

WHITEPAPER

Designing The Ultimate Operator Experience

Seven Critical Design Considerations for
Next Generation Medical Devices

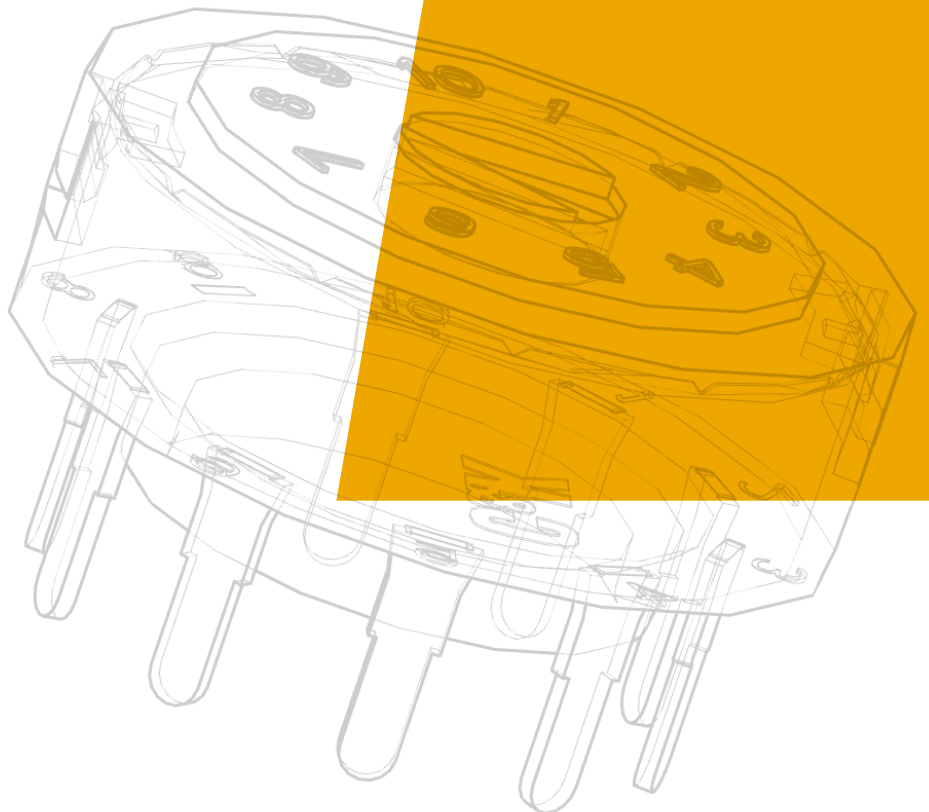


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INTRODUCTION

Healthcare is undergoing a digital transformation. Driven by advances in science and technology, the healthcare of our parents' generation is being replaced by an influx of new devices and systems that promise a better future by using data, artificial intelligence, and genetic markers to deliver an improved user experience, more accurate diagnoses and less invasive treatments to improved patient outcomes.

The US medical device market recently hit the \$156B mark and forecasts show it accelerating at a pace of 5% growth year-over-year. Given the market size and growth potential, competition will be fierce and innovation fast-paced as companies race to capture market share and establish dominance in segments such as drug delivery, diagnostics, and remote monitoring.

In this type of competitive landscape, there will be winners and losers. In order to capitalize on the market opportunity, it has never been more important for product designers and engineers to innovate and change the way they think when designing the next generation of medical devices that are expected to disrupt the industry.

The guidance in this paper aims at improving your chances of success by giving thoughtful consideration in to seven key areas that experience has shown can be the dividing line between success and failure when it comes to product design in the medical segment.

Compiled through interviews with engineers, designers, and medical segment leaders, the wisdom that follows is backed by 100 years' worth of combined experience servicing the medical industry.

We hope this guidance drives the creation of new, innovative, well-designed medical devices that reduce pain and suffering, save lives, and helps us realize the bright future promised through this transformation in our healthcare system.

