A Risk-Analysis-Based Redesign of a Stand-Up Wheelchair for J58: Enhancing Safety and Usability

I. Abstract

This thesis project presents a targeted redesign for **risk mitigation** based on the findings of a comprehensive **risk analysis** of the Ezer 1.0 (Figure 1) mechanical stand-up wheelchair, developed by J58, a startup focused on enhancing independence and quality of life for wheelchair users. The risk analysis follows international standards that guide risk management for medical products (ISO 14971) and the safety standards that relate to manual wheelchairs (ISO 12183.

Figure 1: Ezer 1.0

Identifying the single most crucial risk and reducing it to an acceptable minimum was the main goal of this project. Through extensive research, **user testing**, and **historical data** analysis, critical hazards were identified, leading to the development of a refined prototype designed to enhance **safety**, **usability**, and ultimately product performance and customer satisfaction.

The design process was guided by a detailed list of requirements, developed in collaboration with the client, ensuring alignment with both regulatory standards and market needs. While 13 of the 20 design requirements were fully met, further refinement and testing are needed to confirm the remaining 5, with only 2 requirements not achieved at this stage.

The project highlights the importance of early risk management in **medical device development**, providing a foundation for J58's future risk management protocols and product iterations. Despite the project's success, additional time and resources are recommended to further refine the final commercial design. This includes optimizing design and material selection for efficient production and cost-

effectiveness, and focusing on ergonomics and aesthetic appeal to ensure a market-ready product that meets all safety standards and maximizes user satisfaction.

II. Challenges

One of the challenges of the project was to accurately quantify the risk of each identified hazard. The risk associated with each harm was calculated (see equation 1) by estimating severity **S** and probability of occurrence **O** to arrive at the risk priority number **RPN**.

$$RPN\ (Risk\ Priority\ Number) = S \times L \qquad (1)$$

Table 1 shows the top 5 critical risks identified involving the use of the Ezer wheelchair.

Table 1: Top 5 critical risks

Risk Assessment						
No.	**Hazard Identification**	**Risk Estimation**	**Harm**			**Risk Eval.**
			S	**O**	**RPN**	
#18	The user forgets to fasten the chest belt when moving into standing position	User may fall forward and sustain injury	S-4	O-5	20	N./Acc.
#24	Gripping main tire or other unintended location to return to seated position	Risk of pinching hand or fingers leading to injury	S-3	O-5	15	N./Acc.
#17	The user forgets to fasten the knee belt	User might be unable to move back to seated position.	S-3	O-5	15	N./ Acc.

Risk Assessment						
No.	**Hazard Identification**	**Risk Estimation**	**Harm**			**Risk Eval.**
			S	**O**	**RPN**	
#15	The user's fingers get trapped in upright locomotion wheel while moving	The user's fingers get trapped or squeezed	S-2	O-5	10	N./Ac.
#25	Accidental activation of stand-up mechanism while chair is unoccupied	Inability to operate device	S-2	O-5	10	N./Ac.

III. Design Solution

Disclaimer: Certain images in this thesis have been modified to protect IP-sensitive details.

To mitigate Hazard #18 a fail-safe safety system was deemed necessary. The result of the design process was a mechanism integrated into the safety belt, which allows the stand-up mechanism to be activated when and **only when** the buckle is securely fastened.

Figure 2 shows the ideation phase.

Figure 4 shows the prototype that was used as proof of concept for the functional requirements before moving to the refined development stage.

Along with the functional requirements the design was developed to be cost-effective in manufacturing, biomedically safe, and aesthetically in line with the next generation of the Ezer 1.0. The results of this step are shown in Figure 3.

