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WHITE PAPER

# Step by step: ensuring your instructions are as intuitive as your medical device

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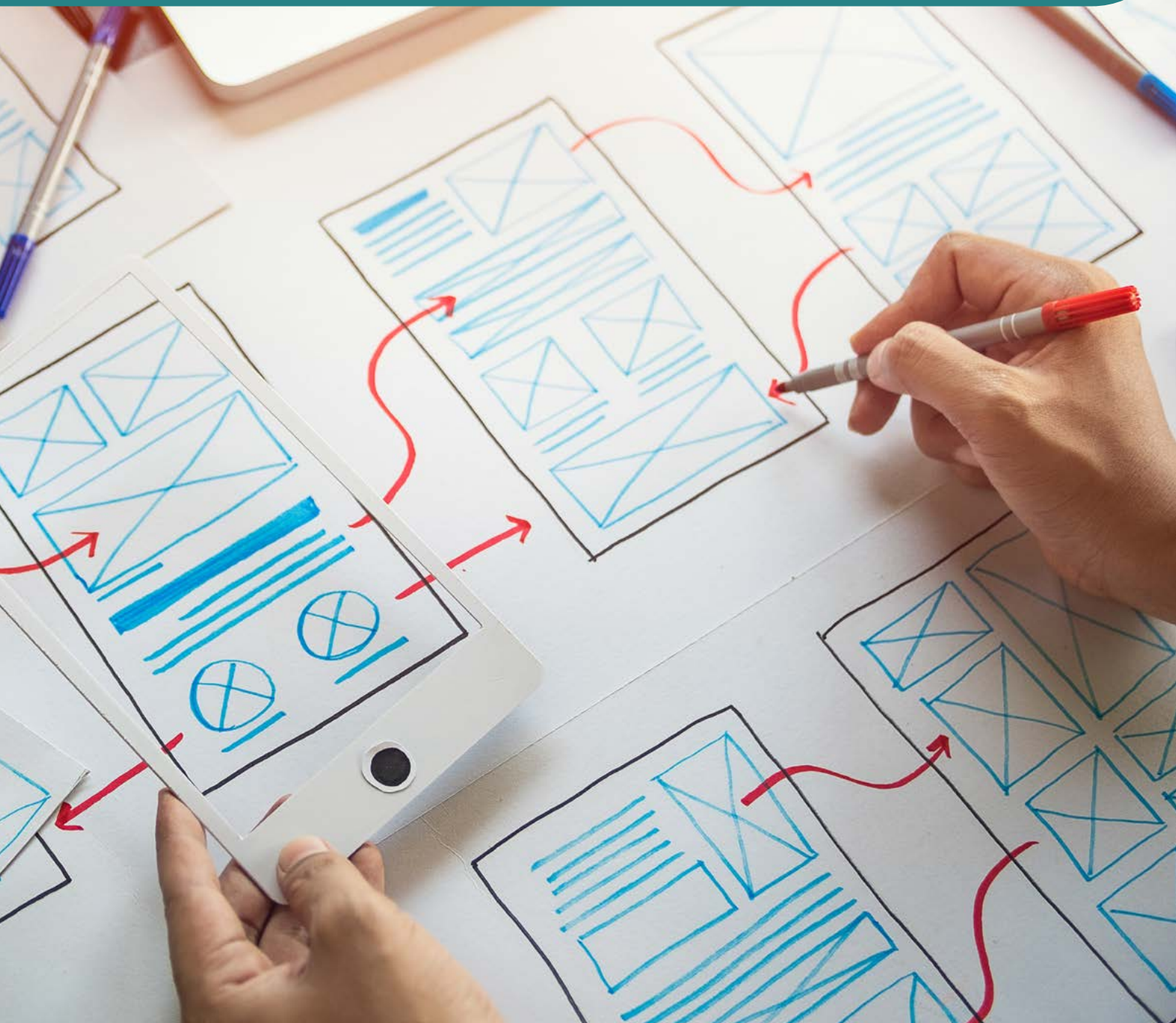

Products with a low number of user steps are often perceived as user-friendly, efficient, and easy-to-use. However, if critical steps are omitted from instructions, confusion and user error can ensue. In this whitepaper, Simon Thorne, Usability and Human Centred Design Consultant at Sagentia Innovation, considers how to achieve true ease of use via an empathy-led approach that accounts for users' needs, capabilities, and environments.

