Is usability engineering anticipation possible during the initial research actions? An example with the R-Link in vitro self-monitoring device.

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Abstract: Bipolar disorders are severe and complex psychiatric disorders and lithium remains one of the most effective drugs for relapse prevention. Despite its effectiveness, prescription of lithium therapy can be complicated because of its narrow therapeutic range. Furthermore, adherence to treatment is generally low. One means of improving adherence would be to make the patient an actor of his/her treatment. The possibility to control the lithium level with a device that can be used at home would favor this involvement. Although the main part of the work to produce a device is research and development, regulatory analysis, including usability, should not be neglected. Indeed, some design choices should be made taking into account usability constraints. This ensure the fabrication of a device which will be safe, effective and well accepted by the intended users. In this conference, we present actions taken in this direction during the R-Link project.

1. INTRODUCTION

The R-Link project, "Response to Lithium Network", is a collaborative project funded by the European Commission (Grant agreement n° 754907). It proposes a clinical study involving people with bipolar disorder type I when lithium treatment is initiated (NCT04209140). The consortium includes 22 European partners among which research institutes, hospitals, clinical investigation centers and companies. It is led by Prof. Franck Bellivier (Department of Psychiatry and Addiction Medicine - Expert Centers University of Paris Diderot - INSERM UMR-S144).

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The goal is to identify early biomarkers that will allow stratification of patients with bipolar I disorder according to their Lithium (Li) response. This response is being assessed prospectively over a two-year period based on a thorough clinical assessment coupled with measurements of blood omics, anatomical/structural magnetic resonance imaging (MRI) and ^{7}Li MRI derived markers. These markers will be tested as predictors of response status at the end of the study. Each patient will be involved in the study for two years. Translation will be assessed in terms of positive and negative predictive values of the markers, usefulness of the markers when used alone or in combination, patient acceptability, and cost-effectiveness. As it is essential to monitor adherence to treatment, interactive software for self-assessment of mental status will be introduced and electronic reminders will be offered throughout the study. A device that will allow self-monitoring of salivary lithium levels at home will be developed to be provided to patients. This last point is the focus of this paper.

Indeed, the design and development of this device raise some interesting questions related to the compatibility between (i) the design choices of the device and its usability and (ii) the regulatory framework to be compliant with. The regulatory analysis guides some design choices. In a context where the device is still at the conceptual stage and its design is progressing at the pace of the complex regulatory analysis, can we already plan and conduct a usability engineering process?

In this paper, we will present the different aspects of usability engineering process on a general basis and we will specify what was performed in the frame of the R-Link project. Regulatory aspects must be treated but will not be described in this communication. After an introductory part on bipolar disorders and the technical progress of the R-Link device, we will detail the usability studies plan before concluding.

2. BIPOLAR DISORDERS

Bipolar disorders are severe and complex psychiatric disorders that affect approximately 45 million people worldwide (James *et al.*, 2018). In France, it is estimated that between 1 and 2.5% of the population is affected by these disorders, but it seems that these figures are underestimated. It is one of the most serious psychiatric pathologies, frequently leading to suicide attempts: 50% of patients with bipolar disorder will make at least one suicide attempt, and 15% will die (*Troubles bipolaires*, n.d.)[not dated]. In addition, bipolar disorder often leads to functional impairment and reduced quality of life (Oldis et al., 2016) and is associated with a decrease in lifespan of approximately 10 years. The World Health Organization has ranked this condition among the 10 most worrying of the 21st century (*WHO | The Global Burden of Disease*, n.d.).

According to the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders-5th edition), bipolar disorders can be classified into bipolar I disorder, bipolar II disorder, cyclothymia and residual categories. This sub-classification depends on the severity and duration of manic (or hypomanic) and depressive episodes (Vieta et al., 2018).

Bipolar disorder is recurrent, even when diagnosed and treated. Various molecules are available to treat bipolar disorders, among them are mood stabilizing agents. Clinically, the main actions that qualify a molecule as a mood stabilizer are its effects at both ends of the mood spectrum (depression and mania) and its ability to maintain euthymia by preventing future mood instability. According to these factors, lithium is the best and therefore the gold standard mood stabilizing agent (Malhi et al., 2021).

