
Makeup Application Device for Bilateral Upper Limb Amputees

Product Design Specification

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1.0 Introduction

1.1 Significance

Upper limb loss can result from trauma, cancer, infections, burns, and congenital deformities [1]. While bilateral upper limb loss is rare, it is a very challenging disability to live with as there is no remaining arm to complete daily self-care tasks [2]. The use of assistive devices may help an amputee attain independence, but nonetheless, bilateral upper limb amputations can significantly diminish an individual's self-esteem.

The proposed solution allows bilateral transhumeral or transradial upper limb amputees to apply makeup independently. Makeup can be empowering and allow for an increase in self-confidence and self-love. Thus far, a makeup application device for bilateral amputees has not been considered, making the development of such a device an important design endeavor.

1.2 Upper Limb Prosthetics

There are five types of prosthetics available for upper limb amputees: passive, myoelectric, body-powered, hybrid, and activity-specific. Passive prosthetics look like a natural limb and are used for balance, stabilization of objects, as well as recreational and vocational activities. These types of prosthetics do not provide active hand and joint movement [3]. In contrast, myoelectric and body-powered prosthetics provide active movement via different control mechanisms. Myoelectric prosthetics are controlled using electric signals generated by the muscles of the residual limb while body-powered prosthetics are controlled using a system of cables and harnesses that are operated by moving the shoulders, elbows, or chest [4]. Body-powered prosthetics are most commonly prescribed for bilateral upper limb amputees [5]. Hybrid prosthetics employ a combination of myoelectric and body power and are typically used for higher level amputations. Lastly, activity-specific prosthetics are used when there is a potential to damage the residual limb or everyday prosthetic, or when the everyday prosthetic does not provide the necessary function to the amputee [3]. The appropriate choice of prosthetic depends on many factors including: amputation level, residual limb geometry, sensation, range of motion, strength, cognition, vocation, hobbies, importance of cosmesis, cost, operating environment, and weather [6].

Depending on the level of amputation, upper limb prosthetics are comprised of one or more of the following parts: terminal device, wrist unit, elbow system, and shoulder joint [7]. The latter two components are not directly related to the proposed makeup application device and thus will not be discussed further. The terminal device is a replacement for the amputee's hand and can either be active or passive. Active devices open and close while passive devices are primarily cosmetic. Terminal devices can be myoelectric or body-powered and include hooks, hands, or activity-specific devices such as catcher's gloves [8]. Wrist units connect the terminal device to the prosthetic. They position the terminal device and allow terminal devices to be exchanged if desired [7]. As will be discussed in Section 2.3, typically for bilateral amputees, the terminal device attaches to a flexion unit that connects to a wrist unit capable of facilitating rapid interchange of terminal devices [5].

2.0 Product Identification

2.1 Product Description

The proposed design consists of an intermediary device that integrates with body-powered prosthetics via a universal insert and acts as a modular attachment point for various makeup brushes (Figure 1). The brush end-effectors are located in a specialized change-out station that allows the user to attach and remove the brushes effectively.

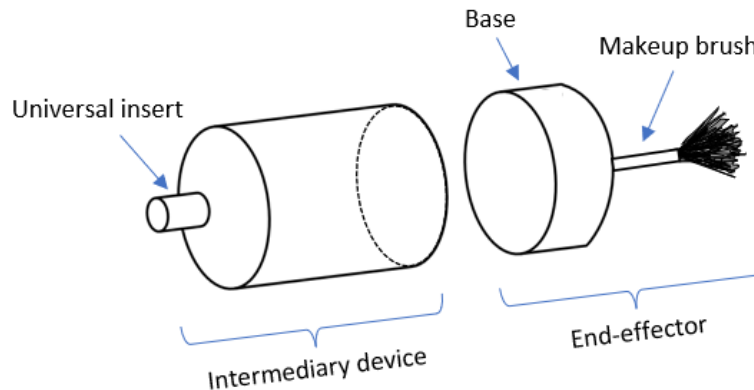


Figure 1: Intermediary device and brush end-effector

2.2 Basic Functions of the Product

A makeup application device designed for bilateral amputees is not currently available on the market. Therefore, amputees are required to apply makeup by grasping the appropriate cosmetic unit with their residual limbs or hooks that open and close (Figure 2) [9]. The proposed product allows makeup brushes to attach to the user's prosthetic via an intermediary device which should allow for more efficient application.



