

Learning by Doing

Usability testing
of an innovative medical device



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EuroSTAR
Software Testing
CONFERENCE

STOCKHOLM
31.10 - 03.11
2 0 1 6



Welcome to Scotland
Fàilte gu Alba

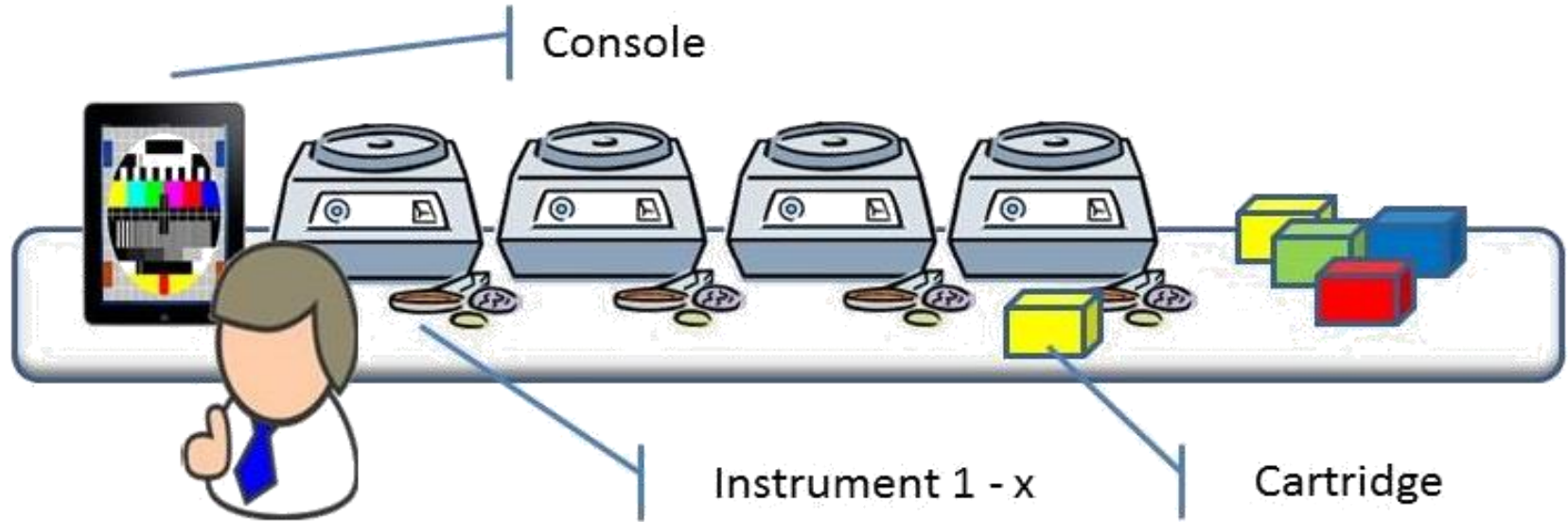


Plan for this journey...

- Context
- Usability & Standards
- Usability Program
- Deployment
- Results & Conclusion
- My next journey...



Molecular In Vitro Diagnostics Platform



Regulations & Regulatory bodies: i.e. FDA

Norms & standards:

- ISO 13485 Quality Management System for the design and manufacture of medical devices
- ISO 14971 MDs - Application of Risk Management to Medical Devices
- ISO 62304 Medical Device Software - Software life cycle processes
- **ISO 62366: Medical Devices – Part 1:
Application of usability engineering to medical devices**

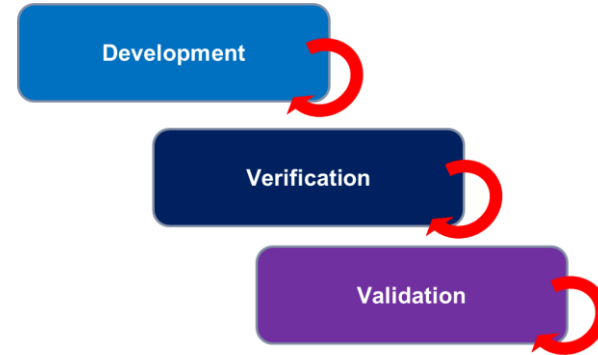
What is Usability?



