In Touch. An investigation of the benefits of tactile cues in safety-critical product applications

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Abstract:
This paper details the theoretical and practical implications of a collaborative project that investigates the safety and usability of medical products. The project focuses on the design of medical connectors used in the administration of drugs to patients in intensive care. The aim is to help prevent potentially fatal misconnection errors.

The paper describes the design methods employed in the development and testing of a new connector identification system that is based on tactile cues, such as contrasting shapes and surface textures. The project demonstrates a unique contribution made by design practice to developing knowledge within the field of medical product development and understanding the context of use.

1 Tactile cues

The North American raccoon has extremely sensitive paws. In order to process all the sensory information received from its paws, the raccoon uses about the same proportion of the brain as humans use for sight. Scientists believe that through touch, raccoons are capable of constructing a picture of the world that is as complex as humans perceive through sight. When hunting for food in streams and rivers, raccoons rely on the sense of touch. The ability to interpret tactile cues enables raccoons, in a split second, to detect the difference between an edible clam and a pebble. [1]

The puffer fish exhibits both visual and tactile cues, expanding in size and projecting spikes, to ward off predators. Victorian medicine bottles were often embossed with a distinctive surface texture, so that they could be identified in the dark, and to warn if the contents could be harmful if consumed.

Figure 1 The puffer fish inflates and projects spikes to ward of predators.
A traditional view of the industrial design profession is that it tends to be preoccupied with visual appearance, at the expense of other factors. In America, the first industrial designers were known as “stylists”, since their chief concern was the cosmetic appearance of products (Chamberlain et al 1999, Margolin 1997, Rothstein 2000). However, a change of direction appears to be taking place, as Moggridge (in Myerson, 2001) and Ward (2002a) identify a demand from end-users for products that satisfy all five senses, not just the visual.

This paper describes a project in which designers explore how both visual and tactile qualities of products might be exploited. The designers investigate how tactile cues, such as contrasting shapes and surface textures, might be applied in product interface design, to improve usability and to help prevent error. The project, a pilot study, identifies considerable scope for further research in this field. Potential outcomes for future research include the formulation of a set of design guidelines for the effective use of tactile cues in product and packaging applications.

2 Introduction to the Pilot Study

Industrial Designers at Sheffield Hallam University have been actively involved in a collaborative project that aims to investigate the safety and usability of medical devices. The principal focus for the project is the design of the ‘Luer’ connector system (shown in figure 2) used in the administration of anaesthetic and other drugs, primarily in the treatment of patients on intensive care wards. The aim of the project is to help prevent misconnection errors; a number of fatalities have occurred because patients have been connected to the wrong drug line.

The project aims to develop a failsafe mechanical system, to prevent misconnection, and also an identification system to make it easier to select the correct connector. The pilot study investigates the feasibility of an identification system that is based on both visual and tactile cues.

Work on the project began following the publication of a UK Government report which calls for the redesign of connecting devices (Toft 2001; see also Woods 2001, Berwick, 2001). The findings of the pilot study have been presented to Senior Representatives of the UK Department of Health, and the European Safety Standards Advisory Committee (CEN) for Medical Devices.

A colour coding system could be used to identify the five most common drug delivery routes (Intravenous, intrathecal, respiratory, cardio-vascular and enteral). However, in intensive care wards, it is common practice to maintain low levels of ambient light. This could make colour-based identification problematic. In hospitals, there already exists a whole gamut of colour coding systems; to introduce an additional set of colours may add a further level of complexity to the problem.

An identification system employing both visual and tactile cues (such as shape and surface texture) could be particularly useful in intensive care settings, where clinicians may often be required to identify connectors which are
not in their immediate field of vision, e.g. when concentrating their visual attention on a VDU monitor. Also, clothing, blankets, bandages or other medical devices may obscure immediate sight of the connectors.

![Figure 3](image3.png)

**Figure 3** All the of tubes coming from this machine have the same connector fitting; there is nothing to distinguish between the different drug lines. For reasons of privacy, the patient could not be shown in the photograph.

### 3 Literature Review

A literature review identified studies within perceptual psychology discourse that describe the various dimensions of human tactile sensitivity, and the ability to recognise and discriminate between different objects using the sense of touch (Lederman and Klatzky 1998, Gibson 1962, Hughes and Jansson 1994). Whilst useful and relevant, these existing studies are not directly or specifically applicable to the design of products. However, key texts from the field of ergonomics and human factors engineering have provided evidence of the potential benefits of the application of tactile cues, in the design of product interfaces (Burnett and Porter 2001, Sanders and McCormick 1993).

Norman (1988), stresses the importance of designing product controls that ‘look and feel different’, especially in safety critical applications. He gives the example of a control panel for a nuclear power plant. Control-room operators have modified similar-looking switches by fitting them with different beer-pump handles to prevent misidentification (figure 4).