¹ <https://www.prnewswire.com/news-releases/us-medical-device-market-reaches-156-billion-mark-300805696.html>

² <https://www.prnewswire.com/news-releases/us-medical-device-market-reaches-156-billion-mark-300805696.html>

THE FUTURE IS NOW



Adding data collection and detection capabilities are just the beginning...our medical device customers are already asking us to help them drive engineering innovation much, much further.

Roger Bohannon
Medical Segment Leader, C&K

As we speak, medical devices capable of detection, data collection and connectivity are beginning to make their way into the market. But what's next? In order to get ahead of the curve, we have to start thinking now about what the medical device landscape will look like in 10 years and begin designing the products of the future, today.

The medical market is undergoing a transition. Everything will change: remote monitoring, diagnostic and even drug delivery systems will all have a way to detect, collect and transmit data. You can argue that everything is moving towards data collection and connectivity. Products that do not have power, detection, data collection and connectivity will convert.

The growth of the market is substantial. CAGR's for the wearables market alone are expected to increase between 14% and 17% from 2018 to 2025¹. This sort of growth will see the wearables market worth \$58 billion by 2025².

When the hundreds of billions of unconnected devices, are converted over to connected devices, the innovative companies that were able to adapt and evolve quickly to this growing trend will be able to capitalize on the market opportunity. This is a good thing as the demand for design excellence will be essential in the success of the products. That means an increased focus on the components that are enabling these new capabilities.

Switches can perform numerous critical functions in a medical device. From giving the device the ability to be turned on/off, to being used to control system performance, acting as a bridge to manage tolerance stack up challenges in a complex design, to being used as a key component for detection or driving data collection functionality.

Given its importance in shaping the user experience, defining quality and performance, and literally bringing devices to life (via on/off switch), it is the epitome of a component that acts as the human/machine interface and should be a starting point in medical device design.

The first part of any medical designer's switch search is likely to look at a few fundamental criteria such as switch type, poles and throws and the basic electrical specifications including voltage rating, maximum current handling capability and contact resistance. However, once such 'table stakes' are addressed, there are many other factors that need to be considered when selecting the best component for a medical application.

¹ <https://www.mordorintelligence.com/industry-reports/global-wearable-medical-device-market-industry>

² <https://themarketresearchnews.com/2019/05/31/enormous-possibilities-of-smart-wearables-market-to-grow-with-a-cagr-of-14-66-in-near-future-by-top-companies-like-fitbit-xiaomi-apple->

WHERE TO START



It's amazing the engineering challenges our switches are helping customers overcome... building in competitive advantages that can't be reversed engineered, asking a single switch to perform multiple functions, and having our switch technology act as a bridge to fill-in gaps within design tolerance considerations

Roger Bohannon

Medical Segment Leader, C&K

You're building a medical device, not a puzzle, so why start from the outside? It's amazing to see how many designs start by building the frame of a device (taking an outside-in perspective), rather than thinking about the operator and starting at the human/machine interface instead (inside-out perspective).

Thoughtful design begins by adopting and thinking about how your operator is going to use, interact, and engage with your device, and where the possible breaks in customer satisfaction could be hiding. Questions such as how the device will feel, sound, and move - the beauty in the details - should guide your decisions. Keeping this idea in mind, it's necessary for designers to change their "hierarchy of needs" when approaching medical devices, and begin by placing the interface between the operator and the device on the top of the pyramid... here's why.

Products built for the medical space need to exhibit high-performance and durability. They need to withstand harsh, challenging environments and usage that will test a device's tolerances and push them to the limit. A critical component that lives at the crux between performance and customer satisfaction, is the switch.

The same way that tires on a car are the only piece of the vehicle to touch the road, the switch is often the only part of the device that the user interacts with - therefore setting the tone for how the entire device is perceived. As the interface between the human and the technology, the performance and tactile properties of a switch is one of the few components that can give the user an elevated level of confidence in a device's performance and reliability. The importance the switch commands within a product should never be overlooked or left as an afterthought given its ability to drive brand loyalty and enhance a product's reputation.