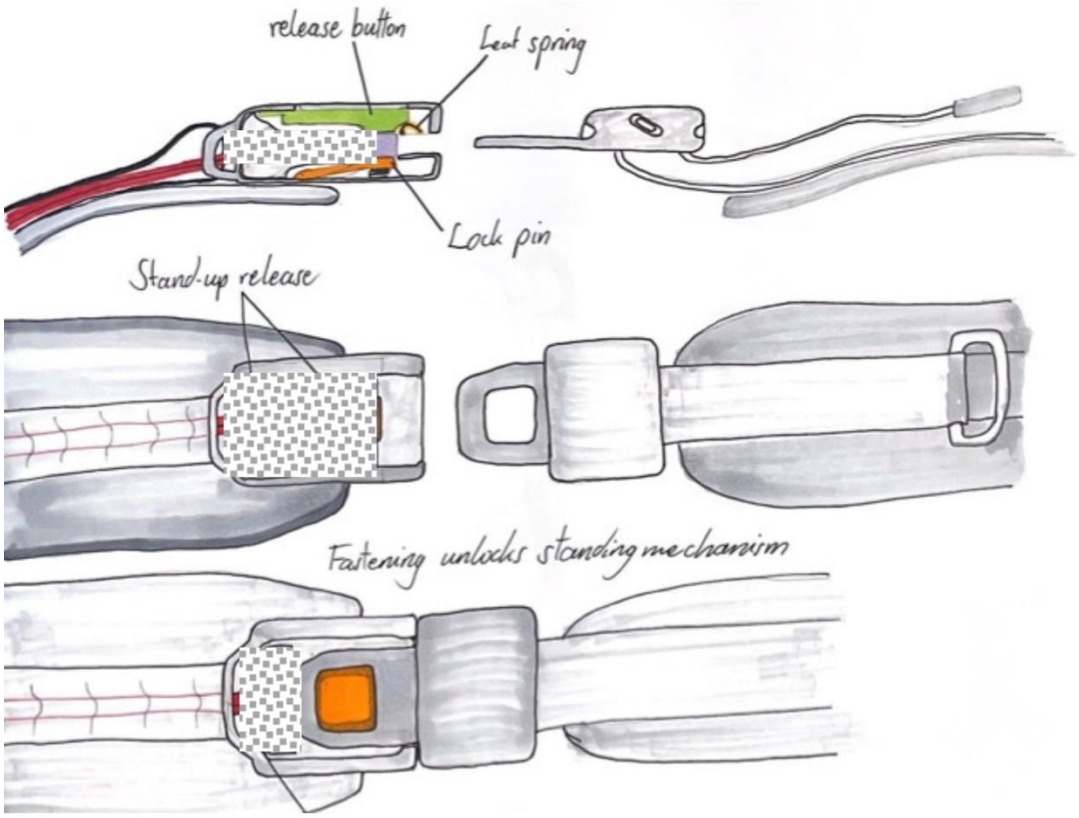

Figure 2: Mechanism Ideation

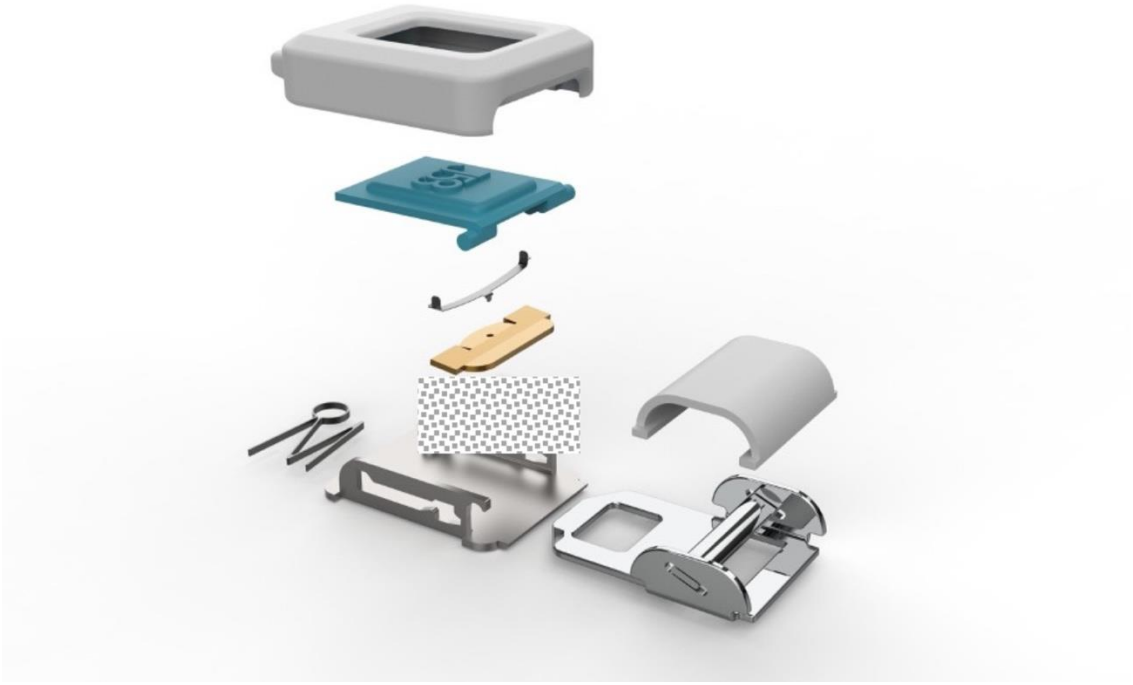

Figure 3: Final Design Exploded View

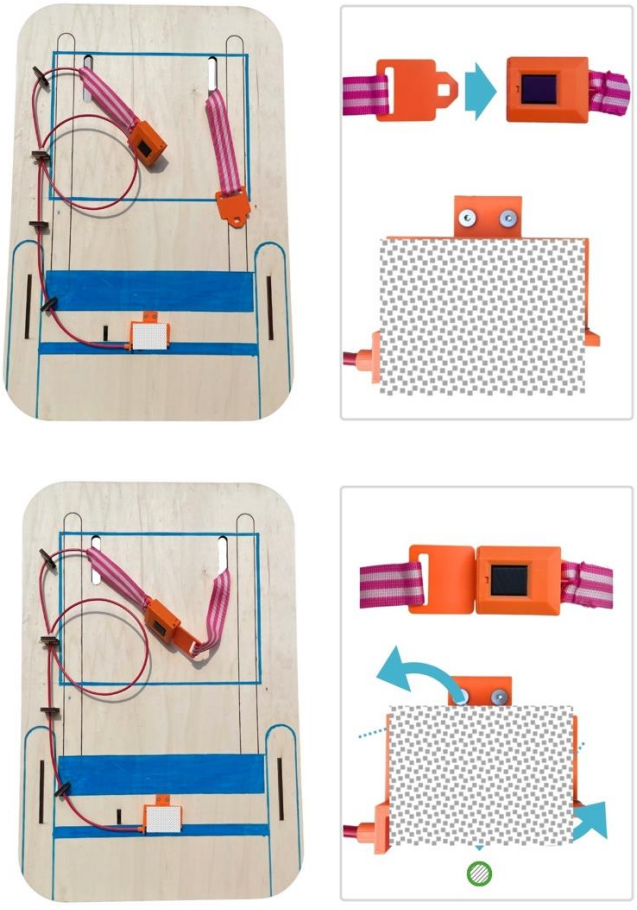

Figure 4: Physical Prototype