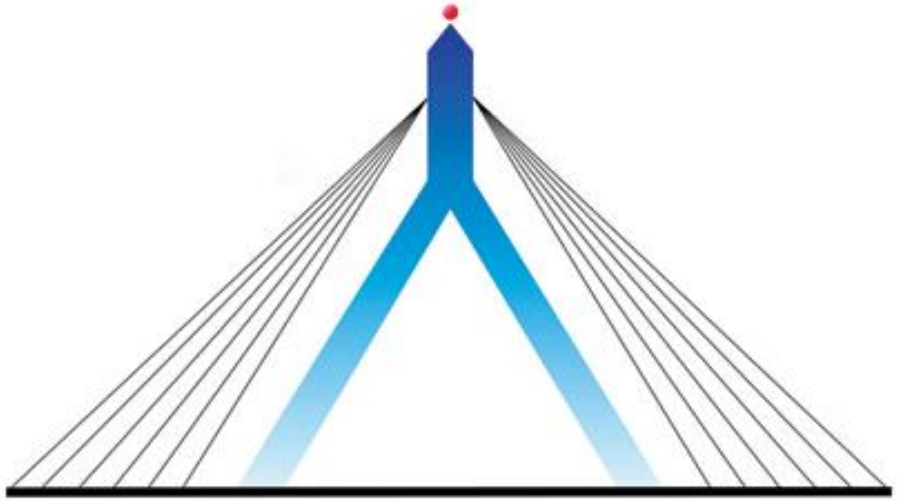


BOSTONCHI

A Research and Design Community
Making Technology Work for People

Welcome!

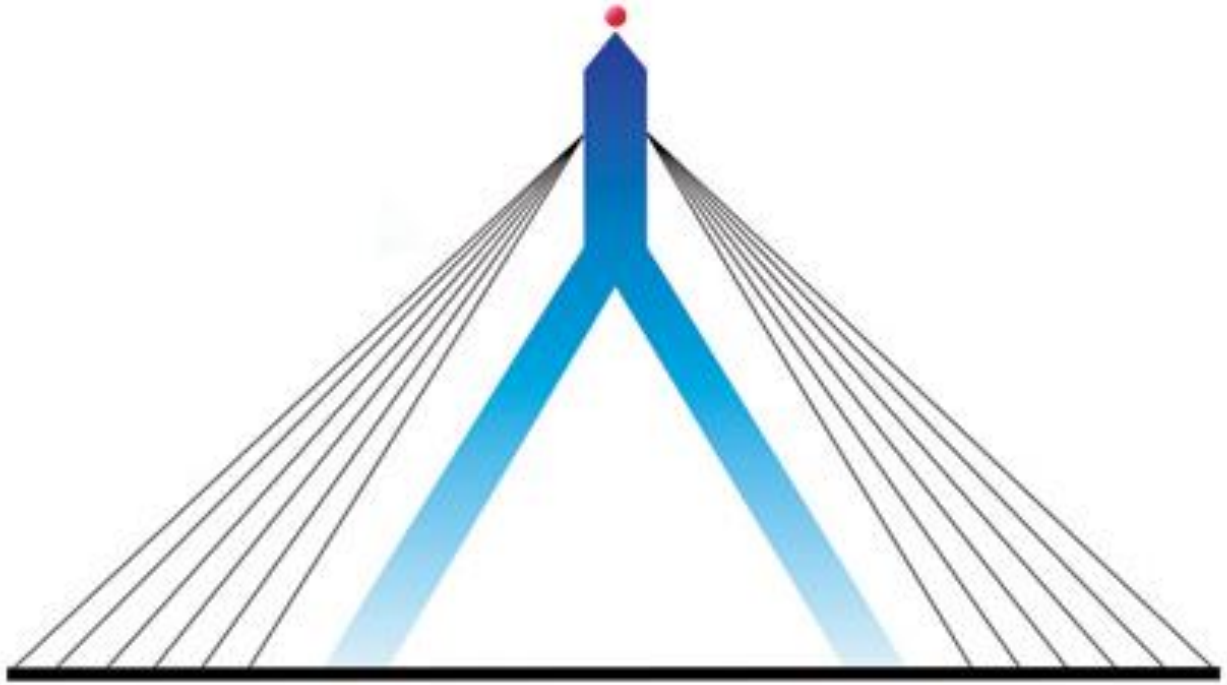
November 10, 2015

Tonight's Guest Speakers

Michael Wiklund
Jon Tilliss
UL-Wiklund

Applying Human Factors in Medical Software Development

#bostonchi



BOSTONCHI

A Research and Design Community
Making Technology Work for People

Applying Human Factors in Medical Software Development

Michael Wiklund
General Manager, Human Factors Engineering

Jon Tilliss
Design Director, Human Factors Engineering

UL–Wiklund
Underwriters Laboratories' Human Factors Engineering Practice

Presenter

Michael Wiklund, MS, PE, CHFP

General Manager – Human Factors Engineering, UL–Wiklund

Certified Human Factors Professional

Professor of the Practice, Tufts University

Author/Editor:

Medical Device Error – Root Cause Analysis (pending)
Usability Testing of Medical Devices (2nd edition pending)
Handbook of Human Factors in Medical Device Design
Designing Usability into Medical Products
Usability in Practice

Voting Member:

AAMI Human Factors Engineering Committee
IEC Human Factors Engineering Committee

Presenter

Jon Tilliss, MPS, CHFP

Design Director – Human Factors Engineering, UL–Wiklund

Certified Human Factors Professional

Lecturer, Tufts University

MPS, Information Design and Visualization, Northeastern University; BS Mechanical Engineering, Tufts University

Co-author:

Conducting Effective Summative Usability Tests of Medical Devices

Medical technology with software UIs

- Therapeutic devices
- Diagnostic devices
- Critical care devices
- Combination products
- Lab instruments
- Electronic health records
- Disease management applications
- Wellness applications

Medical device portfolio (subset)

Anesthesia workstation

Automated external defibrillator

Blood gas analyzer

Blood vessel imaging system

Cardiac ablation catheter

Cerebral oximeter

CPR assist device

Drug reconstitution system

Endoscopic instrument

Glucose meter

Heart pump

Hemodialysis machine

Hospital bed and scale

Hospital intercom

Infusion pump

Infusion set

Insulin pump

Left ventricular assist device

Microscope

MRI scanner

Nerve stimulator

Nurses' central monitor

OCT system

Patient monitor

Patient warmer

Peritoneal dialysis machine

Pill dispenser

Proton beam radiotherapy system

PSA analyzer

Pulse oximeter

Respiratory therapy system

Surgical robot

Surgical suction machine

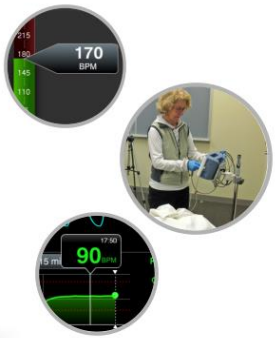
Syringe pump

Telemetry system

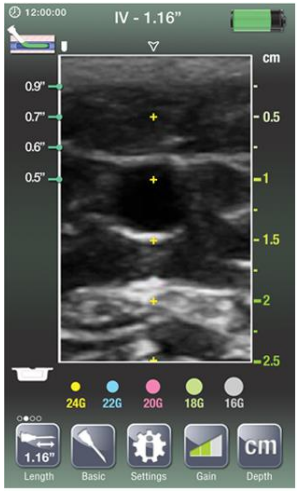
Ventilator

X-ray machine

Collaborations



Collaborations



Our business is human factors engineering (HFE)

We help clients ensure the quality of interaction between people and their devices / systems / machines.

