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Article

Effects of user characteristics on the usability of home connected medical device: The case of *Smart Angel*

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Abstract: The *Smart Angel* connected medical device allows ambulatory surgery patients to monitor their health by taking their own blood pressure and oxygen levels and by answering a health questionnaire from home. This preventive device must necessarily be "usable" by patients with different profiles. The objective of this article is, therefore, to better understand the links between certain characteristics of potential patients and usability. We conducted an experimental study involving thirty-six participants, investigating the effects of four patient characteristics (i.e. age, education, technophilia and health literacy) on usability measured in terms of *effectiveness*, *efficiency*, and *satisfaction.* The results show a moderate correlation between age, health literacy and usability. However, there is a weak correlation between technophilia and usability and no relationship between the level of education and usability. This study provides theoretical insights into the effects of user characteristics by means of personas in usability (ISO 9241-11).

Keywords: user characteristics; home medical devices; usability.

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1. Introduction

Outpatient surgery has been on the rise in recent years. The operations performed are increasingly complex and dangerous for the patients who have to manage their convalescence at home. The *Smart Angel* device is a Home Connected Medical Device (HMD), specifically designed to prevent post-surgical complications related to outpatient surgery. The purpose of this device is to facilitate the patient's return home by maintaining a link with the hospital. This requires patients to use the device upon returning home after the operation, sending all their vitals three times a day for one week, before returning the equipment to the Hospital Centre. This post-operative follow-up may also enable patients to manage their convalescence better by avoiding the all-too-frequent returns to the emergency services or outpatient consultations [1]. Currently, this system is at an early design stage. Like any medical device, this tool must follow safety and quality standards [2], as well as usability standards [3] to meet the requirements of European Conformity (CE marking) for marketing. However, even today, the deployment of these connected medical devices is still hindered by -- among other things -- their complexity of use, directly implying a lack of usability [4–6], thus impacting patient safety. With this in mind, Kortum and Peres commented: *"A lack of usability may cost lives"* [7] (p.2).

1.1. Usability

Usability can be defined by ISO 9241-11 [3] (p.2) as "The degree to which a product can be used, by identified users, to achieve defined goals in an effective, efficient and satisfactory manner, within a specified context of use". This concept, which is still being discussed by the scientific community, has three distinct dimensions ISO 9241-11:

- *Effectiveness:* the accuracy and completeness with which users achieve certain objectives;

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- *Efficiency*: the relationship between accuracy and the resources used to attain it;
- *Satisfaction*: user comfort and positive evaluation of user interaction.

Usability defined by these three dimensions (*effectiveness*, *efficiency*, and *satisfaction*) is linked to its context of use (ISO 9241-11, 2018), itself characterized by four components (the *task*, the *environment*, the *resources*, and the *users*).

Despite the use of methodologies that involve the user in the design process (e.g. [8–10]) usability problems persist. There are two arguments in the literature that may explain this finding: 1) the lack of a standardized framework and method in usability studies (e.g. [11–15]) and/or 2) the lack of knowledge of the impact of the use context (e.g. [16, 17]) on usability, in particular user characteristics.

1.2. User characteristics: age, level of education, technophilia, health literacy.

Several researchers have recently investigated the relationship between user characteristics and usability of connected devices in health care (e.g. [11, 18–22]). Four user characteristics have been particularly studied in the scientific literature: age (e.g. [11, 20, 22–26]); level of education (e.g. [11, 19, 20]); technophilia, i.e., experience in information technology (IT) and previous experience with medical devices (e.g., [11, 23, 27]); and health literacy (e.g., [20, 24, 28, 29]).

In most studies, authors tend to agree on these interrelationships, while investigating different devices. We detail these studies below.

1.2.1. Age

Many authors have examined the influence of age on the usability of connected devices in health care. Most of these authors concur on the influence of age on usability. For example, Georgsson and Staggers [11] investigated the usability of a diabetes management application running on a smartphone using the metrics of ISO 9241-11 (*effectiveness*, *efficiency*, and *satisfaction*). The authors found that the younger group (30-49 years old) made fewer errors (i.e. was more *effective*), was faster (i.e. more *efficient*) and more *satisfied* (System Usability Survey (SUS) score of 88.33 versus 77.14) than the older group (50-69 years old). Sparkes et al. [23] examined the usability of remote cardiac testing and found that the age of the participants impacted on their ability to install the equipment. Younger subjects appeared to be more comfortable than older subjects. Jones and Caird [25] examined the use of a blood glucose meter. They found that younger subjects had fewer difficulties and made fewer errors (i.e., were more *effective*) than older subjects. Mykityshyn et al. [26] also examined the use of a glucometer. They found that young subjects were faster (i.e., more *efficient*) than older subjects regardless of the instruction format provided (written + drawn vs. video). Van der Vaart et al. [20] evaluated the usability of an application for monitoring the symptoms of 32 narcoleptics. The authors found that usability (measured in terms of the number of tasks completed and problems encountered) was moderately and positively correlated with age as well as with e-Health literacy level.

However, Liang et al. [19] found no relationship between age and *satisfaction* as measured by the SUS score in their study on the evaluation of seven health devices used by the general public (e.g. connected watches) conducted with a sample of 388 participants. Similarly, Jensen et al. [18] found no relationship between usability and age of participants with respect to access and use of online health information. The authors explain that this lack of result is probably due to the contrast in health literacy levels that would have taken precedence over the other variables.

1.2.2. Level of education

Level of education is also a variable found in many usability assessments. However, to our knowledge, no studies have proven this link. Georgsson and Staggers [11], Liang et al. [19] and Van der Vaart et al. [20] have all found a lack of association between participants' level of education and usability (*effectiveness*, *efficiency*, and *satisfaction*).