In the following pages, we breakdown the seven essential criteria designers need to consider to ensure their product meet the new requirements for next generation medical devices.

DESIGN CONSIDERATIONS

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**DESIGN
CONSIDERATIONS**

Consideration #1

Are You Building a Product or an Experience?

How haptics can transform your product experience

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The critical importance of haptics can be perfectly summed up by this anecdote from a leading manufacturer of electro-surgery instruments. ‘When we proposed potentially replacing a series of double-action key switches on the device, the surgeons came back and told them they would not use the product without that specific component due to its particular tactile feel.

Roger Bohannan

Medical Segment Leader, C&K

When an OEM is creating a family of products, they will typically want a universal ‘look and feel’ – the DNA of the brand, if you like. There are various ways to achieve this. For example, you can make sure every member of a product family shares the same design, colour scheme or branding elements – to convey consistency and wholeness as a family. But there is also another, even more effective way to achieve this... through the switch.

As the primary interface between the device and the operator, the switch offers a way to set a standard. The ‘feel’ when operating a switch is referred to as haptics (based on the science and physiology of the human sense of touch) and making this feel consistent across all the switches in a range can both improve the user experience and send signals regarding brand quality and reliability.

The potential for both switch haptics and acoustics in the modern medical application is exciting. Take an insulin pen, for example. When you design this device with an electromechanical interface, you are characterizing the sound and force used to actuate medicine delivery. This sensation can transform the experience – from quiet and peaceful to a shock – very quickly.

Likewise, if you are designing a laparoscopic closure and detach tool, the haptic sensations give the medical professional a positive confirmation that the device has performed as expected – a surgeon will depend on the tactile feedback from their electro-surgery instruments before cutting and sealing tissue. The feel of the capture of the vessel comes with the travel of a switch. The sound and feel of closure come with a sound and a tactile feel of an actuating medical switch. Even the detach feature comes with a slightly higher force and more impressive sound. Those differences enable medical professionals to know exactly what is happening at the end of this advanced procedure, supporting the best patient outcome.

A correctly specified and engineered switch can make a crucial difference not only to the sound and feel that mirror the performance, but to the levels of reassurance provided to the user. This can be a vital consideration, and one that we’ve seen in the field to be the determining factor for whether a device is used and relied upon or ultimately abandoned.

**DESIGN
CONSIDERATIONS**

Consideration #2

Will It Be Used in a Harsh Environment?

How environment can determine a product's success or failure

The environment a medical device operates in matters. Whether it's a wearables device used for remote monitoring that needs to function in the world in which its user travels, to surgical devices that need to function in the sterile environment of the operating theatre – each has its own unique set of requirements and challenges.

For the switch component, this is an important consideration, since the environment will determine the level of protection that needs to be built into the switch.

Questions about how it will be sealed and whether it needs to protect against invasive fluids and contaminants all need to be answered to ensure the right switch is selected for the environment it will operate in.

In urban outdoor locations such as swimming pools, sports arenas or shopping centres these devices are exposed to extremes of weather and are vulnerable to tampering. Contrast that to the more controlled and sterile conditions of medical facilities where they are exposed to damaging fluids and harsh sterilising technologies.

More than any other industry, medical and critical care equipment needs to perform in a diverse spectrum of conditions. From exposure to blood and body fluids or harsh sterilization chemicals, to getting bumped around in the hectic atmosphere of a hospital emergency room – this equipment needs to be corrosion-resistant and durable. Components that can handle a serious impact or an operator pressing too hard on a button, for example, help the medical device to work reliably for years – even in challenging situations.

There are different applications, different configurations and different capabilities required for switches in these environments. A switch can be sealed to either IP67 or IP68. IP67 means the unit can be dropped into a body of fluid up to a meter deep for half an hour, while IP68 guarantees protection in liquid up to 1.5m deep for the same period.

