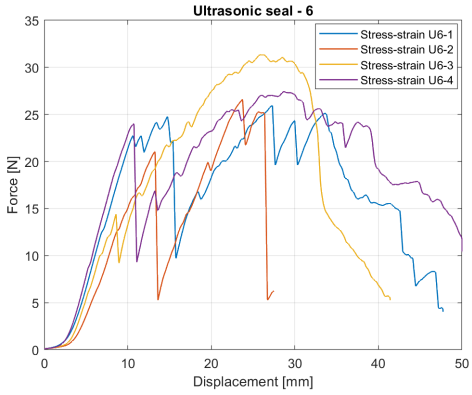
Future research can be established on improving the wrapping methods of the PP sterilization wraps to better facilitate

the use of the sealers. Going forward, in the following subsections, the results presented within this study will be discussed.

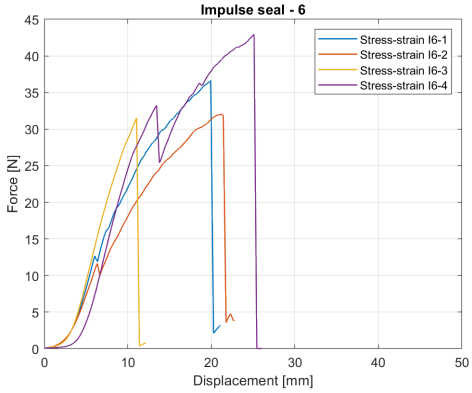
A. Seal strength and seal profile

As described in section IV, the product characterization tests were conducted on the basis of T-peel tests from ASTM F88/F88M-21. The primary results of this test produced seal profile of every individual sample (Appendix C).

The nature of seal profiles from ultrasonically sealed samples present all three stages in the progression of failure modes as described in results. The initial peak in the force is observed to be the break at the edge of spot seals, and the nonwoven fabric in between these spot seals resists the separation producing a delamination phase, hence even the individual fabrics in the wrap play a role here. However, when the seal profiles of the impulse-sealed samples are compared, a clear distinction can be observed (Fig 23). Here the progression of the failure lacks the delamination phase.



(a) Seal profile of the ultrasonically sealed sample with the seal time setting U-6.



(b) Seal profile of the impulse sealed sample with the seal time setting I-6.

Fig. 23: Comparison of the seal profiles of the samples sealed with impulse and ultrasonic sealer.

As the impulse sealer produces a seam seal for the total width of the samples, the tensile force is applied to the total width of the seal. Hence no individual fabric of the nonwoven encounters the tensile force, as the edge of the seal failed under a peak load it leads to the separation of the specimens. However, excluding the seal profiles of the three initial seal times of I-1, I-2, and I-3, as these were not able to seal all four individual layers of the specimen. This is consistent with the seal profiles of 80% of the considered impulse sealed samples. Nonetheless, these samples do exhibit the behavior of breaking at the edge of the seal at a higher maximum force than the ultrasonically sealed samples. This contrast in the behavior of failure can be concluded as a factor of difference in the type of seal and total sealed area with respect to the width of the specimens. Regarding the objective of the product characterization test to tune the seal time settings on the prototypes;

- Ultrasonic sealer: The seal time setting of U-6 is identified as the best optimization available by providing a seal strength of 0.93 ± 0.08 N/mm. It is found to be consistent with the seal strength and efficient in sealing up to eight individual layers of PP sterilization wraps effectively.
- Impulse sealer: The seal time setting between I-5 and I-6 is considered to be efficient for providing a seal strength of 1.21 ± 0.05 N/mm and 1.19 ± 0.18 N/mm, respectively. Notably, the prototype of impulse sealer seals up to four layers of PP sterilization wraps at most.

The ASTM F88/F88M-21 standard provides protocols for tensile testing, but it does not specify any minimum requirements for the observed seal strength on sealing PP sterilization wraps. Part-5 of the standard EN 868-5:2019 specifies a minimum required seal strength for the sealable pouches to be ranging from 1.2 N per 15 mm to 1.5 N per 15 mm used in sterilization departments [10]. However, if necessary, this requirement on the seal strength can be met with the current prototypes as the width of the specimen would decrease from 30 mm (current) to 15 mm (EN 868-5:2019) in turn increasing the seal strength.

B. Performance of the prototypes

Both the prototypes of the impulse & ultrasonic sealer were found to be reliable by providing more than 50 effective seals each respectively. Around 34 individual seals were performed using the impulse sealer during the sample preparation for tensile tests alone. However, if the device is consistently used at a higher seal time of $>$ I-6, the layer of nonadhesive PTFE tape placed over the heating element has to be replaced after every 25 seals. The replacement of this was included as a factor in development criteria and implemented during the design phase. Moving on to the ultrasonic sealer, the PTFE tape is observed to wear out after 15 seals when regularly used at the highest seal time of U-6. The PTFE tape can be easily replaced by just removing the damaged one and placing a new adhesive PTFE tape. Apart from these known frequently replaceable parts, the rest of the prototypes are found to be reliable and consistent with the seal strength when set at their effective seal time settings as per the results of the product characterization tests. Additionally, it is noticed that frequent use of the ultrasonic sealer with no recess between the operation increases the heat in the components present in

oscillator unit. This results in premature cut-off in power to the piezoelectric present in the handheld piece. The same can be observed in the plot presenting with the mean seal strength (Fig 17), with a dip in performance at seal time U-4.

Furthermore, from the usability and functionality tests, the prototypes are found to perform excellently well based on the feedback received from demonstration. The suggestions on the impulse sealer included a feature incorporating a modular handheld piece with options for varied seal lengths which can be implemented during further design phases of product development. However, most of the issues encountered during the trial runs of sealed sterile packages were related to the wrapping method. Such as the presence of the redundant PP sterilization wrap as highlighted in Fig 24, the amount of this redundant material is highly dependent on the initial placement of the instrument tray over the PP sterilization wrap. This potentially increases the probability of human error and event-related breaches to the integrity of sterile barrier system. Be it during transportation or storage activities post sterilization.

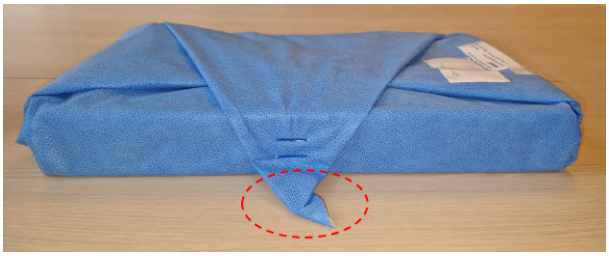


Fig. 24: The extended wrap (highlighted) can cause a potential event-related breach in sterile packaging, during transportation and storage activities.