USABILITY: characteristic of the USER INTERFACE that facilitates use and thereby establishes **EFFECTIVENESS, EFFICIENCY** and **USER SATISFACTION** in the intended **USE ENVIRONMENT** (after ISO 62366-2015)



Elements of ISO 62366

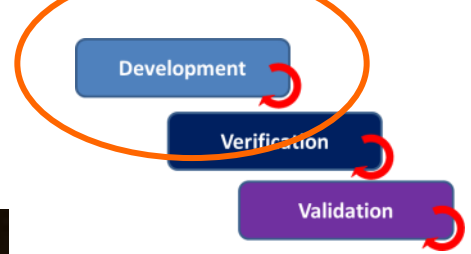


Usability Program

- Reviews & testing
- Usability testing & survey
- Observations & survey



Development



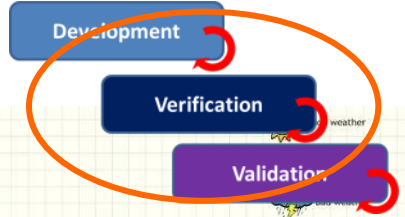
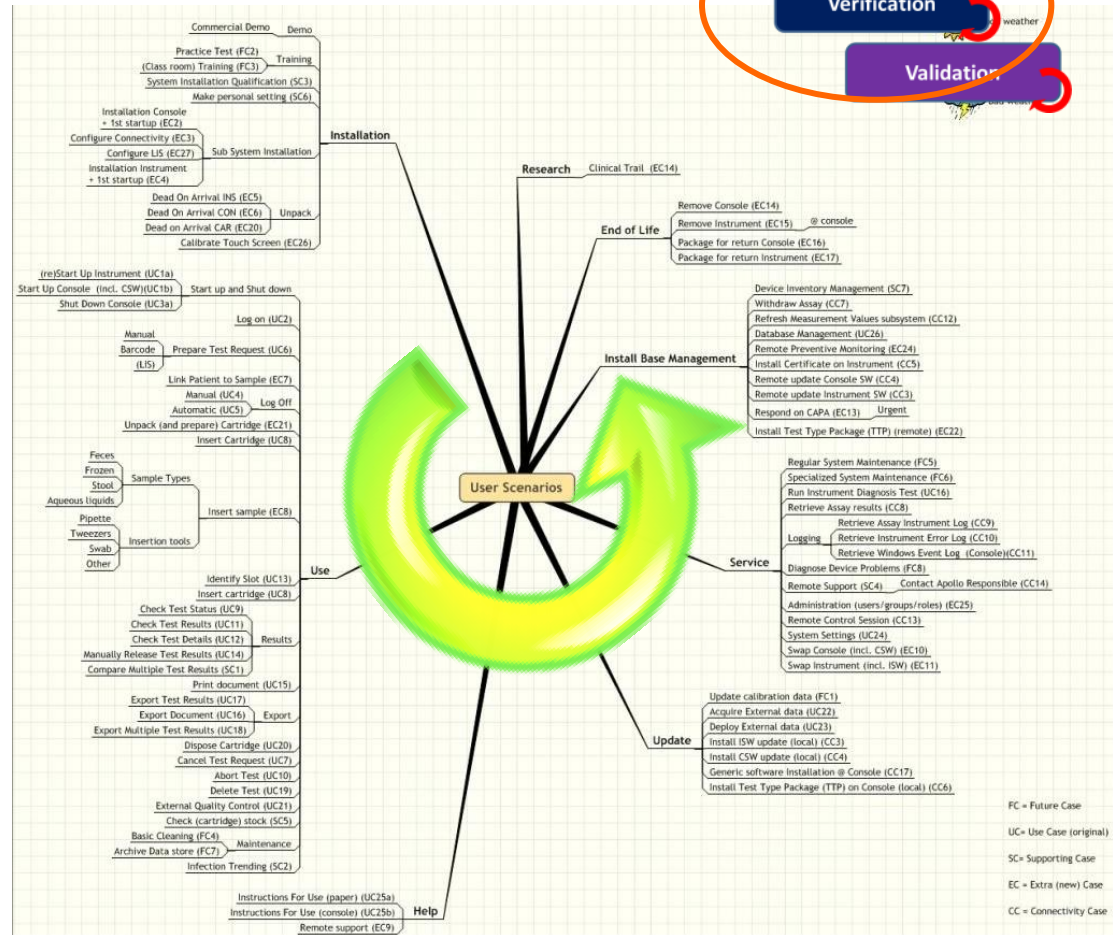
- Heuristic Analysis
- Exploratory Testing

