Usability in healthcare: a matter of life and death

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April 2016

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Sudden Cardiac Arrest (SCA)

- Anyone, at anytime
- Heart stops **instantly**. (not a heart attack / electrical)

- Leading cause of death for people over **40**.
- **Kills more than** Colon cancer, Breast Cancer, Prostate Cancer, Diabetes, HIV, Car Accidents and House Fires combined.
- Kills **350,000+** people in US per year.

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First 4 minutes are crucial to saving a life

Chance of survival decreases by about **10% for every minute** the heart goes without Defibrillation.

00:41.41

00:41.41

01:15.56

01:15.56

03:53.45

03:53.45

What is an AED & CPR

AED (Automatic external defibrillator)

- Stop the **chaotic** heart rhythm
- Allows the internal ‘conductor’ to start over
- AEDs are designed to guide you every step of the way; accessible by anyone

CPR (Cardio Pulmonary Resuscitation)

- Typically the procedure is 30 **compressions** and 2 **ventilations**
- CPR can be performed by anyone (press fast and hard)

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Designing for emergencies


Difficulty – Patient removal


Difficult – Terrain


Distraction – O god…


Terrain – AED / CPR


Nurse - Distraction


Difficulty – shock


Confidence – Am I doing…


Fire coming – Patient moved


Saying – “You did…”

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How do you design
for that type of situation?

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Walking in your users shoes

Hear what they see and see what they hear

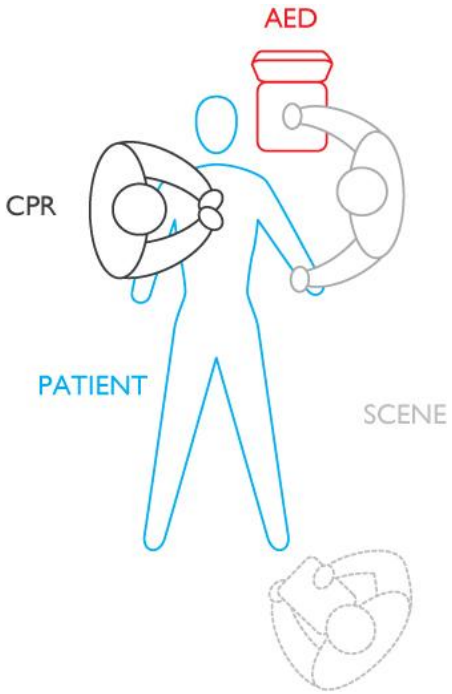
- Define user profiles
- Observe multiple teams/locations in action
- Interview the people who use them (and the ones that don't)
- Understand the users' workflow and needs