Current wrapping methods emphasize the sterile integrity of the barrier with the use of autoclave tapes. Future research can address these challenges by developing new innovative protocols for wrapping methods that can enhance the efficiency and effectiveness of sealed sterile barrier. One such potential improvement can be the incorporation of a blue wrap strip at the ends to create a designated sealing area. This modification can enhance the performance of sealed sterile barrier systems and increase efficiency by further reducing human errors. Furthermore, it can be succeeded with stability tests to validate these protocols through shelf-life testing using membrane filtration methods.

Currently, the prototypes have been demonstrated only at a single CSA facility, but as the shelf-life tests are preferred to be conducted with a bigger sample size, including several CSA facilities will help. It is worth noting that protocols for wrapping methods may vary across different CSA facilities. Hence, in future research, it would be beneficial to introduce the new wrapping method protocol utilizing these sealers to multiple CSA facilities. This would provide a more comprehensive evaluation of the protocols' effectiveness.

VII. Conclusion

In conclusion, this study successfully addressed the potential risk of recycling contamination caused due to the use of autoclave tapes on sterile packages. Ultimately developing prototypes of sealing devices capable of securely sealing PP sterilization wraps and eliminating the need for autoclave tapes, a practical and efficient solution is achieved. The prototypes developed using ultrasonic and impulse sealing devices proved to be consistent as the seal time was optimized based on the results of product characterization tests. Furthermore, valuable input from the employees at Maastad CSA was gathered, ensuring that usability improvements are considered.

By redesigning the handheld piece of the impulse sealer for injection molding and ensuring compliance of components with ROHS standards, the prototypes can be transformed into final products suitable for mass production at affordable costs. This study can be continued based on further refinement in the implementation of these sealing devices with the research on wrapping methods. New wrapping methods can be developed with sealing in focus rather than the autoclave tapes, instances like Halyard Smart-Fold sterilization wraps hold significant potential with the addition of designated sealing areas to secure the SBS. These can be further validated by carrying out stability tests in collaboration with several CSA facilities, with a higher sample size for significant results.

Overall, this research provides a promising alternative with sealing devices to mitigate the risk of recycling contamination associated with autoclave tapes in sterile packaging processes, while promoting sustainability and maintaining the sterile integrity of SBS.

References

[1] International Organization for Standardization. Requirements for materials, sterile barrier systems and packaging systems, geneva. *ISO 11607-1:2006/Amd 1:2019 Packaging for Terminally Sterilized Medical Devices—Part*, 1, 2019.

[2] EN 556-1. Sterilization of medical devices - requirements for medical devices to be designated "sterile". *EUROPEAN STANDARD*, 2001.

[3] Chris Newmarker. How to select sterile barrier systems for reusable medical devices. *Nelson labs*, 2017. Available at https://www.medicaldesignandoutsourcing.com/sterile-barrier-systems-reusable-medical-device/.

[4] Thierry Wagner, Jennifer Van Mullekom, Jane Severin, and Michael H. Scholla. Chapter 5 - package/container closures. In Byron J. Lambert, Stan Lam, Joyce M. Hansen, and Trabue D. Bryans, editors, *Assurance of Sterility for Sensitive Combination Products and Materials*, pages 79–134. Academic Press, 2020.

[5] Halyard Health. H400 - technical data sheet, halyard sterilization wrap, 2016. Available at https://www.vingmed.dk/wp-content/uploads/sites/3/2017/03/Technical-Data-Sheet_H400.pdf.

[6] ISO/TS 22421. Sterilization of health care products - common requirements for sterilizers for terminal sterilization of medical devices in health care facilities. *ISO*, 2021.

[7] EU-MDR. Regulation (eu) 2017/745 of the european parliament and of the council of 5 april 2017 on medical devices, amending directive 2001/83/ec, regulation (ec) no 178/2002 and regulation (ec) no 1223/2009 and repealing council directives 90/385/eec and 93/42/eec. *Medical Device Regulations, EU*, 2017.

[8] Barry A. Morris. Chapter 7 - heat sealing in flexible packaging. In Barry A. Morris, editor, *The Science and Technology of Flexible Packaging (Second Edition)*, Plastics Design Library, pages 205–286. William Andrew Publishing, Oxford, second edition edition, 2022.

[9] ASTM F88/F88M-21. Standard test method for seal strength of flexible barrier materials. *Book of Standards, ICS code:55.040*, 15.10:11, 2021.

[10] EN 868-5:2019. Packaging for terminally sterilized medical devices - part 5: Sealable pouches and reels of porous materials and plastic film construction - requirements and test methods. *CEN*, 2019.

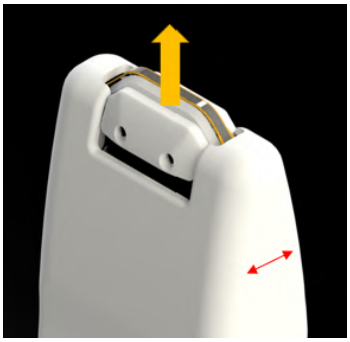
APPENDIX A
DESIGN IMPROVEMENTS FOR MANUFACTURING AND ASSEMBLY

The ultimate configuration of the proof-of-concept (Concept 2.1) serves as the foundation for pursuing additional enhancements in terms of its manufacturing process. The DFMA (Design for Manufacture and Assembly) objectives, which have been delineated below, stand as directives to be adhered to throughout the design phase, particularly when aiming for efficient mass production.

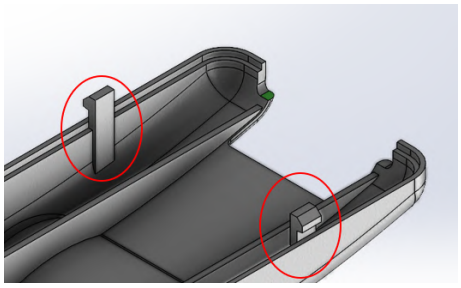
1) Minimize part count; make parts multi-functional
2) Facilitate parts handling
3) Use standard parts and hardware
4) Use stack assemblies
5) Design parts with self-locating features
6) Simplify and optimize the manufacturing process
7) Design for injection molding and machining
8) Reducing the surfaces/parts with critical tolerances; reducing the cost of the product

The initial concepts for the handheld component of the impulse sealer were developed for rapid prototyping techniques. However, it becomes apparent that when production quantities rise and personalization is not a requirement, this fabrication approach becomes cost-prohibitive. During the initial design phases, the objectives encompassing points 1 through 5 were meticulously factored in, leading to only essential custom components being enclosures and the slider. The remaining components are readily available off-the-shelf parts. For the optimized performance of the device, the slider is suited for fabrication via the machining of PTFE blocks. On the other hand, the enclosures necessitate some design modifications to align with the demands of injection molding. As a preliminary step, an assessment of the design's compatibility with injection molding is conducted through a comprehensive draft analysis.

