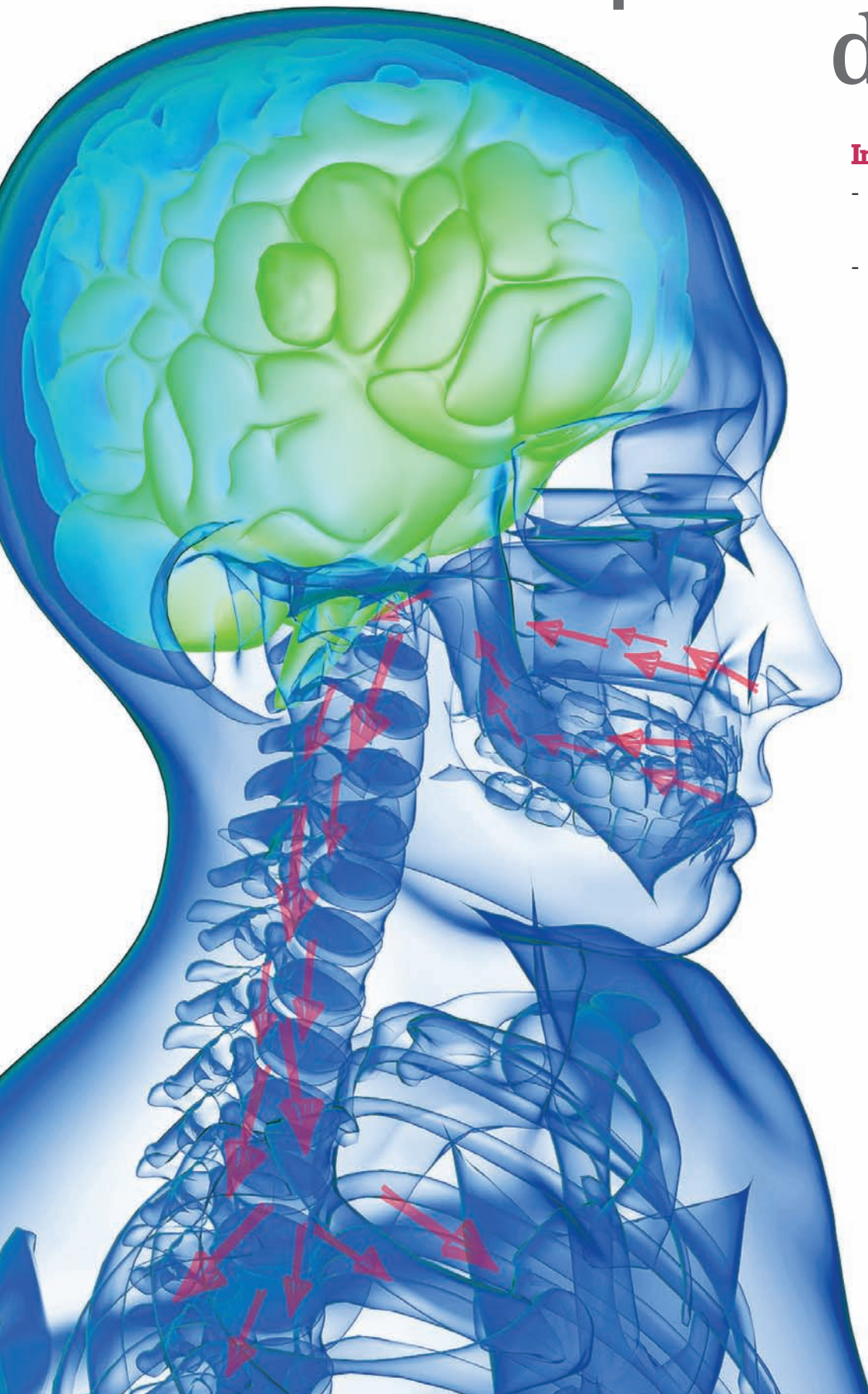


Patient-centred approaches to respiratory drug delivery

Inside:

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Helping clients bring innovative medical products to market

We are experts in medical product design and development. Working closely with our clients we apply our expertise in engineering, human factors, industrial design and technology consulting to identify concepts and take them from the drawing board to clinical trials, and then on to commercial launch.

