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This study is being conducted on behalf of the U.S. Food and Drug Administration.

Attachment B, Moderator's Script

Moderator's Script for Study Sessions

IMPORTANT: Note that text in italics or bold should NOT be read aloud to participant.

Study session start date and time: _____

Study Session Type: Trained Evaluation Untrained Evaluation
(if Trained Evaluation) Training Decay Length: No Decay One Hour One Day One Week

1. **Untrained Users - Introductory Script**

1.1. **Key Reminders for Untrained Participants**

- *Make sure the section regarding potential risks in the ICF has been read out loud to the participant*
- *Make sure that the participant has signed the ICF*

1.2. **Introduction for Untrained Participants**

- Hello, my name is _____. I am the moderator who will be walking you through this session and I have some colleagues who may be observing at times.
- First off, we want to thank you for your time and for participating in this usability study.
- Now, do you have any questions about the informed consent form or any potential risks due to taking part in this study?
- As a reminder, if you feel unwell or wish to end the session at any point for any reason, please let me know.
- The purpose of this session is to evaluate an insulin pump to identify whether it can be used safely in a simulated use environment. For the duration of this session, please turn off or silence your phone. We would appreciate if you do not use your phone throughout the session.
- Please bring a real-world mindset while performing tasks.
- I may wait to answer your questions until the end of the session, because I'm interested in exploring how you might resolve issues or interact with the product in real-life.
- Keep in mind that we are evaluating the device, not your individual skills or abilities.
- Do you have any questions before we begin?

Note Taker Name:

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Participant ID:

Date:

1.3. Introduction for Trained Participants

- Hello, my name is _____. I am the moderator who will be walking you through this, do you have any questions about the informed consent form that you signed before your training session or any potential risks due to taking part in this study?
- As a reminder, if you feel unwell or wish to end the session at any point for any reason, please let me know.
- The purpose of this session is to evaluate an insulin pump to identify whether one can use it safely in a simulated use environment. For the duration of this session, please turn off or silence your phone. We would appreciate if you do not use your phone throughout the session.
- I’m going to start by asking an informational question:
 - Based on the training you received, how confident are you that you would be able to correctly deliver an insulin dose using an insulin pump? Please give your rating on this scale (*show rating prompt card*) from 1 - Not Confident to 5 - Very Confident.
 1- Not Confident 2- Unsure 3- Neutral 4- Confident 5- Very Confident
 - Why did you rate it this way?

- I may wait to answer your questions until the end of the session, because I’m interested in exploring how you might resolve issues or interact with the product in real-life.
- Keep in mind that we are evaluating the device, not your individual skills or abilities.
- Do you have any questions before we begin?

2. Simulate Use Data (All participants)

Prompt:

- For the duration of this session, please turn off or silence your phone. We would appreciate if you do not use your phone throughout the session.
- For the purpose of the session today, I want you to imagine that you are a caregiver. The manikin here, Sam, (*point to manikin*) will represent your patient, which may be a family member or friend you are caring for. Please care for her as you would care for someone in real life, so please bring a real-world mindset while performing tasks.
- During this session, we request that you perform all of the steps needed to deliver the medication dose using the insulin pump. If there is something that you would normally do for this process that you can’t do here, please let me know.
- In the room, this cabinet (*point to cabinet*) has your patient’s medical supplies that you may or may not need to deliver the dose of insulin. During this session, you are welcome to use all items available to you in the room at any time.
- *Minimum items available to the participant in the cabinet:*

<i>Insulin Pump User Manual</i>	<i>Reservoir in packaging (2)</i>	<i>Hand sanitizer (on table)</i>
<i>An Insulin Pump</i>	<i>Alcohol wipes</i>	<i>Insertion device</i>
<i>Vials (2)</i>	<i>A sharps container</i>	<i>A trash can (in study room)</i>
<i>Infusion set in packaging (2)</i>	<i>Cotton balls</i>	<i>Phone (available)</i>

- If there is anything else you need, please let me know and I can either try to find it or I will make a note of it.
- Just so you know, you will be injecting into this injection pad (*indicate injection pad*) that will be placed on Sam. I’ll set up the injection pad on Sam for you in the location that you select whenever you are ready for that step.