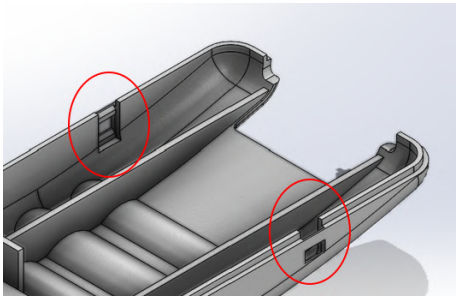
Upon visual examination of the proof-of-concept, a noticeable defect is noted. This flaw arose due to the exertion of force by the compression springs, leading to a gap emerging between the enclosures. This could be attributed to the presence of a sole fastener at the proximal end, with no corresponding assembly features at the distal end of the enclosures. Notably, the introduction of an additional fastener was deemed infeasible due to spatial constraints, as there was limited available room without expanding the dimensions of the enclosures. Hence, separable snap fits were introduced as a feature as described in figure 25.



(a) As the slider is pushed out due to the compression spring, a visible gap between the enclosures is noted (highlighted in the red arrows).



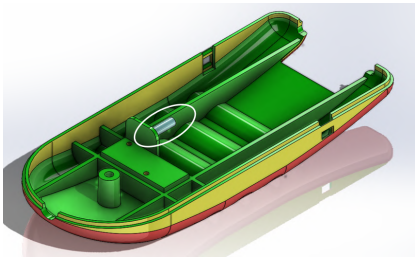
(b) Straight beam snap-fit incorporated on the upper enclosure, resolving this defect.



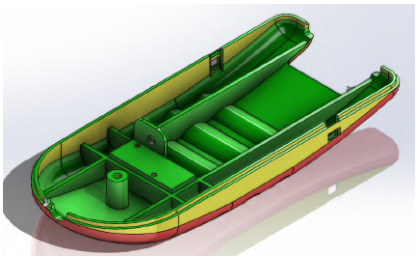
(c) Counter attachment for the separable snap-fit incorporated in the lower enclosure.

Fig. 25: Design change (A); incorporating a snap-fit feature at the distal end of the handheld piece to resolve the issue of the visible gap between the enclosures.

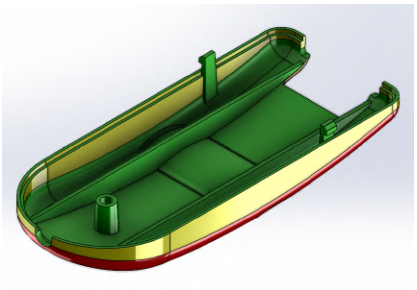
Continuing forward, the draft analysis was conducted employing a traditional vertical pull direction relative to the horizontal facet of the enclosures. The initial focus was directed toward the lower enclosure, designed to serve as the foundation for the stacked assembly, accommodating the slider unit before being sealed shut using the upper enclosure. A revision of the self-locating attribute, responsible for maintaining the compression spring, lower enclosure, and slider unit in their designated positions, was needed as a way to optimize the part for the injection molding technique. The specifics of this modification are elaborated upon in the accompanying figure 26.



(a) The self-locating feature on the lower enclosure (highlighted) is noted to be incompatible with injection molding.



(b) Replaced with a press-fit hole for a dowel to be assembled later, required drafts are added to the internal features of the lower enclosure.



(c) Upper enclosure with drafts added to the ribs and snap-fit features.

Fig. 26: Design change (B); the self-locating feature incorporated within the lower enclosure during rapid prototyping had to be replaced with a dowel & required drafts were added to all the ribs, optimizing the enclosures for injection molding.

The final resulting design concept of the overall assembly of the device should be as represented in the figure below.

Fig. 27: Representation of the final design of concept for impulse sealer.

APPENDIX B
PHOTOGRAPHS OF THE SAMPLES USED FOR TENSILE TESTING.

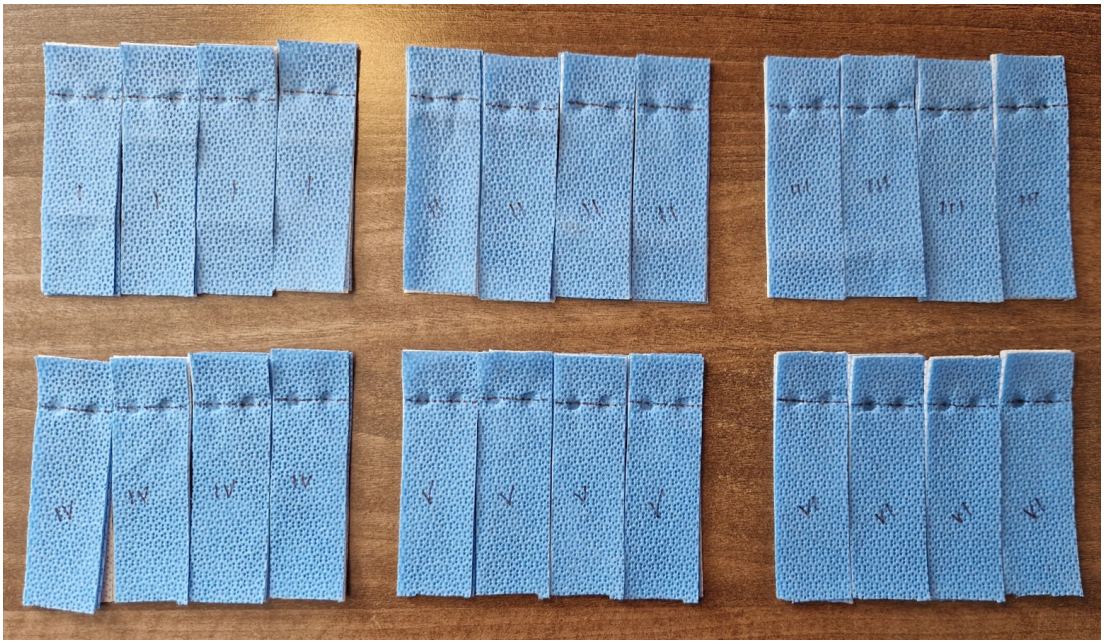


Fig. 28: Test samples sealed using an ultrasonic sealer.