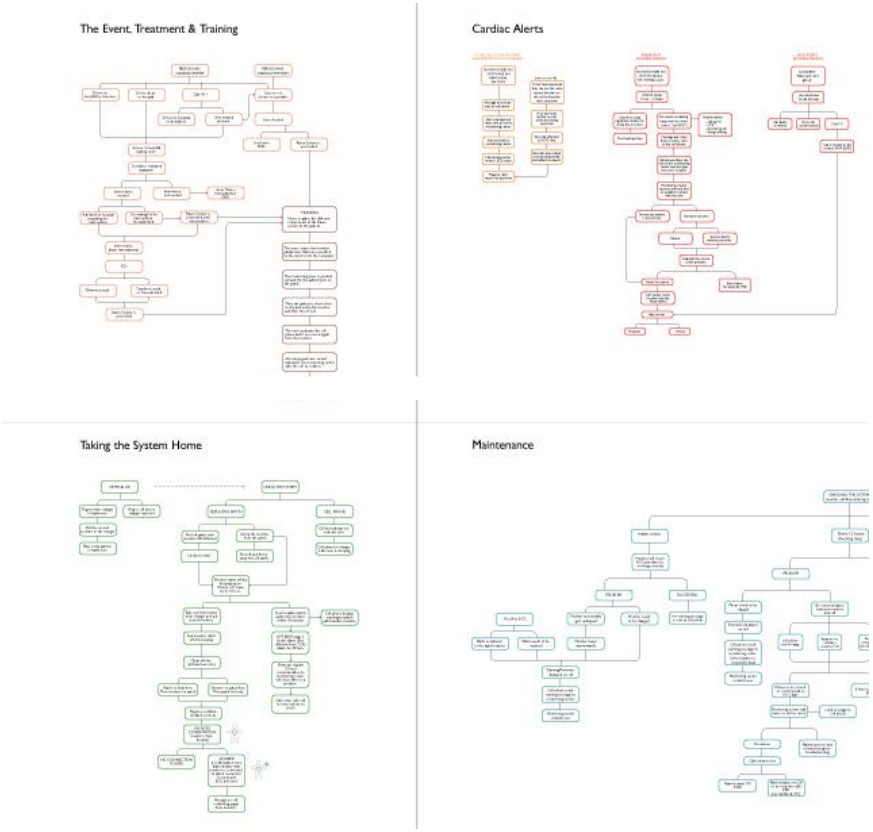
Understand the environment

Workflows

Look for intersections of device & user:

- **PCA + emotion**: perception, cognition, emotion, action
- essential/ **risk related** tasks





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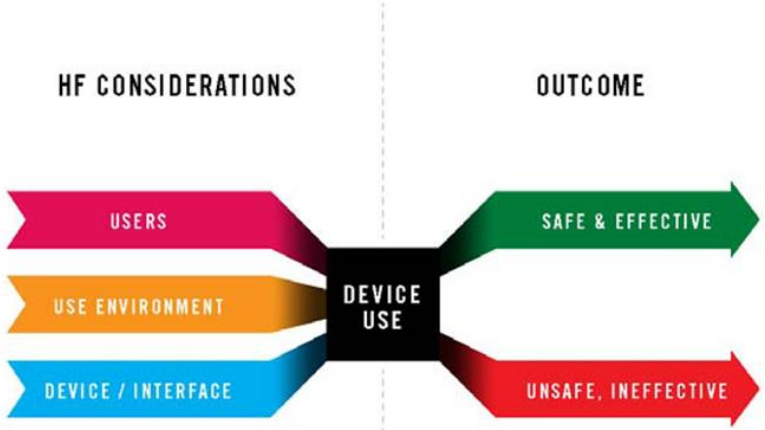
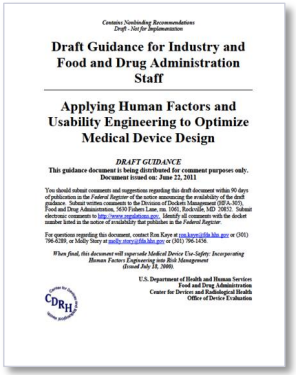
Key elements impacting usability





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

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For questions regarding this document, contact Tom Kerzee at tom.kerzee@fda.hhs.gov or (301) 796-8289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-5456.

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
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But also…
Efficiency
Engaging
Easy to Learn