- Safe
- Effective

} Regulatory imperative

- Efficient
- Satisfying

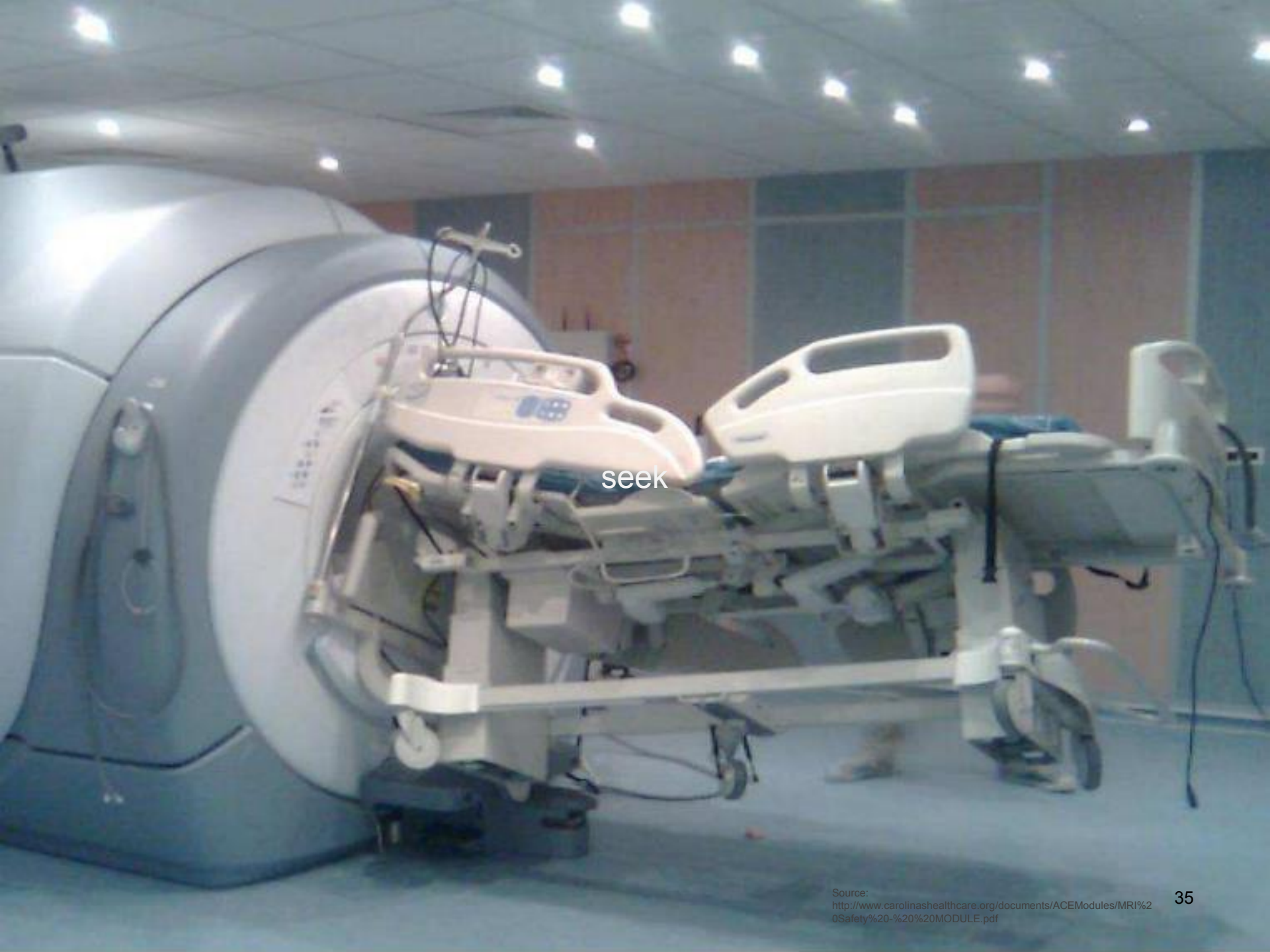
} Commercial imperative
(usability-related)

Regulators (e.g., FDA) seek to ensure the safety and efficacy of medical devices through the application of HFE.

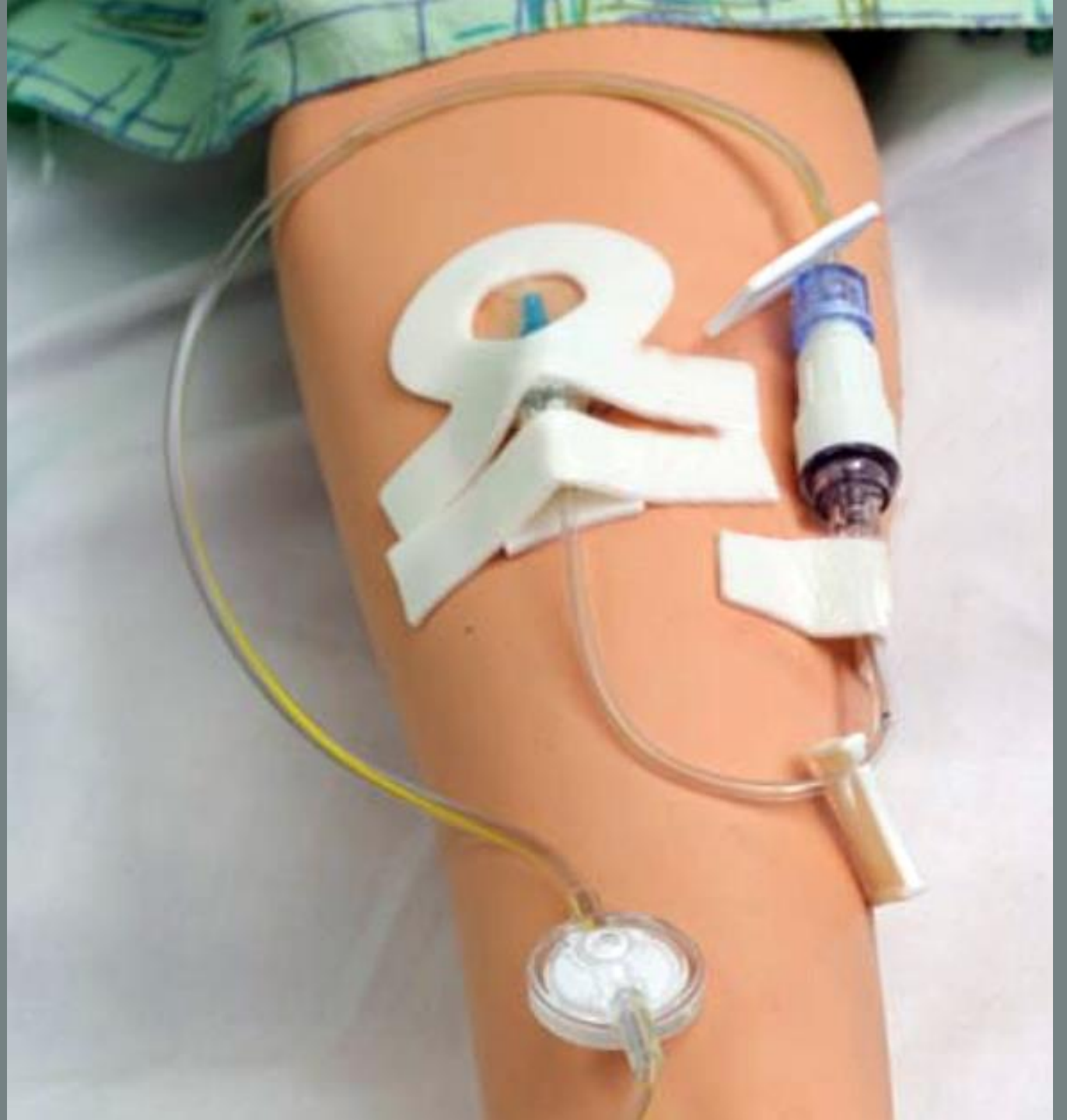
Source: http://betanews.com/wp-content/uploads/2014/07/Shattered-iPhone-5s.jpg

