MEDICAL DEVICE DESIGN STRATEGY FOR A CONNECTED FUTURE

JABIL
HEALTHCARE

Introduction

The Internet of Things, or IoT, refers to the billions of everyday devices that are now connected to the internet. Our cars, home appliances, phones and fitness armbands have all been transformed into smart devices, capturing data and experiential inputs in a holistic feedback and analysis loop. In healthcare, this combination of digital-sensing technology and cloud computing has dramatically accelerated growth in the Internet of Medical Things, or IoMT.

Today's connected medical devices enable new models of engagement between patient and provider, enhancing the exchange of vital metrics and health information at both the personal and population level of healthcare delivery. Better informed, time-efficient, safe and clinically effective outcomes are at the heart of the promise in digital healthcare. The numbers bear this out as well: the global connected healthcare market is expected to reach a market value of around US$6,600 million by 2027 and is anticipated to grow at a CAGR of approximately 11% in terms of revenue from 2020 to 2027[1].

Manufacturing variability is always a primary concern within the tightly regulated healthcare industry. Medical device product development, at minimum, requires subject matter expert (SME) input for both electronics and mechanical componentry. Connected devices also require additional expertise related to software, automation, and user experience. With millions of devices potentially impacted, it's vital that both engineers and developers establish comprehensive system-level understanding of how these components will come together at assembly.

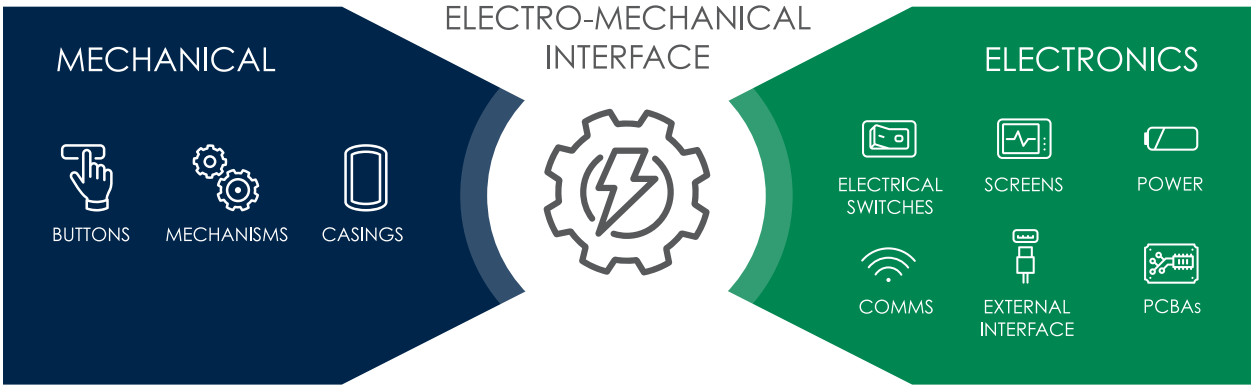


Figure 1: Electro-Mechanical Interface

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 tactile and visual feedback. This gives the user confidence that the action has been 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 understanding of both the electrical and the mechanical component specifications, particularly when manufacturing at high volumes.

The example shown (Figure 2) is a simplified rendering of a switch which has been mounted on a PCBA (Printed Circuit Board Assembly). Actuation of the switch is accomplished by a mechanical button positioned at the top of the device. Design requires that it is flush to 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.

