To Be Completed By Tester			
Session Date:	Session Time:		
Participant Name: _____ Recruitment Method: _____ Contacted PH via: _____ PH responded via: _____ Email: _____ Phone: _____			
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:		Reimbursement:	
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 test is to assess the effectiveness of Sensor Model 2014-D in detecting Diskus inhaler usages and, in the event of ineffectiveness, to determine primary factors contributing to detection success or failure.

1.2. Non-bolded text in italics indicates a prompt to be read aloud to the participant.

1.3. Check boxes indicate procedure items to be conducted. Check each as it is performed. Missed checkboxes constitute prompt deviations

1.4. Circles are used to represent both:

1.4.1. Configuration options that should be checked if used and summarized in the configuration details section of the first page.

1.4.2. Answers to questions given to the participant.

1.5. Note any deviations from the prompt.

1.6. The preconditions to execute this inspection protocol are:

1.6.1. Tester has been trained in running/completing usability test protocols and has been familiarized with the type of defects that they may see as a function of executing this test protocol.

1.6.2. Tester initials: _____

2. Scope:

2.1. The scope of this test procedure is to assess the performance of the SM 2014-D detection algorithm using fixed parameter values specified below. The test procedure also assesses factors contributing to detection failure. The dynamic thresholds algorithm is not included in this assessment.

2.2. Participants will be from the following age groups:

2.2.1. Two to four participants ages 18-39

2.2.2. Two to four participants ages 40-59

2.2.3. Two to four participants ages 60-79

2.2.4. Two to four participants ages 80+

2.3. At least ten total participants will be included.

3. Definitions

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

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>Sensor and Inhaler</u>

4.1.2.1.1. ☐ Sensor Model 2014-D with attachment label

4.1.2.1.1.1. Firmware specifications:

4.1.2.1.1.1.1. ☐ Dynamic thresholds have been disabled

4.1.2.1.1.1.2. ☐ Sensor has been modified to record breath sounds whenever the touch sensor is activated

4.1.2.1.1.1.3. ☐ Sensor has been modified to show an amber LED when awake and a green LED when both awake and the touch sensor is activated

4.1.2.1.1.2. Preparation:

4.1.2.1.1.2.1. ☐ Sensor has been taken out of inventory mode

4.1.2.1.1.2.2. ☐ Sensor has a thick, opaque cloth sticker

covering the LED so it can only be viewed from behind
- 4.1.2.1.1.2.3. ☐ Surface cleaned with isopropyl alcohol
- 4.1.2.1.1.2.4. ☐ Previous breath sounds recordings have been removed from the device to clear memory

4.1.2.1.2. ☐ New Diskus canister including foil tape but containing no medication
- 4.1.2.1.2.1. ☐ Surface cleaned with alcohol wipe while wearing gloves
- 4.1.2.1.2.2. ☐ Packaged in new press-to-seal bag

4.1.2.2. Measurement Equipment
- 4.1.2.2.1. ☐ EasyOne Spirometer with batteries
  - 4.1.2.2.1.1. ☐ Cleaned with isopropyl alcohol
- 4.1.2.2.2. ☐ New, unopened Spirette for EasyOne Spirometer
- 4.1.2.2.3. ☐ EasyOne Spirometer cradle with attachment cable
- 4.1.2.2.4. ☐ Computer running EasyOne software
- 4.1.2.2.5. ☐ Diskus resistance adapter cleaned with isopropyl alcohol
- 4.1.2.2.6. ☐ Video camera positioned to view the participant from the side
- 4.1.2.2.7. ☐ Clock in view of the video camera

4.1.2.3. Supporting Materials
- 4.1.2.3.1. ☐ Thermometer
- 4.1.2.3.2. ☐ User guide
- 4.1.2.3.3. ☐ Sensor packaging
- 4.1.2.3.4. ☐ Gloves
- 4.1.2.3.5. ☐ Consent form
- 4.1.2.3.6. ☐ Reimbursement ($100 VISA gift card)
- 4.1.2.3.7. ◎ Bottled water (optional)

