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# Identifying and Mitigating Potential Use Errors



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**FDA / CDRH / ODE**

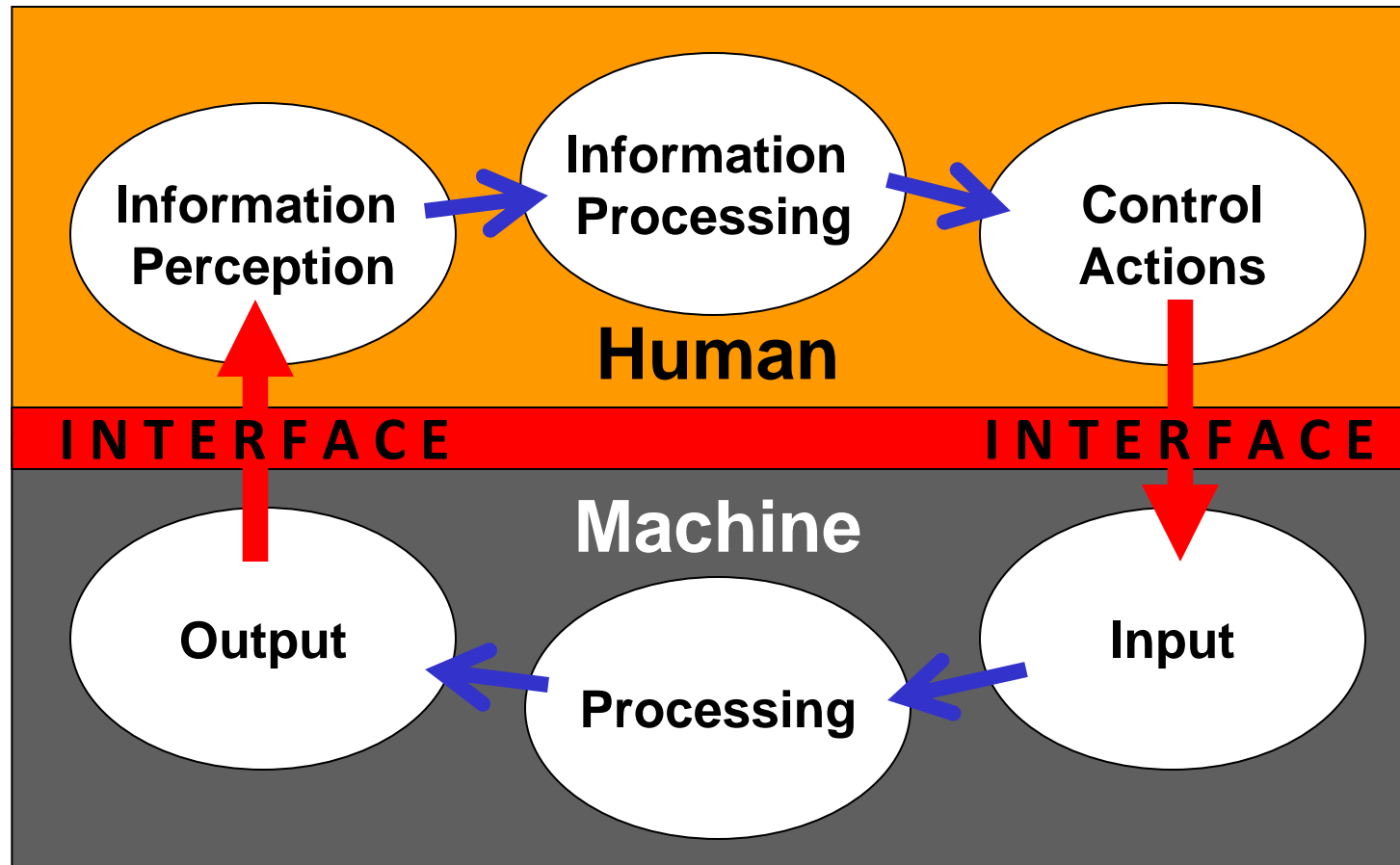
**MDM East – June 7, 2011**

# Overview

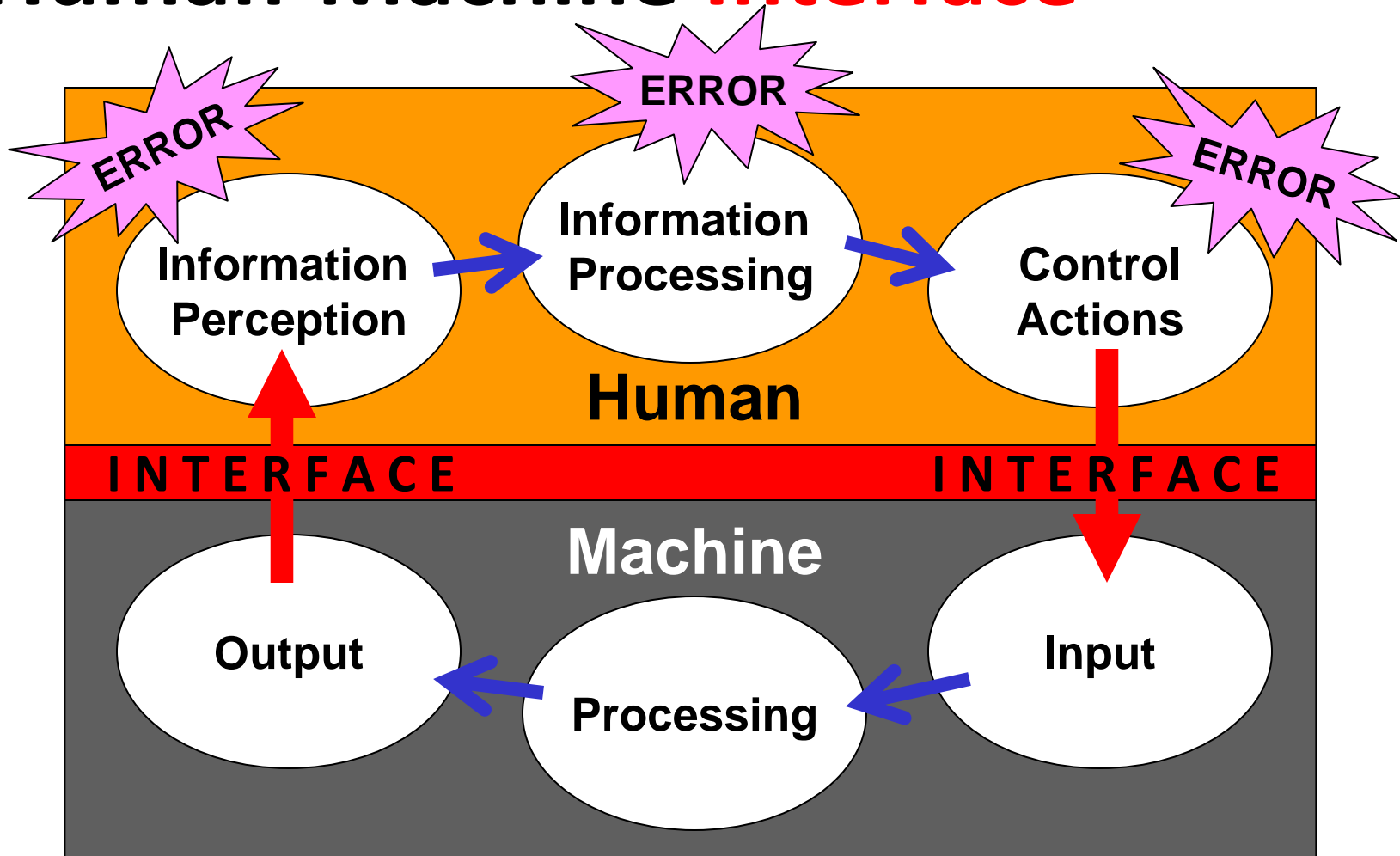
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- **Introduction to Human Factors**
- **Risk Analysis for Use-Related Hazards**
- **Analytical Human Factors Methods**
- **Formative Studies for Device Design**
- **Human Factors Validation Testing**
- **Discussion**

