Learning by Doing: Usability testing of an innovative medical device

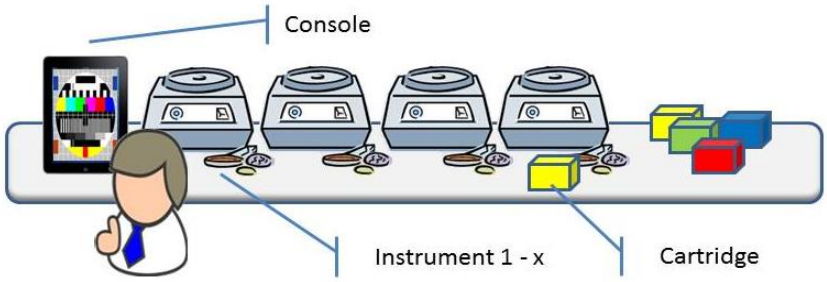
In this paper I will tell you about my journey on I initiated and lead usability testing of a new medical DNA analysis system in a young company and what I learned from that 'trip'.

I will share details on how and what I have done to test and verify the user-friendliness and learnability of the system in a regulatory environment and what I learned from applicable standards. It will tell about the challenges to deploy a transparent and auditable usability program, using different heuristics, methods and tools and involving various intended users.

My experiences and learnings will be discussed regarding working with a team of biologists, researchers, hardware and software engineers, and how collaboration and perseverance lead to appreciated test results making myself and laboratory staff enthusiastic about usability testing.

These experiences might be of help to you in your own testing journey.

The context and the system
A young company is developing a new and revolutionary molecular diagnostics system. The system is to be used to automate analysis of human DNA to check whether a patient has a disease or not, e.g. cancer or MRSA. Currently such analysis is laborious and complex, and therefore are often carried out in batches in central laboratories. Resulting in waiting time up to weeks and even worse: uncertainty for the patient while waiting for the outcome. The great advantage of this system is that, with a disease specific cartridge, the research can be conducted with minimal user intervention: "Sample - Result out" in about 1.5 hours.



The system consists of a console, one or more instruments and (disposable) cartridges containing specific chemicals. A patient sample is being introduced into the cartridge with tweezers, a pipette or a swab. The cartridge is closed and inserted into an available instrument. The instrument processes the cartridge, analyses the data and concludes the result. The console supports the workflow for creating analysis requests and making the results available.

Risk management & Regulations
Regulatory bodies such as the FDA, consider "user friendliness", "learnability" and "Error Prevention" as very important. This is why it is important to comply to the ISO 62366: a standard for application of usability engineering to medical devices. If you comply to this standard, there is less to explain to FDA.

From the beginning of the development of the system attention has been paid to usability, but the company was still searching for a suitable "usability" test approach. Therefore, as test architect for Verification, I composed a test approach and guided the implementation and execution.

Important elements from ISO-62366:
- Deployment of risk management in the engineering approach for medical systems is required. Think about active prevention of (user) errors, such as input validation and a robust workflow, or placing the cartridge into the instrument in only one way.
- Iterative development and testing. Evaluation as early as possible by reviews and testing during the design, verification and validation phases of product development (V-model).

However, this was the first time that I was actively involved in usability testing and also '62366' was new to me. At that moment in time I had some time and took the opportunity to dive into the standard. I started studying the content and thought about how I could implement this standard in a practical way.

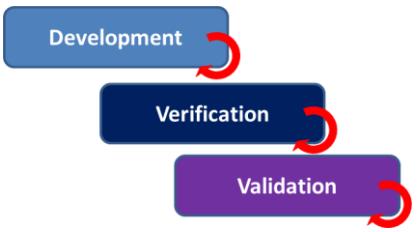
Usability Program

Based on the above, the following test approach was recommended:

1. Analyse all requirements and mark those that are usability related. This will demonstrate that usability has been taken care of throughout the development.
2. Compose a usability test program containing appropriate tests for the various V-model phases (development, verification and validation). Make use of heuristics and methods well-known in the software world, such as Heuristic Evaluation [Nielsen, http://www.nngroup.com/articles/ten-usability-heuristics/] and Software Usability Measurement Inventory and (SUMI) [http://sumi.ucc.ie/].