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1.2.3. Technophilia (experience of IT/medical devices)

Differing results have been reported regarding the influence of experience in technologies as well as previous experience of medical devices on usability. Georgsson and Staggers [11] found that those with more technology experience (what the authors call "IT/computer experience") made fewer errors (i.e. more *effective*), are faster (i.e. more *efficient*) and were more *satisfied* with the diabetes management application (+ 5 points for the System Usability Scale score). Conversely, Harte et al. [27] conducted regression analyses between technology experience and System Usability Scale (SUS) score and found no significant effect when evaluating a smartphone health application. Finally, Sparkes et al. [23] showed that familiarity with the technologies seemed to have an influence on the correct installation of their device.

1.2.4. Health Literacy

1.2.4.1. Definition and assessments

Health literacy is a user characteristic that can be expected to influence the usability of medical devices [e.g. 10, 13, 14]. Due to its multi-dimensional perspective, however, this characteristic is complex to define and is difficult to assess. Sørensen, Van den Broucke, Fullam, Doyle, Pelikan, Slonska, and Brand [30] (p.3) define it as: "An individual's knowledge, skills, motivation, and ability to identify, understand, evaluate, and use health information in decision-making in health care, disease prevention, and health promotion to maintain or improve lifelong quality of life." However, this notion is often mentioned as a determinant to be considered in therapeutic education [16, 17], prevention [33], therapeutic adherence, access to health information [18] and even cure [17, 19]. However, to our knowledge, no study has assessed the level of health literacy of the French at the national level.

In terms of evaluation, health literacy is particularly difficult to measure for at least two reasons. The first reason concerns its multidimensional specificity [30]. The second reason is that health literacy is not related to socio-economic criteria as might be intuitively assumed [35].

Currently, there are two main methods of measuring health literacy [36]: 1) questionnaire methods by which an individual's abilities are assessed and 2) self-reported methods by which an individual's behaviors towards a health professional are directly observed. Currently, few tools exist in French compared to the 51 English-language instruments identified by Haun, Valerio, McCormack, Sørensen and Paasche-Orlow [37]. The most frequently used and cited instruments are part of questionnaire-based methods: they are the TOFHLA [38], the REALM (The Rapid Estimate of Adult Literacy in Medicine [39]), the HLS-EU (European Health Literacy Survey [30]), and the NVS (New Vital Sign [40]). However, these instruments have several limitations. Among these instruments, the REALM is more like a reading test than a comprehension test since participants are asked to read medical terms. The short version of the TOFHLA (i.e., S-TOFHLA: The Short Test of Functional Health Literacy in Adults), which allows for an assessment of the respondents' level of comprehension, seems more adapted to Swiss culture than to French culture [41]. Indeed, reference is made to the Swiss "health insurance" system and the transmission of certain documents that do not apply to the French social security model. In addition, the validity of S-TOFHLA is currently the subject of some controversy due to inconsistencies in the interpretation of its component items [42]. Another instrument proposed in the literature, the NVS [40], shows a strong correlation (Cronbach $\alpha > 0.76$) with the measurement of S-TOFHLA [43]. It also assesses some of the respondents' cognitive skills (Reading Writing Comprehension Numeracy). Finally, the HLS-EU is based on the multidimensional literacy model of Sørensen et al. [30]. This tool has identified important gaps in eight European countries, as approximately 1 in 2 people reportedly have a limited or low level of health literacy [44].

1.2.4.2. Health literacy and usability

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In the context of health technologies such as connected medical devices that are increasingly becoming part of the patient's life, studies on the correlation between health literacy and usability are still rare and/or exploratory. Monkman and Kushniruk [21] propose an assessment of usability by considering health literacy through the design and validation of heuristic criteria. To do so, the authors adapted a set of existing guidelines for designing health-specific websites to make the content more understandable to users with a reliable level of health literacy. Czaja et al. [28] were able to show, using an electronic personal health record system, that populations with low literacy levels had more difficulty using these tools. Kim and Xie [29] conducted a systematic review of articles examining the impact of low health literacy on the use of e-health devices. Based on 74 studies, the authors conclude that the major barrier to accessing and using online health information for individuals with low literacy is strongly related to website usability. Jensen et al. [18] found that participants with low levels of health literacy (as measured by REALM) used health technologies less. Those with low levels of health numeracy (as measured by TOFHLA) would have limited access to these technologies. This latter finding is consistent with those of Kaufman et al. [24] who also concluded that low numeracy can be a barrier to using a telemedicine system. Finally, to our knowledge, no experimental studies have empirically characterized links between health literacy and usability in terms of *efficiency, effectiveness*, and *satisfaction*.

1.3. Objective of the study

We have seen that the complexity of use of medical devices resides essentially in usability problems [29], all the more so as they must be usable by patients with diverse profiles [33, 34]. In this sense, consideration of user characteristics including age, education, technophilia (IT and medical device experience) and health literacy are important factors to consider in the design of a connected medical device for the patient's home, such as the *Smart Angel* device. However, to our knowledge, no study involving all these four characteristics has been conducted. Moreover, the relation between these characteristics and usability is still little exploited in the literature. Thus, the aim of this work is to better understand the relationships between the four user characteristics (i.e. age, educational level, technophilia and health literacy) and the usability (ISO 9241-11: *effectiveness, efficiency*, and *satisfaction*) of a connected medical device intended for the patient's home.

To do this, we formulated four hypotheses:

(H1) older users will be less *effective, efficient*, and *satisfied* with the *Smart Angel* connected medical device than younger users (e.g.[8, 10, 35, 36]).