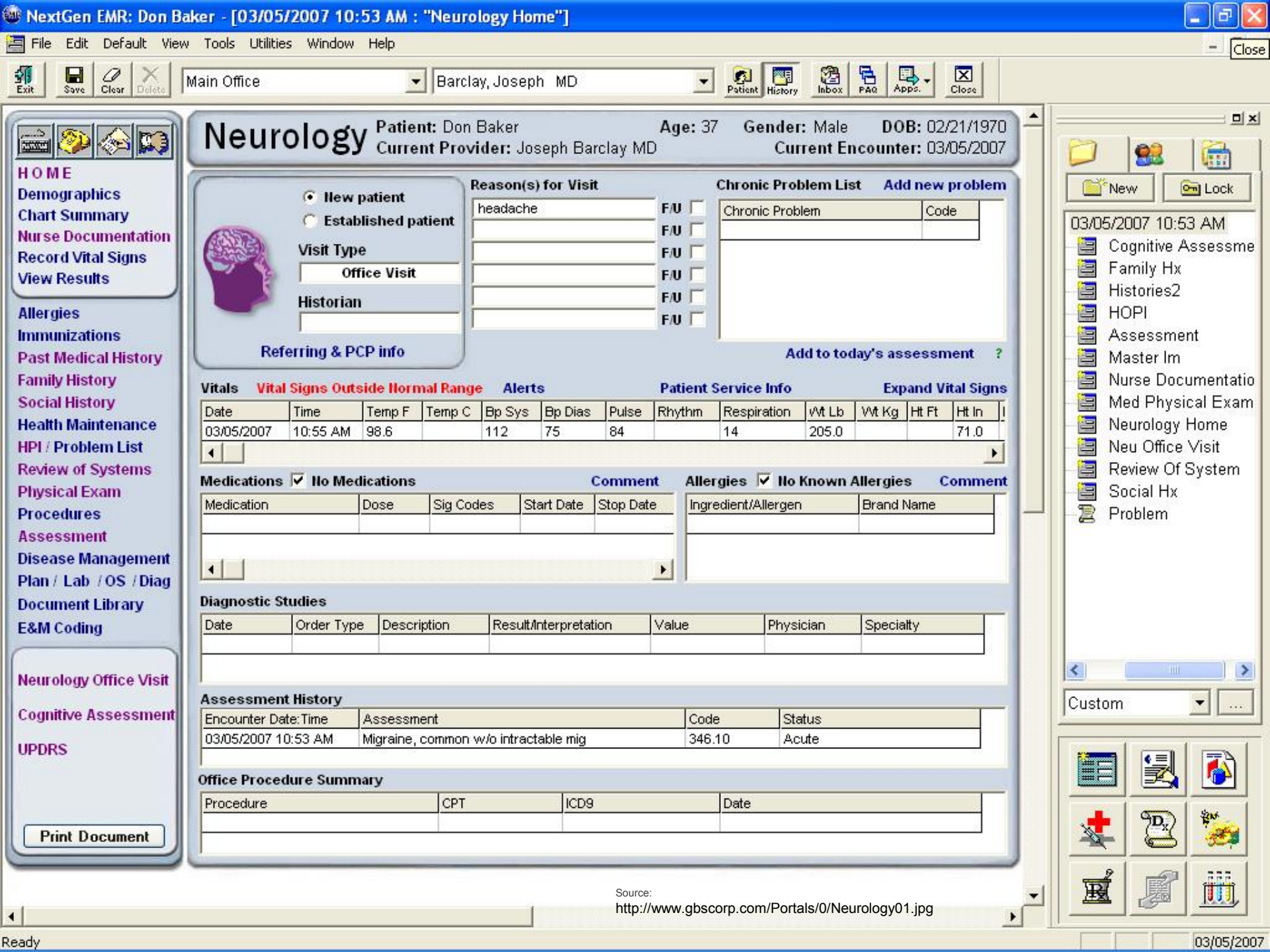
Source:
http://www.unionleader.com/storyimage/UL/20150130/NEWS07/150139918/AR/0/AR-150139918.jpg?q=100

Source:
https://upload.wikimedia.org/wikipedia/commons/f/f3/Melting_ice_cream_on_a_bridge.JPG



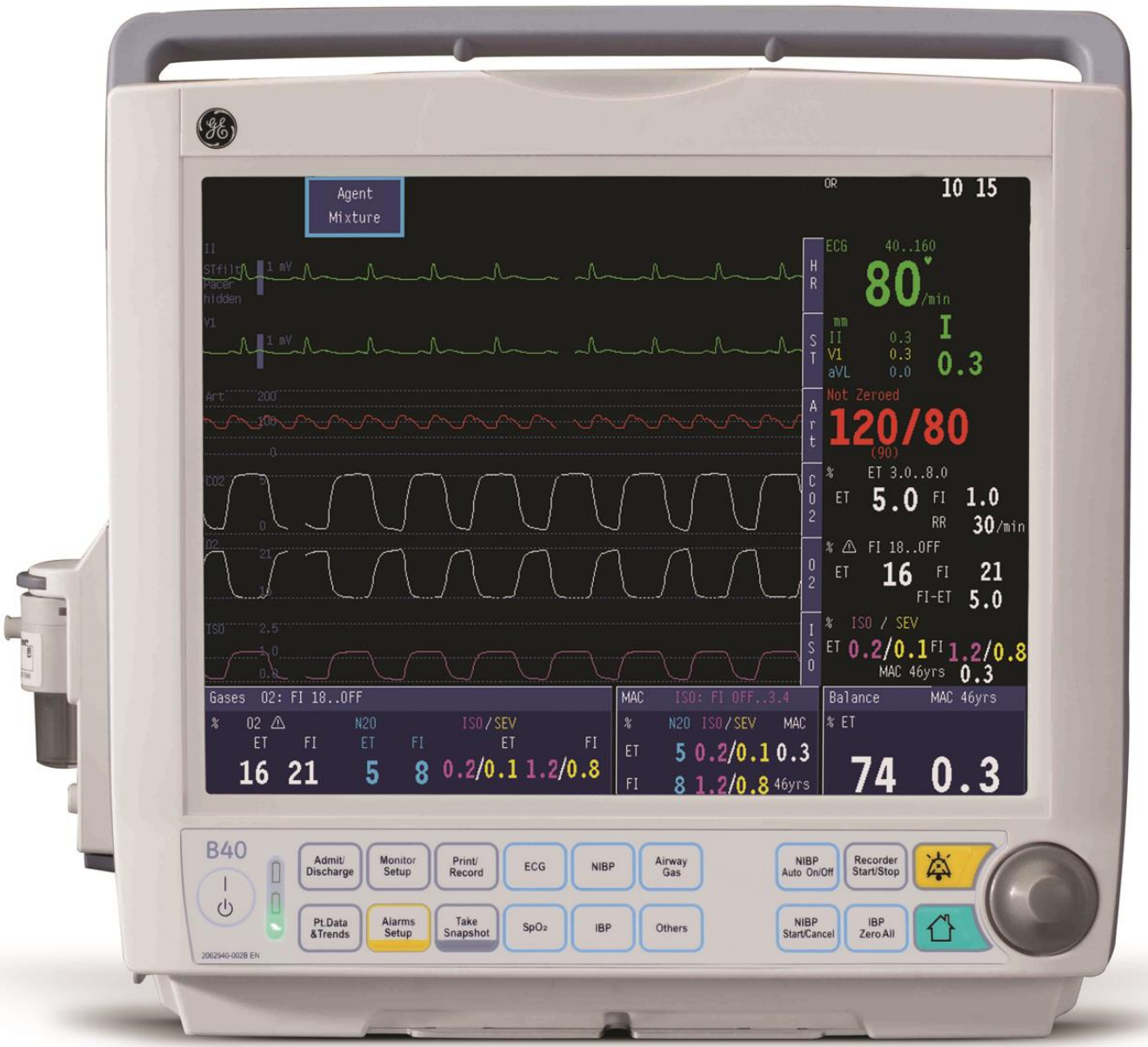
Source:
http://www.carolinashealthcare.org/documents/ACEModules/MRI%20Safety%20-%20%20MODULE.pdf





Source:
http://www.gbscorp.com/Portals/0/Neurology01.jpg

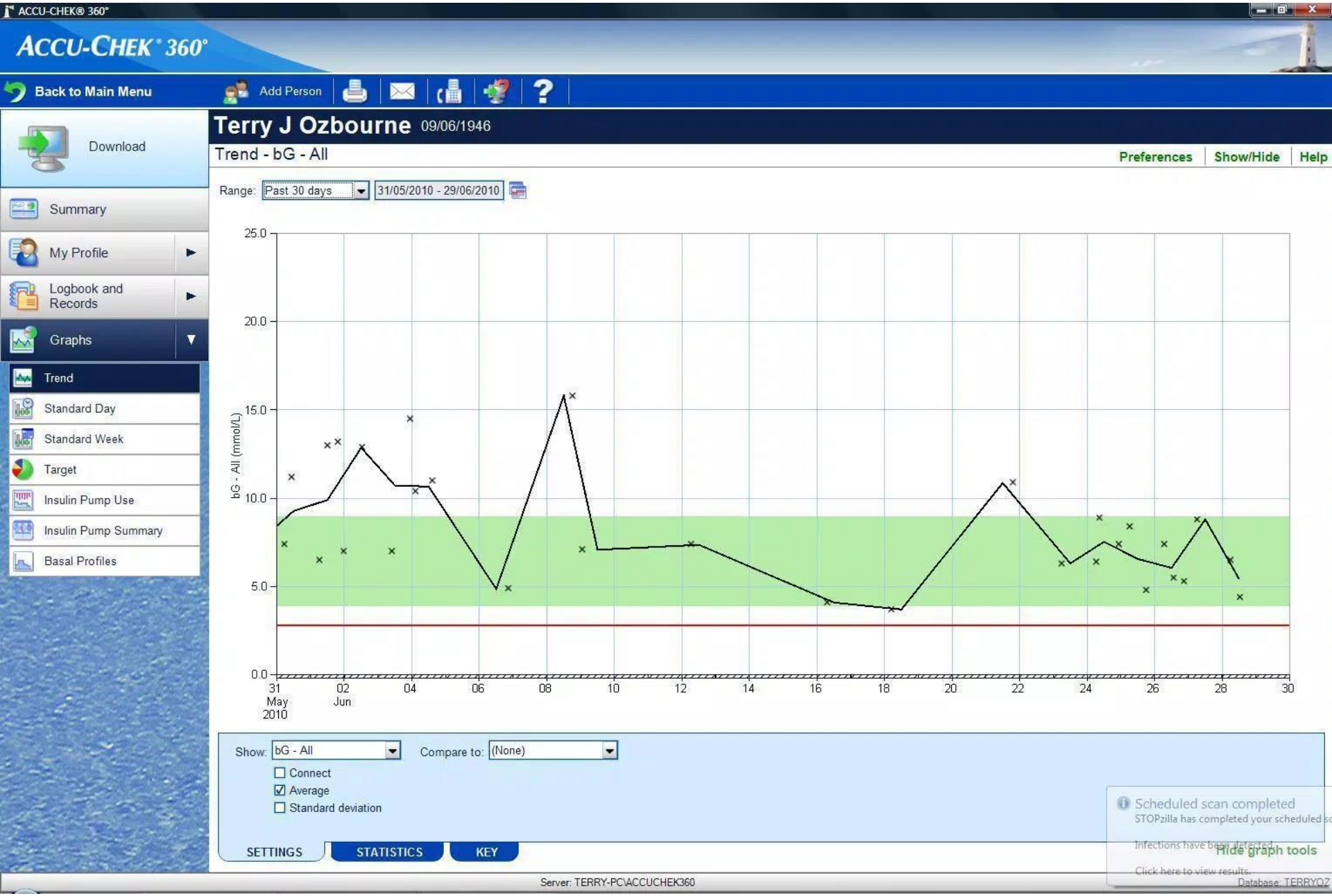
Source: http://icu.vch.ca/wp-content/uploads/sites/17/2014/06/IMG_0841