The usability test program consisted of:

- Reviews and testing with internal users during the development phase.
- Usability testing and surveys with external users in the company laboratory during the verification phase.
- Observations and surveys with external users in their own workplace during the (clinical) validation.



Deployment and execution
The analysis of the requirements was a relatively easy step: all system requirements were analysed and marked if a usability aspect was recognizable. During regular verification tests these requirements were verified and proved that the system meets these usability aspects.

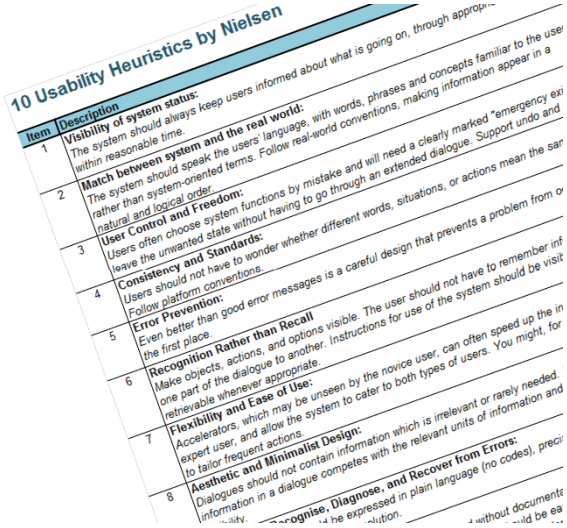
For the implementation of the usability testing, I assembled a team with a project manager, a biological laboratory representative and myself as test architect.

Available 'use cases' formed an important basis for our usability testing. However, these use cases were far from complete, so we tackled this first. In a workshop the system life cycle stages were defined: from installation, use, service, up to removal from the laboratory. For these stages all (user) activities we could come up with where inventoried. Based on that, we revised the use cases for each stage and provided details such as the type of user, knowledge level, use case paths (happy flow, alternatives and unhappy flows) and frequency of use.

Development: Reviews and Exploratory Testing
In parallel, during development the first usability tests were conducted in an exploratory way. We prepared charters for some common use cases and for system issues on which fast feedback was needed: insertion and cutting of a swab within the cartridge, and insertion of the cartridge into the instrument. These exploratory tests were very effective and efficient: within a few hours we got a lot of feedback! "For the record" and for further analysis, we made notes and video recordings.

By this, the usability test program was "put on the map". Collaboration between developers and testers was boosted as well as the enthusiasm of management and the usability team.

Although late, in parallel with the exploratory tests, usability reviews have been conducted in the development phase, using the 10 heuristics of Nielsen. Despite careful preparation, including an explanatory kick-off, the review started slowly. One of the arguments: "but we have already reviewed?". True, but never with a focus on usability aspects. Based on the first usability testing results and after repeated explanation of the heuristics, finally feedback was obtained. Several review findings were also found during our exploratory testing. So, a missed opportunity to find and fix the issues in an earlier stage, e.g. before testing. For me a good reason to focus more on early (heuristic) reviewing in my next project.


10 Usability Heuristics by Nielsen

Item	Description
1	**Visibility of system status:** The system should always keep users informed about what is going on, through appropri... within reasonable time.
2	**Match between system and the real world:** The system should speak the users' language, with words, phrases and concepts familiar to the user rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.
3	**User Control and Freedom:** Users often choose system functions by mistake and will need a clearly marked "emergency exi leave the unwanted state without having to go through an extended dialogue. Support undo and
4	**Consistency and Standards:** Users should not have to wonder whether different words, situations, or actions mean the sar Follow platform conventions.
5	**Error Prevention:** Even better than good error messages is a careful design that prevents a problem from o the first place.
6	**Recognition Rather than Recall** Make objects, actions, and options visible. The user should not have to remember inf one part of the dialogue to another. Instructions for use of the system should be visit retrievable whenever appropriate.
7	**Flexibility and Ease of Use:** Accelerators, which may be unseen by the novice user, can often speed up the in expert user, and allow the system to cater to both types of users. You might, for to tailor frequent actions.
8	**Aesthetic and Minimalist Design:** Dialogues should not contain information which is irrelevant or rarely needed. information in a dialogue competes with the relevant units of information and
	ecognise, Diagnose, and Recover from Errors: d be expressed in plain language (no codes), preci olution. without documenta ld be ea