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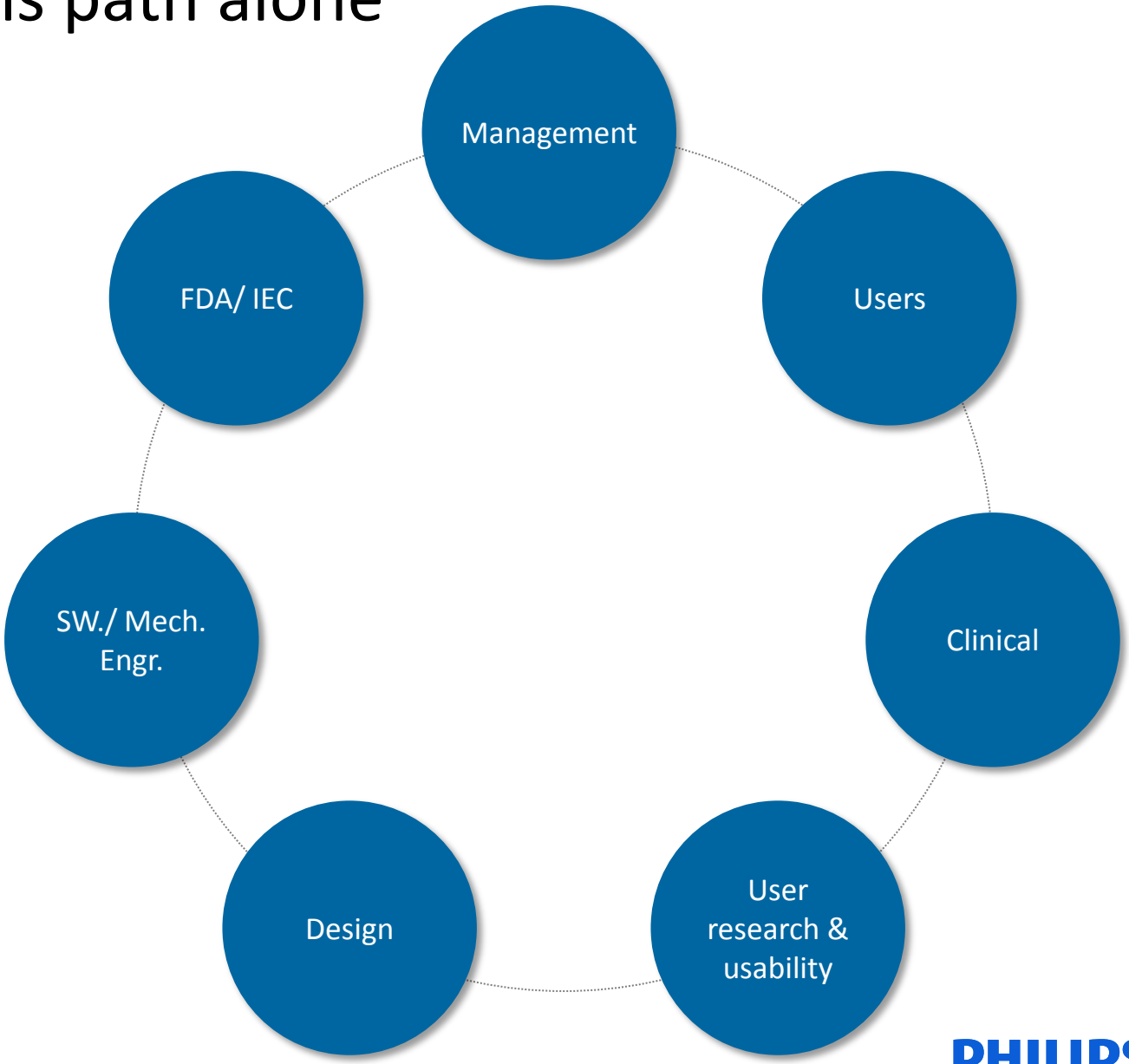
Don’t go this path alone



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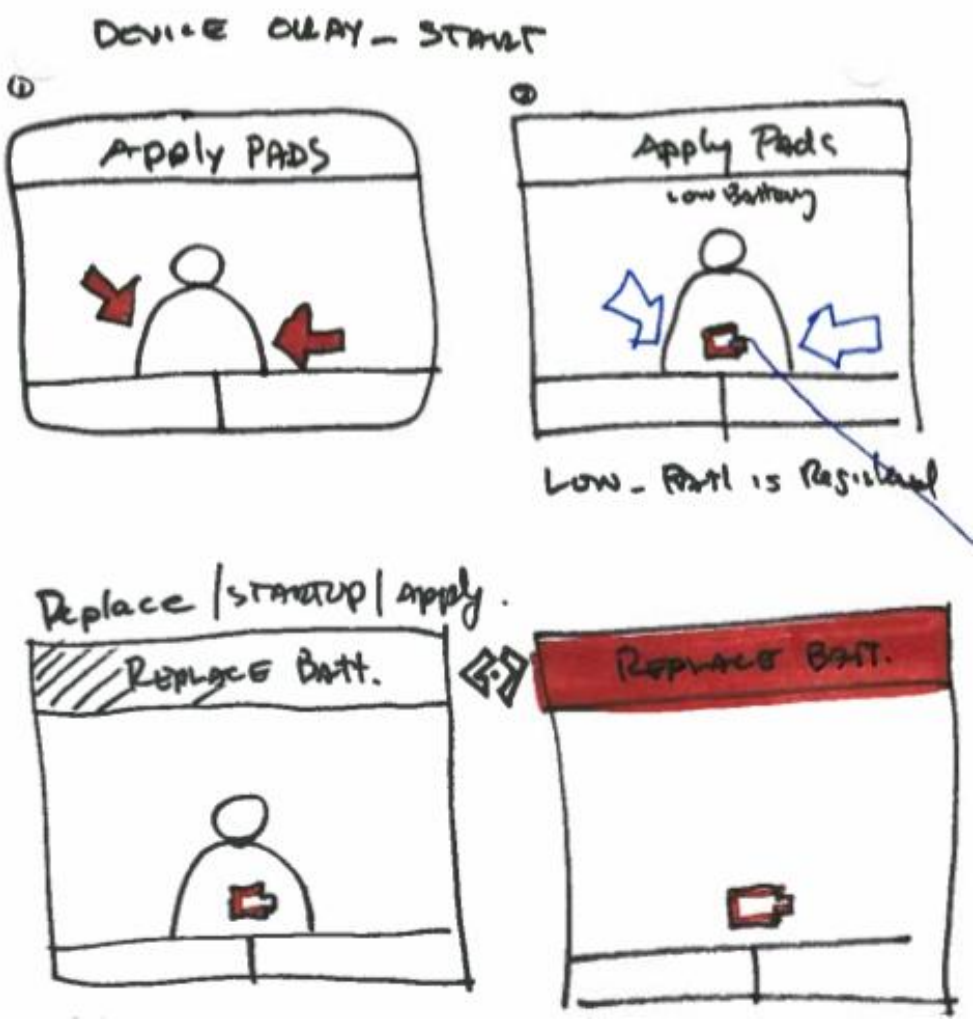
Design opportunities

