UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education

Medical devices Usability and design

Ing. Alice Ravizza

Hard truth…

Infusion pump inferno

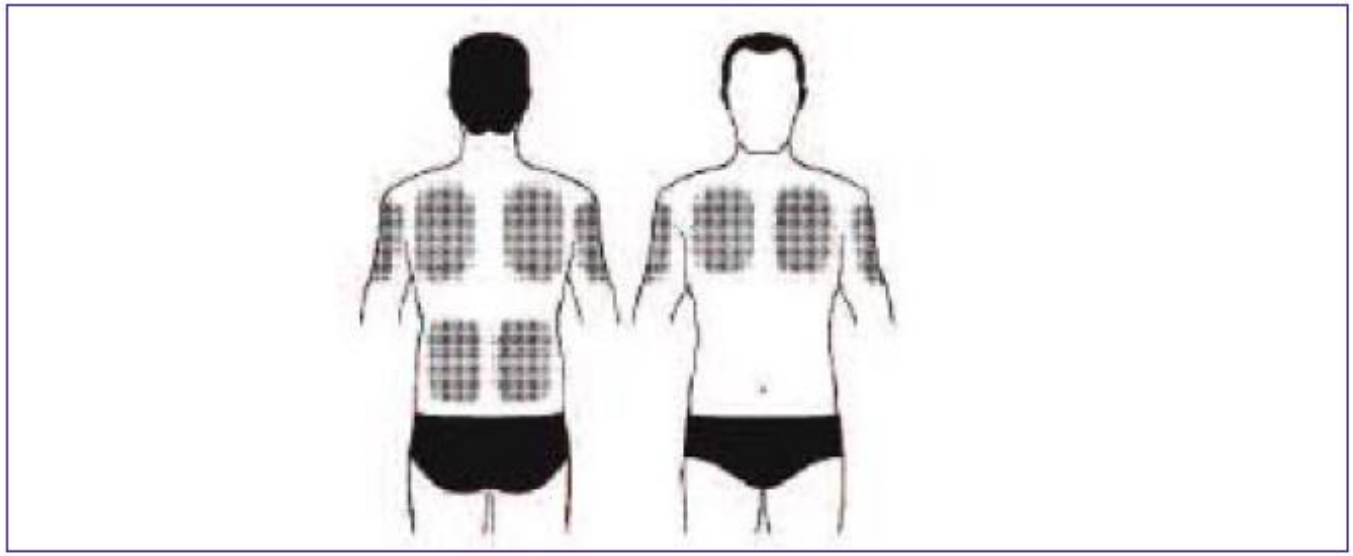
FDA White Paper: Infusion Pump Improvement Initiative, April 2010

- Between 2005 and 2009, FDA reported:
  - 56,000 infusion pump incidents
  - 710 deaths
  - 87 recalls
- Infusion devices account for up to 35% of all medication errors that result in significant harm
- A large percentage of these adverse events are due to programming errors that can be attributed to poor usability
  - Entering weight in pounds instead of kg – results in 2.2x overdose
  - Incorrectly placed decimal point – results in 10x under or over infusion
  - Select incorrect dose mode – mg/kg/min instead of mcg/kg/min – results in ***1000x*** **overdose**

