



Quickstart Guide: V3+ Use Specification



Are you a tech developer looking to start building your use specification?



Are you considering implementing a sensor-based digital health technology (sDHT) for research or clinical care?



This quickstart guide is for you.

Developing a use specification is the first step of the usability validation component of V3+.

The use specification contains detailed descriptions of all user groups, all use environments, and all aspects of the sDHT user interface. This document is the counterpart to the sDHT technical specification and is directly impacted by the intended use statement or the context of the use statement.



STEP 1. Identify all user groups.

A. Create a list of user groups.

End-users are the individuals from whom sDHT-derived clinical data will be captured. End-users will always be a sDHT user group, but in addition, consider the following:

- ✓ Carepartners

Example: An end-user with limited mobility may seek help from a carepartner when placing an adhesive patch.

- ✓ Clinicians

Example: An endocrinologist may need to review blood glucose measurements in a sDHT online portal to adjust prescribed medication.

- ✓ Researchers

Example: A clinical research coordinator may be responsible for downloading data during a study visit.

- ✓ Administrators

Example: An administrator may be responsible for configuring each sDHT used in their practice.



Tip: Create sub-categories within each user group; for example, researchers might include principal investigators, study monitors, and study coordinators.

B. Describe the characteristics of each user group.

- ✓ Sociodemographics and cultural customs include age, sex/gender, race/ethnicity, language fluency, and cultural practices.
- ✓ Health literacy: The degree to which individuals can find, understand, and use information and services to inform health-related decisions.
- ✓ Tech literacy: The ability to appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.
- ✓ Physical capabilities, including but not limited to strength, stamina, dexterity, and flexibility.
- ✓ Sensory capabilities, including but not limited to sight and hearing
- ✓ Cognitive capabilities, including but not limited to the level of education or the presence of learning impairments
- ✓ Anthropometry, including but not limited to height, weight, body shape, and disease-specific characteristics such as joint swelling
- ✓ Disease characteristics, including comorbidities
- ✓ Aspects related to vulnerable populations
- ✓ Level of familiarity with the sDHT or similar products
- ✓ Years of professional training
- ✓ Motivations for using the sDHT



Tip: Not all characteristics will apply to all user groups.

Tip: Consider whether the identified characteristic is permanent, temporary, or situational. For example, visual impairment could be permanent if resulting from blindness from birth, temporary if resulting from recent eye surgery, or situational if the sDHT is used in a sunny environment, creating glare on the screen.

C. Use the information above to create detailed descriptions of representative users, considering their needs, values, motivations, and preferences and how their characteristics might impact their use of the sDHT.



STEP 2. Identify all likely use environments.

A. Create a list of likely use environments, such as:

- ✓ Home
- ✓ Hospitals
- ✓ Surgery theaters
- ✓ Clinic exam rooms
- ✓ Educational settings
- ✓ Workplaces
- ✓ Community and leisure spaces
- ✓ Transit settings, such as in planes and cars



Tip: Identifying all use environments for sDHTs is usually not feasible. Identify the most likely use environments, then consider ‘edge cases’ such as the use of the sDHT in extreme weather, areas without power and/or network access, or water immersion.

B. Describe the characteristics of each use environment, such as:

- ✓ Temperature
- ✓ Humidity
- ✓ Lighting
- ✓ Noise
- ✓ Cleanliness and sterility
- ✓ Space availability and clutter
- ✓ Physical security and risk of theft
- ✓ Power availability, such as electricity
- ✓ Network availability, such as data reception or wifi
- ✓ Privacy and the presence of others
- ✓ The presence of additional sDHTs.

C. Use the information above to create a series of use scenarios and describe how the sDHT might differ between environments.



STEP 3. Describe the sDHT user interface.

A. Describe all aspects of the sDHT hardware and/or software, such as:

- ✓ Visual cues, such as text, graphical displays, indicator lights, or color coding
- ✓ Auditory cues, such as beeps and alarms, as well as unintentional sounds, such as a fan, pump, or motor
- ✓ Tactile cues, such as haptics, knobs, buttons, and dials, as well as unintentional factors such as overheating
- ✓ Taste, if applicable
- ✓ Smell, if applicable
- ✓ Positioning of the sDHT
- ✓ Areas of bodily contact, if applicable
- ✓ Method of ingestion, if applicable
- ✓ Method of implantation, if applicable



Tip: Think about the entire end-to-end user journey.

B. Describe all sDHT accessories, such as:

- ✓ Packaging
- ✓ Data hub
- ✓ Chargers, cords, or power packs
- ✓ Batteries
- ✓ SD cards or USB sticks
- ✓ Replaceable parts

C. Describe all written materials and training provided to users, such as:

- ✓ Instructions for use or user manual
- ✓ Instructional videos
- ✓ Sizing charts
- ✓ Procedures for live demos
- ✓ Helpdesk troubleshooting
- ✓ In-app chat or similar features

D. Use the information from all three parts of the use specification to describe the various foreseeable interactions that users from within each user group will have with the sDHT.

The use specification is a living document requiring maintenance and updates throughout the sDHT development process.



STEP 4. Keep it up to date!

The use specification is a living document requiring ongoing updates and maintenance throughout the usability validation process.

What comes next for V3+ Usability Validation?



Check out our [Quickstart Guide: V3+ Use-Related Risk Analysis](#).

See the [V3+ usability validation glossary](#) for key terms and definitions.