# Usability engineering for a complex, medical device: a case study of an MR-Linac

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#### ABSTRACT

This paper summarises the activities required and complexities encountered while undertaking the usability engineering process for a large, complex, and new-to-the-world medical device – namely Elekta Unity, the first high field Magnetic Resonance (MR)-Linac. The early design-oriented activities have been presented previously, but the usability engineering has predominantly taken place since then. The main challenges lie in the sheer complexity of such a device – combining two potentially harmful technologies into one, in a usage context with many users with different roles to play, and where different components may have their own regulatory documentation.

#### **KEYWORDS**

Medical Devices, Usability Engineering, Case Study, Radiation Therapy, FDA

#### Introduction

Elekta Unity is the world's first high-field MR-Linac, enabling real-time viewing of diagnostic quality images during daily delivery of radiation therapy in cancer treatments. This means that changes in the tumor's size or position can be more easily seen and treatments adapted to enable much greater precision in the delivery of the harmful radiation.

As a potentially harmful medical device Elekta Unity requires a complete usability engineering process in order to acquire various regulatory approvals (e.g. 510K from the US government Food & Drug administration (FDA), CE Mark for Europe). Although we have previously presented the design work that lies behind Unity (Jenkins et al., 2017), in this case study we wish to share our experiences completing the usability validation. Our simple goal was to conduct an evaluation of the usability of all critical tasks (embedded in coherent, complete usage scenarios) for all relevant user groups on a production-equivalent system with production-ready training, thereby demonstrating that the product is safe and effective for use in clinical treatments. Most published accounts of this usability validation have tended to focus on relatively simple devices such as insulin pens and infusion pumps. To our knowledge there have not been (m)any accounts of usability validations for complex, multi-user medical devices.

#### The problem – the sources of complexity

From a regulatory perspective, Elekta Unity consists of a number of products (including the Linac, the patient positioning devices, the informatics system and the treatment planning system, for example) – yet for the user(s), a single use scenario might touch all of these. Furthermore, the everyday clinical workflows for Unity involve multiple users who have different skills and different roles. Radiation therapy is usually done by a team of two, and in the USA it is normal for one to be

a qualified radiation therapist and the other a qualified treatment planner (dosimetrist). Again almost every single use scenario requires actions from both users according to their qualifications.

#### Insights along the way

### Taking a systems approach

In order to resolve these complexities many questions arose – for example, do we do a usability validation per regulatory product? And an extra one for interoperability? Can we test two user groups at the same time, collaborating together on the overall tasks, but each doing their own critical tasks? And where would we be able to most easily access a fully updated and integrated, production-ready system on which the usability validation could occur?

We made the decision that we would conduct a single usability validation and create a single report that would be referenced by all the different regulatory submissions. We also decided that we would test each user group in isolation and use actors to play their collaborative colleague, so that we would have full control over exactly what their colleague did. Finally we decided that the validation should occur at a live customer site in the USA, so that we had easier access to US residents as participants for each user group – this meant taking re-possession of their research Unity in order to upgrade it to a production-ready, but not yet federally-approved version.

### Training is a critical constraint

In order to establish a timeline for the validation we needed to estimate how long each use scenario might take, as well as how much training would be required beforehand and with what decay period. The outcome of this analysis was the discovery that we would need 2-5 days of training for a usability validation session of around 2 hours and that some of the training would need to be conducted some months in advance in order to give them chance to practice and become familiar with pre-existing software tools.

In order to conduct our training and testing at a customer facility, without too much disruption, we also had to develop and build a training system simulator which was capable of mimicking Unity in every way except for having no magnet and no beam generator. This was installed in a different building, with a simulated control room as well, in order to provide classroom-style learning facilities.

#### Participants have to make a big commitment

In order to ensure our participants were invested in spending up to 5 days learning about the new system, we had to draw all our participants from our Unity Consortium partners. Fortunately they generally had quite a number of staff who would be expected to use Unity once it was approved for patient treatment, but who knew little about it yet – though even then, there were of course limits to how many staff they could lose at the same time. In the end, we were able to recruit the bulk of our three user groups from Unity customers within the USA. However, we were not able to reach 15 in each user group (let alone 18 to allow for some dropping out or getting sick) and had to draw in some participants from Canada, Australia and the UK to make up the numbers.

#### The role of domain knowledge

Running a usability validation of a system such as Unity requires a very substantial amount of domain knowledge – each of the user groups is themselves expert and they expect the moderators of the usability test to be similarly expert. However, since the study was to occur in Houston, Texas continuously over a 3 month period, we did not have a large enough pool with the required domain knowledge: We had moderators with expertise, but not observers and notetakers. This situation

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When	Activity	Location
August 2017	Initial Planning	Elekta
Sept 2017 - Jan 2018	Planning, Preparation & Recruitment	Elekta
Feb 2018	System Upgrade	Customer Site
March - June 2018	Usability Validation	Customer Site
June - Sept 2018	Analysis & Documentation	Elekta

Table 1: A rough timeline for the Usability Engineering of Elekta Unity

forced us to conduct a dry-run of the usability study with 2 users per user group (drawn from internal Elekta staff) in order to provide a basic training opportunity for the entire usability team. An unexpected benefit of this was that it also gave us an opportunity to ensure that the informatics system had enough sample patients and data within it to run the whole study, as well as to uncover places where the use of simulated data might cause problems for the hardware.

## Having a patient actor

Although we were not going to image or treat anyone, we did, of course, need a 'volunteer patient' to be positioned inside Unity's bore and to be 'rescued' in the emergency stop scenario. For this we were able to use three local medical students who very patiently went through the same testing routine 6-8 times per day! This strategy did however create a few challenges ... firstly that these volunteers knew a little more than a patient would and we had to instruct them carefully to not do or say anything more than was asked of them, which they found harder than expected. Secondly, we had earlier discovered that our patient positioning photos had to show the same person as the users actually were positioning (or else they would make uncontrolled decisions to resolve the contradictions), which meant we had to get our volunteer patients in early in the morning in order to take a set of setup pictures before the testing itself began.

## End Game

Despite many small (and not so small) disruptions to plans, including the delivery of a brand new Linac though the wall next to Unity's bunker, and delays to the start-date, the actual usability plan ran out almost exactly as originally scheduled 6 months earlier. Some pieces of training ran rather late into the night and some usability testing was delayed by thunderstorm-diverted flights, but in the end everything wrapped up on the forecast day and 15 participants for each of the three user groups were successfully tested. In total, there were around 90 different people who stayed for an average of 8 nights each in order to complete the summative validation. Remarkably the only changes to people's flight plans were either caused by the weather, or were to allow them to go home earlier than planned – no-one had to change to a later flight than they had already booked!

Most importantly, however, the process of going through all of this has enabled us to manage our next usability engineering projects in a much more efficient manner and with far fewer surprises. However, the challenge of locating a machine / system which is production ready and which can be blocked off for usability testing for an extended period of time is still a significant challenge, as is the problem of identifying the detailed training needs far enough in advance to make it possible to plan out the detailed schedule.

The broad timeline for achieving this usability validation is shown in Table 1. CE Mark was achieved in June 2018 and the first patients were treated in Europe in September 2018. Following

the FDA's normal review process Unity achieved its US approval in December 2018 and the first patients in the USA were treated in January 2019.

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### References

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