User & Time

Explore scenarios with sketches



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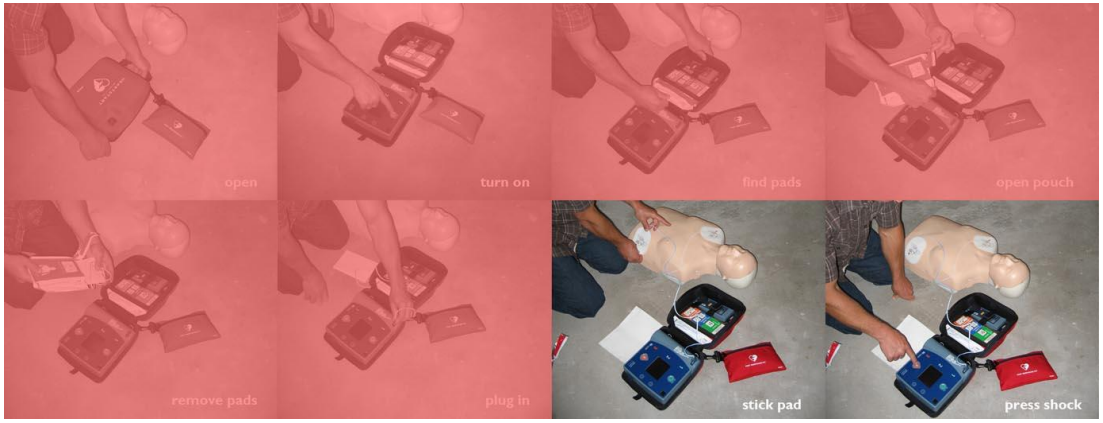
Speed and simplify startup

