Medical device usability testing

Report of the formative study 1

Figure 1: Picture of the cover page.

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Purpose

In this formative study, the usability of a medical device was tested.
It was a bright cold day in April, and the clocks were striking thirteen. Winston Smith, his chin nuzzled into his breast in an effort to escape the vile wind, slipped quickly through the glass doors of Victory Mansions, though not quickly enough to prevent a swirl of gritty dust from entering along with him.

Background

The hallway smelt of boiled cabbage and old rag mats. At one end of it a coloured poster, too large for indoor display, had been tacked to the wall. It depicted simply an enormous face, more than a metre wide: the face of a man of about forty-five, with a heavy black moustache and ruggedly handsome features. Winston made for the stairs. It was no use trying the lift. Even at the best of times it was seldom working, and at present the electric current was cut off during daylight hours. It was part of the economy drive in preparation for Hate Week. The flat was seven flights up, and Winston, who was thirty-nine and had a varicose ulcer above his right ankle, went slowly, resting several times on the way. On each landing, opposite the lift shaft, the poster with the enormous face gazed from the wall. It was one of those pictures which are so contrived that the eyes follow you about when you move. BIG BROTHER IS WATCHING YOU, the caption beneath it ran.

Scope

ETH Zurich has created this new device and Luca Autunno had to test it.
Inside the flat a fruity voice was reading out a list of figures which had something to do with the production of pig-iron. The voice came from an oblong metal plaque like a dulled mirror which formed part of the surface of the right-hand wall. Winston turned a switch and the voice sank somewhat, though the words were still distinguishable. The instrument (the telescreen, it was called) could be dimmed, but there was no way of shutting it off completely. He moved over to the window: a smallish, frail figure, the meagreness of his body merely emphasized by the blue overalls which were the uniform of the Party. His hair was very fair, his face naturally sanguine, his skin roughened by coarse soap and blunt razor blades and the cold of the winter that had just ended.

Terms definitions

Abnormal use

Conscious, intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer. [2]

Clinical evaluation

‘Clinical evaluation’ means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. [1]

Clinical investigation

‘Clinical investigation’ means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device. [1]

Critical task

A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care. [3]

Formative evaluation

User interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated user errors. [2]

Human factors engineering

The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use.
Human factors engineering and usability engineering can be considered to be synonymous. [3]

Medical device

'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [1]

Summative evaluation

User interface evaluation conducted at the end of the user interface development with the intent to obtain objective evidence that the user interface can be used safely. [2]

Usability

Characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment. [2]

Usability engineering

Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability. [2]

Use environment

Actual conditions and setting in which users interact with the medical device. [2]

Use error

User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by

device failure and (3) did or could result in harm. Use safety Freedom from unacceptable use-related risk. [3]

Use specification

Summary of the important characteristics related to the context of use of the medical device. [2]

User interface

Means by which the user and the medical device interact. [2]

Ethics statement

Outside, even through the shut window-pane, the world looked cold. Down in the street little eddies of wind were whirling dust and torn paper into spirals, and though the sun was shining and the sky a harsh blue, there seemed to be no colour in anything, except the posters that were plastered everywhere. The black-moustachio'd face gazed down from every commanding corner. There was one on the house-front immediately opposite. BIG BROTHER IS WATCHING YOU, the caption said, while the dark eyes looked deep into Winston's own. Down at street level another poster, torn at one corner, flapped fitfully in the wind, alternately covering and uncovering the single word INGSOC. In the far distance a helicopter skimmed down between the roofs, hovered for an instant like a bluebottle, and darted away again with a curving flight. It was the police patrol, snooping into people's windows. The patrols did not matter, however. Only the Thought Police mattered.

Device specifications

Behind Winston's back the voice from the telescreen was still babbling away about pig-iron and the overfulfilment of the Ninth Three-Year Plan. The telescreen received and transmitted simultaneously. Any sound that Winston made, above the level of a very low whisper, would be picked up by it; moreover, so long as he remained within the field of vision which the metal plaque commanded, he could be seen as well as heard. There was of course no way of knowing whether you were being watched at any given moment. How often, or on what system, the Thought Police plugged in on any individual wire was guesswork. It was even conceivable that they watched everybody all the time. But at any rate they could plug in your wire whenever they wanted to. You had to live – did live, from habit that became instinct – in the assumption that every sound you made was overheard, and, except in darkness, every movement scrutinised.

