Simulation-Based Validation of a Remote Digital Stethoscope for Patient Monitoring: A Repeatable Framework and Insights for Usability

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ABSTRACT

BACKGROUND
Mayo Clinic's AI Validation and Stewardship Program (AVSP) partners with the Multidisciplinary Simulation Center to rigorously evaluate digital health technologies in realistic, simulated clinical environments.

OBJECTIVE
To assess usability, task performance, and user perceptions of a digital stethoscope and mobile app for remote patient monitoring using a repeatable simulation-based human factors methodology.

METHODS
Fifteen standardized patients (SPs) completed simulated home-use sessions involving device setup, recording lung sounds with the adhesive sensor, and sharing data with healthcare professional (HCP). Task performance, success rates, and qualitative feedback were collected through structured observation and interviews.

RESULTS
All participants successfully recorded and shared lung sounds, though setup and sharing workflows revealed recurring usability challenges. Repetition improved accuracy and confidence, and realistic conditions surfaced legibility and dexterity barriers for older adults.

CONCLUSIONS
Simulation-based testing reliably identifies usability risks and supports safe, reproducible evaluation of remote monitoring technologies, improving design inclusivity and user comprehension to enable scalable clinical deployment.

OBJECTIVES

To ensure users can operate the device safely and effectively by:

- Assessing user completion of critical tasks.
- Characterizing usability breakdowns and any use errors.
- Capturing qualitative impressions.

PROCEDURAL FACTORS

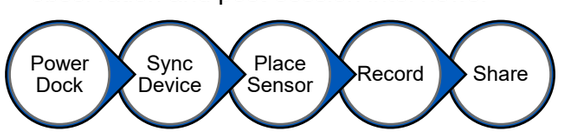
Setting & Modality
SP sessions conducted in the Simulation Center, and recordings were performed on manikin to ensure safety and repeatability.

Structure
30-45 minutes per SP with training; think-aloud observation; access to all user manuals; immediate qualitative debrief.

Study Controls
Minimal risk usability study under IRB protocol 25-006355. No PHI was collected and no data shared to vendor.

METHODS

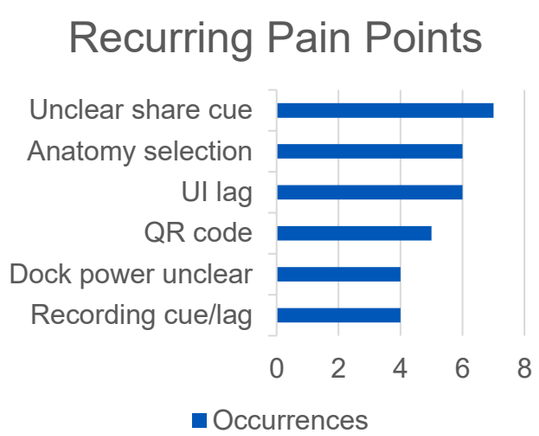
A structured usability study was conducted with 15 SPs, who participated in simulated sessions replicating home-use conditions at Mayo Clinic's Multidisciplinary Simulation Center. Critical tasks included setting up the device, recording lung sounds using adhesive sensors, and data sharing with healthcare providers under realistic conditions. Usability performance, task success rates, and qualitative user feedback were collected through structured observation and post-session interviews.



Outcome Measure(s)
Task completion rate, observed use errors, and qualitative usability themes were analyzed to assess device readiness and simulation reproducibility.

RESULTS

Task Completion
All 15 standardized patients successfully completed core tasks—device setup, lung-sound recording, and sharing with a HCP. Despite universal completion, first-time friction was common with task accuracy and confidence improving on repeated attempts.



Qualitative Themes

- Perceived value of capturing real-time symptoms at home
- Appreciation for the simplicity of the overall workflow after repetition
- Difficulty maintaining confidence when the device feedback loop was ambiguous or delayed
- Requests for larger fonts, clearer instructions, and more intuitive labeling

"Once you do it two times, it seems pretty easy." –SP11

"The writing is too small for me." –SP5

"I didn't know I needed to plug in the docking station." –SP9

DISCUSSION

This evaluation highlights key considerations for future deployment and next-phase studies:

- Cohort skewed to older adults (Table 1): Ensure future cohorts reflect the population of the primary users.
- HCP Workflow: Parallel test HCPs and how remote data is incorporated into clinical decisions.
- Preparation for AI Detection: User interpretations of AI outputs and their appropriate follow-up actions.

TABLE 1: SP Characteristics

Variable	Value
N	15
Age >65	11 (73%)
Gender	9F / 6M

CONCLUSIONS

Simulation-based testing reliably uncovers usability risks and strengthens safe, reproducible assessment of remote monitoring technologies. By surfacing workflow challenges and user-comprehension barriers, it informs more inclusive design and supports scalable deployment. Validation is not the endpoint – post-market monitoring, user feedback, and iterative refinement remain essential to ensure continued safety and effectiveness.

REFERENCES

1. U.S. Food and Drug Administration. "Applying Human Factors and Usability Engineering to Medical Devices." FDA, 3 Feb. 2016, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.

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