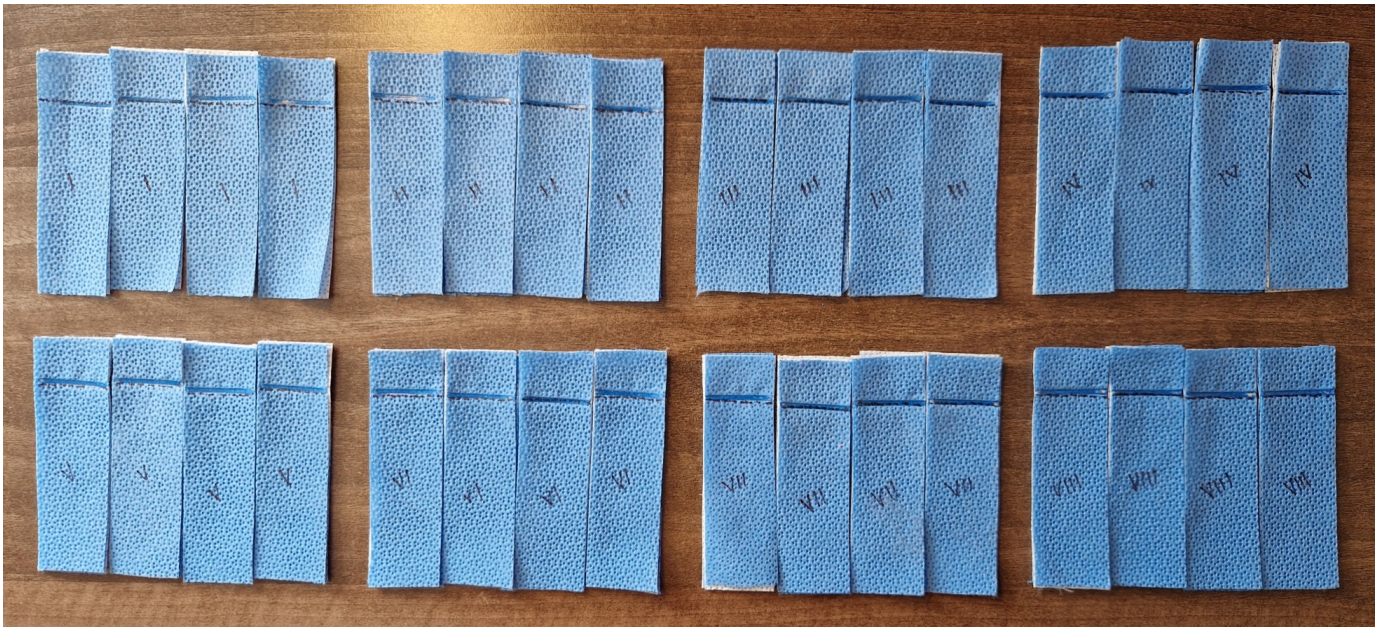
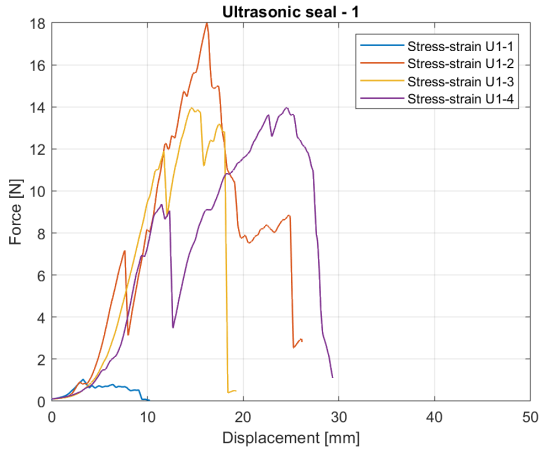


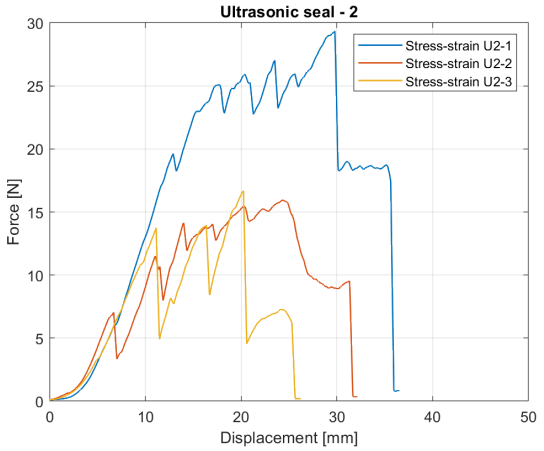
Fig. 29: Test samples sealed using an impulse sealer.

APPENDIX C
RESULTS OF TENSILE TESTS.

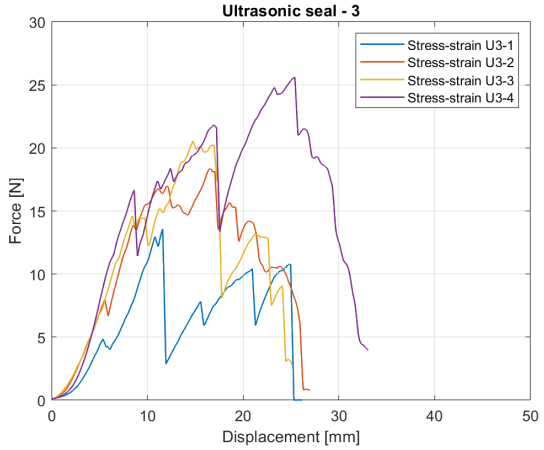
A. *Tensile test results of the ultrasonically sealed samples.*



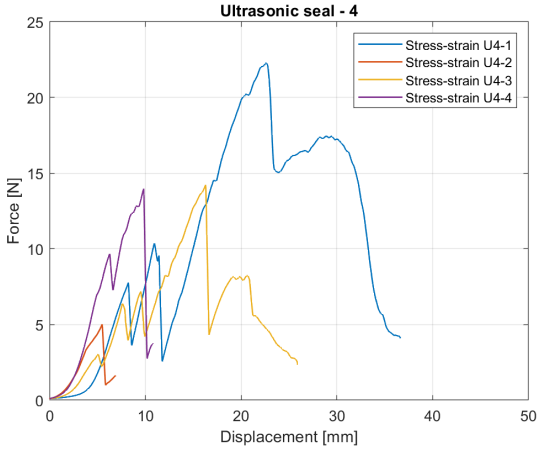
(a) Ultrasonic sealer with the lowest seal time setting '1'



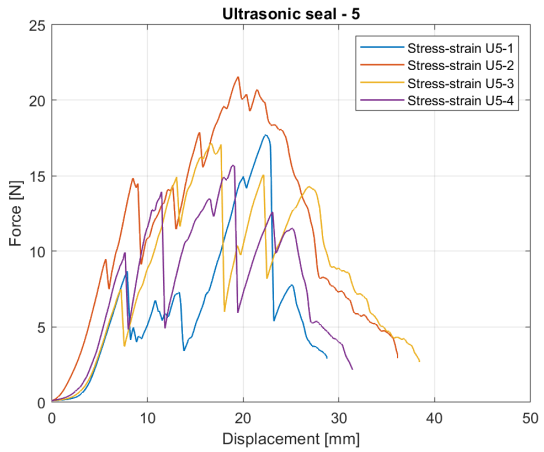
(b) Ultrasonic sealer with the seal time setting '2'



