

Medical device usability testing

Report of the formative study 2



Figure 1: Picture of the cover page.

Role	Name / Function	Date	Signature
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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

pd|z has created this new device and Tintin 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.



Figure 4: A third picture of a device.

Test procedure

Goal

In this study, 8 were asked to perform 3 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 5: 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 6: This looks like a medical device.

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

The idea had even crossed his mind that she might be an agent of the Thought Police. That, it was true, was very unlikely. Still, he continued to feel a peculiar uneasiness, which had fear mixed up in it as well as hostility, whenever she was anywhere near him.



Figure 7: Here is another medical device.

Results

Effectiveness analysis

	P1	P2	P3	P4	P5	P6	P7	P8
Discovering	1				2			
Hearing			3		3			
Writing								4
Closing			5				5	

No problem found

Marginal problem found

Important problem found

Critical problem found

Problems description

1. Participant did not properly discover.
2. Participant did not discover at all.
3. Participants could not hear well
4. Participant write something false.
5. Participants forgot to close.

Discussion

He knew the reason. It was because of the atmosphere of hockey-fields and cold baths and community hikes and general clean-mindedness which she managed to carry about with her. He disliked nearly all women, and especially the young and pretty ones. It was always the women, and above all the young ones, who were the most bigoted adherents of the Party, the swallows of slogans, the amateur spies and nosers-out of unorthodoxy. But this particular girl gave him the impression of being more dangerous than most. Once when they passed in the corridor she had

given him a quick sidelong glance which seemed to pierce right into him and for a moment had filled him with black terror.

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

Dwell times

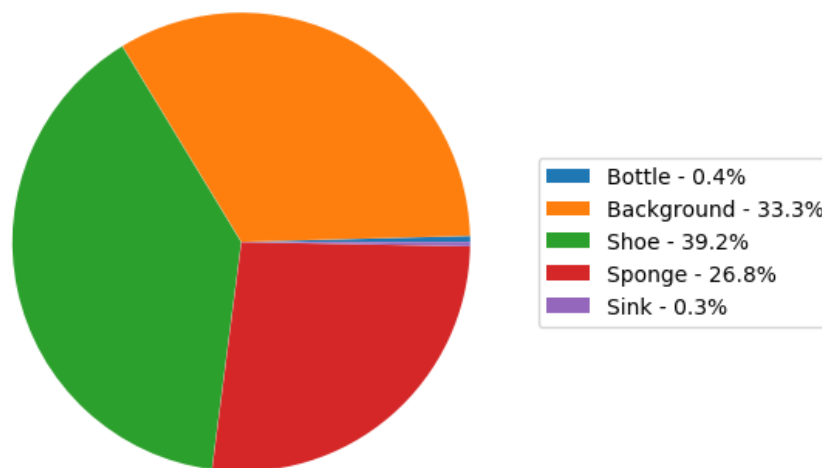


Figure 8: Average total dwell times amount for each area of interest over all participants.

Discussion

It was nearly eleven hundred, and in the Records Department, where Winston worked, they were dragging the chairs out of the cubicles and grouping them in the centre of the hall, opposite the big telescreen, in preparation for the Two Minutes Hate. Winston was just taking his place in one of the middle rows when two people whom he knew by sight, but had never spoken to, came unexpectedly into the room. One of them was a girl whom he often passed in the corridors. He did not know her name, but he knew that she worked in the Fiction Department.