**DESIGN
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Consideration #3

Does Your Manufacturer Support a Digital Engineering Process?

How digital design support can drive faster development

In the modern digital world of product design and lifecycle management, it is essential that suppliers of components, including switches, can support the digital process. It is important that a supplier provides complete and total detail right from the start with full 3D CAD models that can be incorporated into any design process and utilized for Digital Twins and other requirements.

Following this strategy will serve both the device designer and supplier. A component cannot be designed and manufactured without a sophisticated model or a complete set of specifications in terms of sizing, fit and articulation. These specifications and digital models must be available for the design teams to work from if needed.

This can help product designers because they must take the complete system to verify and validate the construction. Effective collaboration between a device manufacturer and a component supplier - where they speak the same language and use the same technologies - allows the designer to integrate the product in digital form, long before the parts are produced.

³ Requires footnote

**DESIGN
CONSIDERATIONS**

Consideration #4

Will it Fit?

How solutions with a small footprint can make a big impact

Minimally invasive surgery (MIS), such as robot-assisted surgery and laparoscopy has been a big growth segment in recent years. When a medical device is placed within a patient during such surgery, it will be a minimally invasive device. This technology utilizes techniques that limit the size of incisions needed, resulting in shorter recovery time, which has brought enormous benefits for patients. Here the requirements are for high-performance tact switch and the K12S key switches that combine form factors with the reliability needed when used on endoscopic cameras and electro-surgery instruments.

Other high-tech devices such as narrowband imaging, confocal micro-endoscopes, endoscopes and high-definition cameras will also require switches that are both compact and correctly oriented. With MIS devices, size is a critical factor in the design.

Furthermore, when it comes to medical wearables, which are being developed for a variety of medical problems such as COPD, asthma, breast cancer, pain management and heart arrhythmia, size and orientation can be all-important. The burgeoning use of communication is also influencing the design, as space is further limited by the addition of antennas, transmitters and extra circuitry. Even though the switches have less space, they still require all the functionality to interface with the user.

³ Requires footnote

**DESIGN
CONSIDERATIONS**

Consideration #5

Is It Built to Last?

How product longevity can define customer satisfaction

Medical devices are often expected to have a long-life span, and it is vital that all the components can either support lifetime operation, or that there are provisions for a replacement if required.

This is particularly important as components often have to withstand harsh conditions such as exposure to fluids, severe impact, or, as mentioned previously, something as simple as a doctor pressing too hard on a button. Ideally, the switches and components that make up these medical devices will have a significantly longer lifecycle than the device itself if they are to stand up to these conditions.

Components such as sealed nano pushbutton switches and detect switches, for example, are ideal for handling the realities of the operating theatre, ensuring medical devices will work reliably for years in all kinds of challenging situations.

For situations where the components that make up a medical device have a lifecycle shorter than that of the target product, it is crucial that designers ask the following questions:

- Does the component's expected usage align with the component's capabilities?
- Is the supplier familiar with the demands of the medical industry?
- Does the supplier's technology and product roadmap meet the needs of the end customer?
- Can the supplier make the small modifications to the component configuration to support your needs?
- Does the manufacturer understand lifetime cycles of medical devices and will they develop the same component a year or 12 years from now?
- What type of revision control is employed?

³ Requires footnote

**DESIGN
CONSIDERATIONS**

All of this is paramount to the longevity and the consistent integrity of the final product.

Quality products with long lives can only come from a committed supplier. As a result, it is essential engineers find and identify the right supplier early in the design process to avoid potentially damaging issues that may reveal themselves later in the product lifecycle.

A component's performance must be weighed against the cost of a failure during the device's expected life. The advantage of selecting the best switch on the front end of a design could make the greatest impact in terms of brand reputation and device performance. The switch can provide the best customer impression on a design with the smallest cost impact. If there is one way to change the impression and performance of your device, it's the switching components.