- Now, I want you to imagine that you are the caregiver for Sam (*point to manikin*), as I mentioned before. Sam is a diabetic and has just been given this prescription from her doctor (*show prescription card*) and provided with an insulin pump set (*point to pump and accessories in cabinet*), but she needs your help to set up the pump. Let’s imagine that you are at Sam’s home and this is the first time you need to use the new pump to deliver Sam’s insulin dose.
- Sam’s doctors checked her blood-glucose levels and have determined that the pump needs to be set up to deliver several doses of insulin throughout the day. The pump should be set up to deliver at 12am and 1pm, as written on the prescription.
- When you are filling the reservoir, please fill it to 1.8 mL (*show volume prompt card*).
- Please note that I may stop you at times to check something. This doesn’t mean you did something wrong; I just may not have been able to see what was going on. It’s also going to be difficult for me to see the device at times, and I might have to get close to the device to see what is going on. So please don’t be alarmed if I am close to you.
- Whenever you are ready, please proceed to set up the insulin pump and deliver Sam’s first dose based on the doctor’s prescription.

2.1. Prepare the Vial

2.1.1. Check vial expiration date*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM¹

2.1.2. Swab the vial septum with alcohol*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.1.3. Extend the plunger and pressurize the vial (in less than 3 attempts*)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.2. Filling the reservoir

2.2.1. Fill the reservoir (without pulling out plunger and continuing to use reservoir*)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.2.2. (if applicable) Gently tap the side of the reservoir and slowly push up on the plunger to attempt to remove any large air bubbles*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

¹ “U-Study Artifact”=Unsuccessful behavior primarily due to Study Artifact.
 “U-Non-Critical”=Unsuccessful behavior unlikely to lead to harm to patient/user if this were to occur in real life and not primarily due to study artifact.
 “U-Critical”=Unsuccessful behavior that could potentially lead to harm to patient/user if this were to occur in real life and not primarily due to study artifact.
 “DNP”=Did Not Perform. “DNR”=Did Not Record. “UM”=Participant referred to User Manual when performing this task.

No Notes

2.3. Setting up the Reservoir

2.3.1. Dispose of transfer guard in sharps container*

Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.3.2. Disconnects the reservoir from the vial

Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.3.3. Twist to fully lock connector onto reservoir*

Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

No Notes

2.3.4. *(if applicable) Gently tap the side of the reservoir and slowly push up on the plunger to attempt to remove any large air bubbles*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.3.5. *Push up on the plunger until liquid is in the tubing (when disconnected from the injection pad*)*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.3.6. *Unscrew the plunger from the reservoir**

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.4. Preparing the Infusion Set

2.4.1. Insert the tubing connector and twist to lock the reservoir into the insulin pump*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.4.2. Select the correct response on the FILL TUBING screen to proceed to fill tubing (disconnected from body)*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.4.3. Fill infusion set tubing until liquid is visible*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

(if needed) Prompt: Please let me know when you are ready to set up the infusion set tubing on the injection pad and I will help you set up the injection pad.

2.5. Insert Infusion Set

2.5.1. Remember to use hand sanitizer or state that they would wash hands*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.2. Select an appropriate injection site*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

Prompt: [when participant indicates that they are ready to use the injection pad] Where on Sam’s body would you do this injection? [set up the injection pad to reflect the choice on the manikin]

No Notes

2.5.3. Clean the injection site on the injection pad with alcohol*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.4. Secure the infusion set into the insertion device

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

Prompt: [when participant has inserted the infusion set into the insertion device] May I take a look at that?