Average fixation

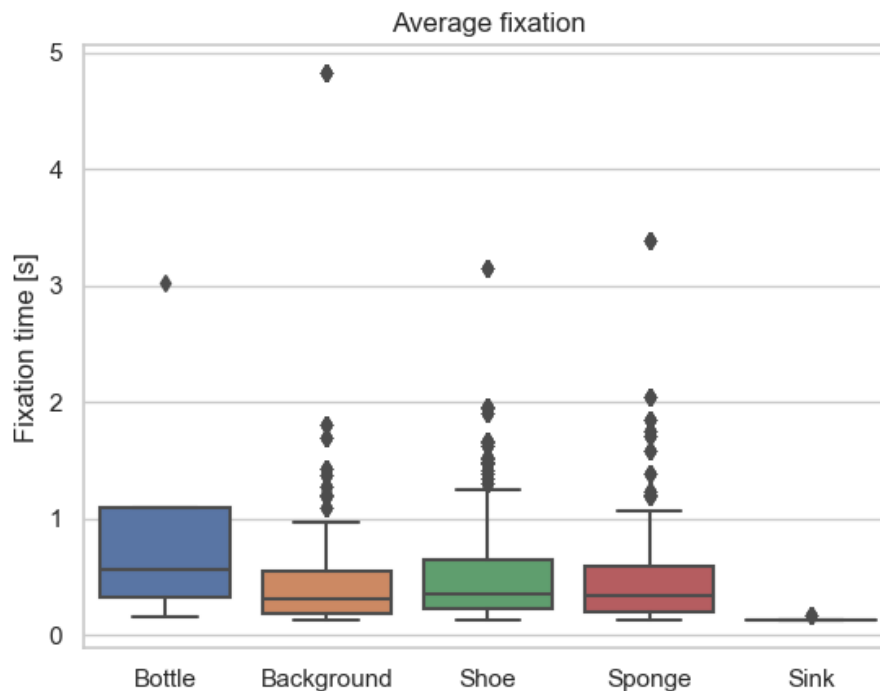


Figure 9: Box plot showing the mean, the 25% and 75% quartiles and the distribution of the fixation time.

Discussion

It had happened that morning at the Ministry, if anything so nebulous could be said to happen.

Transitions

		Transitions				
AOI source (from)	Bottle	0.00%	0.04%	0.09%	0.02%	0.00%
	Background	0.07%	15.76%	10.91%	7.07%	0.37%
	Shoe	0.07%	9.85%	18.26%	8.58%	0.37%
	Sponge	0.00%	8.39%	7.83%	11.38%	0.00%
	Sink	0.00%	0.00%	0.19%	0.56%	0.19%
		Bottle	Background	Shoe	Sponge	Sink
		AOI destination (to)				

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

Discussion

Winston stopped writing, partly because he was suffering from cramp. He did not know what had made him pour out this stream of rubbish. But the curious thing was that while he was doing so a

totally different memory had clarified itself in his mind, to the point where he almost felt equal to writing it down. It was, he now realized, because of this other incident that he had suddenly decided to come home and begin the diary today.

Conclusion

Suddenly he began writing in sheer panic, only imperfectly aware of what he was setting down. His small but childish handwriting straggled up and down the page, shedding first its capital letters and finally even its full stops:

April 4th, 1984. Last night to the flicks. All war films. One very good one of a ship full of refugees being bombed somewhere in the Mediterranean. Audience much amused by shots of a great huge fat man trying to swim away with a helicopter after him, first you saw him wallowing along in the water like a porpoise, then you saw him through the helicopters gunsights, then he was full of holes and the sea round him turned pink and he sank as suddenly as though the holes had let in the water, audience shouting with laughter when he sank, then you saw a lifeboat full of children with a helicopter hovering over it, there was a middleaged woman might have been a jewess sitting up in the bow with a little boy about three years old in her arms, little boy screaming with fright and hiding his head between her breasts as if he was trying to burrow right into her and the woman putting her arms round him and comforting him although she was blue with fright herself, all the time covering him up as much as possible as if she thought her arms could keep the bullets off him, then the helicopter planted a 20 kilo bomb in among them terrific flash and the boat went all to matchwood, then there was a wonderful shot of a child's arm going up up up right up into the air a helicopter with a camera in its nose must have followed it up and there was a lot of applause from the party seats but a woman down in the prole part of the house suddenly started kicking up a fuss and shouting they didnt oughter of showed it not in front of kids they didnt it aint right not in front of kids it aint until the police turned her turned her out i dont suppose anything happened to her nobody cares what the proles say typical prole reaction they never –

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