MEDICAL DEVICE DESIGN STRATEGY FOR A CONNECTED FUTURE

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Introduction

Design Considerations for High-Volume Manufacture of User-Actuated Push Buttons

Let's consider the mechanics of a push button as an example. As one of the primary interfaces for the user with a device, it is important that the button achieves the correct

carried out correctly and is important for the overall quality and 'feel' of the device. How many times have you been frustrated by buttons getting stuck or having action that is sticky? Your initial reaction to the product is to question the quality of its build. Consistent button action doesn't just happen; it requires thorough design work up-front as well as excellent

particularly when manufacturing at high volumes.

on a PCBA (Printed Circuit Board Assembly). Actuation of the switch is accomplished by a

the surface of the outer case. Controlling the distance between the electrical switch and the button is critical in order to achieve the correct tactile feedback and continuous surface appearance.

Figure 2: Button Actuation Profile Accuracy Contributors

Mounting the switch on the board itself (S2 in Figure 2) is another consideration, and positioning accuracy is paramount. Recognize that this position may have a large

PCBA manufacture. For post-soldering inspection purposes, a larger contact pad and

Switch Interactions

Tolerance of the switch itself is another primary factor. Achieving tighter tolerances typically requires integration of expensive, high-end or bespoke switches.

Tolerances are dependent upon the materials used, the design of the tool (injection-moulded parts) and the distance to the measurement datums on the parts. All of these must be optimised and addressed to meet end-tolerance requirements.

Checklist of Considerations

- Molding tolerances of the plastic casing
- Relative position of the PCB retention features
- Geometry of the PCB retention features
- Position of the button mounting
- Thickness of the button
- Wall thickness of the housing

Figure 3: Impacts of Design for Manufacturing (DFM) Optimisations

At a system level, when all these sources of variation from both the electronic and mechanical components are taken into account, one can begin to understand how critical it is to have cross-functional expertise when optimising a connected device design for high-volume manufacture.

Whichever tracking method is selected, it is important to understand the challenges presented by the measurement technology and the potential limitations of its accuracy. Direct measurement of the stopper position within the syringe is not usually feasible, so an analogue must be used e.g. the back of the plunger, or movement of another part of the system. The chosen sensing method must be precise enough to provide accurate dosing information, while also allowing for a reasonable tolerance in accuracy of placement of the sensor itself.

Available locations for siting and integrating electronics within the device may be limited. Integrating electronics to areas of least sensitivity to variation should be prioritised in the design. A detailed tolerance analysis (see tolerance discussion in Section 1, Page 4) will be critical at this stage to understand if accuracy requirements can be met—taking into account the sensor accuracy, the sensor placement accuracy and the variation within the device itself.

Component tolerances, component interactions and assembly all contribute to potential variations in autoinjector product performance. Some sources of variation that should be considered and optimized prior to sensor selection are:

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- Syringe Barrel internal volume dimensions
- Syringe Barrel mounting area dimensions
- Needle dimensions
- Plunger Stopper dimensions
- Plunger Stopper assembly position
- Change in Plunger Stopper position due to transport
- Change in properties of all device elements due to temperature and humidity
- Mechanical position of the Syringe in the device
- Mechanical position of the Plunger component
- Injection mechanism forces
- Frictional effects

Accommodating all these considerations helps ensure collection of the most accurate drug

Designing for Connectivity — A Standardized Approach is Best

fullest range of potential applications, a breadth of SME's with different skillsets should be engaged, working across the project over different timelines and phases. Variability is again a primary challenge and must be accounted for throughout the design and

A standardized approach is ideal; without it, each device solution becomes a time-intensive

development must be accommodated from the start—not delayed—as that would risk the need to solve connection issues when the devices are connected to their solution. The potential range of issues include needing code work-arounds or patches for addressing