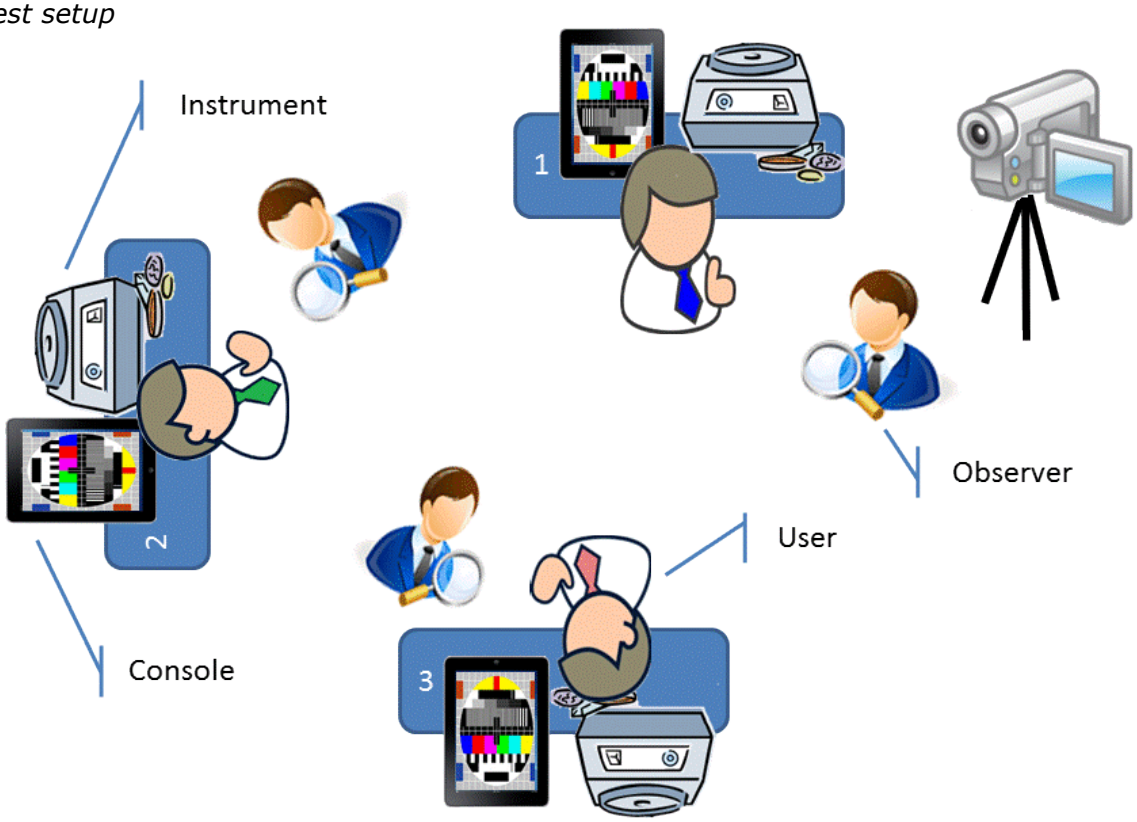
Verification: Test specifications and test sessions
For the usability tests with real and external laboratory user during the verification phase, we needed test specifications. We created scenarios based on the use cases which were grouped by user type (novice users, experienced users, administrators) taking into account the basic, alternative and exception paths of the use cases as well as the frequency of use of the use cases.

The scenarios (test protocols) only had a limited level of detail. If the user can independently work with the system without further explanation, this would show "learnability".