8 Steps/
90 sec

2 Steps/
45 sec



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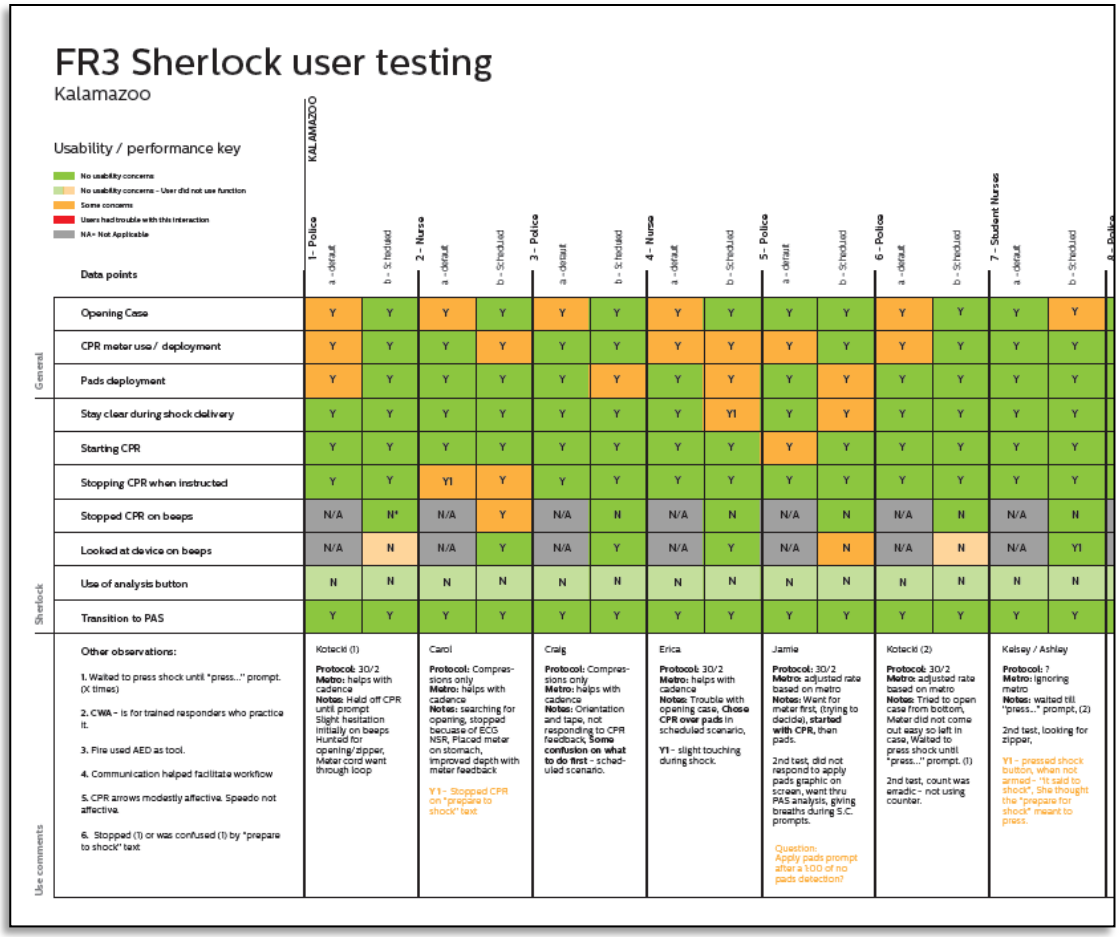
Formative test, test, and re-test

Real life

- Immerse the people who use our devices in **'real'** scenarios'
- Evaluate your ideas in **their workflows and contexts of use**
- **Test for failure**: look for cognitive, emotional and physical challenges
- Test early and often! (test assumptions)

Analyze the data

Looking for **patterns** of use error & any potential **safety** issues



FR3 Sherlock user testing

Kalamazoo

Usability / performance key

- No usability concerns
- No usability concerns - User did not use function
- Some concerns
- Users had trouble with this interaction
- NA= Not Applicable

	Data points	KALAMAZOO													
		1 - Police		2 - Nurse		3 - Police		4 - Nurse		5 - Police		6 - Police		7 - Student Nurses	
		a - default	b - Scheduled	a - default	b - Scheduled	a - default	b - Scheduled	a - default	b - Scheduled	a - default	b - Scheduled	a - default	b - Scheduled	a - default	b - Scheduled
General	Opening Case	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
General	CPR meter use / deployment	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
General	Pads deployment	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Sherlock	Stay clear during shock delivery	Y	Y	Y	Y	Y	Y	Y	Y1	Y	Y	Y	Y	Y	Y
Sherlock	Starting CPR	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Sherlock	Stopping CPR when instructed	Y	Y	Y1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Sherlock	Stopped CPR on beeps	N/A	N*	N/A	Y	N/A	N	N/A	N	N/A	N	N/A	N	N/A	N
Sherlock	Looked at device on beeps	N/A	N	N/A	Y	N/A	Y	N/A	Y	N/A	N	N/A	N	N/A	Y1
Sherlock	Use of analysis button	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Sherlock	Transition to PAS	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Use comments	Other observations:	Kotecki (1) **Protocol:** 30/2 **Metro:** helps with cadence **Notes:** Held off CPR until prompt Slight hesitation initially on beeps Hunted for opening/ zipper, Meter cord went through loop		Carol **Protocol:** Compressions only **Metro:** helps with cadence **Notes:** searching for opening, stopped because of ECG NSR, Placed meter on stomach, improved depth with meter feedback Y1 - Stopped CPR on "prepare to shock" text		Craig **Protocol:** Compressions only **Metro:** helps with cadence **Notes:** Orientation and tape, not responding to CPR feedback, **Some confusion on what to do first** - scheduled scenario.		Erica **Protocol:** 30/2 **Metro:** helps with cadence **Notes:** Trouble with opening case, **Chose CPR over pads** in scheduled scenario, Y1 - slight touching during shock.		Jamie **Protocol:** 30/2 **Metro:** adjusted rate based on metro **Notes:** Went for meter first, (trying to decide), **started with CPR**, then pads. 2nd test, did not respond to apply pads graphic on screen, went thru PAS analysis, giving breaths during S.C. prompts. Question: Apply pads prompt after a 'NO' of no pads detection?		Kotecki (2) **Protocol:** 30/2 **Metro:** adjusted rate based on metro **Notes:** Tried to open case from bottom, Meter did not come out easy so left in case, Waited to press shock until "press..." prompt. (1) 2nd test, count was erradic - not using counter.		Kelsey / Ashley **Protocol:** ? **Metro:** Ignoring metro **Notes:** waited till "press..." prompt, (2) 2nd test, looking for zipper, Y1 - pressed shock button, when not armed - "It said to shock", She thought the "prepare for shock" meant to press.	