(H2) Users with a low level of technophilia (IT and medical device experience) will be less *effective, efficient*, and *satisfied* with the *Smart Angel* connected medical device than those with a high level of technophilia. (e.g. [11, 23, 27]).

(H3) The level of education will not affect the *effectiveness, efficiency*, and *satisfaction* with the *Smart Angel* connected medical device. (e.g. [11, 19, 20]).

(H4) Users with low levels of health literacy (as measured by NVS and HLS-EU scores) will be less *effective, efficient*, and *satisfied* with the *Smart Angel* connected medical device than those with high levels of health literacy. (e.g. [18, 24]).

2. Methods

2.1. Participants

Thirty-six participants, 17 females and 19 males (47.22 and 52.78%, respectively), aged 20-64 years (mean = 40.75 years, SD = 14.45) participated in this study. The inclusion criteria for this study were that the participant had to have a 4G connection at home, be under 70 years of age, be eligible for outpatient surgery, and not be at home alone. All participants were native French speakers and signed a consent form after being informed of the study's progress. The study complies with the ethical recommendations of the Declaration of Helsinki. The participants were recruited on a voluntary basis and no compensation was given to them. Handover of the *Smart Angel* device took place at the participant's home or workplace.

2.2. Materiel and measurements

The material of our experiment is composed of: 1) the *Smart Angel* device, 2) personas and their scenarios, and 3) questionnaires (two questionnaires assessing the level of health literacy, namely, the NVS and the HLS-EU, a questionnaire relating to socio-demographic data, and a questionnaire assessing *satisfaction*, namely the SUS).

2.2.1. The Smart Angel device

The *Smart Angel* device (Figure 1) consists of a Samsung 9-inch tablet with the *Smart Angel* application and two connected objects available for the general public with European certification: a wrist blood pressure monitor (iHealth BP7) for blood pressure measurement and an oximeter (iHealth Oximeter PO3) for oxygen saturation and pulse measurement. To use the *Smart Angel* device designed by Evolucare Technologies, it is necessary to enter the *Smart Angel* application and perform a digital medical "*appointment*" from a tablet application.

Figure 1. The Smart Angel components: a pulse oximeter (iHealth Oximeter PO3) in the upper left, a wrist blood pressure monitor (iHealth BP7) in the lower left, and a tablet with the Smart Angel application on the right.

The *Smart Angel* includes (figure 2):

- A procedure for using the connected objects (blood pressure monitor and pulse oximeter) in which the patient finds out the information one step at a time and can initiate the connection and then the measurement using these objects. Once the blood pressure or oxygenation measurement has been taken, the patient's health data is displayed on a coloured gauge (from green to orange) according to the level of severity of the constant collected.
- A form in which the user answers a questionnaire with various items related to general health, pain, sleep, and nausea. These items are presented either in SCQ format (e.g. "How are you feeling today? Good, not good, not good at all") or on a Likert scale (e.g. "Rate your pain on a scale of 1 to 10").

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Figure 2. Screenshot of the Smart Angel application manufactured by Evolucare Technologies. On the left is the form allowing an overview of the subjective state of health, and on the right is the procedure for using the monitor.

Procedures for using the blood pressure monitor and pulse oximeter are built into the application. They include text and images for each step of the operation. For the two connected objects, the participant must first have a correct body position, connect the equipment, and then install it correctly on themselves, start the measurement, remove and switch off the equipment. A schematic representation of the procedure for using the equipment is shown in figure 3 below.

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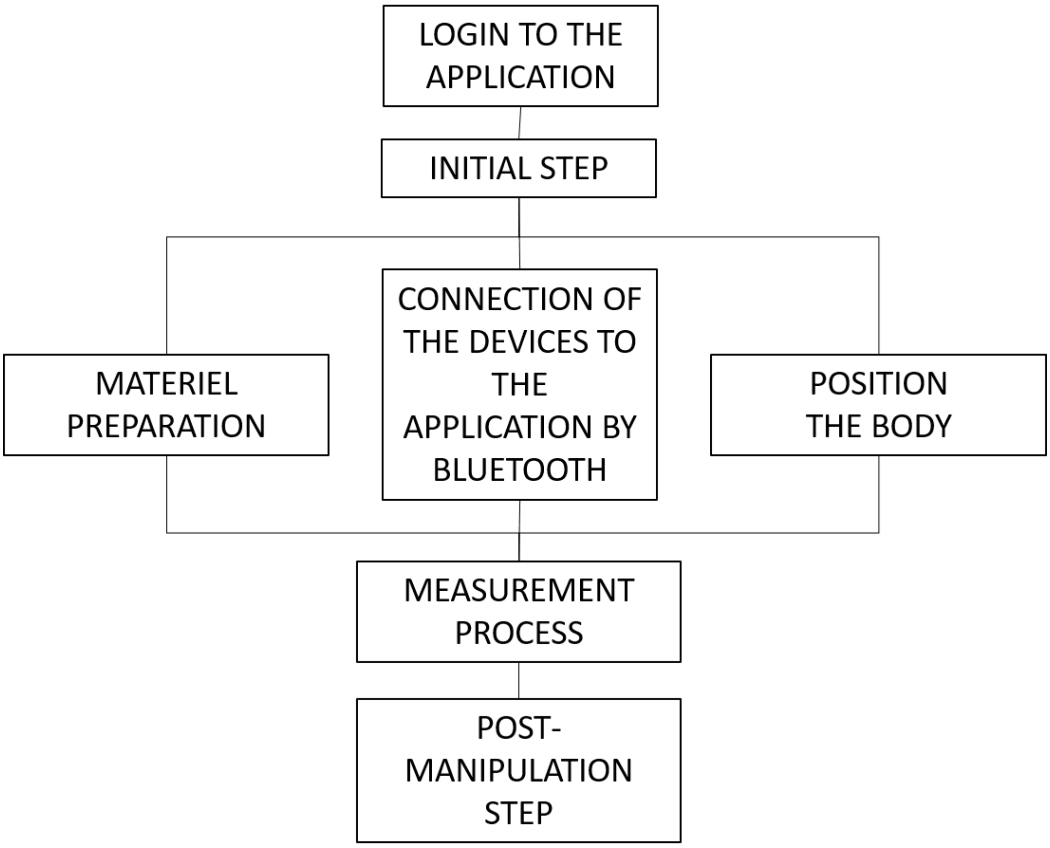

Figure 3. Schematic representation of the main steps in the use of the Smart Angel device.

