



This presentation was delivered on the 12<sup>th</sup> October 2016 at the Chartered Institute of Ergonomics and Human Factors and Ergonomics (CIEHF) Beds, Bucks and Herts regional group in Harpenden.

This version of the presentation has been annotated with text boxes to provide an approximate narrative of the talk.

#### Medical device design

This presentation is intended for those who have a good understanding of human factors and ergonomics, but are perhaps new to medical device design.

The presentation will cover:

- 1. What makes medical devices different from other domains.
- 2. My experience of medical device development (that I can talk about).
- 3. Historic examples of when it goes wrong.
- 4. Interesting trends in medical device development and what this means for HF.



What makes medical devices different?

#### Still about system performance

In a lot of ways, human factors for medical devices, is just like human factors in other domains. It's about understanding and improving system performance.



#### Core FDA focus

The difference, to some other domains, may lie in the priority placed on these values.

The FDA have an almost exclusive focus on safe and efficacious uses, at times this is to the detriment of the other factors.

In a recent white paper, Ron Kaye (formerly of the FDA), said the following:

"All the FDA is concerned about is whether the device interface has been designed in a way that retains some kind of a flaw in the interface. The flaw being something that would cause a user not to do something that they need to do, or when they do something with the device, they do it incorrectly."





#### Standards

In terms of standards, there is one main document that describes the process BS EN 62366. Recently, this was expanded and split into two parts.

The first part, BE EN 62366-1, focuses more on the process of integrating HF while the second part turns its attention towards the tools and techniques for delivery.

Another useful document is called HE75, this provides even more detail on the tools and techniques. And also contains look-up table data.

62366 is essential reading while HE75 is strongly recommended.



ANSI/AAMI HE75-2009

#### Changes in updated version

A recent additions to the updated version of 62366 are two new terms, *Formative* and *Summative* evaluation. These terms are really quite useful as they help to differentiate between two quite different human factors activities.

Formative design studies are primarily concerned with informing the design of better products and services. It involves using user studies and other HF techniques to identify ways of improving the design. Formative studies are the basis of good iterative user-centred design.

Summative studies are primarily concerned with proving that the product can be used safely. In other industries this might be referred to as assurance.

The two terms are very useful as they help describe what different consultants and consultancies do. As a design consultancy, DCA tend to focus on formative work, whereas others tend to gear up for summative work.

#### 3.7

#### FORMATIVE EVALUATION

USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS

Note 1 to entry: FORMATIVE EVALUATION is generally performed iteratively throughout the design and development PROCESS, but prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary.



#### 3.13

#### SUMMATIVE EVALUATION

USER INTERFACE EVALUATION conducted at the end of the USER INTERFACE development with the intent to obtain OBJECTIVE EVIDENCE that the USER INTERFACE can be used safely

Note 1 to entry: SUMMATIVE EVALUATION relates to validating the safe use of the USER INTERFACE.

#### IEC 62366-1 (2015)

This is one of the most useful diagrams in BS EN 62366-1

[Don't worry, I will zoom in on the next slide]

What it shows, at this level, however, is the expected workflow for human factors within a device development programme. It is the kind of table you might expect to see in a Human Factors Integration Plan (HFIP). Critically, it shows the alignment with the risk management standard ISO 14971.





#### IEC 62366-1 (2015)

Starting from the top, this will probably look familiar to those working in other domains of human factors.

- The process starts by exploring and defining how the product will be used.
- 2. The user interface is then defined using tools like task analysis.
- 3. Task models are then explored to identify hazards.
- 4. Hazardous scenarios are then identified.
- 5. These are then defined for summative testing.
- 6. A user interface specification is then defined and explored using prototypes.

RISK MANAGEMENT ISO 14971 (decision making process)

USABILITY ENGINEERING IEC 62366-1 (design and development process)



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#### IEC 62366-1

- 7. A discussion guide or evaluation plan is the defined.
- 8. An iterative loop of formative testing them takes place.
- 9. Finally summative testing.