# Human-Machine **Interface**

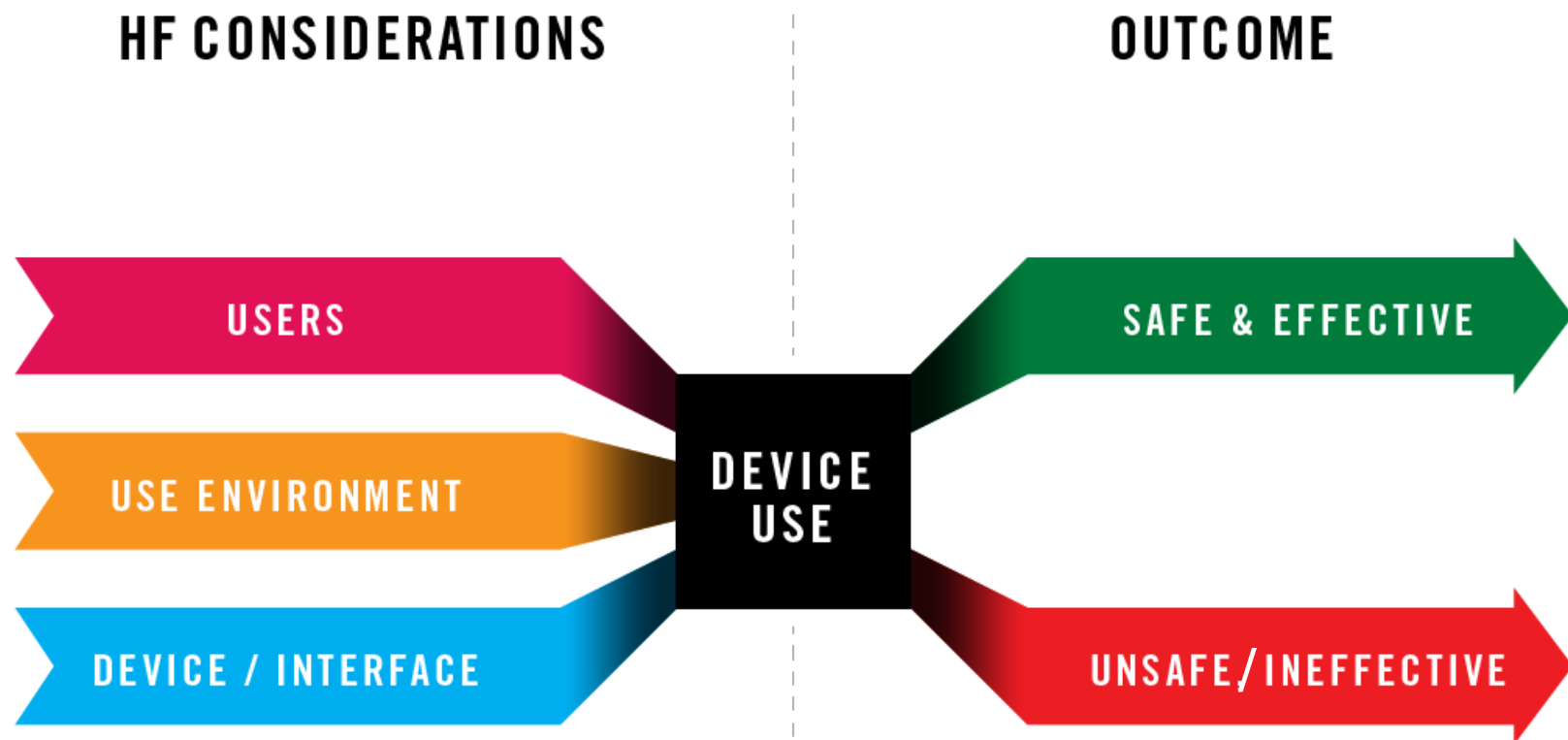


# Human-Machine Interface

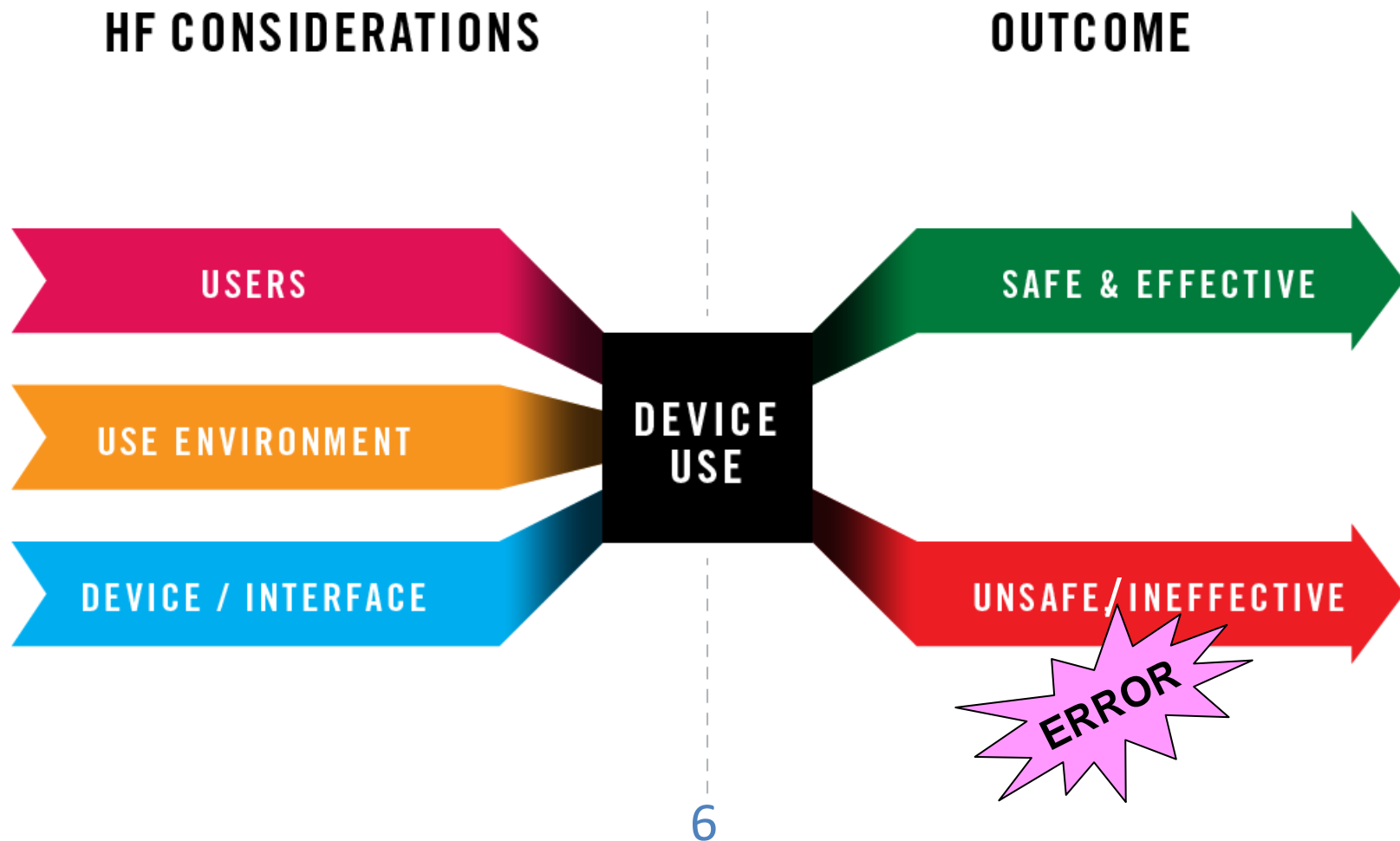


# Human Factors of Device Use

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# Human Factors of Device Use



# Device Users

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- **Professional or non-professional**
  - Job title and responsibilities
- **Knowledge and experience levels**
- **Age and functional capabilities**
  - Physical, sensory/perceptual, cognitive/intellectual
- **Mental and emotional condition**