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 appropriate feedback 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 natural and logical order.
3	User Control and Freedom: Users often choose system functions by mistake and will need a clearly marked "escape" mechanism to leave the unwanted state without having to go through an extended dialogue. Support undo, redo, and other "emergency exit" actions.
4	Consistency and Standards: Users should not have to wonder whether different words, situations, or actions represent the same thing. Follow platform conventions.
5	Error Prevention: Even better than good error messages is a careful design that prevents a problem from occurring in the first place. Accepting that errors will occur, and providing a clear path to the right solution, rather than blaming the user, is a better approach.
6	Recognition Rather than Recall Make objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible whenever appropriate.
	Help and Assistance: Users may not know what they want, or may not know how to get it. A good system is one that caters to both types of users.

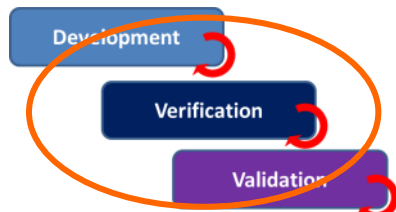
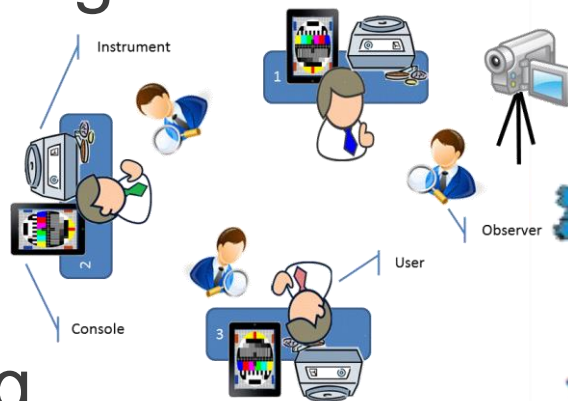
Verification (1/2)

- User analysis
- Use cases
- Primary operating functions
- Frequently used functions