Figure 2: Some medical devices.

Figure 3: Another medical device is shown here.

Test procedure

Goal

In this study, 10 participants were asked to perform 5 critical tasks.

Winston kept his back turned to the telescreen. It was safer; though, as he well knew, even a back can be revealing. A kilometre away the Ministry of Truth, his place of work, towered vast and white above the grimy landscape. This, he thought with a sort of vague distaste – this was London, chief city of Airstrip One, itself the third most populous of the provinces of Oceania. He tried to squeeze out some childhood memory that should tell him whether London had always been quite like this. Were there always these vistas of rotting nineteenth-century houses, their sides shored up with baulks of timber, their windows patched with cardboard and their roofs with corrugated iron, their crazy garden walls sagging in all directions? And the bombed sites where the plaster dust swirled in the air and the willowherb straggled over the heaps of rubble; and the places where the bombs had cleared a larger patch and there had sprung up sordid colonies of wooden dwellings like chicken-houses? But it was no use, he could not remember: nothing remained of his childhood except a series of bright-lit tableaux, occurring against no background and mostly unintelligible.

Participants

The Ministry of Truth – Minitrue, in Newspeak1 – was startlingly different from any other object in sight. It was an enormous pyramidal structure of glittering white concrete, soaring up, terrace after terrace, three hundred metres into the air. From where Winston stood it was just possible to read, picked out on its white face in elegant lettering, the three slogans of the Party:

WAR IS PEACE

FREEDOM IS SLAVERY

IGNORANCE IS STRENGTH.

Figure 4: Some professionals looking at a screen.

Use environment

The Ministry of Truth contained, it was said, three thousand rooms above ground level, and corresponding ramifications below. Scattered about London there were just three other buildings of similar appearance and size. So completely did they dwarf the surrounding architecture that from the roof of Victory Mansions you could see all four of them simultaneously. They were the homes of the four Ministries between which the entire apparatus of government was divided. The Ministry of Truth, which concerned itself with news, entertainment, education and the fine arts. The Ministry of Peace, which concerned itself with war. The Ministry of Love, which maintained law and order. And the Ministry of Plenty, which was responsible for economic affairs. Their names, in Newspeak: Minitrue, Minipax, Miniluv and Miniplenty.

Figure 5: This looks like a chair… or a bed…

Use scenarios

The Ministry of Love was the really frightening one. There were no windows in it at all. Winston had never been inside the Ministry of Love, nor within half a kilometre of it. It was a place impossible to enter except on official business, and then only by penetrating through a maze of barbed-wire entanglements, steel doors and hidden machine-gun nests. Even the streets leading up to its outer barriers were roamed by gorilla-faced guards in black uniforms, armed with jointed truncheons.

Winston turned round abruptly. He had set his features into the expression of quiet optimism which it was advisable to wear when facing the telescreen. He crossed the room into the tiny kitchen. By leaving the Ministry at this time of day he had sacrificed his lunch in the canteen, and he was aware

that there was no food in the kitchen except a hunk of dark-coloured bread which had got to be saved for tomorrow's breakfast. He took down from the shelf a bottle of colourless liquid with a plain white label marked VICTORY GIN. It gave off a sickly, oily smell, as of Chinese rice-spirit. Winston poured out nearly a teacupful, nerved himself for a shock, and gulped it down like a dose of medicine.

Setup

Instantly his face turned scarlet and the water ran out of his eyes. The stuff was like nitric acid, and moreover, in swallowing it one had the sensation of being hit on the back of the head with a rubber club. The next moment, however, the burning in his belly died down and the world began to look more cheerful. He took a cigarette from a crumpled packet marked VICTORY CIGARETTES and incautiously held it upright, whereupon the tobacco fell out onto the floor. With the next he was more successful. He went back to the living room and sat down at a small table that stood to the left of the telescreen. From the table drawer he took out a penholder, a bottle of ink and a thick, quarto-sized blank book with a red back and a marbled cover.

Figure 6: Kind of computer that is used in a hospital.

Results

Effectiveness analysis

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Disinfection			1				1	1		
Opening	2					2			2	
Collect sampling				3				3		

Storing	**4**	**4**								**4**
Cleaning		**5**				**5**			**5**	

No problem found
Important problem found
Marginal problem found
Critical problem found

Problems description

1. Participants forgot to disinfect.
2. Participants did not manage to open the box.
3. The participant did an error in the number.
4. Participants forgot to use soap.
5. Participants did not clean the device at all.