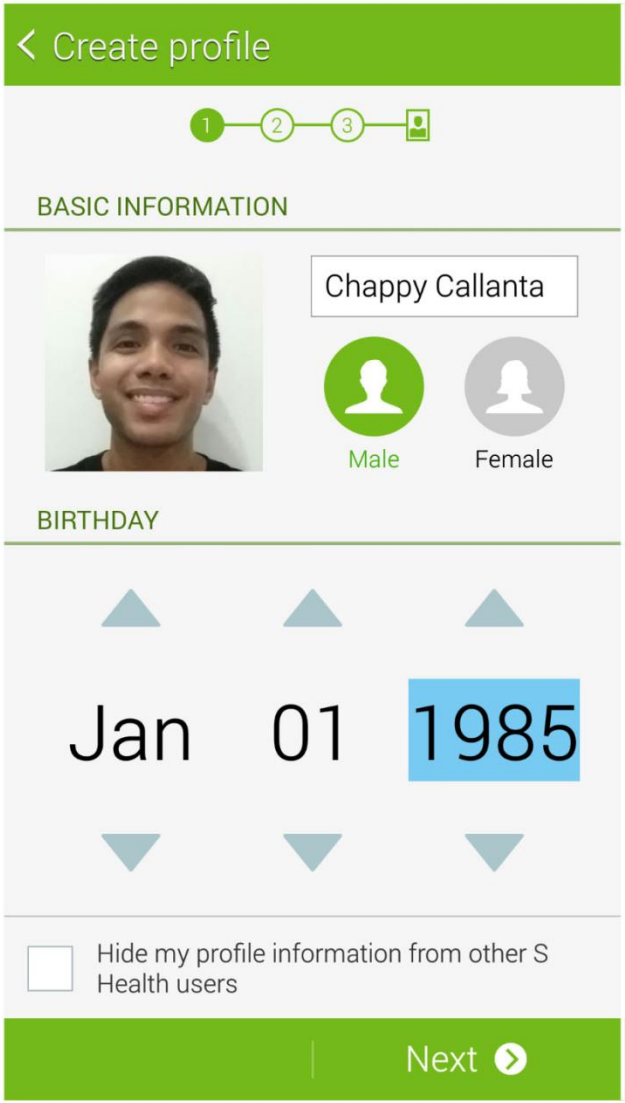
Source: http://www3.gehealthcare.com/~/media/images/product/product-categories/patient-monitoring/patient-monitors/b40%20patient%20monitors/gehc-b40-patient-monitors_overview.jpg?la=en

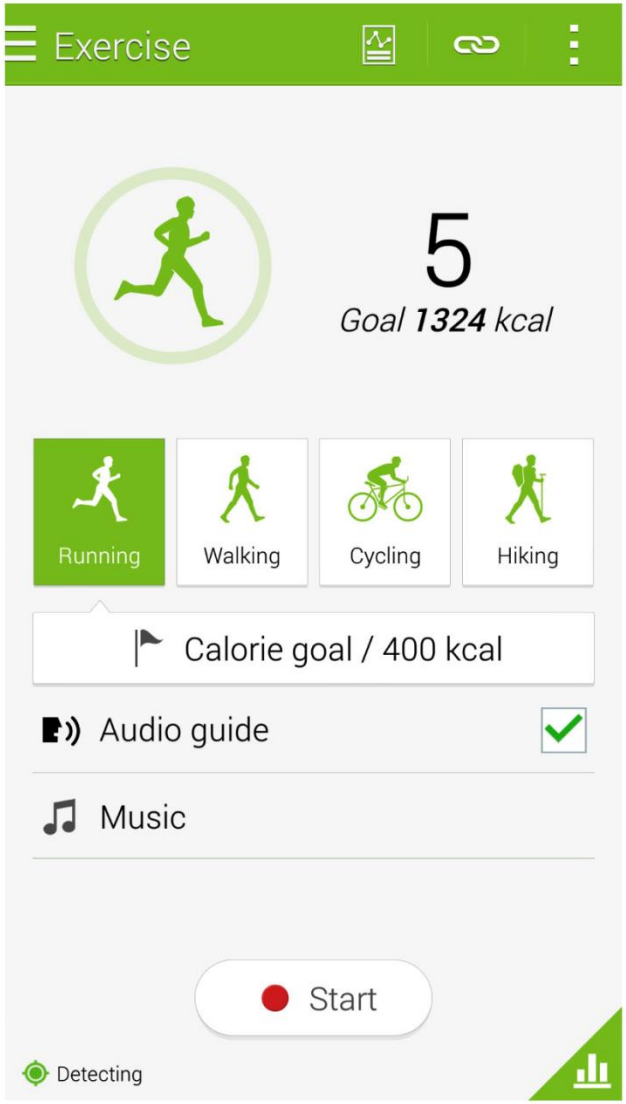
Source: http://4.bp.blogspot.com/-1Sy78VMvxyo/T4ceRh0oqGI/AAAAAAAAA_M/_ReN3gWGKkI/s1600/TSV_5938-773878.JPG

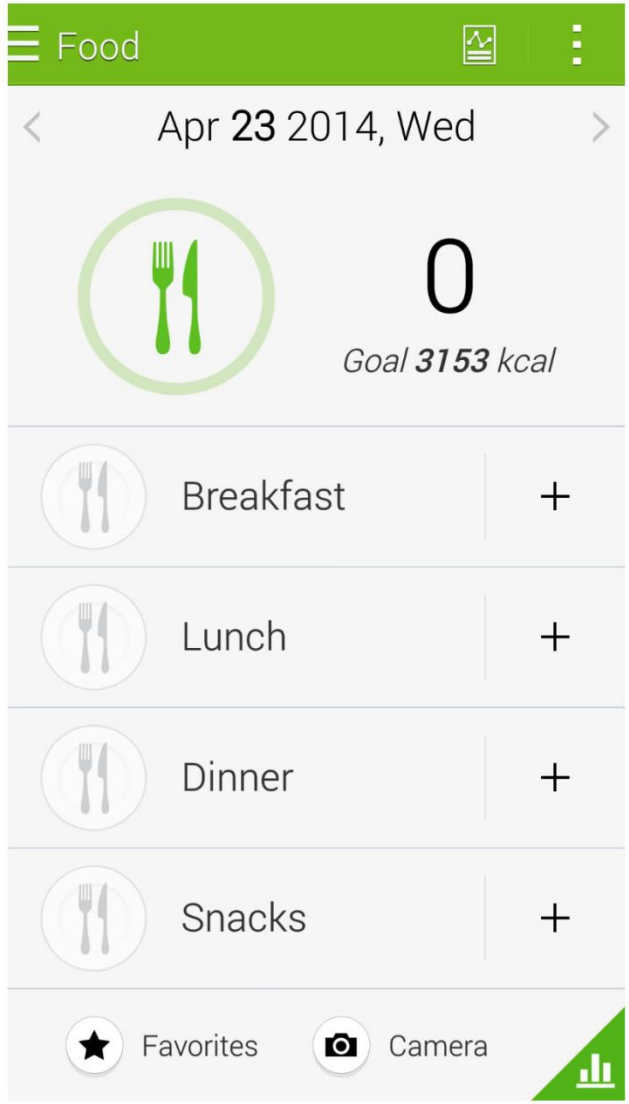
Source: http://asweetlife.org/wp-content/uploads/2015/05/Meter-Collage-3.jpg



Source: http://i0.wp.com/www.shootuporputup.co.uk/wp-content/uploads/2010/07/AC360-Graphs.jpg







Source: http://chappycallanta.com/wp-content/uploads/2014/04/s-health-1.jpg

Use error – a term of art

The term use error has been introduced to replace the commonly used terms human error and user error.