# Device Use Environment

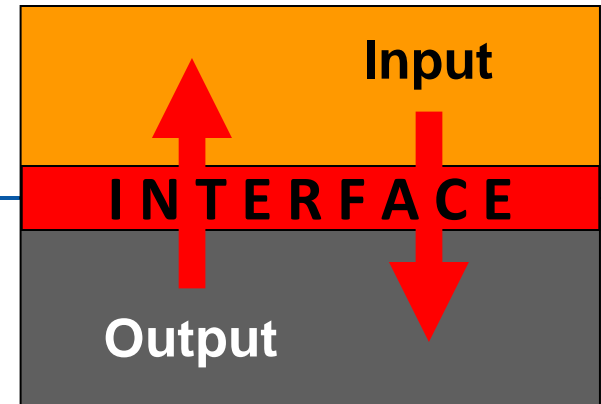
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- **Clinical environment(s)**
- **Rehabilitation, assisted living, long-term care**
- **Home environment**
- **Community setting**
  - Office, school, retail, outdoors, etc.
- **Mobile environment**
  - Car, plane, train, bus, ambulance, medevac, etc.



# Device User Interface

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- **Tasks**
  - Unpacking, assembly/set up
  - Use
  - Supply replenishment, maintenance, repair
- **Input**
  - Knobs/dials, switches, buttons; connections
- **Output**
  - Displays, lights; beeps, alerts/alarms, voice; vibration, heat

# Risk Analysis

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- Essential for ensuring that medical devices are safe and effective
- Hazards:
  - Chemical, mechanical, thermal, electrical, radiation, biological + **use-related**

# Risk Analysis

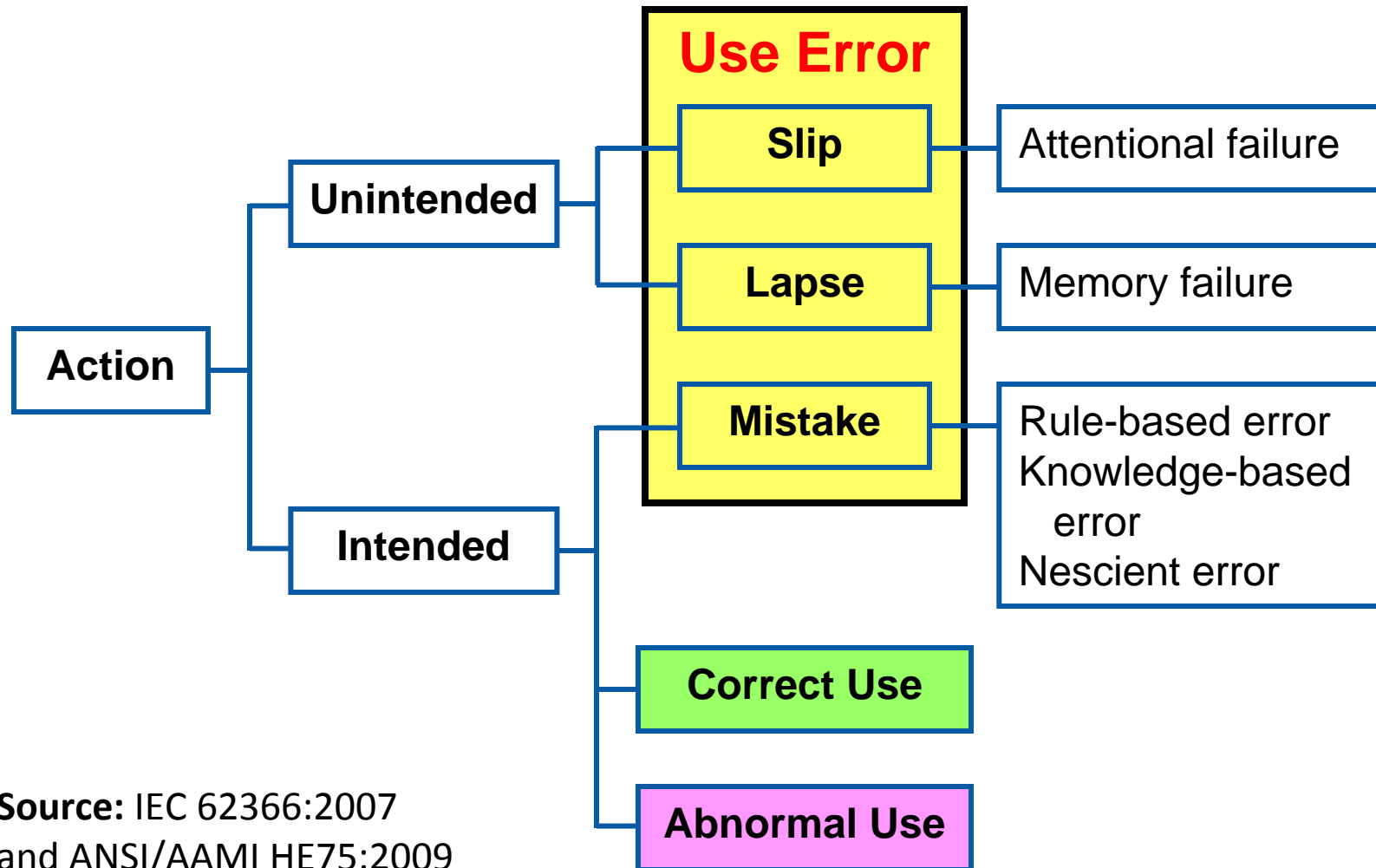
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- **Risk management process for use-related hazards:**
  - Identify anticipated use-related hazards (through analytical methods);
  - Identify unanticipated use-related hazards (through formative studies);
  - Develop and implement mitigation strategies;
  - Demonstrate safe and effective use through human factors validation.

