Performing comparative UI and use-related risk analyses to justify CDRH-regulated devices' safety and effectiveness in lieu of HF validation

Allison Y. Strochlic (Emergo by UL)
Research Director – HFR&D
allison.strochlic@ul.com

Brittany Lim (Outset Medical)
Senior Human Factors Engineer
blim@outsetmedical.com

Merrick Kossack (Emergo by UL)
Research Director – HFR&D
merrick.kossack@ul.com

Introduction

In lieu of HF validation testing, it may be appropriate and acceptable to regulators to perform a detailed comparison of a new or modified device against an existing, marketed device to substantiate the new device's usability and use-safety. Such comparisons could be leveraged to justify…

1. Why supplemental HF validation testing is not required to validate changes to a device's user interface after HF validation testing, and
2. Why HF validation testing is not required when a device's user interface is similar to that of a predicate device (e.g., for a 510k submission)

Comprehensive comparisons should reflect on the intended use, users, and use environment, and closely examine the (1) user interfaces, and (2) use-related risks and critical tasks of the two devices.

About the Tablo Hemodialysis System

Manufactured by Outset Medical, the Tablo® Hemodialysis System ("Tablo") is an all-in-one, easy-to-learn system indicated for clinic, hospital, and home settings. Tablo includes an onboard water prefiltration system and a touchscreen Graphical User Interface (GUI) with step-by-step instructions to guide the user through system operation.

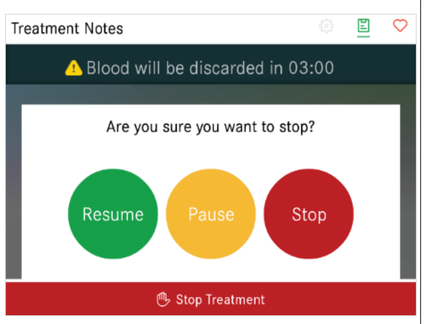
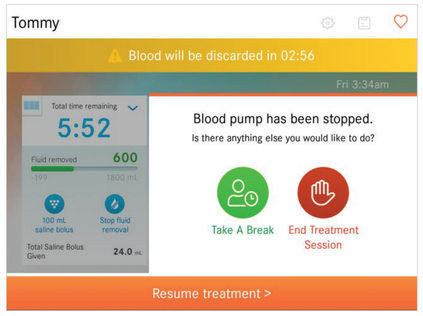
Tablo's design resulted from a robust and compliant HFE process from early-stage preliminary analyses through product development and post-market surveillance, including iterative formative evaluations and UI refinements, HF validation testing, and regular monitoring of product and user feedback. Outset Medical has performed comparative analyses throughout Tablo's development to identify the appropriate scope of HFE work for each round of system design changes.

Tips for Comparative Analyses

- Only include user-facing (versus device-internal) changes
- Link each design modification to a specific issue tracking number
- Be concise, focusing on key changes and associated impacts
- Include illustrations and descriptive captions for each comparison point
- Provide supplemental information to describe complex changes (e.g., detailed screen flows, relevant User Manual excerpts)
- For the Use-Related Risk Analysis (URRA) comparison, focus on new or impacted critical tasks
- In the residual risk analysis commentary, focus on why the risk "remains acceptable" or "remains unchanged"
- Reference HFE data to support use-related risk assessments and final justifications (e.g., from formatives, HF validation, post-market surveillance)
- Integrate UI comparison and use-related risk information to streamline HFE submission content (see example below)

Sample Comparative Analysis for Tablo

After changing Tablo's UI, Outset Medical assessed whether any UI changes might impact users' performance of critical tasks based on the Use-Related Risk Analysis (URRA). Outset Medical concluded that while the UI changes were associated with critical tasks, the updates did not change the system's risk profile and the pre-existing mitigations remained acceptable (as per prior HF validation testing). Therefore, Outset Medical performed a comparative analysis of the changes, rather than additional HF validation testing. See below for a sample excerpt from the comparative analysis submitted to the FDA.

Modification Description	Image of Existing Version	Image of Modification	Description of Modification	Affected Risk ID(s)	Critical Task (Y/N)	Use-Related Risk Analysis (URRA)	Residual Risk Analysis
#1 **Updated Pause Treatment Menu Screen** 1	 2	 3	Minor GUI updates were made to the Pause Treatment menu screen to improve the overall look and feel, present additional information to guide the user, and clarify the button labels. These GUI updates are associated with critical tasks because they change the look and feel of the Pause Treatment menu screen. However, we determined that the updates do not impact the URRA because the changes provide additional guidance without adding or modifying user tasks. Formative testing was conducted with users to evaluate and confirm which button labels and on-screen text best informed the user and most clearly communicated the system response to each button press. 4 7	URRA-XXX 5	Yes 6	Per the Tablo URRA, GUI updates to the Pause Treatment menu screen are associated with critical user tasks because selecting the incorrect option on the Pause Treatment menu screen may lead to serious injury as defined by 21 CFR § 803.3. However, the GUI updates to the Pause Treatment menu screen are minor and do not impact use-related risk. Rather, the changes provide additional guidance to users on how to proceed through the screen and, as such, they further mitigate the risk associated with selecting the wrong option. 8	ACCEPTABLE The residual use-related risk associated with the critical tasks is deemed acceptable. The use-related risk of the associated critical tasks remains unchanged after the GUI updates. The risk mitigations of the existing UI were confirmed effective during HF validation testing. 8

Relevant Regulatory Guidance References

Several HFE and risk management guidance documents reference comparative analyses as a means to assess and understand the impact of UI changes made to an existing medical device, as well as to compare a new device in development to existing, marketed devices.

Examples include:

- **US FDA draft guidance from December 2022,** *Content of Human Factors Information in Medical Device Marketing Submissions*, calls for comparing various aspects of a device's users, use context, user interface, and use-related risks when determining HF data to submit for a new or modified device developed by the same manufacturer.
- **ISO 14971:2019 and ISO/TR 24971:2020**, *Medical devices — Application of risk management to medical devices* and the associated technical report, call for a "state of the art" analysis on similar, marketed products and suggest that manufacturers compare the intended use and risk level of a new product in development to that of similar, marketed products.
- **China's National Medical Products Administration (NMPA) draft guidance from 2020,** *Guidelines of Human Factors Design of Medical Devices (translated),* recommends performing comparative analyses to assess design changes and focus HFE efforts on new features between an existing and proposed medical device.

US FDA's Draft Guidance

Cross-references: Tables 4 (top) and 3 (bottom) from US FDA's Dec 2022 draft guidance.

1 2 3 4

Modification description	Image of existing device-user interface component	Image of modified device-user interface component	Description of the modification made to the modified device
Modification #1	DRAFT		
Modification #2			

5 6 7 8

Existing Device						Modified Device			Submitter's comparison comments
URRA Task #	User Task	Possible use error(s)	Potential hazards and clinical harm	Severity of harm	Critical task (Y/N)	Comparison of use task description to existing device	Labeling content and/or design change differences	Comparison of proposed risk mitigation measure to existing device	
Task #1				DRAFT					
Task #2									