Figure 2: An amputee applying makeup using her body-powered prosthetics [9]

2.3 Special Features of the Product

Typically for bilateral upper limb amputees, a flexion unit is attached to a wrist unit that facilitates rapid interchange of terminal devices. The ability to flex the terminal device is essential in enabling bilateral amputees to reach midline and perform activities such as eating, brushing teeth, and applying makeup.

The terminal device connects to the flexion unit and can be removed by pushing a button on the wrist unit [5]. Two wrist units commonly used by bilateral amputees are shown in Figure 3 [10].

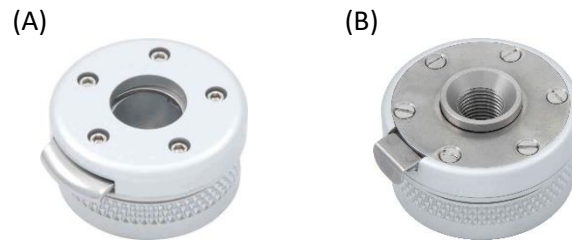


Figure 3: Two wrist units that enable rapid interchange of terminal devices include the Quick Disconnect Wrist (A) and the FM Quick Change Wrist (B) [10]

The proposed makeup application device consists of three units: an intermediary device, brush end-effectors, and a change-out station. The intermediary device will be designed to integrate with existing flexion units as well as brush end-effectors which are located in a special makeup kit that also serves as a change-out station. Each end-effector is contained within its own compartment in the station. The user positions the intermediary device in front of the desired end-effector which can attach via several mechanisms, as described in Section 6.0. Once the end-effector is attached, the user can position it as required using the flexion unit. After makeup application, the end-effector is brought back into the starting position, placed in the appropriate compartment, and removed from the intermediary device.

2.4 Key Performance Targets

Key performance targets associated with the proposed makeup application device include the ability to integrate with flexion units, rapid and energy-efficient exchange or removal of end-effectors, and accurate makeup application to the skin, eyes, and mouth. The user should be able to exchange the proposed intermediary device with their current terminal device within 1 minute. In addition, the user should be able to swap end-effectors using the change-out station within 15 seconds.

2.5 Service Environment

The makeup case and change-out station will be made to open with the push of a button and can be pushed closed. In addition, the case will have a handle to allow the user to travel with it as required. Similar to other makeup cases available on the market, the proposed makeup case and change-out station should not be left in hot environments, as high heat can melt the glue holding the brush and wand together [11].

2.6 User Training Required

The makeup application device will come with a manual that outlines how to attach and remove end-effectors using the change-out station.

3.0 Market Identification

3.1 Target Market

The target market for the proposed makeup application device includes bilateral transhumeral or transradial upper limb amputees that utilize prosthetics. The majority of bilateral upper limb amputees utilize prosthetics and rely on at least one of their prosthetic devices to become their main method of upper limb manipulation [12].

The upper limb prosthetics market was valued at 1,077.8 million USD in 2018 and is expected to grow at a compound annual growth rate of approximately 11% from 2019 to 2025. In 2025, the market is expected to be valued at 2.3 billion USD [13].