2.2.2. The personas and scenarios

Five personas and their scenarios were constructed, based on statistical surveys of the types of outpatient surgical procedures in France [47] as well as observations made in the field [48]. Generally used in the design phase, the personas method draws on the theory of mind and the theory of stereotypes and can provoke certain emotional states [49]. The personas scenarios were presented to the participants in the form of a cartoon (audio-visual). All scenarios were constructed in the same way. Only the type of operation and the cause of the operation changed according to the persona.

2.2.3. Questionnaires

2.2.3.1. Measuring Health Literacy

Given the limitations of health literacy questionnaires translated and validated in French, we chose to use two health literacy questionnaires so as to have a holistic view of this multidimensional skill: the New Vital Sign (NVS) and the Health Literacy Suvey (HLS-EU-Q16):

- New Vital Sign (NVS) [40] translated into French [50] is a validated test assessing patients' ability to understand reading and manipulate numbers (numeracy). Participants are asked to use an ice cream nutrition label to answer six questions (e.g. *"If I am allergic to peanuts, can I eat this ice cream?" Answer: no because the ice cream contains traces of peanut oil*). NVS identifies patients with low health literacy by classifying them by level: 0-1 point, "*low*" level, 2-3 points, "*limited*" level, 4-6 points, "*fair*" level of health literacy. The inter-item reliability of the NVS in this study is good [51]: Cronbach's α is 0.883.

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- Health Literacy Survey – Europe (HLS-EU-Q16) [30] translated into French [52], is the short version of the Health Literacy Survey questionnaire. This version is composed of 16 items, 13 of which assess the four types of health literacy skills: the ability to access, understand, evaluate, and apply health information. Respondents are asked to rate their own ability to access information (e.g., *"Please rate, on a scale of very easy to very difficult, how easy is it for you to understand your doctor's or pharmacist's instructions on how to take your medication?"*) Four categories of answers are provided on a four-point Likert scale ranging from "*very easy*" to "*very difficult*". To calculate the total score, the answers "*easy*" and "*very easy*" have one point per item, the answers "*difficult*" and "*very difficult*" do not earn any points. The total sum of the items (from 0 to 16 points) classifies respondents into three categories: (0 to 8 points) low health literacy; (9 to 12 points) limited health literacy; (13 to 16 points) correct. The inter-item reliability of the HSL-EU in this study is good [51]: Cronbach's α is .803.

2.2.4. Socio-demographic measurement (age, education level, technophilia, etc.)

This questionnaire included personal details: age, gender, educational level, residential area, technophilia (IT and medical device experience), hospital experience.

2.2.5. Measuring usability (ISO 9241-11:2018)

2.2.5.1. Measuring Effectiveness

Effectiveness was measured by counting the number of manipulation errors, such as not putting the blood pressure cuff in the correct position. Five categories of errors were identified with respect to the use of the monitor ((i) the participant does not position the monitor correctly; (ii) in the direction of the palm of the hand (iii) does not position the forearm correctly (iv) moves during the measurement (v) does not connect the monitor's Bluetooth to the tablet); and four categories of pulse oximeter use were identified ((i) the participant does not position the oximeter the right way (ii) does not insert the finger as far as the sensor (iii) removes the oximeter too early during the measurement (iv) does not connect the Bluetooth from the oximeter to the tablet); one type of error regarding the tablet was observed (the participant does not enter the "appointment" of the application). A scoring grid was used to identify these manipulation errors. When the participant made several attempts, we recorded the cumulative number of errors.

2.2.5.2. Measuring Efficiency

Measuring *efficiency* is based on the manipulation times of the various device tools for three measurements: manipulating the blood pressure monitor, manipulating the pulse oximeter, and total manipulation of the device including the complete "*appointment*". These times were measured from the time participants first touched the device (monitor, pulse oximeter, or tablet) to the time they turned it off after taking the measurement.

2.2.5.3. Measuring satisfaction

Satisfaction was measured using the System Usability Survey (SUS). This "*quick and dirty*" questionnaire [53] consists of 10 items with five response options on a Likert scale ranging from "*strongly disagree*" to "*strongly agree*" and allows for subjective assessment of usability [54]. We used the adapted and validated version [55] in which we replaced the term "*system*" with the term "*medical device*". Scores were calculated according to the recommendations of Brooke [53] and range from 0 to 100. Lower scores indicate low usability.

2.3. Procedure

The average duration of this experiment was 45 minutes. Participants were first invited to choose among 5 personas proposed to allow them to project themselves into the needs of future users of the *Smart Angel* device [56]. The persona chosen had to be consistent with at least their age, profession, and previous surgery. Then, the researcher demonstrated the use of the *Smart Angel* device to the participant for about 3 minutes, listing information about the correct manipulation (e.g., "*the monitor should always be at heart level*") on themselves. Participants were then asked to complete three questionnaires: the socio-demographic data questionnaire, the Health Literacy Survey - Europe (HLS-EU-Q16) and the New Vital Sign (NVS) and then asked to operate the *Smart Angel* device by first taking a blood pressure measurement, followed by an oxygen saturation measurement, and finally by completing the general health questionnaire. There was no time limit for this. They were filmed during the manipulation. The researcher could only intervene in the event of a technical problem (e.g. battery problem). Finally, after the experiment, the participant had to respond to the SUS.

