Human Factors Considerations for Medical AI Applications

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Agenda

What is Human Factors?

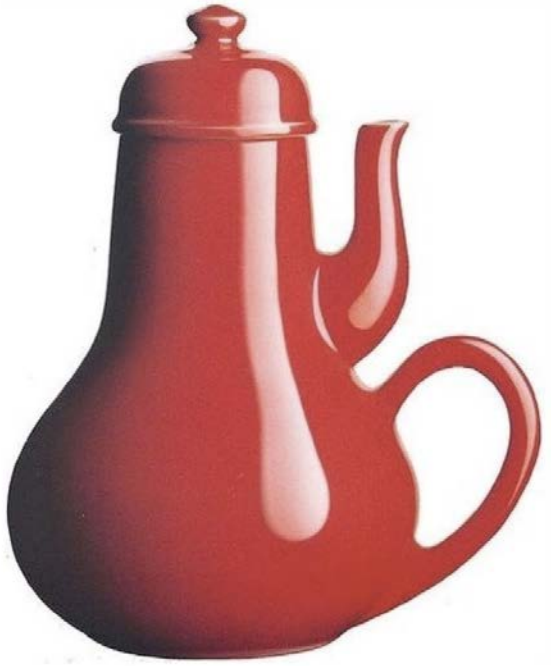
FDA/CDRH Human Factors Overview

User Interface Design Considerations for AI Applications

An AI-Guided Image Acquisition example: Human Factors Process

Human Factors

Ergonomics and human factors use knowledge of human abilities and limitations to design systems, organizations, jobs, machines, tools, and consumer products for *safe*, *efficient*, and *comfortable* human use.



(Source: http://osha.oregon.gov/edu/grants/wrd/cergos/Pages/ergonomics.aspx)

Regulatory Basis for Human Factors in Medical Devices: Quality System Regulation

21 CFR 820.30 Design Controls

(c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the ***needs of the user and patient***.

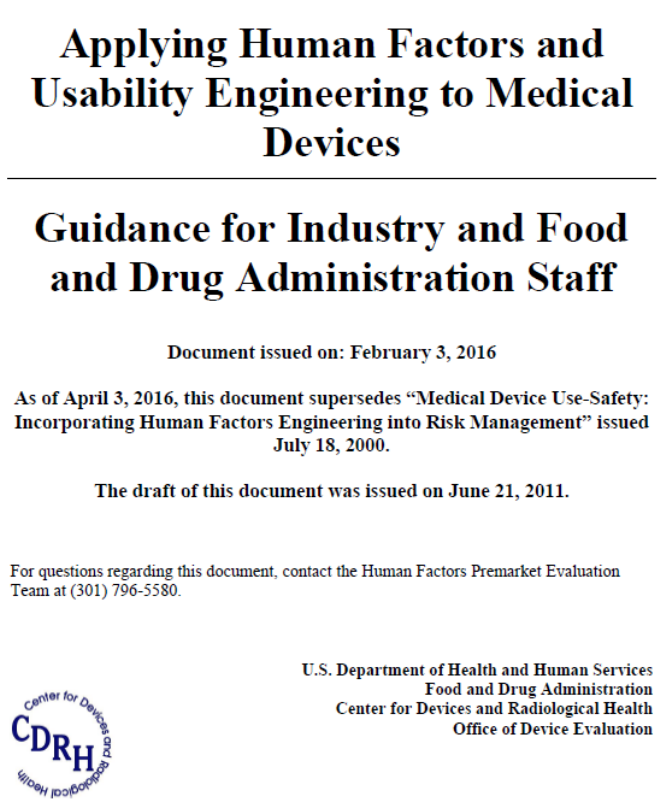
(g) Design validation. Design validation shall ensure that devices conform to defined ***user needs and intended uses*** and shall include testing of production units under actual or simulated use conditions.

Quality System Regulation Preamble

i.72. …"when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed.."

(Source: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.30)

FDA/CDRH Human Factors Guidance: Risk-based Approach



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"…FDA is primarily concerned that devices are safe and effective for the intended users, uses, and use environments."

"…CDRH believes that for those devices where an analysis of risk indicates that users performing tasks incorrectly or failing to perform tasks could result in serious harm, manufacturers **should** submit human factors data in premarket submissions (i.e., PMA, 510(k)). "

"…where harm is defined to include **compromised medical care**."