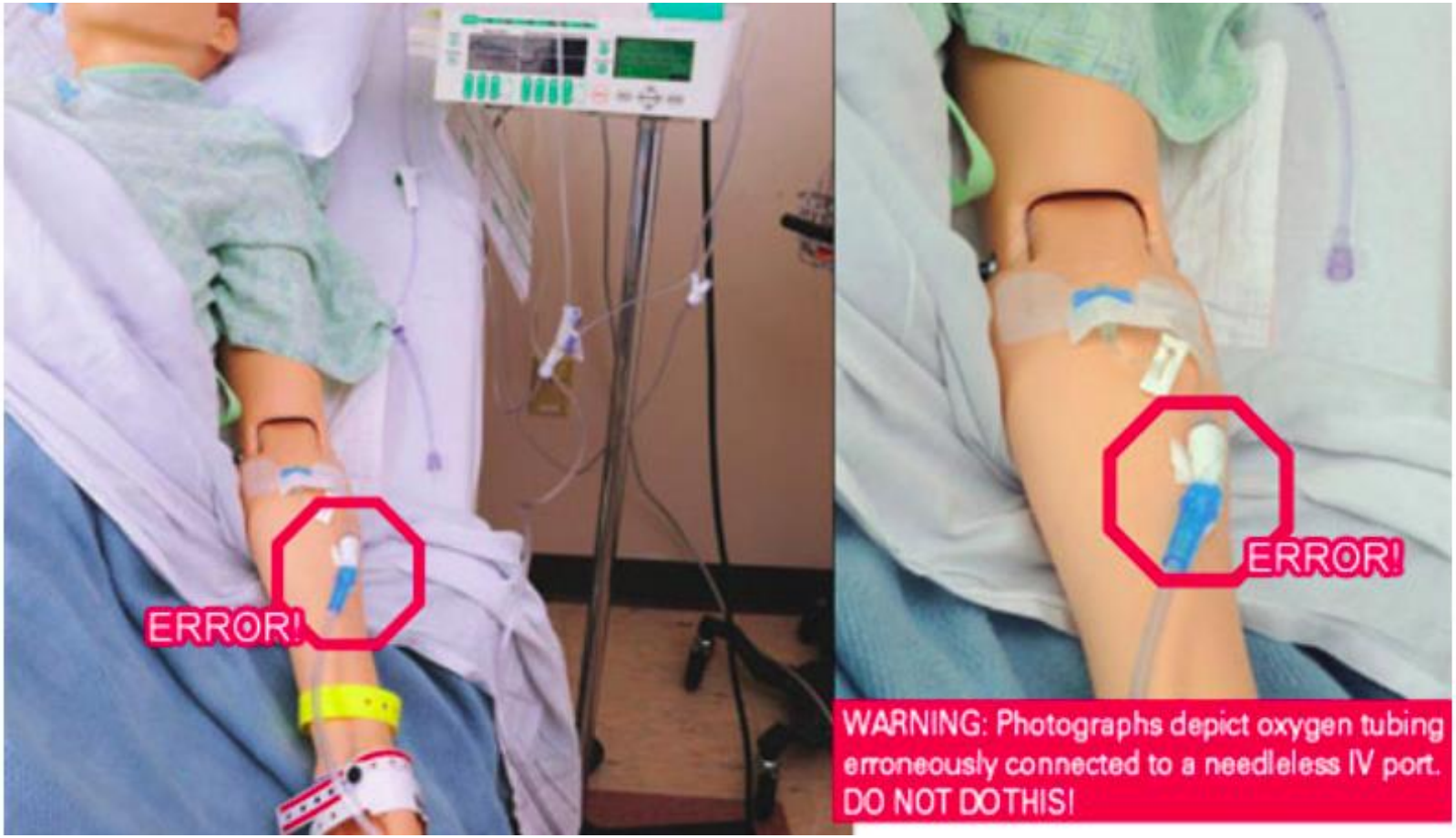
Overdosing from dermal patch

Transdermal Patch Products

- Original user instructions: where to apply patch

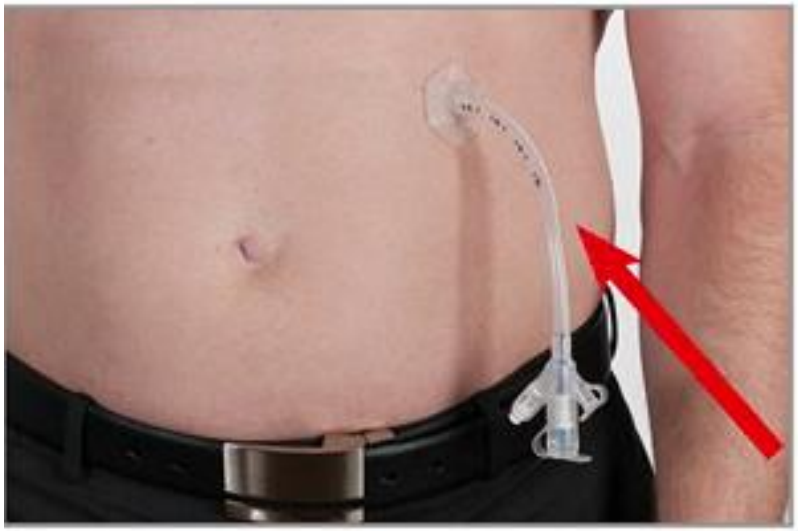


Examples from the web

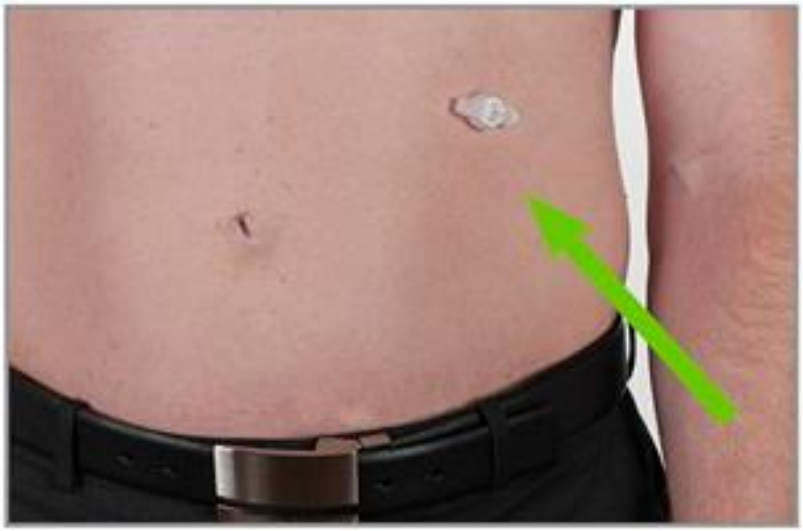


Pleasurable device

Which tube does your patient deserve?



Standard Feeding Tube



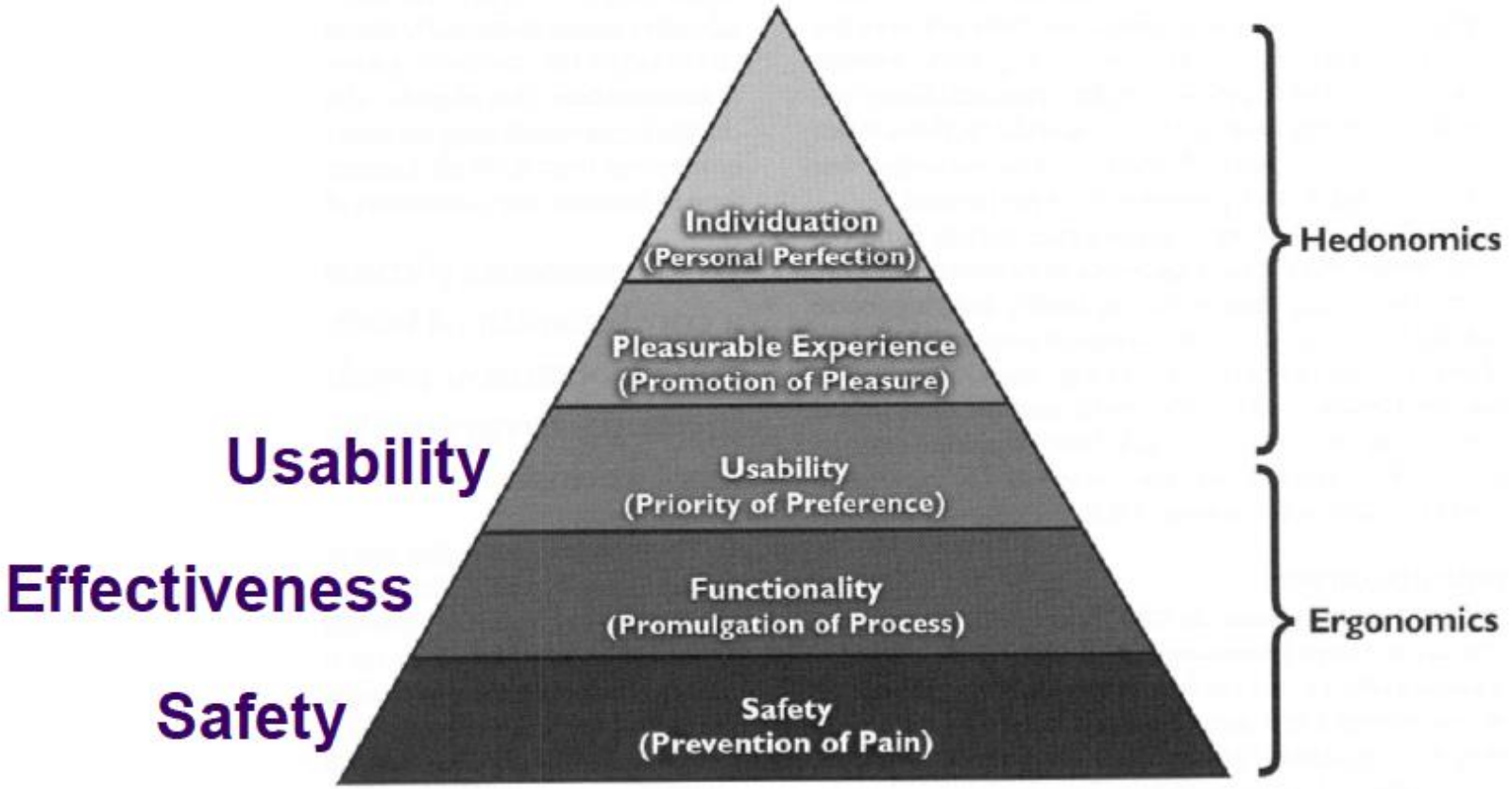
MIC-KEY® G Feeding Tube

DISCOVER THE "NO-SHOW DIFFERENCE."