According to the network meta-analysis by Miura et al., lithium remains one of the most effective drugs for relapse prevention and should remain the first-line treatment (Miura et al., 2014).

Current recommendations call for a serum lithium concentration between 0.6 mM and 0.8 mM for the most effective treatment. In the acute manic phase, concentrations can be increased to 1 mM, depending on the patient's tolerance (Malhi et al., 2020). Despite its effectiveness, lithium therapy can be complicated to administer. Indeed, lithium can cause safety problems due to its narrow therapeutic range. Below 0.5 mM lithium, treatment may be ineffective and may lead to relapse. Above 1.5 mM, there is a risk of toxicity. The Li intoxication symptoms are variable and depend on the intoxication severity. Nevertheless, if lithium levels are correctly controlled, it seems that its long-term toxicity may be limited (Malhi et al., 2020). According to the practical guide of Malhi et al., follow-up should be performed during the initial maintenance phase as well as whenever there is a significant change in therapy or when adverse effects occur (Malhi et al., 2011, 2016).

Despite existing guidelines, many clinicians remain reliant on an empirical "trial and error" approach to effective lithium prescribing. Indeed, 18 to 24 months is often required to ensure a clinically meaningful effect of lithium, with shorter-term outcomes not reliably predicting prophylactic

outcomes. In addition to concerns about potential side effects, this trial-and-error strategy likely leads to increased non-adherence to treatment potentially increasing the likelihood of treatment failure. For example, only 30% of patients treated with lithium show an excellent long-term response, most show a partial response, and up to one-third do not respond (Scott et al., 2018).

Furthermore, adherence to prescribed treatment is generally low in most chronic illnesses including bipolar disorder, with nonadherence as high as 50% of most patients (Goodwin et al., 2016). The possibility to strongly involve patients through regular and home self-monitoring would be a valuable help, probably allowing for increased adherence to treatment but also for finer monitoring of lithium levels. This is why a part of the R-Link H2020 project aims to develop such a device.

3. THE SALIVARY LITHIUM SELF-MONITORING DEVICE

The R-Link device aims to:

- improve adherence to treatment for patients with bipolar disorder type I,
- prevent lithium overdose
- prevent relapse into a manic or depressive phase.

To achieve these goals, the idea is to help patients to become active in their treatment - and more particularly in its monitoring - by regularly monitoring their salivary lithium levels.

Although there are still many uncertainties to be resolved before an usable product is available for the first pilot studies, the final configuration of the device is already broadly defined (Figure 1). It will consist of three distinct parts. Two parts will be single-use: a system for collecting the patient's saliva (A) and a "cartridge" containing the reactive zone and the solutions necessary for the reaction (B). The third part will be the device itself, *i.e.* the reusable apparatus (C) allowing: (i) the driving of the solutions on the dedicated reaction zone, (ii) the reading of the reaction, (iii) the display and recording of the results.

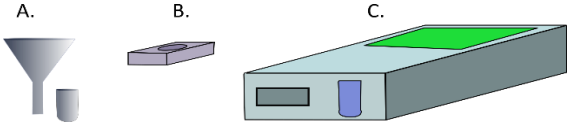

Figure 1: Diagram of the 3 parts of the final device. A. saliva collection system, B. cartridge with reagent area and C. reader-actuator for performing, reading and interpreting the reaction.

4. USABILITY STUDIES FOR MEDICAL DEVICES

As mentioned above, the prototype is not yet available but some technical solutions have already been defined and technical validation tests are currently underway. It is therefore possible - and necessary to meet the time constraints set by the H2020 project - to move forward in parallel on certain tasks, including the implementation of a usability plan.

Usability is an integral part of the MDR/IVD, in particular point 19, chapter II of Annex VIII concerning “protection against risks arising from devices intended for self-diagnosis or diagnosis near the patient […]”. So, usability engineering process aims to improve the safety of use of the device and ultimately the safety of the patients as end-users by reducing the risks associated with errors in use during normal use of the medical device. Usability studies have to be mobilized to anticipate the risks of abnormal use, in order to avoid, as much as possible, the associated errors. The process should be documented in the usability studies file for obtaining CE marking.