(Source: https://www.fda.gov/media/80481/download)

Examples When Use Error in Medical Products Could Cause Serious Harm to Patients Directly

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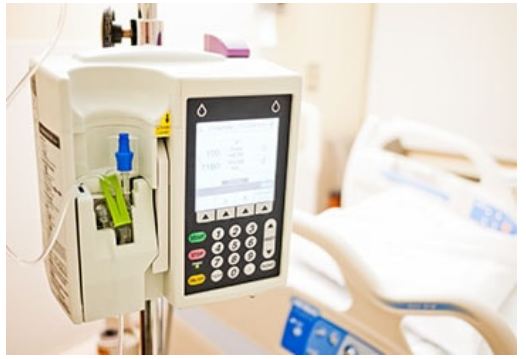
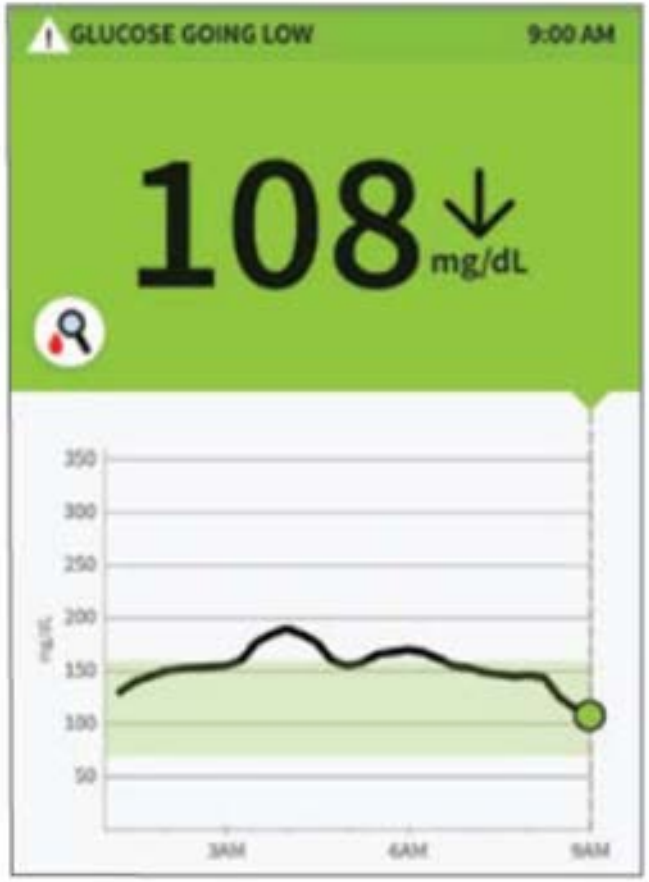


Can the Use Error in Radiology Imaging Devices Leading to Serious Harm to Patients?

Example of Use Error Which May Lead to Wrong Treatment Decision: Continuous Glucose Monitor (CGM)



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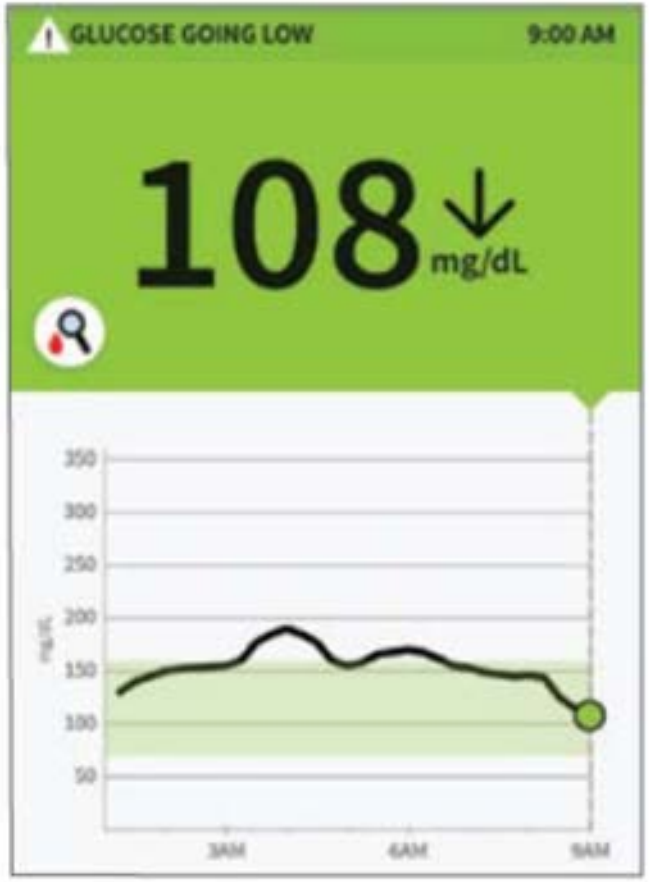