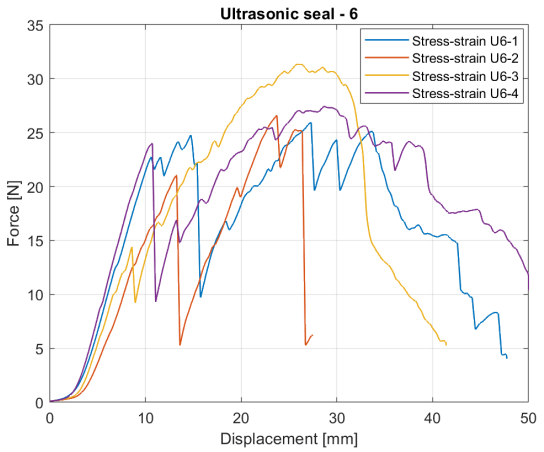
(c) Ultrasonic sealer with the seal time setting '3'



(d) Ultrasonic sealer with the seal time setting '4'



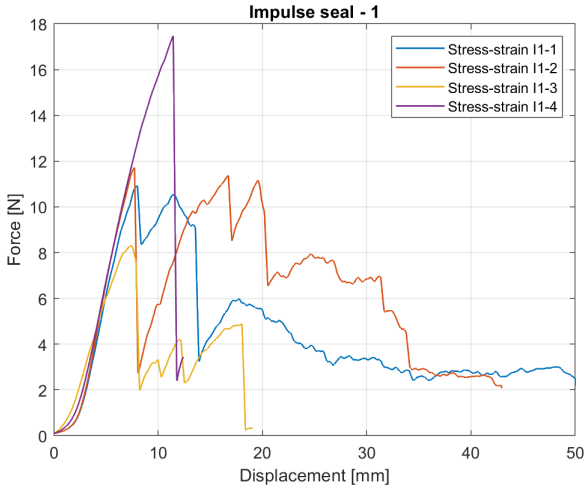
(e) Ultrasonic sealer with the seal time setting '5'



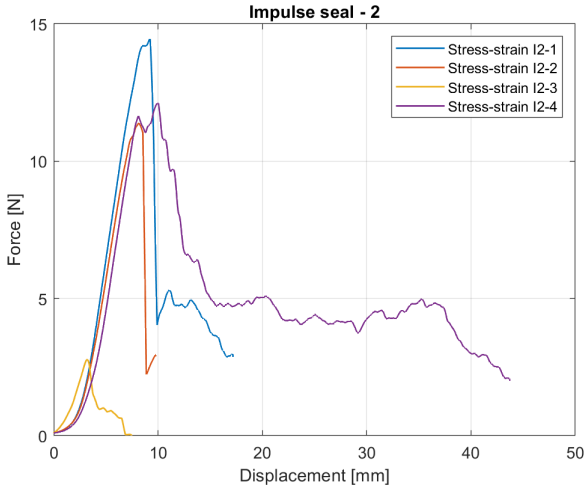
(f) Ultrasonic sealer with the highest seal time setting '6'

Fig. 30: Results from the tensile tests of Ultrasonic sealer samples.

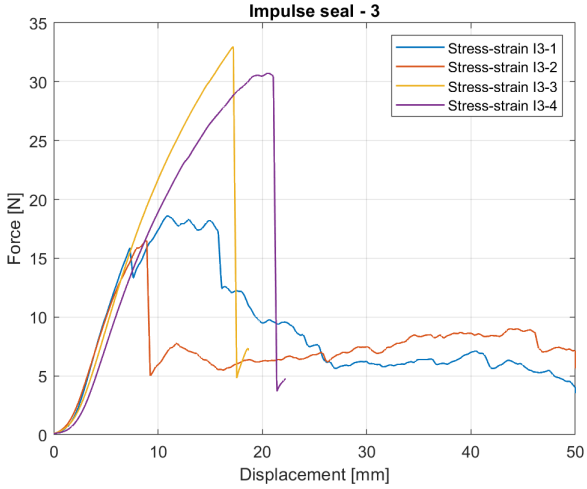
B. Tensile test results of the impulse sealed samples.



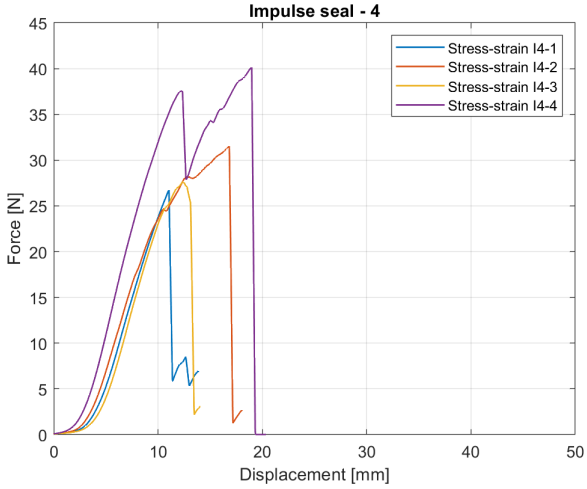
(a) Impulse sealer with the lowest seal time setting 'A'



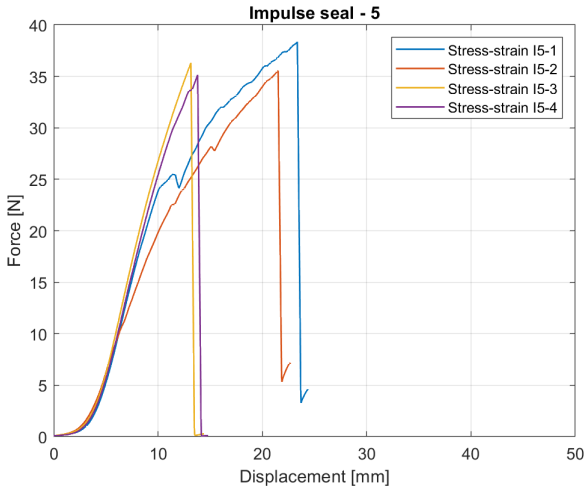
(b) Impulse sealer with the seal time setting 'B'