Usability: what is it
63366-1 3.16

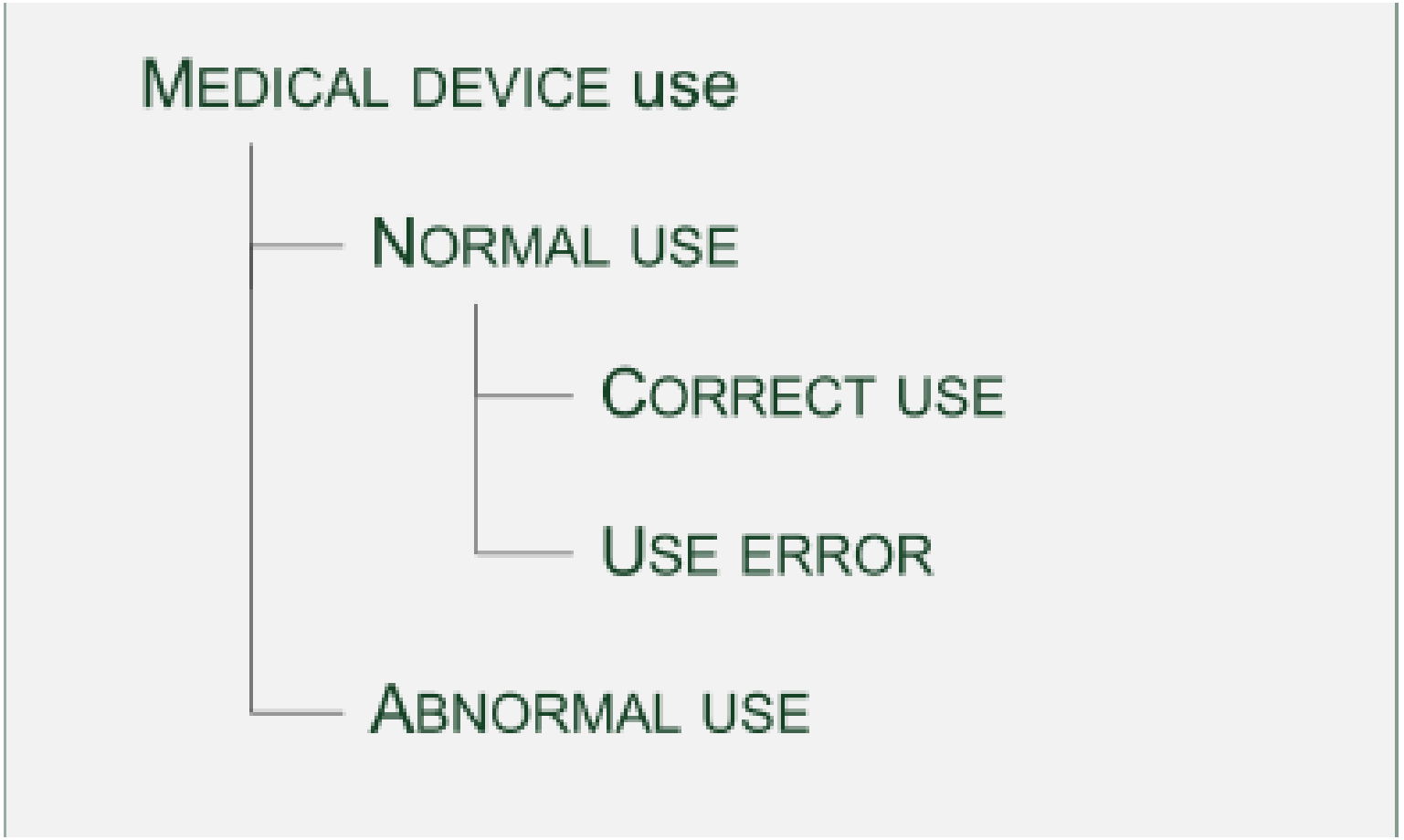
- characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS , EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT
  - All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY.

Safe, effective, easy, pleasurable



Source: Hancock, Pepe & Murphy (2005), *Ergonomics in Design*, 13 (1), 8-14

Medical device use



NORMAL & INTENDED USE

- NORMAL: operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use
- INTENDED purpose: : the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials

A “wrong” use

- 3.21 USE ERROR: USER action or lack of USER action that leads to a different result than that intended or expected

USE ERROR caused by cognition error

- Memory Failures:
  - Inability to recall knowledge which was gained before
  - Omitting (e.g. forgetting) a planned step
- Rule-based Failures:
  - Misapplication of appropriate generally accepted rule
  - Inability to recall knowledge which was gained before
- Knowledge-based Failures:
  - Improvisation under unusual circumstances
  - Misinterpretation of information due to incorrect mental model

A “bad” use

- 3.1 ABNORMAL USE: conscious, intentional act or intentional omission that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER
  - Reckless use or sabotage or intentional disregard of information for SAFETY
  - “reasonably foreseeable misuse” from 4.2 of ISO 14971
- Usually not controllable by Usability Engineering processes

Examples of ABNORMAL USE

IEC 62366-1 Annex A

- exceptional violation (e.g. using the MEDICAL DEVICE as a hammer);
- conscious disregard of contraindications
- reckless use (i.e. USERS making their own RISK benefit decision)
  - EXAMPLE 1 Using a MEDICAL DEVICE after removing its protective guards.
  - EXAMPLE 2 Ignoring the output limit
- sabotage.

A “right” use

- 3.3 CORRECT USE: NORMAL USE without USE ERROR
  - Deviation from instructions for use is only considered USE ERROR if it leads to deviceresponse that is different than intended/ expected
  - Off label may not be Use error

HF engineering: actors

- The people
  - Intended user
  - User groups
- The machine
  - Human- machine interface

Example of complex Human-Machine Interface

Involved people

- 3.10 PATIENT: living being (person) undergoing a medical, surgical or dental PROCEDURE
- 3.24 USER: person interacting with (i.e. operating or handling) the MEDICAL DEVICE
  - clinicians, PATIENTS, cleaners, maintenance and service personnel

And more…

- 3.25 USER GROUP: subset of intended USERS who are differentiated from other intended USERS by factors that are likely to influence USABILITY, such as age, culture, expertise or type of interaction with a MEDICAL DEVICE
  - Different user profiles in a SW interface
  - Special needs patients
  - Caregivers

Device users

- The intended users of the device
  - physician, nurse, professional caregiver, patient, family member
  - installer, maintenance, reprocessor, disposer
- User characteristics
  - functional capabilities (physical, sensory and cognitive),
  - experience and knowledge levels and behaviors
- The level of training users are expected to have and/or receive.

User profiles: general

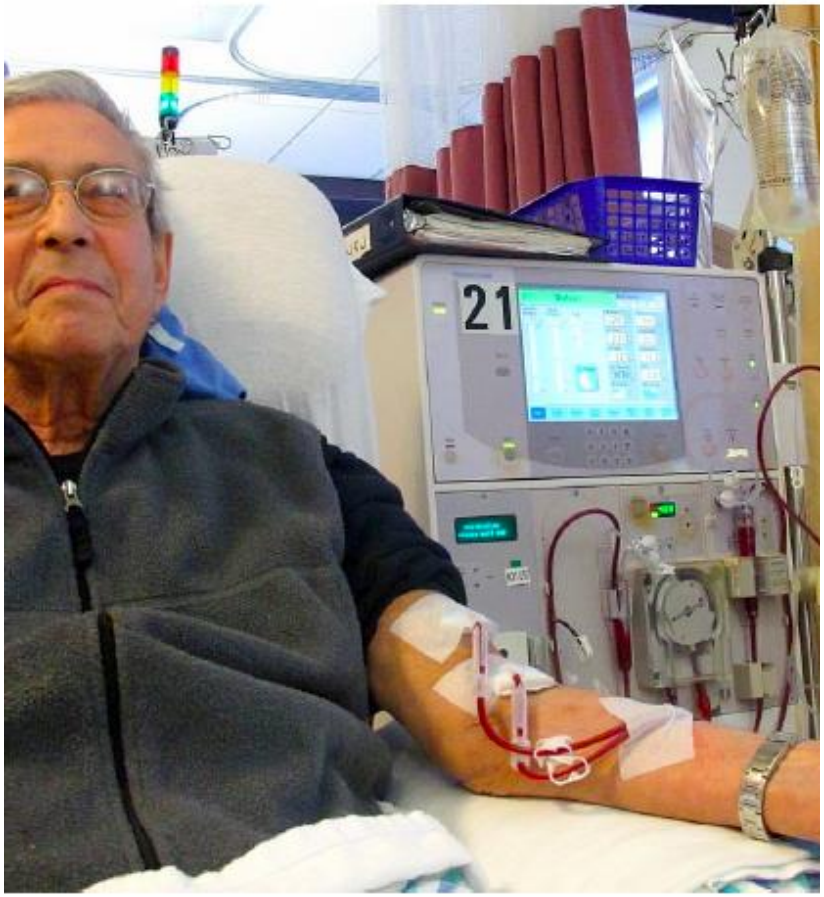
- Physical size, strength, and stamina, dexterity, flexibility, and coordination,
- Sensory abilities (i.e., vision, hearing, tactile sensitivity),
- Cognitive abilities: memory, Literacy and language skills, emotional state
- Willingness and motivation