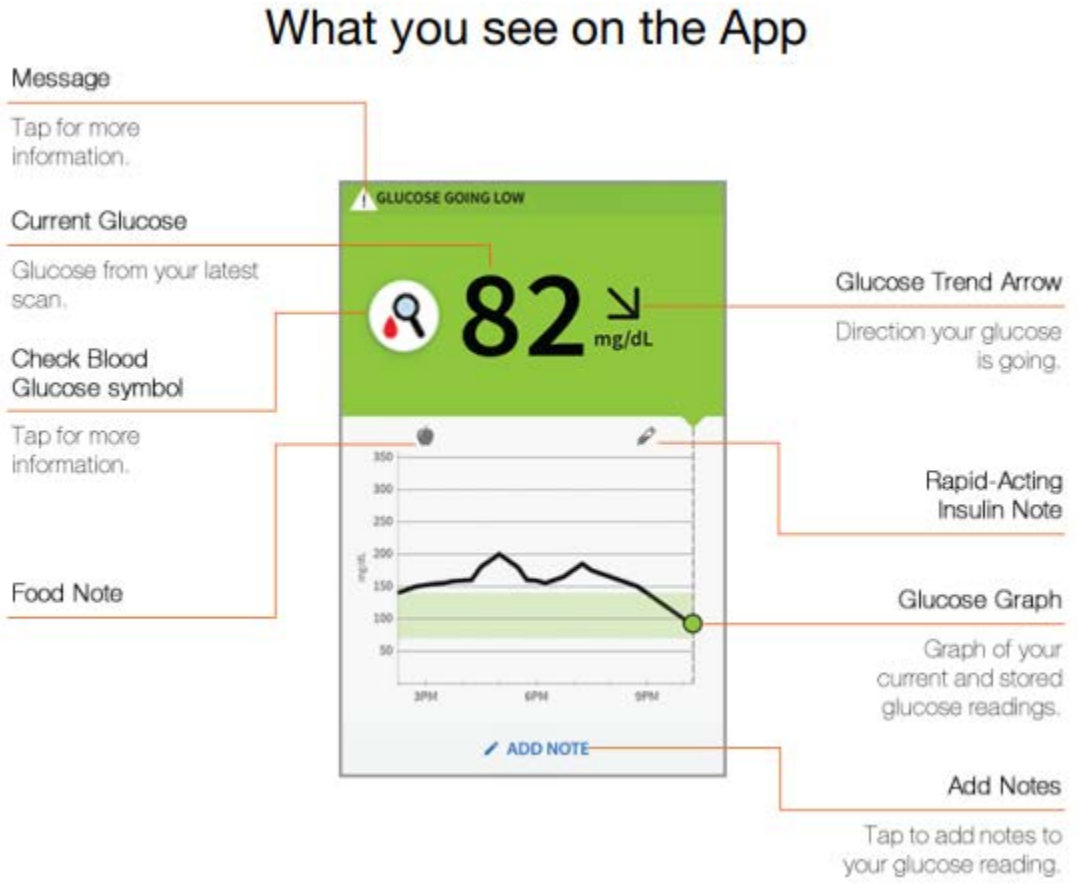

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