### IEC 62366-2 (2016)

62366-2 provides a similar table, however, this provides a little more detail on the process and the types of tools that might be used.

In this part of the standard it's a little more explicit than in part 1.



USER research	8 Prepare USE SPECIFICATION Conduct contextual inquiries Conduct focus group with advisory panel
	9 Identify characeristics for SAFETY
	Conduct TASK analysis incl. PCA analysis Review historical internal POST-PRODUCTION information Review publicly available databases
	10 Identify HAZARDS and HAZARDOUS SITUATIONS
Analysis	Conduct workshop with RISK MANAGEMENT team
	11 Identify and describe HAZARD-RELATED USE SCENARIOS 12 Select HAZARD-RELATED USE SCENARIOS FOR SUMMATIVE EVALUATION
	Identify, describe, and categorize HAZARD-RELATED USE SCENARIOS



#### IEC 62366-2 (2016)

The table shows the iterative nature of formative studies and highlights how they would be repeated as the fidelity of the design and prototypes increases.







#### Useful tools

The following is a list of useful and commonly used tools within medical device design.

- Task analysis.
- PCA model (described in the diagram on the right).
- uFMEAs.
- Error prediction (e.g. TRACEr, SHERPA).
- User trials.
- Interviews.
- Ethnography.
- Force assessments.
- Postural assessments.
- Manual handling assessments.
- Link analysis.

Less frequently used.

- Abstraction hierarchies (CWA).
- · Decision making assessments (decision ladders).



#### PCA example

The PCA model can be applied to each base-level task of a Hieratical Task Analysis model (HTA).

Taking the example of removing a cap from a medical device:

- At a sensory (perceptual) level, users need to be able to see or feel where the cap is on the device.
- At a cognitive level, users need to know how to remove the cap (should it be twisted, pulled, etc). This could be recalled from memory or the user could use problem solving skills. Here the design the cap can help to make it more intuitive.
- Finally at a physical level, the user needs to have enough strength and dexterity to perform the removal operation.

Once identified these requirements can help form a design specification as well as highlight opportunities for error.



# My experience

## Work at DCA

DCA is a design consultancy that has been developing products for over 60 years.



### Based in Warwick

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DCA



And its not just about medical together we work on everything from toothbrushes....



# NO SMOKING

ARCE COAD HAVE 90"/4" VECTOR COAD HAVE 90"/4" 2.1" 3.0" 3.75" 5.4"





A fair proportion of our medial work is in developing mechanical drug delivery devices

G



We also help develop large installations such as radiography machines.

DCA

/Illasand

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Powerful examples of where it goes wrong

### IEC 62366-2 (2016)

I am going to talk about two powerful example of where medical devices use has resulted in undesirable outcomes.

I want to talk about these for two reasons:

- 1. They are useful example for communicating the value of human factors.
- 2. There is a requirement in IEC 62366-2 that we learn from past experience to improve products.



IICED	research	8 Prepare USE SPECIFICATION Conduct contextual inquiries Conduct focus group with advisory panel
		9 Identify characeristics for SAFETY
		Conduct TASK analysis incl. PCA analysis Review historical internal POST-PRODUCTION information Review publicly available databases
	Analysis	10 Identify HAZARDS and HAZARDOUS SITUATIONS Conduct workshop with RISK MANAGEMENT team
		11 Identify and describe HAZARD-RELATED USE SCENARIOS 12 Select HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION
Y		Identify, describe, and categorize HAZARD-RELATED USE SCENARIOS



#### Example

Here is a historic example from the FDA website of a sleep apnoea monitor. It is a device designed to sound an alarm if the child stops breathing.

Before moving on to the next slide take a few moments to think about how this could go wrong?



This picture shows the correct way to connect the infant to the Monitor. The ELECTRODE LEADS are plugged into the PATIENT CABLE which in turn connects to the MONITOR. The MONITOR is connected to the WALL SOCKET by the POWER CORD.

