Harmonizing Medical Device Regulation Environmental and Human Factors

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Nozomi Yagi
Senior Regulatory Affairs Manager
Infraredx, a Nipro Company
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Objectives

- **Understand** the basic concepts of human factors/usability engineering (HFE/UE)
- **Highlight** the importance of HFE/UE in the context of the 2018 IMDRF guidance titled *Essential Principle of Safety and Performance of Medical Devices and IVD Medical Devices*
- **Review** the 3 step model of HFE and recognize what manufacturers should do before they bring their products to market

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Presentation Outline

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- Understand the basic concepts of HFE/UE
- Highlight the importance of HFE/UE in the context of IMDRF Guidance
- HFE 3 step model

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What is Human Factors (HF)?

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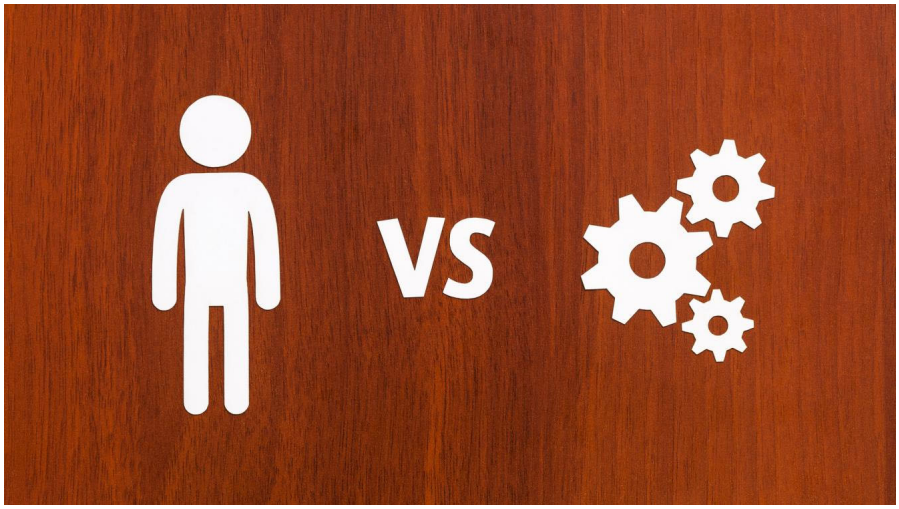

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Cont'd: What is Human Factors (HF)?

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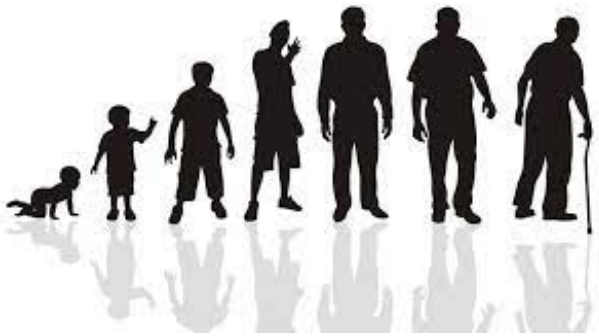
- Humans possess physio-cognitive limitations
- The more complex the tasks, the more errors we make

→ It is part of being human!



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What is HF Engineering (HFE)?

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Human Factor Engineering is defined as….

the application of **knowledge about human capabilities** (physical, sensory, emotional, and intellectual) **and limitations** to **the design and development of** tools, **devices, systems**, environments, and organizations. HFE might also be called human factors, ergonomics, human engineering, usability engineering, or human–computer interaction (HCI). HFE involves the use of behavioral science and engineering methodologies in support of design and evaluation.

HFE is focused on how the intended user interacts with the device

Badly designed systems or equipment can cause even the most experienced user population to make mistakes

Association for the Advancement of Medical Instrumentation (2018) *Human Factors Engineering - Design of Medical Devices* (AAMI HE75:2009 (R2018)

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When you don't consider how the intended users interact with the device.....

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Bad designs are everywhere!

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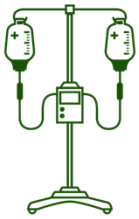
What if bad design happens to a high risk medical device?

"Death by decimal" – Case of Infusion Pumps

A nurse attempting to program an infusion pump to deliver at 130.1 mL/hr, pressed the keys "*1 3 0 . 1*", but unaware that the decimal point on the pump only worked up to 99.9

RESULT → Medication was delivered at 1301 mL/hr, x10 overdose



Branaghan, R.J., O'Brian, J.S., Hildebrand, E.A. and Foster, L.B., 2021. *Humanizing Healthcare: Human Factors for Medical Device Design.* Springer.