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There's a widely held belief that products with few user steps are easier to use than those with many steps. Minimising user steps is often a key design goal to aid product marketing. However, oversimplifying instructions for use can be counterintuitive.

This is especially true when designing medical devices. Usability practitioners must consider who users are, as well as their background, cultural exposure, experience, education, and needs. Use case scenarios and the use environment (e.g. in clinic or at home) also impact overall usability.

True ease of use doesn't necessarily equate to fewer steps in the instructions for use. It requires empathy-led design and careful articulation of instructions, accounting for users' real-world needs and experiences. In this whitepaper, we look at how to achieve this via usability engineering and empathic design principles. We also consider how to streamline and enhance instructions without omitting important user steps.

## User steps and ease of use

Keeping user steps to a minimum is often equated with ease of use. For instance, an in-stream pregnancy test may appear to follow a simple three-step process: 'perform the test', 'wait xx minutes', 'read the result'. Yet this omits steps which may hinder ease of use, such as opening the packet, removing the cap from the device, and correctly placing the device in the urine stream.

*Figure 1: A simple three-step process.*

True ease of use is where a task, step or action comes naturally. Opening a car door is a good example. It's usually obvious where the door handle is located, and it gives good haptic feedback so you can 'feel' that the door is unlocked. Actions that require no instruction or 'just make sense' can be classified as intuitive.

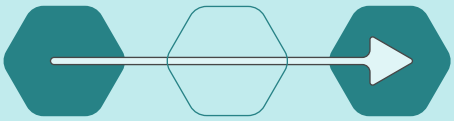

*Figure 2: Intuitive action that requires no instructions.*

# Usability engineering

Medical device regulations IEC 62366 and BS EN 14971 require a type of risk assessment called a task analysis. This involves breaking down individual tasks or steps, identifying where users could go wrong, and assessing the implications of errors. One aspect of this analysis is Perception, Cognition, Action and Violation (PCAV), which involves assessing the following aspects of user engagement:

- What are the users doing; how could those actions be performed incorrectly?
- Do users perceive the information provided (e.g., verbal, or written instructions) and can they follow it correctly?
- How do users perform the task?
- Do users complete the task as intended to achieve the desired outcome safely, or is there any risk of causing harm, and is it therefore a critical task?

Any task outcome that is critical to device performance must be assessed with representative users in a formative study. This should be performed as early as possible in the product development process. Identifying user errors enables refinement of the design to eradicate or mitigate any issues observed. The process also indicates whether users will require training and, if so, whether this would require periodic refresher training. During a formative study, we can use metrics to assess users' performance of each task, focusing on number of errors, help requests, user actions, time spent on the task, user satisfaction, and task success. Of these metrics, task success, time on task and number of errors are central to understanding ease of use and, therefore, intuitiveness.

## Use scenario: making a cup of tea

Analysing the steps involved in making a cup of tea neatly illustrates how an everyday task may be more complex than it appears. As Figure 3 shows, deconstructing the process of preparing a cup of tea with milk reveals 30 distinct steps and that's without adding sugar.

Many of these steps are intuitive and easy for most people. So, on-pack instructions are generally limited to the need to pour boiling water onto the teabag, brew for two to three minutes, and add milk if desired. However, viewing the 30 steps through a human-centred lens introduces new perspectives.

For instance, the simple act of picking up a cup may be difficult for someone with dexterity issues caused by conditions such as Parkinson's Disease or arthritis. The tasks may be physically challenging, time consuming, and mentally taxing for these individuals. While purveyors of tea would not be reasonably expected to address this, in medical device development the human factor must be accounted for in every step, no matter how small.