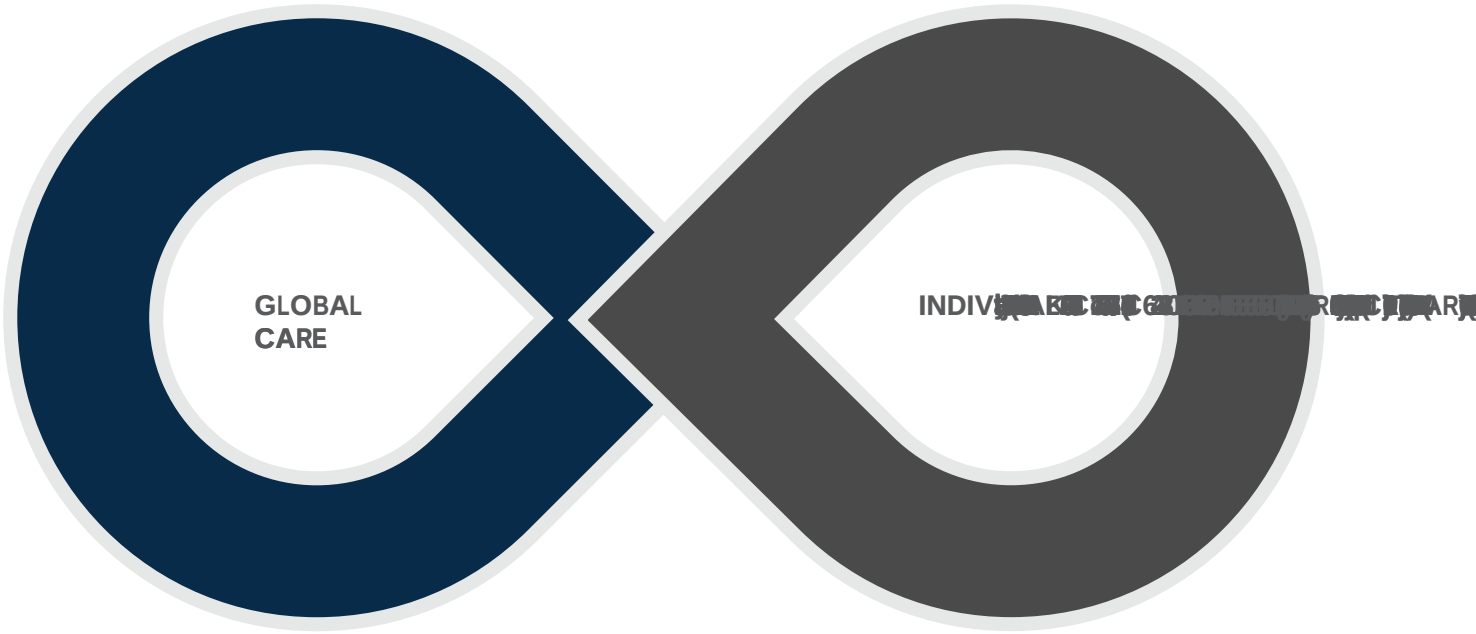
embedded code. This can be challenging at the best of times and too late to address at others.

many industries. In the plumbing industry, some professional plumbers will only quote and engage in a job if the homeowner or designer will be installing Grohe faucets. Grohe has become known for its "quick connect coupling" system throughout its portfolio of products. Standardization, in this case, helps ensure that tools, and other connection supplies are reliable and predictable, avoiding delays, or other potential installation pitfalls. The professional is prepared every time, and quoting a job accurately becomes a seamless transaction.

architecture that is scalable to different micro controllers and maintains reference code libraries of different sensors and device types. A communication protocol is required to enable the device and solution to communicate the telemetry and attributes of the device and what they require to interface and communicate with the solution.

Not long ago, getting a personal computer up and running had users scrambling for installation instructions for the drivers for each unique device, (i.e., mouse, keyboard and printer) to enable connection and operation. Today, all of this happens by simply plugging the device in or pairing over a Wi-Fi connection. It's become as simple as a handshake. The devices communicate a representative model of their capabilities and this allows the operating system to reference a known model and understand how to interact with the device.

COMMUNICATIONS “HANDSHAKES” AMONG POTENTIAL PLAYERS OF THE IoMT



Microsoft Azure Plug and Play is an excellent example of a service product that has the power to standardise across the industry for connected medical devices. In exchange for a common open modeling language between IoMT device and IoMT application, their service removes the requirement for extensive embedded code. Just as described with peripheral devices, this creates a model for compatibility across the platform.

Azure's plug and play modeling language is based on JSON-LD and RDF[3]. Each device

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