Discussion

For some reason the telescreen in the living room was in an unusual position. Instead of being placed, as was normal, in the end wall, where it could command the whole room, it was in the longer wall, opposite the window. To one side of it there was a shallow alcove in which Winston was now sitting, and which, when the flats were built, had probably been intended to hold bookshelves. By sitting in the alcove, and keeping well back, Winston was able to remain outside the range of the telescreen, so far as sight went. He could be heard, of course, but so long as he stayed in his present position he could not be seen. It was partly the unusual geography of the room that had suggested to him the thing that he was now about to do.

Time on tasks

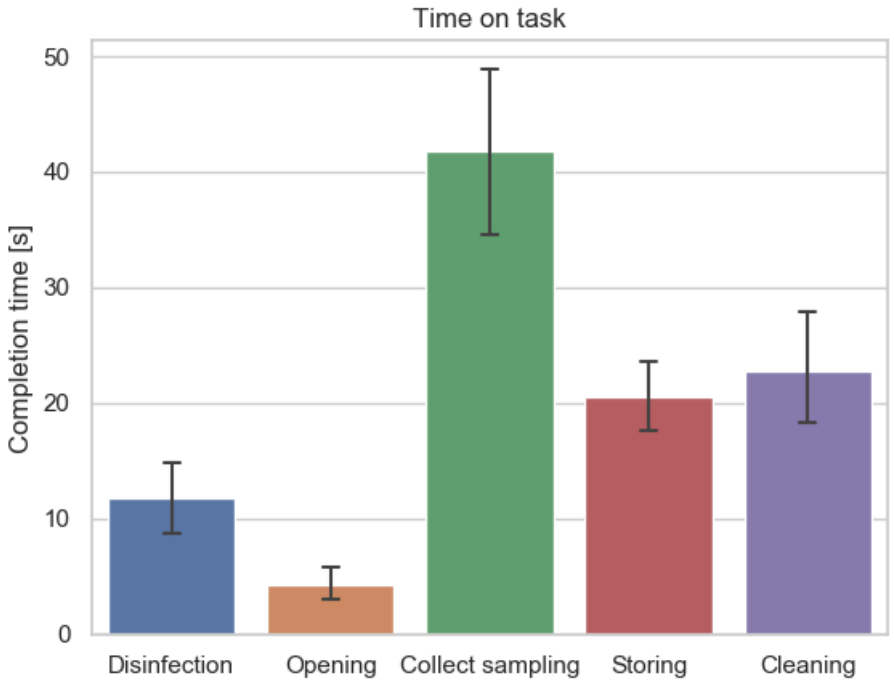

Figure 7: Bar plot showing the mean of the time on tasks and the 95% confidence interval.

Discussion

But it had also been suggested by the book that he had just taken out of the drawer. It was a peculiarly beautiful book. Its smooth creamy paper, a little yellowed by age, was of a kind that had not been manufactured for at least forty years past. He could guess, however, that the book was much older than that. He had seen it lying in the window of a frowzy little junk-shop in a slummy quarter of the town (just what quarter he did not now remember) and had been stricken immediately by an overwhelming desire to possess it. Party members were supposed not to go into ordinary shops ('dealing on the free market', it was called), but the rule was not strictly kept, because there were various things such as shoelaces and razor blades which it was impossible to get hold of in any other way. He had given a quick glance up and down the street and then had slipped inside and bought the book for two dollars fifty. At the time he was not conscious of wanting it for any particular purpose. He had carried it guiltily home in his briefcase. Even with nothing written in it, it was a compromising possession.