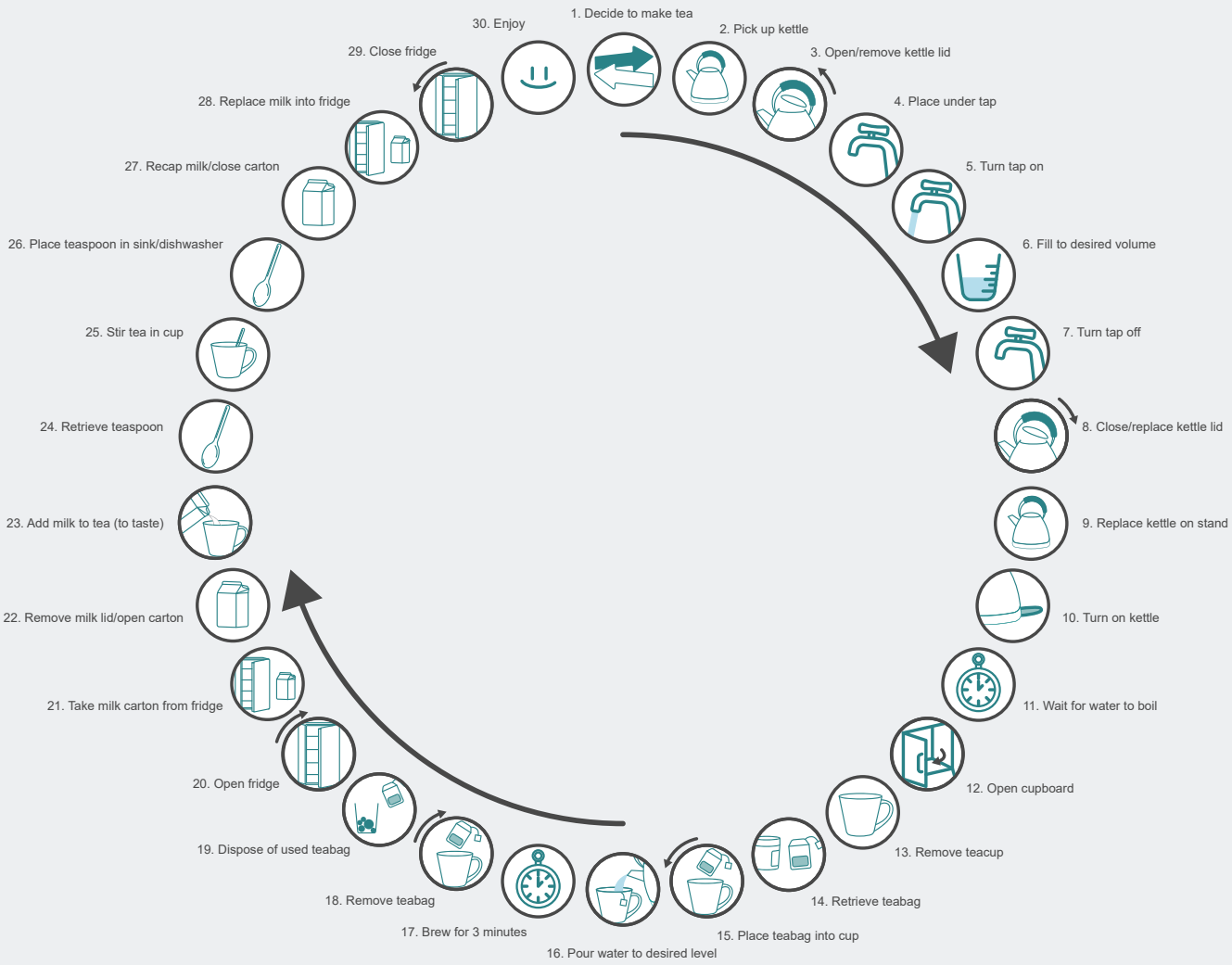


*Figure 3: The 30-step process of making tea with milk.*

# Three ease of use considerations

There are many elements to consider in the design of a medical device. When it comes to usability and optimising instructions or user steps, three come to the fore: intuitiveness, inclusivity, and match.