4.1.3. Machine Configuration:

4.1.3.1. ☐ Sensor detection parameters are set to:
- 4.1.3.1.1. ACCEL_ACTIVITY_THRESHOLD = 240
- 4.1.3.1.2. **ACCEL_ACTIVITY_TIMER = 16**
- 4.1.3.1.3. ACCEL_INACTIVITY_THRESHOLD = 360
- 4.1.3.1.4. ACCEL_INACTIVITY_TIMER = (12 * 25)
- 4.1.3.1.5. TOUCH_HOLD_TIME = 30
- 4.1.3.1.6. TOUCH_DIFF_THRESHOLD = 60
- 4.1.3.1.7. MIC_ENVELOPE_THRESHOLD = 50
- **4.1.3.1.8. MIC_OFF_PEAK_SCALAR = 77**
- 4.1.3.1.9. MIC_PEAK_THRESHOLD = 150
- 4.1.3.1.10. MIC_PEAK_THRESHOLD_MAX = 350
- **4.1.3.1.11. MIC_COUNT_SCALAR = 77**
- **4.1.3.1.12. MIC_COUNT_THRESHOLD = 80**
- 4.1.3.1.13. MIC_COUNT_THRESHOLD_MAX = 200

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. Welcome the participant

5.1.1.1. ☐ List name

5.1.1.2. ☐ List company

5.1.1.3. ☐ Offer bottle of water

5.1.1.4. ☐ Thank participant for their time

5.1.1.5. ☐ Summarise purpose for session

5.1.2. ☐ Give overview of each portion of the consent form (TST_2014-D_DetectionAssessment_Consent).

5.1.2.1. If participant agrees, continue.

5.1.3. Establish comfort level

5.1.3.1. ☐ *Evaluating the product, not the participant*

5.1.3.2. ☐ *You can stop at any time without forfeiting payment*

5.1.3.3. ☐ *Please tell us if you are uncomfortable or need a break*

5.1.3.4. ☐ Video recording acceptable? (Check all that are acceptable)

5.1.3.4.1. ◎ Video ◎ Audio ◎ Screen capture ◎ None

5.1.4.

5.2. *Interview questions*

5.2.1. You do not have to answer the following questions if you do not feel comfortable.

5.2.1.1. How frequently do you take Diskus? _____

_____

5.2.1.2. Where do you store your Diskus? _____

_____

5.2.1.3. In what decade were you born? _____

5.2.1.4. What condition do you take Diskus for? _____

5.2.1.5. *Any vision problems?* ◎ No ◎ Y, corrected ◎ Y, uncorrected

5.2.1.6. *Any hearing problems?* ◎ Yes ◎ No

5.2.1.7. *How is your dexterity?* ◎ Good ◎ Difficulty

5.2.1.8. How frequently do you use a computer?

5.2.1.8.1. ◎ Daily ◎ ~3 days/week ◎ Weekly ◎ Monthly ◎ Less than 1x/month

5.2.1.9. Does participant have a mustache? ◎ Yes ◎ No

5.2.1.10. Is participant wearing lip gloss / lipstick? ◎ Yes ◎ No

5.3. *Task 1: Installation and first inhalation*

5.3.1. Task prompt:

5.3.1.1. ☐ *We will be using a few different things in this test:*

5.3.1.1.1. ☐ *The sensor: This is our product, called a "sensor." It is used to keep track of when you use your Diskus inhaler so it can remind you to take it every day.*

5.3.1.1.2. ☐ *The sample inhaler - This Diskus is just a sample. It does not have any medication in it.*

5.3.1.2. ☐ *We are testing how hard it is to attach the sensor to the inhaler.*

5.3.1.2.1. ☐ *Your task is to attach the sensor to the medication.*

5.3.1.2.2. ☐ *When you are finished, demonstrate how you normally take your inhaler. The inhaler is new and hasn't been used by anyone but you, so you can actually take it as if it were your normal inhaler.*

5.3.1.3. ☐ *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.