Usability is defined by the 62366-1 standard (*NF EN 62366-1/A1 - Août 2020*, n.d.) as "the characteristic of the user interface that facilitates use and thus establishes the effectiveness, performance and satisfaction of the user in the intended use environment". The usability engineering process is a risk management process focused on potential use errors. This usability process is closely intertwined with the standard 14971 for the application of risk management to MD (Medical Device) (*NF EN ISO 14971 - Décembre 2019*, n.d.).

The usability engineering process is an iterative process that applies to all stages of the MD life cycle and for all users. It concerns, of course, the use of the device itself with the user interface, but also the accompanying documentation and the delivered training. It must take into account the end users (patients and non-medical caregivers) and the secondary users such as the medical staff who will be responsible for training in the use of the device or the staff who will have to manufacture, package, store, maintain, recycle or dispose of the device. We have related here only the end users: patients and non-medical caregivers.

The main steps of the proposed usability engineering plan for the R-Link device are summarized in Figure 2. They consist in establishing first, the usability specifications and second, the

functional specifications (Figure 2, points 1 and 2). The usability-related safety characteristics must be then established accordingly and will complete the technical risk analysis made by the manufacturer (Figure 2, point 2). On this basis, the dangerous situations and the different scenarios arising from them can be identified to guide the MD design. Future assessments can then be planned to test to what extent the design of the device prevents that use errors occur (Figure 2, points 3 and 4). The evaluation plan for the user interface (Figure 2, point 5) should be established integrating formative evaluations (Figure 2, point 6). It may be necessary to run iterative evaluations with several models or demonstrators (Figure 2, points 6 and 7), before reaching a system satisfactory for conducting summative evaluation(s) (Figure 2, point 9).

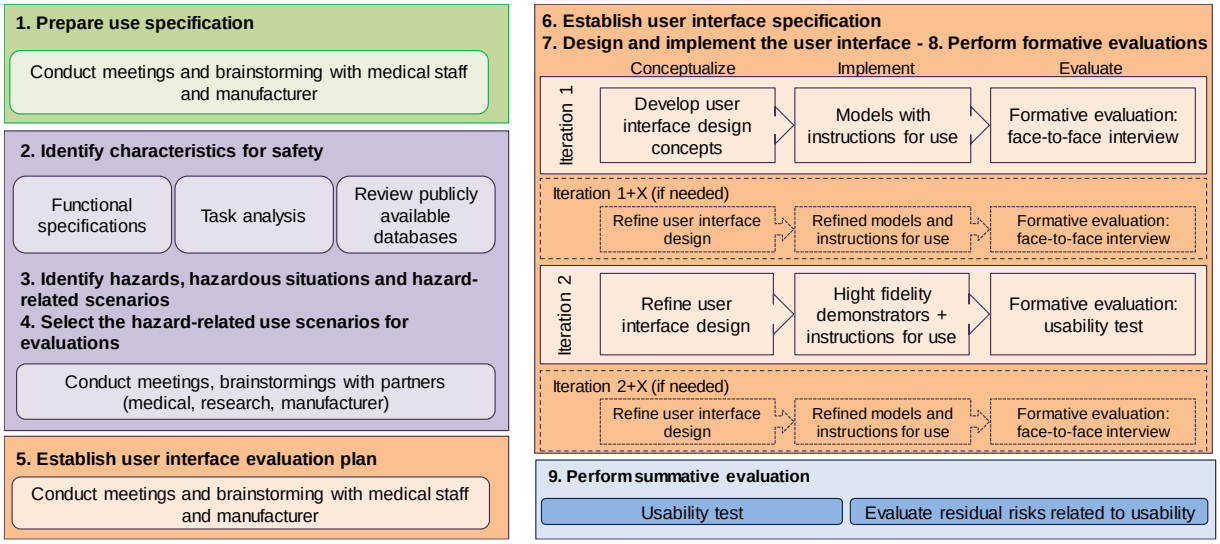

Figure 2: Schematic of the usability plan for the R-Link device

4.1 Use specifications

Establishment part of the use and functional specifications was done during the functional analysis (Charrière et al., 2021). However, the usage specifications do not only include the required functions of the final device but must also establish the characteristics of the environment in which the device will be used, as well as the characteristics of the users, considering both the physical and cognitive characteristics of the primary and secondary users.