2.4. Data analysis

The videos were analysed using BORIS (Behavioral Observation Research Interactive Software, http://www.boris.unito.it/) and enabled data to be obtained on *effectiveness* and *efficiency*.

Results were analyzed using SPSS® version 22 (IBM Corporation, 2013). Each user characteristic was systematically compared to usability components including *effectiveness*, *efficiency*, and *satisfaction*. For the health literacy measurement, we first analyzed the HLS-EU-Q16 result and then the NVS result. Bivariate correlations, ANOVAs and Student t-tests were performed when the sample met the homoscedasticity criteria, while non-parametric tests (Kruskal-Wallis and Mann-Whitney) were performed when the sample did not meet these criteria.

2.5. Inter-judge reliability: objective measures of effectiveness and efficiency

We used Intra-Class Correlation (ICC) to verify inter-judge reliability for quantitative data [57]. A 33% double coding of the collected video data was performed. The mean ICC measurement for total manipulation time (*efficiency*) was .978 with a 95% confidence interval of .918 to .994 (F (11,11) =45.436, P < .001). The mean ICC measurement (*efficiency*) for manipulating the monitor was .988 with 95% confidence interval .954 to .997 (F (11,11) = 81.635, P < .001). The mean ICC measurement (*efficiency*) for manipulating the pulse oximeter was .956 with 95% confidence interval .838 to .988 (F(11,11) = 22.955, P < .001). The mean ICC measurement (*efficiency*) for manipulating the tablet was .906 with 95% confidence interval .652 to .975 (F(11,11) = 10.688, P < .001). The mean measure of the number of manipulation errors (*effectiveness*) was .952 with a 95% confidence interval between .842 and .985 (F(11,11) = 20.789, P < .001).

3. Results

3.1. Effects of user characteristics on usability

The correlations between user characteristics (see Table 1) and usability components (i.e. number of manipulation errors: effectiveness; manipulation time: efficiency and SUS score: satisfaction) were systematically analysed.

Table 1. Descriptive analyses of user characteristics, user experiences in health, medical devices and technology

Variable (N=36)	n(%)	Ave. Effectiveness (ET)	Ave. Efficiency (ET)	Ave. Satisfaction (ET)
Characteristics				

Age	40,75 years (14.45)	36(100)			
Gender group (M/F)	Male	19 (52,78)	1,21 (1,27)	362,09 (144,16)	87,24(11,18) 81,03(11,73)
	Female	17 (47,22)	2,06(1,25)	373,91 (126,3)	
Educational Level	Secondary	5 (13,9)	2,8(1,64)	337,96 (89,67)	77 (9,75)
	Higher education 1st cycle				
	Higher education 2nd cycle	11 (30,6)	1,36(1,1)	334,99 (106,25)	87,05 (13,82)
	Higher education 3rd cycle	11 (30,6)	1,64(1,2)	412,95 (198,6)	82,73 (13,34)
		9 (25)	1,22(1,3)	368,77 (80,88)	86,94 (5,97)
Residential Areas	Rural	6 (16,7)	1(0,89)	362,92 (76,48)	88,75 (6,85)
	Semi-urban	5 (13,9)	1,8(2,05)	339,11 (72,3)	87 (11,37)
	Urban	25 (64,9)	1,72(1,24)	374,52 (154,78)	82,7 (12,62)
Persona chosen	Persona 1	8 (22,2)	Highly correlated with the age of the participants		
	Persona 2	8 (22,2)			
	Persona 3	8 (22,2)			
	Persona 4	4 (11,1)			
	Persona 5	8 (22,2)			
Experience of health care					
Operation(s)	Yes	32 (88,9)	1,59(1,21)	376,18 (136,24)	85,39 (11,72)
	No	4(11,1)	1,75(2,22)	299,55 (106,9)	75,62 (8)
Outpatient operation(s)	Yes	18 (50)	1,39(1,33)	367,15 (142,09)	86,11 (11,8)
	No	18 (50)	1,83(1,29)	368,19 (130)	82,5 (11,66)
Suffering from a chronic illness	Yes	11 (30,6)	1,27(1,35)	386,68 (184,62)	81,14 (15,26)
	No	25 (69,4)	1,76(1,3)	359,3 (108,77)	85,7 (9,8)
Experience with medical devices					
Taking blood pressure	Yes	24 (66,7)	1,54(1,32)	361,43 (131,26)	63,3 (11,22)
	No	12 (33,3)	1,75(1,36)	380,15 (145,06)	86,25 (12,9)

Blood oxygenation testing	Yes	5 (13,9)	0,4(0,55)	309,16 (70,87)	89 (8,02)
	No	31 (86,1)	1,81(1,3)	377,11(140, 31)	83,56 (12,12)
Experience of information technologies (IT)					
Ease of use of tablet/computer/ telephone	Very comfortable with technology	23 (63,9)	1,35(1,23)	360,16 (120,21)	86,85 (11,24)
	Relatively comfortable with technology	11 (30,6)	2,27(1,42)	401,34 (166,78)	78,18 (11,78)
	Moderately comfortable with technology	2(5,6)	1(0)	268,81 (33,95)	88,75 (5,3)
	Rather uncomfortable with technology	0(0)	-	-	-
	Not at all comfortable with technology	0(0)	-	-	-
Frequency of use of technology	Every day (very often)	5(13,9)	1(1,22)	314,42 (48,65)	92,5 (6,85)
	Several times a week (often)	12 (33,3)	1,25(1,36)	364,46 (133,26)	90,42 (6,47)
	From time to time (rarely)	17 (47,2)	2(1,27)	364,08 (99,16)	79,26 (11,38)
	Occasionally (very rarely)	1 (2,8)	3(-)	856,33(-)	55(-)
	Never	1 (2,8)	1(-)	244,8(-)	85(-)

