

HUMAN FACTORS ENGINEERING: DESIGN OF MEDICAL DEVICES

General Principles

- Knowledge of detailed human factors guidelines is helpful when designing a medical device
 - ▣ Command of the general principles (rules of thumb) is critical
- Clinicians and users can usually cope with devices that have specific design shortcomings, provided that the flaws do not lead to serious use errors or pose insurmountable obstacles to accomplishing a task
- few device–user interface designs are perfect
 - ▣ usually violate one specific guideline or another
 - ▣ Much more serious if device violates a general design principle

General Principles

- Serious violations render a medical device unsafe and unusable
 - ▣ Presenting information too quickly
 - ▣ Expecting users to carefully read a manual before
- Designers should focus on meeting the high-level design principles before they perfect the details
 - ▣ no sense in refining a fundamentally flawed product

High-level design principles

- Seek user input
 - ▣ Involve users early and often
 - ▣ Refine designs through usability testing
- Establish design priorities
 - ▣ Keep it simple
 - ▣ Ensure safe use
 - ▣ Ensure essential communication
 - ▣ Anticipate device failures
 - ▣ Facilitate workflow



High-level design principles

- Accommodate user characteristics and capabilities
 - ▣ Do not expect users to become masters
 - ▣ Expect use errors
 - ▣ Accommodate diverse users
 - ▣ Maximize accessibility
 - ▣ Consider external factors that influence task performance

Sample user	Level of mastery of performing specific tasks		
	Determine the total volume of IV fluid infused	Set up a “piggyback” infusion	Change the battery
Nurse X	High	Medium	Low
Physician Y	Medium	Low	Low
Biomedical Engineer Z	Medium	Low	High



High-level design principles

- Accommodate users' needs and preferences
 - ▣ Prioritize user input
 - ▣ Do not rely exclusively on “thought leaders”
 - ▣ Let users set the pace
- Establish realistic expectations of users
 - ▣ Do not rely on training
 - ▣ Do not rely on instructions for use
 - ▣ Do not rely on warnings
 - ▣ Do not rely on users' memory
 - ▣ Avoid information overload
 - ▣ Do not assign users tasks that are better suited to the device

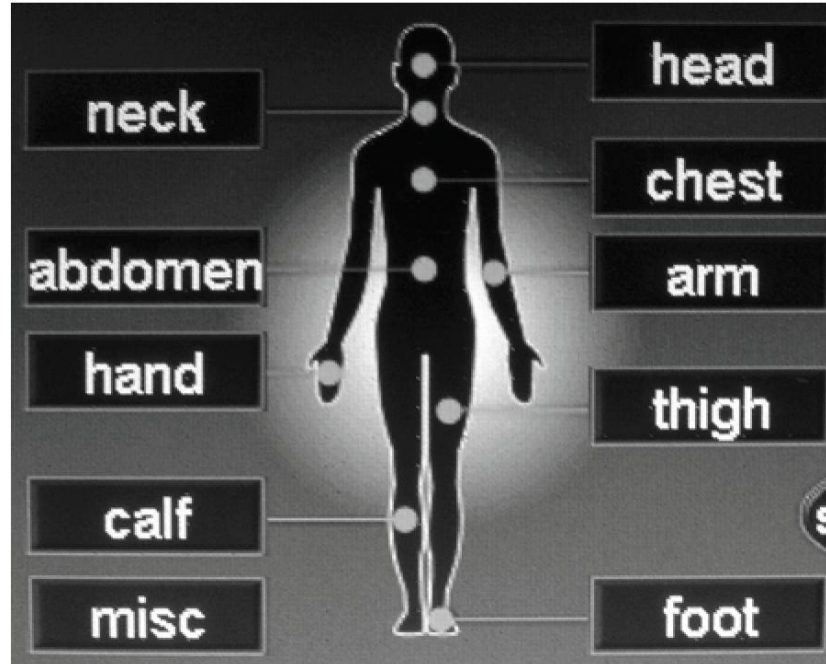
High-level design principles

- Consider real-world demands
 - ▣ Consider the context of use
 - ▣ Consider worst-case scenarios
 - ▣ Make devices as rugged as necessary
 - ▣ Limit user workload
 - ▣ Consider potential for device migration into other uses or use environments



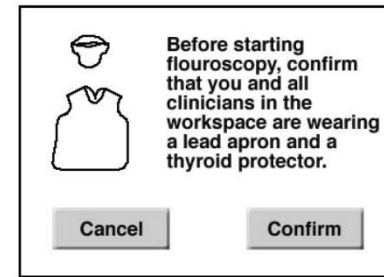
High-level design principles

- Develop compatible designs
 - ▣ Accommodate mental models
 - ▣ Establish natural or conventional mappings
 - ▣ Follow industry conventions and consensus standards



High-level design principles

- Optimize user interactions to enhance safety and effectiveness
 - ▣ Make devices error-tolerant and fail in a safe manner
 - ▣ Avoid physical strain, repetitive motions, and cumulative traumas
 - ▣ Help users anticipate future events
 - ▣ Confirm important actions
 - ▣ Make critical controls robust and guard them
 - ▣ Clarify operational modes
 - ▣ Employ redundant coding
 - ▣ Design to prevent user confusion
 - ▣ Don't neglect device appeal



Covered Material

- Chapter 4