1. Waited to press shock until "press..." prompt. (X times)
2. CWA - is for trained responders who practice it.
3. Fire used AED as tool.
4. Communication helped facilitate workflow
5. CPR arrows modestly affective. Speedo not affective.
6. Stopped (1) or was confused (1) by "prepare to shock" text

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Tests uncover additional unmet needs

Help manage our “system”

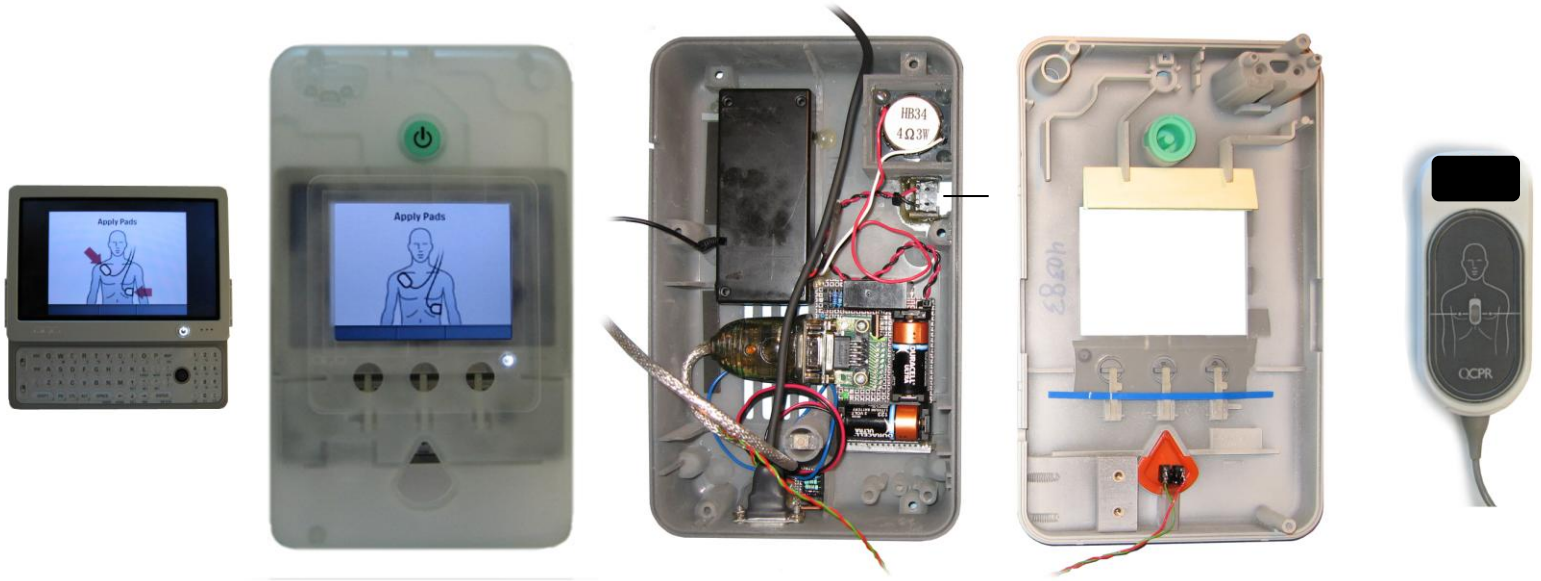
- We need to carry so much stuff (AED, spare pads, spare battery, ventilation mask) can you help us organize things…