#### Example

Well it's all to do with the leads and making incorrect connections.

As the diagram shows the pins on the electrodes are the same size as those for the power outlet. As such it's possible to connect the electrodes directly to the mains socket or to one of the leads. And this happened on a number of occasions.

Given the consequences these kind of things are hard to predict. Who would guess that someone would plug their baby into the electrical socket? But its also worth considering the context of use. Parents using these devices are likely to be tired and fatigued often connecting them in the dark.

Given that it's a low frequency error, it's the kind of fault that you would be unlikely to see happen in a simulated use trial or other form of user study. However, a well structured error identification process is likely to pick this up.

It's is a hazard that can be easily 'designedout', poke-yoke, or error proofing, is central to this. If the product's leads were different shapes to the power socket this particular fault could have been avoided.



#### Therac-25

Here is another example on a different scale. This time a radiography machine from the 1980s.

Essentially, radiotherapy works by exposing targeted areas of the body with radiation. In most cases, it is used to eliminate or control the growth of tumours.

The challenge with radiotherapy as a treatment is that the radiation is also harmful to healthy tissue. Thus, it's critical that the radiation is delivered to the right place in the right dose.

The Therac 25 machine was withdrawn from service after a number of fatalities.

The following slide describes one of those cases.



#### Two modes of operation

The Therac 25 machine had two modes of operation, a low energy electron mode for treating tumours on near the surface of the skin and a high energy focused beam for treating tumours deeper in the body. In the case of the high energy mode, a thick shaping plate is required to focus the beam to a small area, reducing its intensity.

In one case in Tyler Texas, a patient was due to receive a low energy electron mode, so the shaping plate was not in place; however, the machine delivered the high energy dose giving a fatal overdose (the shaping beam not being in place to reduce the intensity).

It was an experienced operator on the day, who had been using the equipment for two years and delivered over 500 treatments. It was also a relative straightforward and routine treatment. So what went wrong?





This was the user interface, which was fairly typical of its time.

Data was entered via a keyboard.

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The user entered the patient data as follows:

1. Operator entered prescription data (treatment type and dose).

#### JVC

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SCREENS ASPECT AREA CHECK MARKER

INPUT SELECT

MENU

The user entered the patient data as follows:

- 1. Operator entered prescription data (treatment type and dose).
- Operator confirmed settings noting that she had mistyped X (for X-ray mode) rather than E (for an Electron treatment).

#### JVC

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The user entered the patient data as follows:

1. Operator entered prescription data (treatment type and dose).

JVC

- Operator confirmed settings noting that she had mistyped X (for X-ray mode) rather than E (for an Electron treatment).
- 3. Operator used the up arrow on the keypad to move the cursor up over the **X** to edit it.
- 4. Operator typed **E** to overwrite **X** (within 8 seconds of the first entry).

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SCREENS ASPECT AREA

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The user entered the patient data as follows:

- 1. Operator entered prescription data (treatment type and dose).
- Operator confirmed settings noting that she had mistyped X (for X-ray mode) rather than E (for an Electron treatment).
- 3. Operator used the up arrow on the keypad to move the cursor up over the **X** to edit it.
- 4. Operator typed **E** to overwrite **X** (within 8 seconds of the first entry).
- 5. Operator typed **B** for beam on.
- 6. An unfamiliar error was presented on the screen *"Malfunction 54"* however, no information was provided on the details of this error. The operator manual supplied with machine did not explain or address the malfunction codes, nor did it give any indication that these malfunctions could place a patient at risk.
- 7. As system errors were a relatively common occurrence and routinely accepted, the operator typed **P** for proceed.

JVC



- 🕑 POWER

#### Malfunction 54

It was later found that there was a little bit of carryover code in the software, that ignored data entry changes made within 8 seconds, so the machine disregarded the change (from the high energy to low energy mode). JVC

There were no mechanical interlocks in place to check for the shaping plate, thus no defence in place.