Dwell times and revisits

Areas of interest	Dwell times [s]	Average [s]	Max [s]	Min [s]	Revisits
Bottle	0.9587	0.4736	0.6585	0.2937	0.8
Background	76.0603	0.7698	5.1971	0.1299	182.3
Shoe	89.683	0.8862	3.5584	0.1299	199.0
Sponge	61.1355	0.7027	3.498	0.13	147.0
Sink	0.6699	0.1675	0.2399	0.13	4.0

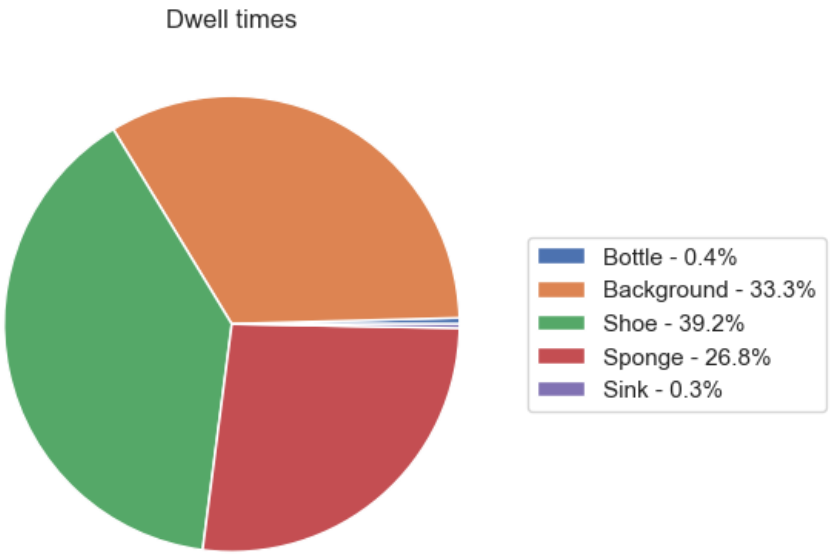

Figure 8: Average total dwell times amount for each area of interest over all participants.

Discussion

The thing that he was about to do was to open a diary. This was not illegal (nothing was illegal, since there were no longer any laws), but if detected it was reasonably certain that it would be punished by death, or at least by twenty-five years in a forced-labour camp. Winston fitted a nib into the penholder and sucked it to get the grease off. The pen was an archaic instrument, seldom used even for signatures, and he had procured one, furtively and with some difficulty, simply because of a feeling that the beautiful creamy paper deserved to be written on with a real nib instead of being scratched with an ink-pencil. Actually he was not used to writing by hand. Apart from very short

notes, it was usual to dictate everything into the speakwrite, which was of course impossible for his present purpose. He dipped the pen into the ink and then faltered for just a second. A tremor had gone through his bowels. To mark the paper was the decisive act. In small clumsy letters he wrote: April 4th, 1984.

Average fixation

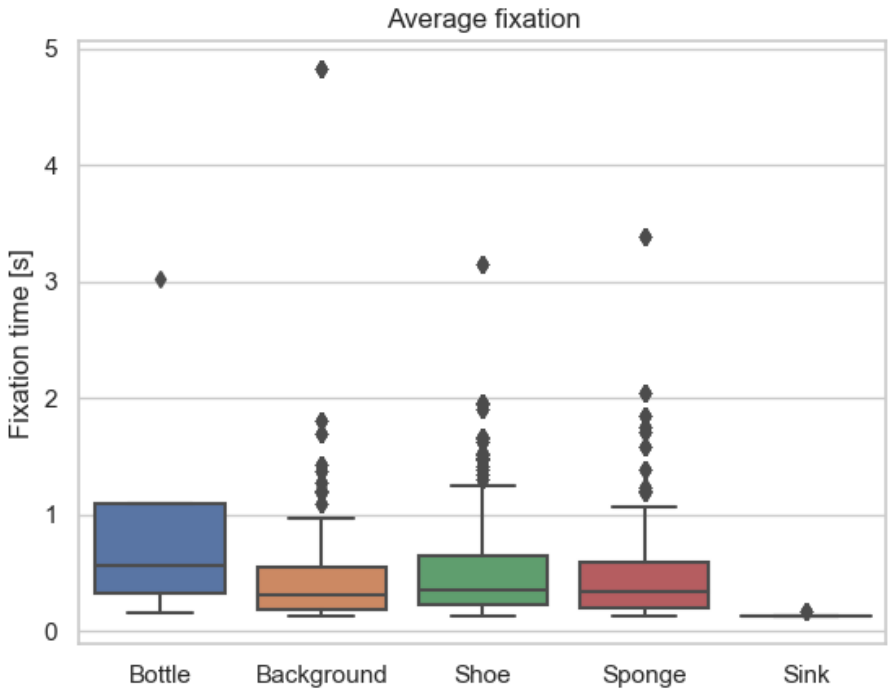

Figure 9: Box plot showing the mean, the 25% and 75% quartiles and the distribution of the fixation time.