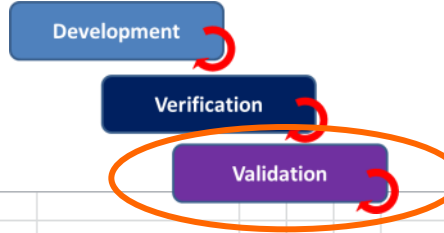
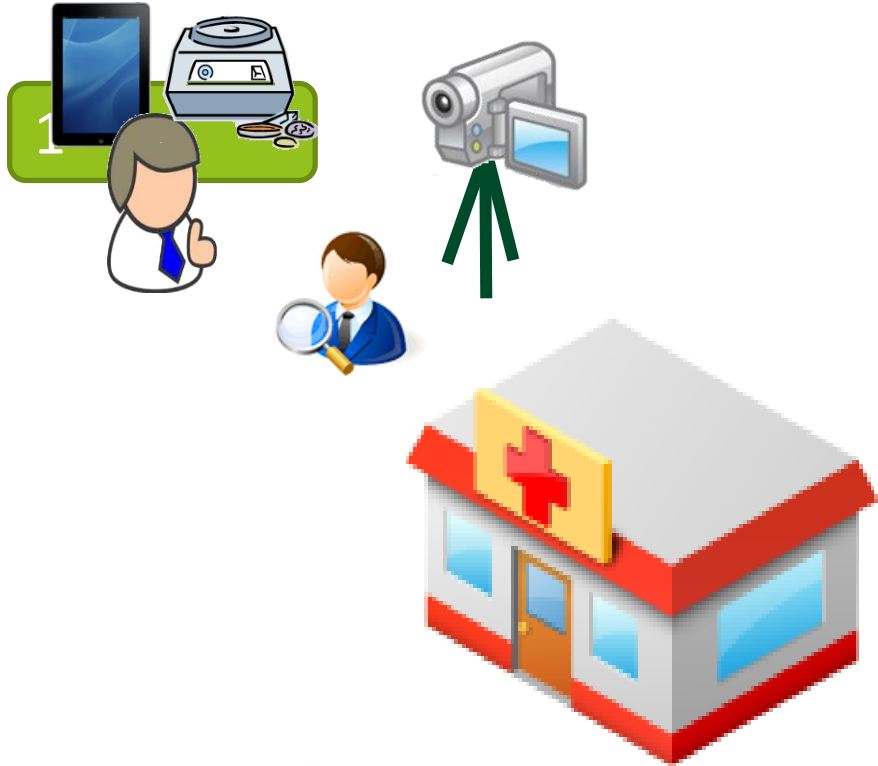
Verification (2/2)

- Test environment & test procedures
- User selection & gathering
- “User training”
- Execution
- Debrief
- Results & Reporting



Usability Questionnaire Results Summary				
Test Charter Colulshka (raz sled front page)				
Scoring Results Usability Szozinar				
August/September 2013				
Date	4-Sep-2013			
Test Item	IVU			
Description	System Usability Measurement Inventory			
Number of participants: 7				
I Installation & Training				
i1	After the user training I feel confident to operate the system	5	1	F
P Test Preparation				
p1	The assay type can easily be recognized through the labeling on the	2	4	F
p2	The assay type can easily be recognized through the labeling on the	1	5	F
p3	When I open the cartridge pouch I will not use a tool.	7	0	Q
p4	When I prepare a cartridge I usually will read the instructions for use.	1	2	Q
p5	The (liquid) sample can easily be introduced into the cartridge.	7	0	F
p6	The sample can easily be introduced into the cartridge.	1	1	F
p7	It is easy to introduce a sample on swab into the cartridge.	4	0	F
p8	The opening of the cartridge is stable to use.	7	0	F
p9	The cartridge is NOT suitable for use during sample	2	2	F
p10	The instructions for introducing sample into the cartridge are	3	4	F
p11	Creating a new test using the system is as easy as	1	5	F
p12	refer to a close instrument in which I want to run the test,	1	2	Q
p13	The test is already started when the test request is completed.	3	1	Q
p14	The cartridge can easily be inserted into the instrument.	7	0	F
C	Do you have any other questions, remarks, suggestions for			
R Test Request (console) (1)				
r1	This system responds too slowly to inputs.	1	0	F

Validation



Usability Questionnaire

Test Charter Colophon (see also front page) BC-002483

Tester name	Version
Date	Status
Test Item Apollo	
Description System Usability Measurement Inventory	

Please first fill in your scores (Agree, Undecided, Disagree), and only then fill in the WHY as suggestion for improvement

		Agree	Undecided	Disagree
I	Installation & Training			
ii	After the user training I feel confident to operate the system			
P	Test Preparation			
p1	The assay type can easily be recognized through the labeling on the cartridge packaging			
p2	The assay type can easily be recognized through the labeling on the cartridge			
p3	When I open the cartridge pouch I will not use a tool.			
p4	When I insert a cartridge I usually will read the instructions for use			