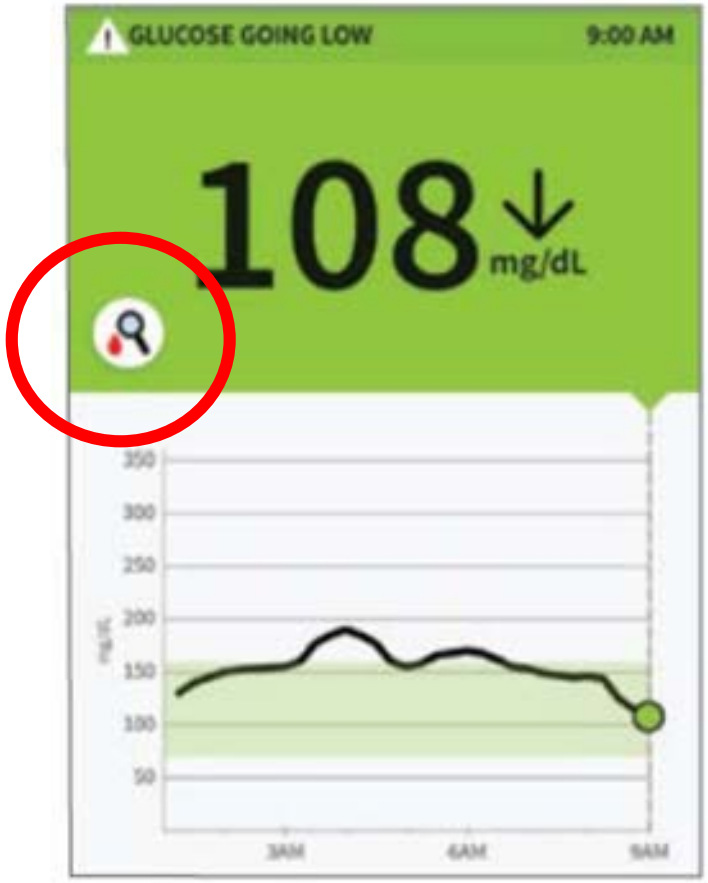
