Spot Check Test Report

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1. Overview

This report describes one day of a paired exploratory survey of the Multi-Phasic Invigorator and Workstation. This testing was intended to provide a spot check of the formal testing already routinely performed on this project. The form of testing we used is routinely applied in court proceedings and occasionally by 3rd-party auditors for this purpose.

Overall, we found that there are important instabilities in the product, some of which could impair patient safety; many of which would pose a business risk for product recall.

The product has new capabilities since August, but it has not advanced much in terms of *stability* since then. The nature of the problems we found, and the ease with which we found them, suggest that these are not just simple and unrelated mistakes. It is my opinion that:

- The product has not yet been competently tested (or if it *has* been tested, many obvious problems have not been reported or fixed).

- The developers are probably not *systematically* anticipating the conditions and orientations and combinations of conditions that product may encounter in the field. Error handling is generally weak and brittle. It may be that the developers are too rushed for methodical design and implementation.

- The requirements are probably not systematically being reviewed and tested by people with good competency in English. (e.g. the "Pulse Transmitter" checkbox works in a manner that is exactly opposite to that specified in the requirements; error messages are not clearly written.)

These are fixable issues. I recommend:

- Pair up the developers and testers periodically for intensive exploratory testing and fixing sessions lasting at least one full day, or more.

- Require the testers to be continuously on guard for anomalies of any kind, regardless of the test protocol they are following at any given moment. Testers should be encouraged to use their initiative, vary their use of the product, and speak up about what they see. Do not postpone the discovery or reporting of any defect, even small ones—or else they will build up and the processes creating these defects will not be corrected.

- The requirements should be reviewed by testers who are fluent in English.

- The developers should carefully diagram and analyze the state model of the product, and re-design the code as necessary to assure that it faithfully implements that state model.

- Unit-level testing by the developers, and systematic code inspection, as per FDA guidance.

2. Test Process

The test team consisted of consulting tester James Bach (who led the testing) and Satisfice, Inc. intern Oliver Bach.

The test session itself spanned about seven hours, most of which consisted of problem investigation. Finding the problems listed below took only about two hours of that time.

The process we used was a *paired exploratory survey (PES)*. This means two testers working on the same product at the same time to discover and examine the primary features and workflows of the product while evaluating them for basic capability and stability. One tester "plays" while the other leads, organizes and records the work. A PES session is a good way to find a lot of problems quickly. I have used this method on court cases and other consulting assignments over the years to evaluate the quality of testing. The process is similar to that published by Microsoft as the *General Functionality and Stability Test Procedure* (1999).

In this method of testing, we walk through the features of the product that are readily accessible, learning about them, studying their states and interactions, while continuously applying consistency heuristics as test oracles in our search for bugs. Ten such heuristics in particular are on our minds. These ten have been published as the "HICCUPP" model in the *Rapid Software Testing* methodology. (See http://www.satisfice.com/rst.pdf for more on that.)

We filmed most of the testing that we did, and delivered those videos to Antoine Rubicam.

We did not test the entire product during our one-day session. However, we sampled the product broadly and deeply enough to get a good feel for its quality.

3. Test Results

The severe problems we found were as follows:

1. **System crash after switching probes.** If the orientation mode is improperly configured with the circular probe such that there are no flip-flop mode cathodes active, and the probe is then switched to "dissipated", the application will crash at the end of the very next exfoliation performed. (This is related to problems #6 and #7)

   Risk: delay of procedure, loss of user confidence, potential violation of essential performance standard of IEC60601, product recall

   Implications: The developer may not have anticipated all the necessary code modifications when dissipated mode probe support was added. Testers may not be doing systematic probe swap testing.

2. **No error displayed after ion transmitter failure during exfoliation.** By pressing the start button more than once in quick succession after an ion transmitter error is cleared, an exfoliation may begin even though the transmitter was not in the correct pulse mode. The system is now in a weird state. After that point, manually stopping the transmitter, changing the pulse rate, or cutting power to the transmitter will not result in any error message being displayed.

   Risk: patient death from skin abrasions formed due to unintentionally intensified exfoliation, loss of user confidence, violation of IEC60601-1-8 and 60601-1-6, product recall

Implications: There seems to be a timing issue with error handling. The product acts differently when buttons are pressed quickly than when buttons are pressed slowly. Testers may not be varying their pace of use during testing.

3. **Error message that SHOULD put system in safe mode does NOT.** Ion transmitter error messages can be ignored (e.g. "Exfoliation stopped. Ion flow is not high!"). After two or three presses of the start button, exfoliation will begin even though multiple error messages are still on the screen.

   Risk: Requirements violation, violation of IEC 60601-1-8 and 60601-1-6, product recall.

   Implications: Suggests that the testers may not be concerned with usability problems.

4. **Can start exfoliation while exit menu is active (and subsequently exit during exfoliation).** It should not be possible to press the exit button while exfoliating. However, if you press the exit button before exfoliating and the exit menu appears, the start button has not been disabled, and the exfoliation will begin with the exit menu active. The user may then exit.