Because all we do is design medical products, we understand the regulations and constraints that we all work within. We believe that this in-depth knowledge of the sector leaves us free to focus on using our creativity and rigour to solve problems and design the best possible products for our clients.

At Team we believe it is the way we work with our clients that is key to our success. We pride ourselves on the quality and independence of our advice, and the strength of our relationships, which are based on integrity, honesty and trust.

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Usability validation is “a game of words, not a game of numbers”

By Julian Dixon,
Head of User Research

At the end of March I was invited by Stephen Eason, Director of Device Development at Vectura, to join him in presenting to the IPAC-RS 2011 conference, which had a particular focus on patient needs and concordance.

During our presentation Stephen reviewed the published research around inhaler usage, which highlighted some well-known, but always striking figures, such as:

- “In actual pulmonary clinical practice, the majority of patients were unable to use a pMDI correctly (75%)”¹
- “Nearly one in three patients (30.9%) used DPIs ineffectively in a study of 224 newly referred outpatients”²
- “Failure to correctly perform essential steps for reliable lung delivery with the Aerolizer®, Turbohaler® and Diskus® was found in 17%, 23% and 24% of patients, respectively”³

Stephen’s conclusion was that this evidence provided us with a benchmark of between 25% and 33% of DPI users who are using their inhalers ‘incorrectly’. Clearly, this suggests that as OINDP device developers we face a challenge: to design and produce more usable inhalers.

I then stood up to talk about how we can rise to this challenge – using ANSI/AAMI HE75:2009 as a sound guide to what human factors (HF) activities to do, and when they should be used through the development process. I argued that when applied correctly, analytical and empirical HF techniques do help us to achieve our objective of safe and appealing devices.

Following our presentation, Ron Kaye from the FDA stood up and discussed the Agency’s evolving process for assessing the usability of drug delivery devices and, in particular, its expectations regarding how companies should validate the usability of their device.

It was during his presentation that Ron stated his view that usability validation is “a game of words, not a game of numbers”.

This view may surprise many of us in the pharmaceutical industry. But it is a reality of human factors work that we have recognised for many years. Numbers are important in HF and they must be presented clearly and accurately – for example, the frequency of occurrence of a particular use-error in a user trial is a number that matters a great deal. But there are many reasons why the numbers are only the start of the matter.

Firstly, in our usability validation of drug delivery devices we will be concerned with justifying claims of the expected non-occurrence of potential use-errors and statistically justifying an estimate of a very-near-zero failure rate cannot practically be done – we would need to observe thousands of users. But secondly, even if we were to conduct a vast usability study in the pursuit of sufficient statistical power, a HF study can never be a perfectly valid assessment of what will happen in the ‘real world’. The numbers will not mean exactly what they might seem to mean. The events observed in our studies must be unpicked, challenged, discussed qualitatively and, as far as possible, their causes uncovered – whether they lie in the psychology of the user, the design of the device or its instructions. Only then can we support our claims of acceptable usability.

Hence a game of words, not numbers. The numbers cannot provide a full picture, important as they are. It is the intense qualitative investigation of what we observed that is key.

If you’d like a copy of our presentation slides from IPAC-RS 2011 or would like to discuss the topic of human factors in more detail then please get in touch directly. ●

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- (1) Handling of inhaler devices in actual pulmonary practice: metered-dose inhaler versus dry powder inhalers, Khassawneh et al; Respiratory Care 2008
- (2) Dry powder inhalers: factors associated with device misuse, Sigfried Wieshammer and Jens Dreyhaupt, RDD 2009
- (3) Inhalation technique and variables associated with misuse of conventional metered-dose inhalers and newer dry powder inhalers in experienced adults, Melani et al; Annals of allergy, asthma and immunology 2004



Which shade of beige?

The importance of Visual Language in medical devices

By David Robinson,
Design Consultant

As consumers we know that the way a product looks and feels is important to purchasing decisions and that it plays a significant role in determining the emotional connection between us and the product. In the medical sector this emotional connection could provide many benefits to the manufacturer and, crucially, the patient.

We, at Team, believe that combining a considered Visual Language with excellent technical design enables us to produce robust, usable and ultimately satisfying medical products that form a strong emotional connection with the user or patient.