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Cont'd: What if bad design happens to a high risk medical device?

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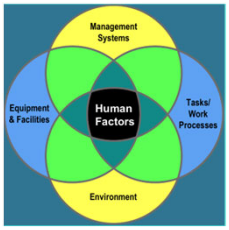
Person-Centered Approach

- Blame the nurse
- Assign more training and aim for 'error-free' practice

System-Centered Approach

- Evaluate the system
  - Are nurses overworked?
  - Should the setting double-checked?
- Evaluate the device
  - Is the decimal point visible?
  - Should the decimal point be available beyond 99.9?



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2018 IMDRF Essential Principles of Safety and Performance Guidance

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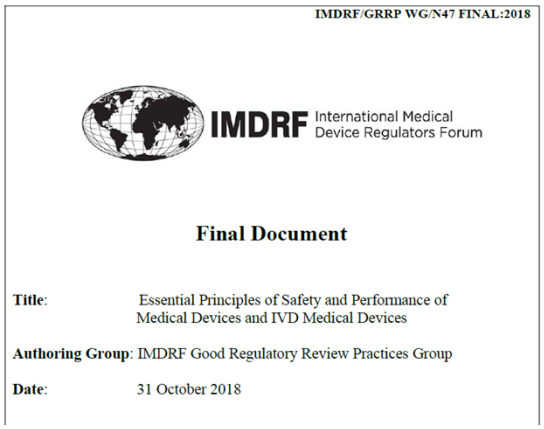

IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

'Essential Principles of Safety and Performance' that, when met, provide assurance that a medical device and IVD medical device is safe and performs as intended, by the manufacturer.

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Harmonized Standards for HFE

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Internationally recognized standards for HFE are available and should be utilized globally

Utilizing harmonized and globally recognized standards helps streamline development and support timely access of innovative products to patients

Harmonized HFE standards:

- IEC 62366-1 *Medical devices -- Part 1: Application of Usability Engineering to Medical Devices*
- IEC 62366-2 *Medical devices -- Part 2: Guidance on the Application of Usability Engineering to Medical Devices*

HFE standards are linked to the Risk Management standard:

- ISO 14971: - *Medical Devices -- Application of Risk Management to Medical Devices*

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Searching the 2018 IMDRF Guidance for "62366"

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Essential Principle	Details
5.5	**Considerations of Environment and Conditions of Use**
5.9	**Medical Devices and IVD Medical Devices with a Diagnostic or Measuring Function**
5.12	**Protection against the Risks posed by Medical Devices and IVD Medical Devices intended by the Manufacturer for use by Lay Users**

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Searching the 2018 IMDRF Guidance for "62366"

5.5 Considerations of Environment and Conditions of Use

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5.5.2 Medical devices and IVD medical devices should be designed and manufactured in consideration of the intended environment and conditions of use, and in such a way as to remove or appropriately reduce the:

a) risks of injury to the users or other persons in connection with its physical and ergonomic/usability features;

b) risks of user error due to the design of the medical device or IVD medical device user interface, ergonomic/usability features, and the environment in which the medical device or IVD medical device is intended to be used;

c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, and/or variations in pressure and acceleration;

d) risks associated with the use of the medical device or IVD medical device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during intended conditions of use;

e) risks associated with the possible negative interaction between software and the information technology (IT) environment within which it operates and interacts;

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Searching the 2018 IMDRF Guidance for "62366"

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5.9 Medical Devices and IVD Medical Devices with a Diagnostic or Measuring Function

5.9.1 Medical devices and IVD medical devices with a diagnostic or measuring (including monitoring) function should be designed and manufactured in such a way as to provide, among other performance characteristics, sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods.

a) Where applicable, the limits of accuracy should be indicated by the manufacturer.

b) Whenever possible, values expressed numerically should be in commonly accepted, standardized units, and understood by users of the medical device or IVD medical device. While generally supporting the convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity and established clinical practice may justify the use of other recognized measurement units.

c) The function of the controls and indicators should be clearly specified on the medical device and IVD medical device. Where a medical device or IVD medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

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5.12 Protection against the Risks posed by Medical Devices and IVD Medical Devices intended by the Manufacturer for use by Lay Users

5.12 **Protection against the Risks posed by Medical Devices and IVD Medical Devices intended by the Manufacturer for use by Lay Users**

5.12.1 Medical devices and IVD medical devices for use by lay users (such as self-testing or near-patient testing intended for use by lay users) should be designed and manufactured in such a way that they perform appropriately for their intended use/purpose taking into account the skills and the means available to lay users and the influence resulting from variation that can be reasonably anticipated in the lay user's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay user to understand and apply when using the medical device or IVD medical device and interpreting the results.