The term, which has already been adopted by international standards organizations for medical devices…suggests that accidents should be attributed to the circumstances, rather than to the human beings who happened to be there.

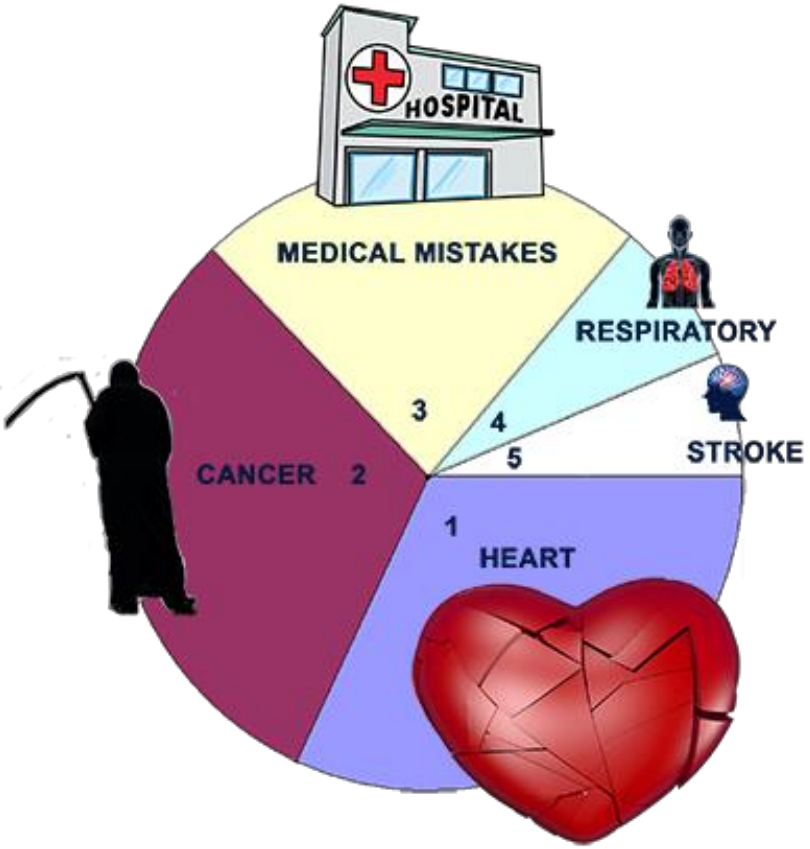
Source: Hyman, W. (1995, May) The Issue is 'Use,' Not 'User,' Error. Medical Device and Diagnostic Industry. Accessed from http://www.mddionline.com/article/issue-use-not-user-error

Use errors are deadly

Hospital Errors are the Third Leading Cause of Death in U.S., and New Hospital Safety Scores Show Improvements Are Too Slow

Washington, D.C., October 23, 2013 – New research estimates up to 440,000 Americans are dying annually from preventable hospital errors. This puts medical errors as the third leading cause of death in the United States, underscoring the need for patients to protect themselves and their families from harm, and for hospitals to make patient safety a priority.

Use errors are deadly



Source: http://www.encoreboomer.com/images/medical_mistakes_infographic.png

Let’s take a close look at the regulatory framework in the USA.

Quality System Regulation (the law)

Subpart C -- Design Controls, § 820.30 Design controls.

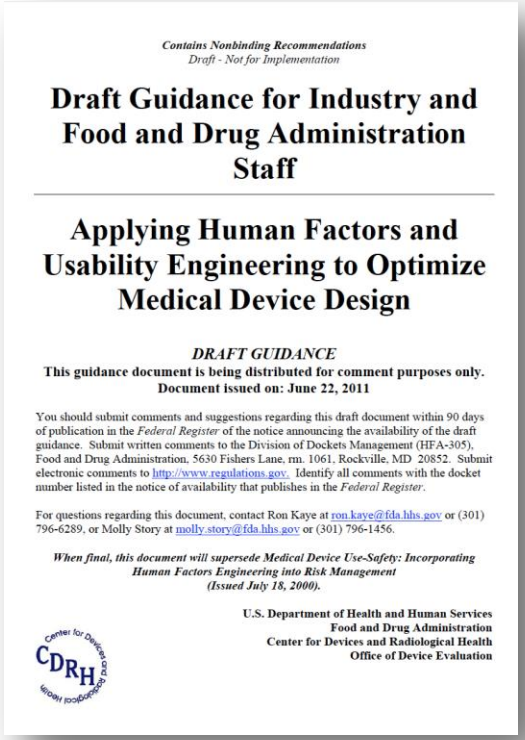
Design input: "Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and **address the intended use of the device, including the needs of the users and patient.”**

Design verification: "Each manufacturer shall establish and maintain procedures for verifying the design input. Design verification shall **confirm that the design output meets the design input requirements.”**

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.”

Key documents

FDA's Draft Guidance



Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

IEC 62366-1:2015

IEC ISO
IEC 62366-1
Edition 1.0 2015-02
INTERNATIONAL STANDARD

American National Standard
ANSI/AAMI/ IEC 62366-1:2015
Medical devices – Part 1: Application of usability engineering to medical devices
AAMI

AAMI HE75:2009

American National Standard
ANSI/AAMI HE75:2009
Human factors engineering - Design of medical devices
AAMI

Basic expectations

- Implement an HFE (Usability Engienering) program
- Define intended users, use environments, potential hazards, potential use errors, and use-related risks
- Mitigate use-related risk
- Validate user interface designs, proving risk control measures work
- Document HFE activities and outcomes

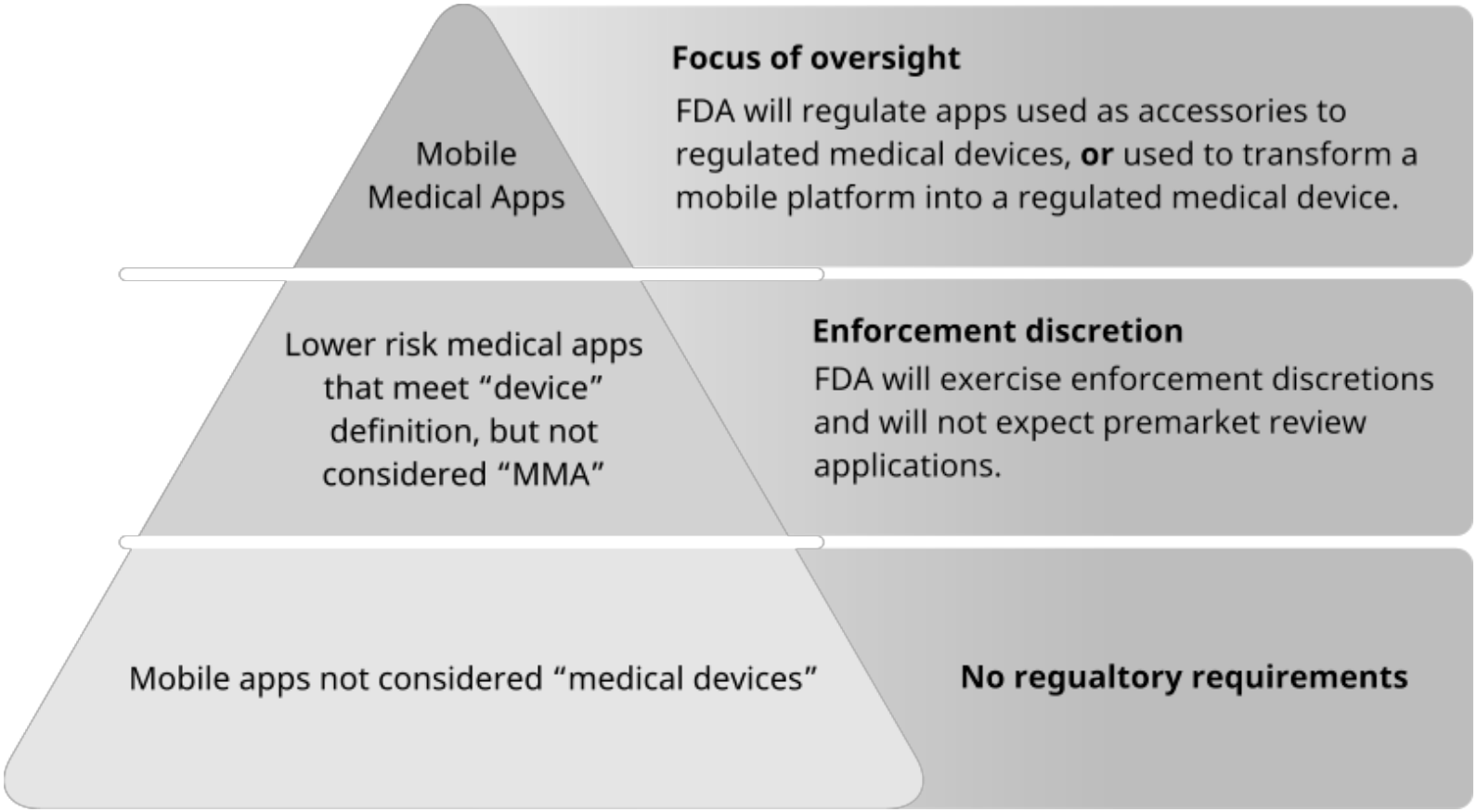
General applicability

- Software embedded into a device
- Software that provide information that is a foundation for making a diagnosis and/or therapeutic decision