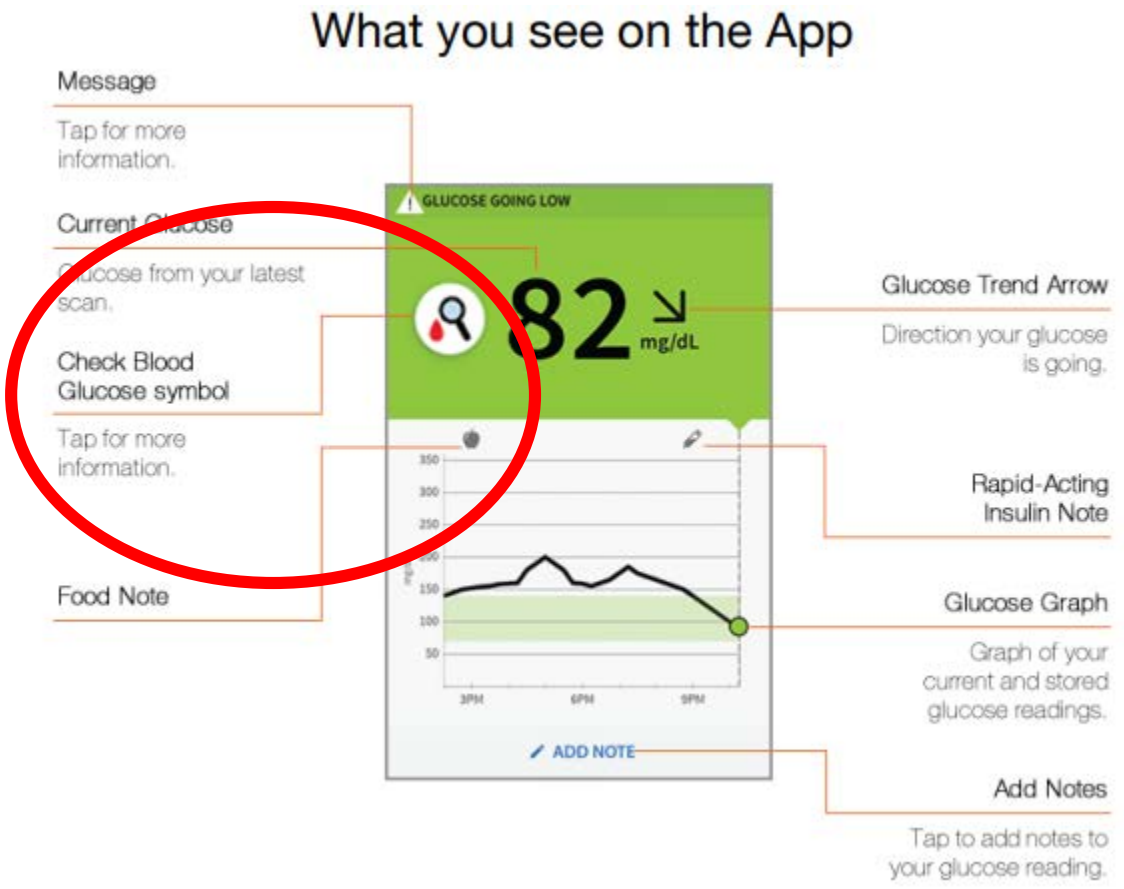
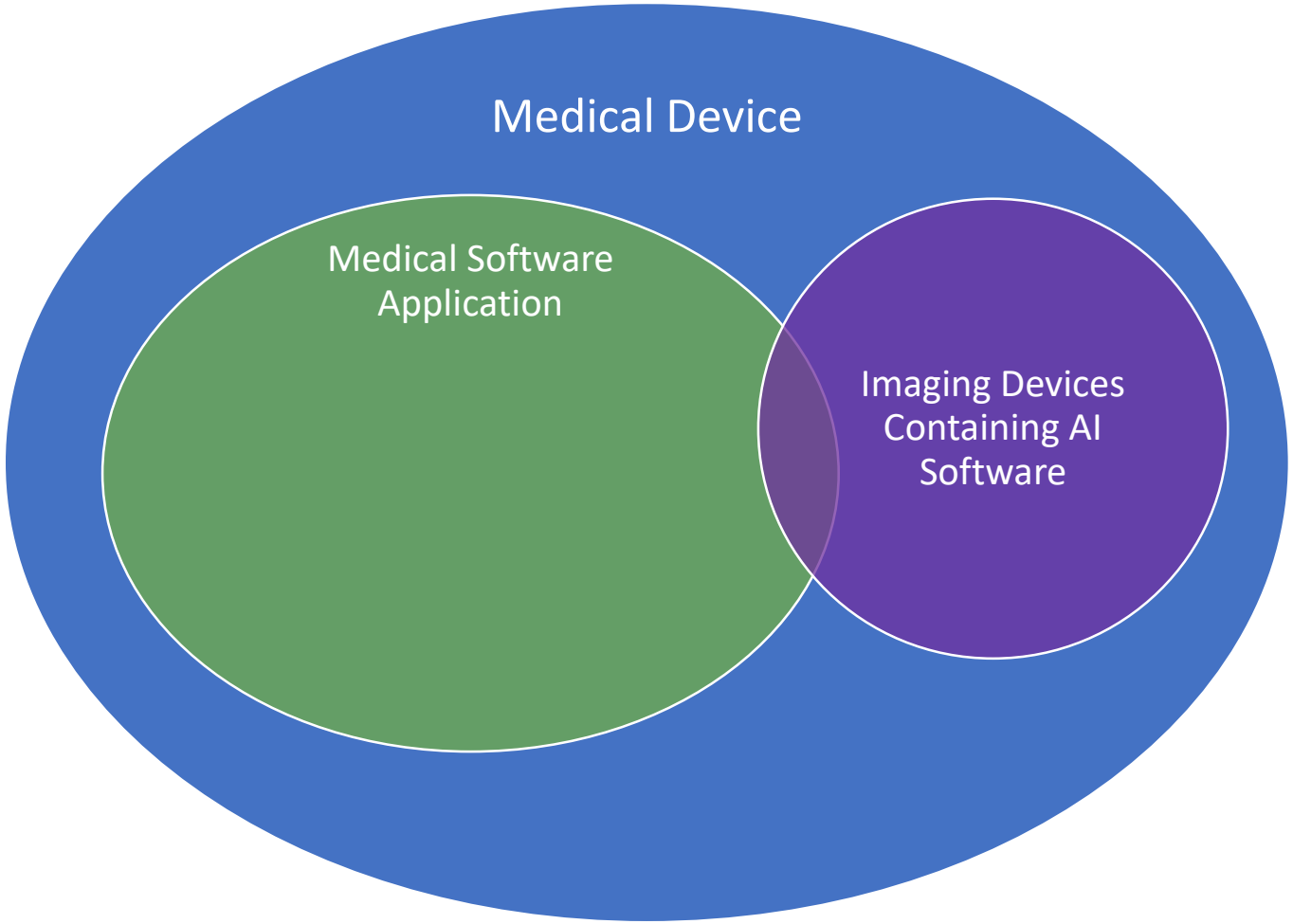