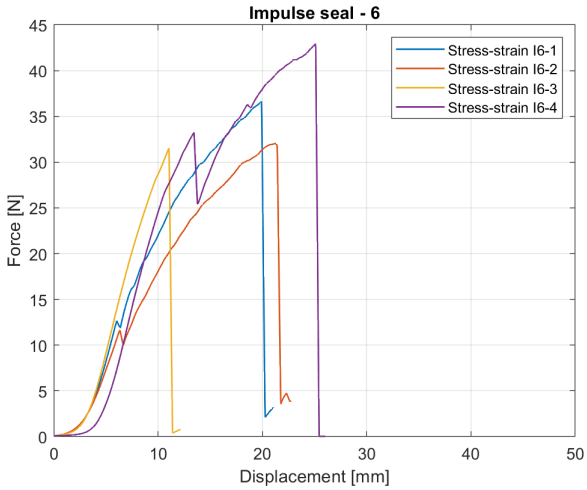
(c) Impulse sealer with the seal time setting 'C'



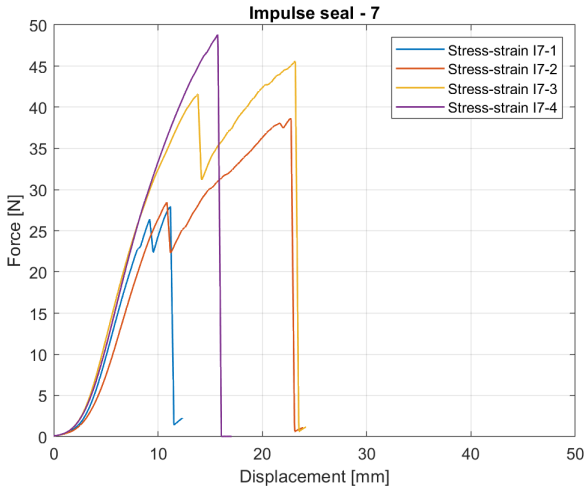
(d) Impulse sealer with the seal time setting 'D'



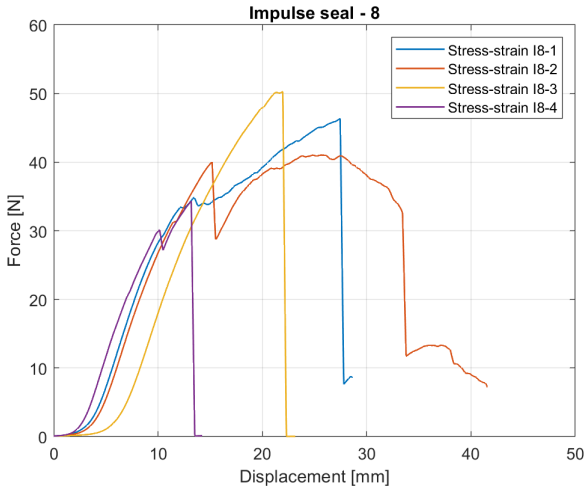
(e) Impulse sealer with the seal time setting 'E'



(f) Impulse sealer with the seal time setting 'F'



(g) Impulse sealer with the seal time setting 'G'



(h) Impulse sealer with the highest seal time setting 'H'

Fig. 31: Results from the tensile tests of Impulse sealer samples.

APPENDIX D
STATISTICAL ANALYSIS

Statistical analysis is performed on the data of the tensile test. This includes the data of every individual trial of impulse and ultrasonic sealers. Data is gathered from noting the maximum force measured during the tensile test of the seals to failure from each case. Since the objective of the product characterization test was to tune the seal time of each prototype, statistical analysis is done separately on tensile test data of the impulse and ultrasonic sealer. First, the Shapiro-Wilk test is performed to test whether the data is normally distributed based on each case/trial. Then based on the results of the Shapiro-Wilk test, it is decided whether to proceed with One-way ANOVA or a Non-parametric test.

A. *Statistical analysis of the data from the impulse sealer.*

Normality test: The results of the Shapiro-Wilk normality test of the data of the tensile test on the samples from impulse sealer are presented below in Table VII. The data on Maximum Force [N/mm] is normally distributed as $p > 0.05$ in every case of seal time.

TABLE VII: The Shapiro-Wilk normality test of the data of the tensile test on the samples from impulse sealer. The data is normally distributed if $p > 0.05$.

Tests of Normality

		Shapiro-Wilk		
	Seal Time	Statistic	df	Sig.
Max Force [N/mm]	I - 1	.920	4	.536
	I - 2	.844	4	.206
	I - 3	.854	4	.241
	I - 4	.865	4	.278
	I - 5	.878	4	.329
	I - 6	.885	4	.361
	I - 7	.940	4	.651
	I - 8	.983	4	.920

Statistical test: Since the data is found to be normally distributed the analysis is proceeded by a One-way ANOVA test. The null hypothesis is that the distribution for each seal time case is the same. This is rejected if the results of that One-way ANOVA test provide a $p < 0.05$. Table VIII shows the results of the descriptive statistical analysis and followed by Table IX shows the results of the ANOVA with $p < 0.05$, proving that there is a significant difference between the groups/cases of seal time.

TABLE VIII: Results of descriptive statistical analysis on the data from the tensile test of impulse sealed samples.

Descriptives

Max Force [N/mm]

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
I - 1	4	.4025	.12712	.06356	.2002	.6048	.28	.58
I - 2	4	.3375	.17056	.08528	.0661	.6089	.09	.48
I - 3	4	.8225	.27765	.13883	.3807	1.2643	.55	1.10
I - 4	4	1.0500	.20543	.10271	.7231	1.3769	.89	1.34
I - 5	4	1.2100	.04967	.02483	1.1310	1.2890	1.17	1.28
I - 6	4	1.1925	.17557	.08779	.9131	1.4719	1.05	1.43
I - 7	4	1.3425	.30934	.15467	.8503	1.8347	.93	1.63
I - 8	4	1.4325	.23258	.11629	1.0624	1.8026	1.14	1.68
Total	32	.9738	.43561	.07701	.8167	1.1308	.09	1.68

TABLE IX: Results of One-way ANOVA test on the data from the tensile test of impulse sealed samples. The results between the groups significantly differ if $p < 0.05$.

ANOVA

Max Force [N/mm]

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4.840	7	.691	15.911	<.001
Within Groups	1.043	24	.043		
Total	5.883	31			

B. Statistical analysis of the data from the ultrasonic sealer.

Normality test: The results of the Shapiro-Wilk normality test of the data of the tensile test on the samples from ultrasonic sealer are presented below in Table X. The data on Maximum Force [N/mm] is normally distributed as $p > 0.05$ in every case of seal time.

TABLE X: The Shapiro-Wilk normality test of the data of the tensile test on the samples from an ultrasonic sealer. The data is normally distributed if $p > 0.05$.