5.12.2 Medical devices and IVD medical devices for use by lay users (such as self-testing or near-patient testing intended for use by lay users) should be designed and manufactured in such a way as to:

a) ensure that the medical device and IVD medical device can be used safely and accurately by the intended user per instructions for use. When the risks associated with the instructions for use cannot be mitigated to appropriate levels, these risks may be mitigated through training.

b) appropriately reduce the risk of error by the intended user in the handling of the medical device or IVD medical device and, if applicable, in the interpretation of the results.

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Why is HFE Important?

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HFE helps to optimize product design and labeling

- **Reduces use errors**, which could injure or kill the patients and/or users
- Includes optimization of mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and **demonstrate safe and effective use** of the device
- Helps **reduce post-market issues**

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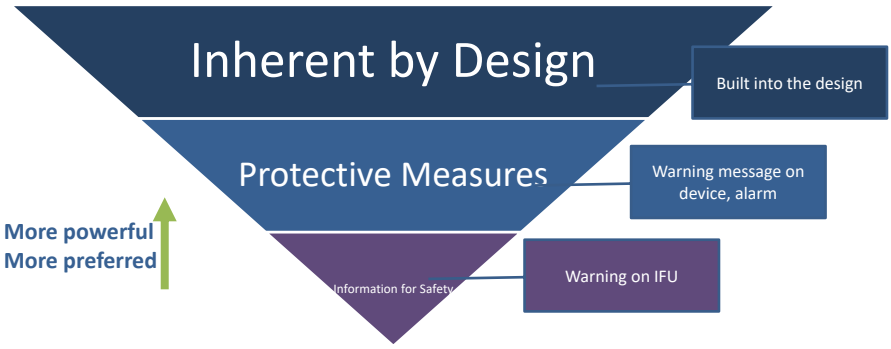
Reduce or Eliminate Use-Related Hazards

- "Inherent by Design" is most powerful but not always possible.
- To build HFE into design, HFE must be started early in TPLC.



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Example: COVID-19 Antigen At-Home Self Tests

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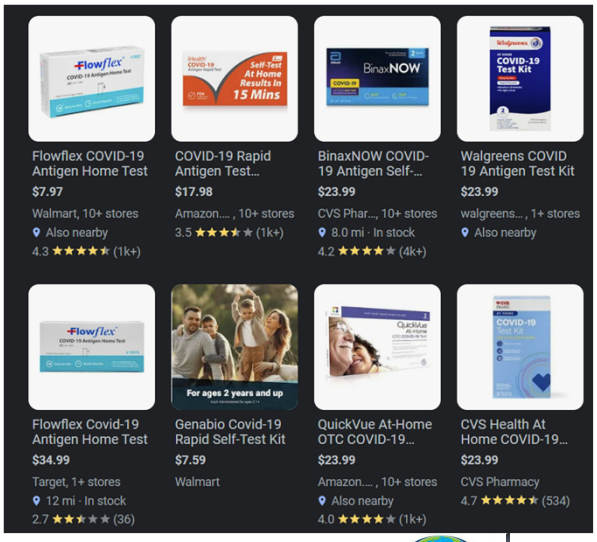

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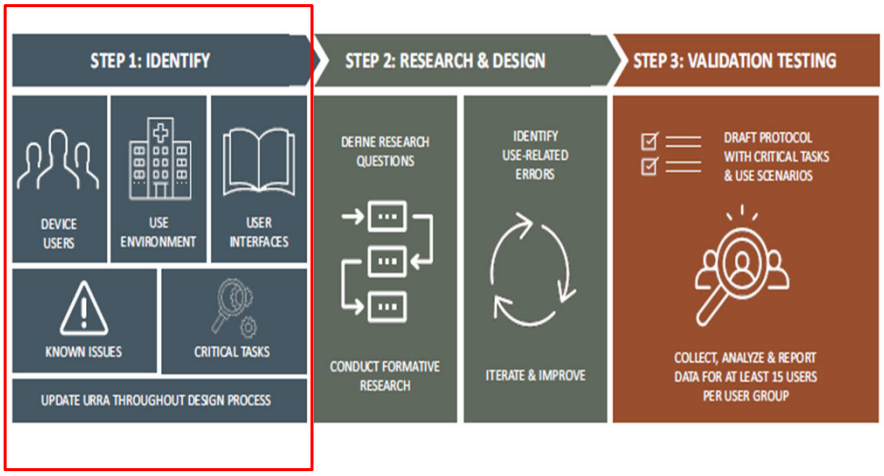
Step 1: IDENTIFY