User Interface Design for Imaging Devices Containing AI Software



AI/Robots in Hollywood Movie are… Somewhat *Concerning*…

Many concerns over AI Applications Seems to be Human Factors-related

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E.g. What is *AI*'s role? What is *user*'s role?

Example: Hands-off process in the ICU

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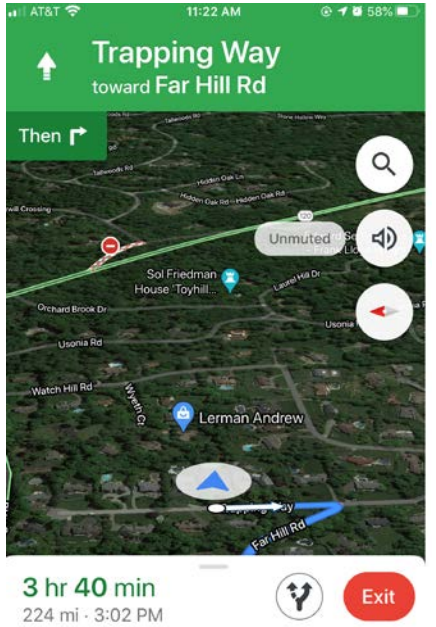
E.g. What is AI's role? What is user's role?

E.g. How does the user tell the context/status of the AI Application?

Example: "*Wait, where is the destination again?*"



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E.g. What is AI's role? What is user's role?

E.g. How does the user tell the context/status of the AI Application?

E.g. How does the user retain the control?

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E.g. What is AI's role? What is user's role?

E.g. How does the user tell the context/status of the AI Application?

E.g. How does the user retain the control?

E.g. How does the user verify the result, in particular for lay user/novice user?

Example: CGM/BGM

Example Design Guideline for Human-AI Interaction (Amershi et al., 2019)

	AI Design Guidelines	
Initially	G1	**Make clear what the system can do.** Help the user understand what the AI system is capable of doing.
	G2	**Make clear how well the system can do what it can do.** Help the user understand how often the AI system may make mistakes.
During interaction	G3	**Time services based on context.** Time when to act or interrupt based on the user's current task and environment.
	G4	**Show contextually relevant information.** Display information relevant to the user's current task and environment.
	G5	**Match relevant social norms.** Ensure the experience is delivered in a way that users would expect, given their social and cultural context.
	G6	**Mitigate social biases.** Ensure the AI system's language and behaviors do not reinforce undesirable and unfair stereotypes and biases.
When wrong	G7	**Support efficient invocation.** Make it easy to invoke or request the AI system's services when needed.
	G8	**Support efficient dismissal.** Make it easy to dismiss or ignore undesired AI system services.
	G9	**Support efficient correction.** Make it easy to edit, refine, or recover when the AI system is wrong.
	G10	**Scope services when in doubt.** Engage in disambiguation or gracefully degrade the AI system's services when uncertain about a user's goals.
	G11	**Make clear why the system did what it did.** Enable the user to access an explanation of why the AI system behaved as it did.
Over time	G12	**Remember recent interactions.** Maintain short term memory and allow the user to make efficient references to that memory.
	G13	**Learn from user behavior.** Personalize the user's experience by learning from their actions over time.
	G14	**Update and adapt cautiously.** Limit disruptive changes when updating and adapting the AI system's behaviors.
	G15	**Encourage granular feedback.** Enable the user to provide feedback indicating their preferences during regular interaction with the AI system.
	G16	**Convey the consequences of user actions.** Immediately update or convey how user actions will impact future behaviors of the AI system.
	G17	**Provide global controls.** Allow the user to globally customize what the AI system monitors and how it behaves.
	G18	**Notify users about changes.** Inform the user when the AI system adds or updates its capabilities.