## 1. Intuitiveness

If a product isn't intuitive, its use is likely to be difficult, resulting in low product satisfaction and user annoyance, which could harm brand image. This is where engaging usability engineers early in the design process adds value. They can identify those challenging areas and improve them while development costs are low.

In the case of the IVD lateral flow tests developed in the UK during COVID-19, user steps might simply have been defined as 'run test', 'wait', 'read result'. However, the instructions were carefully broken down into 22 separate tasks, with additional detail provided at key points. These instructions almost certainly benefitted from a co-creation process involving graphic designers and usability practitioners. For instance, as Figure 4 illustrates, users were advised to 'take care' when breaking open the fluid sachet. We can surmise that during a user study, some participants struggled with this step resulting in spillages of the elution fluid, potentially reducing the effectiveness of the test, the additional note was added to help ensure the correct outcome.

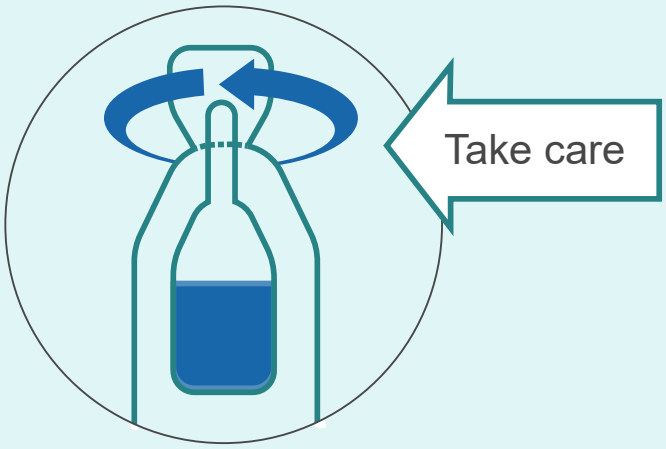


*Figure 4: Lateral flow tests for COVID-19 advised users to 'take care' when opening the fluid sachet.*

Intuitive design doesn't just rely on understanding why something happens, it also involves asking why something else didn't happen, or what the consequences would be if something was done differently. For instance, as well as asking 'why did users dispense X amount?', it's useful to consider 'what happens if users over or under dispense?' or 'why didn't users dispense the correct amount?'.

## 2. Inclusivity

Inclusivity has become a watchword of human centred design in recent years. When considering ease of use, understanding potential differences between users is crucial. This encompasses factors such as education and cultural differences as well as physical capabilities.

Cultural differences can introduce significant challenges to medical product design. The collection of urine samples is a case in point. While standard tests require a collection vessel and sample container, the design and use of toilets in different parts of the world can impact their use. Differences between the squatting and seated positions affect users' stance and level of control, and therefore their ability to collect a clean urine sample.

Empathetic design requires active consideration of users, product use environments and scenarios across all potential markets. For instance, until very recently, it was common for women in Nepal and other parts of South Asia to be quarantined when menstruating. This meant having to sleep in a separate 'period hut' due to historical practice and beliefs as well as cultural stigma surrounding blood and urine.

From a commercial perspective it might be advisable to focus on an initial launch in one region followed by wider rollout. However, care must be taken to ensure potential user errors for future markets are not overlooked during the design phase and that the design is empathetic to those market needs.

## 3. Match

Usability practitioners must look beyond the obvious to better understand the outcome of user errors. What are the repercussions if a user completely misunderstands a task? Can they still obtain a satisfactory outcome, does it become a user annoyance, or is fail-safe design required?

The World Health Organization recommend when using lateral flow tests in Central and South America for diagnosing Chagas disease[1], that two different lateral flow tests are used. This is to increase the likelihood of detecting Chagas by utilising two different antibodies present in the lateral flow tests. In addition, some lateral flow test responses to other known diseases can be especially strong, resulting in an anticipated bias in healthcare workers who are accustomed to strong lateral flow test responses, potentially missing faint lines in test results.