4.1.1 Intended Use Environment

The device is intended to be used at the patient's home, by the patient himself or by non-professional caregivers. Environmental characteristics are therefore likely to vary according to location, especially countries. For example, the first models of the R-Link device will have to be connected into the mains. In France, the voltage is 220 V, whereas it is 110 V in the United States.

The patient could be away from home at the time of the test. Ideally, the device should be easily transportable and usable in mobile conditions. It will therefore be important to provide an appropriate device size and weight.

The appropriate luminous flux to illuminate a space varies according to the room. Recommended levels can be found in NF EN 12464-1 standard "indoor lighting for workplaces" (*NF EN 12464-1 - Juillet 2011*, n.d.). It is desirable that the result can be read from 20 cm to 50 cm under appropriate light conditions.

Since the device is intended for home use, the temperature can be varied in the range of 14°C to 35°C. However, previous summer heat waves should be taken into account. If this is not the case, the manufacturer will ensure that this risk is controlled by clearly indicating it in the instructions or by adding an internal control to the device.

Based on the reagent cost, the estimated production costs after industrialization and, above all, the recommendations of the project's partner physicians, patients will be encouraged to perform a test every 15 days. This frequency could be adapted throughout the project duration.

The description of the technical environment of the device cannot yet be finalized at this stage of the project. However, some characteristics can now be specified: hardware configuration such as processor speed, memory size, network, storage, input and output devices; screen type and size, resolution and color depth; whether or not the visual interface elements (such as text or symbols) can vary in size (and size(s) available); configuration of the electronic board; assistive technologies available if required.

4.1.2 Target users

User characteristics (functional, physical, sensory and cognitive capabilities, experience,knowledge levels and behaviors) could impact the safe and effective use of the device.

For example, elderly people may have reduced visual acuity or polyarthritis problems. A small text on a screen or a too complicated handling of the device will most likely lead to user errors. Since the ultimate goal is to eliminate sources of error related to perception, cognition or handling as much as possible, it is important to correctly identify the primary users (*i.e.* the person who will use the device in its actual medical use) and the secondary users (*i.e.* all persons who may have the device in their hands during its life cycle, from manufacture to disposal).

In the case of the R-Link device, the primary users of the device are patients with bipolar disorder type I. Bipolar disorder affects both men and women, regardless of social class or location. The illness can occur throughout the lifespan, from the age of 15 to over 60. If patients are unable to use the device due to physical or cognitive impairments, caregivers may do it for them and then become the primary users. Bipolar disorder causes comorbidity that can lead to impairments, and patients (or caregivers) may have age-related physical and cognitive impairments, such as loss of vision, hearing, dexterity, etc. Patient and non-professional caregiver categories for the device should include: adults (18-49 years old), seniors (50-64 years old), and the elderly (65 years old and older).

4.2 User-centered safety features

Risk analysis is often understood as an analysis of technical risks like electrical, thermal or biological risks. They are related to a failure of the device or of a component, and therefore do not depend on the way the device is used, *i.e.* on the interaction between user and interface.

However, some risks are directly related to this interface/user interaction and can be the result of user interface design problems. For example, the result is not clearly readable or difficult to interpret, resulting in a more or less serious damage (Health, 2019). Therefore, the risk analysis - and the entire risk management plan - must also include the risks associated with the use of the device throughout its life cycle. It is therefore necessary to be able to identify the hazards, estimate and quantify the associated risks, control them and be able to monitor the effectiveness of these measures (*NF EN ISO 14971 - Décembre 2019*, n.d.).