![Figure 4](image4.png)

**Figure 4** Control switches from a nuclear power station, where the handles have been modified by fitting them with different beer pump handles to prevent misidentification (source Norman, 1988)

Research carried out by the US Air Force investigated the benefits of ‘shape coded’ aircraft controls. In one study, Jenkins (1947) found that blindfolded pilots could identify these specially shaped control knobs using only the sense of touch. (Figure 5)

![Figure 5](image5.png)

**Figure 5** Shape-coded Aircraft control knobs
Figure 6 shows sketches of a second set of control knobs, proposed by the US Air Force System Command (1980). In this case, the knobs have been designed to symbolically represent the intended function of the aircraft controls: e.g. the landing flap control is shaped like a wing, and the landing gear control is shaped like a wheel. Although the use of symbolic shapes appears quite crude, it is considered to be advantageous as it makes it easier for pilots to learn the functions of the different controls and reduces the likelihood of error.

These examples indicate the potential benefits of an identification system that is based on the use of contrasting shapes. However, the control knobs used in these studies appear to be much larger in size than the medical connectors (The knobs tested in Jenkins’ study were approximately 36mm in diameter, existing Luer connectors measure approximately 15mm diameter). They do not take into account the range of materials used in contemporary product design. For example, tactile cues might be created using a combination of contrasting materials such as “soft feel” rubber, rigid plastic, and metal. Also, the participants in the US Airforce studies were military pilots and trainee pilots. It could be argued that, because of the nature of their professional training, these participants were more capable of quickly identifying and responding to complex sensory information, than the general public as a whole.

There is clearly considerable scope for further research in this area. The pilot study focuses on tactile cues based on contrasting shape and surface texture, at a size and scale appropriate to the medical connectors. Further research will explore the use of contrasting materials - the physical properties of weight, thermal conductivity, hardness/softness - used in combination with shape and texture, to further enhance object differentiation. Research will also investigate how tactile cues might be used in other product applications, for example, in the design of buttons and switches used in consumer electronics, or automotive control systems.

4 User-Centred Design

As Margolin (1997) observes, ‘the relation of products to users has become a central theme of design discourse.’

‘User-centred’ design methods have been widely discussed, within product design discourse, and also in the disciplines of human computer interaction (HCI), human factors engineering and ergonomics. McDonagh-Philp (1998) introduces us to the following definition of user-centred design:

‘User-centred design is a design methodology that utilises the target product users as a designing resource to increase the understanding of the design practitioner.’

If the aim is to improve the usability of products, it is essential that designers acquire knowledge of product use that is derived from first hand experience. In some cases, such as when designing familiar consumer products,
Designers can draw on their own “real-life” experience of using these products. However, it becomes more difficult when designing products that are used in unfamiliar contexts (e.g., in hospitals), or for people whose age and/or capabilities lie outside of the designer’s own experience. It is therefore necessary for designers to build close collaborative relationships with product users and, where possible, to take part in user activities themselves.

Quoting from Dreyfuss (1955):

“I have washed clothes, cooked, driven a tractor, run a diesel locomotive, spread manure, vacuumed rugs, and ridden in an armored tank. I have operated a sewing machine, a telephone switchboard, a corn picker, a lift truck, a turret lathe, and a linotype machine….We ride in submarines and jet planes. All this in the name of research.”

Rothstein (2000) reports how designers have adopted observational research techniques more commonly associated with ethnography and the social sciences. Ward (2002b) describes a study on the use of “video ethnography” in design, carried out at London’s Royal College of Art. Using video techniques, observational data on product use can easily be recorded, reviewed and analysed by designers. She reports ‘one frame of video footage can show a multitude of detail about context and usage’.

5 Conducting user-centred research in the intensive care ward – the ethical challenges and constraints

The project team proposed a period of observational research, to be carried out in the Intensive Care Unit at Bradford Royal Infirmary. The aim was to spend time observing and recording the activities of hospital staff in “live” situations on the intensive care ward. Video ethnography was considered to be an extremely valuable research tool in this context: it would allow user activities to be recorded, reviewed and analysed in detail. However, the team soon found that conducting user-based research in the setting of an intensive care ward was going to be an ethical and practical minefield.

Firstly, ethical guidelines warn against conducting research without the proper consent of research subjects (Social Research Association Statement of Ethical Practice, British Sociological Society Ethical Guidelines - cited in Bryman, 2001). In the case of patients on the intensive care ward - they are clearly not in a condition to give consent because they are seriously ill and, in most cases, unconscious. It would be viewed as an invasion of their privacy to conduct research with patients who are unable to give consent.