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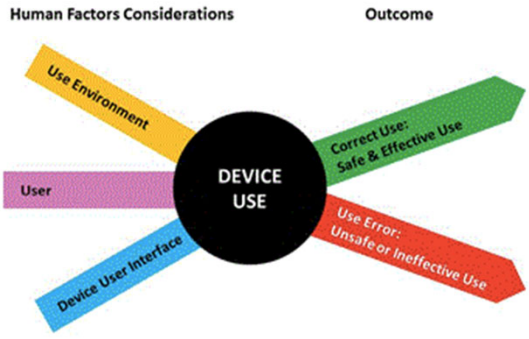
STEP 1 IDENTIFY : Users, Environment, and UI



The key inputs for the Human Factors framework involve understanding:

- Who is the **intended user** for the device?
- What **environment** will the device be used in?
- What is the **interface** for the user to obtain the relevant information regarding use of the device?

FDA Guidance: *Applying Human Factors and Usability Engineering to Medical Devices*

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STEP 1 IDENTIFY : Critical Tasks via Use-Related Risks Analysis (URRA)

Hypothetical FMEA for COVID-19 Antigen Self-Test

#	Device Tasks	Potential use-errors	Potential harm of use-errors	Severity of resulting harm	Critical Task? (Y/N)
1	Hold dropper bottle straight over the top hole, put 6 drops into top hole	User does not hold bottle straight	Not enough reagent is applied	3 (severe)	Y
2		User puts less than 6 drops	Not enough reagent is applied	3 (severe)	Y
3		User puts more than 6 drops	Too much reagent is applied	3 (severe)	Y
4		User puts drops into bottom hole	Not enough reagent is applied	3 (severe)	Y
5		User performs this step while holding the card in hand	Not enough reagent is applied	3 (severe)	Y

Critical Task: A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user

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STEP 1 IDENTIFY : Known Issues

Actual MAUDE Database Search

(COVID-19 Antigen Self Test)

Event Description

Customer reported that she had put six (6) drops of reagent onto the swab, instead of the test card as indicated in the product insert, prior to swabbing her nose. Customer stated she is feeling some kind of burning sensation in her both nostrils. Although requested, no additional patient information including treatment and outcome was provided.

Manufacturer Narrative

Customer reported experiencing a burning swabbing nostril using the XXXXXXXX covid-19 antigen self test. Customer reported putting 6 drops of reagent on the swab before swabbing their nostrils. The customer reported being confused by test instructions, technical service assisted customer with test procedure. Technical service was unable to provide the customer with the relevant sds sheet. Technical service contacted customer for additional information, however the customer declined to provide any information and disconnected the call. The product will continue to be monitored and tracked.

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STEP 2 RESEARCH & DESIGN

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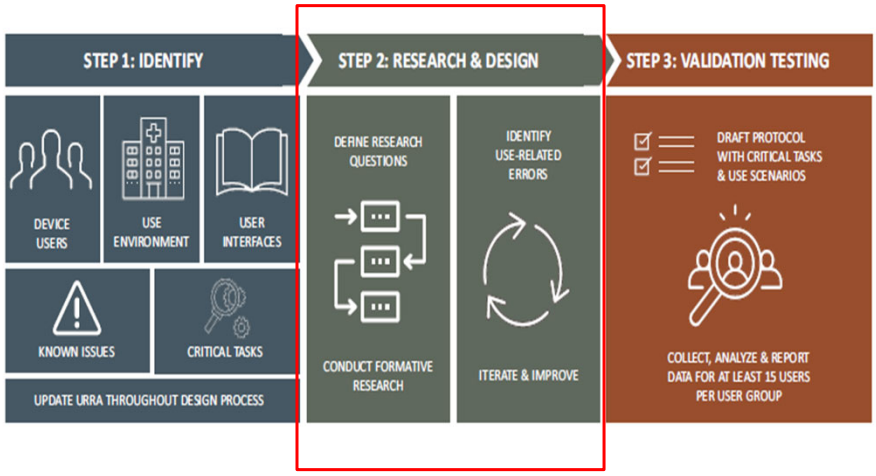

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STEP 2 RESEARCH & DESIGN: Formative Studies and Design Iteration

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STEP 2 RESEARCH & DESIGN: Formative Studies and Design Iteration

- Prototype designs
- Data can be obtained from : Observation, shadowing, etc.
- Formative studies are not required – but the summarized formative research results are included in final report
- Typically done with smaller groups

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STEP 2 RESEARCH & DESIGN: Formative Studies and Design Iteration