# Use-Related Risks: Infusion Pumps

Hazard (samples)	Corresponding Risk(s) to Health	Potential Cause(s)
Infusion stopped prematurely	<ul style="list-style-type: none"> <li>• Underdose</li> <li>• Delay of therapy</li> </ul>	The user forgets to resume the pump after suspending it
		User is unaware of battery capacity
The user fails to detect or understand pump notifications	<ul style="list-style-type: none"> <li>• Overdose</li> <li>• Underdose</li> <li>• Delay of therapy</li> <li>• Incorrect therapy</li> </ul>	Background noise or nuisance alarms cause user to fail to detect/ignore them
		User muffles pump's speaker/audio, either intentionally or unintentionally
Wrong medication or concentration is delivered	<ul style="list-style-type: none"> <li>• Incorrect therapy</li> <li>• Delay of therapy</li> </ul>	User selects and sets up pump with incorrect medication or concentration
		Medication is correct but user selects incorrect concentration or delivery rate

# Use Errors



Source: IEC 62366:2007  
and ANSI/AAMI HE75:2009

# Analytical HF Methods (1 of 4)

## Identification of known problems

- **Customer complaint files**
- **Knowledge of training and sales staff**
- **Publications**
  - Journal articles, proceedings, newsletters
  - Web sites
    - FDA/CDRH: MAUDE/MDR, MedSun, recalls, alerts and notices, public health notifications
    - ECRI: Medical Device Safety Reports

# Analytical HF Methods (2 of 4)

## With current device users

- Who will use the device?
- Where will they use the device?
- **Contextual inquiry**
  - User demonstration
  - Researcher observation and inquiry
- **Interviews and focus groups**
  - Targeted discussion

# Analytical HF Methods (3 of 4)

## With study staff

- **Function and task analysis**
  - Break down device use into discrete steps
  - Are any use-related hazardous scenarios possible?
  - How might they occur?
  - How likely are they?
  - What are the possible consequences of each?
  - How might they be prevented?
- **Apply mitigations; reassess hazards**



# Analytical HF Methods (4 of 4)

## With expert analysts

- **Heuristic analysis**
  - Formally evaluate user interface against well-established design rules or heuristic guidelines
- **Expert review**
  - Clinical and human factors experts
  - Provide personal opinions of usability and safety of user interface, based on professional knowledge and experience

# Formative Studies

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## With potential device users

- **Test design ideas and prototypes**
  - Fidelity can be low
- **Representative test participants**
  - Numbers can be low
- **Simulated use conditions**
- **Identify major problems; develop solutions**
- **Best when performed iteratively**



