# Human Factors in connected device development



In response to market dynamics, Owen Mumford, has developed a platform reusable auto-injector which has well proven technology of mechanical operation for drug delivery. The device accommodates UniSafe® 1mL pre-filled safety syringe with 0.1mL to 1mL fill volumes. A key requirement for the device is to prevent needle exposure before and after the injection process, utilising the UniSafe<sup>®</sup> sharps protection feature. The platform incorporates connectivity and is suitable for a wide range of therapy areas to support and encourage patient adherence and provide stakeholders with access to patient medication data. Whilst Owen Mumford has a long track record in the development of auto-injectors, this is our first product incorporating connectivity.

The potential for digital connectivity in medical devices is well documented for a range of stakeholders including payer, pharma, patient, and caregiver. Finding a simple solution with a clear regulatory pathway is essential to ensuring a successful product. This poster describes how we applied a user centred approach during the development of the UniSafe® 1mL Auto-injector, and some of the lessons learned along the way.

## **Early-stage Human Factors**

### During the early stages of device development, we have:

- Simplified the user steps by incorporating the priming function into the device open/close action.
- Worked closely with design engineers to guide optimum user interface whilst accommodating the technical solutions. Managing different battery and power solutions along with connectivity, would have a considerable impact on user steps and the complexity of the user interface. Human Factors concentrated on desktop ergonomics, using anthropometric data to shape the physical interface and cognitive psychology to guide display solutions.
- Conducted early in-house user testing with device naive participants to gain early insights into general handling, understanding of the display and controls, and interpretation of the signals for connectivity.

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## Learning from formative studies helped to:



Evaluate the app content and flow - Owen Mumford was committed to generating a 'demonstrator' app that would allow us to consider the full impact on safe and effective use of the device. As the prototype matured there were inevitable stop/ starts in the flow of app use. It required creation of use scenarios that had to be mocked up in isolation, simulating the appearance of connectivity in several cases.

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Develop a generic IFU with a layout that meets user needs and aligns with potential packaging solutions - a landscape booklet emerged as the best way to provide enough space to present intended use steps in an easy-to-follow sequence.



Experiment with colour - participants successfully loaded and unloaded the device guided by effective use of colour on key touch points. Human Factors played an important part in emphasising the impact of colour on user interaction whilst competing with different aesthetic and marketing proposals.



Identify use related errors before testing with external representative users performance data helped to understand more about foreseeable use errors and focus on design mitigation measures.



Confirm general usability - the interface was modified with shaping and colour to support user understanding of door opening(priming), syringe loading, RNS removal and the injection process. Participants intuitively understood the door opening mechanism and successfully opened and closed the door, thereby automatically priming the device.



## Lessons learned on connectivity

#### User confidence

Participants' ages ranged from 23 to 73 with a median age of 50, all stated that they use apps daily, illustrating just how pervasive app usage has become. Once connectivity was obtained, all users understood the mobile app was connected to the UniSafe® 1mL Auto-injector, and that injection information was being sent from the device to the app.

Just 2/15 participants displayed some difficulty connecting the device to the app:

- One difficulty with connectivity was attributed to the low fidelity of the app used.
- The second participant understood connectivity was the goal but expected it to be automatic.

#### User reservations

At least one user expressed a reluctance to provide confirmatory actions on the app. It was perceived as redundant with no material advantage (asking the user to provide confirmatory actions is currently needed to prevent the app being classed as a medical device).

#### Redundancy

Some expressed doubt as to whether they would use it themselves for several reasons. Firstly, they lacked confidence in the app as a critical part of their own therapy management. Some distrusted the information that was presented and found it difficult to work with a 'pretend' scenario that suggested they had missed a dose as people generally did not believe they would do so in real life. However, there are limits to the realism that can be achieved in a simulated use scenario. Another stated that they would probably revert to pen and paper.

#### Study artefacts

Several features have been incorporated to ensure that user concentration during the injection process is not disturbed by any requirements for app interaction, and or failure/loss of connectivity, allowing a safe and effective injection experience. However, by its nature, the user evaluation process itself forced a degree of parallel interaction with the app, which influenced the user experience.

#### Adherence and consistency

Connectivity provides a great opportunity for stakeholders to access patient injection data. Any immediate benefit to the patient is reliant on their own consistent usage and adherence.



## Conclusion

Incorporating connectivity into our latest device platform was an exciting and challenging process. Whilst connection brings a wealth of possibilities, it can introduce some complexity to the user. User-centred iterative design coupled with multiple formative studies of the physical and connected interfaces sought to harness its potential and optimise ease of use.

Our study participants surprised us with their immediate recognition of the connected element, and effective interaction with the connected device and app.





Pharmaceutical Services