User profiles: health state

- Medical condition, comorbidities (i.e., multiple conditions or diseases)
- Health literacy
  - General knowledge of similar types of devices,
  - Knowledge of and experience with the particular device,
- Ability to learn and adapt to a new device

Different users

Different use profiles



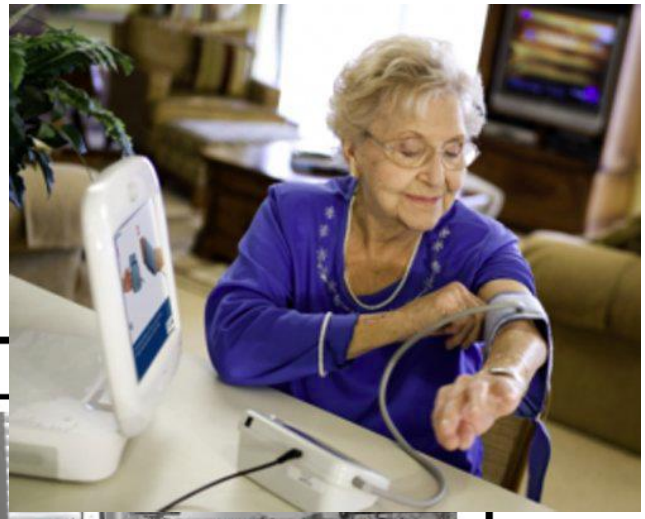
Device Use Environments

- Light, noise, clutter or busy room, External use, rain, darkness
- Moving vehicle

- Multiple models of the same device in the same room
- Multiple other alarms or sounds

Use environment description
IEC 62366-2 annex H

- provide designers with information



Intensive Care Unit

Photos	

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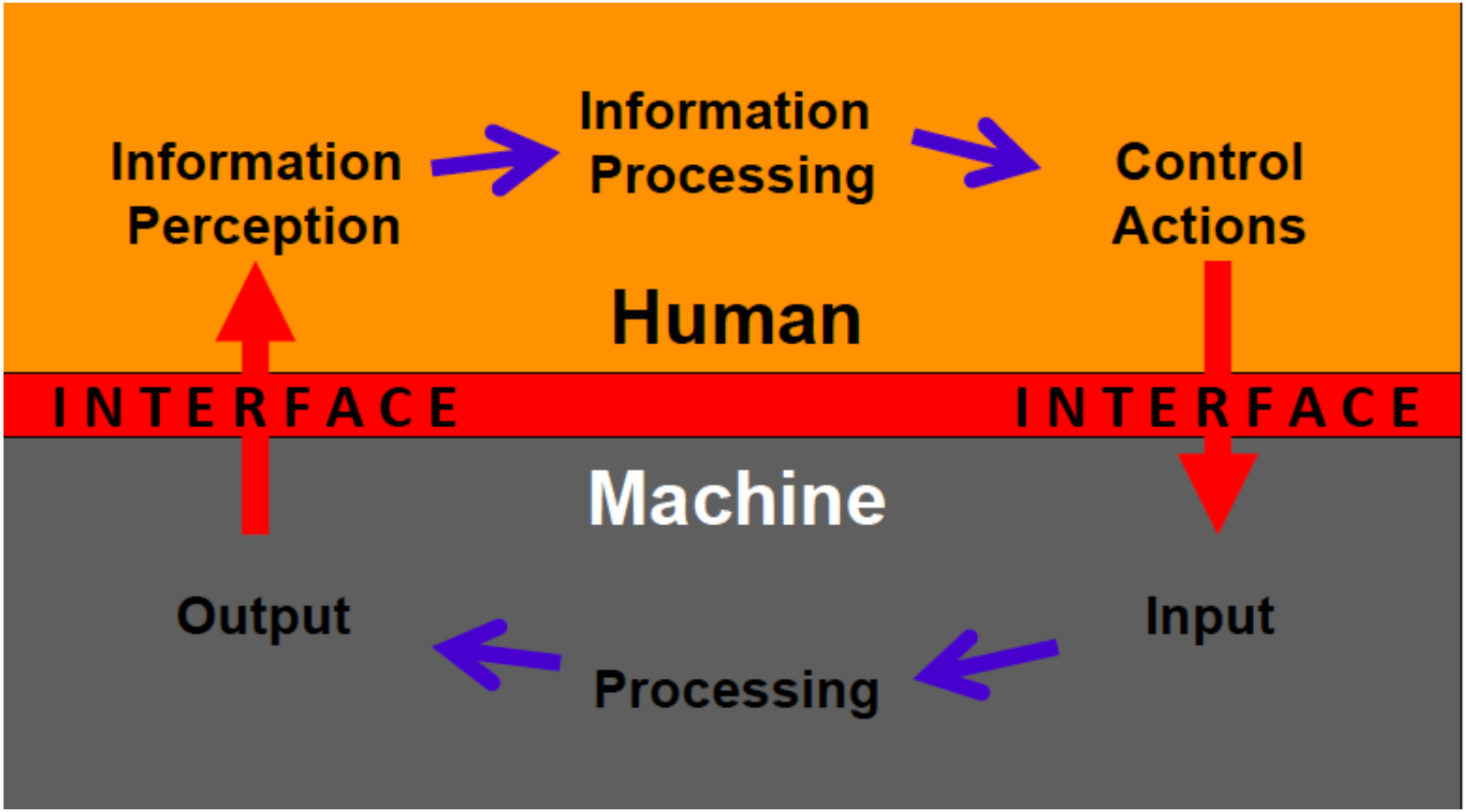
Central workstation (left) and intensive care unit bay (right)

Human- machine interface



User interface

FDA guideline 3.12

- All points of interaction between user and device
  - including all elements of the device with which the user interacts (see, hear, touch).
- All sources of information transmitted by the device
  - including packaging, labeling
- All physical controls and display elements
  - including alarms

Interface description

- **Tasks**
  - Device set-up: installation, assembly, calibration, etc.
  - Device use: various aspects
  - Device cleaning, maintenance, disposal, etc.
- **Interactions**
  - Input: Connections, knobs/dials, switches, buttons, touch screens, etc.
- Output
  - Visual: component status, displays, lights, etc.
  - Auditory: motors/fans, clicks, alerts/alarms, beeps, voice, etc.
  - Tactile: resistance, vibration, temperature, etc.

