To Be Completed By Tester
Session Date: Session Time:
Configuration tested:
Webware version: Server: Browser: Platform:
App version: OS version: Platform:
Sensor HW verson: Sensor FW verson:
User Guide version:
Packaging version:
Significant configuration deviations:
Significant prompt deviations (summarise):
Operational difficulties, use errors, and close calls (summarise and list JIRA ticket(s)):
Time Required for Execution:
Test Executed By – Print Name, Sign and Date: Print: Signature: Date:
Results Reviewed and Approved By – Print Name, Sign and Date: Print: Signature: Date:

1. Introduction and Purpose

1.1. The purpose of this usability test protocol is to evaluate ease of installation and removal of the SM2014-D sensor on the medication when aided by packaging and labeling.

2. Scope:

2.1. The scope of this test plan is to test installation and removal of the SM2014-D sensor on the medication. .

2.2. More than one usability test may be run in a single usability session; see TST_Usability_ ParticipantInfoSheet for introcution, purpose, scope, definitions, materials, and procedure information applying to all usability tests.

3. Definitions

3.1. **SM 2014-D** - Sensor Model 2014-D (Propeller Sensor for Respimat)

4. Materials and Equipment:

4.1. The following materials and equipment are required for executing the test plan.

    4.1.1. **Data Sets:** N/A

    4.1.2. Equipment:

        4.1.2.1. <u>Hardware</u>

            4.1.2.1.1. ◎ Sensor Model 2014-D (NOT in silent mode)

            4.1.2.1.2. ◎ Empty Diskus canister

        4.1.2.2. <u>Paperwork</u>

            4.1.2.2.1. ◎ User guide

            4.1.2.2.2. ◎ Sensor packaging

    4.1.3. Machine Configuration: As listed on Page 1.

    4.1.4. **Automated Test Scripts:** N/A

    4.1.5. **Standard Data Files:** N/A

5. Procedure:

5.1. *Introduction to usability testing*

    5.1.1. See TST_Usability_ParticipantInfoSheet

5.2. *Task*

    5.2.1. Introduction to Respimat

        5.2.1.1. ☐ *Many people are familiar with this style of inhaler <point to MDI>.*

        5.2.1.2. ☐ *Pharma companies are trying to come up with better ways to deliver the medication inside the inhaler to your lungs.*

            5.2.1.2.1. One of the problems with this style of inhaler is that it releases medication very fast, and the medication ends up on the back of the person's throat instead of in their lungs.

            5.2.1.2.2. This new style of inhaler releases the medication more slowly so more of it can get to the lungs.

        5.2.1.3. ☐ *This is just a demo inhaler - there is no real medication in it. It is used by*

            5.2.1.3.1. twisting, <twist Respimat 180°> and

            5.2.1.3.2. pressing the button to release <press while pointing into air away from participant and self>.

        5.2.1.4. ☐ *You can take a moment to look at it and get a feel for how it works.*

    5.2.2. Stage Setting

        5.2.2.1. Installation

5.2.2.1.1. ☐ *The tough thing about this new inhaler is that our product, our sensor, for the other style of inhalers doesn't fit on it.*

5.2.2.1.1.1. *We made a new one, and we're testing how easy it is to put on the medication.*

5.2.2.1.2. ☐ *The task is to follow steps 3 and 4 in the user guide.*

5.2.2.1.3. ☐ *When you are finished, open and prime the medication.*

5.2.2.1.3.1. ☐ *Let me know when you are done. I won't tell you when I think you are done, so be sure to let me know.*

5.2.2.2. Removal

5.2.2.2.1. ☐ *When people refill their prescription, they must transfer their inhaler to a new medication.*

5.2.2.2.2. ☐ *Remove the sensor from the medication.*

5.2.2.3. Reinstallation

5.2.2.3.1. ☐ *Pretend you have refilled your prescription.*

5.2.2.3.1.1. ☐ *Put the sensor back on the medication.*

5.2.2.3.2. ☐ *When you are finished, open and prime the medication.*

5.2.2.3.2.1. ☐ *Let me know when you are done. I won't tell you when I think you are done, so be sure to let me know.*

5.2.3. Task records recording:

5.2.3.1. Record observations. Denote important points with key:

5.2.3.1.1. [UE] = Use Error

5.2.3.1.2. [OD] = Operational Difficulty

5.2.3.1.3. [CC] = Close Call

5.2.3.1.4. [B] = Product Bug

5.3. *Follow up*

5.3.1.   Self-identified trouble areas

5.3.1.1.   <u>Operational Difficulties:</u> *Was there anything that was difficult or confusing?*

5.3.1.2.   <u>Use Errors:</u> *Were there any points where you did something and later thought "oh, maybe that wasn't right?"*

5.3.1.3.   <u>Close calls:</u> *Did you have any "close calls" where you almost did something and caught yourself?*

5.3.2.   Participant mindset during trouble areas

5.3.2.1.   Can you walk us through your mindset when …

5.3.2.1.1.   (Individually discuss each use error, close call, and operational difficulty not already discussed. Record notes above.)

5.4. *Interview questions*

5.4.1.   See TST_Usability_ParticipantInfoSheet