3.2. Age

Age (M = 40.75, SD = 14.45, range =20 - 64 years) is significantly correlated (positively and weakly) with the number of manipulation errors (*effectiveness*: r = 0.359; p = .032*) and manipulation time (*efficiency*: r = 0.357; p = .033*). On the other hand, there was no significant correlation between age and SUS score (*satisfaction*: r = -0.138; p = .424). In addition, it is important to note that age is not correlated with the literacy level of the HLS-EU-Q16 (r = .013; p = .942) or the NVS (r = -.013; p = .942) (Figure 4).

3.3. Technophilia (IT Experience and medical devices)

IT experience showed no impact on the number of manipulation errors (*effectiveness*: F (5, 30) = 1.229; p = .32); manipulation time (*efficiency*: F (5, 30) = 1.39; p = .256). On the other hand, there was a significant correlation between IT experience and SUS score (*satisfaction*: χ (3) = 8.671; p = .034*).

Previous experience of using medical devices that allow users to take their own blood pressure did not influence the number of manipulation errors (*effectiveness*: t = 0.443; ddl = 34; p = .661), the manipulation time (*efficiency*: t = 0.39; ddl = 34; p = .555) or the SUS score (*satisfaction*: Mann-Whitney U = 104; p = .188). Previous experience of using medical devices for taking oxygen levels shows a significant effect on the number of manipulation errors (*effectiveness*: t = 2.359; ddl = 34; p = .024*; $\eta2$

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= 0.14), but this effect is not significant on the manipulation time (*efficiency*: t = 1.052; ddl = 34; p = .3) or on the SUS score (*satisfaction*: t = -0.965; ddl = 34; p = .341).

3.4. Educational level

Educational level has no impact on usability in terms of number of manipulation errors (*effectiveness*: F (3, 32) = 1.889; p = .151); manipulation time (*efficiency*: F (3, 32) = 0.698; p = .56); and in relation to the SUS score (*satisfaction*: F (3, 32) = 1.076; p = .373).

3.5. Health Literacy

Systematic analyses were performed comparing the level of literacy (HLS-EU-Q16 and NVS) with each of the components of usability (*effectiveness*, *efficiency*, and *satisfaction* according to ISO 9241-11, 2018). A descriptive representation of the results of the two health literacy questionnaires is presented in Table 2 below:

Table 2. Descriptive statistics of the HLS-EU-Q16 and NVS questionnaires

Groups	Number of people (%)
Health literacy Survey (M = 12,97/16 ; ET = 2,952 ; rank = 5-16)	
Inadequate Health Literacy	3 (8,3)
Problematic Health Literacy	9 (25)
Sufficient Health Literacy	24 (66,7)
New Vital Sign (M = 4,17/6 ; ET = 2,223 ; rank = 0-6)	
Inadequate Health Literacy	6 (16,7)
Problematic Health Literacy	7 (19,4)
Sufficient Health Literacy	23 (63,9)

3.5.1. Results of the HLS-EU-Q16 questionnaire

There is no significant correlation between the results of the European version of the Health Literacy Survey (HLS-EU-Q16) and usability either in terms of the number of manipulation errors (*effectiveness*: r = 0.34; p = .844), manipulation time (*efficiency*: r = -0.40; p = .816) or in relation to the SUS score (*satisfaction*: r = 0.144; p = .402).

After correlation analysis, participants were clustered according to the HLS-EU-Q16 measures (Table 2) following the recommendations of Sørensen et al. [30]. No inter-group differences could be observed between the HLS-EU-Q16 results and usability (Table 3) in terms of the number of manipulation errors (*effectiveness*: F (2.33) = 0.277; p = .76), manipulation time (*efficiency*: F (2.33) = 0.015; p = .985) and the SUS score (*satisfaction*: F (2.33) = 0.483; p = .621).

Table 3. Analyses of Health Literacy Survey-Europe-16 (HLS-EU-Q16) score according to usability (effectiveness, efficiency, and satisfaction)

Health Literacy Survey – Europe – 16 items N = 36	Effectiveness – Average number of errors (ET)	Efficiency – Average manipulation time (ET)	Satisfaction (score SUS)
Inadequate Health Literacy (N = 3)	1,67 (2,08)	373,26 (88,76)	83,33 (3,82)
Problematic Health Literacy (N = 9)	1,89 (1,27)	373,35 (98,53)	81,11 (14,53)
Sufficient Health Literacy (N = 24)	1,50 (1,28)	364,84 (152,73)	85,62(11,3)

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ANOVA	F (2,33) = 0,277 p =,76	F (2,33) = 0,015 p =,985	F (2,33) = 0,483 p =,621

2.5.2. Results of the NVS questionnaire

There is a significant mean-size correlation between the results of the French version of the New Vital Sign (NVS) questionnaire and usability in terms of the number of manipulation errors (*effectiveness*: r = -0.417; p = .011*), manipulation time (*efficiency*: r = -0.38; p = .022*) and the SUS score (*satisfaction*: r = 0.45; p = .006**). In other words, the higher a participant's level of health literacy (measured using NVS) the fewer manipulation errors they make (i.e., they are more *effective*), the faster they manipulate (i.e., they are more *efficient*), and the higher their SUS score will be (i.e., they will be more *satisfied*).

