Determining Minimal Environmental Fidelity for Simulated-Use Studies

GODDARD PRODUCT DEVELOPMENT

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Background

Simulated-use human factors validation studies must be conducted in environments that reasonably represent the intended use environment and include factors that might negatively affect user-device interactions. In complex use environments, the challenge is **balancing environmental fidelity with feasibility.**

Minimally simulating relevant use environment conditions offers an efficient alternative that:

- Reduces burden and resource demands.
- Elicits realistic use behaviors.
- Evaluates contextual factors influence on performance, risk, and use error.
- Strengthens study quality and support regulatory rigor.

Framework Impact

This poster presents a practical framework to determine the **minimal environmental fidelity** needed for safe, effective device design, offering the following benefits:

Maintain Experimental Control
Reduced variability improves consistency, increases data reliability, and isolates UI-related findings.

Improve Resource Efficiency
Simple setups require fewer resources, enable faster design iterations, and promote data accessibility.

Reduce Cost and Complexity
Enhancers and environmental controls elevate realism by focusing on factors critical to safety, usability, and workflow.

1: Define

- Understand device UI, use context, and study objectives.
- Identify and prioritize critical tasks to evaluate based on uniqueness, user groups, and UI touchpoints.
- Scope manufacturer's responsibility (predicate and standard-of-care tasks may not require use-based evaluation).
- Assess environmental conditions that align with study tasks and might affect user-device interaction.

Use conditions

Lighting, Noise, Temperature, Humidity, Pressure

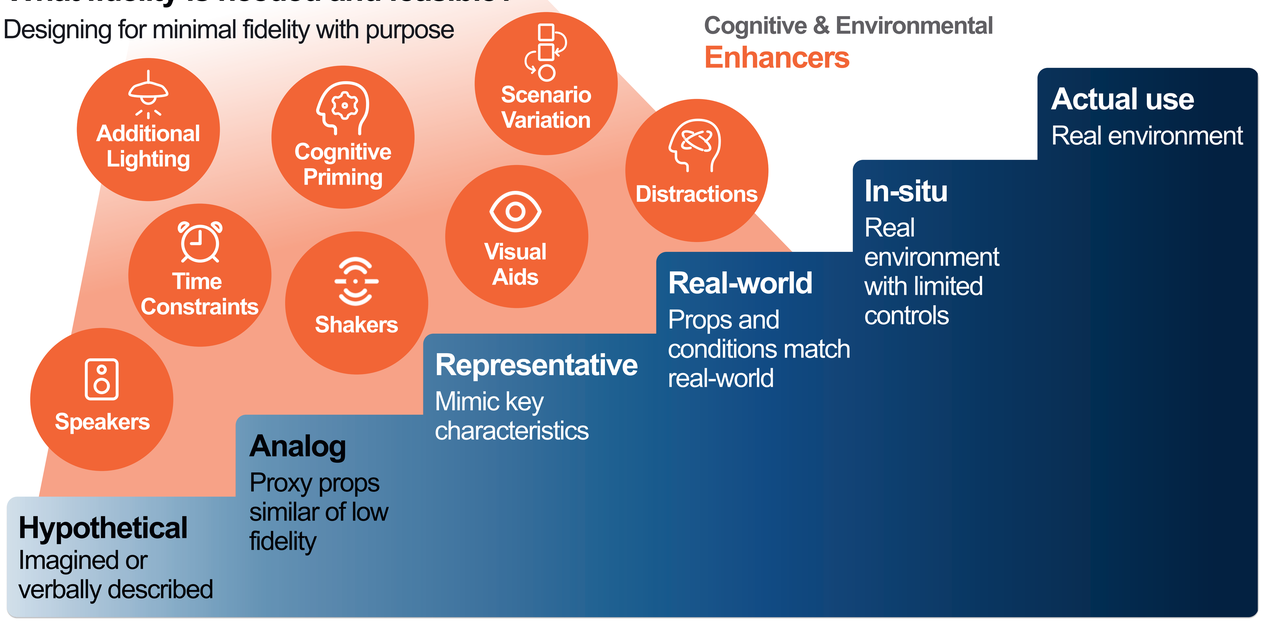
Vibration, Equipment, Supplies, Workspace, Clutter

Time Constraints, Hygiene Requirements, Access & Security, Global Variations

2: Design

What fidelity is needed and feasible?

Designing for minimal fidelity with purpose



Formative Study

- Scale environmental fidelity to the evaluation phase, study objectives, and available resources.
- Control fixed and variable environmental factors with defined measures to ensure consistency, representativeness, and to isolate UI-related impact.

Validation Study

- Document fidelity decisions to demonstrate regulatory rigor when real-world evaluation is not feasible.

3: Iterate

- Challenge assumptions and iterate to refine fidelity and to improve realism, control, and representativeness.
- Engage stakeholders and regulators early to obtain feedback and align on simulated environment design and expectations.
- Conduct pilot sessions to evaluate strengths and limitations of the simulated environment.
- When direct feedback is not feasible, draw on similar projects or expert colleagues.

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Case Study

A minimally simulated Sterile Processing Department was created to assess critical tasks in a representative workspace with environmental and cognitive enhancements.

360 view
Scan to immerse yourself
SCAN ME

Legend
- **Fidelity** / Use Condition
- Zone
- Controls