5.3.2. Task results:

5.3.2.1. Record observations. Denote important points with key:

5.3.2.1.1. [UE] = Use Error
5.3.2.1.2. [OD] = Operational Difficulty
5.3.2.1.3. [CC] = Close Call
5.3.2.1.4. [B] = Product Bug

5.3.3. Self-identified trouble areas

5.3.3.1. Operational Difficulties: *Was there anything that was difficult or confusing?*

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

5.3.3.3. Close calls: *Did you have any "close calls" where you almost did something and caught yourself?*

5.4. Task 2: Inhalation attempts

5.4.1. **Task prep:**

5.4.1.1. ☐ While wearing gloves, correct the positioning of the sensor on the medication if necessary.
5.4.1.2. ☐ Take the sensor out of inventory mode.
5.4.1.3. ☐ Apply the thick sticker to the sensor so that only the test operator can view the LED during Diskus use.

5.4.2. **Task prompt:**

5.4.2.1. ☐ *In this part of the test, I'll ask you to demonstrate taking the Diskus several times, and I'll write down if the sensor could tell whether you had taken it.*
5.4.2.2. ☐ *We'll take a break after each try to give you time to rest.*
5.4.2.3. ☐ *When you are ready, demonstrate how you normally take your inhaler*

using the sample inhaler.

5.4.3. **Task results:**

5.4.3.1. If a sensor fails to register an event, pause to let the participant react. Then ask:

5.4.3.1.1. ☐ *What do you assume has happened?*

5.4.3.1.2. ☐ *What would you do if that happened at home?*

5.4.3.2. Repeat this task until 10 inhalations have been completed. Leave a minimum of two minutes between each attempted inhalation. Other non-inspiratory tasks may be done in the intervening time.

Description			**Sensors activated**			
No.	**Event Registered?**	**Qualitative Description**	**Accel.**	**Touch**	**Inhalation Peak**	**Inhalation Duration**
1	P / F		P / F	P / F		
2	P / F		P / F	P / F		
3	P / F		P / F	P / F		
4	P / F		P / F	P / F		
5	P / F		P / F	P / F		
6	P / F		P / F	P / F		
7	P / F		P / F	P / F		
8	P / F		P / F	P / F		
9	P / F		P / F	P / F		

10	P / F		P / F	P / F		

5.4.4. Additional Notes:

5.5. Task 3: In-series flow rate measurement

5.5.1. **Task prep:**

5.5.1.1. ☐ Record the temperature of the room: _____

5.5.2. **Task prompt:**

5.5.2.1. ☐ *In this test, we're going to measure how fast you breathe when inhaling air through the Diskus. To do this, we'll use a spirometer <point to instrument>.*

5.5.2.1.1. ☐ While wearing gloves, open a new sterile spirette and insert it into the spirometer.

5.5.2.1.2. ☐ Attach the Diskus resistor to the spirometer.

5.5.2.2. ☐ *What will happen is that I'll turn this on and get it ready for the test. I'll hand it to you, and you need to*

5.5.2.2.1. ☐ *put this mouthpiece in your mouth,*

5.5.2.2.2. ☐ *exhale into the mouthpiece, then*

5.5.2.2.3. ☐ *inhale as if you were taking your Diskus medication.*

5.5.2.3. ☐ *The spirometer will beep while you are breathing - that is normal.*

5.5.2.4. ☐ Press ENTER when the patient is ready. Block one end of the spirometer with a gloved hand until the spirometer baseline is set.

5.5.2.4.1. ☐ Hand the spirometer to the participant and coach them through the inhalation.

5.5.2.5. ☐ Ensure that the participant is feeling comfortable.

5.5.2.6. Record the results of the PIF value displayed on the device.

5.5.2.7. Repeat the procedure three times or until the spirometer indicates that repeatable results have been obtained.

5.5.3. **Task results:**

Attempt	PIF	Quality Grade	Notes

No.		and Message	
1			
2			
3			
4			
6			
7			
8			

5.6. Post-session interview questions

5.6.1. Interested in participating again? ◎ Yes ◎ No

5.6.2. ☐ Remind the participant that the sample inhaler contained no medication and they should continue taking their actual Diskus as prescribed.

5.6.3. ☐ Note that we are not medical doctors and the patient should follow up with their doctor if they have any questions about their Diskus technique.