Utilising two different lateral flow tests, increases the likelihood of a stronger response and better interpretation of the result by the health care worker. As well as an increase in compliance to future testing of individuals through a higher accuracy and therefore trust in the product.

When a product is well thought through and matches what the user thinks it should do, users are left feeling confident that they 'got it right'. On the other hand, when a product doesn't match the users' expectations, they are often left frustrated and confused.

Designing products to be intuitive with minimal risk of an unrecoverable or critical error usually requires a multi-pronged approach. In the following theoretical example, the instructions for a lateral flow test include multiple measures to reinforce the importance of dispensing a 3-drop sample.

As Figure 5 shows, '3 drops' is written in bold font, the diagram shows three droplets in a darker colour, and the device casework also features three droplet icons. A warning symbol is used too. This could have been emphasised further with the statement 'max 3 drops', but users may have surmised that anything less than 3 drops is fine, potentially leading to under sampling. Users complying with dispensing 3 drops as requested, ensures that the lateral flow test is neither under or oversampled, both of which could lead to an incorrect diagnosis, caused by user error.


*Figure 5: COVID-19 lateral flow test instructions reinforce the need for '3 drops' multiple times.*

# Streamlining and enhancing instructions

With the 22-step COVID-19 test, reducing risk of error was the primary goal and it outweighed other concerns. However, in general, reducing the number of steps to streamline instructions is considered highly desirable so a product can be marketed as ‘easy-to-use’. The challenge for usability practitioners is determining the optimum number of steps to maximise ease of use without compromising safety or increasing user errors.

In some situations, the answer may lie in grouped instructions, where numbered steps are replaced with grouped items or workflows. Figure 6 shows how our 30-step process for making a cup of tea can be reduced to 18 steps contained in three activity streams: ‘prepare’, ‘brew’, ‘adjust and enjoy’. Tasks which are truly intuitive are removed, but any which may cause user difficulty are retained.