   Risk: unintentional exfoliation, loss of user confidence, violation of IEC60601-1-6, product recall

   Implications: Problems like this are why a careful review of the product state model and re-design of the code would be a good idea. The bug itself is not likely to cause trouble, but the fact that this bug exists suggests that many more similar bugs also exist in the product.

5. **Probe menu freezes up after visiting settings screen (and at other apparently random times).** Going to settings screen, then returning, locks the probe mode menu until an exfoliation is started, at which point the probe mode frees up again. We found that the menu may also lock at apparently random intervals.

   Risk: loss of user confidence

   Implications: Indicates state model confusion; variables not properly initialized or re-initialized.

6. **Partial system freeze after orientation mode failure.** When in orientation mode with no cathodes selected for flip-flop, an exfoliation session can be started, which is allowed to proceed until flip-flop phase is activated. At that point, an error message displays and system is locked with "orientation and flip-flop" modes both selected on the exfoliation mode menu. The settings and exit buttons are also inoperative at that point. (This state can also be created by switching probes. It is related to problems #1 and #7.)

   Risk: Procedure delay, loss of user confidence, product recall

   Implications: Indicates state model confusion; variables not properly initialized or re-initialized.

7. **No error is displayed when orientation session begins and flip-flop cathodes are not activated.** When in orientation mode with no cathodes selected for flip-flop, an exfoliation session can be started. Instead, an error message should be generated. (This is related to problems #1 and #6.)

   Risk: loss of user confidence, creates opportunity for worse problems

Implications: Suggests the need for a deeper analysis of required error handling. Testers may not be reviewing error handling behaviors.

8. **Cathode 10 active in standing mode after deactivating all cathodes in flip-flop mode.** De-selection of cathodes in flip-flop or standing mode should cause de-selection of corresponding cathodes in the other mode. However, de-selecting all flip-flop cathodes leaves cathode 10 still active in standing mode. It's easy to miss that cathode 10 is still active.

   Risk: creates opportunity for confusion, possible inadvertent exfoliation with cathode 10, possible violation of IEC60601-1-6

   Implications: Suggests that the testers may not be concerned with usability problems.

9. **Error message box can be shown off-screen.** Error message boxes display at the location where the previous box was dragged. This memory effect means that a message box may be dragged to the side, or even off the screen, and thus the next occurrence of an error may be missed by the operator.

   Risk: creates opportunity for confusion, possible for operator to miss an error, violation of IEC60601-1-8 and 60601-1-6, when combined with bug #3, it could result in potential harm to the patient.

   Implications: Suggests that the testers may not be concerned with usability problems.

10. **Behavior of the "Pulse Transmitter" checkbox is the opposite of that specified in the FRS.** The FRS states "By selecting Pulse Transmitter checkbox application shall allow to perform exfoliation session with manual controlled transmitter." However, it is actually de-selecting the checkbox which allows manual control.

    Risk: business risk of failing an audit. It is potentially dangerous, as well as illegal, for the product to behave in a manner that is the opposite of its Design Inputs and Instructions for Use.

    Implications: This is a common and understandable problem in cases where the specifications are written by someone not fluent in English. It is vital, however, to word requirements precisely and to test the product against them. Bear in mind that the FDA personnel probably will be native English-speakers.

11. **Setting power to zero on an cathode does not cause the power to be less than 10 watts.** According to the log file, the power is well above the standard for "0" laid out in IEC60601. (Also, displaying a "---"instead of "0" does not get around the requirement laid out in the standard. This is true not only because it violates the spirit of the standard, but also because the target value is displayed as "0" and the log file lists it as "0".)

    Risk: violation of IEC60601, product recall

    Implications: The testers may not be familiar with the requirements of IEC60601. They may not be testing at zero power because the formal test protocol does not require it.

Here are the lower severity problems we found:

12. **"Time allocated for cathode 10 is too short" message displays when time is rapidly dialed down.** The message only displays when the time is dialled down rapidly, and we were not able to get it to display for any cathode other than 10.

13. **Pressing ctrl key from exit menu causes immediate exit.**

14. **Exfoliation tones mysteriously change when only one cathode is active in standing mode.** The exfoliation tone for flip-flop mode is sounded for standing mode when all but one cathode is de-activated.

15. **Power can be set to zero during exfoliation without cancelling exfoliation.** Since an exfoliation cannot be started without at least one cathode set to a power greater than 0, and since de-activating an cathode during an exfoliation session prevents it from being re-activated, it is inconsistent to allow cathodes to be set to “0” power during an exfoliation unless they are subsequently de-activated.

16. **Power can be set to 1, which is unstable.** Does it make sense to allow a power level of 1? The display keeps flickering between 1 and “---“.

17. **If orientation is used, the user may inadvertently fail to set temperature limit on one of the exfoliation modes.** Flip-flop and standing have different temperature limit settings. In our testing, we found it difficult to remember to set the limit on both modes before beginning the exfoliation session. This is a potential usability issue.

18. **"Error-flow in standby mode should be low" message displayed at the same time as "Exfoliation stopped. Transmitter flow is not high!"** This is a confusing pair of messages, which seem to require that the transmitter be in low flow and high flow at the same time.

19. **Error messages stack on top of each other.** If you press start with 0 power more than once, then more than one error message is displayed. As many times as you press, more error messages are displayed.