- Wellness applications – FDA will exercise enforcement "discretion," meaning that they will not expect HFE data (i.e., no HFE Report, no summative usability testing

Medical Mobile App (MMA) Guidance

The FDA is taking a tailored, risk-based approach:



Adapted from: http://www.fda.gov/downloads/Training/CDRHLearn/UCM435363.pdf

MMA Definition (Feb 2015)

In a Feb 2015 webinar, FDA edited the MMA as follows:

Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or ~~displaying, storing,~~ analyzing~~, or transmitting patient-specific~~ medical device data.

Adapted from: http://www.fda.gov/downloads/Training/CDRHLearn/UCM435363.pdf

Mobile apps under enforcement discretion

Apps that:

- Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to healthcare providers;
- Automate simple tasks for health care providers;
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems;
- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG).

Adapted from: http://www.fda.gov/downloads/Training/CDRHLearn/UCM435363.pdf

Let’s look at the potential for use errors when using a glucose meter with a simple software user interface.

Opportunities for use errors

Perception Cognition Action

Samples

Perceptions

Reading information from a screen, including critical health parameter values.

Cognitive tasks

Recalling the correct assay run on a blood sample.

Actions

Press the correct touch target to start an infusion pump rather than turn off the device,

Sample task flow diagram – close-up

User inserts new test strip

User inserts test strip into meter's port.

Meter detects test strip

Meter detects test strip and prompts user to apply blood sample.

User applies sufficient blood sample

No

Yes

Meter displays glucose reading

Meter analyzes sample and displays glucose reading.

User selects "Re-test blood glucose"

Yes

No

User accepts result

User selects "Accept result" and the meter returns to the main menu.

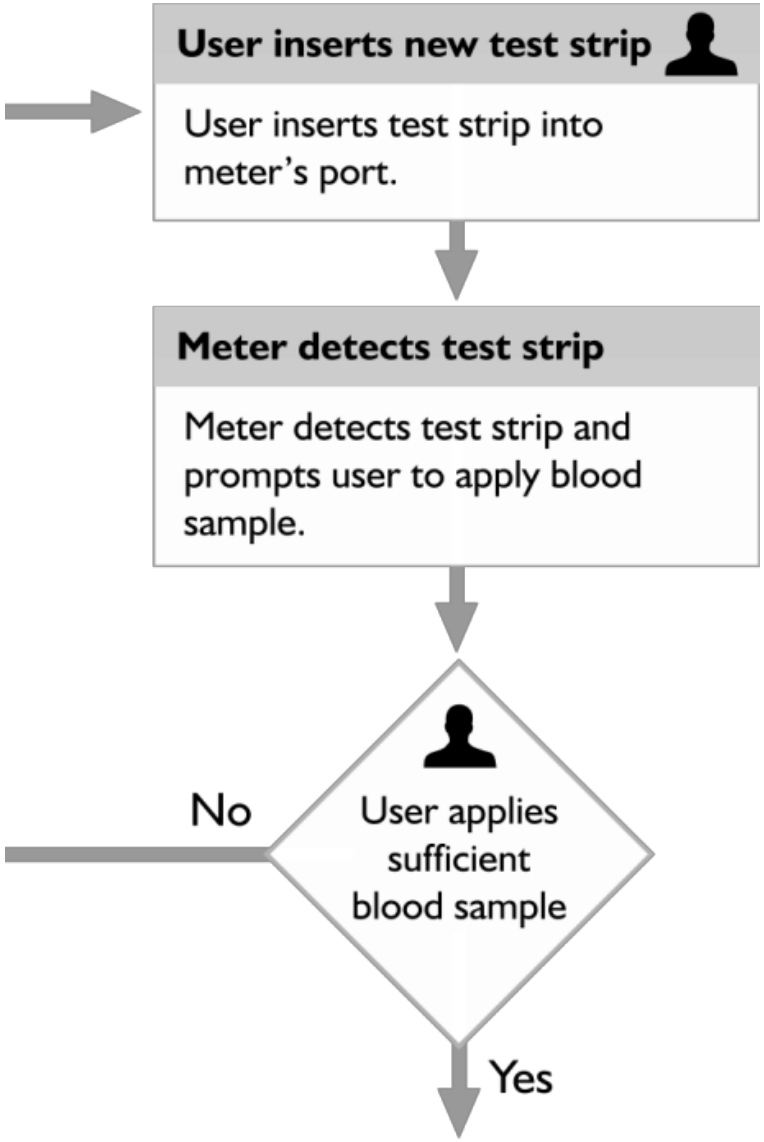
Meter prompts user insert new strip

Meter notifies user that sample is too small and prompts user to insert a new test strip.

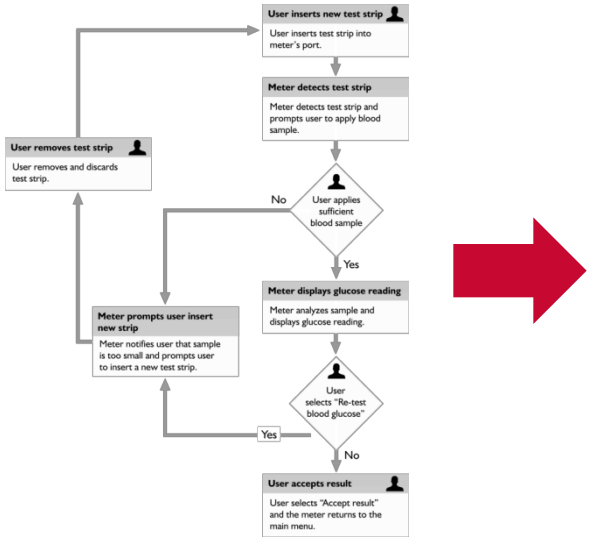
User removes test strip

User removes and discards test strip.

Sample task flow diagram – close-up



Use errors derived from task analysis



- User inserts **wrong test strip**
- User inserts test in **wrong orientation**
- User inserts test strip in **wrong port**
- User **damages test strip** during handling
- User **applies blood to wrong part** of strip
- User applies **too much blood** to strip
- User applies **too little blood** to strip
- User **does not select re-test** when prompted
- User **does not remove used strip** from meter
- User **misreads** the blood glucose readout

Common User Interface (UI) Issues

- UI complexity causes user confusion, delay in use, or inability to use the device
- UI makes it difficult for user to correct data entry errors or modify device settings in a timely fashion
- UI falsely causes the user to believe a critical situation exists when it does not, or vice-versa
- UI does not draw attention to dangerous conditions of device operation or patient status
- UI does not prevent known, likely data input errors

Source:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/UCM290561.pdf

Common software-related use errors

- User enters the incorrect value (double-press, missed decimal, misread value, wrong units)
- User overlooks critical alarm
- User misinterprets alarm, and takes incorrect action
- User select incorrect operational mode (or overlooks current mode)
- User does not know how to proceed, delaying therapy
- User does not realize therapy is paused

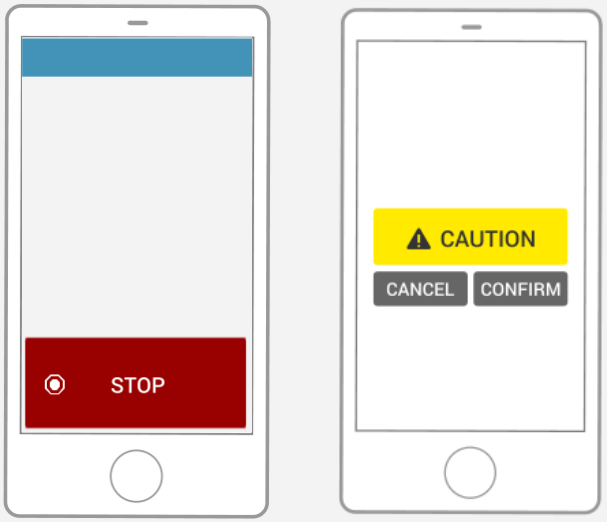
Top 5 ways to maximize use safety through user interface design

1. Provide helpful alarms and alerts

- Clearly indicate alarm cause, priority and severity.
- Provide succinct troubleshooting steps and provide more guidance “on demand.”
- Do not present too many alarms at once. Filter them so that users can develop an accurate picture of what’s happening.
- Write simple warnings and prompts (e.g., imperative voice) to facilitate a rapid response.