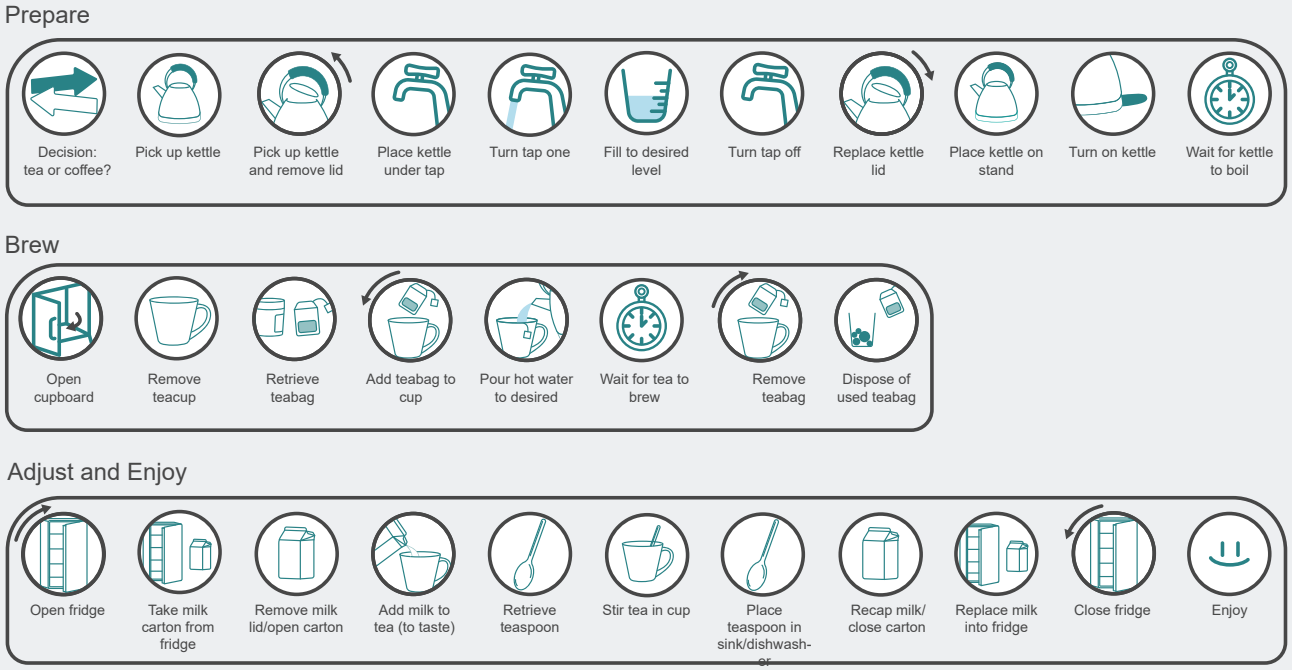


*Figure 6: Three workflow streams for making tea with milk.*

An understanding of user abilities should influence decisions throughout the design process. Will users be able to tear open the foil packet? Can they unclip the lid? Are they able to squeeze this bottle and dispense the correct amount? It’s important to consider where confusion, frustration, and misunderstanding might arise.

Novel approaches to instructions could also enable better understanding of tasks. While medical device regulations require the inclusion of printed instructions, augmenting these with animated and/or audible versions could prove beneficial. Automatic External Defibrillation (AED) devices for public locations demonstrate how this can work in practice. Contact pads are clearly illustrated so users can see where to place them, and the devices are engineered to ‘speak out’ the instructions clearly. This means people with little to no training can use the devices in stressful and emotionally charged situations.

## The advantages of 'live' instructions for use

In 2019 a TikTok influencer suggested that Clearblue pregnancy tests contained a hidden morning after pill. Her followers were encouraged to break open the device and take this 'pill' if needed. In fact, the tablet inside the device is a desiccant to keep the test strip dry throughout its shelf life. The tablets are not intended for consumption, and pregnancy test manufacturers had to react quickly to correct this misinformation, which took considerable time, expense, and effort.

If the instructions had been held on a live digital document, they could have been updated with immediate effect to include a more obvious warning. This would have greatly improved speed of response to a newly identified user error, negating the need for product recall and mass printing and restock of updated instructions for use.

QR codes also hold great potential. Instructions could evolve from a printed leaflet in a box, to an on-pack or on-device sticker that directs users to live instructions which are updated as needed throughout the product lifetime.

As Augmented Reality (AR) and Virtual Reality (VR) technologies become mainstream, it is entirely foreseeable that they could be harnessed to improve medical device instructions too. Figure 7 illustrates how COVID-19 lateral flow test instructions might have been enhanced using a combination of traditional step-by-step instructions and AR.


*Figure 7: AR could have been used to enhance the instructions for COVID-19 lateral flow tests.*

# Conclusions

With today's technologies, it is already feasible to train an app with a dataset for correct and incorrect set-up for each user step of a medical device. This capability can be used to assure users that the device is functioning as intended throughout the process. The same principle can be applied to alert users if they are about to commit an error, with on-screen or audible warnings allowing them to correct their actions.

Such approaches would be especially useful in situations where a device is used by individuals with different levels of experience or who have physical challenges to overcome. Whether they are using the device for the first time or the thousandth time, they can be confident in the outcome, at home, in the field, or in the hospital.

Rather than focusing solely on the reduction of user steps, it's important to test and refine them to fully understand what instruction steps are needed. Accounting for different users' needs, capabilities, and experiences is central to this. Clear instructions maximise ease of use, reduce errors and ensure the intended outcomes are achieved.

Contact info@sagentiamedical.com to speak with the team and find out how we can support your company in achieving true ease of use via an empathy-led approach to product development.

## References

1 Evaluation of 2 Lateral Flow Rapid Tests in the Diagnosis of Chagas Disease in the Washington Metropolitan Area (2021) https://academic.oup.com/ofid/article/8/4/ofab096/6157001

## About Sagentia Medical

Sagentia Medical is a specialist independent advisory and leading-edge product development services focused on science and technology initiatives in healthcare. Working across diagnostics, surgical devices, and medical devices, Sagentia Medical works with start-up disruptors through to world leading brands in MedTech to extract maximum value from R&D and innovation investments.

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