After analyzing the correlations, the participants were clustered according to the NVS measurements (Table 2) following the recommendations [40]. No intergroup differences could be observed between NVS literacy and usability (Table 4) except for the number of errors (*effectiveness*: $\chi 2$ = 6.679; p = .035*).

Table 4. Analyses of New Vital Sign (NVS) results according to usability (effectiveness, efficiency, and satisfaction)

New Vital Sign (NVS) N = 36	Effectiveness – Average number of errors (ET)	Efficiency – Average manipulation time (ET)	Average (ET) Satisfaction (score SUS)
Inadequate Health Literacy (N = 6)	2,67 (0,816)	463 (165,18)	77,08 (14,27)
Problematic Health Literacy (N = 7)	1,71 (0,756)	387,72 (219,2)	80,71 (15,05)
Sufficient Health Literacy (N = 23)	1,30 (1,43)	336,7 (75,79)	87,28(9,07)
ANOVA	Impossible	Impossible	F (2, 33) = 2,392 p = ,107
Kruskal-Wallis Test (Khi2)	χ^2 = 6,679 ; p =,035*	χ^2 = 3,07 ; p =,21	χ^2 = 2,618 ; p =,270

* p < 0,05

Further intergroup analysis shows (Figure 4) a significant effect between the "*inadequate health literacy*" and "*sufficient health literacy*" groups as a function of the number of manipulation errors (*effectiveness*: Mann-Whitney U =27; p = .022*).

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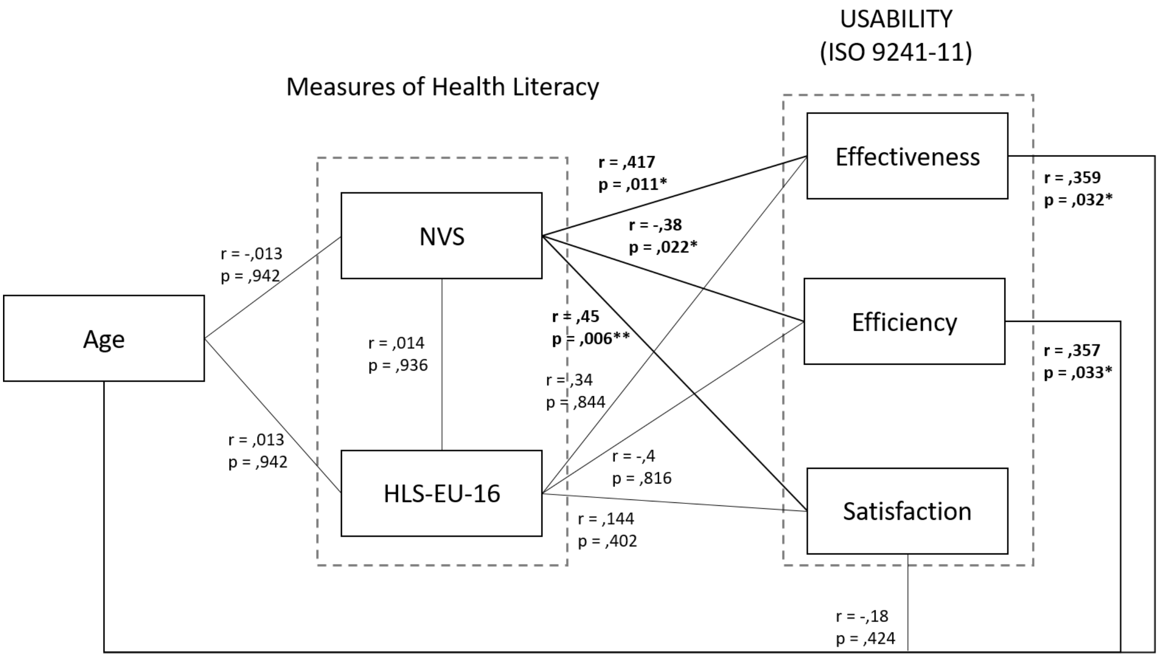

*p < 0,5
**p < 0,01

Figure 4. Schematic representation of correlations between age, measurement of participants' health literacy and usability (ISO 9241-11)

4. Discussion

The objective of this study was to better understand the relationships between four user characteristics (age, education, technophilia, and health literacy) and usability [3] including *effectiveness*, *efficiency*, and *satisfaction* with the use of the *Smart Angel* device. To do this, socio-demographic data were collected, literacy levels were investigated using the Health Literacy Survey - Europe [30] and the New Vital Sign [40], and usability measures were performed (errors and manipulation time, SUS questionnaire).

We made four hypotheses that age, technophilia, and health literacy would have an impact on usability, while education level would not.

Our first hypothesis was that older users would be less *effective*, *efficient*, and *satisfied* with the device compared to younger users. We can partially validate this hypothesis. The results show that the younger the individuals are, the less likely they are to make manipulation errors (i.e. they are more *effective*) and the faster they manipulate the device (i.e. they are more *efficient*). On the other hand, we did not observe any difference between the age of the subjects and the SUS score (*satisfaction*). All these results are in line with different works [19, 20, 25, 26]. Indeed, younger users are more *effective* (e.g. Jones and Caird's glucometer, [25]) and *efficient* (e.g. Mykityshyn et al.'s glucometer, [26]and Van der Vaart et al.'s application for narcoleptics, [20]) compared to older users, with a positive and medium correlation [20]. However, younger users are as *satisfied* (System Usability Scale score) with the device as older users, which is consistent with the findings of Liang et al. [19] while at variance with those of Georgsson and Staggers [11].