2.5.5. Remove both adhesive cover strips from infusion set*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.6. Spring load the insertion device handle until it locks in place

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.7. Remember to remove the needle guard*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

No Notes

2.5.8. Place the infusion set over the cleaned area on the injection pad*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.9. Press the two green side buttons on the insertion device at the same time to insert the needle*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.10. Press down on the grey button to release the infusion set from the insertion device

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.11. Press adhesive onto injection site to seal (if needed)*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.12. Remove the needle from the infusion set*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.13. Remembers to place the needle guard over the needle

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.14. Dispose of the infusion set needle in a sharps container*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

No Notes

2.5.15. Remember the cannula gets filled to 0.5 units*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.5.16. Enter the intended fill amount on the pump screen to fill the cannula*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.6. Basal Dose (Program and deliver basal dose)

2.6.1. Navigate to the Basal menu*

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.6.2. Correctly set basal 1* (Record basal 1 rate: _____)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.6.3. Correctly set basal 2* (Record basal 2 rate: _____)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

2.7. Throughout the Study

2.7.1. If participant compromises sterility of a component, they get a replacement or re-sterilize component*

- Successful Difficulty U-Study Artifact U-Critical DNP DNR

2.7.2. Participant did not have any needle sticks*

- Successful Difficulty U-Study Artifact U-Critical DNP DNR

3. Knowledge Tasks

3.1. Remove the Infusion Set

Prompt: For this next section, please draw on your knowledge to answer these questions. If you are unsure, please let me know what you would typically do to find the answers.

3.1.1. **Prompt:** How long would it be safe to keep an infusion set attached to Sam before you needed to change it? (*No more than three days**)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

3.1.2. **Prompt:** What would you do with the used reservoir once it has been removed from the insulin pump? (*Dispose, do not reuse**)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

3.1.3. **Prompt:** What would you do with the infusion set tubing once it has been removed from Sam? (*Put the tubing in the sharps container – the cannula may be disposed in trash or sharps.)**)

- Successful Difficulty U-Study Artifact U-Non-Critical U-Critical DNP DNR UM

No Notes

4. Subjective Feedback

- 4.1. **Prompt:** Did you experience any moments of hesitation while using the product? *[if yes, but participant doesn’t elaborate: What moments of hesitation did you experience?]*
- 4.2. **Prompt:** Do you have any concerns about using the product?
- 4.3. **Prompt (if participant was trained):** How much did you think about the training during the session?
 - 4.3.1. *(if participant did think about it):* Please explain what parts of the training you thought about.

No Notes

- 4.4. **Prompt (if participant was trained):** Was there anything that distracted you between the time you trained until the start of this session? *[If yes, but participant doesn’t elaborate: What distracted you?]*
- 4.5. **Prompt (if participant was trained):** Did you study any of the training materials or look up information on the product online after the training session? *[If yes, but participant doesn’t elaborate: What did you do?]*

5. Debrief on Use-Related Issues

Prompt: It was difficult for me to tell all of the steps you were taking, so I wanted to follow up on a couple steps.

- 5.1. (If needed) Did you happen to notice the expiration date on the product? What is the expiration date?
- 5.2. (If needed) Did you happen to notice any air bubbles in the reservoir when you were filling it?

[These questions should be used as guidance for debriefing on simulated use. Additional follow-up questions along the same lines may also be asked, based on specific observations or participant responses.]

- I noticed _____. Could you walk me through what happened?
- Do you have any concerns about what just happened? / Why do you think that occurred?

No Notes

- *(if applicable)* Do you recall what was taught in the training video?
- *(if information was not recorded)* I am going to take a quick minute to review the pump, since I wasn’t able to see everything. that was going on. *(check pump basal history)*

6. End of Session Script

Prompt: Before you leave today’s session, we have a short questionnaire for you to complete (*lead participant to laptop with end of session questionnaire*). Please take a few minutes to complete the questionnaire and let me know if you have any questions and when you’re done.

(When participant has completed the end of session questionnaire, read the below prompts. May be read by the Study Facilitator, Trainer, or Moderator)

Prompt: Thank you for completing the questionnaire. Now that the study is complete, I want to provide more insight on what we were looking for in the study. We are collecting data so we can understand the impact of time between training and testing on task performance. Do you have any questions about this, general questions, or questions about the way the study was run?

Prompt: That’s it for our session today, thank you for your time. Please keep in mind that the simulation performed today does not represent actual device training, and you should not consider yourself better equipped to handle an insulin pump or other medical equipment based on what you learned and saw in this simulation study. Please remember, because some of your peers might also be taking part in this study, we would appreciate it if you didn’t talk about the study session in detail to anyone outside this room. Thanks again for your participation in our study today. *(If needed)* Please wait here a minute while we get information regarding your token of appreciation for participating in this study.