Tests of Normality

		Shapiro-Wilk		
	Seal Time	Statistic	df	Sig.
Max Force [N/mm]	U - 1	.823	4	.150
	U - 2	.800	3	.114
	U - 3	.996	4	.984
	U - 4	.943	4	.675
	U - 5	.909	4	.478
	U - 6	.854	4	.239

Statistical test: Since the data is found to be normally distributed the analysis is proceeded by a One-way ANOVA test. The null hypothesis is that the distribution for each seal time case is the same. This is rejected if the results of that One-way ANOVA test provide a $p < 0.05$. Table XI shows the results of the descriptive statistical analysis and followed by Table XII shows the results of the ANOVA with $p < 0.05$, proving that there is a significant difference between the groups/cases of seal time.

TABLE XI: Results of descriptive statistical analysis on the data from the tensile test of ultrasonically sealed samples.

Descriptives

Max Force [N/mm]

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
U - 1	4	.3925	.24932	.12466	-.0042	.7892	.03	.60
U - 2	3	.6900	.25159	.14526	.0650	1.3150	.53	.98
U - 3	4	.6475	.16581	.08290	.3837	.9113	.45	.85
U - 4	4	.4625	.23286	.11643	.0920	.8330	.17	.74
U - 5	4	.6000	.08524	.04262	.4644	.7356	.52	.72
U - 6	4	.9250	.07937	.03969	.7987	1.0513	.86	1.04
Total	23	.6165	.24274	.05062	.5116	.7215	.03	1.04

TABLE XII: Results of One-way ANOVA test on the data from the tensile test of ultrasonically sealed samples. The results between the groups significantly differ if $p < 0.05$.

ANOVA

Max Force [N/mm]

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.697	5	.139	3.959	.015
Within Groups	.599	17	.035		
Total	1.296	22			

APPENDIX E
WRAPPING METHODS PLANNED FOR THE USABILITY AND FUNCTIONALITY TESTS

A. Conventional envelope wrapping method

The protocol for the conventional envelope wrapping method at Maastad CSA for an instrument tray of 480 x 250 x 60 mm is as follows;

(i) Take a bonded double PP sterilization wrap of grade H400 with dimensions 114 x 114 cm.

(ii) Spread PP sterilization wrap flat on the work table.

(iii) Place the instrument tray on the wrap (as shown in step 1 of Figure 32).

(iv) Proceed with the wrapping of the PP around the instrument tray chronologically as per Figure 32 shown below.

(v) Finally, use a piece of autoclave tape to secure the wrap as shown in step 6 of Figure 32.

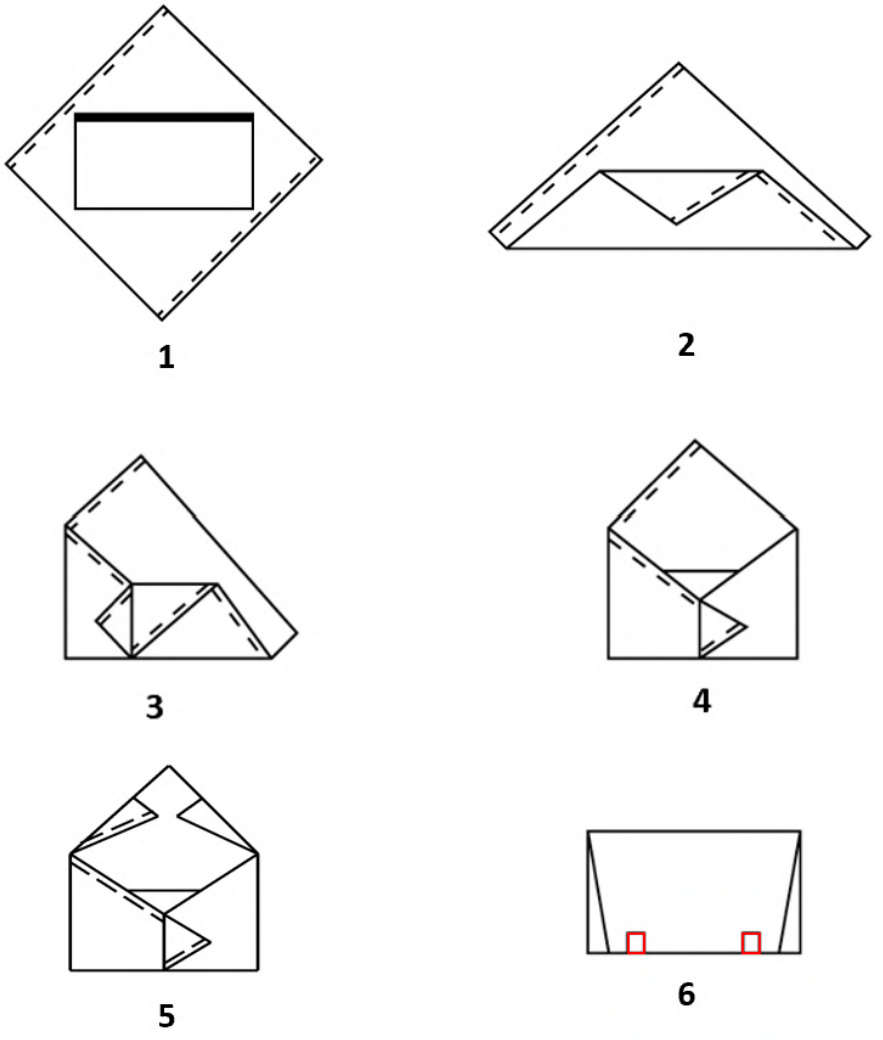


Fig. 32: Steps of standard envelope method, securing the loose ends using conventional autoclave tape.

B. Protocol of impulse sealed sterile packaging.

The protocol for the modified envelope wrapping method for an instrument tray of 480 x 250 x 60 mm to facilitate the use of impulse sealer to secure the loose ends is as follows;

(i) Take a bonded double PP sterilization wrap of grade H400 with dimensions 114 x 114 cm.

(ii) Spread PP sterilization wrap flat on the work table.

(iii) Place the instrument tray on the wrap (as shown in step 1 of Figure 33).

(iv) Proceed with the wrapping of the PP around the instrument tray chronologically as per Figure 33 shown below.

(v) Finally, flip the top cover and use the provided impulse sealer to secure the wrap. Seal at a single spot highlighted in red on the front of the package as shown in step 6 of Figure 33.

