INTRODUCTION:
GENERAL PRINCIPLES

Prof. Yasser Mostafa Kadah – www.k-space.org

Recommended Reference

- ANSI/AAMI HE75: 2009

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
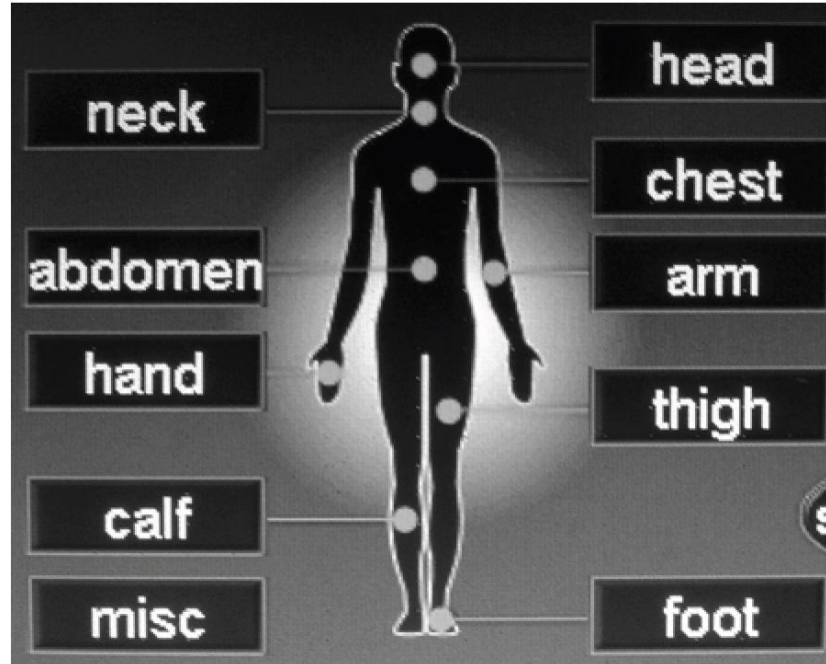
High-Level Design Principles

□ 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
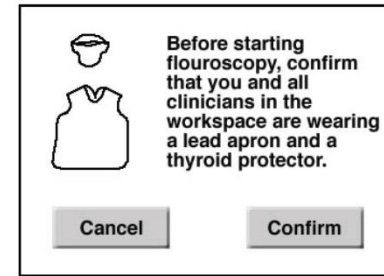
Further Reading and Assignments

- □ Chapter 4 of Recommended Reference