Firstly, what do we mean by 'Visual Language'? To us Visual Language is the construction of visual stimuli to convey a specific message, meaning and/or concept. This could be the form, colour, label (graphical elements) and surface finish or even other qualities such as the smell, material quality and weight. As a designer you can use these tools to craft multi-sensory experiences that evoke a positive emotional response from the user and create semantic signals that guide the user's interactions with the product. For the purpose of this article I'm focusing on the importance of establishing an emotional connection between the product and user, before talking about the process of developing a Visual Language.



Despite performing the same function, these products evoke different reactions: high quality and cleanliness versus disposability and low quality

Understanding the conflicts and constraints of the medical sector

All reputable industrial design firms understand the discipline of Visual Language. However, product design within the medical sector presents a number of unique challenges and constraints, which in turn demand a high level of rigour.

Over the years of designing and developing medical devices we've established a robust toolset and approach to Visual Language. Using this toolset and supporting guidance material provides us with the freedom to be creative without introducing unnecessary risk. By understanding the impact of regulation, technical constraints (like DFMA for example), and usability throughout the development stages we are able to avoid design cul-de-sacs and expensive redesigns.

After all, if you don't understand the constraints how can you develop market-leading medical devices that make a positive connection with the user? Below I've highlighted a few of the regular constraints that we come across during the development of a medical device:

Usability

During the development of a medical product it's important that a Visual Language mapped onto a product does not distract from the intended method of use. We adhere to the HE75 standard from the outset and go through stringent user testing and human factors analysis to validate any key aesthetic decisions that might compromise usability.

Materials

Not many materials have been certified for use in medical applications and an even smaller number can be used for prolonged drug contact. We continue to evaluate the market and build a library of materials for different medical applications.

Colours

Colour is a critical element to Visual Language. Colour subconsciously triggers emotions, memories, ideas and thoughts based on past experience. Colours can be used to create positive imagery among users instantly¹. A broad range of colour guidance material supported by scientific research allows us to select colours appropriate to the user requirements rather than relying on subjective opinions.

We are working closely with colour manufactures to define a standard colour range whose ingredients have been biologically evaluated to medical standards (such as ISO 10993). This enables us to select colours that are already approved for medical use, therefore speeding up the development process when compared to creating custom colours.

Label designs (graphical elements)

Medical labelling and packaging is subject to stringent regulations from government agencies, which dictate: print size, print colour, syntax and content layout. By understanding these regulatory constraints we are in a position to incorporate brand elements without impacting on the effectiveness of the label.

Future-proofing

A diabetes type 1 sufferer wrote an open letter to Apple's Steve Jobs that was posted on the popular diabetesmine.com community site asking 'why can't an insulin pump look like an

iPod?'. To develop medical devices with the same kind of appeal as consumer products would suggest the impossible - that we need to drastically shorten development timelines and reduce the regulatory approval cycle to keep up with key design trends and fads. However, by eliminating unnecessary visual stimuli and using styling elements that do not adhere to fads gives the design a classic Visual Language that is less likely to age.

Mass-market appeal

In many cases medical devices need to appeal to a wide cross section of society, transcending social, demographic or geographic factors, all with different perspectives on values and messages. Consultation with stakeholders and users will give key insights into visual stimuli that may appeal or repel users. This information may be contradictory so it's important to create a balance between wants so as not to alienate users.

Disposability

We hear from users regularly that medical devices need to look and be robust and safe, however, in many cases they need to be disposable and therefore cheap to manufacture. This contradiction can be overcome through understanding the various materials and finishes available, and specifying and designing a device that will be inexpensive to manufacture and meet user expectations in terms of quality. >

Our work in the sector has enabled us to create a number of reference boards for the symbolic properties of colour, hue and saturation, and the regulatory constraints on labels and packaging.



(1) A, Wright, The beginners guide to colour psychology, 1 Dec 1998

The impact of Visual Language on the user's emotional connection

User compliance is of utmost concern to everybody. You might have the most effective drug in the world or the most efficient device but if the user doesn't use it correctly (either wilfully or accidentally) or at all, then the success of a prescribed treatment is adversely affected.