Here, the analysis is focused on the risks related to the use of the device. The analysis of technical risks, resulting from a failure of the device, will not be dealt with. Use errors analysis is difficult to carried out when the technical solutions are not yet known and when the development of the device is not advanced, which is the case for the R-Link device. Some of main trends are already decided in terms of design: a saliva sample is inserted in the system manually or automatically, a chemical reaction takes place, the result is read by an analyzer and delivered to the patient who must interpret it and react accordingly.

There are analytical approaches for identifying hazard-related tasks or scenarios. Such an approach is based on the task analysis method, which breaks down the process of using the device into discrete sequences of tasks. This analysis has been applied to the R-Link device.

To perform the salivary lithium level self-test, all parts of the R-Link device are required: the reader, a cartridge and a saliva collector (Figure 1). The cartridge and saliva sampler are independent of the reader. Five major steps have been identified for performing salivary lithium self-testing with the R-Link device: (i) collect saliva using a saliva sampler, (ii) insert the saliva sample in the designated area, (iii) insert the cartridge into the R-Link reader, (iv) after a few minutes, the result appears on the screen and (v) the patient reads and interprets the result.

For each of these tasks, a questioning based on the WWWWHW model (Who, What, Where, When, How, Why) is performed. Based on this questioning, we identified anticipated subtasks that will be performed by the patient, with the exception of the automated tasks.

Based on these identified subtasks, the user risk analysis can start relying on a Failure Mode and Effects Analysis (FMEA) method. It is used to identify all the hazards and harms associated with the use of the device according to its characteristics and

its intended use. In order to conduct this analysis in the best way, all project partners (clinicians, researchers and manufacturers) must be involved. For each of the previously defined subtasks, it is determined whether or not a hazard can be associated with. This hazard may lead - either on its own or as a result of a sequence of events - to a dangerous situation that will result in damage for the user. The risk level is then assessed according to the probability and severity of the damage.

If the risk level is high, risk control measures must be put in place to ensure that the residual risk is acceptable. At the research and development step, a certain number of control methods could be suggested. The final choice of the control method will be made considering the adequacy between use added value and production costs.

For the R-Link device, several types of damage have been identified. The most serious is an erroneous chemical reaction leading to a false result, namely an over- or under-estimation of the lithium level. In both cases, the damage is severe.

In case of overestimation of the lithium level by the device, the patient might actually be beyond the zone for which no toxicity is to be feared. Nevertheless, this risk is to be put in comparison with the patient's feeling. Indeed, lithium overdoses are often well estimated by the patient who then immediately contacts his doctor.

In case of lithium level underestimation, the patient would probably not be aware of it and would risk a relapse - either into a manic state or into a depressive state. It is precisely these cases that the R-Link device targets in priority. Thus, in both cases, the damage to the patient could be significant and countermeasures must be taken to reduce it.

Several causes could be at the origin of this bad estimation: too high temperature, expired consumable, bad salivary sampling, bad reading and bad interpretation of the result delivered by the device. To reduce these risks, several control methods are suggested: designing the device with a thermostatic chamber, or at least incorporating a temperature controller; designing the device with an integrated expiration date controller; training end users in saliva sampling and deliver clear instructions for use; making sure that the result is clearly displayed.

Other non-critical errors of use have been identified. For example, if the patient does not connect the device properly to the power source, the test cannot be performed. Nevertheless, this problem should be rare and will not cause any direct damage since the test cannot be performed. It should also be easily controlled by learning how to use the device and a clear instruction manual.

4.2.1 Review of public databases

A review of available databases was also conducted to identify known use errors with similar devices: MAUDE (Manufacturer and User Facility Device Experience), Web of Science, PUBMED. Only one search carried out with the key words "self-test lithium" on google gave interesting results (*Self Test Lithium - Google Search*, n.d.). The first comes from the Dutch company FISIC: the Medimate Multireader (*Fisic | Lithium Self Test*, n.d.). The second comes from ReliaLAB, an American company: the Instaread lithium system (*Finger-Stick Lithium Test*, n.d.).