The product will initially be launched in the United States. Records from the U.S. National Trauma Data Bank® (NTDB®) spanning 2000-2004 indicate that 151 amputees (7.3%) experienced multiple limb loss. Of those 7.3%, 17 individuals (11.3%) were bilateral upper limb amputees. These records also showed that approximately 75% of amputees were male [14]. Since not all amputees are registered in the NTDB® and the records are not current, the data is incomplete. However, considering that the total number of individuals living with limb loss in the U.S. is approximately 2.1 million and 70% of amputations are at the transradial or transhumeral level, the number of female bilateral transradial or transhumeral amputees in the U.S. can be estimated to be 3030 [15] [16].

3.2 Anticipated Market Demand

Each year in the U.S., approximately 185,000 individuals have an amputation [15]. Based on this information and the aforementioned statistics, it can be estimated that approximately 270 females undergo bilateral transradial or transhumeral upper limb amputation annually. The initial demand is expected to be higher since there are no competing products and there is an existing pool of clientele who may benefit from the proposed device. However, the demand will taper off as the market becomes saturated, with clientele comprising individuals who have recently undergone amputation. Only 10% of women in the U.S. never wear makeup [17]. Assuming the ratio remains the same amongst amputees, it can be assumed that the anticipated market demand will initially be approximately 2730 units per year and decrease to 240 units per year once the market becomes saturated.

3.3 Competing Products

A makeup application device for bilateral amputees is not currently available on the market, making the development of such a device an important design endeavor. Currently, amputees apply makeup by grasping the appropriate cosmetic unit with their residual limbs or prosthetics which can be challenging [9]. Thus, there is a need for a novel device that facilitates makeup application for these individuals.

4.0 Key Project Deadlines

Key project deadlines are shown in Table 1 below.

Table 1: Key project deadlines

Activity	Deadline
System-level design kick-off	February 15, 2022
System-level design review	October 15, 2022
Engineering design finalized	November 15, 2022
Detail design review	May 1, 2023
Testing and refinement complete	July 15, 2024
Pilot manufacturing run complete	August 15, 2024
Product launch and final review	December 15, 2024

The planning and concept development phases have been completed. System-level design is expected to start in February 2022 and should be completed by mid-October. Detail design should be done by the

beginning of May 2023 after which testing and refinement will begin and continue until July 2024. The product will be launched just before Christmas and a final review will be held focusing on lessons learned.

5.0 Physical Description

The physical requirements of the proposed makeup application device are outlined in Table 2 below.

Table 2: Physical requirements of proposed makeup application device

Component	Physical Requirement			
	Dimensions [18]–[20]	Weight [18], [19]	Color	Materials [21], [22]
Makeup case / change-out station	Length: 9.0 in. Width: 6.0 in. Height: 6.0 in.	1 kg*	Exterior: silver, pink, blue Interior: silver	Exterior: polyvinyl chloride (PVC), aluminum Interior: PVC
Intermediary device	Length: 2.5 in. Diameter: 2.0 in. 12 mm insert	100 g	White	PVC
Brush end-effector	Length: 2.5 in. (0.5 in. base, 2.0 in. brush) Diameter of base: 2.0 in. Diameter of brush wand: same size as commercially available brands	5-20 g	Base: white Brush: colors used by commercially available brands	Base: PVC Brush: materials used by commercially available brands

* Weight does not include end-effectors.

The size of the makeup case and change-out station allows the necessary amount of brush end-effectors to be accommodated while minimizing storage space. It also allows the user to travel with it if needed. The makeup case will have two levels and can hold the following 8 cosmetic brushes: powder, foundation, concealer, blush, lip, eyeshadow, eyeliner, and mascara. The brush end-effectors will be located in separate compartments within the case and each compartment will have enough room to store the end-effector as well as the intermediary device.

The diameter of the brush wand, as well as the color and material of the various brushes will be the same as what is used by commercially available brands. Similarly, the case will be made from materials commonly used in commercial makeup cases and will be available in silver, pink, and blue.