(Source: https://www.microsoft.com/en-us/research/uploads/prod/2019/01/Guidelines-for-Human-AI-Interaction-camera-ready.pdf)

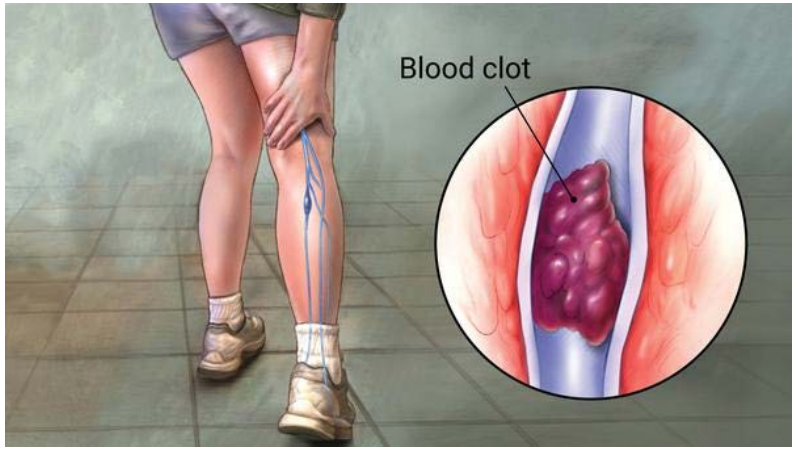
Hypothetical Example AI-Guided Image Acquisition Device Use, Users, Use Environment, and Use-Related Risks

Use: AI-guided image acquisition for early screening deep vein thrombosis

Users: Family member, caregivers, lay user

Use environment: home environment

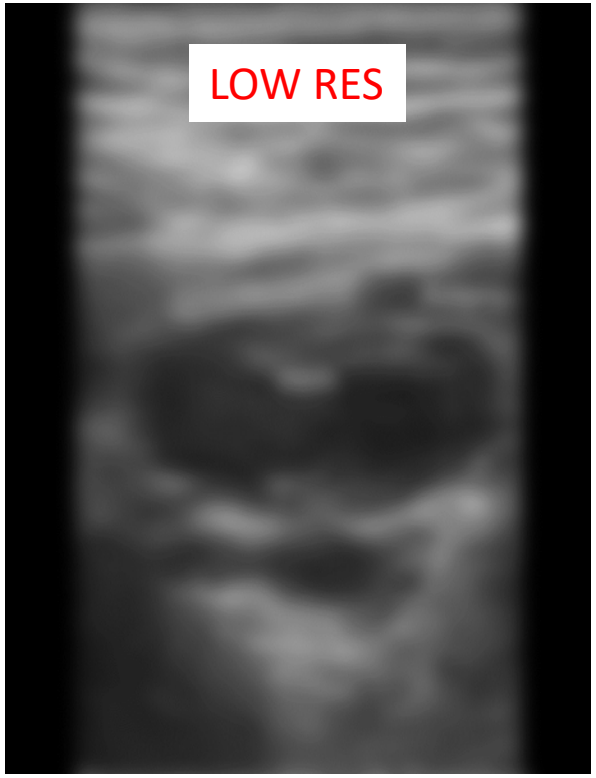
Example Use Error/Use-related Risk: Failure to follow instruction or labeling may lead to poor quality image, which will miss the opportunity of thrombosis diagnosis, which can potentially cause serious harm to the patient.



(Source: https://g.co/kgs/rw29TU)

Hypothetical Example AI-Guided Image Acquisition Device
Example Finding from Human Factors Study

Does the message make sense to the lay users/home users?

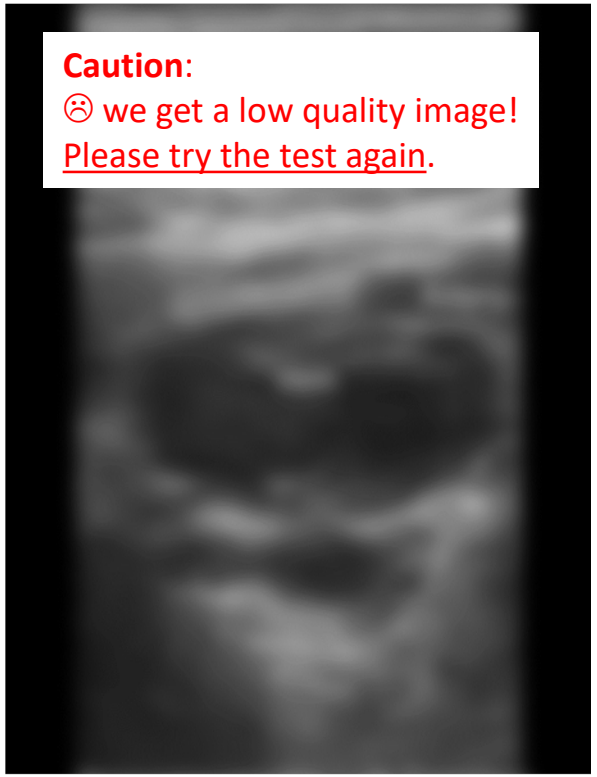


Hypothetical Example AI-Guided Image Acquisition Device Design Modification to Address the Use-related Risk