For the Instaread lithium system an adverse reaction report exist. . This report mentions that the results obtained with the Instaread lithium system can differ of up to 0.5 mM compared with the results obtained during a laboratory test. (*INSTAREAD LITHIUM SYSTEM * Adverse Event MAUDE*, n.d.). Finally, the 510k data sheet for this MD/IVD is available, but it only enumerates device performance data (*510(k) Premarket Notification*, n.d.). No data regarding usability was found.

More documentation is available from the second MD/IVD, the Medimate Multireader from the company FISIC (*Fisic | Documentation*, n.d.). This one is not FDA approved but is EC labelled according to the European Directive for IVDs (98/79/EC). In a study, authors aim to evaluate the usability of the Medimate Multireader when used by the patient for self-testing at home, or when used in a health care facility for point-of-care testing. Healthcare workers (for point-of-care testing) and patients (for home testing) completed a System Usability Scale (SUS) questionnaire. The SUS is a validated method to quickly assess the perceived usability of a system and consists of 10 items covering different aspects such as complexity, ease of learning, frequency of use (Affairs, 2013; Bangor et al., 2008). Based on this scale, authors concluded that the usability of their device is "good", even if the blood collection was considered unpleasant and/or difficult in terms of sampled volumes.

The analysis of the competing devices is a key point, which allows to anticipate the requirements expected for similar devices. Thus, the studies for the design and then the validation of the R-Link device - similar in its specification of use to the Medimate Multireader and Instaread lithium system - could be inspired by this already compliant competition for a diffusion on the European market or for the American

market. For the Instaread lithium system, the 510k data sheet of the system could be a source of inspiration for the performance validations of our MD/IVD as well as the instructions for use (complete and abbreviated), the study designs used and the various articles published in peer-reviewed journals from the company FISIC (Floris et al., 2010; Muñoz et al., 2011; *Nieuwe Mogelijkheden Voor Een Lithiummeting Op de Poli En in de Huiskamer*, 2019; Staal et al., 2015).

4.3 Formative and summative evaluations

Although the R-Link device is at a very early development stage , it is possible to anticipate future evaluations. In addition to the 62366-1 and 2 standard (*IEC/TR 62366-2:2016 - Avril 2016*, n.d.; *NF EN 62366-1/A1 - Août 2020*, n.d., pp. 62344–2), the FDA guide for manufacturers and their staff is freely available and is a good support to design the plan of the different usability evaluations of a device (Health, 2019). Usability evaluations can be classified into two categories depending on the objective: formative and summative evaluations.

4.3.1 Formative evaluations

Formative evaluations should help in the design of the MD during its development and focus primarily on points that could jeopardize the safety of use identified during the risk analysis and on undefined design options. They should complement the preliminary analyses (task analyses, risk analyses) and reveal previously unidentified errors in use. Thus, formative evaluations should be performed throughout the development process, depending on the amount of information needed for the design, the complexity of the device and its use, the variability of the user population or the conditions of use. They can be done with very simple mockups, even drawings, or with very advanced prototypes (Health, 2019).

Standard 62366-2 recommends several types of methodologies for conducting these formative evaluations, including face-to-face interviews, cognitive walkthroughs, and/or usability tests. For face-to-face interviews to be productive, the objectives must be established beforehand and an interview guide defined. This guide should not present closed questions but include short, open-ended, organized questions around topics of discussion. In the cognitive walk, a very preliminary design - which may be in the form of drawings - is presented to a small group of people. A session involves a single participant who must imagine his/her reactions to the MD and verbalize all his/her thoughts and actions. Usability tests are conducted with a few users who have to complete some tasks representing the important functions of the future MD (*IEC/TR 62366-2:2016 - Avril 2016*, n.d.).

For the R-Link device, the risk analysis reveals four tasks for which the risk of use errors leading to damage is significant: (i) saliva collection, (ii) insertion into the cartridge, (iii) reading the result, and (iv) interpreting the results. The formative evaluations should ensure that the design chosen for the parts of the device supporting these tasks effectively eliminates or limits any risk associated with misuse. It is performed in an iterative way and the first steps could be done with experts instead of end users. For each of the four domains mentioned, two types of formative evaluations are retained: a face-to-face interview with hospital staff (experts) and a usability test with patients. A summary sheet for each of these tasks was designed (Table1). These sheets, as the whole file, are not fixed yet and may evolve according to the progress and design choices of the project.