The upper and lower levels of the makeup case will each contain 4 square rods that can pass through holes present in the base of the end-effectors. The rods will have a width of 0.25 inches and be 0.5 inches tall and their purpose is to prevent movement of the end-effector when the user is attaching and detaching the intermediary device. The intermediary device will be made to fit on top of flexion units and will contain an insert that is universal and present on all upper limb terminal devices [5]. It will be available in white and be made from PVC, which is a strong, lightweight, durable, and cost-effective material. PVC can also be cut, shaped, and welded in a variety of styles, thus making it an appropriate material choice for this application [23]. The base of the brush end-effector will also be made from PVC. The length of the intermediary device together with the brush end-effector should not exceed 5 inches

which is the approximate length of an adult size prosthetic hook. In addition, the combined weight should be similar to the weight of an adult size aluminum hook which is used for light or moderate duty environments [19].

6.0 Concept Generation

The attachment and detachment of the various brush end-effectors to and from the intermediary device can be accomplished in several ways.

6.1 Concept 1: Twist Lock

The end-effectors can attach to the intermediary device through a twist lock mechanism (Figure 4). The user places the intermediary device in front of the desired end-effector. Rotation of the intermediary device one way locks the end-effector in place, while rotation the other way removes it from the intermediary device. The twist lock mechanism allows for a strong connection; however, it may be difficult for the user to manipulate the intermediary device appropriately to enable rapid attachment and detachment of the end-effector [5].

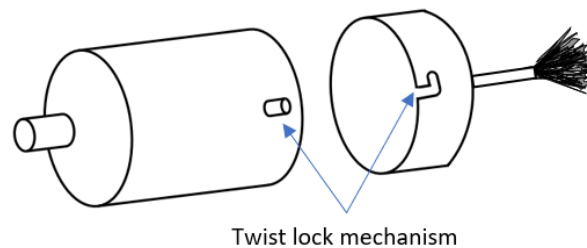


Figure 4: Twist lock concept for the makeup application device

6.2 Concept 2: Push Latch

The end-effectors can attach to the intermediary device through a push latch mechanism (Figure 5). The push latch is commonly used to open and close cabinet doors and drawers without handles. It consists of two components, a strike plate and a floating ball striker, which will be located on the intermediary device and end-effector, respectively [24]. The user pushes their prosthetic with the intermediary device against the end-effector to enable attachment of the striker to the strike plate. After makeup application, the user pushes the intermediary device against the end-effector a second time to disengage the striker from the strike plate. This concept should also allow for a strong connection, however, push latches are not as durable as twist locks.

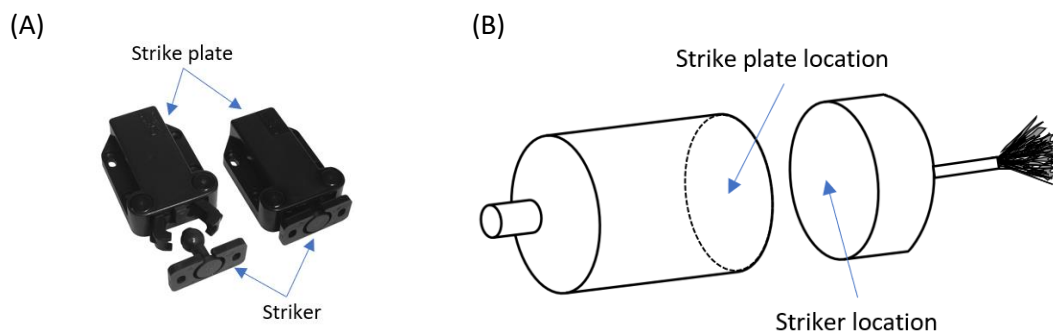


Figure 5: Push latch components (A) and their location on the makeup application device (B) [25]

6.3 Concept 3: Magnet

The end-effectors can attach to the intermediary device through a magnetic connection (Figure 6). This concept should enable rapid attachment and detachment of the end-effector, with effective makeup application depending on the strength of the magnet. If the connection is too weak, disconnection of the end-effector can occur during makeup application. If the connection is too strong, it may be difficult for the user to disconnect the intermediary device from the end-effector once the end-effector is back in the change out station. Therefore, a balance must be found to ensure user needs are satisfied.