Discussion

He sat back. A sense of complete helplessness had descended upon him. To begin with he did not know with any certainty that this was 1984. It must be round about that date, since he was fairly sure that his age was thirty-nine, and he believed that he had been born in 1944 or 1945; but it was never possible nowadays to pin down any date within a year or two.

Transitions

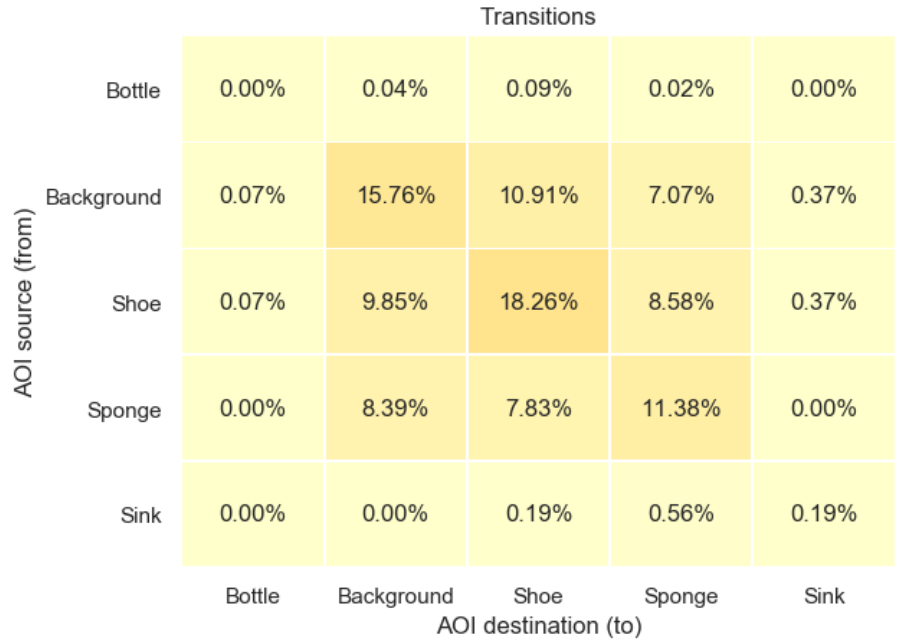

Figure 10: Amount of transitions from an area of interest to another.

Discussion

For whom, it suddenly occurred to him to wonder, was he writing this diary? For the future, for the unborn. His mind hovered for a moment round the doubtful date on the page, and then fetched up with a bump against the Newspeak word doublethink. For the first time the magnitude of what he had undertaken came home to him. How could you communicate with the future? It was of its nature impossible. Either the future would resemble the present, in which case it would not listen to him: or it would be different from it, and his predicament would be meaningless.

Conclusion

For some time he sat gazing stupidly at the paper. The telescreen had changed over to strident military music. It was curious that he seemed not merely to have lost the power of expressing himself, but even to have forgotten what it was that he had originally intended to say. For weeks past he had been making ready for this moment, and it had never crossed his mind that anything would be needed except courage. The actual writing would be easy. All he had to do was to transfer to paper the interminable restless monologue that had been running inside his head, literally for years. At this moment, however, even the monologue had dried up. Moreover his varicose ulcer had begun itching unbearably. He dared not scratch it, because if he did so it always became inflamed. The seconds were ticking by. He was conscious of nothing except the blankness of the page in front of him, the itching of the skin above his ankle, the blaring of the music, and a slight booziness caused by the gin.

Document history

Version	Author	Description of changes

Appendix

References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. Edition 1.0. Geneva: International Electrotechnical Commission; 2015. ISBN:978-2-8322-2281-2.
3. FDA (2016) Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff.

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Participants' characteristics

Participant	Gender	Age	Function	Disease / Handicap	Experience	Known similar devices
P1	Male	105	Patient	Blind	No experience	
P2	Female	24	Nurse		Expert	ETH device
P3	Male	35	Doctor		Expert	EPFL device
P4	Male	64	Patient		No experience	
P5	Female	32	Patient		Expert	EPFL device
P6	Male	18	Student		No experience	
P7	Female	54	Doctor		Expert	EPFL device
P8	Male	27	Patient	Deaf	Little experience	EPFL device
P9	Female	33	Student		Little experience	ETH device
P10	Female	72	Patient	Paraplegic	No experience	