User interface: general considerations

- the “look and feel” logical and intuitive
  - More effective than labeling or training
- information display and control actions consistent with expectations
- Kind of interaction:
  - knob, handle,
  - keyboard, mouse, stylus, touchscreen;
  - future devices might be controlled through other means, such as by gesture, eye gaze

User interface: HW examples

- The size and shape of the device
  - hand-held and wearable devices
- Components that the operator connects, positions, configures or manipulates,
- Components or accessories that are applied or connected to the patient
- Packaging
- Labeling, including operating instructions, training materials, and other materials.


IBP
C.O.
SpO2
T1
ECG
NIBP
Masimo SET


400


0
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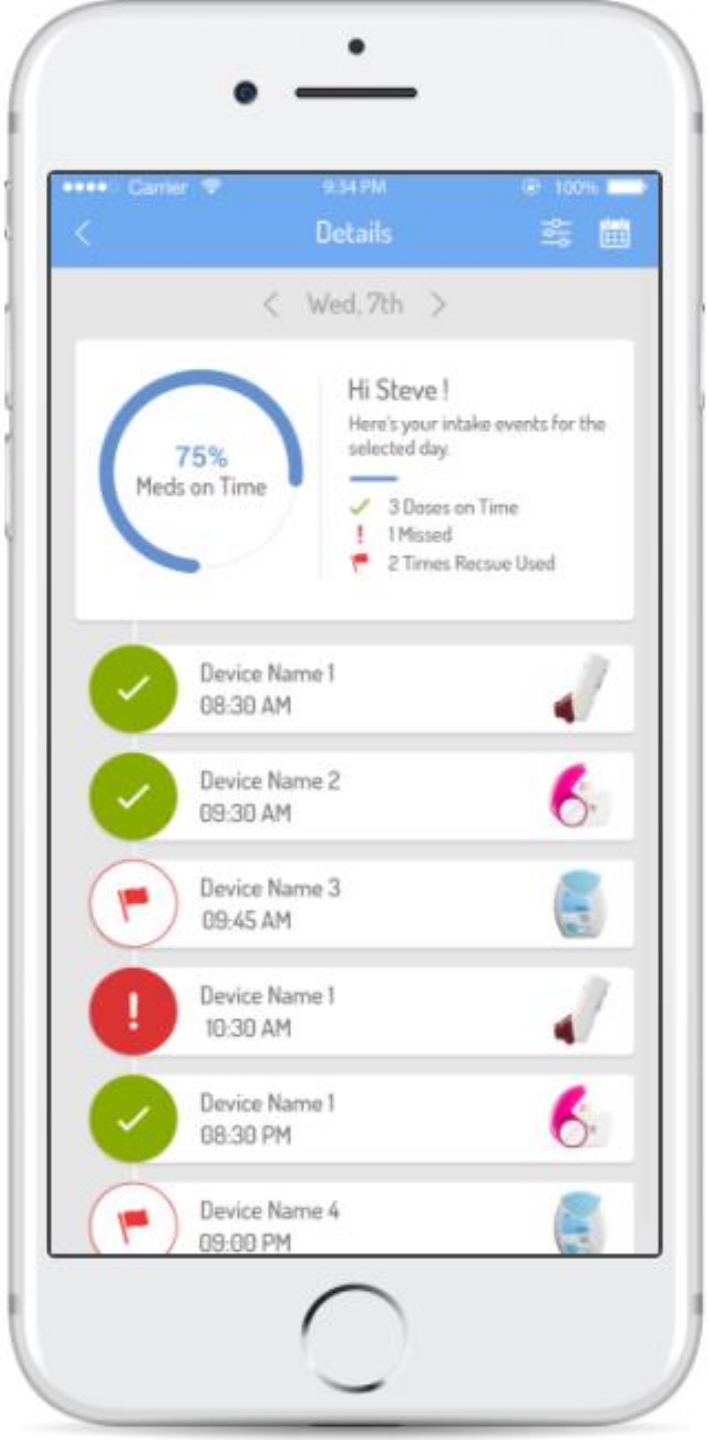
ORVALL RC 12BP
4700 RPM MAX

User interface: SW examples

- Elements that provide information to the user
  - indicator lights, displays, alarms,
- Graphic user interfaces of device software systems,
- The logic of overall user-system interaction, including how, when, and in what form information (i.e., feedback) is provided to the user


Carrier
4:34 PM
100%
SIGN UP
amiko
Weight (kg)
Height (cm)
Birth Date (Optional)
Gender (Optional)
Male
Female
Why do we ask your gender and age?
Terms & Conditions
Sign Up
Already have an account ?


Carrier
9:34 PM
100%
Details
Wed, 7th
75%
Meds on Time
Hi Steve !
Here's your intake events for the selected day.
3 Doses on Time
1 Missed
2 Times Recsue Used
Device Name 1
08:30 AM
Device Name 2
09:30 AM
Device Name 3
09:45 AM
Device Name 1
10:30 AM
Device Name 1
08:30 PM
Device Name 4
09:00 PM

PRIMARY OPERATING FUNCTION

IEC 62366-1 3.11

- function that is directly related to the SAFETY of the MEDICAL DEVICE
  - setting alarm–related USER controls;
  - setting of parameters
  - components that have to assembled;
  - Connections
  - MEDICAL DEVICE controls that the USER has to understand
  - series of display screens that the USER has to navigate through;
  - MEDICAL DEVICE operating PROCEDURES that the USER has to learn

Examples of hazardous situations
FDA guideline

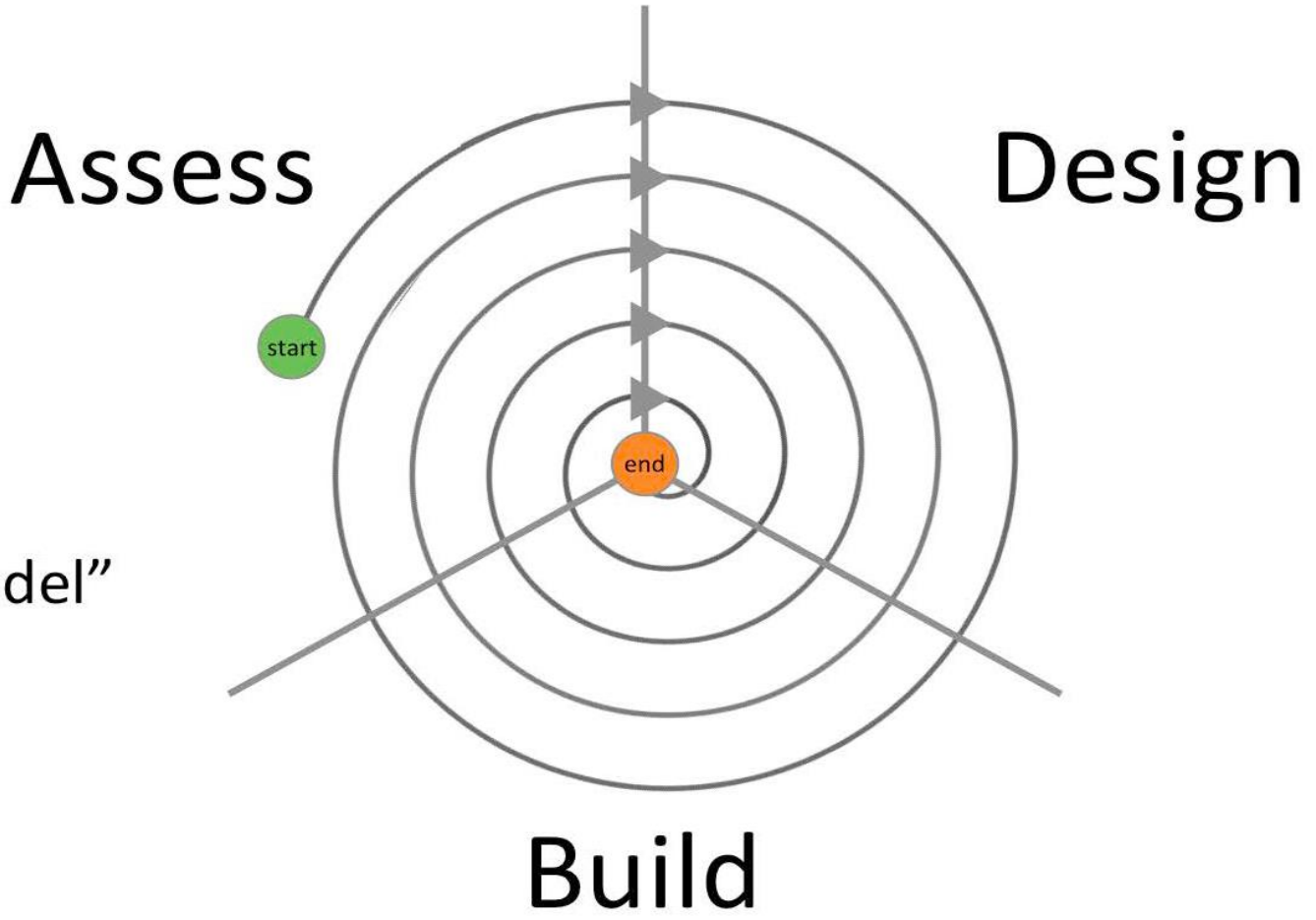
- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;
- Device use is inconsistent with the user's expectations or intuition about device operation;
- The use environment affects operation of the device and this effect is not recognized or understood by the user;
- The particular use environment impairs the user's physical, perceptual, or cognitive capabilities when using the device;