# Human Factors Validation

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- **Final design of device/system and labeling**
- **Critical tasks and use scenarios**
- **Realistic use environments and conditions**
- **Representative test participants**
  - Test the device, not the users
- **Realistic training levels and methods**
- **Data collection:**
  - Subjective and performance data

# Validation: Post-Test Interview

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- **Open-ended and non-judgmental debrief**
- **Obtain general participant impressions of the device and the use experience**
- **Ascertain participant awareness of and reasons for making errors**
- **Solicit specific comments on design of the device, labeling and training**

# Analysis of HF Validation Data

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- Identify use errors, “close calls,” difficulties
- Identify potential negative clinical consequences and root causes of problems
- Determine whether additional risk mitigation strategies are needed
- If so, design and implement strategies and revalidate:
  - Were strategies successful at reducing risks?
  - Did strategies introduce new risks?

# Formative $\neq$ Validation! (1 of 2)

## HF Formative Studies

- **Purpose is to inform product development:**
  - Explore/assess preliminary design decisions and options for device/system, labeling, and training
  - Identify previously unknown use hazards
  - Assess success of risk mitigation strategies
- **Study can be interactive**

# Formative $\neq$ Validation! (2 of 2)

## HF Validation Studies

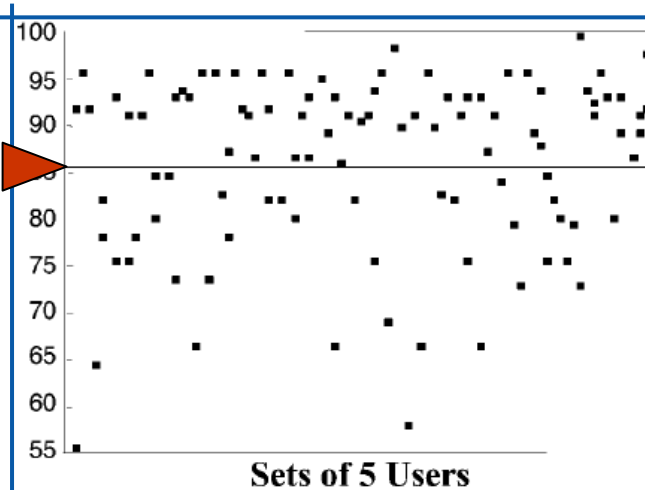
- **Purpose is to confirm final product design:**
  - Anticipate, as completely and accurately as possible, actual device use experience
  - Study participants' performance on critical and essential tasks
  - Study quality of user interactions with device
  - Obtain subjective feedback from users
- **Should not influence participant behavior**

# Sample Sizes (Faulkner, 2003\*)

**5 users:**

**Min. 55%**

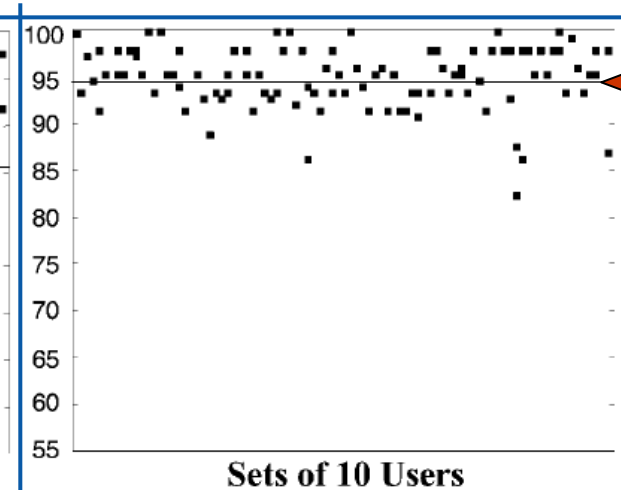
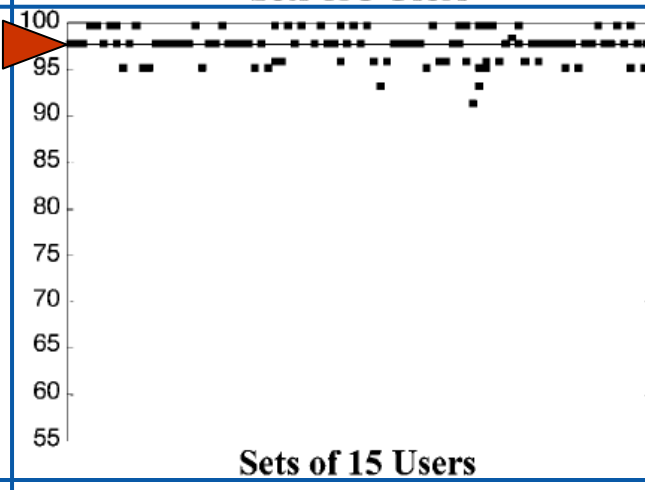
**Mean 85.6%**