A considered Visual Language can ensure that the medical device creates a positive emotional connection with the user or patient by reinforcing certain messages either linked to the 'brand' (such as trust) or to the materials used (such as sterility, safety or cleanliness). These factors can play a role in ensuring the patient complies with their treatment.

Positive messages

Think about how a VW, Apple, Ferrari, Philips or Tesco product makes you feel. They all create different images in your mind, providing reassurance and certain assumptions of quality, reliability, cost and simplicity. Even before we've purchased a product from one of the above, we form opinions on how it works, how it makes us feel and how it makes us look to others. Generating positive perceptions about your product or drug can, as studies² have revealed, generate a placebo effect.

As an example, in any UK supermarket you can buy own-brand Ibuprofen at as low as £0.28 for 16 tablets, however, the Nurofen equivalent for 16 tablets is £1.50. When out of the box, the tablets look identical and are almost identical, however Nurofen's brand forms an emotional connection with the consumer and they trust it will deliver the therapeutic benefit expected.

The power of branding in the mind of the patient and the healthcare professional is important when it comes to increasing compliance and loyalty, or when you want to differentiate your product.

Negative messages

Whether you intend to or not, your product is communicating messages that the user takes in consciously or sub-consciously. It is important that you control these messages and not overlook their impact.

Not thinking about how aesthetic design decisions impact on the emotional connection can have some serious unintended consequences, such as emotional rejection, which can adversely affect adherence and compliance.



(2) A Branthwaite, Analgesic effects of branding in treatment of headaches, British medical journal, 16 May 1981

Defining the message

Visual direction

Embodiments

Visual specification

User research

Establishing a Visual Language

Over the years of medical product development we've established a reliable process to help our clients create an appropriate Visual Language. Our approach allows us to remove subjective opinions on appearance and put some theory behind our decisions on the way a product should look.

Defining the message

Consultation with the client and key stakeholders gives us insight into the messages and values that the product needs to convey, which can come from an existing brand, company brand, product family or it could be a new brand. What is important at this stage is to understand the target market and what Visual Language is appropriate for the user. The opinion of the patient or user is the primary focus. With devices, like inhalers, time should be taken to understand the condition and the treatment regime. In terms of hospital or lab equipment, the environment in which it will be operated needs to be considered. Does the product need to stand out or project a message of high quality? Does it need to look comforting and safe, whilst blending into the background? Each of these answers is unique to each client and product.

Visual direction

At this point in the process a series of Visual Language boards are created (see below). These boards use visual stimuli to convey the attributes and messages defined in the first stage. These boards contain products from various sectors (such as consumer electronics and automotive) providing inspiration from a diverse range of sources and piecing visual elements together to create a distinct appearance.

Embodiments

A range of different aesthetic directions are chosen and mapped onto the product. These visual embodiments are

created to assess the Visual Language. These embodiments can be sketches, 2D/3D renderings and models. They help to capture the visual specification and ensure that the product design is heading in the right direction.

Visual specification

Following the steps set out before, a visual specification that communicates the key building blocks of the aesthetic as a guide can be created. This guide can be referred to throughout the complex and detailed product engineering phase to ensure the final product is as close to the original visual specification as possible. This reference material can be used to create a succinct family of products or to align branding material. The visual specification must exist as a fluid document that responds to the development programme, rather than a rigid set of rules that constrain the product development process.

User research

The visual or physical embodiments are evaluated with key stakeholders to gain feedback on the Visual Language and to make sure that none of the design decisions made on the appearance of the product conflict with the usability or safety of the device.

Our deep knowledge of the medical sector, coupled with our skills in industrial design and human factors, has resulted in us becoming a global authority on the use of Visual Language in medical products. Our clients are already taking advantage of our experiences to ensure that their products are not only innovative from a formulation or functional perspective, but also innovative in how they build a positive emotional connection with the user or patient. ●

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Visual Language boards

Visual Language Case Study



The client wanted an aesthetic that communicated the key attributes of the inhaler:

- Sophisticated yet simple-to-use technology
- Robust and reliable
- Hygienic.

As we were developing a DPI platform that was appropriate for the broadest range of therapies and user groups, the final embodiment needed to support marketing to potential licensees, who could in turn map their own brand aesthetic onto the inhaler.

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