Inducing factors

IEC 62366-2 clause 6.5.1

- External
  - environmental distractions; inattention; excessive workload; fatigue;
  - working at a fast pace;
  - TASK interruptions
- Personal
  - insufficient experience, insufficient training;
  - Overconfidence
  - lack of familiarity with terminology; lack of fluency in the language
  - misapplication of experience using other existing MEDICAL DEVICES (i.e. negative transfer of learning
- USER impairments
  - vision, hearing, body movement, cognition

Design for Usability



he “Spiral Model”

FORMATIVE EVALUATION
IEC 62366-1 clause 3.7

- USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS
  - generally performed iteratively throughout the design and development
  - prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary

Function analysis
IEC 62366-2 clause 9.3

- identify those functions a MEDICAL DEVICE should perform automatically or semi-automatically
- identify functions to be performed by the USER
- including PRIMARY OPERATING FUNCTIONS listed in applicable product standards
  - Manual
  - Automatic

How to

- Identify functions
- Assign the functions to the MEDICAL DEVICE or the USER based on the known competencies of each

Is the machine better than the human?

Yes…

Humans do not excel in	Machines excel in
Force: Limited strength.	Great forces possible.
Endurance: Fatigues easily.	Does not fatigue easily.
Speed: Significant time needed for decision-making and movement.	High speed.
Accuracy: Unreliable, makes constant and variable errors.	Great accuracy attainable.
Computing: Slow and error-prone.	Large short-term working memory.
Decision-making: Best strategy not always adapted; emotions interfere.	For narrow applications, superior long-term memory.
Information processing: Basically a single-channel processor that is easily overloaded; performance greatly dependent on motivation.	Complex problems can be handled deductively.
Limited short-term working memory; long-term memory, although large, has unreliable and slow access.	Excellent for repetitive work; unaffected by emotions and motivational needs.
	Can perform simultaneous operations easily.

…and no

Humans excel in	Machines do not excel in
Visual acuity and range very good.	
Visual information processing system extremely logical and flexible.	Need to be monitored.
Range of detection extremely wide with good sensitivity for audition and vision.	
Perception: Ability to make order out of complex situations; detection possible under high noise.	Decision-making limited.
Can reason inductively; can follow up intuition.	Inductive reasoning not possible.
Very flexible; can easily change rules of operation with changes in situation.	All activities need to be planned and pre-programmed thoroughly.
Attention is easily shifted; only essential information can be selected for processing.	
When highly motivated, can perform under adverse conditions with parts out of order (injuries).	Needs to get careful maintenance. Might not operate at all, if some parts are broken.

Planning FE

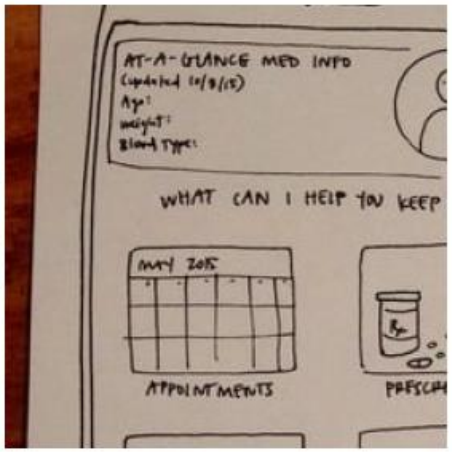
- Simple mock-up devices, preliminary prototypes or more advanced prototypes as the design evolves.
- May be tailored to focus on specific accessories or elements of the user interface or on certain aspects of the use environment or specific sub-groups of users
- Iterative evaluation of Design modifications

Credits:

http://www.jessaminebartleymatthews.com/zompopo/

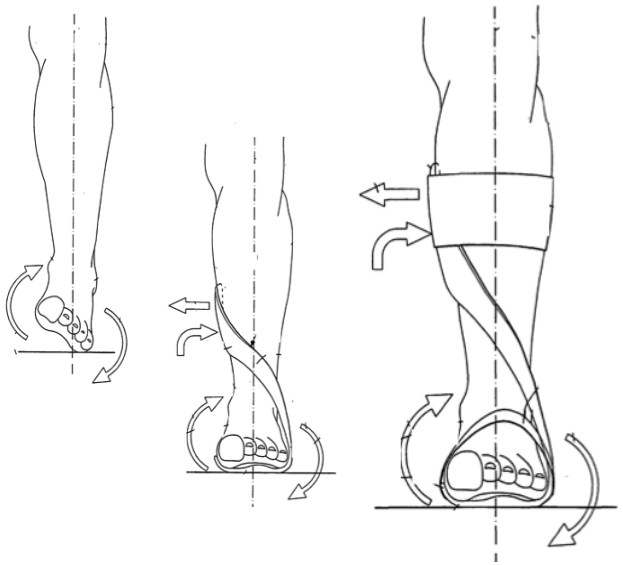
WIREFRAMES:

Taking the team's research into consideration, I sketched wireframes for a card-like design that incorporated all desired features into a cheerful and user-friendly interface. For added security, we decided to implement a fingerprint recognition mechanism to be sure that a user's personal medical information stays private.

