Patient usability form for uniform usability testing of devices measuring nocturnal scratch

This document is a suggested usability form to be administered to the patients in AD trials to assess satisfaction and usability with the used technology to measure nocturnal scratch.

About this form:

- Usability form is intended for use after the patient has used the device - e.g. after a period of use during the study. The form is recommended at the end of the study to capture all insights
- Recommended use is within a feasibility study, an early phase study, or a separate study from Phase 2 or 3 studies
- Response scale for each item (numerical value can be calculated):
  - **1** - Strongly disagree
  - **2** - Disagree
  - **3** - Neither agree nor disagree
  - **4** - Agree
  - **5** - Strongly agree
- The questionnaire can be amended for caregiver use with children

1 Strongly disagree | *2* Disagree | *3* Neither agree nor disagree | *4* Agree | *5* Strongly agree

Using the device:	1	2	3	4	5
It was easy to learn to use the system.					
It was easy to use the system.					
The system or its parts were confusing.					
Optional (freeform): If yes, please describe what was confusing:					
I needed the support of a technical person to be able to use the system.					
I did not encounter issues with hardware parts of the system (define hardware parts, e.g. watch/patch/phone/etc.)					
Optional (freeform): If yes, please describe the issues:					
I did not encounter any issues with software parts of the system (define software parts, e.g. application/Wi-Fi connection/data upload)					
Optional (freeform): If yes, please describe the issues:					

Battery lasted sufficiently long to use the system for ____ hours/days (insert based on the intended wear time in the study)

Your experience with this device:	1	2	3	4	5
I felt physical discomfort during use of the system.					
Optional (freeform): If yes, please describe the physical discomfort:					
The system or its parts irritated my skin.					
Optional (freeform): If yes, please describe in what way the system irritated your skin:					
I felt psychological discomfort during use of the system.					
Optional (freeform): If yes, please describe the psychological discomfort:					
I was not able to use the system according to the instructions.					
Optional (freeform): If yes, please describe what prevented you from using the system according to the instructions:					

1 Strongly disagree | *2* Disagree | *3* Neither agree nor disagree | *4* Agree | *5* Strongly agree

I enjoyed using the system.					
Overall, I am satisfied with the system.					

Future use:	**1**	**2**	**3**	**4**	**5**
I believe that the system has the potential to improve disease symptom monitoring in the future.					
If possible, I would use the system in the future (alternatively: outside of a research study).					

Let us know how you've used this resource in action!

Check out our Resource in Action Hub to learn about how others are using DiMe resources

Additional Relevant Resources:

- The Playbook: Usability and Utility section (slides 139-145)
- FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
- FDA Guidance: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
- System Usability Scale
- Blogpost: How to build medical device usability testing and validation into your quality system