Also, hospital staff could not consent to being recorded whilst caring for patients, either in photographs or on video. It is against Health Service policy to record medical staff whilst at work. This is because, if staff were to make an error, the recording could be used as evidence. This is entirely understandable, bearing in mind the highly demanding nature of the work, and the trend towards litigation against the medical profession. Concerns were raised over the discussion of actual and potential errors with hospital staff. The project team were concerned that staff may, understandably, find it difficult to acknowledge their own potential to make mistakes, because they might view this as a measure of their own professional competence. Again, this is symptomatic of the current “blame culture” within the UK Health Service. Media reports draw attention to the estimated 850,000 “adverse events” within the health service each year, causing more than 40,000 deaths. (See. Ahmed, 2002, Fish, 2001, Wears, 1999).

Concerns also exist that many errors go unreported because hospital staff realise they have made a mistake and correct the error “just in time”.

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For the pilot study, it was possible for members of the project team to observe staff at work on the intensive care ward, but for the reasons described above this could not be recorded in photographs or on video.

A proposal will be made to the Medical Ethics Committee of the UK Department of Health, for permission to carry out further extensive observational research on hospital wards. Further research will investigate existing video footage used in the training of healthcare professionals, and also explore the feasibility of using an intensive care simulator, for testing and evaluation purposes.

6 Observational Research

Our first-hand user-research began with a visit to the intensive care unit at Bradford Royal Infirmary on Monday February 4, 2002.

Observational research revealed an urgent need for a standardised identification system for medical connectors. Intensive care staff demonstrated a “makeshift” identification system currently in use. The system requires the nurses to attach a self-adhesive paper strip to the individual drug delivery lines. A drug code or name can be written onto the paper label by hand. This labeling system causes problems, largely because it is not standardised across the health service, or even across departments within the same hospital. This means that it is easy for inexperienced, newly qualified or, temporary members of staff to become confused.

We observed a patient being brought onto the intensive care ward on a trolley. The patient had to be disconnected from a number of portable dosing pumps and electronic monitoring devices, and reconnected to the equivalent non-portable devices based on the intensive care ward. Intensive care staff aim to make the transfer quickly, in order to limit patient trauma. As the patient is being lifted off the trolley and onto the bed, tubes and wires can become tangled around one another, and caught up in the patient’s clothing and blankets. The patient transfer process appears to be fraught and very stressful. It was clearly easy for us to see how misconnection errors could be made in this context.

7 Designing, Making and Testing

The underlying design principle behind the tactile identification system is that one connector with a particular external shape, recognisable using the sense of touch, should be matched with a another connector of the same external shape. In other words, connector shapes should be matched like-for-like. The design of the prototype connector components was based on combinations of simple, contrasting geometric elements. Some of the contrasting features might be interpreted as “opposites”. For example: concave versus convex sides, or longitudinal versus transverse ribs. The cross sections of the components were based on geometric “primitives” i.e. a square, circle, or triangle. Other distinguishing features include the presence or absence of small surface details such as bumps or dimples.

Early design concepts were developed through freehand sketches and drawings, leading on to 2D CAD drawings and 3D CAD models. We found that, because of the small scale of the components, and the intricate nature of the surface details, it was very difficult to produce accurate physical sketch models of the tactile shapes. We therefore had to rely on an intuitive sense of how the shapes might feel to the touch. It was only when a first set of prototypes were produced that we could really evaluate the tactile qualities of the components. These physical models became a “vehicle” through which the ideas could be tested and evaluated by end users.
The size of the first set of prototypes was based around the overall size of a standard Luer connector – typically 15mm x 15mm x 25mm.

We presented the first set of prototype components to a Consultant Anaesthetist from Bradford Royal Infirmary. He was confident, based on his experience using the existing connectors, and also manipulating other small devices such as spinal needles, that the first set was easily identifiable, using only the sense of touch.

Psychologists on the project team had planned to carry out an extensive phase of tests using this first set of prototypes. However, the anaesthetist recommended that, as the first set of components appeared to be successful, we should instead produce a second set at a smaller scale, to see if the tactile qualities were still detectable. If successful, the tactile cues could then be applied to components smaller in size than the standard Luer connector.

We therefore produced a second set of prototypes, this time measuring typically 8.5mm x 8.5mm x 15mm. These were assessed in a rigorous phase of user tests carried out by human factors specialists from the School of Psychology at the University of Leeds. (Figure 7)

The testing procedure involved 25 participants who were healthcare professionals working in the Intensive Care Unit and the Anaesthetic Department at Bradford Royal Infirmary. Participants were required to carry out matching tasks using the prototype connector shapes, with their hands and the prototype components hidden from sight by a screen. A “target” connector was first placed in the participant’s open hand. The participant was allowed to freely manipulate the target connector using both hands. The target was then handed back, and the participant was then presented with a set of all 6-prototype connectors, and asked to identify the target from amongst the set. The test was repeated using each of the six connectors as the target.