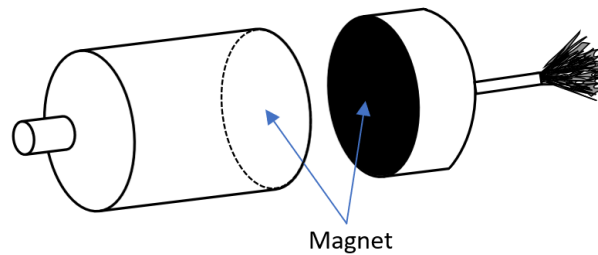


Figure 6: Magnet concept for the makeup application device

7.0 Concept Evaluation

A weighted decision matrix was used to evaluate the design concepts (Table 4). Each criterion was assigned a weighting factor depending on its importance, and all weighting factors summed to 1. The concepts were rated using the 5-point scale shown in Table 3 [26].

Table 3: 5-point scale used in the weighted decision matrix [26]

5-point Scale	Description
0	Inadequate
1	Weak
2	Satisfactory
3	Good
4	Excellent

Table 4: Weighted decision matrix for the makeup application device

Selection Criteria	Weighting Factor	Concept 1: Twist Lock		Concept 2: Push Latch		Concept 3: Magnet	
		Rating	Weighted Score	Rating	Weighted Score	Rating	Weighted Score
Ease of use	0.35	1	0.35	3	1.05	4	1.40
Attachment strength	0.35	4	1.40	4	1.40	2	0.70
Durability	0.20	4	0.80	3	0.60	4	0.80
Ease of manufacture	0.10	4	0.40	2	0.20	3	0.30
Total	1.00		2.95		3.25		3.20

The makeup application device must be easy to use and enable a strong attachment in order to be effective. Thus, these criteria have the highest weighting factor and are weighted equally. Durability of the device allows for a more economical product and helps ensure customer satisfaction and thus has

the second highest weighting factor. Lastly, ease of manufacture was also considered and has the lowest weighting factor in comparison to the other criteria.

Concept 1 has a weak rating for ease of use as it would likely be difficult for bilateral amputees to manipulate the intermediary device appropriately to enable rapid attachment and detachment of the end-effector [5]. Concept 1 requires the amputee to align and twist their prosthetic in order to use the end-effector, whereas Concept 2 requires correct alignment and a slight push, which is an easier motion to perform. In comparison to the other concepts, Concept 3 requires a less precise alignment to use the end-effector, and thus has the highest rating. With regards to attachment strength, Concepts 1 and 2 rely on a mechanical attachment mechanism which allows for a strong connection. In comparison, Concept 3 utilizes a magnetic force and thus exhibits a lower attachment strength. Durability also differs among the concepts. Push latches are composed of more parts than twist locks and magnets, possibly making Concept 2 more prone to breakage. Having multiple parts also potentially makes Concept 2 more difficult to manufacture in comparison to the other concepts. Concept 1 is the easiest to manufacture due to its simple design and because it is made from the fewest number of parts.

Concept 2 has the best average rating for the most important criteria and achieves the highest total score, making it an appropriate choice for the proposed makeup application device. While Concept 2 does not have the highest score for ease of use or durability, it still achieves a good rating and also enables strong attachment of the end-effector. Also, even though Concept 2 was given a satisfactory rating for ease of manufacture, this criterion is the least significant.

8.0 Manufacturing Specifications

Preference will be given to domestic manufactures. The proposed intermediary device, end-effectors, and makeup case must be manufactured to the highest quality and meet all relevant North American regulations. In addition, the intermediary device must integrate with all flexion units manufactured in North America.

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