Results, Conclusion

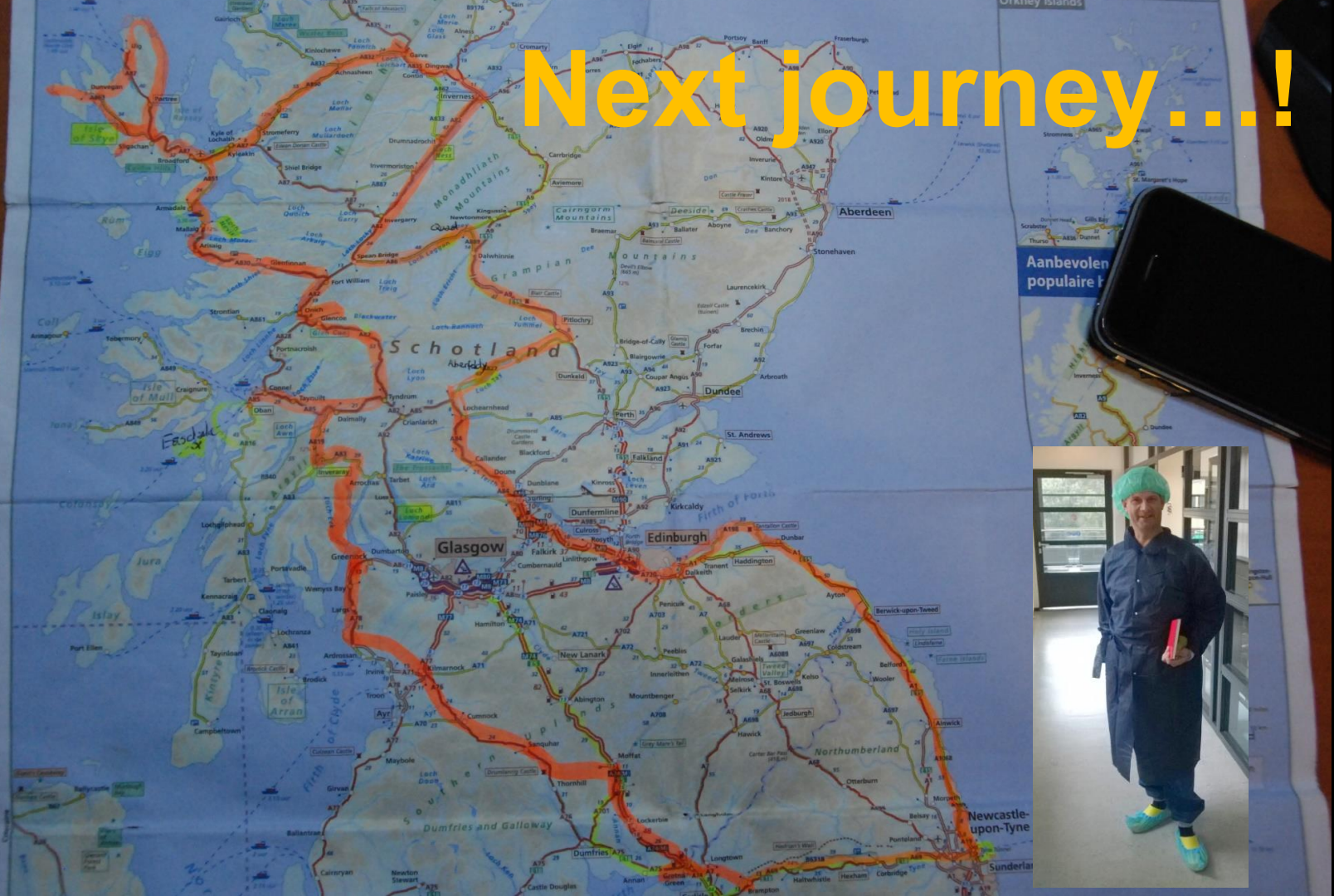
- Subjective vs. Objective
- Expected results & Findings:
 - Verification
 - User Friendliness
 - Learnability
 - Error Prevention
- Standards can be helpful, treat as heuristics
- Proof required? ⇒ Practical solutions

It's so much FUN!

*New?
Explore,
Learn,
DO!*



Next journey...!



Without a journey you will get nowhere!



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