As a result, the machine delivered the much more powerful energy dose resulting in an a massive overdose



PHASE CHROMA BRIGHT CONTRAST

#### Takeaways

There are two takeaways from these case-studies.

The first, the case of the apnoea monitor leads, highlights the importance of exploring low-frequency errors. It also highlights the importance of using methods in addition to user trials to predict errors.

The second addresses the importance of robust demonstrably safe code, and the challenges with using third party modules containing redundant code.

JVC

1. Low frequency errors may seem implausible but they can be fatal

2. Legacy code and the use of third-party modules can have catastrophic consequences if we don't fully understand how they work in all usecases



# Interesting trends (for me at least)

#### Emerging market trends

I would like to end with some trends that have interested us over the last year or so.

The first is emerging markets. Emerging markets are an opportunity for growth in the world of medical devices. armacist

Gillette

to time canales.

COMPANY OF

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10

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=

PAINFUL PERIODS ?

NO-SPA

NO to spassing

Emergizon

More on this topic

For HF this brings new challenges in terms of cultural norms and expectations.

#### **Emerging markets**

In the past it has been acceptable to simply sell last generation products to developing markets. When Volkswagen stopped producing beetles in Europe, the production line was shipped to Mexico.

This has a number of advantages as it allows production at a much lower cost and the production of a car that is incredibly easy to maintain.

However, politically, and perhaps ethically, it's challenging - as it could be perceived as placing different values on health and life.

La Casona

MARISCOS

JUEVESZ POZOLE Y COMIDA CHILAPEÑA

La Mein Cocina

326

At a core level, we cannot compromise the safety or effectiveness of the device or drug by region or market.



#### Everything connected

Another interesting trend is connected devices. The so called 'internet of things' remains a hot-topic. As this diagram shows we now have connected thermostats, cars, and TVs. Right through to nappies cows, bins and cutlery that measures how fast we eat. Some of these have proved to be more successful than others.

The idea of connected medical devices offers some exciting possibilities, most notably in recording compliance and helping patients remember to take their drugs at the correct time.

The challenge is that it brings with it a number of risks, if decisions are to made based on the data produced we need to be very sure that data is correct. Likewise, there are security issues should the data be stolen.

Despite the risks the pull is strong and something that we should expect to see more of.



#### Expectations set elsewhere

When it comes to apps and devices to support medical devices, we also face a number of unique challenges. As we mentioned previously, the code needs to be highly reliable and auditable.

But user expectations are being set elsewhere, users want, if not demand, similar experiences to those from their Smartphone and tablets. They want integration with their operating systems and fancy interactions, animations and graphics.

The trouble of course is that places a huge burden on demonstrating that it is safe. Not to mention the requirement to keep pace with yearly updates in operating systems.



More on this topic

#### **DIY** medical devices

The final trend is one towards DIY medical devices

Regulatory demands that medical device development is a highly structured process and, as we have discussed, all potential errors and adverse outcomes need to be explored and tested in a controlled way.

And this all takes considerable time and money.

Some tech savvy users are starting to find that they can cobble together medical devices and have them faster and cheaper than the regulatorapproved versions. What's more they can share these instruction kits through online communities.

For me this is equally exciting and terrifying, it's amazing to see the ingenuity and agility of the development process often tackling needs taken straight from end users. The fact that the risk assessments on these potentially fatal devices may be substandard or even non-existent is incredibly alarming.



More on this topic

#### Takeaways

Returning to those take-aways from the historic cases, there is a very clear role for HF in helping seek and mitigate for those low frequency errors.

Furthermore we need to be very careful as a society about the role of DIY medical devices.

JVC

1. Low frequency errors may seem implausible but they can be fatal

2. Legacy code and the use of third-party modules can have catastrophic consequences if we don't fully understand how they work in all usecases





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