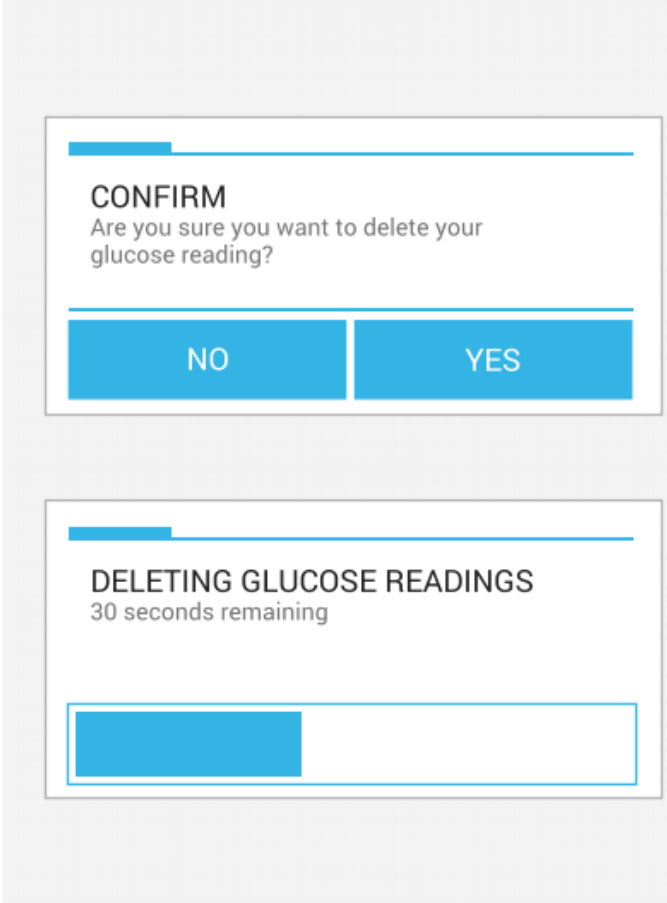
2. Enable rapid action

- Place controls and information that are essential to safe use in a convenient, readily accessible position.
- Touch targets should be sufficiently large to facilitate rapid, error-free inputs. When possible, touch targets should have a width and height of at least 40 mm.
- Ensure that the app or device responds immediately to critical control actions.
- Provide direct access to relevant controls directly from alarm and notification screens.
- On software screens, provide “back,” “cancel,” or “undo” options.



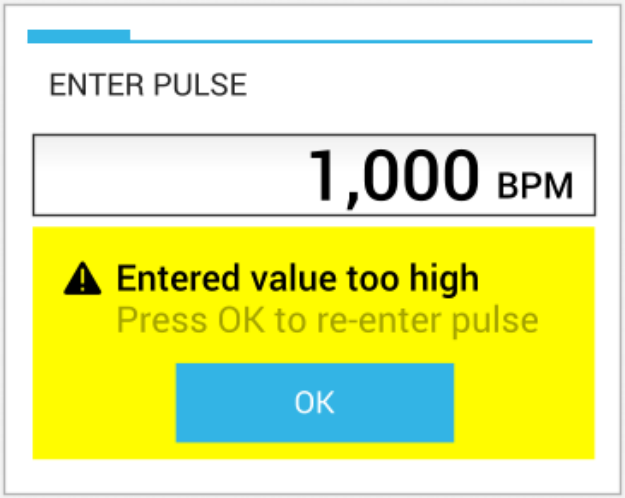
3. Confirm and monitor critical actions

- Require users to confirm critical actions.
- Notify users of the action's consequences.
- Inform users that a critical action is in progress.
- Inform users how long critical actions will take to complete.
- Indicate when critical actions are completed.



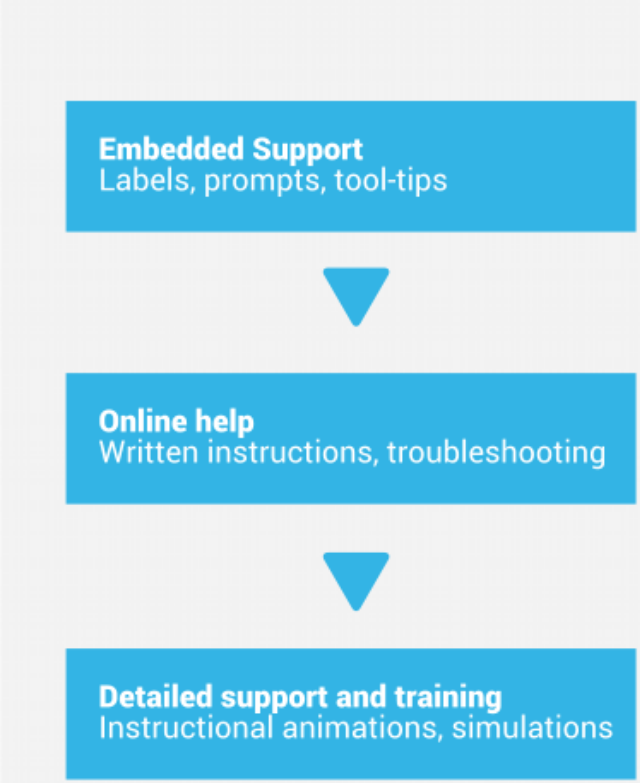
4. Incorporate automatic checks

- Automatically check entered values to ensure they are within a pre-established, safe range.
- If users enter invalid values, provide guidance on acceptable value ranges.
- Prevent “workarounds” that enable users to operate the app or device in unapproved ways.



5. Provide progressive levels of user guidance

- Offer unobtrusive, basic assistance to all users, in the form of labels, prompts, and tool-tips.
- Add headings to each screen to increase user's situational awareness of a medical device's status and the user's progress while completing a given task.
- Enable "needy" users to access more assistance upon request.
- Guide users through lengthy tasks (e.g., setting up a device) rather than relying on users to remember each step and perform each step in the correct order.



Fundamental design principles related to safety

- Functional grouping
- Information legibility
- Limit complexity
- Moderate information density
- Logical ordering and visual hierarchy
- Alignment
- Consistent spacing and sizing
- Information coding

General principle

- Think of the user experience as a conversation between the user and the product.

- Devices and apps should behave as helpful assistants. Specifically, they should:

    - Speak the same language as the user.
    - Speak at an appropriate pace.
    - Do as they are told.
    - Convey what they are doing.
    - Identify potential problems without becoming a nuisance.
    - Occasionally be stern.

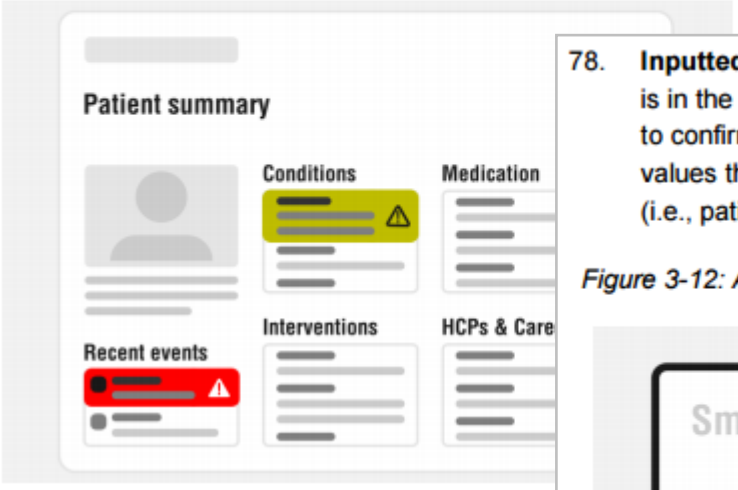
Example: Patient monitor

We can apply similar principles to EHRs

* 343 to be exact

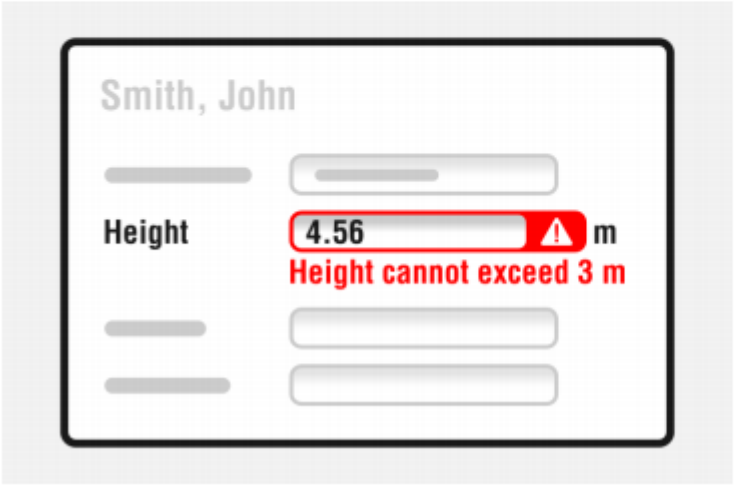
221. **Patient overview.** Present a summary of patient information, in addition to the patient's name, when the added information will help identify the patient and/or immediately bring key information (e.g., last office visit, last diagnosis, and allergy) to the user's attention.