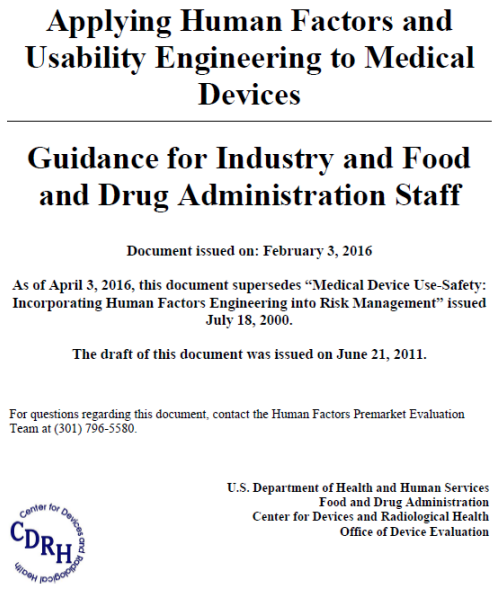
Inform users with the *language* that they understand,

and,

Present next step *action* that users will take.



Medical Device Human Factors Engineering Process



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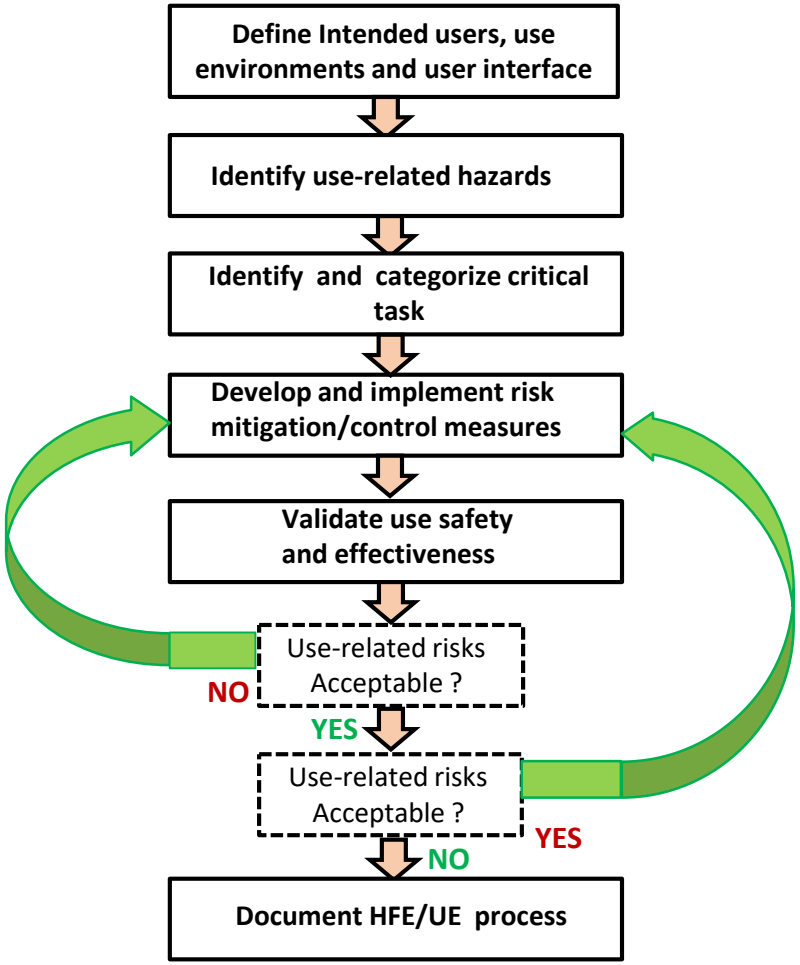

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Integrate the human factors in the design process

The user interface should make sense to the user.

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Understanding the user need and leveraging the design guidelines/best practice in designing the medical AI applications

Repeating the human factors validation study will not save a flawed design

FDA human factors review: Risk-based approach

The goal is to ensure that the device user interface has been optimized to support safe and effective use

We always welcome early discussions via pre-submission program.