Hypothetical Analysis of Critical Task Results

Critical Task	Use-errors (UE) or difficulties	Observation and follow-up	Potential root causes	Potential harm	Possible risk control	Redesign needed? (Y/N)
Put 6 drops into the top hole.	(UE) Two participants from senior user group were unable to complete the task	User 1 – The participant's hand was shaky. Not all 6 drops were put into the top hole. User 2 – The participant only put 4 drops. During the interview, she said she could not see drops well.	"Drop" application step requires physical dexterity and good eye vision.	Not enough reagent, resulting in false negative.	**Consider pre-applying the reagents to the top-hole, or eliminate the drop counting process.**	YES

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STEP 3 VALIDATION TESTING

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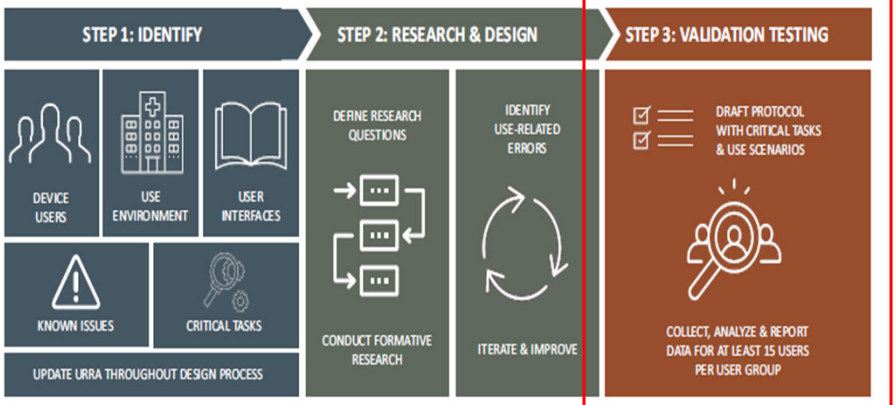

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STEP 3 VALIDATION TESTING

- Should be done with the final design
- Data can be obtained from : Observation, Knowledge-task assessment, and/or Interviews

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STEP 3 VALIDATION TESTING

Observation: Protocol should clearly specify "success criteria" for each tasks

2 = "Success" – Completed a task with little or no difficulty

1 = "Success with difficulty/Close-call" – Completed a task with more than a little difficulty (e.g., confusion, multiple attempts, frustration)

0 = "Use-error" – Did not complete the task, completed it incorrectly, or required assistance

Branaghan, R.J., O'Brian, J.S., Hildebrand, E.A. and Foster, L.B., 2021. *Humanizing Healthcare: Human Factors for Medical Device Design*. Springer.

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STEP 3 VALIDATION TESTING

- Represent the population of intended users (e.g., pediatric, adolescent, adult, senior)
- FDA requires minimum number of participants is 15, for each population

Table B-1. Percentage of Total Known Usability Problems Found in 100 Analysis Samples (Faulkner, 2003).

No. users	Min. % Found	Mean % Found	*SD*	*SE*
5	55	85.55	9.2957	.9295
10	82	94.69	3.2187	.3218
15	90	97.05	2.1207	.2121
20	95	98.4	1.6080	.1608
30	97	99.0	1.1343	.1051

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HF Validation Studies: To Test or Not to Test

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HF validation may not always be necessary if existing evidence can support safe and effective use

Reasons for not requiring a HF validation study may include:

- Device is well understood and commonly used
- Intended users are HCPs and use environment is in-clinic
- Risk analysis (URRA) demonstrates that residual risks are as low as possible with no identified unacceptable risks
- Available data (e.g. post-market, validation) from same or similar products (user interface, user population, and use environment)

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Common Deficiencies in FDA Submissions

- Incomplete / missing data for user groups or use environments (i.e., insufficient exploratory research or documentation thereof)
- Incomplete / missing analysis of known use issues (i.e., insufficient post-market surveillance or documentation thereof)
- Critical tasks not clearly identified, or not all critical tasks assessed (i.e., insufficient use-related task/risk analysis or documentation thereof)
- Insufficient linkage between use-related risk analysis (URRA), critical task definition, and task success criteria
- Reporting only performance rates and/or using preference ratings as a component of acceptance criteria

Johnson, K. (2019) '7 insights from the 2019 HFES Health Care Symposium', *Bold Insight*, 3 April 2019. Available at: https://boldinsight.com/7-insights-from-the-2019-hfes-health-care-symposium/ (Accessed: 10 August 2022).

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Conclusion

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- HFE is an integral part of the device development process
- A robust HF program ensures development of safer, more effective and easier to use product
- Utilizing harmonized standards for HF engineering will help streamline product development and support patient access to innovative products

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Thank You!

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