Figure 3-24: A sample patient overview layout.



78. **Inputted data validation.** Automatically check safety-related, inputted data to ensure it is in the correct format and within an appropriate range. Alternatively, prompt the user to confirm the correctness of inputted values and correct them if necessary. Reject values that are clinically impossible or inappropriate based on patient's characteristics (i.e., patient gender, age) or previously stored values.

Figure 3-12: An example of a data input validation error.



http://nvlpubs.nist.gov/nistpubs/gcr/2015/NIST.GCR.15-996.pdf

How do you prove to regulators that your product (software UI) is safe and effective?

Summative usability test

- Generates evidence that a medical device can be used safely and effectively by the intended users for the intended purposes in the intended use environments.
- Demonstrates that design features intended to prevent harmful use errors are working.

Testing in UL-Wiklund's laboratory

Details

- 15 participants per distinct user group
- Participants may be trained if realistic
- Test sessions usually last 2 hours
- Hands-on tasks linked to identified risks
- Assistance = task failure
- Data: use errors, close calls difficulties, participants comments and answers to questions
- Every safety-related use error requires root cause analysis
- No quantitative acceptance criteria

Root cause analysis

Draw upon HFE design principles

AAMI HE75:2009

19.4.1.2 – Optimal character height: The minimum character height should be 16 minutes of visual angle (ANSI/HFES 100). The preferred height of characters should be 20 to 22 minutes of visual angle when displayed characters are viewed frequently or rapid comprehension is essential (ISO 9241-3).

Credit: http://www.tandemdiabetes.com/Products/t-slim-Insulin-Pump/Touch-Screen/

Draw upon participant comments

Patient 1

The blue numbers are too small for my eyes.

Patient 2

The blue numbers don't show up very well against the glass. They could be a lot darker.

Patient 3

The "1" and "7" are tough to tell apart. Looking at them real quick, I guess I thought the seven was a one.

Draw upon participant comments

Patient 4

I couldn't figure out where to find the calibration option in the menu.

Patient 5

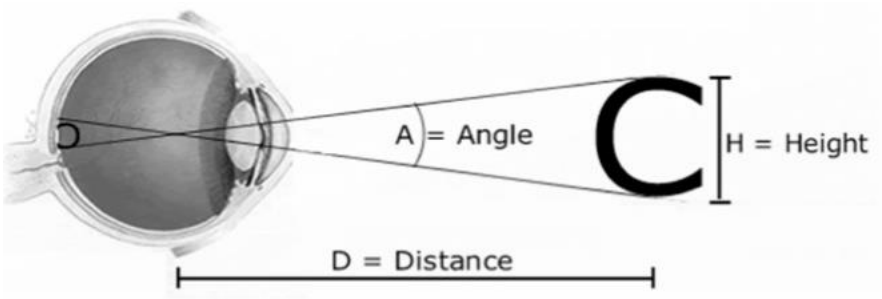
I didn't realize I had to confirm the settings. The software didn't tell me to do so.

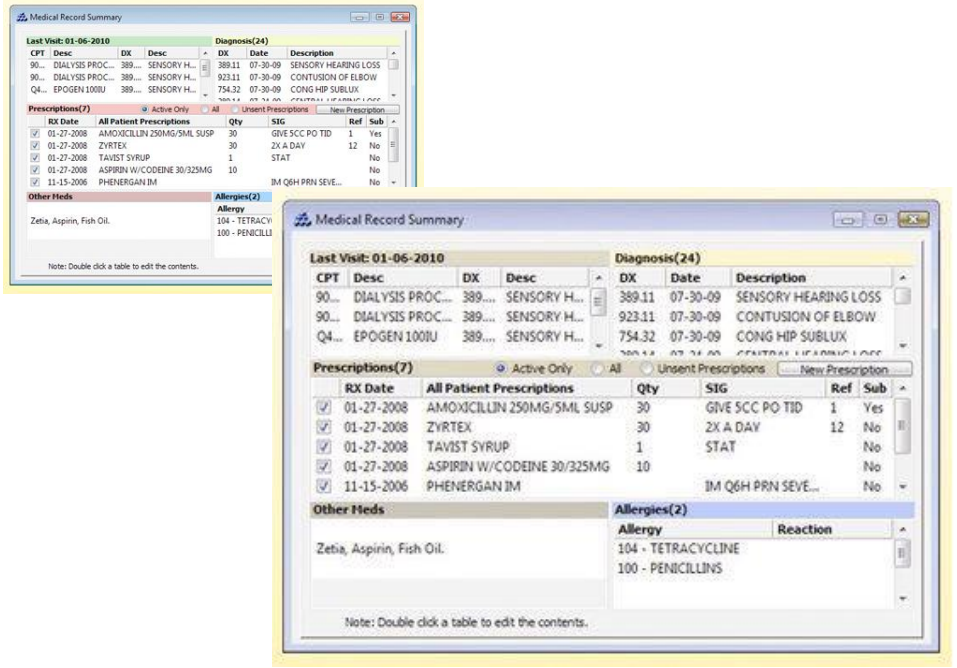
Patient 6

I guess I edited the wrong patient's information. I thought I clicked on Daniel Green. It might have helped if his name was displayed really large at the top of the chart.

Consider perceptual issues

- Text too small to read from expected viewing distance
- Color impaired vision (e.g., deuteranope)
- Effect of information density on information acquisition

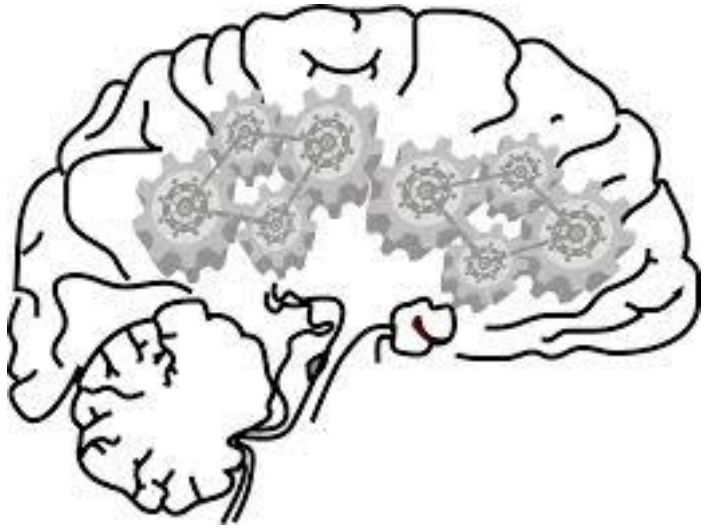




Credit: http://www.hf.faa.gov/webtraining/visualdisplays/VisDispImages/fireworksPNG/eyeangle.gif, http://www.symmetryinfo.com/images/ehr/ehr_mdi.jpg

Consider if device exceeds mental capabilities

- Too much information to assimilate quickly
- Too much to remember
- Too little response time
- Complicated mental math
- Lack of situational awareness to facilitate good decision making



Credit: https://openclipart.org/people/Woofer/Gear_brain_Woofer.svg

Consider possibility of negative transfer

Sample hemodynamic patient monitor

Consider the use environment

Source: http://vector.childrenshospital.org/wp-content/uploads/2013/03/ICU_monitors1-1024x768.png

Using professional judgment

- Professional judgment by HFEs is an essential part of root cause analysis.
- Some root causes can be stated factually (e.g., The reading error was due to the use of small text).
- Some root causes require speculation and should be reported as such (e.g., The use error was likely due to…).

Prepare HFE portion of regulatory submission

Types of submissions

- 510(k) – Device similar to another (predicate)
- PMA (Premarket Approval Application) – high risk device or altogether new type of device
- BLA (Biological License Application) – Combination product that delivers a biological
- NDA (New Drug Application) – Combination product that delivers a drug

HFE Report Contents

- Intended device users, uses, use environments, and training
- Device user interface
- Summary of known use problems
- User task selection, characterization and prioritization
- Summary of formative evaluations
- Validation testing

HFE Report Contents

Claim:

"The [Device/Application] has been found to be reasonably safe and effective for the intended users, uses and use environments."

Discussion