Our second hypothesis was concerned with the lack of correlation between education level and usability. The results support our hypothesis, as no significant correlation was found between participants' level of education and usability in terms of *effectiveness*, *efficiency*, and *satisfaction*. These results are also consistent with previous works [11, 19, 20].

Our third hypothesis focused on technophilia (experience of information technology and medical devices). The results provide partial validation of this hypothesis, as no correlation could be observed between IT experience and usability in terms of *effectiveness* and *efficiency*. On the other hand,

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the technophile participants gave a significantly better SUS score (*satisfaction*) than participants with a low level of technophilia. While these results are consistent with those of Harte et al (2018), they are in contradiction with previous works [11, 23]. We explain these results by a relatively homogeneous representation of IT experience as a function of the age of participants in our sample. We believe that these items [58] highlight the subjective representation of technology use (in relation to age) rather than actual performance in the use of hardware. It is possible that older people may feel that they can properly manipulate a tablet without using other features available in the tool. They would then consider themselves to be quite technophile, as they would be effective in the day-to-day use of the technology. However, their real capacity to adapt to the technologies is unknown. For example, if an update were to be performed on one of the applications commonly used, it is possible that this would destabilize the manipulation carried out by these individuals.

We also observed a correlation between experience with medical devices and usability. However, previous experience in the use of a blood pressure monitor had no impact on usability. Conversely, previous experience in the use of a pulse oximeter had a significant effect on effectiveness. Participants who had previously manipulated a pulse oximeter made significantly fewer errors than those who had never manipulated a pulse oximeter. In contrast, previous experience using a pulse oximeter had no effect on efficiency and satisfaction. All subjects who reported previous use of a pulse oximeter also reported previous manipulation of a blood pressure monitor. This result suggests that prior use of a pulse oximeter in combination with a blood pressure monitor would facilitate manipulation of the *Smart Angel* device in terms of effectiveness. We believe that participants who are accustomed to using this type of complex device are accustomed to being involved in health issues, which may be evidence of strong patient involvement in their own health [59].

Finally, the fourth hypothesis postulated that health literacy influences usability (*effectiveness*, *efficiency*, and *satisfaction*). The HLS-EU-Q16 scores showed no effect on usability (Figure 4). In contrast, the NVS scores showed a significant effect on the number of manipulation errors (*effectiveness*), manipulation time (*efficiency*), and SUS score (*satisfaction*). This is consistent with the results of previous studies [18, 28, 29]. Significant and medium-size correlations between the NVS score and each of the usability dimensions were observed (Figure 4). This suggests that the higher the literacy level of the participants, the fewer manipulation errors they make (i.e., the more *effective* they are), the faster they are (i.e., the more *efficient* they are) and the higher the SUS score will be (i.e., the more *satisfied* they are). However, after clustering the participants as recommended [40], there is a significant correlation between NVS literacy level and the number of errors (*effectiveness*) but no correlation with the manipulation time (*efficiency*) and the SUS score (*satisfaction*). Participants with a correct literacy level made significantly fewer errors than those with low or limited literacy.

It is important to note that the HLS-EU and NVS results are contradictory and demonstrate the complexity of health literacy assessment. In addition, our results suggest that the HLS-EU questioning the participant's subjective abilities to access health information and make decisions introduces a significant bias in the measurement of health literacy. Some participants may claim to have no difficulty using health information, but there is no verification that this is in fact the case. Conversely, the NVS instrument appears to be better suited to gathering information on subjects' cognitive abilities, as it is a test that collects information on participants' thought processes when reading a food label, thus providing a more objective assessment of health literacy.

5. Conclusions and research perspectives

In conclusion, this study provides theoretical insights into the effects of user characteristics (e.g. age, experience, education, health literacy) through the use of personas with respect to usability (*effectiveness*, *efficiency*, and *satisfaction* according to ISO 9241-11 [3]) in the specific case of the *Smart Angel* connected medical device. This study provides a methodological contribution insofar as it revealed the differences in data collection between the New Vital Sign and the Health Literacy Survey - Europe - 16, thus demonstrating the importance of continuing research in the field of health literacy measurement tools. In addition, these results allow us to better understand the importance of the impact of technophilia among older people with a correct level of health literacy on usability.

As a result of this study, four research perspectives can be suggested.

First, the relevance of the personas method in the prototype evaluation phase has never been proven. This method is classically used in the design phase by designers (ergonomists, designers, engineers, and even future users), but much more rarely used in an evaluation framework. To validate this method in this new context of use in the evaluation phase, it would be necessary to reproduce this study by adding a control group, i.e. a group without presentation of the personas.

Secondly, the training carried out by the researcher could be adapted according to the literacy levels of the participants. Indeed, the main difficulty in the use of a medical device is understanding the procedures and this cannot be achieved if there is insufficient upstream training [60] Training should certainly be adapted to the ages and literacy levels of the participants. Demonstration by the researcher may be sufficient for groups with adequate levels of health literacy. Conversely, for groups with low or limited levels of health literacy, further instruction should be considered.

Third, the choice of questionnaires is a crucial step in measuring health literacy. Indeed, we observed a significant disparity in results between the HLS-EU-Q16 and the NVS. As explained in the discussion, these two questionnaires do not appear to assess the same dimensions of health literacy. Further work is needed to understand what exactly is being assessed by each of the health literacy questionnaires.

Finally, beyond health literacy, it would now be appropriate to measure the level of e-health literacy (e.g.[20]). Unfortunately, there is no valid questionnaire in French on this subject. Thus, more systematic translations/adaptations of these tools should be considered in future studies.

6. Patents

Author Contributions: All authors have read and agreed to the published version of the manuscript.", please turn to the CRediT taxonomy for the term explanation. Authorship must be limited to those who have contributed substantially to the work reported.

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