The next important step was to find and invite (external) representative users for the test sessions. Along with the marketing department users were found with different knowledge / experience levels, in a variety of ages and from different countries: from Norway to Gibraltar. Keep in mind that curious people willing to participate in your test might be too smart to be representative for your intended user group. However, sometimes you just have to deal with what you can get…

We organized sessions of about 1 to 1,5 day, grouped by knowledge / experience level. After a general introduction to the company, the system and an explanation of the usability testing plan, our guests were given a short user training of approximately 30 minutes on the system in a laboratory environment. Then it was their turn to execute the test protocols.
Per user (max. 3 per session), one observer was present to observe and take notes. In principle, the observer will not assist the user with test execution.
For evidence and for further analysis, again video recordings were made using a visible but strategically placed basic handheld video camera (see picture below).

Test setup



Everything came together during these sessions. The careful preparations, a user-friendly system, and enthusiastic users! The level of detail of the testing protocols was just right. The users were able to perform their tasks independently and according to plan with minimal instruction and intervention.

After each session, a feedback round was held with our guests starting with filling out a questionnaire. The questionnaire was based on SUMI questionnaire supplemented with similar questions about e.g. the insertion of the patient sample up to presentation of the concluded clinical result. The guests were asked whether they would recommend the system (Net Promoter Score) and what their 'Top 3' is of strengths and weaknesses.

Subjective vs. Objective
One aspect of usability is the subjectivity, what cannot be made fully objective. Usability according to [ISO 9126] is: the capability of the software to be understood learned, used and being attractive to the user when used under specified conditions. Regularly we had discussions with the developers about subjective topics like 'attractive' and 'inconvenient'.
Analysis of the observations and questionnaires however confirmed and quantified subjective opinions. This made them quantitative, helping in the decision to process a usability issue or not.

A test is not complete without...
…an expected result. For the requirements with a usability aspect the expected outcome was simple: the verification should pass. We inspected the verification test reports to verify whether the tests were performed and the results were 'passed'.

The 'learnability' requirement was specified as '90% of the users must be able to use system after a short training'. After the 30 minutes-course, all of our guests were able to work with the system independently without any problems or aid. Confirmed by the questionnaire results, we concluded that this requirement was 'pass'.

Whether it is "attractive" is to work with the system, was also derived from the questionnaires. With a score of over 8 out of 10, this requirement was also considered 'pass'. Nevertheless, the improvements suggested by the guests will be taken into account during further development.

Validation
As my assignment ended after Verification, I was not involved during Validation unfortunately. Later I heard from the former colleagues that during validation the surveys showed similar results: users were very enthusiastic.
However: usability issues that had been identified during development and verification and that had not been improved during development, were again mentioned by the 'validation users'. Finally, the organization took up some of the improvements after all with bigger development impact.

My next journey….
After more than a year in the automotive industry, I'm now again involved in development of another new medical device. During the interviews I cautiously informed how and who is going to take care about usability engineering and testing. Guess what: I got the assignment. But now I should also organize the usability engineering part, so before the testing. So, another part to be explored, learned and to be done. My next journey has started!

Conclusion
If you want to learn about it, just start doing it, in this case study and explore the ISO 63266.
To implement usability testing succesfully, start early with usability reviews. Prepare and introduce them well, and they will provide early and cheap feedback.

Use and learn from methods and heuristics from the software world. They form a good basis for setting up usability testing, not only in a regulated environment.

Engineering (development and testing) of "non-functionals" is subjective and are not 'automatically' picked up. However, ignoring them will hit you later.

A team that is eager and passionate does not need much to get good results.

And above all, I learned a lot and became even more interested in usability and human factors of users. Just by 'doing it'.

Biography: Patrick Duisters

During his 25+ years professional career Patrick Duisters has been working in various industries. He started in metal constructions and got involved in 'everything with a keyboard'. 19 years ago he switched to IT and started working as a tester. In those years he worked in banking, insurance, government, automotive and in the medical industry.
The last years he has been internationally active as consultant, trainer/teacher, auditor and systems test architect in the medical domain. He has special interests in test process improvement and usability.
Patrick is (co-) author of presentations at conferences and publications of articles in magazines in the area of testing.

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