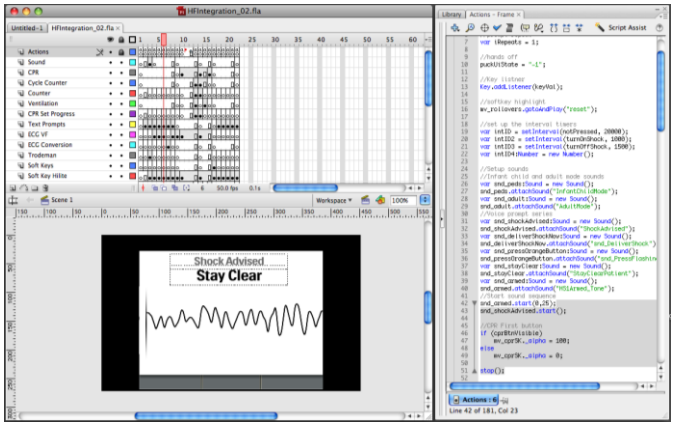
Help with CPR

- Improved feedback and “don’t make me feel like an idiot.”

Validate

Production equivalent





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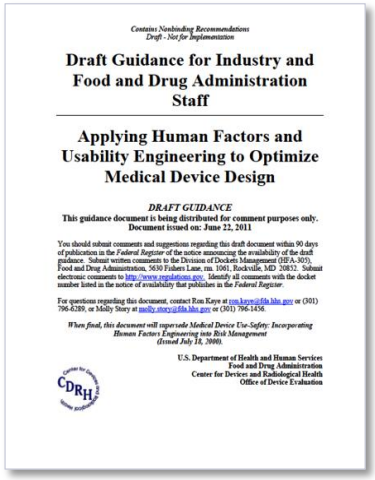
Validation – FDA and IEC focus on safe and effective use

FDA Guidance:
Applying Human Factors and Usability Engineering to Optimize Medical Device Design



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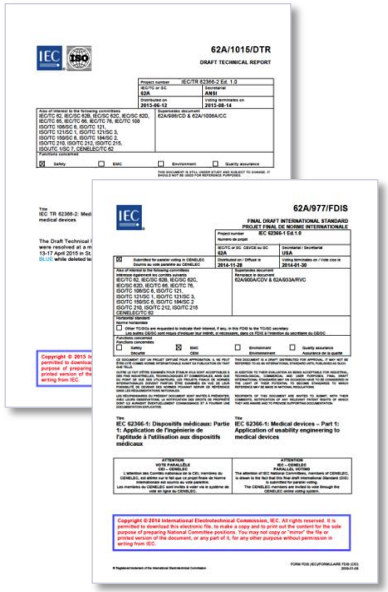
IEC 62366-1 & IEC 62366-2:
Application of usability engineering to medical devices



62A/1015/DTR
DRAFT TECHNICAL REPORT

62A/977/FDIS
FINAL DRAFT INTERNATIONAL STANDARD
PROJET FINAL DE NORME INTERNATIONALE

IEC 62366-1: Dispositifs médicaux: Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices

