# MOBILE DEVICES AND USE-RELATED RISK – TIME TO REINSTATE DETECTABILITY?

**In this article, Richard Featherstone, Managing Director, Medical Device Usability, makes the case for designing detectability into the user interfaces of wearable devices, enabling the user to be an active part of ensuring the device operates safely, as intended.**

Wearable medical devices can free a patient to live a more normal life, but they bring with them a high degree of responsibility on the part of manufacturers to make sure that the device can be worn and used safely whilst the patient is mobile. When a patient wears a medical device, the bond between user and device is very close. Users rely on the device to keep them safe, to keep the medicine flowing and, crucially, to alert them when something goes wrong.

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Risk assessments are at the heart of design for safety. When writing a risk assessment for a medical device, risk is commonly calculated as a function of the probability of a failure mode occurring combined with the severity of harm that would ensue. So, for example, if the infusion line on a portable syringe driver gets kinked, drug flow is impeded and the patient's condition may rapidly deteriorate. Multiplying the probability that the line gets kinked by the severity of the harm that would be caused by impeded drug flow gives an overall estimate of risk.

However, when we consider use-related risk assessments we need to focus on the user. The patient is not a passive component – if they become aware of a problem early enough, they may be able to take corrective action and thus stay safe. Therefore, a wearable device that provides feedback is inherently safer than one that does not.

> "Detectability means that if a user of a wearable device performs a use error, the error state is rapidly, and clearly, communicated back to the user."

So "detectability" – the extent to which a problem is detectable by its user – is surely a critical component of risk. Detectability essentially means that the user can become aware that a failure has occurred, or is about to occur, and is therefore able to take corrective action. However, recent trends in risk assessment have removed this third component. Arguments have been made that the inclusion of detectability redirects attention away from the underlying causes of failure towards improving detectability.[1] Whilst this may be an appropriate concern for failure modes, detectability may be of more relevance when evaluating risk associated with usability of a mobile wearable device.

In the world of human factors, we are interested in identifying the potential use errors. Detectability means that if a user of a wearable device performs a use error, the error state is rapidly, and clearly, communicated back to the user. So, to continue with the example of a portable syringe driver, if the line does get kinked, the risk of harm is greatly reduced if the user is aware that drug flow is impeded. If the user cannot detect that there is something wrong they are in a much more hazardous situation than if they had detected the problem early.

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| Feature | High detectability | Low detectability |
|---|---|---|
| Unambiguous | Distinct, has only one possible meaning | Multiple possible meanings |
| Understandable | The method of signalling is easily understood by the user | Signal not easily understood by user |
| Binary | Either condition A or condition B has occurred | Poor signalling – more than one possible state may have occurred |
| Repeatable | The same signal from the same state, every time | One signal used from multiple possible states |
| Decision-focused | Supports the user when making the decision – Is this right? Have I done this correctly? Is there a problem, and if so, what is it? How do I resolve it? | Poor feedback to user, does not guide the user to safety |
| Timely | Provides feedback to the user in real time, giving them sufficient time to make a safe response | Delay in signalling |

Table 1: Features of a user interface with high detectability.

| UI with high detectability | Why | UI with poor detectability | Why |
|---|---|---|---|
|  Traffic lights | Unambiguous, the states (stop, get ready and go) are obvious and clear. The sequence of moving from red to amber to green is repeatable every time, and corresponds to the actions required of drivers. Drivers can predict the sequence and can take corrective action as required |  Black watch face | Presents information in an unfamiliar way. Poor visibility of the current time. Forces the user to work hard to understand the information being presented. |

Table 2: Examples of user interfaces with high and low detectability.

> "A good user interface should provide clear feedback to users. It should provide a clear, unambiguous and repeatable signal of its status. It should be binary – either the mechanism has worked, or it has not."

A good user interface should provide clear feedback to users (Table 1). It should provide a clear, unambiguous and repeatable signal of its status. It should be binary – either the mechanism has worked, or it has not. Furthermore, to focus on usability, the binary state should be that either the task has been completed correctly or it has not. The user must be left in no doubt as to whether or not they have completed the task in the way the manufacturer intends. The designer of a device's user interface obviously wants to design something that is safe and that supports the user.

Indeed, system visibility is one of the key heuristic principles of good medical device design.[2] A "visible" system should inform users about what is going on with the device through appropriate feedback and display of information. It should inform the user about what actions are available, and the interface should change after an action is made. Why is this of particular importance for wearable devices? Because the user is carrying the device with them into their world. The wider world is unpredictable and the user is very intimately reliant on the device to keep them safe.

To illustrate this concept clearly, let's take some hypothetical examples of high and low detectability user interfaces (UIs) from the wider world (Table 2).

We want product designers to be designing detectability into the user interface of wearable devices, to give clear status signals to the user. A user interface with high detectability is inherently safer. So, perhaps it is time for detectability to be included as a component when calculating use-related risk.

## ABOUT THE COMPANY

Medical Device Usability is one of the world's leading consultancies specialising in usability and human factors for medical devices. Based on the Cambridge Science Park, MDU performs formative and summative human factors studies for global pharmaceutical, medical device and diagnostics clients.

## REFERENCES


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2. *Zhang J et al, "Using usability heuristics to evaluate patient safety of medical devices". J Biomed Inform, Feb–Apr 2003; Vol 36(1–2), pp 23–30.*


## ABOUT THE AUTHOR


**Richard Featherstone** is Founder and Managing Director of Medical Device Usability. Mr Featherstone leads the team of human factors specialists at MDU. With 15 years' experience of usability consultancy for medical devices, he speaks internationally on human factors, and advises some of the world's leading companies on their human factors strategies.