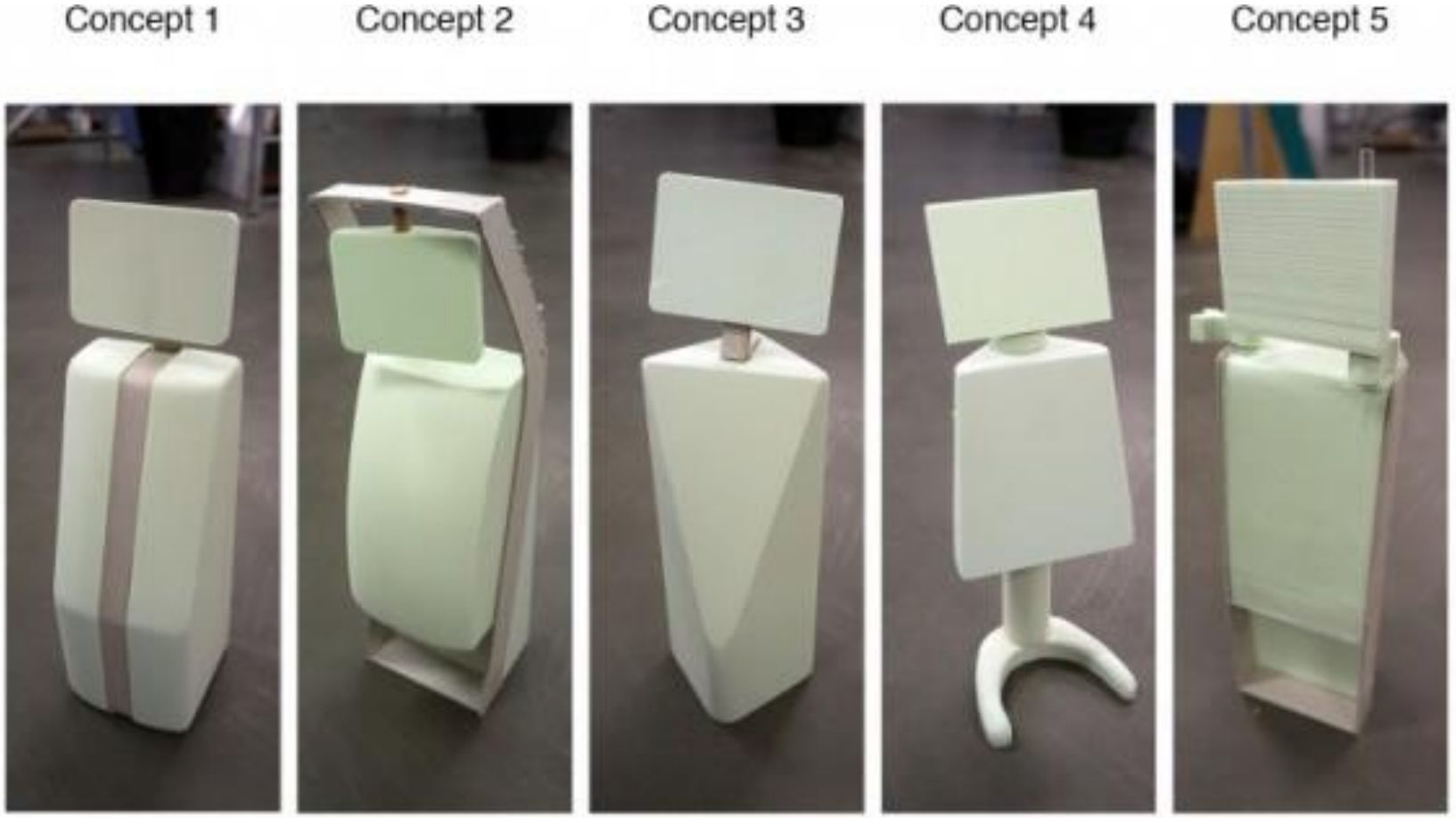


concept sketches

- beneficial to generate multiple hardware design sketches or 3-D prototypes
- obtain USER feedback on them