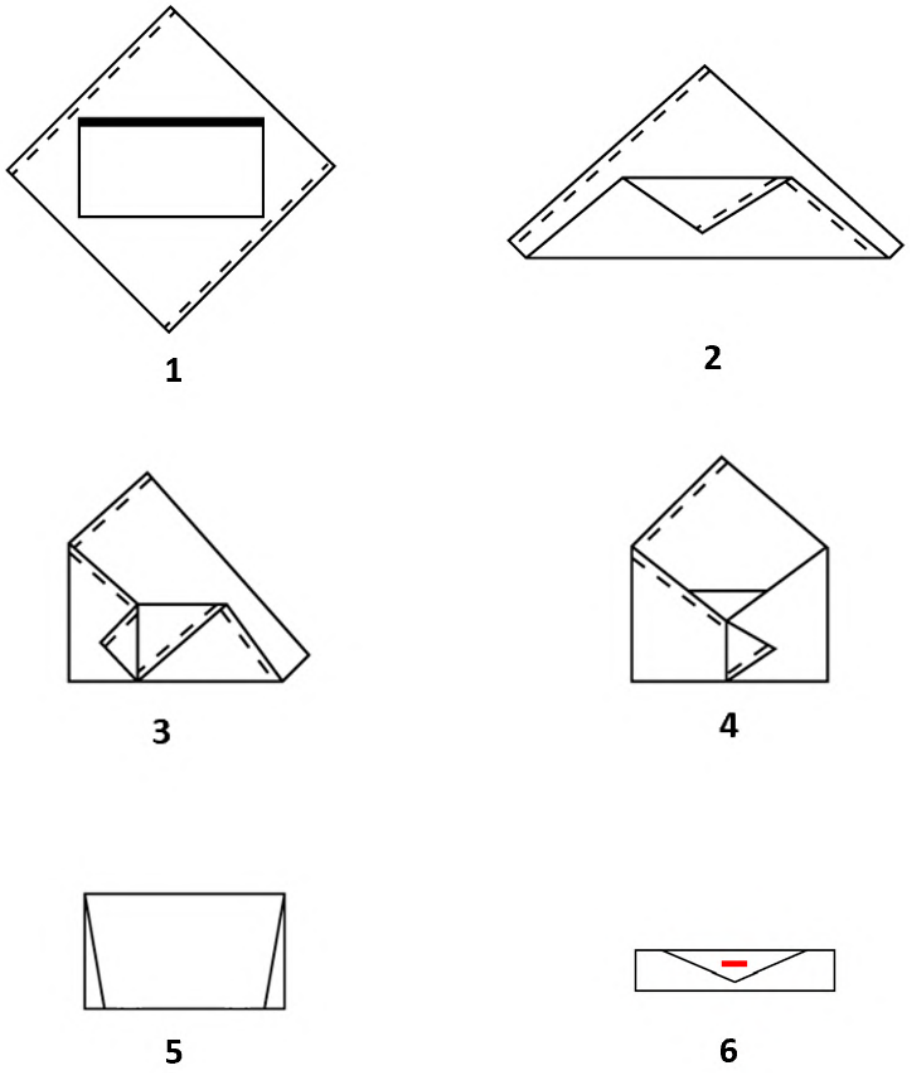


Fig. 33: Steps of modified envelope method, securing the loose ends using impulse sealer.

C. Protocol of ultrasonically sealed sterile packaging.

The protocol for the modified envelope wrapping method for an instrument tray of 480 x 250 x 60 mm to facilitate the use of ultrasonic sealer to secure the loose ends is as follows;

(i) Take a bonded double PP sterilization wrap of grade H400 with dimensions 114 x 114 cm.

(ii) Spread PP sterilization wrap flat on the work table.

(iii) Place the instrument tray on the wrap (as shown in step 1 of Figure 34).

(iv) Proceed with the wrapping of the PP around the instrument tray chronologically as per Figure 34 shown below.

(v) Use the provided ultrasonic sealer to secure the wrap after step 4 of Figure 34, one seal to be done at the center holding the right and left flaps together.

(vi) Finally, flip the top cover and use the provided ultrasonic sealer twice to secure the wrap. Seal at two spots highlighted in red as shown in step 5 of Figure 34.

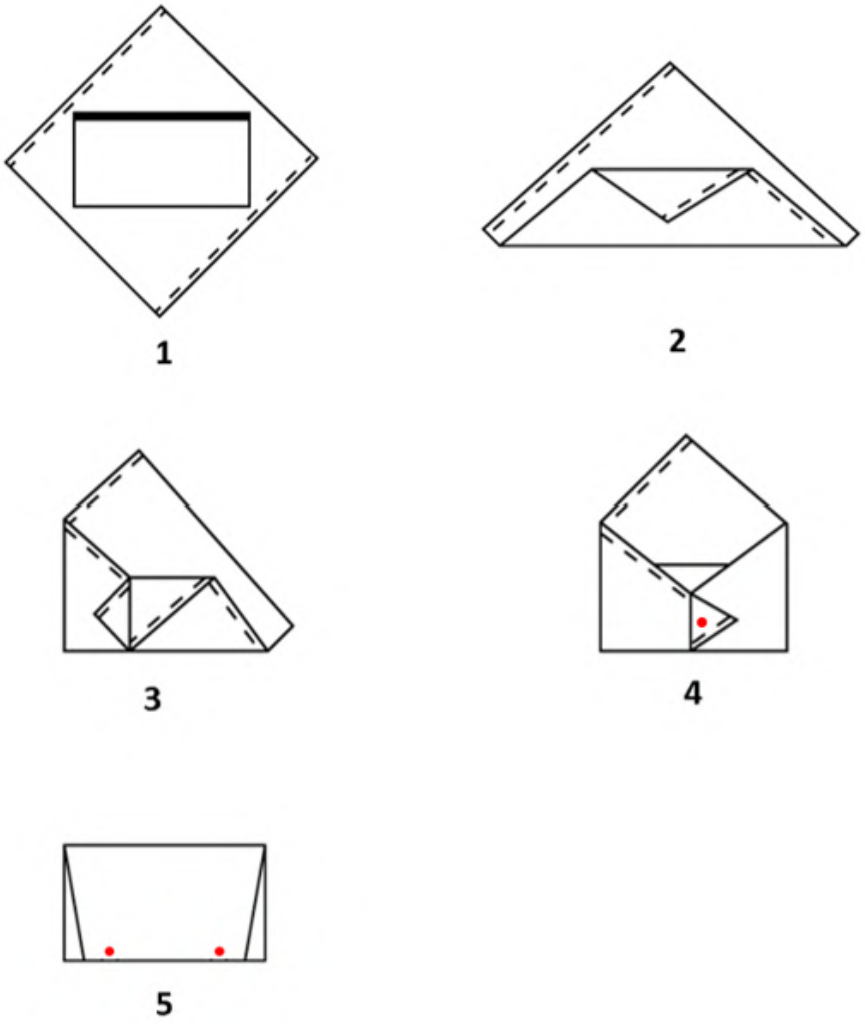


Fig. 34: Steps of modified envelope method, securing the loose ends using ultrasonic sealer.