**DESIGN
CONSIDERATIONS**

Consideration #6

Does Uniqueness Matter?

How custom solutions can drive brand loyalty and protect you from the competition

For many medical device suppliers looking to use commercial components, the end design may have to involve some compromises to provide the exact performance required. However, there are solutions available that can allow commercial components to be adjusted to make them better suited to the task at hand. There is always a possibility that if something does not entirely match the application design in terms of configuration or size, modifications can be made to the switch, detection or data collection point. Indeed, the ability to customize a component can be a crucial factor for engineers who need to design medical devices that meet today's changing industry requirements. And while it may at first seem a daunting prospect, customization need not be complicated or expensive. When you pick up a renowned product and the touch and feel leaves an impression after the consumer interaction, it is safe to say a custom switch was designed to attain that impression.

The right supplier will take the time to work collaboratively and fully understand the requirements of the target application and then, by working closely with the product designer, will make recommendations on the best way to integrate their component. In such cases the supplier is more than simply a component seller but a trusted advisor that can provide a fully customized solution.

The lesson here is that rather than simply referring to catalogues, datasheets and the results of web searches there can be real benefits to picking up the phone and asking a question. Talking to a knowledgeable, experienced switch engineer, for example, can make the difference between compromise and designing perfection into a medical device. Such customization can not only deliver the best possible interface between the medical device and the doctor, but can be a true representation of the quality and the engineering built into a sophisticated application.

**DESIGN
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Consideration #7

Is Time on Your Side?

How the need to compress timelines can define your decisions

Compressing the time-to-market to take advantage of a short sales window is common in electronic applications, but for medical devices the reality of design-to-manufacture can be slightly different. Although manufacturers will want to get the product to market as quickly as possible, they are often constrained by several design cycles to ensure patient needs are met, followed by the FDA approval process, before finally being able to release their product to market.

One of the best ways that a component or switch supplier can support a medical device manufacturer is by making sure the component works correctly every time it is engaged. To achieve this, it is important that a trusted component advisor engages with an engineering team. A first design should, of course, achieve form, fit and function, but other factors, such as the manufacturing process itself needs to be considered.

There is little benefit in spending time designing a high-volume production component that will ultimately end up needing to be hand-assembled in order to make it into the final product. This is why it's important to consider the production and operation capabilities of the supplier you select. Evidence that a supplier's operation follows a highly automated production process is a good sign you've chosen wisely.

How the target product is to be manufactured, therefore, should be a prime consideration in the initial component design. The form, fit and function of a component must be addressed first, then first samples and prototypes produced before seeking FDA approval. Only then would volume production begin.

It follows, that in order to improve time to market it is critically important that designs are right from the onset. This means eliminating and reducing redesigns that can extend product design and development cycles.

FINAL THOUGHTS

When design engineers are building the next generation of medical devices, it's important for them to know that they don't have to go at it alone. They can stand on the shoulders of partners invested in the same goals, in this case the trusted advisors readily available within high quality component manufacturers. By engaging these resources early, an OEM can shorten product design cycles, reduce risk, and ensure the best possible operator satisfaction with the new devices they are bringing to market.

ABOUT C&K

C&K does more than just make the world's best switches. We are trusted advisors, helping global brands and innovators improve customer satisfaction by building better products. Offering more than 55,000 standard products, 5.5 million switch combinations, as well as custom designed solutions, C&K products are used to solve the hardest engineering challenges faced in automotive, industrial, IoT, wearables, medical, telecom, consumer products, aerospace, POS terminals, and more.

For over 80 years, leading designers, manufacturers and distributors of electronics have turned to C&K when they require mission-critical reliability in an electromechanical switch, high-rel connectors or custom assemblies. The reason they keep coming back is because C&K's innovative design, cutting-edge production process, and strict quality assurance standards produce the world's best switches and components.

To learn more and get connected with a C&K switch consultant, please visit: <https://www.ckswitches.com/medical>

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