From the web: dialysis machine



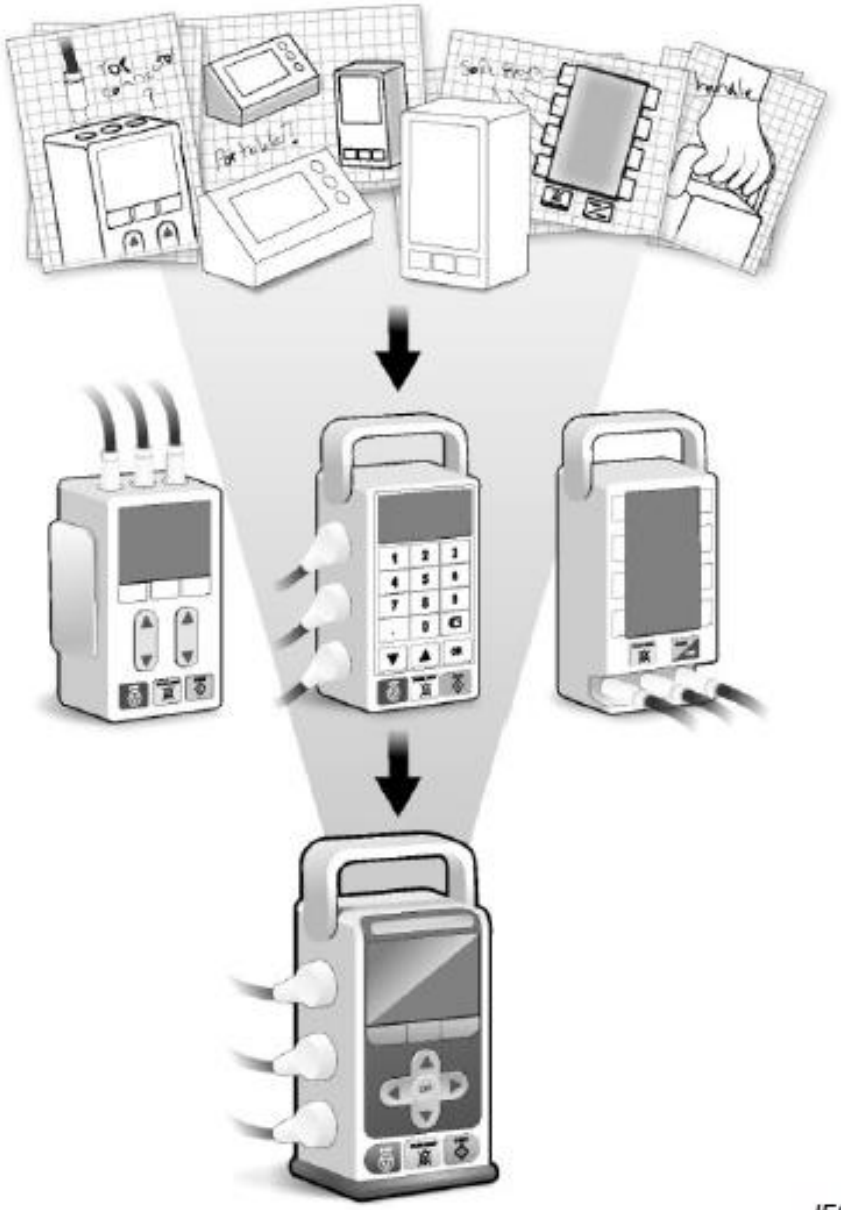


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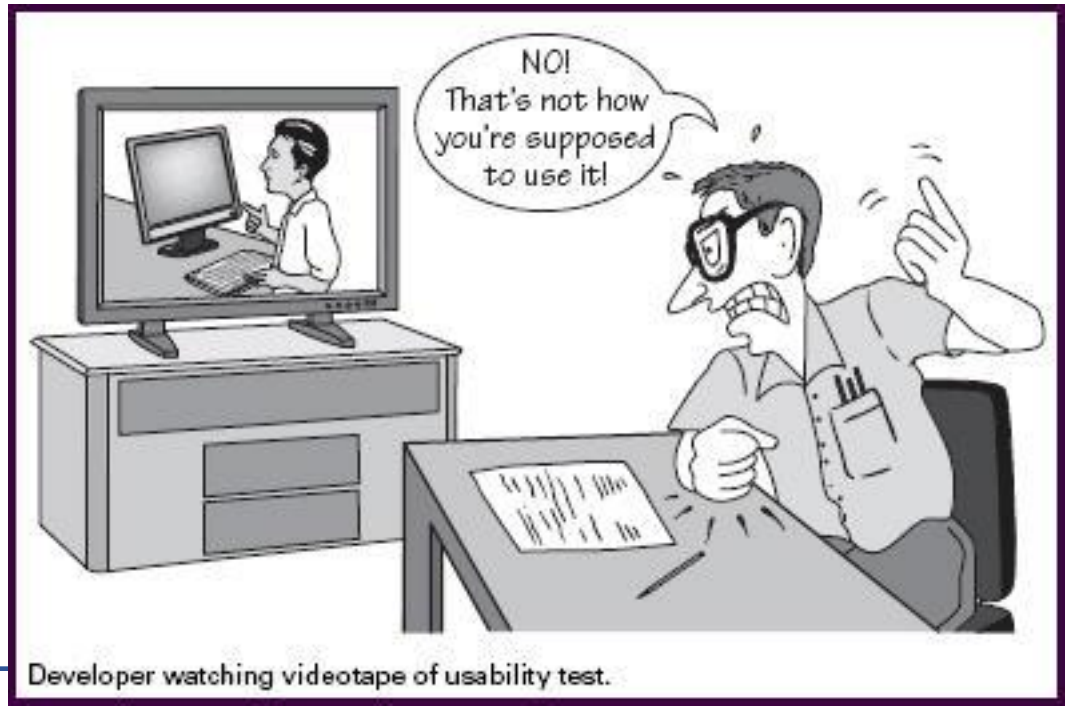
Figure 3 – Progression of concepts from multiple concepts to a few concepts to a preferred concept

Usability tests

- - **real** users, doing **real** tasks
- - observed, not guided



Developer watching videotape of usability test.

Usability tests

- observing USERS while they perform TASKS with the MEDICAL DEVICE
  - recruiting USERS of a specific USER GROUP
  - asking those USERS to complete a set of TASKS .
  - test moderator follows a test script
- simulated-use conditions
  - Group of USERS performing specific TASKS of interest

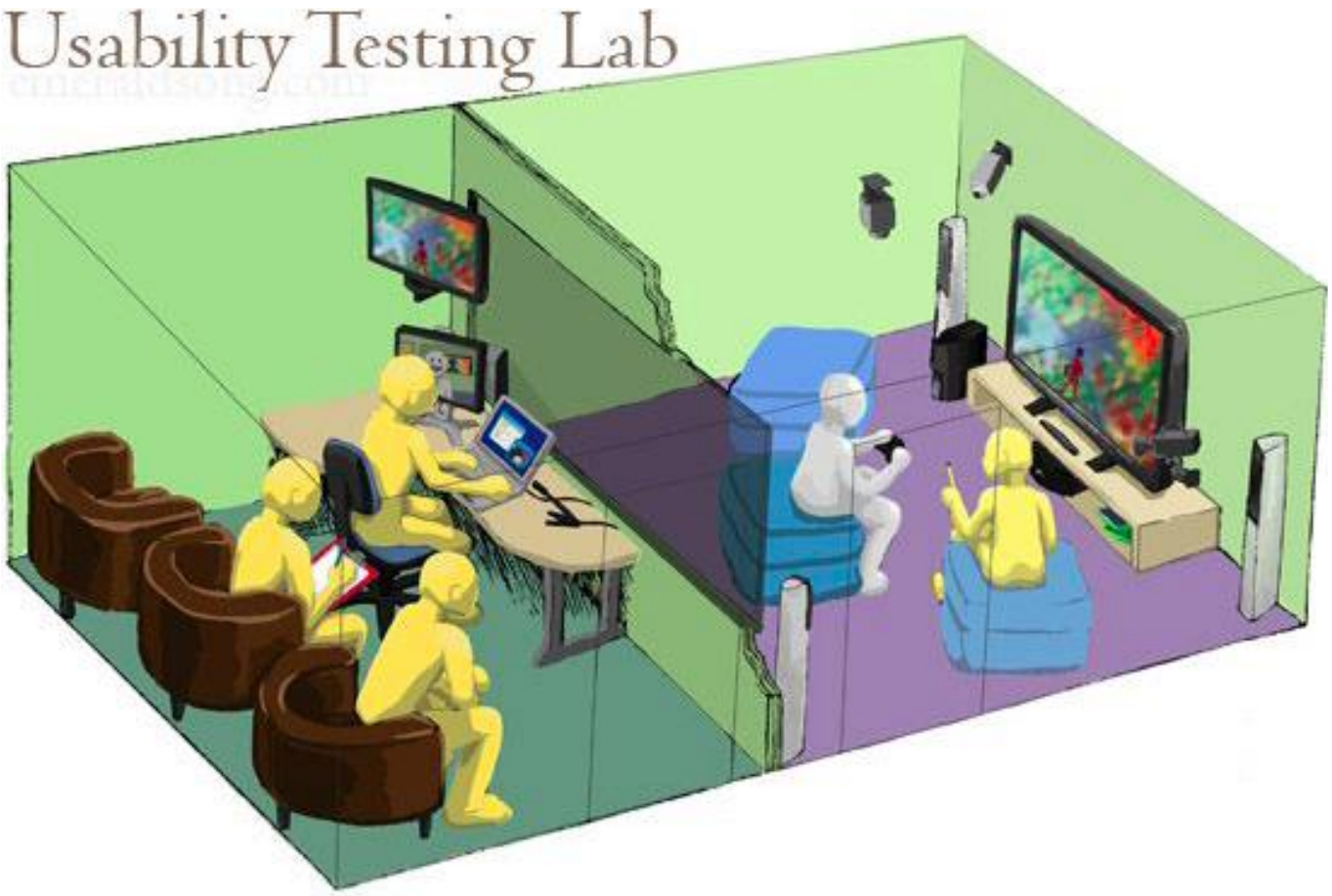
Different user groups
IEC 62366-2 annex L

- a sample of representative USERS
- include all intended USER groups
- Differentiate
  - the intended USERS ’ occupational backgrounds, expected knowledge and skill levels
  - MEDICAL DEVICE use patterns

Examples

- 1 USER GROUP: trained physicians;
- 2 USER GROUPS: trained nurses, untrained nurses;
- 3 USER GROUPS: asymptomatic adults, symptomatic adults, lay caregivers;
- 4 USER GROUPS: physicians, nurses working in high acuity settings (e.g. intensive care units), nurses working in low-acuity settings (e.g. medical/surgical units), PATIENTS;
- 5 USER GROUPS: child, adolescent, adult, elderly, healthcare professional (PATIENT educator)
- 6 USER GROUPS: adults with no impairments, adults with visual impairments, adults with hearing impairments, adults with dexterity impairments, adults with mild cognitive impairments, lay caregivers

Example setting



Other sources of data: Observational

Objective, no interaction

Other sources of data: knowledge task

- Objective, interaction

Other sources of data: interview

Subjective, interaction

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