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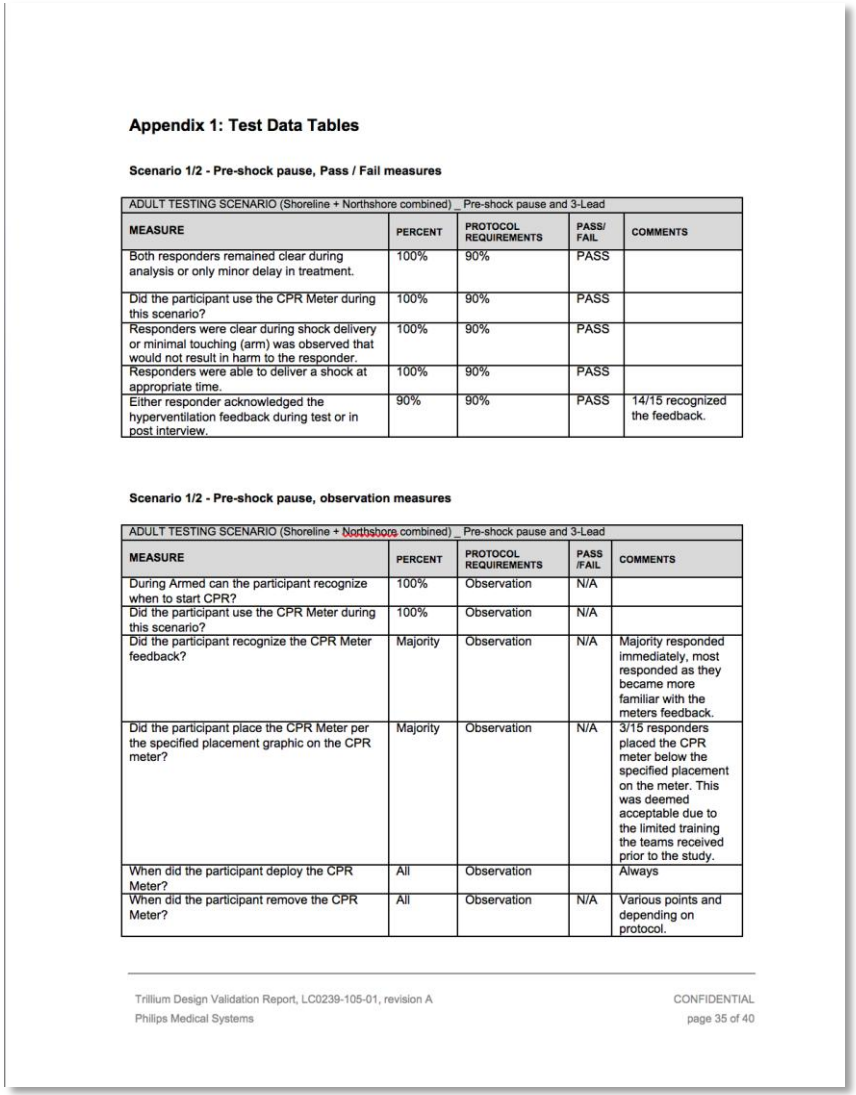
Validation - Reporting



Appendix 1: Test Data Tables

Scenario 1/2 - Pre-shock pause, Pass / Fail measures

ADULT TESTING SCENARIO (Shoreline + Northshore combined) _ Pre-shock pause and 3-Lead				
MEASURE	**PERCENT**	**PROTOCOL REQUIREMENTS**	**PASS/ FAIL**	**COMMENTS**
Both responders remained clear during analysis or only minor delay in treatment.	100%	90%	PASS	
Did the participant use the CPR Meter during this scenario?	100%	90%	PASS	
Responders were clear during shock delivery or minimal touching (arm) was observed that would not result in harm to the responder.	100%	90%	PASS	
Responders were able to deliver a shock at appropriate time.	100%	90%	PASS	
Either responder acknowledged the hyperventilation feedback during test or in post interview.	90%	90%	PASS	14/15 recognized the feedback.

Scenario 1/2 - Pre-shock pause, observation measures

ADULT TESTING SCENARIO (Shoreline + Northshore combined) _ Pre-shock pause and 3-Lead				
MEASURE	**PERCENT**	**PROTOCOL REQUIREMENTS**	**PASS /FAIL**	**COMMENTS**
During Armed can the participant recognize when to start CPR?	100%	Observation	N/A	
Did the participant use the CPR Meter during this scenario?	100%	Observation	N/A	
Did the participant recognize the CPR Meter feedback?	Majority	Observation	N/A	Majority responded immediately, most responded as they became more familiar with the meters feedback.
Did the participant place the CPR Meter per the specified placement graphic on the CPR meter?	Majority	Observation	N/A	3/15 responders placed the CPR meter below the specified placement on the meter. This was deemed acceptable due to the limited training the teams received prior to the study.
When did the participant deploy the CPR Meter?	All	Observation		Always
When did the participant remove the CPR Meter?	All	Observation	N/A	Various points and depending on protocol.

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Results

A good usability engineering process

- Multi-disciplinary **team**
- **Understanding** end-user
  - User profiles, user needs, context of use, …
  - Workflow and possible hazards
- Basis for **iterative design**
- **Test**, test, and re-test
- **Validate**

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Mindset - “to design and produce every device as if the life of someone we love depends on it.”


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