**15 users:**

**Min. 90%**

**Mean 97.1%**



**10 users:**

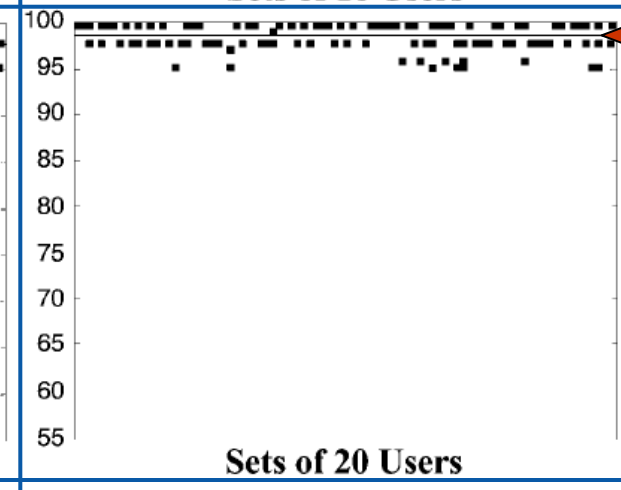
**Min. 82%**

**Mean 94.7%**

**20 users:**

**Min. 95%**

**Mean 98.4%**



Faulkner, L. (2003). Beyond the five-user assumption: Benefits of increased sample sizes in usability testing. *Behavior Research Methods, Instruments, and Computers*, 35(3), 379-383.



# Questions for Formative Studies

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- Which design alternative generated the best use performance?
- What use problems were identified? Are design modifications needed?
- Is the labeling (e.g., instructions for use) effective?
- Is the training effective?
- Is design ready for validation testing?

# **Selection of Tasks for Validation**

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## **Critical tasks:**

- **Associated with moderate or greater risk to users**
- **Risk mitigation strategies might have been implemented**

## **Essential tasks:**

- **Associated with typical use of device**
- **Associated with critical tasks**

# Use-Related Hazards for Pumps

Hazard (samples)	Corresponding Risk(s) to Health	Potential Cause(s)
Infusion stopped prematurely	Underdose; Delay of therapy	The user forgets to resume the pump after suspending it
		User is unaware of battery capacity
The user fails to detect or understand pump notifications	Overdose; Underdose; Delay of therapy; Incorrect therapy	Background noise or nuisance alarms cause user to fail to detect/ignore them
		User muffles pump's speaker/audio, either intentionally or unintentionally
Wrong medication or concentration is delivered	Incorrect therapy; Delay of therapy	User selects and sets up pump with incorrect medication or concentration
		Medication is correct but user selects incorrect concentration or delivery rate

# Use-Related Hazards for Pumps

Potential Cause(s)	Assessment Strategies - ?
The user forgets to resume the pump after suspending it	
User is unaware of battery capacity	
Background noise or nuisance alarms cause user to fail to detect/ignore them	
User muffles pump's speaker/audio, either intentionally or unintentionally	
User selects and sets up pump with incorrect medication or concentration	
Medication is correct but user selects incorrect concentration or delivery rate	

# Review

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- **Risk Analysis for Use-Related Hazards**
- **Analytical Human Factors Methods**
- **Formative Studies for Device Design**
- **Human Factors Validation Testing**

# Final Thought

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- To err is human...
- To follow good human factors practices to minimize potential use error – *divine!*



# Questions



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