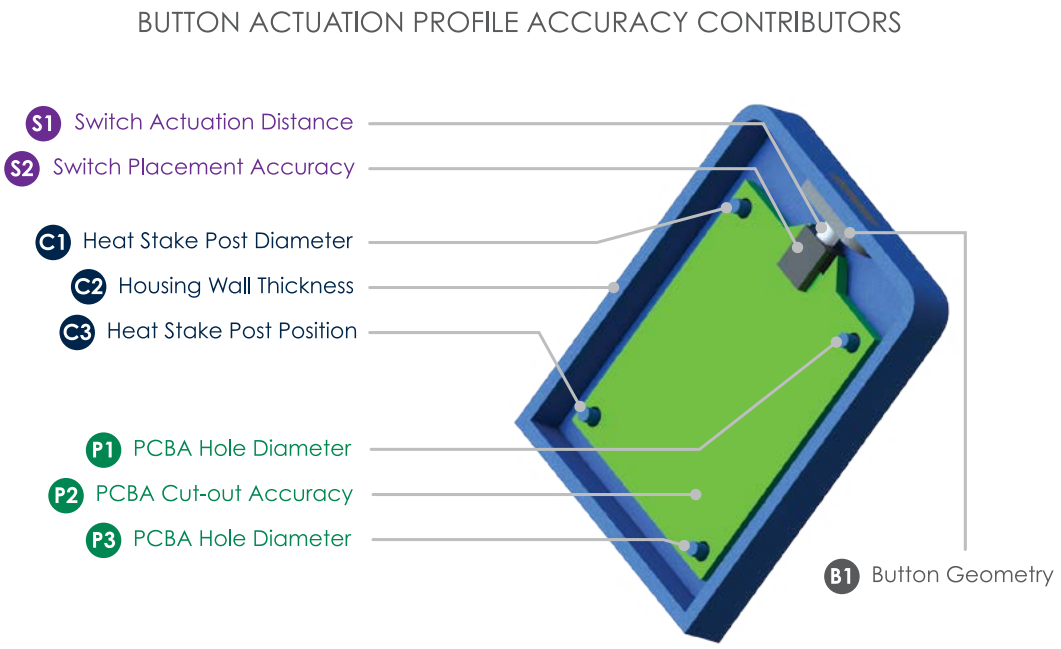


Figure 2: Button Actuation Profile Accuracy Contributors

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 tolerance band, which is typical in the reflow soldering processes used for high-volume PCBA manufacture. For post-soldering inspection purposes, a larger contact pad and solder amount is preferable to confirm correct electrical connection. However, this will require a large tolerance for the end position of the surface mounted switch post reflow, as it may land anywhere in the large contact pad. Therefore, the smaller the contact pad, the better the positional accuracy.

There is a trade-off with inspection requirements and the placement accuracy of the automated line to land on a smaller contact pad. For fine placement accuracy, the mechanical mounting can be used, but this will add to PCBA cost and complexity. In a real-world example, there are likely to be many more interacting components, such as sensors and connections ports, that will only add to this complexity.

Cut-out tolerances must also be accounted for. PCBs can be manufactured to a range of tolerance standards and fine tolerances are challenging to achieve at high volumes. The accuracy of the cut-out will be dependent to a large extent on the routing process used. Typical cut-out tolerances here may be in the range of ± 0.1 to 0.2 mm, which can be significant in the stack up of tolerances. One potential solution for reducing offset inaccuracies could be drilling the PCBA mounting holes at the same time as the panel tooling holes.

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

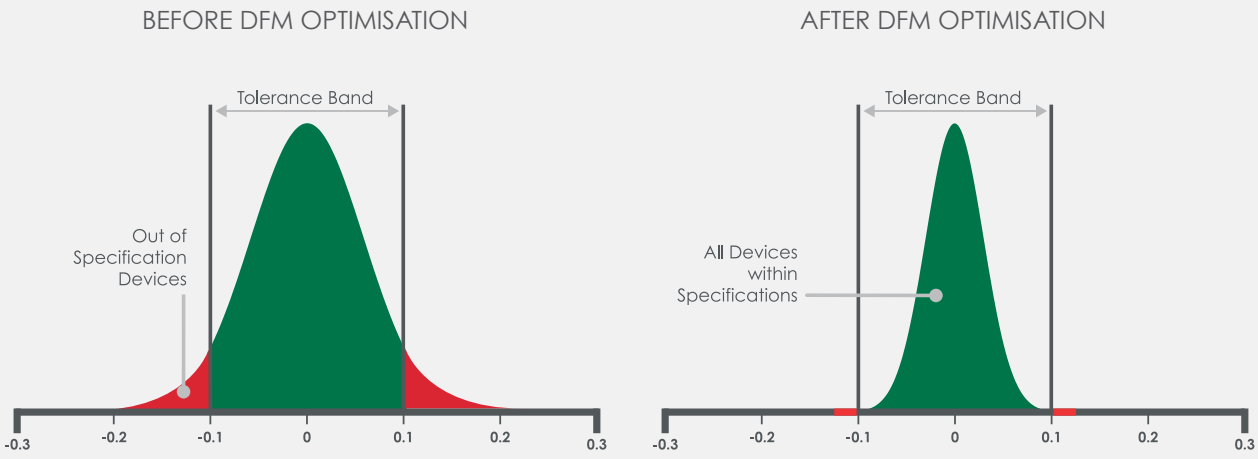


Figure 3: Impacts of Design for Manufacturing (DFM) Optimisations

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.