4.3.2 Summative Evaluations

The summative evaluation is always the very last step of the fitness-for-use engineering process. It must demonstrate that the MD can be used under the specified conditions of use, by the intended users and without unacceptable residual risk: it is therefore the validation step of the device in terms of safety risks related to use. The summative evaluation must implement the scenarios relating to the previously defined dangerous phenomena, under conditions as close as possible to reality, but without a clinical effect. Thus, for the summative evaluation to be valid, it is important to ensure that the participants represent all the intended users, that all critical tasks are performed during the test, that the user interface represents the final design, and that the test conditions correspond to the real conditions of use.

As with a traditional clinical investigation, a rigorous protocol must be established, including the introduction, the objectives of the test and the method used, the description of the MD, the necessary equipment and environment, the description of the participants and the personnel involved, the list of tasks to be carried out, the methods of data collection and analysis, an operating procedure for the test and, if necessary, a description of the training.

Table 1: Example of summary sheet; task "Insert the sample in the slot provided in the cartridge".

Hazardous event	Description of the use scenario related to the hazardous phenomenon	Associated damage(s)	Hazardous situation
Wrong test result	The system for transferring saliva from the collection tube to the cassette has not yet been determined. The user has difficulties in transferring saliva from one container to another. The user does not insert a sufficient volume into the cassette and/or causes numerous bubbles in the reaction area. The chemical reaction does not take place correctly, leading to an over- or underestimation of the lithium level.	Anxiety, relapse or risk of toxicity	Use of the saliva collection device is difficult for the user.
Formative evaluation(s) - "Sample tube / cartridge / leaflet" interface			
Face-to-face interviews	*Objective:* To assess the understanding of the instructions in relation to the use of the system and the clarity of the training. *Method:* Face-to-face interviews with an interview grid focused on the understanding of the instructions and the instructions given by the trainer. Presentation of a low definition model, then high definition, allowing the sample to be placed in the cassette, with the associated instructions. Collect opinions on the clarity of instructions. Explanation of the use of the device. Collect opinions on the clarity of the use of the device after explanation. *Data collection:* audio recording and note taking. *Analysis:* Qualitative analysis of verbatims. *Population:* Nursing staff doctors + nurses + clinical research officer. *Note:* Refine the design according to the results and repeat the evaluation until the device for depositing the sample in the intended location in the collection cassette is satisfactory. Conduct the usability test when this stage is reached.		
Usability test	*Objectives*: To assess the number of usability errors and to identify the causes. To assess the number of non-compliant deposits of the sample into the cassette. To assess the understanding of the training. *Method*: Usability test with video recording, interview and questionnaire. 1 session per participant. *Population:* Patients with bipolar disorder type I, 3 age groups (18-24, 25-62, over 62), 1 male and 1 female/group. Non-medical carers, 3 age groups (18-24, 25-62, over 62), 1 male and 1 female/group. *Course of the session:* Presentation of the device allowing the sample to be placed in the location provided in the cassette selected following the initial evaluations, with the associated instructions. Explanation of the use by the trainer, as in a real situation. Immediately afterwards, the user will carry out all the tasks requested, following only the instructions, without any external help. The session will be filmed to allow analysis (number of hesitations during sampling, number of times the instructions are consulted). Immediately after the collection, the volume of saliva deposited in its place will be recorded in the observation book, as well as the presence or absence of bubbles/foam. Proposal of the SUS questionnaire with an interview targeted on the difficulties of use encountered, including the understanding of the instructions given. *Data collection:* Video recording + observation booklet + questionnaires + note taking. *Data analysis:* Quantitative analysis of the number of errors, hesitation/consultation of the instructions, non-compliant deposits + analysis of SUS + qualitative analysis of verbatims.		

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