

Design of a steerable guidewire controller

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Designing a steerable guidewire (SGW) controller Alpha prototype that is a development of the established Proof of Principle controller at Demcon Advanced Mechatronics in Enschede.

Background Information

“DEMCON is a high-end technology supplier of products and systems, with focus areas high-tech systems, industrial systems, embedded systems and medical systems. As a system supplier, DEMCON can meet the entire needs of its clients, from proof of principle, prototype and pre-production to serial production. In more than 20 years, the business has grown to become the DEMCON Group (with more than 600 employees in 2020).” (Demcon, 2022)

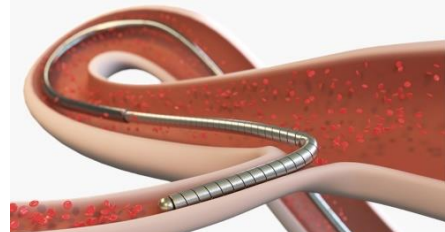


Figure 1, The steerable guidewire in an endovascular environment.

The assignment that is this Bachelor Thesis came about when DEMCON saw a technological opportunity in developing a small diameter guidewire which is steerable once in position in an endovascular environment (figure 1), a novelty compared to existing floppy or pre-bent guidewires. DEMCON has managed to create this wire however, it is not yet sufficiently controllable for the user, which makes the product not ready for use and market implementation. Therefore, the existing proof of principle prototype controller needs to be further developed into a functional demonstrator prototype. This is the assignment.

Practical Relevance

Once the controller will be further developed into a working prototype, the steerable guidewire can actually be presented to potential users to convince them into the added value of this new product.

Research Question

The research question that is leading in the thesis is formulated as follows: “What does the design for a user friendly, fully functional steerable guidewire controller look like?” The research question will be answered by delivering a fully functional prototype.

Approach

The answering of the research question started with literature research into the existing requirements at DEMCON. Next to this, literature research was done into what ergonomics imply for handheld devices, what the dimensions of the controller should be, what the workflow is of a surgery using guidewires, what the critical preliminary failure modes are, using an FMEA as a tool. Finally, the mechanical functionality is researched through analysis and experiment. This led to a requirements specification list that the new controller needs to fulfil.

The design process was initiated with an ideation process from which three different concept directions were developed. These were tested among users and led to a concept choice together with a weighted criteria scoring. The chosen concept was then further iterated. Six different iterations were again tested among users to give an indication into the design directions that worked and that did not work. Using this information, the final design was developed. This final design was then validated by performing a final user test and by looking into what extent the requirements had been met.

Simultaneously, a clamping solution that connects the SGW to the controller was developed. Out of several ideas, two concepts were developed out of which one was chosen through weighted criteria scoring. In a final stage, the clamps were integrated into the controller.

Results & Limitations

The final result of this thesis is a working Alpha prototype with a proof of principle clamping solution that is fully functional for demonstrational purposes. Thus, although the controller redesign has been successful as final user test results provided positive reactions in term of ergonomics, dimensions, tip control and intuitiveness, the clamping solution needs to be developed further to be able to test it properly in order to conclude if it is a proper solution. The proof of principle is however promising as it is a rather simple design that clamps the SGW without damaging it.

Conclusions and Recommendations

The research question: “What does the design for a user friendly, fully functional steerable guidewire controller look like?” is answered for a large part as the fully functional prototype has been finished and tested among users at DEMCON. Secondly, preliminary recommendations into follow up steps have been given regarding design for production, production scenarios and production prices. This is however a topic that needs to be looked into more thoroughly. The first steps in follow up design are however firstly, the further development of the clamp solution. Secondly, testing the product among intended users and validating the design accordingly before further steps into production can be and should be taken.

References

(Demcon, 2022): Retrieved February 25, 2022, from <https://demcon.com/>