Sensing the Plunge — What's Measured and How?

Data collection is at the heart of design strategies for connected devices. Its critical to optimise a sensor's placement — or an array of sensors — in tandem with the device electronics and firmware. For example, in a connected autoinjector there's a wealth of insight to be gleaned through tracking and measuring plunger travel. Depending on the level of detail and accuracy required, plunger travel data can be captured by sensors in a variety of ways. (See our previous *OnDrugDelivery* article on a trial smart inhaler device, for discussion of sensor integration in a connected inhalation device[2].)

What can be detected by plunger travel?

- Needle shield removal
- Contact with skin
- Start of plunger travel
- End of plunger travel
- Incomplete delivery of medication
- Full dose administration (when coupled with a skin contact sensor — e.g. capacitive or push switch)
- Occlusion detection
- Delivery rate
- Anomalies in the delivery profile

Once the items to be detected have been identified, it is necessary to understand the technology requirements and how to incorporate them into the design of the device. The range of technologies for tracking plunger position include: mechanical switches, hall sensors, inductive measurements, and optical sensing.

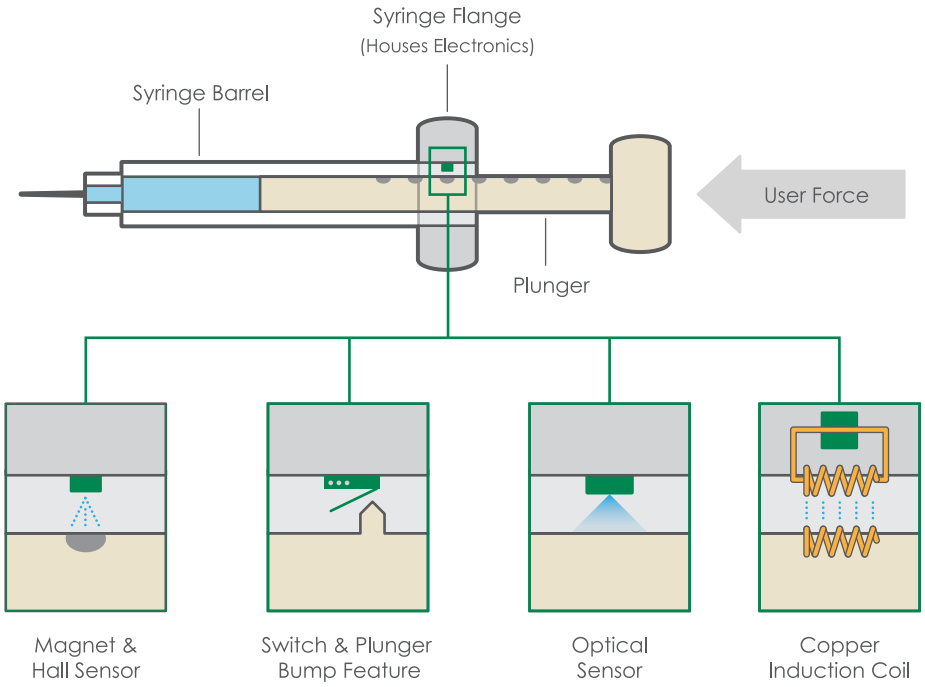


Figure 4: Examples of Sensor Options

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:

- Drug fill volume
- 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 delivery information possible from the autoinjector, which sets up the next step: connecting the device for communication to the cloud.

Designing for Connectivity — A Standardized Approach is Best

Connected devices fulfill a wide array of use cases and purposes. To accommodate the 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 development workflow.