The time taken to carry out the matching task was recorded, using a millisecond stopwatch. Tests were carried out with both gloved and ungloved hands, using standard latex-free surgical gloves, and any identification errors were recorded.

A statistical analysis of the mean identification times revealed an average rate of error of 2.72%. The mean identification times for 4 of the 6 prototype connectors was between 5 and 6 seconds. Two of the connectors took significantly longer to identify. This was because, at such a small scale, certain tactile features appeared to “overlap”; for example, the spacing of lateral ribs on one of the connectors correlated almost exactly with the spacing of a pattern of bumps on another.

Modifications were made to the design, so that the tactile features no longer overlapped, and a third set of prototypes produced. The test procedure was repeated. In the second phase of tests, the mean rate of error dropped from 2.72% to 1.73%.

![Figure 7 Testing of the tactile components was coordinated by Neil Carrigan of the Human Factors Research Group at Leeds University School of Psychology](image-url)
8 Discussion, conclusions, potential for further research

The pilot study clearly shows the potential benefits of an identification system based on tactile cues. This was demonstrated in tests, where participants were required to perform matching tasks with two sets of prototype components, using only the sense of touch. Some of the prototype components were identified more quickly and easily than others. The components that could be identified most easily were those which were based on simple, contrasting 3-dimensional elements.

In a second phase of tests, the overall rate of error was 1.73%. Although low, this figure may still be considered unacceptable for safety-critical applications, since the consequences of any error would be very serious. It is recommended that the tactile identification system should not be used as a “stand alone” safety system. It should, however, be beneficial, when used in conjunction with a “failsafe” mechanical system.

The UK Government has set a target of zero misconnection errors [2]. The combination of a mechanical system that prevents misconnection, and an identification system that provides a means of quickly selecting the correct connector would seem like an ideal solution.

However, concerns exist that, when using a failsafe mechanical system, there may be situations when the correct non-interchangeable connector is not available. This could slow down or even prevent certain emergency procedures taking place. As a response to this, a system of interchangeable “snap-on” tactile markers could be developed, to fit over the chosen non-interchangeable connector. This could operate as a “customisable”, task-specific identification system. As long as the tactile markers are matched like for like, a misconnection error could not occur.

There is clearly a need for further research and investigation. In order for the research to be “ecologically valid”, tests need to be carried out in an environment that simulates the working conditions of the intensive care unit, such as distractions, high stress level, high workload, multi-tasking, poor lighting, inexperienced staff etc. Investigations should be made into the feasibility of using a “high-fidelity” intensive care simulator, as a means of testing future design proposals. Also, we should aim to obtain permission from the UK Department of Health, in order to record live video footage of health care professionals carrying out procedures that involve the use of existing connectors. Analysis of this live video footage should provide the design team with a greater level of insight into the way that the existing connectors are used.

So far the research has investigated tactile differentiation through the use of shape and surface texture. There is also clearly the potential to explore the tactile properties of different materials, either alone or combination with shape and texture. For example, a set of 5 components of different shapes and /or surface textures, could be available in 3 different materials such as hard plastic, soft rubber and metal. Practical limitations on material selection exist in certain medical applications eg metal connectors would not be suitable for use in X-ray or MRI scanners.

The diagram in Figure 8 is an analogous model, showing how a combination of different visual and tactile cues might, when used together, operate like a layered filter, preventing a potential error. We developed this model as part of our research, and wish to test out its validity though further practical making and testing.

The project highlighted the often-intuitive nature of the design process. Because the connector components were initially developed on CAD, physical feedback was unavailable. In the early stages of the project, design decisions therefore relied on us having some “intuitive sense” of how the components might feel to the touch. This “intuitive sense” is an example of “tacit knowledge”; knowledge based on previous experience handling 3-dimensional form and materials.
It was only through the production of physical prototype models that others could assess the tactile components. Tacit knowledge also played a role in the Anaesthetist's assessment of the first set of connector components.

However well-designed the connector system is, it still relies on ability of staff to administer drugs correctly. Further research should aim to take a “systems approach” to safety, investigating the application of tactile cues within the wider context of the hospital. This should include the design of other products used within that system, such as drug packages and labels, and also the syringes, needles and catheters that are used with the connectors.

Future research will also explore other potential applications for the tactile cues. For example, in the design of equipment used by the fire service in poor visibility conditions such as within smoke filled buildings. Other potential applications include the design of controls used in vehicles or heavy industrial machinery, or other products where the operators need to activate switches or controls whilst their visual attention is directed away from their hands.
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Endnotes


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