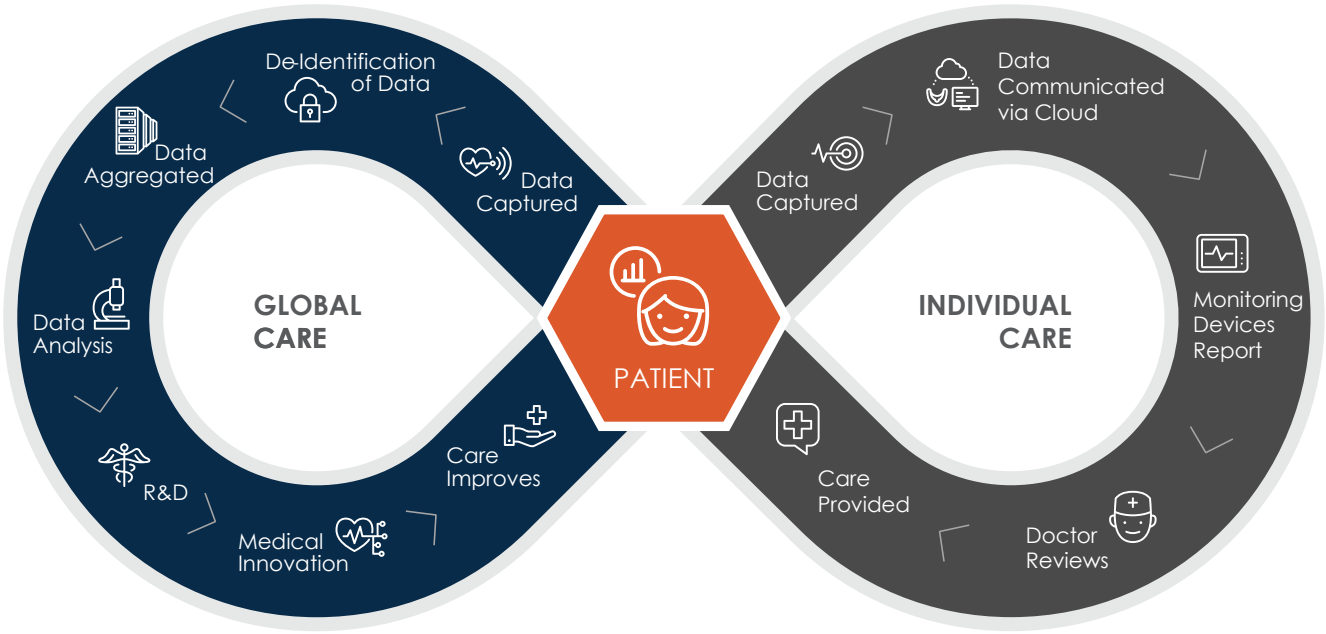
A standardized approach is ideal; without it, each device solution becomes a time-intensive and bespoke effort, requiring the creation of new firmware for every device. Backend development must be accommodated from the start—not delayed—as that would risk the need to solve connection issues when the devices are connected to their solution. The potential range of issues include needing code work-arounds or patches for addressing unanticipated connectivity problems or even requiring a return to the device firmware embedded code. This can be challenging at the best of times and too late to address at others.

The benefits of a standardized approach are many and a potent differentiator across 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.

Taking this approach with connected devices involves the creation of a firmware 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 model has a unique identifier or Digital Twin Model identification (DTMI) number. Each model ID in the library has a set of interfaces. The device and cloud solutions interface at the different levels. At each level, the communication protocol enables the devices to "advertise" their attributes. In other words, they are able to answer all the questions about the device regarding on-board sensors, how they communicate, and what they need to connect.

Interactions, such as the device's digital twin model running "search" functions to query and understand the device's attributes, how it functions and communicates, enable the system to self-regulate and improve. These solutions also help create an appropriate environment, dashboards, or insights from the device's data, enabling users to send management commands to the device, ultimately, guaranteeing more seamless connection to any compatible platform solution using this approach.

Ease of connection is a huge advantage. In todays' communication protocols, software maintenance and calibration are built right in, removing the burden of complex embedded code and allowing the lab technician to focus on understanding and applying laboratory results, not software upgrades. This frees IoMT designers and developers to apply the bulk of their time and effort where it provides the greatest impact and value: the use cases and insights that data and applied analytics provide.

The ability to model interactions and build libraries and protocols enriched by metadata will only increase with the volume of devices added and integrated. All these data collection and communication enhancements providing more leverage in the pursuit of improving individual wellness, disease state management and population health.

Our future, and increasingly our present, has us working with connected and interoperable ecosystems providing a clearinghouse of shared and structured data. Devices connected to patient, provider and the cloud are building out networks of complex connections and applied analytics enabling deeper insights and problem-solving for improved patient care.

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